S. HRG. 108–390

EXAMINING THE SENATE AND HOUSE VERSIONS OF THE "GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT"

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

AUGUST 1, 2003

Serial No. J–108–34

Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE

91–832 PDF WASHINGTON : 2004

For sale by the Superintendent of Documents, U.S. Government Printing Office
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EXAMINING THE SENATE AND HOUSE VERSIONS OF THE "GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT"

FRIDAY, AUGUST 1, 2003

UNITED STATES SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Committee met, pursuant to notice, at 9:36 a.m., in room SD–226, Dirksen Senate Office Building, Hon. Orrin G. Hatch, Chairman of the Committee, presiding.

Present: Senators Hatch and Schumer.

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

Chairman HATCH. Good morning, everybody. Today, we will explore important features of the Senate and House versions of the Greater Access to Affordable Pharmaceuticals legislation. In the Senate, this was the Gregg-Schumer amendment to the Medicare bill, S. 1. I seem to recall that this measure was adopted by the Senate by an overwhelming 94 to 1 vote. There is always somebody who doesn't get the message. Similar but not identical legislation was included in the House Medicare bill, H.R. 1.

A chief purpose of this hearing today is to help the Medicare conferees and others evaluate the merits of the Senate and House provisions. I want to commend my colleagues, Senators Gregg, Schumer, McCain, and Kennedy for all of their hard work on this legislation. I believe that the legislation does present a major improvement over last year's vehicle, which, if I recall correctly, was S. 812.

I am pleased that the sponsors of this legislation have adopted a version of the 30-month stay provision that I first suggested last May and argued for on the floor last July. The one-and-only-one 30-month stay for all patents filed when the NDA is submitted was also a centerpiece of the Federal Trade Commission report released last summer. The proponents of this legislation were wise to reject all of the various previous legislative proposals in this area.

I want to commend again Chairman Muris and the FTC for the agency's constructive contributions to this important debate. In addition to a recommendation pertaining to the 30-month stay, the FTC report contained a second recommendation calling for the reporting of any potentially anti-competitive agreement between pioneer and generic drug firms to the FTC and the Department of Justice.

My colleague, Senator Leahy, developed just such legislation, the Drug Competition Act, that was included in the Senate Medicare bill. I have worked with Senator Leahy in developing this bill and I, of course, support it.

Today, I want to spend some time examining some key differences between the Senate and House versions of the bill. For example, here are some of the differences between the House and Senate versions of the Leahy language that must be ironed out, in my opinion.

One of the most significant differences between the Senate and House bills centers on the manner in which the declaratory judgment provisions are drafted. These provisions were the subject of a spirited written debate between two esteemed lawyers, both of whom are friends of mine—Boyden Gray, former White House Counsel, and John Yoo, a former member of my staff.

Today, we will hear testimony from the Department of Justice that the administration has concluded that the Senate declaratory judgment provision is constitutionally infirm. Moreover, the Patent and Trademark Office will tell us that the Senate language, quote, "could result in unnecessary harassment of patent owners," unquote. In addition, PTO believes that the manner in which the Senate bill treats the award of treble damages is unwise.

On the other hand, we will hear from the FTC that it believes a key feature of the House declaratory judgment provision, the right to confidential access, may not be necessary and, as a matter of policy, the Senate declaratory judgment provision may have some advantages.

Consistent with its 2002 report, the FTC takes exception with the manner in which both the Senate and House language eliminate the current district court decision triggering mechanism for 180-day marketing exclusivity.

We will also hear from the FDA about how the provisions of these bills would interact with the agency's recently issued final rule on patent listing. The FDA disagrees with the FTC on the matter of the court trigger and supports an appellate court triggering scheme.

It is my hope that after we have heard from our panel of governmental experts, the conferees and other interested parties will gain additional knowledge about the strengths and weaknesses of the House and Senate bills. Our goal should be to forge a conference report that preserves the best features of these measures or results in the crafting of better language.

Finally, we will also hear today from a private sector expert who will talk about the ramifications of an identical section of both the Senate and House bills. These are the provisions related to the award of 180-day marketing exclusivity where pioneer patents are found to be invalid or not infringed by generic competitors.

Both bills adopt a first-to-file regime. I am a proponent of what I call a successful challenger system. It seems to me that the first successful challenger, be it the first generic to be sued, the first to win in court, or the first to be granted a covenant not to be sued by the pioneer firm, is more deserving than a mere first filer.

As I explained in my June 26 Congressional Record statement, it appears to me that the 180-day marketing exclusivity provisions

in the pending legislation contain perverse incentives that may result in unfortunate, if unintended, consequences.

I plan to ask the Congressional Budget Office to review the provisions of the 180-day marketing exclusivity provisions and consider whether these new rules may actually prove costly to consumers. It is possible that a consensus will emerge to revisit this issue, and frankly it seems to me that simply adding a new forfeiture event in cases where a challenger is not sued, succeeds in court, or obtains a covenant not to be sued, could materially improve this legislation. It is also possible that the Medicare conference will not be the best time or place to reconsider these issues. I can accept that, but I also believe that we have not heard the last word on these new 180-day rules.

Let me close by stating that it is my hope that the Congress will enact a Medicare drug benefit this year. I plan to work in a constructive fashion toward the success of this legislation. In that spirit, I hope that today's hearing will help inform the discussion of reconciling the House and Senate versions of the important provisions that address generic drug competition.

So I am personally looking forward to hearing the witnesses today. We have a distinguished first panel. The Honorable Timothy J. Muris is our first panelist today. He is Chairman of the Federal Trade Commission.

I appreciate you, Chairman Muris, returning to testify to the Committee on these important matters.

The next panelist is Mr. Jon W. Dudas, the Deputy Under Secretary for Intellectual Property, and Deputy Director of the United States Patent and Trademark Office of the Department of Commerce. Previously, he has served as the Deputy General Counsel and Staff Director for the House Judiciary Committee and as Counsel to the Courts and Intellectual Property Subcommittee. Mr. Dudas will share the PTO's observations regarding the House and Senate versions of the Greater Access to Affordable Pharmaceuticals Act.

We welcome you here.

Our third panelist is Mr. Daniel Troy, Chief Counsel for the United States Food and Drug Administration. Throughout Mr. Troy's career in the public and private sectors, he has specialized in constitutional and appellate litigation. Mr. Troy also will discuss recent Congressional action on amendments to the 1984 law.

We are really honored to have you here, Dan.

Finally, Mr. Sheldon Bradshaw, no stranger to this Committee, holds the position of Deputy Assistant Attorney General in the Office of Legal Counsel at the Department of Justice. Earlier this summer, Mr. Bradshaw shared some tentative concerns of the Department of Justice regarding the constitutionality of the Greater Access to Affordable Pharmaceuticals Act.

I appreciate you taking time to share the administration's position on these important constitutional concerns.

We are also happy to have you here, Mr. Buehler, and we look forward to any participation you care to offer.

So we will turn to Mr. Muris first.

STATEMENT OF TIMOTHY J. MURIS, CHAIRMAN, FEDERAL TRADE COMMISSION, WASHINGTON, D.C.; ACCOMPANIED BY SUSAN CREIGHTON

Mr. MURIS. Thank you very much, Mr. Chairman. It is a pleasure to be here again to talk on behalf of the Federal Trade Commission regarding this important issue.

As you mentioned, both the House and the Senate have passed versions of Hatch-Waxman reform. These reforms do incorporate most of the recommendations that the Commission made last year, and overall we are certainly supportive of the thrust of the bills.

Both bills, as you mentioned, amend Hatch-Waxman to allow only one 30-month stay per drug product per ANDA for patents listed in the Orange Book prior to the generic filing its ANDA, a proposal, as you mentioned, that you made and that we support. This provision, if it does become law, would have eliminated all eight of the instances in our study in which a brand name company's later listing of patents resulted in an additional 30-month stay.

Both bills provide generic applicants a new tool to correct patent information listed in the Orange Book. Generic applicants would be able to assert a counter-claim that Orange Book information is improper and should be corrected or removed. We support this provision and suggest that Congress extend the bases on which such a claim could be brought to parallel the basis for which a brand may submit a patent for Orange Book listing. So we think that the same bases for listing that are available should be available for delisting.

The Senate bill adds a provision clarifying that if a brand name company fails to bring an infringement action within 45 days of receiving notice of an ANDA containing a paragraph IV certification, the generic applicant can bring a declaratory judgment action that the patent is invalid or not infringed. Without commenting on its constitutionality, we support this provision because it allows any patent questions to be resolved simultaneously with FDA approval of the ANDA.

Both bills require drug companies to file certain patent settlement agreements with us, as you mentioned, within ten days of execution. The House bill also requires the filing of agreements between generic applicants, and we support these notice provisions.

Let me turn to a point you mentioned, which is the bill's reform of the 180-day exclusivity period. Both bills eliminate the current court decision trigger. Accordingly, only the first generic's commercial marketing will trigger the 180-day exclusivity period.

Consistent with our study, both bills clarify that the first generic's marketing of the brand name product constitutes commercial marketing to trigger the period. Eliminating the court decision trigger could allow, however, the first generic applicant to park the exclusivity by delaying the start of its commercial marketing.

The bill contains forfeiture provisions that attempt to safeguard against this possibility. Despite this safeguard—and I believe that your opening statement addressed this point as well—the Commission believes that the bills virtually ensure that the first generic applicant will receive the 180-day exclusivity.

The 180-day exclusivity near-guarantee arises because the failure to market forfeiture provision is triggered when the first ge-

neric applicant fails to market within 75 days of the latter of, A, receiving final approval of the ANDA, or, B, an appeals court decision on the patents that were subject to the first applicant's paragraph IV certifications.

We have two concerns about this provision. First, it may delay the first generic applicant's commercial marketing by an additional ten months, as compared to the current regulatory structure. And ten months in this world, particularly with blockbuster drugs, is a lot of money for consumers.

Under the current rule, the 180-day exclusivity is triggered by any district court decision, not an appellate court decision. This rule encourages the first generic applicant to market as soon as possible thereafter or risk losing its exclusivity.

The FTC study found that appeals courts overturn only about 7 percent of district court decisions of patent invalidity or non-infringement in the Hatch-Waxman context. If the 180-day period starts only after an appeals court decision, then consumers may wait longer for the price reductions that generic entry cause.

Second, the district court decision trigger is important to encourage subsequent generic entry. Our study suggested that a district court decision in a case involving a subsequent generic applicant trigger the first applicant's 180-day period. The first applicant's exclusivity—and again this is a point that you raised—should not unreasonably block subsequent entry.

To address these issues, we suggest that the failure to market provision reference a district court rather than an appeals court decision. We also suggest amending the language of the failure to market forfeiture provision to state that court decisions dismissing a declaratory judgment action for lack of subject matter jurisdiction would trigger the first applicant's 180-day period. This change will ensure that the 180-day period does not unreasonably block a subsequent generic applicant's market entry after allowing the first applicant a reasonable time to begin commercial marketing.

I want to thank you again, Mr. Chairman, and we look forward to working closely with the Committee, as we have in the past, to ensure that competition in this critical sector of the economy remains vigorous.

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

Chairman HATCH. Thank you so much.

Mr. Dudas.

STATEMENT OF JON W. DUDAS, DEPUTY UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY, AND DEPUTY DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE, DEPARTMENT OF COMMERCE, ARLINGTON, VIRGINIA

Mr. DUDAS. Mr. Chairman, before I begin testifying, I want to apologize. You mentioned that I was a former staffer on the House Judiciary Committee, and every time I come to testify before Congress—I had built up a reputation as a staffer of giving particularly aggressive questions to the Chairman—I realize how wrong I was in doing that and I like to acknowledge that publicly whenever I have the chance.

Chairman HATCH. We Chairmen never ask aggressive questions. We appreciate that admission.

Mr. DUDAS. Thank you for the opportunity to share the Administration's views on the patent-related provisions of the Senate- and House-passed versions of H.R. 1, the Prescription Drug and Medicare Improvement Act of 2003.

Mr. Chairman, as you know, the Administration has placed a high priority on ensuring that the American people have access to existing prescription drugs at prices they can afford. We have worked and will continue to work with Congress to promote access to affordable medication for all consumers. We all share that goal, and I presume that we all share an additional goal to ensure that the United States continues to encourage the development of new prescription drugs that can in turn be accessible to all consumers on an affordable basis.

I have read of a 1988 study of 12 industries by the University of Pennsylvania that estimates that 65 percent of pharmaceutical patents would not have entered the market without adequate patent protection. Can you imagine the difference today if this hearing were focused not on making a multitude of prescription drugs more accessible and affordable to Americans, but on why America was failing to develop cures to this multitude of diseases?

It is critical that our efforts to provide access do not inadvertently jeopardize the benefits of medical innovation by adversely impacting the intellectual property rights of those who have dedicated significant resources to researching, developing, and commercializing new drugs. Furthermore, the time-tested and systematic incentives afforded by our patent system must be respected for all innovations, regardless of whether they are pharmaceuticals, micro processors, or aircraft engines.

Mr. Chairman, the Drug Price Competition and Patent Term Restoration Act of 1984, which you authored, is a landmark statute that has arguably done more than any law on the books to increase access to affordable prescription drugs.

Through careful balancing of interests of consumers and drug innovators, the Hatch-Waxman Act has facilitated the entry into market of over 10,000 generic drugs, while still respecting the patent rights of brand name drug manufacturers.

Given the success of Hatch-Waxman, it is paramount that any revisions to the statute be carefully considered and balanced to maintain the right level of incentives and deterrents. In that regard, we have concerns that some of the patent-related provisions in the Senate version of H.R. 1 could undermine the patent system, while doing nothing to make prescription drugs more affordable or accessible.

The Senate version of H.R. 1 would amend Title 35 to establish an actual controversy between the generic and the patent owner if the patent owner failed to file an infringement action within the statutory window. This is problematic from a patent standpoint for several reasons.

First, by lowering the threshold for challenging a patent, the patent owner would have to bear significant litigation costs which ultimately may be passed on to the consumer in the form of higher drug prices.

Secondly, the presumption of validity that attaches to all patents would become clouded in this area. This would make it riskier for patent owners to market, commercialize, and license their pharmaceutical innovations. In the long run, this could reduce the access to valuable new medicines because the incentives of the patent system will itself be reduced. Finally, the amendment raises consistency issues with respect to our obligations under applicable international trade agreements.

Our second area of concern relates to the circumstances for denying treble damages. The Senate version of H.R. 1 would permit a court to refuse to award treble damages to a patentee who failed to list certain patents in the FDA's Orange Book. This proposal appears to be a relatively harsh and unjustified penalty.

The purpose of treble damages is to deter a willful patent infringement by punishing the willful infringer. The law already provides appropriate consequences for failing to list certain patents, including a loss of the 30-month stay. However, the failure of the patent owner to perform a ministerial task administered by another agency has absolutely nothing to do with whether the accused infringer has acted in bad faith or in good faith. For these reasons, providing the court with discretion to deny treble damages for failure to list certain patents is problematic.

In summary, Mr. Chairman, while the goals of the drug affordability provisions of H.R. 1 are indeed laudable and ones that the Administration shares, it appears that the patent-related amendments in the Senate version will alter aspects of the Hatch-Waxman Act which continue otherwise to work well, while doing nothing to expedite the approval of lower-cost generic drugs.

As a result, the amendments actually threaten to reduce the protections in our patent system that will encourage the development of new drugs, the drugs of the future. Americans will certainly lose out if we reduce the incentives to find the next generation of medical cures and treatment for diseases such as Alzheimer's, cancer, SARS, and West Nile virus.

Given these potential pitfalls, we caution against the adoption of these patent-related provisions which not only fail to provide benefits to Americans who use prescription drugs, but risk that needed cures may not be discovered.

Thank you.

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

Chairman HATCH. Thank you, Mr. Dudas.

Mr. Troy.

STATEMENT OF DANIEL E. TROY, CHIEF COUNSEL, U.S. FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MARYLAND; ACCOMPANIED BY GARY BUEHLER, DIRECTOR, OFFICE OF GENERIC DRUGS, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MARYLAND

Mr. TROY. Thank you, Senator Hatch, Mr. Chairman. As you mentioned today, I am joined today by Gary Buehler, who directs our Office of Generic Drugs in the Center for Drug Evaluation and Research. I am very pleased and grateful to be with you today to

discuss reform of the Drug Price Competition and Patent Term Restoration Act, which we will continue to call the Hatch-Waxman amendments.

We are pleased to see that the proposed legislation, both bills, complements and builds on elements of our rule, as well as things that you have proposed in the past, and builds on the FTC's recommendations. We are, of course, committed to help speed generic drugs to market without compromising needed protections for innovation.

As I think you know, the Administration supports generally H.R. 1 and S. 1, and we have been very grateful for the opportunity to provide technical assistance. We think that both bills have come a long way both from last year and from what was initially proposed, and we think that they are very much workable. What we have really focused on is something that we can administer and that we can work with.

Let me start by talking a little bit about our rulemaking, which you mentioned before. Our reforms of the generic drug approval process are intended to help speed and reduce the cost of determining that a new generic drug is safe and effective. So on June 12, we announced final regulations that will streamline that process.

Our economic analysis shows that that rule is expected to save patients over $35 billion in drug costs over 10 years, while avoiding unnecessary litigation and protecting the process of approving and developing new breakthrough drugs.

In the final rule, as in all things we do with respect to Hatch-Waxman, we tried to maintain a balance between the innovator company's intellectual property rights and trying to get generic drugs to market in a timely manner. As I think you know, the final rule eliminates multiple 30-month stays, clarifies patent submission listing requirements, and requires a more detailed signed attestation accompanying a patent submission. We believe that these actions will significantly reduce opportunities to list inappropriate patents just to prevent access to low-cost generic drugs.

Of course, both the Senate and House have added generic drug access provisions to their versions of Medicare. They have passed both chambers and are in conference, and we are pleased that both of them include, as I mentioned, these key ideas embodied in our regulations and are improvement over last year. We do look forward to continuing to provide technical assistance, if requested.

To briefly list some of the key components of the Senate bill, it amends the existing statutory 30-month stay in the following three ways.

First, it would require the ANDA applicant to provide notice to the patent owner and NDA-holder within 20 days after the applicant has been notified that FDA has filed the applicant's ANDA if the applicant has submitted a certification that can trigger a lawsuit resulting in a 30-month stay, the so-called paragraph IV certification.

Second, it would limit the patents eligible for the 30-month stay to those that are submitted to the agency before submission of the ANDA. So it limits the universe and the generic knows which patents it must certify against.

The third is it would allow approval of an ANDA if, before any 30-month stay expires, a district court were to find the patent invalid or not infringed. Or if the district court judgment that finds the patent infringed is overturned on appeal, then it is the judgment of the court of appeals.

The Senate bill, as it was mentioned, also allows an ANDA applicant to file a declaratory judgment action against a patent owner or the NDA-holder if no patent infringement suit has been brought within 45 days after the ANDA applicant has provided notice of the certification challenging the patent. It seeks to make the failure to file such a challenge an actual controversy under the declaratory judgment statute. If a suit has been filed, the applicant may assert a counterclaim for an order to require deletion of patent information that the NDA-holder shouldn't have submitted for listing in the Orange Book.

The amendments to the existing statutory 180-day exclusivity provisions are essentially as follows.

One, it applies exclusivity on a product basis rather than a patent-by-patent basis, something that we strongly believe is preferable.

Second, it would allow exclusivity for all ANDA applicants that challenge patents on the first day that ANDAs challenging patents can be submitted for the particular listed drug, which incidentally is a topic we have addressed in a guidance that we released today.

Third, it would trigger the 180-day exclusivity with commercial marketing only as Chairman Muris mentioned before.

Fourth, it would provide for forfeiture of an applicant's eligibility for exclusivity under the following circumstances: first, if the drug isn't marketed within a particular period of time or after the court resolves the status of the challenged patents; two, if the applicant withdraws its ANDA; three, if the patent challenges are withdraw; four, if the applicant fails to obtain tentative approval within 30 months; five, if the applicant enters into an anti-competitive agreement; or, six, if all qualifying patents expire. We have provided technical assistance with respect to this last provision suggesting deletion.

The bill defines bioavailability and bioequivalence for non-systemic drugs. And, of course, the bill states that a court can refuse to award treble damages under certain circumstances.

I want to conclude just by going through at least what are the key differences from our perspective between the House and Senate generic drug bills.

First, approval of a different listed drug. The House bill prohibits ANDA applicants from amending or supplementing an application to seek approval of a generic drug referencing a listed drug that is different from the listed drug identified in the original application. This prohibition does not apply to different strengths and the Senate bill does not have such language.

The second difference is the civil action for patent uncertainty. The Senate bill allows the ANDA applicant to bring a civil action for declaratory judgment that the patent is invalid or will not be infringed if the patent owner or NDA-holder has not brought suit within 45 days after notice has been received. Of course, the House bill is somewhat different.

Third, access to confidential ANDA information. The House bill allows a DJ action to be brought if the 45 days expires and the notice was accompanied by a document providing a right of confidential access to the ANDA applicant's application in order to determine if a lawsuit could be brought.

This provision sets forth the contents of the document, including restrictions on access to the application and the uses that the information can be put to through the process. The Senate bill doesn't have such a confidential access provision. Failure to bring a patent infringement action in the Senate bill makes a failure to bring such an action within 45 days of notice an actual case or controversy, as I mentioned. There is the treble damages provision which is in the Senate bill, but not in the House bill.

Finally, with respect to filing of certain agreements with the FTC, they both have requirements that certain agreements between generic manufacturers and innovators about the marketing of generic drugs should be filed with the FTC. But the House bill requires that certain agreements between generic manufacturers also be filed with the FTC, while the Senate bill does not.

The legislation does not address all of the provisions of the final rule. If the legislation were to pass, based on our review we believe that only the 30-month stay provision of the final rule would be impacted. We continue to address the issues that have been raised regarding the statute and we continue to try and implement the Hatch-Waxman amendments as best we can, given the statutory text, the history of the legislation, and the many court challenges. We have tried to maintain a balance, as we mentioned, between protecting innovation in drug development and expediting the approval of lower-cost generic drugs.

I am grateful for the opportunity to talk with you. I am grateful for the opportunity that the FDA has had to provide technical assistance and to work with staffs on both sides of the aisle with respect to this important legislation and this important issue, and I will be happy to answer any questions.

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

Chairman HATCH. Well, thank you. We are grateful to have you here and we are grateful for the work you are doing out there.

Mr. Bradshaw, we will turn to you.

STATEMENT OF SHELDON BRADSHAW, DEPUTY ASSISTANT ATTORNEY GENERAL, OFFICE OF LEGAL COUNSEL, DEPARTMENT OF JUSTICE, WASHINGTON, D.C.

Mr. BRADSHAW. Thank you, Mr. Chairman, for inviting me here today to provide the Administration's views on H.R. 1, the Medicare Prescription Drug and Modernization Act of 2003.

My testimony today will focus on a single provision in the Senate version of the bill, Section 702(c), which declares that the Federal court shall have subject matter jurisdiction over certain declaratory judgment actions. Specifically, the provision in question provides that the failure of a patent owner to bring an action for patent infringement against a company that files a new drug application or the FDA that is based on one of its patents within 45 days of receipt of notice of the application shall establish an actual con-

troversy between the applicant and the patent owner sufficient confer subject matter jurisdiction in the courts of the United States to hear an action brought by the applicant under the Declaratory Judgement Act.

As you noted, Senator Hatch, on June 17, 2003, I provided this Committee with the Administration's tentative views on a similar provision contained in S. 1225, the Greater Access to Affordable Pharmaceuticals Act. At the time, the Administration had not yet formulated a view on whether cases brought pursuant to such a provision would satisfy the Article III case or controversy requirement.

I did, however, make several general observations about the matter. I noted that, among other things, the case or controversy requirement set forth in the Declaratory Judgment Act was constitutionally compelled, and that like other Article III requirements, it could not be waived by Congress.

Having now had an opportunity to examine the provision in greater detail—and I also note that I have reviewed the materials submitted by both Professor Yoo, who, as the Chairman is aware, was in the Office of Legal Counsel for the last several years and who I had the opportunity to serve with as a deputy, along with the materials submitted by Boyden Gray.

Having had a chance to review those materials, along with the relevant law, the Administration is of the view that in its present form, Section 702(c) is inconsistent with Article III of the Constitution. This provision, which again does not appear in the House version of the bill, attempts to vest the lower Federal courts with jurisdiction over disputes that, because of Article III's case or controversy requirement, the Constitution does not empower these courts to hear. Accordingly, it is the view of the Administration that this provision should either be deleted from the bill or rewritten.

As you are aware, both the Senate and the House versions of H.R. 1 make amendments to the process by which n new drug applications are approved. As amended, the process would require certain applicants to give notice to existing owners of a patent or to holders of an approved application. The notice must provide a detailed factual and legal basis for why the application does not infringe the recipient's patent or why the recipient's patent is invalid.

If the recipient of the notice sues for infringement within 45 days following receipt, it receives a significant benefit. Among other benefits, the application may not be approved until the resolution of the infringement suit, the expiration of the relevant patents, or the passage of 30 months from the date of the notice.

Both the Senate and the House versions of the bill provide that if a patent holder does not bring suit within the 45-day period, the applicant may then bring a declaratory judgment action for non-infringement or patent invalidity. The Senate, again, but not the House, goes further and provides that the failure of the owner of the patent to bring an action for infringement of a patent within this 45-day period shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States.

Herein lies the Constitutional infirmity. The Declaratory Judgment Act requires that a dispute be an actual controversy before the Federal courts have subject matter jurisdiction over actions to declare the right of the parties. The Senate version of H.R. 1 purports to declare this requirement satisfied in every case by the failure of the patent holder to bring an action within 45 days and thus vest the Federal courts with subject matter jurisdiction in all of these cases. Congress, however, cannot so declare.

The limitation on the Federal courts jurisdiction emanate from the Constitution, not merely from the actual controversy requirement of the Declaratory Judgment Act. Under the Constitution, Federal courts have jurisdiction over a dispute only if it is a case or controversy within the meaning of Article III. The restriction on the court's authority is fundamental to the separation of powers established by the Constitution and enjoins the Federal courts from issuing advisory opinions. This requirement, consequently, operates as a limitation on Congress' power to grant the courts jurisdiction.

Put simply, Congress cannot expand the court's power to hear cases beyond what the Constitution itself provides. In fact, that was the holding of the Court's decision in Marbury v. Madison.

Courts have read the Declaratory Judgment Act's actual controversy language to track the Constitution's case or controversy requirement. The Supreme Court has adjudged the Act constitutional only by interpreting it to confine the declaratory judgment remedy within conventional case or controversy limits.

If the Declaratory Judgment Act were effectively amended with respect to these patent cases, satisfaction of the statutory actual controversy requirement would no longer be sufficient to grant the courts jurisdiction. The courts would still have to satisfy themselves that the dispute was an actual case or controversy under the Constitution.

Although Congress made it clear that a certain set of facts fulfills the statutory requirement, it cannot declare Article III's limitation satisfied. If it did so, it would be improperly intruding on the courts' province to interpret the Constitution.

Just as Congress may not declare the Article III standing requirement satisfied, so may it not declare Article III's case or controversy limitation satisfied. Congress simply cannot expand the Federal courts's jurisdiction beyond the bounds established by the Constitution.

Section 701(c) of the Senate version of H.R. 1 thus can have no effect. In many cases, the actions brought following the 45-day period will meet the constitutional case or controversy requirement independently of Section 701(c)'s declaration, and as applied to those cases, the provision is constitutional, but without any purpose.

Currently, to determine whether Article III and the Declaratory Judgment Act are satisfied in patent disputes, Federal courts have asked whether the applicant has a reasonable apprehension that the patent owner will sue for infringement. Applying this standard, courts look to a variety of factors, including communications between the patent holder and the applicant and the actions of the patent holder with respect to other possible infringers.

Indeed, in light of the statutory benefit conferred on the patent holder if he sues within the 45-day period, it is likely that a court would consider the applicant's reasonable apprehension to be diminished if the patent holder does not sue for infringement within that time.

Over disputes the courts determine are insufficiently definite and concrete to rise to a case or controversy, the Constitution prohibits Congress from granting the courts jurisdiction. Accordingly, the courts would decline to hear such cases and Section 701(c) would again be rendered ineffectual.

For these reasons, it is the view of the Administration that the Senate version should be amended to delete the language purporting to confer the Federal courts with subject matter jurisdiction whenever a recipient of the required notice has not sued within the 45-day waiting period.

I look forward to addressing or answering any questions that you or Senator Schumer might have.

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

Chairman HATCH. Well, thank you so much. I appreciate all the witnesses here today. You have really done an excellent job.

I am going to turn to Senator Schumer because he has to head back to New York, and I want to compliment him for being willing to listen not only to me but to others to try and get this bill as perfect as we can, because it is a very, very important bill and we all know that. I take a personal interest in it, as you know, but I want to personally compliment my friend for being open and willing to effectuate some of these changes that have already been effectuated, but I think there are a few more that we need to work on.

So I will turn to you, Senator Schumer, for your statement and any questions you might want to ask.

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

Senator SCHUMER. Thank you, and again I want to thank you, Mr. Chairman, for your leadership in holding this hearing today, but more importantly for your leadership on the issue.

As I have said throughout the course of working on this issue, I think that Hatch-Waxman was one of the greatest pro-consumer pieces of legislation in the last 25 years. It has saved Americans billions of dollars and made very important drugs more available to many people who wouldn't get them. Your leadership in authoring the bill back in 1984 was truly ground-breaking.

But as we know—and we both know this—the law has been abused in recent years, and I especially want to thank you for recognizing that and calling the multiple hearings you have had over the last few years to bring the issue to light and to move the ball forward as we go where we are going today.

I also want to thank Senator Leahy, and, Mr. Chairman, I would ask unanimous consent that Senator Leahy's full statement and my full statement be put in the record.

Chairman HATCH. Without objection, and we will keep the record open for any other statements by members of the Committee.

Senator SCHUMER. Senator Leahy, along with you, Mr. Chairman, drafted the Drug Competition Act, another piece of legislation key to ending the anti-competitive behavior in the pharmaceutical industry. I have always supported this legislation. I did when I was in the House, and I am very happy to see that it has been included in both the Senate and House versions of the Medicare bill as well.

It is this bill, along with the Gregg-Schumer bill which we are here to discuss today, that will ensure that as the Federal Government implements a Medicare drug benefit, precious taxpayer money will not be wasted due to anti-competitive gaming.

I would also want to thank Senator Gregg for his leadership in approaching me and bringing together Senators McCain and Kennedy, with whom I have worked on this issue for the past few years to craft a strong bipartisan compromise which is now part of the Medicare bill in conference that passed the Senate 94 to 1. I am not going to mention who the 1 was.

In drafting the bill this year, we have made modifications to address the concerns that kept the bill's critics from supporting it last year, including many of those of the Chairman. And he is certainly correct, he has given great advice in this area.

I was also, of course, pleased to see similar provisions in the House bill, though I do have very serious concerns about the areas in which there are significant differences in this approach, and I will touch on those in a minute.

The Senate bill, passing nearly unanimously, is an effective, efficient approach to achieving the goals of the original Schumer-McCain bill, making sure that after a pharmaceutical company has gotten a return on their investment, generic drugs are available quickly.

Specifically, the Gregg-Schumer bill in S. 1 will remove barriers to access and increase competition in the pharmaceutical marketplace. Simply put, it will get lower-cost generics into the pharmacies and into the hands of consumers as quickly as possible. I do not believe the House bill will effectively achieve these goals.

But before I get into the details on the differences of the bills, I just want to say that we have come a long way in the past few years on this issue. With these bills in conference, we are on the verge of making some real progress for consumers. We are all familiar with the abuses, and over the past year or two support for this legislation has only continued to swell.

In past hearings, we have heard from the FDA, the FTC, and witnesses representing consumers and States, all of whom shared their concern about the ways in which the pharmaceutical industry was taking advantage of loopholes in the law at the expense of the consumer.

For years, the carefully crafted balance of Hatch-Waxman worked as it was intended, to bring low-cost generic drugs to the market quicker, while continuing to provide ample rewards for innovation. But as profits spiraled higher and as blockbuster drugs no longer came on with the frequency that they did in the past, the pharmaceutical industry began to see their multi-billion-dollar monopolies coming to an end.

Without new blockbusters ready to replace the old, they changed their approach to innovation. In too many instances, instead of in-

novating new drugs, they have been innovating new patents. Find a good lawyer, he will find a good loophole. But as we attempt to close the loopholes, as they say, the devil is in the details, and I am sure my friend, Chairman Hatch, would agree there is perhaps no other statute for which this phrasing is more true. Change an "and" to a "the" and you go from huge savings to huge costs.

I want to reiterate that the bill that Senators Gregg, McCain, Kennedy and I put together is extremely carefully crafted. It is fair and balanced, and I will not watch and stand by as it is watered down in conference. Though there are only a few areas of difference between the bills, the differences could mean seriously different outcomes for consumers, and that causes me serious concern.

First and foremost is the difference between the declaratory judgment provisions, which were just spoken about by Justice. First, I understand that some have raised questions about the constitutionality of the Senate approach, and I understand, and I have just heard DOJ testify to that effect.

Mr. Chairman, quite frankly, I am floored. Last fall, the President went to the Rose Garden and made it his mission to, quote, "close the loopholes and promote fair competition." This is precisely what the declaratory judgment provision will achieve.

We have heard from Chairman Muris of the FTC and he said, again, the importance of timely resolution of patent disputes to ensuring robust competition, the importance of which was also clearly communicated in the FTC report released last summer. To hear the Department of Justice sitting here today suggesting we delete a provision which is at the very heart of promoting timely, robust competition—well, I am sorry to say this to our President, but you can't have it both ways. You can't say you are for the consumer and you want to bring generics onto the market quickly and then have your Administration testify to rip out the heart of this bill without even proposing an additional solution.

We originally had litigation. Many on the other side said litigation is not the way to go. I understand the bias, so we came up with this provision, and now they say get rid of it. Well, I have to tell you this is becoming—and I am sorry to get excited here, but this is becoming a trend of this Administration.

The President goes and pats the head of a kid on Head Start and then cuts money from Head Start. The President talks about AIDS in Africa and lets Congress cut money in Africa. The President says he is for renewal of the assault weapons ban and then whispers to the House you can kill it. Well, it is not going to happen on this bill, at least not if there is anything I can do about it.

If there was good faith and they proposed something else, another quick way for timely resolution, that is fine. But we spent months and months and months coming up with a solution for timely resolution and this is it, and it flies in the face—PhRMA, of course, says this is not constitutional. I don't think you should be a voice piece for PhRMA if you believe in the consumer, because most every expert says it is not unconstitutional. And if you believe it is, let the courts decide.

Let me just say a few more things about this. I have letters from two well-respected constitutional experts. One is Henry Dinger—he is with Goodwin, Procter—who has decades of experience with con-

stitutional questions such as this. The other is from John Yoo, who worked for the Administration. He is formerly from the Office of Legal Counsel and now he is fellow at the American Enterprise Institute and a very well-respected scholar, perhaps the most respected in the field. Clearly, he doesn't agree with me on politics if he is at AEI. He is a professor at Berkeley.

Both of them make it perfectly clear there is no constitutional issue with this provision, and I would ask unanimous consent that they be put in the record.

Chairman HATCH. Without objection, we will put them in the record.

Senator SCHUMER. I want to stress the importance of the declaratory judgment provision in this bill. It is key to making the system work. There is not currently a clear pathway for a generic drug company to get a declaratory judgment to show that they do not infringe a patent.

We saw yet another example of this just three weeks ago when the District Court for the District of New Jersey dismissed Dr. Reddy's case for declaratory judgment that their generic does not infringe on a patent to Pfizer's blockbuster drug Zoloft. Basically, Dr. Reddy challenged the patent. Pfizer did not choose to sue within 45 days and Reddy wanted assurances from the court that they were clear to go to market without the risk of Pfizer suing later.

The court dismissed the case for lack of subject matter jurisdiction, and now Dr. Reddy has to go back to the drawing board and generic competition on a significant drug will be delayed for a long time. On a drug with sales of $2.4 billion per year, this decision could cost consumers hundreds of millions of dollars, and that is just one drug and one decision.

At the very heart of Hatch-Waxman is the goal of ensuring that patent disputes are resolved before generics come to the market. Without a clear right for the generics to bring a suit for declaratory judgment, the brand companies are in a position to leave the generics in the dark. The brand company can list a new patent, sit back and wait and wait and wait and wait.

Sure, the generic could go ahead and go to market at risk, and then the brand company could pounce. And if they win the suit, they could collect triple their lost profits. I ask the audience, I ask anybody, what generic company in its right mind, with its shareholders watching closely, would be willing to take that risk?

We must ensure that if there are issues of potential patent dispute which the brand company decides to take its sweet time in addressing that at least the generic will be able to go to court and say, look, I want to go to the market, get this product to consumers, will you give me clearance to go?

Without a strong declaratory judgment provision to amend Title 35, we are not reducing delays. We are simply changing the nature of those delays and leaving wide open the potential for gaming and abuse. The approach taken in the Senate bill is fair and workable, and in Title 35 it parallels the creation of the artificial act of infringement that was created by Hatch-Waxman in 1984. As I said, I will not sit idly by and watch this provision and watch our whole compromise gutted. I am not here for a hollow victory. I believe in this issue.

The House bill, instead of enhancing the ability of the generic to seek declaratory judgment, takes a step backward. It makes the right of the generic to bring an action for declaratory judgment contingent on the generic handing over sensitive proprietary information about its product, all without any kind of protective order from a court and with no enforcement of any kind to prevent the brand company from using this information inappropriately. I don't know of any precedent for this type of disclosure, nor do I know any company that would simply turn over highly sensitive proprietary information with no assurance that the information will be protected.

Now, the second major difference in the bills is that the House version is devoid of a mechanism to enforce the brand companies to list patents appropriately. The Gregg-Schumer bill includes a provision to ensure that brand companies comply with the new rules by saying that if a brand company doesn't list a patent which should have been listed, the court may decide not to award treble damages if the generic chooses to go to market.

Without such a provision, who will enforce that the brand companies comply with the new rules? After all, Mr. Chairman, the FDA has never taken enforcement action with regard to patent listing and we have every reason to believe they won't start. In fact, Mr. Troy has repeatedly testified that this is not their job. So an independent enforcement action is key to making these rules work.

Finally, there is a provision in the House bill which is commonly referred to as the anti-bundling provision. Quite frankly, I can't figure out why it is in there. What I hear is that it is intended to codify existing FDA guidance on what can and can't be included in a generic application.

Well, it is my understanding that the FDA's guidance is very clear on this point and its system has been working just fine. I don't know of a single example of how these procedures have been problematic in the drug approval process.

As I mentioned earlier, Mr. Chairman—and I am coming to a conclusion here because I know we are trying to catch planes and things—as I mentioned earlier, the statute is extremely complex. And as we have plainly seen, any change we make to the statute runs the risk of being interpreted overly broadly or of opening new loopholes.

Why we would want to take the risk of opening up new loopholes that could cost consumers billions when there is no evidence that this is an area in need of clarification is beyond me. I strongly feel we should leave this one to the FDA.

Before I close, Mr. Chairman, I would like to make a plea to the brand pharmaceutical companies. You make a great product. Me, my family, everyone I know has benefitted, but you are losing your goodwill day by day. Don't become like the tobacco industry. They made a product that hurt people. You make a product that helps people.

I understand the desire of CEOs to have high profits, to maximize profits. That is their job. But, you know, they shouldn't just think of the next quarter because very time the pharmaceutical industry goes against a reasonable provision like this, they increase the chances that provisions they like even less, such as reimportation, will become law.

Everyone knows this is fair. Everyone knows Hatch-Waxman is right, and everyone knows there are abuses. Instead of fighting it head-on, you go to the House and get these provisions slipped in that you know will decimate the bill.

Well, this generic drug provision is like the escape valve on the pressure cooker, the pressure cooker of high drug costs, and if we close this escape valve in compliance with your wishes, we are just going to create more pressure and sooner or later the lid on the whole pressure cooker is going to blow off.

So I would ask you to work with us on this bill. I would ask you to make sure that we get a strong bill, but I will tell you this: I am not going to sit by with a compromise that decimates this proposal, into which went a lot of hard work.

I am sorry for my lengthiness, Mr. Chairman, and I will apologize to the panel. I did have questions which I would like to submit in writing.

Chairman HATCH. Without objection.

Senator SCHUMER. I have to get on my way. I am sorry.

Chairman HATCH. Well, thank you, Senator.

Senator SCHUMER. Thank you.

Chairman HATCH. You have taken a great interest in this, and even though you are wrong, you have been very persuasiveness, though, I have to admit.

[Laughter.]

Senator SCHUMER. Persuasive.

Chairman HATCH. But not quite there.

Senator SCHUMER. Thank you, Mr. Chairman.

Chairman HATCH. I am personally happy that you have taken an interest in this. You have a good break, too.

Let's turn to you, Mr. Bradshaw.

Mr. BRADSHAW. Well, sure. I—

Chairman HATCH. Well, let me ask a question first.

[Laughter.]

Mr. BRADSHAW. I was anxious to respond to some of Senator Schumer's comments.

Chairman HATCH. I will give you every opportunity. I am really happy to have you here and it is good to see you back here again. We appreciate you coming back to your Committee with your determination on the constitutionality of the declaratory judgment provision in the Senate bill.

I read with great interest the correspondence from Boyden Gray, former White House Counsel; John Yoo, a former staffer of mine, a brilliant man, no question about that. I understand that Mr. Yoo has submitted additional comments just this morning, and I look forward to reviewing those. I didn't have a chance to do that yet. I have no doubt that Mr. Gray and his colleagues will probably choose to submit additional views themselves about your testimony and Mr. Yoo's supplemental comments.

Your testimony comes down squarely on the side of Mr. Gray and concludes that this is a bald attempt to legislate around the case or controversy constitutional requirement. Now, I can't speak for any of the other 94 Senators who voted for this bill, but this Senator thinks that the better view is that the Senate-passed language has major problems. I don't think anybody looking at it who has

studied case and controversy litigation and law can just dismiss this question.

Now that you have diagnosed the Senate bill as being broken because of this, please help us fix it. Your testimony suggests that the offensive language simply should be deleted. Now, if I understand your testimony at page 3, you believe that even without the offending actual controversy language, there is good reason to believe that the courts would confer jurisdiction in a bona fide patent challenge situation.

Am I correct on that?

Mr. BRADSHAW. Well, yes, several things. There certainly is a way to fix this to make this constitutional. On the latter point, also, just as certain, if Congress were to pass the Senate version as it currently stands, a court would nevertheless not entertain an action if it felt the case or controversy requirement were not satisfied.

It is a constitutional requirement embedded in Article III of the Constitution. Notwithstanding the fact that Congress asserts that a case or controversy has, in fact, been established by the failure of a patent-holder to bring a lawsuit during the 45-day period, the court would still independently require there be a case or controversy. So, yes, a court would find this provision to be without effect.

Chairman HATCH. Well, constitutional considerations aside, from a civil justice reform perspective, do you have any thoughts on the House declaratory judgment language with its right to confidential access provision, versus the Senate language absent the offending actual controversy language?

Mr. BRADSHAW. I don't have any specific comments on the House language other than to say that a bill could just simply allow an individual who has not been sued, an applicant who has not been sued during that 45-day period to bring a case under the Declaratory Judgment Act. The Declaratory Judgment Act itself then would require that there be an actual case or controversy.

Chairman HATCH. Besides deleting the language, which you have suggested here, do you have any other suggestion as to how we might fix the language?

Mr. BRADSHAW. Well, I think you could do several things. The suggestion I would have is to leave in the language allowing an applicant to bring a declaratory judgment action and just simply striking the language that asserts that by doing so, the district court shall have subject matter jurisdiction and there shall be an actual controversy. That language simply isn't necessary.

If the goal of the sponsors is simply to allow individuals to have access or to be able to bring an action under the Declaratory Judgment Act, that can simply be asserted in the legislation that they have such a right. Then they would have to satisfy the statutory requirements of the Declaratory Judgment Act, along with the constitutional ones.

Chairman HATCH. Thank you.

Mr. Muris, welcome back to the Committee. We are delighted to have you here again. Now, before DOJ came down on the constitutionality question, you appeared to state a preference for the Sen-

ate language, and let me just work on your thoughts for a minute or tease them out on the House bill.

Your testimony states that the right of confidential access to the ANDA application may be unnecessary. My question is this: Are you saying that the right to access language is superfluous or somehow counterproductive?

Mr. MURIS. I think what we are saying is that the generics have every incentive not to get entangled in complex litigation with the branded companies, with the innovators. Therefore, they have incentives to provide sufficient information about whether their ANDA infringes. In that sense, we think it is superfluous.

Chairman HATCH. Do you have any preference between the House declaratory judgment language and the Senate language, with the troublesome, quote, "actual controversy," unquote, language stricken?

Mr. MURIS. We have not opined on the constitutionality. That is beyond our expertise, my personal expertise. I have a lot of respect for both lawyers on the opposite side. In fact, I worked for Boyden Gray in the Reagan Administration. That doesn't mean I always agreed with Boyden, but he is obviously a very powerful mind.

Chairman HATCH. Well, no one always agrees with Boyden, I have to say, and Boyden doesn't always agree with everybody.

Mr. MURIS. Right, but we all remain very fond of Boyden.

Chairman HATCH. That is true.

Mr. MURIS. The reason we have the preference for the provision of the Senate is there is a real concern on the part of generics that the brandeds will opt out of the system, the Hatch-Waxman system, and just sit back and wait. And so instead of having the FDA review of the generics ANDA and the court review occurring more or less on the same time frame, you will have them run consecutively and you will have greater delay.

It is true that the generics have—depending on the circumstances, but our report revealed that the generics were very cautious—entered before a district court decision, not with some of these more bogus claims that we challenged, but with some more basic patent disputes.

Therefore, I understand their concern. I think it is a legitimate concern. We are talking about a world that hasn't existed in the past that may exist in the future. For that reason, because we think it is a legitimate concern is why we have expressed a preference, leaving the constitutionality aside, for the Senate language.

Chairman HATCH. Well, thank you so much.

Mr. Troy, we are happy to have you here again. I think you are doing a great job out there. But the same question to you: what are your thoughts on the declaratory judgment matter, now that the Department of Justice has found the Senate language is constitutionally problematic? And how should the conferees fix this problem in a way that will achieve the goal of giving generic challengers the appropriate opportunity to litigate the patents?

Mr. TROY. Well, let me say that we entirely defer to the Department of Justice on the constitutional issue. The declaratory judgment action sort of takes place, if you will, of outside the context or outside the rubric of FDA. So we don't have strong views one way or the other with respect to the DJ provisions.

I guess I will have a few observations. Of course, the Senate bill allows the ANDA applicant to bring a civil action for declaratory judgment that the patent is invalid or won't be infringed if the suit isn't brought within 45 days. That essentially makes express what we think is implied already, so it is not necessarily necessary for the bill to do that. But it certainly does no harm and it does not really affect us.

With respect to the House with respect to the confidential access, we don't have, again, strong views on that one way or the other. We do think that it would be helpful if it made clear that there was no obligation on FDA at all to do the redactions or anything like that.

I don't think the intention is for FDA to play a role in that process. It is, of course, helpful for us for it to be made clear that we have no obligation in that process because, in general, when there is patent litigation ongoing, we don't get involved and we seek not to get involved, and we don't want there to be any suggestion that we really should get involved.

So, again, deferring entirely to the Department of Justice on the constitutionality, I think we think that there are salutary features of this bill that would make the world better—of both these bills that would make the world better, the DJ action issue aside. We think that building on your suggestion and on the FTC suggestion and our rule to make clear that there is one 30-month stay is a good thing. We think the way that the 180-day exclusivity would operate would be improved under both bills.

Chairman HATCH. Thanks. I know Mr. Muris has to go in about 5 minutes, so let me approach both of you. Both of you can answer this if you would like.

Mr. Muris, on our next panel we are going to hear from Bob Armitage, of Eli Lilly, who will argue that this new 180-day marketing exclusivity system will routinely result in 180 days of marketing exclusivity being awarded to generic drug firms who don't defeat the basic composition of matter or method of use patents, but merely find a way of inventing around the formula of the drug.

Now, I understand that Mr. Armitage has met with both of your staffs. My friend, Senator Schumer, criticizes the R and D firms for inventing new patents, not inventing new drugs. But might it be the case that the legislation contains a system whereby potentially billion-dollar rewards will be granted to generic firms who have not invented around or defeated the basic patent rights, but really invented around what may be considered relatively unimportant formulation patents and, let me put it this way, parked the exclusivity?

And a follow-on question on that: why should multi-drug generic competition be delayed for 180 days, at great cost to consumers, merely because some non-infringing challengers of drug formulation patents filed papers with the FDA earlier than others?

Mr. MURIS. Mr. Chairman, there are at least three points there. One point which you were mentioning at the end is this question of whether we should give 180-day exclusivity at all. Our approach has been to respect the original balance in Hatch-Waxman, and we see no compelling reason in the facts of our study that the 180-day provision by itself caused particular problems.

However, a second point, and your mention of the word "park," raises this serious issue and we think there is the real possibility of delays in generic entry. You mentioned in your opening statement, and you had, I think, an intriguing idea of another trigger where there is a second generic ready to go. The way the bills are currently written, that first generic would have a right to block the second generic.

We are also particularly concerned about the additional delay that we think would be caused by the circuit court trigger. If you look at our data, the district court rule is a new rule. It has only been in effect since the *Mylan* decision in 2000. Before that, when generics had the option, they often entered, but they probably just as often—probably a little more than just as often—did not. This provision is meant, I think, to give the generics some more flexibility. The innovators like it in the sense that it may delay generic competition, but I think the consumer is left out of that.

The third and final point is in terms of basic patents, I think if those patents are valid that the generics are most often not entering, and that is not what the dispute is about. The dispute is often about the sort of patents that you are talking about. But, again, I think in the original Hatch-Waxman balance, that is a valid reason for generic competition.

One of the very important things you did and what, quite frankly, I am concerned about from a competition and consumer perspective is the tendency to pile on the pharmaceutical industry. There is an overwhelming incentive for government to act as a monopsonist, a power buyer, and thereby lower the price that it pays for prescription drugs, which is penny-wise and pound-foolish in the long run.

So I understand that point and I don't think that is a problem with Hatch-Waxman as proposed because you, in fact, extended patent life. That was a very important part of the compromise. And, in fact, I don't think that is a problem here. I think that is a problem with other possible legislation.

But I do think, to sum up, that for the generics, the 180 days does provide them an incentive to innovate and that is a useful incentive. Unfortunately, as we have talked about before, I have several hundred physicians waiting to hear me and if you would like, I have Susan Creighton, who will be the Director of the Bureau of Competition, and she could sit here and address any other questions.

Chairman HATCH. Well, thank you. We will sure release you and we will be happy to have Susan sit there.

Mr. MURIS. Thank you. I appreciate it, Mr. Chairman.

Chairman HATCH. Well, thank you so much.

Mr. Troy, do you have anything to add to that, or do you agree or disagree with what was said?

Mr. TROY. Thank you, Mr. Chairman. Let me say that Eli Lilly and Mr. Armitage raised new issues that were really not addressed or discussed during our discussions on either side. We certainly are happy to have a lot of smart people thinking about this and trying to avoid unintended consequences because I think as everyone agrees, there are few areas of legislation that I know about where the law of unintended consequences operates with the same force.

That said, let me offer just a few initial thoughts, and they are, let me just say, tentative initial thoughts on the Lilly piece.

We think that some of the 180-day provisions could create unintended difficulties. The testimony doesn't really provide specific language. When we gave technical assistance to the staff, we did raise the need to change particular language and I want to clarify what I may have misstated or may have been misunderstood during my opening statement.

In particular, we think the (CC) provision under failure to market, where it says when the patents expire—we think that should be deleted. We made that technical suggestion. There wasn't time during the many changes that were happening in the last few days for that to be made. We were not told there was any objection to it, and so we are interested in continuing to have a dialogue on that. I think that if that technical suggestion is made, it would at least address some of the concerns that are raised in the Lilly testimony.

There are some other deficiencies that are posed in the testimony that we are not quite sure are as problematic as that testimony may suggest. In particular, our regulations and court decisions interpreting pretty similar language preclude the possibility that a generic would still be eligible for exclusivity if they lose a patent infringement suit. At least we interpret these provisions with the intent that our regulations and court decisions on that point would apply.

So in other words, the ANDA applicant files a IV. If they lose, we don't think they can still under the rubric of that same paragraph IV certification commence entirely new litigation. That is the way we interpret it. Would it be helpful to clarify this interpretation? Perhaps. Is that necessary? We don't really think so.

We do think that this concept of basic patents is somewhat troublesome and we haven't seen a good definition of it. But to get to your, I think, philosophical question on 180-day exclusivity, I do entirely agree with Chairman Muris. We have approached the 180-day exclusivity provision with the end of giving effect to the original compromise.

The logical conclusion of some of the arguments raised in the Lilly testimony is that perhaps there shouldn't be 180-day exclusivity. Obviously, the existence to a certain extent delays full generic competition, which is when you really see the price drop.

On the other hand, the argument is that 180-day exclusivity does create a powerful incentive for people to come in and challenge these patents and to bring generic drugs to market in the first place. So we have, again, as the FTC has, tried to administer the statute making the 180-day provision as workable as possible.

Again, we were very grateful for the openness of the Senate staff on both sides of the aisle to talking with us about ways to make it more workable. We do think that the provisions in both bills with respect to 180-day exclusivity, which are identical, would make the scheme more workable.

Chairman HATCH. Thank you.

Mr. Dudas, we don't want to leave you out here today. We welcome you back to the Committee and appreciate the work you have done up here on Capitol Hill, as well as your work at the PTO.

I take it from your testimony that the PTO is not enamored of the Senate amendment to the patent code. Is it your view that PTO prefers the House language which does not alter the patent code?

But before you answer that question, I want to recognize Mary Critharis, who is with PTO and was on loan to the Judiciary Committee a few years ago. So we are grateful to have her here.

If you would take a crack at that, I would appreciate it.

Mr. DUDAS. Absolutely, and thank you for acknowledging Mary. We were very happy to take her back, and I know it was kicking and screaming.

The answer is yes. As we look at the patent provisions, in particular, there are concerns we have raised with patent provisions that are in the Senate bill that don't exist in the House bill. Our main concern, again, is maintaining the balance that is in Hatch-Waxman, the balance of making sure you have affordable medicines, but also making sure that new prescription drugs will come about.

What we have found in the patent provisions as we look at them is that we are creating a different system. We fail to see how it provides more accessible medicines, but we recognize that it could undermine the patent system and the balance that is in Hatch-Waxman today.

Chairman HATCH. One of your positions, and your testimony, I think, stated that any amendment to Title 35 must be consistent with your obligations under the applicable international trade agreements.

Mr. DUDAS. Absolutely. Any time there is a change in patent law, it is important to analyze the effects on existing international trade agreements and potentially new trade agreements, especially if the change in patent law will affect a particular industry or particular technology.

The United States is by far the leading innovator of new prescriptions drugs, and as we negotiate agreements throughout the world, we often point out to other nations their need to have a systematic approach to intellectual property and patent law, in particular. So as we do that, we need to analyze and evaluate the effects of our own changes to patent law.

Chairman HATCH. Our lead may very well end if we continue these schemes of drug importation, which would impose price controls on our industries here. That is why Canada doesn't have any real innovator pharmaceutical industry. So there is a lot going on here.

Let me just say this: could you comment upon today or provide for the record—in fact, I wish you would provide for the written record after consulting with USTR your opinion on whether the Senate language is consistent with the TRIPS provisions and the Paris Convention. Could you do that for us?

Mr. DUDAS. Absolutely. We will talk to our colleagues at USTR and communicate that.

Chairman HATCH. In short, I guess what I am saying is, does the Senate language run afoul of the international IP restrictions against singling out a class of patents from discriminatory treatment? Perhaps Utah's favorite son, Sheldon Bradshaw, will help you with this analysis. We would appreciate having that, okay?

We are very proud of you and the position you have and the work that you are doing. So, if you folks would do that for us?

Mr. DUDAS. Absolutely.

Chairman HATCH. Now, let me just ask the whole panel this question.

Susan, we are happy to have you join in on this.

Generally speaking, a patent is a negative right and comes down to a power to exclude. I think that is a fair statement. Patent-holders generally have a wide latitude in determining when, where, and against whom to exercise this right of exclusion. I understand and sympathize with the generic industry's desire to force resolution of patent challenges right up front.

But what evidence is there, if any, to support the fear that pioneer firms will not vigorously defend their patents against a paragraph IV patent infringement challenge? Is there any evidence of that?

Ms. CREIGHTON. There is none in the FTC's drug study that focused on that issue.

Chairman HATCH. All right. Does anybody else care to comment?

A lot of blank stares there. Not so blank, but at least—okay.

Let me ask the panel about the dramatically new 180-day marketing exclusivity provisions. I am mindful of the fact that we are facing identical 180-day provisions in the House and the Senate language. It is known that I am no friend of the first-to-file system. I prefer to stimulate and reward successful challengers.

Frankly, I don't understand a system where a successful patent invalidity challenger could be forced to share exclusivity with other first, but unsuccessful, challenging filers. Or, worse, why should a subsequent-filing but successful non-infringing challenger have to wait 180 days to enter the market, during which time infringing first filers were not able to get to market? Why not simply add a new forfeiture event whereby the first challenger not sued, succeeding in court or obtaining a covenant not to be sued, gets the 180 days?

Who would like to take a crack at that?

Mr. Troy?

Mr. TROY. Well, I can say that FDA initially interpreted the 180-day provisions as embodying a successful defense requirement, and the courts told us that that was not the right way to read the statute. Since that time, we have been trying to administer the statute as best we can, in light of the court decisions.

What you raise is a policy question that we have taken no position on. There are pros and cons to the whole question of 180-day exclusivity and setting forth the conditions on it, and those are just fundamental policy choices that Congress needs to decide.

Our primary concern, again, given the experience and expertise that we have, is trying to ensure that whatever system is designed is one that we can administer with a minimum degree of ambiguity, cost, inefficiency, because one of the things that is very important, as I think you know, is that people understand what the rules are. Everybody wants to know what the rules are. People can deal with the rules once they know what they are, but they want to know what they are. So we have tried to, again, work closely with everybody to try and make sure that there is clarity.

Chairman HATCH. Well, thank you.

Now, Mr. Troy, before you leave I want to mention one other thing. Senator Harkin and I have written to the FDA twice. This is off the subject, but I want to take advantage of you while you are here.

We have written twice and talked to the Commissioner and you about the andro situation, and we are farther than ever from having it resolved. I take this very, very seriously, and I think you do, too.

In July, my staff and I had a staff meeting with the DEA and FDA in my office. Now, it appears that FDA is not taking action against andro products because you can't decide whether it is a supplement or a drug. At least, that is what it appears to me. You could go after it under either theory, as a non-grandfathered supplement or an unapproved drug. I don't care which way you go, but I think you have to act. It is a dangerous situation, and while you are not acting, people, and especially kids, are getting hurt.

Now, when we come back in September, we may have to have a hearing, or perhaps we may have to do a bill. I would prefer not to do that. You folks are good guys. You are doing a good job. You are trying to do the best you can. You have inherited a myriad of problems out there and I think you are straightening them out.

We are moving ahead on our unitary, state-of-the-art campus that really will augment FDA like never before under our FDA Revitalization Act. But I think inaction can give us all a bad name if we don't do something about this. There are some who believe that there are those out at FDA who would like nothing better than to have a tragedy in what is called the, quote, "dietary supplement," unquote, industry. I hope that is not true, but there are some who believe that.

Now, I am counting on FDA moving forward on this to protect the public health because I think this inaction has been going on far too long. Will you take that message back?

Mr. TROY. I will.

Chairman HATCH. And tell Dr. McClellan I would like this resolved before I get back in September, and I don't see any reason why it can't be resolved. So help us here, Dan, okay?

Mr. TROY. I will take that back, Mr. Chairman. Nobody has any intention of waiting around for a tragedy. That is not our modus operandi. We do try and act proactively to try and protect the public health. That is why we are there, and I will certainly talk to Dr. McClellan about this issue.

Chairman HATCH. I don't want it to go beyond the next few weeks.

Mr. TROY. I will take that back.

Chairman HATCH. And if it does, I am going to be really upset.

Mr. TROY. I will take that back.

Chairman HATCH. And I have been known to kill.

[Laughter.]

Chairman HATCH. But it takes a lot to get me there; it takes a lot to get me there.

Mr. TROY. I have had some chats with Brent about this. I don't want to see you mad.

Chairman HATCH. That is great.

I want to compliment all of you for your excellent testimony. We have discussed some very difficult technical issues, but this bill is that important. Everybody admits it is one of the great consumer bills, and it was so hard to put together at the outset. I mean, it was just awful, but when we finally got it together, it worked magnificently well, except some have gamed the system and we have got to solve that.

These bills are good-faith intentions to do that, but I want to make sure that when we get them done, they are constitutionally sound and that they really work and that they don't upset the balance between the need to have new, innovative drugs created at a cost of $800 million to $1 billion, where you have got to get that money back or you can't keep investing in it—the need to do that and the need to get them into generic form as quickly as possible. That is the balance of Hatch-Waxman that we worked hard to create and really has worked remarkably well, in spite of even some of these conflicts and problems that we have had.

So your testimony here today is very, very important, and I believe that the conferees will pay attention to it, as they should. And if you will get me the written materials that I have asked you to do as quickly as possible, that will mean a lot to us, too. And then if you will work on the andro thing, I would be very grateful.

Thanks so much. I want to thank each of you. You are great people, you are great public servants, and I appreciate the efforts that you have made to be with us today and the intelligent testimony that you have given.

Now, Mr. Robert Armitage is our sole panelist for the second panel. Mr. Armitage is Senior Vice President and General Counsel at Eli Lilly and Company. Prior to joining Lilly in 1999, Mr. Armitage was a partner in the law firm of Vinson and Elkins, one of the great law firms in this country, and headed the firm's intellectual law practice in Washington, D.C.

In addition, Mr. Armitage has served as an adjunct professor of law at George Washington University School of Law, and as president of both the American Intellectual Property Law Association and the Association of Corporate Patent Counsel.

I am particularly interested in hearing your views, Bob, on how this legislation might affect generic drug entry and drug innovation for brand name companies. So we appreciate you making the effort to be here, the effort to testify, and the effort to educate us on some of these very important questions.

So we will turn the time over to you.

STATEMENT OF ROBERT ARMITAGE, VICE PRESIDENT AND GENERAL COUNSEL, ELI LILLY AND COMPANY, WASHINGTON, D.C.

Mr. ARMITAGE. Senator, it is an honor to be here this morning. Let me say to begin with that I am not here to talk about reforming the Hatch-Waxman Act. The issue we have before us today is quite a narrow one. What should happen to S. 1, what should happen to H.R. 1 in the event a compromise would be reached on Medicare?

Also, contrary to what might have been implied, there is nothing in my testimony today—

Chairman HATCH. I think you might want to restate that. Maybe you had better start over.

Mr. ARMITAGE. Let me just say, Mr. Chairman, that I may have to start over in just a second myself. Sorry.

Chairman HATCH. I am going to make one other statement before you start.

Mr. ARMITAGE. Sure.

Chairman HATCH. Before we receive your testimony, I think it is important for me to say that we made a good-faith attempt to have a representative from the generic drug industry to be with us today, as well. We invited two witnesses, and also asked their trade association to recommend a witness. They apparently did eventually identify a witness, but the logistics just didn't work out.

We did ask both the GPhA and PhRMA to provide written statements explaining their views on the Senate and House language, and we will make these responses part of the record, in addition to the lively correspondence between Boyden Gray and John Yoo on the constitutionality issue.

So we will certainly keep this record open for the generic companies to make whatever comments they would care to make. We feel badly that they couldn't make it at this point. There was not an intention not to make it, I don't believe. It is just that they were unable to. So we just wanted to make that clear.

Mr. Armitage, we will take your testimony.

Mr. ARMITAGE. Thank you. Also, it is refreshing experience for an executive in a pharmaceutical company to be on a panel and have no fellow panelists disagreeing with him.

Chairman HATCH. That must be a first.

Mr. ARMITAGE. For me, it would be a first, yes.

As I think I indicated earlier, we don't see our testimony here today to talk generally about Hatch-Waxman reform. We are really very narrowly focused on the provisions in S. 1 and H.R. 1, particularly those that would make what we believe would be a fundamental difference in the way we would look at patents to protect our innovation, and also the way the consumer would be impacted by the 180-day generic exclusivity provisions.

Also, just to be very clear at the outset, we are not looking at a change in S. 1 that would produce a loophole that would allow gaming of the system that would in any way result in even a single extra day of exclusivity for an innovator.

Also, there is nothing in anything that we have in our prepared testimony and there is nothing that I am going to say in the few minutes I will have for these remarks that will in any way suggest that we seek to repeal or eliminate the 180-day exclusivity.

More to the point, what we are looking for, I believe, is what the Senator was looking for in 1984 when the Hatch-Waxman Act was first put into effect. If we are going to continue the 180-day exclusivity, if it is to be part of Hatch-Waxman and it is dealt with in S. 1, then it should serve its purpose.

Its purpose was perhaps two-fold: one, to accelerate generic drug entry, which in situations it has done. The second potential use of the 180-day period is to cause patents to be challenged by generic drug companies that might not otherwise be challenged.

It is in the context of these assumptions that we believe the provisions in S. 1 will not serve the intended purpose of their sponsors and will, in fact, have what we believe are profoundly counterproductive effects in not only delaying generic drug entry in a number of situations, but also delaying competition among generic companies, which is the real value that consumers receive from the 180-day challenge when it achieves its intended function.

Now, some of you may already be wondering why someone from a multinational research-based pharmaceutical company is coming here trying to explain to you why I might possibly want a law changed to facilitate not only earlier generic drug entry, but also to facilitate competition among generic companies.

The answer is very simple. If, indeed, by changing the Hatch-Waxman law, you do as the FTC and Chairman Muris stated in his testimony, created an opportunity for each of our innovative products to receive a patent challenge at the earliest possible date—that is 4 years after the product is approved—and if a challenge can be made against all of our patents, including the basic patents that are the reason we are able to invest in a new molecule, and that patent challenge has no prospect of failing, failing in the sense that it may fail to clear the way for generic drug entry, it may fail to accelerate generic competition by 1 day; it may fail as an incentive for other generic companies to be able to get to the market.

But it may nonetheless succeed in producing a 180-day monopoly period that might return $100 million, might return $500 million, for a true blockbuster drug might return $1 billion just for being first to come to the FDA with a paper that says I made a patent challenge, and whether the defense was there, whether the defense was successful, nonetheless have this guaranteed reward. That, in effect, is why we are so concerned about the provisions of S. 1 because they, in practice, then become highly anti-innovation, as well as being anti-consumer.

Now, I would love to sit here and explain to you what is in my 12-page, single-spaced typed testimony on exactly how it is that removing a court trigger has all of these impacts that I believe, frankly, are an unintended loophole in the law. As exciting as that would be to me, I can guarantee you that to everyone else in this room it would probably be a relatively boring exercise in drawing elaborate diagrams.

Chairman HATCH. We will put all 12 pages into the record, and I assure you we are going to read them.

Mr. ARMITAGE. I appreciate that.

Let me also just talk for a second, because I think this is to me a very important part of understanding where we see a solution to this issue that we have raised. I was delighted to see that the FTC indeed has taken this issue seriously enough to have a set of possible solutions that they would like obviously be considered in conference.

I think if I listened to Mr. Troy carefully, he believes that through a combination of perhaps some changes to the statute and a technical amendment suggested by the FDA during the process that led to S. 1, plus relying on FDA regs and interpretations,

which I think based on the experience of the last 20 years would not be wise, perhaps we could accomplish a closing of this loophole.

But let me say there is another way that meets Senator Schumer's requirement, basically, that we not allow new gaming of Hatch-Waxman, that we not provide new prerogative or incentives that he might say innovators do not deserve, but nonetheless targets in precisely on some of the difficulties with the 180-day period with S. 1, and perhaps even without S. 1.

So what is it that in our prepared remarks we have discussed at length? It is to say that if you get to the point where all of the basic patents have expired. Now, while the FDA may have difficulty defining this, the definition can be quite simple. They are patents that, if they are valid, can't be gotten around because they are not infringed. They are the active ingredient, they are the approved uses. If you are decreed by a court not to infringe the patent, it is not a basic patent. Otherwise, obviously it may be.

But when we look at the time that is perhaps 12 or 14 years after a new drug has been first approved by the FDA, and if no patent challenger has at that point been able to use the 180-day period because their challenge is not complete, their challenge was not successful in clearing the way or they wish to park a challenge, then we believe that competing generic companies who have gone through the entirety of the same patent challenge, faced the same obstacles, been required to design the same non-infringing generic drug products, been required to make the same patent certification statements and been required to demonstrate to the innovator whether through litigation or otherwise that they do not infringe, and have done so obviously without the incentive of the 180-day period—then we have reached a point where there ought to be a forfeiture event.

Mr. Chairman, it is much like your notion that he who succeeds in demonstrating that he is completely and totally free from patent issues by using the Hatch-Waxman patent challenge process ought to at that point at least be entitled to get to the market even if that challenger cannot get the 180-day exclusivity period.

Again, what we are talking about with the prolonged ability of someone to make a successful challenge and use the 180 days, with then the ability of the first applicant to still use and still maintain, and perhaps even still park the 180-day period if another competitor has not completely gone through the challenge process and been demonstrated to be totally free from patent issues and ready to market, we see no possible reason or no possible way why that does not both allow full, extended opportunities for 180-day exclusivity that will and can be used when they—and I will use the term "earned" in this sense, in quotes, and yet prevent this new ability that is noted by both the FDA and the FTC to indefinitely park that exclusivity, particularly park it until all the basic patents have expired, and then take it out and have it have its direct anti-consumer effects by delaying generic competition and its obvious anti-innovator effects of being a no-risk, guaranteed reward way of financing early and entirely speculative patent challenges.

Now, I assume my time is up. I would be happy to talk a little bit about some of the provisions that the first panel talked about in perhaps a minute or less if that would be of any interest.

Chairman HATCH. Go right ahead, Mr. Armitage.

Mr. ARMITAGE. First of all, let me say that while I am speaking today only on behalf of Eli Lilly and Company, PhRMA has submitted a paper which I think accurately captures some of the difficulties that I think the pharmaceutical industry, including Lilly, share.

Let me just say on the constitutional issue, having been through patent challenges where declaratory judgment actions were brought and resolved, I cannot for the life of me, not being a constitutional scholar, figure out how a provision of law that is either redundant or a court would ignore because there is no case or controversy as required by the Constitution could be the proper solution to the concerns that Senator Schumer raises, much less the concerns that the Department of Justice has raised.

As we look at the House bill and consider perhaps the comment of the FTC about whether or not providing access to generic drug applications on a confidential basis, in a way equivalent to a protective order in a court, would be superfluous, let me say from my real-life experience that is not a superfluous issue.

We know that the gaming of the Hatch-Waxman system has included generic companies refusing to provide any information during a 45-day period, sometimes providing just so little information that an innovator company who genuinely wants the issues of patent infringement resolved faces a Rule 11 issue under the Federal Rules of Civil Procedure. There may be a patent for which, without knowing what the drug substance is that the generic is using, you do not have a basis for concluding you have a possible case of infringement.

So before one would cast aside the House language on providing confidential access as being totally superfluous, I look at it as a major step to prevent an aspect of gaming that I have experienced in terms of the generic drug industries.

I have never seen a sit-back-and-wait situation where an innovator who had a basis for keeping a generic drug off the market because the innovator believed there was a genuine issue of patent litigation that ought to result in the innovator winning would somehow not bring the lawsuit and allow the generic competition to begin. I would like to find that patent attorney, if indeed such an attorney works at Eli Lilly and Company, so I could have a brief discussion with him.

The last issue that I will just comment on for a second deals with our TRIPS obligation to provide non-discriminatory protection for all fields of technology. It may be that we can find a way to discriminate against pharmaceutical patents that doesn't violate the TRIPS agreement.

I would submit that denying a normal patent remedy in a field of technology for the failure to undertake a ministerial act gives a road map around the world to companies who would like to do very similar things that will differ only in degree.

I would urge the Senate, even if it believed that this must only be a minor issue to deny treble damages, to perhaps consider that other countries with TRIPS obligations may decide to deny lost profit damages, or may decide to deny anything more than a nominal royalty as damages in a situation where some ministerial act

relating to a pharmaceutical patent, particularly one that is at best ambiguous in its ultimate application, has not been fulfilled.

With that, I do appreciate, Senator, the opportunity to make these remarks.

Chairman HATCH. Thank you. We are grateful to have you here, as well, and I thought your remarks were excellent, but I do have some questions.

Let me see if I get the crux of your testimony. You believe, if I interpret it correctly, that the new system guarantees large rewards for relatively minor inventions around relatively unimportant patents, such as drug formulation patents. Did I get it right? Can you explain that?

Mr. ARMITAGE. Sure, I would be happy to explain just that point. Obviously, when we develop a new pharmaceutical product, we will patent the active ingredient on the drug. That is the very simplest case.

Also, as we are developing a new drug—and I will use an example that has been in the popular press and been in the FDA regulations—we may find a particular polymorph or a particular physical way in which the drug forms a crystal to be very advantageous in manufacturing and we may patent that.

Then what a generic company needs to do, if those are the two patents in the Orange Book, is to say the active ingredient is invalid and we have decided not to use the polymorph the innovator uses. They may simply make no invention at all and pick some alternative physical form to use in their drug.

The FDA merely requires that the active ingredients be identical. You can make a drug in any physical form that will turn out to be bioequivalent to the active ingredient. Doing just that and making a patent challenge at 4 years, even if you have no reason to believe that the active ingredient patent could ever be invalidated, will earn you under S. 1 180 days of exclusivity.

You may have to wait 7 or 8 years, but because you can lose on the basic patent in court and park the exclusivity until the basic patent expires, then just when all the other competing generic companies who have done just what you did—they took off the shelf a polymorph that wasn't patented, they went through the patent certification process, they demonstrated they don't infringe—you will keep all your competitors off the market and you will get 180 days of exclusivity.

If the drug happens to be a drug like—we will take Zantac, which was a Glaxo drug that indeed had a patent both on the active ingredient and on the polymorph. You will be able, going forward, to keep a product like that off the market for an additional 6 months, all your generic competitors off the market.

A product like Zantac, which was a billion-dollar product—you may make $2 or $3 million in monopoly profits that under today's law, that very same early patent challenge would have produced no monopoly.

Chairman HATCH. I see. Can you please take me through some of the examples in your appendices where you describe the results if the proposed 180-day exclusivity provisions had been in effect? Now, you have kind of given some examples, but I wouldn't mind having some more.

Mr. ARMITAGE. Let me go to what I believe is Appendix B in my testimony, and it is a—actually, that is not where I want to go. It is Appendix A and it will be on page A–5. This is the example that I think clearly indicates the categorical need for a form of technical amendment to S. 1 or what Senator Schumer fears most. That there is a loophole in S. 1 that can game the system and delay generic competition is all too true.

In the example on page A–5, we have a situation where there are only two patents left in the Orange Book. This is the most common situation that Chairman Muris talked about for most of the 180-day periods that have arisen. They arise after the basic patents have expired or at the time the basic patents will expire.

Here is a situation where, just to get to the details, the formulation patent—that is how the drug is actually put together, the way the innovator put together his drug—expires in 2013, and a polymorph patent or a patent on any physical form of the drug expires several years later.

Now, the first applicant who is in a hurry to get there first manages to not succeed in designing around the formulation patent and simply is found to infringe that patent. It expires in 2014. In the example I have given you, the first applicant has completed the FDA review process and has tentative approval in 2007, 6 years before this first patent in the Orange Book will expire.

Now, in this example I have listed below three competing generic drug companies who did exactly the same thing the first company did, tried to design a non-infringing formulation, tried to find a source of the bulk drug that was not patented. In this example, each of those three companies not only succeeded in doing that, but succeeded in making the patent challenge and succeeded in demonstrating to the innovator that they did not infringe the patents. In this case, the demonstration was so convincing they were never sued for patent infringement.

Under current law, there is no possibility—I am sorry—under S. 1, there is no possibility that the 180-day exclusivity can expire until 75 days after the formulation patent expires because of the new parking right. Indeed, competing generic companies stay off the market under this particular example until sometime in 2013, almost 2014.

That, I submit, is a loophole that, while it perhaps would warm the heart of the innovator company who faced no generic competition for 6 1/2 years, is not the bargain consumers thought they were getting when Hatch-Waxman was enacted.

Chairman HATCH. Any other examples you would care to give us, please feel free to do that.

Mr. ARMITAGE. I am happy to do that.

Chairman HATCH. You don't need to do it right now. That was a very interesting, but difficult to understand—

Mr. ARMITAGE. It is almost the true-life story, Senator, of the Prilosec patent challenge, which is another example.

Chairman HATCH. Right, yes. You believe that the proposed legislation effectively eliminates the court decision trigger that allows exclusivity to be parked sometimes for years until the basic patents covering the molecule and the method of use expire.

Can you walk us through how that works a little bit?

Mr. ARMITAGE. Well, unfortunately, except for the court decision trigger, the only thing left that triggers the start of the 180 days is what necessarily must trigger it, the start of commercial marketing by the generic drug company.

So the way S. 1 is written, but for the forfeiture provisions that the first panel talked about, the generic drug company would have total discretion as to when to bring the 180-day monopoly into force and could indeed tie up competing generic companies for an indefinite period of time.

So it turns out that under the structure of Hatch-Waxman, taking out the court decision is equivalent to taking one of the wheels off a bicycle. It really makes it harder to get the bicycle to go anywhere, much less work the way it was intended.

Unfortunately, when the forfeiture provisions were written, they did not put in place a forfeiture that stopped a generic company from parking indefinitely. In fact, what the forfeiture provisions did, I think, as the first panel indicated, is add an additional 75-day period in which there could be no forfeiture after a court decision, then move the court decision from the district court trigger to the appellate court trigger, and then, I think as Mr. Troy's testimony suggested, for all the patents that block your way to FDA approval, made the expiration of the patent the earliest possible date that the forfeiture could take place.

In other words, not only was the court decision written out as a trigger for the start of the 180-day period, but the court decision was then delayed, then changed to a different court decision, and then utterly written out on all the patents, particularly the basic patents if they survived a patent challenge.

So it ended up being the perfect creation of a loophole, moving something from one section of a statute to a brand new section of a statute, and then not have the new section of the statute do the most fundamental thing the old section did, and that is prevent this parking of the exclusivity until it will become anti-consumer and anti-competitive.

Chairman HATCH. Well, let me just ask one other question, and we will be happy to have you submit anything else you would care to for the record.

As you know, I am asking CBO to see if this new system would actually cost consumers money, the new system under S. 1. Do you have any estimates on how much this new system might cost consumers over time?

Mr. ARMITAGE. It is like McDonald's, billions and billions.

Chairman HATCH. So, what is billed as a consumer bill could actually be costly to consumers? Is that what you are saying?

Mr. ARMITAGE. Amazingly costly. Let me just give you an example of what—well, it is in my testimony. I won't go into it in any detail.

Chairman HATCH. I don't want anything to take away from Hatch-Waxman's pro-consumer stance while we try and resolve some of these loophole problems.

Mr. ARMITAGE. Well, let me just say one thing, if I could. One of the most pro-consumer parts of Hatch-Waxman is that it is pro-innovation. The greatest benefit, I believe, consumers have received over the last 20 years that Hatch-Waxman has been in effect is the

two or three generations of some of the most amazing medicines known to mankind.

As much as being a pro-consumer bill in terms of saving consumers money warms my heart as a taxpayer and someone responsible for medical bills, indeed I think the anti-innovation part of parking is a far greater consumer threat in this bill, although I believe that if you are talking about just the pocketbook effects and you just look at the Prilosec patent challenge, you would see there a potential delay of all generic competitor for an additional year, which I will submit would have been almost a certainty had S. 1 become law.

Chairman HATCH. Well, I wrote a letter as of August 1, today, to Mr. Douglas Holtz-Eakin, the Director of the CBO, the Congressional Budget Office. "This letter is to request your prompt evaluation of the potential effects of Section 703 of S. 1, the Prescription Drug and Medicare Improvement Act of 2003, that have recently come to my attention."

I think all too often, some of our people around here get all caught up in the politics of this thing and don't really look at what they are doing to what is an otherwise very, very good bill. I was somewhat surprised that I was the only one to vote against S. 1; 94 voted for it.

But then I go on and talk about the various sections, and so forth, and I will make this letter a part of the record. I point out to CBO that the conference of S. 1 and H.R. 1 will be continuing throughout this month and I want these answers as quickly as possible so that we can at least have every possible help we can so we get the very best bill we can.

I don't have any axes to grind here. I recognize that both sides of this industry are very crucial to America. Without the innovators, we won't have the drugs to go off patent into generic form. Without the generics, the innovators would be able to charge forever and make profits that would be unconscionable.

If we turn and completely balance it in favor of the generics because it is the cheap, easy thing to do, in any event we will lose our capacity to do the R and D necessary to come up with the blockbuster drugs and the treatments and cures that our pharmaceutical industry, the greatest in the world, is capable of doing. So this has to be balanced.

I have to say I think we did an amazingly good job back in 1984. Yes, there are some people, that have gamed the system, but they are relatively few and the system has worked very well. Now, I am not advocating that we should keep Hatch-Waxman exactly the way it was or we shouldn't improve it, in light of the last 19 years of practice. But I don't want to, quote, "improve it," unquote, so that it doesn't work, and that it works to the detriment of consumers, not to the benefit.

I think your testimony here today is very important and I will look forward to having the generics' response to this. But in all honesty, I am not sure they can show that what you have said here today is wrong. On the other hand, we are interested in what they can give us that will help to bridge the differences between these two bills and hopefully help us to, if we are going to reform Hatch-

Waxman, have true reform, not just political reform, which never works, in my opinion.

True reform, I think, can work, and to that extent we need both sides of this. There are many sides to this very complex pharmaceutical business, but basically, the PhRMA companies, the innovators, and the generic companies can come together and help us to do this right.

I am doing my dead-level best to try and get it right and it has come largely my way from the original Schumer-McCain bill, which was just plain awful. But to their credit, they have been willing to work with us down the line to try and get it more correct. The purpose of this hearing is try and get it as perfect as we can.

I want to compliment Senator Schumer, Senator McCain, and above all Senator Judd Gregg, who, along with Senator Schumer, has really worked hard to try and get this bill in the best form they possibly can. They deserve a lot of credit, but so do you people who have testified today. All of you deserve a lot of credit because with this kind of expert testimony, hopefully we can do a better job.

The bill has come a long way. It is quite a good bill compared to what it was, but I still voted against it because there are, in my opinion, unconstitutional aspects to it and there are some other aspects which you and others have pointed out here today that might work against the interests of consumers, and in the end against the interests of the two basic sides of this equation that have to be effective if we are going to benefit consumers.

So I just want to thank you for taking time out to be here with us today and to give the excellent testimony that you have.

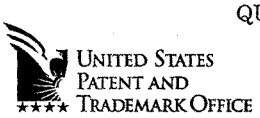
[The prepared statement of Mr. Armitage appears as a submission for the record.]

Chairman HATCH. With that, we are going to recess until further notice.

[Whereupon, at 11:36 a.m., the Committee was adjourned.]

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

QUESTIONS AND ANSWERS



Under Secretary of Commerce For Intellectual Property and
Director of the United States Patent and Trademark Office
Washington, DC 20231
www.uspto.gov

OCT 21 2003

The Honorable Orrin G. Hatch
Chairman, Committee on the Judiciary
United States Senate
Washington, DC 20510

Attention: Mr. Barr Huefner

Dear Mr. Chairman:

Thank you for giving us the opportunity to share the views of the Administration at the Senate Judiciary Committee hearing regarding "Examining the Senate and House Versions of the Greater Access to Pharmaceuticals Act" on August 1, 2003.

Attached are the written questions for the record submitted by Senator Charles E. Schumer and our responses thereto.

Sincerely,

JON W. DUDAS
Deputy Under Secretary and
Deputy Director

Enclosure

Examining Differences between House and Senate Versions of the "Greater Access to Affordable Pharmaceuticals Act"
Senate Judiciary Committee Hearing, August 1, 2003
Questions for the Record
Senator Charles E. Schumer

1)a) The FTC report identifies several patents listed at FDA after generic drug applications were filed that triggered second, third, fourth, and even fifth 30 months stays of generic drug approval. When these patents have been resolved by the courts, they have found them to be invalid or not infringed. In fact, the large majority of them have been declared by the courts to be invalid. In other words, PTO never should have issued those patents, and the fact that PTO issued invalid patents cost consumers billions of dollars. Some commonly known examples are the drugs Prozac, Taxol, and Platinol. Can you explain why the PTO is issuing patents that are invalid?

The United States Patent and Trademark Office (USPTO) exercises great care not to issue patents improperly. All patent applications are examined on their merits by persons who are familiar with the relevant area of technology. In determining the patentability of an invention, the USPTO follows applicable law as enacted by Congress and interpreted by the courts. A determination of patentability is not an arbitrary decision on the part of the examiner, but rather the result of a considered judgment required by the patent laws. Patent files containing the prosecution correspondence between the examiner and the applicant are available for public inspection.

We continue to consider and implement programs to improve the quality of issued patents. The USPTO's 21st Century Strategic Plan, developed at the direction of Congress, is targeted toward timeliness, e-Government, employee development and competitive sourcing -- all with a central quality focus. We recognize that quality must permeate every action taken by every employee of the USPTO, and the Plan will assure quality by enabling us to hire the people who make the best patent examiners, certifying their knowledge and competencies throughout their careers, and focusing on quality in all aspects of the examination of patent applications. For example, quality will be engineered into our processing by ensuring proper training and certification of examiners and expanding the "second-pair-of-eyes" review in selected technology areas. We believe these initiatives will bolster confidence in the quality of U.S. patents thereby spurring our economy and reducing litigation costs.

Successful implementation of these quality initiatives and other elements of the Plan is dependent on enactment of the USPTO fee reform legislation currently pending in the House. The fee reform legislation would realign patent fees to more accurately reflect the costs of the services we provide and would produce the income levels necessary to attain the goals and objectives of the Plan.

b) **How much time does the average reviewer take to review a pharmaceutical patent?**

The time is dependent upon the examiner's experience level and the specific technology of the patent application. For example, an examiner with 2-3 years experience receives between 19.7 and 25.9 hours to examine an application in the pharmaceutical area.

c) **I understand that a lot of the patents pending at PTO have to do with drug-drug interactions and the effect of a drug in the body -- issues which I understand can only be fully understood by pharmacologists. Yet it is my understanding that the PTO doesn't have a single pharmacologist on staff. Is this the case? Are there plans to expand the pharmaceutical expertise at the PTO?**

The USPTO has a number of pharmacologists and pharmacists on staff as patent examiners. All patent applications are examined by persons who are familiar with the relevant area of technology. The USPTO makes every effort within budget and regulatory constraints to hire, train and retain the most qualified persons as examiners in all technology areas.

2) **The FTC report also documents how PTO allows drug companies to get a patent for something that is already patented so long as the second patent ends on the same date as the first patent -- using the PTO's "terminal disclaimer" proceeding. This practice of essentially issuing multiple patents on the same invention seems counter to the entire mission of the PTO -- to identify and grant protection for truly novel inventions. While this process -- though perplexing -- may seem harmless as it applies to other industries, as you well know, in the case of pharmaceutical patents one of these patents can have consequences that harm consumers, like triggering a 30 month stay that delays the approval of a generic drug by FDA. What justifies the PTO's granting more than one patent on the same invention? Has the PTO considered the anticompetitive consequences of issuing such patents? Why does the PTO allow these "terminal disclaimers" when it knows that a patent does not claim a patentably distinct invention?**

As you know, terminal disclaimers are considered to be an important part of a balanced patent system since they limit patent term and accordingly play a vital role in the examination process. In determining the patentability of an invention, the USPTO follows applicable law as enacted by Congress and interpreted by the courts. While the law is clear that multiple patents cannot be obtained for identically claimed subject matter, a patent may be obtained for an invention that is not patentably distinct from an invention claimed in a prior patent. Under the court-created doctrine of "obviousness double patenting," an applicant is prohibited from obtaining a second patent that claims an obvious modification of an invention claimed in an earlier patent. Under the law, however, an applicant can avoid rejection of claims on that basis, and thereby obtain a second patent, by filing a terminal disclaimer. If such disclaimer is filed, the patent rights

associated with the conflicting claims of the later-filed application expire on the day the earlier-filed patent expires, thereby eliminating any unjust extension of exclusivity. Moreover, those patent rights are only enforceable under the terms of the disclaimer so long as both patents are commonly owned.

Federal jurisprudence has made it clear that filing a terminal disclaimer may overcome an obviousness-type double patenting rejection. The use of a terminal disclaimer in overcoming an obviousness-type double patenting rejection is in the public interest because it encourages the disclosure of additional developments, the earlier filing of applications, and the earlier expiration of patents whereby the inventions covered become freely available to the public.

3)a) It is my understanding that brand companies are increasingly using the PTO's "reissuance" or "reexamination" process to delay generic competition. Valid, infringed patents should be protected, for sure, but why does the PTO allow brand drug companies to have multiple bites at the apple to produce a valid patent after a patent is issued by the PTO?

Patent reexamination and patent reissue procedures were enacted by Congress to serve as expedited, low-cost alternatives to patent litigation in reviewing certain aspects of patent validity. Accordingly, the role of the USPTO in addressing questions of patentability does not necessarily end with the issuance of a patent. Reexamination and reissue proceedings each provide an opportunity for a determination on questions of patentability either as an alternative to, in preparation for, or in conjunction with litigation.

Reexamination proceedings provide that any person may request, and the Director may order, that the USPTO reexamine an issued patent on the basis that certain patents or printed publications raise a substantial new question of patentability as to one or more of the patent claims. Reexamination therefore permits interested parties to assess the validity of an issued patent without having to incur the expense of litigation. It also allows the USPTO to revoke invalid claims on its own initiative after a patent has issued based on printed publications that may not have been available at the time of examination.

Reissue, on the other hand, permits patentees or patent owners to correct wholly or partly inoperative or invalid patents, provided that the error arose without deceptive intent. Under reissue provisions, a patentee or patent owner may enlarge the scope of the original patent claims if the reissue application is filed within two years from the patent grant.

Requests for reexamination or reissue are not automatically granted. In the case of reexamination, the request will only be granted if it raises a substantial new question of patentability. In the case of reissue, the application must allege inoperability or invalidity of the patent by reason of a defective specification or drawing or by virtue of the patentee claiming more or less than he had a right to claim. Moreover, the alleged defect must

have been caused by error that arose without deceptive intent. These safeguards ensure that reexamination and reissue will be used for their intended purposes and not abused.

Reexamination and reissue proceedings are extremely important options for both patent owners and interested third parties because they provide a more expeditious and less costly alternative to litigation to resolve issues of patent validity. A patentee may choose to pursue a reexamination or reissue proceeding in light of newly discovered prior art information. If the patentee is concerned that the information discovered might affect the validity of the patent, the patentee's objective may be to obtain a determination of the effect on patentability before the USPTO before commencing litigation. The most common objective for a third party, such as a competitor or accused infringer, in initiating a reexamination or protesting a reissue is to invalidate the claims of a patent without the expense of litigation. Another objective for a competitor or accused infringer is to limit the scope of a claim. By influencing the file history of the patent, and potentially forcing the patentee to make amendments to the claims, the accused infringer may avoid literal infringement or create a design around opportunity. As you know, Congress recently expanded the reexamination system with the clear intent of benefiting consumers.[1]

b) **Would you please provide the Committee with data regarding the rate at which brand pharmaceutical companies are currently resubmitting patents to the PTO for reissuance (i.e., number of requests for reissuance per patent granted) and compare this to rates of request for reissuance two, five and 10 years ago?**

The USPTO does not maintain data that readily indicate such rates of resubmission or reissuance. According to our Fiscal Year 2002 Performance and Accountability Report, the USPTO issued 466 reissue patents and 160,843 utility patents in that fiscal year. Further, filings during that time frame included 974 applications for reissue patents and 331,580 applications for utility patents.

4) **Given the concerns about the negative effect on pharmaceutical competition of PTO policies allowing for the issuance of multiple patents on the same invention or and the reissuance of patents to make them more defensible, what reforms are needed at PTO to make this process work, to assure a truly defined patent term, and not one that, by manipulation of the generic drug approval process at FDA, can be expanded or strengthened?**

Intellectual property rights serve as an important incentive for the private sector in the development of new and improved drugs. It is unlikely that private entities would commit substantial resources to research, development and marketing of innovative new drugs if they were not assured of receiving adequate patent protection for their inventions. Accordingly, any revision to existing patent protections should maintain that

[1] 21st Century Department of Justice Appropriations Authorization Act, Pub. L. No. 107-273 (Nov. 2, 2002).

incentive and help promote the development and access to the next generation of important medical cures and treatment.

It is our sincere belief that the United States patent system has allowed American industry to flourish. Millions of new inventions have been developed, marketed, and commercialized enhancing the quality of life for present and future generations. It is difficult, if not impossible, to imagine our society without the present-day conveniences and advancements of modern medicine. The contribution of a strong patent system to the increase in technological advances in the United States should not be underestimated.

In granting an inventor a patent, the public is given permanent and valuable consideration. In exchange for the limited grant to exclude, there is the obligation to disclose the workings of the invention in a fashion that would allow those of ordinary skill in the art to replicate the invention without much difficulty. Hence, the patent will disclose new knowledge and information that will inspire others to improve upon or experiment with the disclosed information. Another benefit of the patent system is the incentive to design around a competitor's products, even when they are patented, thus bringing a steady flow of invention to the marketplace. Thus, the dissemination of patent information facilitates the sharing and building on new technologies worldwide.

Nowhere are the benefits and rewards of patent protection more apparent than in the United States. The explosive growth of new technologies in our country has resulted in many new products and methodologies useful in areas from medicine and agriculture to computers and telecommunications. It was the phenomenal development of microprocessors that led to the advent of personal computers while genetic research led to the identification and treatment of many debilitating diseases.

Moreover, there is little evidence that patents harm competition by creating barriers to entry of new substitutes. In fact, patents do the exact opposite: they provide incentive to investigate and develop alternative products. As a result, many patented products often compete with each other. A good example of how this plays out in the marketplace is the availability of many different patented therapies for treating medical conditions. The fact that a particular patented therapy is extremely effective in treating a specific ailment does not in any way suggest that the patentee has any power in the relevant market. Others are always free to develop and commercialize new therapies in that market and compete with existing patented therapies. It is this dynamic competition that offers the additional prospect of new and improved products.

In the end, invention and innovation are fostered best through a strong and effective system of intellectual property. The collective experience of the United States and many other countries demonstrates that an effective system of intellectual property protection is the best way to achieve this purpose. Thus, the continued success of American firms in both domestic and foreign markets depends directly on the availability of effective mechanisms to protect their innovations. Specifically, for small businesses and start-up firms, patent protection may be the only source of bargaining power against larger, multinational corporations.

While the USPTO is unaware of any negative effects of its policies on pharmaceutical competition, it continues to consider and implement programs to improve its operations in all areas of technology. The USPTO's 21st Century Strategic Plan, developed at the direction of Congress, is designed to implement reforms to enhance patent quality and reduce application pendency and backlogs.

The Plan has a strong quality focus and will assure quality by enabling us to hire the people who make the best patent examiners, certifying their knowledge and competencies throughout their careers, and focusing on quality in all aspects of the examination of patent applications. For example, quality will be engineered into our processing by ensuring proper training and certification of examiners and expanding the "second-pair-of-eyes" review in selected technology areas. We believe these initiatives will bolster confidence in the quality of U.S. patents thereby spurring our economy and reducing litigation costs.

Successful implementation of these quality initiatives and other elements of the Plan is dependent on enactment of the USPTO fee reform legislation currently pending in the House. The fee reform legislation would realign patent fees to more accurately reflect the costs of the services we provide and would produce the income levels necessary to attain the goals and objectives of the Plan.

Examining Differences between House and Senate Versions of the "Greater Access to Affordable Pharmaceuticals Act"
Senate Judiciary Committee Hearing, August 1, 2003
Questions for the Record

Chairman Muris' Responses to Questions from Senator Schumer

1. Mr. Muris, you have testified, and made clear in the FTC report issued last summer, of the importance to competition of the timely resolution of patent disputes. Can you explain how the declaratory judgment provision in the Senate bill achieves this? What are some problems you see with the House approach?

Answer: The FTC Study examined whether certain provisions of Hatch-Waxman have been subject to abuse that can delay generic entry given the framework initially struck in the Amendments. One of the trade-offs included in Hatch-Waxman was that final FDA approval of the generic applicant's ANDA would be stayed 30 months to allow for resolution of patent validity or infringement issues. Thus, the legislation contemplated simultaneous running of the time for FDA approval and the time to resolve patent infringement issues.

We understand there may be some concern that because the legislation would permit only one 30-month stay per Abbreviated New Drug Application (ANDA), brand-name companies may not sue during the 45 day period and may wait to sue for patent infringement after the FDA has approved the ANDA. To address this potential problem, the Senate bill adds a provision clarifying that, if the brand-name company fails to bring an infringement action within 45 days of receiving notice of an ANDA containing a paragraph IV certification, the generic applicant can bring a declaratory judgment action alleging that the patent is invalid or not infringed. To overcome possible jurisdictional limits to bringing such an action, the bill adds a provision stating that the failure of the patent owner to bring an action for patent infringement before the expiration of the 45-day period shall establish a controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States.

We do not address the constitutionality of the Senate provision or whether it may help ensure that a federal court has subject matter jurisdiction to consider the patent issue. We note that a court's dismissal of a declaratory judgment action for lack of controversy, however, may resolve uncertainty concerning whether a generic product infringes a brand-name company's patent. It also can reduce the incentives for the brand-name company and the first generic applicant to park the 180-day exclusivity. Without the right to seek a declaratory judgment, a subsequent filer that develops a clearly non-infringing product cannot trigger the first generic applicant's exclusivity because it will not be sued for patent infringement by the brand-name company. If the brand-name company and the first generic applicant agree that the generic will not begin commercial marketing, then the 180-day exclusivity becomes an absolute bar to any generic entrant.[1] Moreover, speedier resolution of patent infringement suits will redound to the

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[1] The Commission also suggests an amendment to the language of the "failure to market" forfeiture provision to accommodate Minor Recommendation #3 in the FTC Study. The

benefit of consumers by resolving any possible uncertainty that prevents a generic applicant from marketing its products. It will also allow for the simultaneous running of the periods for FDA approval and for the resolution of patent infringement issues.

The House bill does not include a similar provision establishing a controversy between the parties. Rather, the bill allows a generic applicant to bring a declaratory judgment action after the expiration of the 45-day period (assuming the brand-name company has not sued for patent infringement) only if the generic applicant provides a "right of confidential access" to its ANDA. This right would allow the brand-name company to make an informed decision about whether it should sue for patent infringement during the 45-day period. The Commission does not believe that the House's "right of confidential access" to a generic applicant's ANDA is necessary. A generic applicant currently has incentives to provide brand-name companies with sufficient information about whether its ANDA infringes the brand-name company's patents to ensure that the dismissal or adjudication of any suit precludes future infringement suits.

Commission recommended clarification that a court decision, which dismisses a declaratory judgment action for lack of subject matter jurisdiction, triggers the first applicant's 180-day period. To accommodate this change under the forfeiture event framework in both bills, Congress may wish to add such a provision to the "Failure to Market" forfeiture event.

2. Both the FTC Report and FTC's comments on the FDA rule addressed the problem of "double patenting" and how the PTO's "terminal disclaimer" procedure aggravates this problem. Could you explain to the committee what your concerns are and whether those concerns still exist?

Answer: The FTC Study recommended that patents that claim subject matter that is obvious in light of the claims of the NDA holder's earlier listed patent, as identified through the use of a terminal disclaimer in the later patent, should not be listed in the Orange Book.

When a patent applicant obtains a second patent claiming subject matter that is either the same as,[2] or obvious in light of, the claims of an earlier patent issued to the same applicant, it is called "double patenting." There are two types of double patenting: statutory and judicially created obviousness-type. Generally, either type of double-patenting renders the second patent invalid. The purpose of these rules is to prevent an inventor from extending the term of patent exclusivity by the subsequent patenting of variations that are not patentably distinct from the first-patented invention.[3]

Unlike statutory double patenting which cannot be cured, obviousness-type double patenting can be cured only if the applicant files what is called a "terminal disclaimer." When the later patent claims the identical subject matter as the earlier patent, as opposed to obvious subject matter, the statutory bar on double patenting cannot be overcome with a terminal disclaimer. The later patent is invalid. [4]

A terminal disclaimer acts to disclaim the term of the later patent that extends beyond the term of the original patent, so that both patents expire on the same day.[5] It is deemed an effective remedy because it restricts the patentee's exclusivity to the term of the original patent. Theoretically, the patentee receives no additional exclusionary term from the later patent.

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[2] This prohibition is rooted in 35 U.S.C. § 101, which provides that an inventor "may obtain a patent" for a new invention. 35 U.S.C. § 101; *see also In re Hallman*, 655 F.2d 212, 216 (C.C.P.A. 1981). The courts have interpreted the word "a" in this provision to mean that only one patent may issue for a single scientific advance. *In re Vogel*, 422 F.2d 438, 441(C.C.P.A. 1970).

[3] *See In re Vogel*, 422 F.2d at 441.

[4] *See* U. S. Patent and Trademark Office, "Manual of Patent Examining Procedure," Section 804.02, *available at* <http://www.uspto.gov/web/offices/pac/mpep/documents/0800_804_02.htm#sect804.02>.

[5] *See id.* at 4 (discussing why a terminal disclaimer is required to overcome judicially created double patenting rejections in applications filed on or after June 8, 1995).

Prior to the FDA's recent rule change limiting the number of 30-month stays available to brand-name companies, when an NDA holder listed the later patent in the Orange Book, the patent holder received an additional term of exclusivity if it generates a second, later-expiring 30-month stay. An NDA holder's ability to list a patent with a terminal disclaimer effectively vitiates the remedial effect of the terminal disclaimer. The NDA holder essentially could obtain an extension of the exclusionary effect of its patent by listing it in the Orange Book. This problem is not a theoretical one. The FTC Study identified that in the case of Paxil and Fosamax, the NDA-holder had listed and sued on both an earlier-listed patent and a later-issued, double patent that contained a terminal disclaimer.[6]

The Senate and House bills will eliminate this problem by restricting the availability of the 30-month stay to those patents listed in the Orange Book prior to the generic applicant filing its patent.

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[6] In the Fosamax case, the NDA-holder dropped the later-filed suit shortly after filing, eliminating the potential for the successive 30-month stay to block generic approval. *See* FTC Study at A-44.

3. FTC's Report noted that 11 of 30 court decisions reviewed by the agency resulted in a finding that a patent was invalid. Does the number of patents being found invalid suggest that PTO's patent prosecution process is being abused by brand companies to obtain multiple, and possibly duplicative, patents?

Answer: The FTC Report stated that recent empirical evidence[7] suggests that the rate at which drug patents are found to be invalid is "not out of line with that of patents generally." The FTC Report based this finding on a comparison of the invalidity rate found in the FTC Study data with that found in broader populations. The patent invalidity rates found in the broader empirical studies ranged between 27 and 36 percent. The Commission found the invalidity rate of the patents involved in the study to be 28 percent."[8]

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[7] *See, e.g.*, Kimberly A. Moore, *Judges, Juries & Patent Cases: An Empirical Peek Inside the Black Box*, 98 Mich. L. Rev. 365 (2000); John R. Allison, Mark Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA L.Q. 185 (1998).

[8] As noted in the FTC Report, the patent invalidity rates may not be comparable in some regards. The invalidity rate calculated in the FTC Report may be understated because patent validity may not have been determined in the cases with a decision of non-infringement or in cases when the brand-name company abandoned the litigation.

4a) It is my understanding that the "reexamination," or "reissuance," process at the Patent and Trademark Office is increasingly being used by brand companies to delay generic competition. My understanding is that some brand drug companies, after receiving notice from a generic applicant detailing the applicant's factual and legal basis for non-infringement or invalidity, send a patent back to the PTO for reissuance to correct any "deficiency" in the patent or to narrow or otherwise alter the claims within the patent – essentially "retrofitting" a patent to avoid a successful generic challenge. This seems on its face to be a gross abuse of PTO procedures with serious anticompetitive consequences. From the FTC's perspective, what is the effect of this reissuance process on timely generic competition?

Answer: This practice, as described, can delay the timely resolution of any patent infringement issues surrounding an ANDA. District courts have stayed patent litigation during the time the PTO reviews a patent under either its reexamination or its reissue procedures.[9] The FTC Study did not examine the extent to which this practice has occurred. To the extent that the Commission finds that abuse of PTO processes in a particular case resulted in anticompetitive conduct, the Commission would take law enforcement action.

4b) During the months and perhaps years during which this reissuance process is taking place, the generic applicant is in the dark about what the patent will look like upon reissuance, and so the reissuance process puts the entire generic approval process on hold. Further, it is my understanding that when a patent is reissued, the ANDA applicant must go back to square one and file a completely new challenge to the reissued patent. Isn't it possible that this process could cause virtually indefinite delays in generic approval and therefore cost consumers billions of dollars?

Answer: As noted above, the FTC Study did not examine the extent to which this practice occurred.

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[9] *See, e.g.*, Braintree Laboratories, Inc. v. Nephro-Tech, Inc., 58 F.Supp.2d 1293 (D.K. 1999); Clintec Nutrition Co. v. Abbott Laboratories, 1995 U.S. Dist. LEXIS 4946 (N.D. Ill. 1995).

SUBMISSIONS FOR THE RECORD

TESTIMONY ON BEHALF OF ELI LILLY AND COMPANY
BEFORE THE COMMITTEE ON THE JUDICIARY – UNITED STATES SENATE
AUGUST 1, 2003
ON THE "GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT"

Offered by
Robert A. Armitage
Senior Vice President and General Counsel
Eli Lilly and Company

Chairman Hatch and Members of the Committee:

Eli Lilly and Company appreciates the opportunity to offer this testimony on the proposed changes to the Hatch-Waxman Act ("Drug Price Competition and Patent Term Restoration Act of 1984") that appear in the "Greater Access to Affordable Pharmaceuticals Act" (Title VII, S. 1). Lilly's testimony today will focus on only one facet of S. 1, the provisions that relate to so-called "generic exclusivity." However, the industry does have additional concerns with S.1 that will be addressed in a separate written submission by the Pharmaceutical Research and Manufacturers of America.

The Hatch-Waxman Act forms the foundation for Lilly's ability to invest in pharmaceutical innovation. It enables innovator companies, such as Lilly, to make the decade-long, nearly billion-dollar investments that are needed to develop the new medicines we discover.

The Hatch-Waxman Act was specifically designed to allow generic companies to get to market after the innovator's basic patents—the patents on the active ingredient and approved uses for a new medicine—have expired. Under the Hatch-Waxman Act, a generic company is entitled to do so if it can demonstrate that it does not infringe any of the innovator's unexpired patents that might then remain. Once generic drug entry takes place, consumers can derive substantial benefits from the resulting price competition among generic companies.

S. 1 manages to simultaneously undermine both of these pro-innovation and pro-consumer underpinnings of the Hatch-Waxman Act. Congress would be unwise to endorse a new incentive contained in S. 1 to attack the basic patents that form the foundation of Lilly's ability to innovate. It would be unconscionable for Congress to do so in a manner that then forces the consumer to finance this new incentive by delaying access to generic drugs.

Lilly's Stake – Thirteen Decades of Answering the Need for Medicines

Lilly was founded nearly 130 years ago. Its mission centers on enriching and extending the lives of people across the globe through its innovative medicines. Today, it

is no exaggeration to state that virtually every family in America has been touched by Lilly innovations.

Our contributions over thirteen decades have included the first medicine to enable juvenile diabetics to live full and productive lives, revolutionary antibiotics that pioneered the conquest of deadly infections, and drugs that have literally revolutionized the treatment of serious mental illnesses, including depression and schizophrenia.

Today, Lilly is busy producing the first medical miracles of the twenty-first century. Just in the past several years, Lilly has offered American families the first medicine ever approved for treating severe sepsis and its often-fatal consequences and the first medicine to actually reverse osteoporosis and its debilitating consequences.

We want to preserve the ability to continue this work tomorrow, next year, and throughout the remaining decades of this century. Within our grasp are even better medicines that will be no less profound in their implications for the health of all Americans.

What Lilly Is Seeking To Have Changed in S. 1 and Why

Against the background of our heritage, it should surprise no one that Lilly would be concerned about any change to the Hatch-Waxman Act. As a result, we have made a thorough study of the provisions of S. 1 through twin lenses. How will it affect *incentives to innovate*? What will it *cost consumers*?

Sponsors of S. 1 claim the intent of the complex changes contained in S. 1 will be to make generic drugs available to consumers on a *faster timeframe* while continuing to *encourage innovation* by brand name companies but *without setting up a massive atmosphere of litigation*. A careful analysis indicates that the bill would do the opposite on all three counts—

- Consumers will wait *longer* for the value that comes from competition among generic drug companies. In the most common situation in which generic drug entry occurs, consumers will wait up to eight months longer for this value-generating competition. In other common situations, the wait will be *years longer*.

- Innovators will see their basic patents on the active ingredients and approved uses for new medicines—the patents that provide the foundation for the ability to invest in innovation—made the subject of a new incentive to attack and destroy them. Generic companies will be driven by new incentives in S. 1 to make early and entirely speculative patent challenges. Generic companies that do so will reap huge rewards for attacking innovator patents—*even when generic drug entry is not accelerated by even one day*. These anti-innovation, and unearned, rewards will come at the expense of consumers.

- The creation of a *massive atmosphere of litigation* is something S. 1 will foster, not restrain. Indeed, its design explicitly drives early, speculative litigation. The costs and risks created by this litigation will ultimately be paid for by the consumer.

Lilly acknowledges that many provisions in S. 1 were motivated by a desire of some in Congress to address conduct by innovator companies that might unfairly delay generic competition once the basic patents on a new medicine had expired. For this reason, Lilly is not seeking changes that would reverse any provision of S. 1 that is calculated to reign in this conduct, would delay by even one day generic drug market entry, or would add to the burdens generic drug companies face in gaining approval to market.

What we cannot accept, and implore the Congress to change, are the S. 1 provisions that are flatly inconsistent with the 1984 guarantees Congress enacted to protect innovators and benefit consumers. Indeed, if S. 1 is to be made true to the stated intentions of its sponsors—protecting consumers, protecting innovation, and avoiding wasteful litigation—then what we are asking for is nothing more than a fix for an unanticipated loophole that S. 1 would otherwise create.

Congress can close the S. 1 loophole by stripping out of the law the opportunity for a 180-day exclusivity period where it needlessly delays generic competition. What we seek can be boiled down to a single sentence. Lilly would ask that Congress add a provision to S. 1 stating that once all the innovator's basic patents have expired and a competing generic company has demonstrated that it does not infringe any of the remaining innovator patents, the 180-day exclusivity period will be forfeited.

Why should Congress do this? First and foremost, it obliterates any anti-consumer effects of S. 1. Generic competition starts when the Hatch-Waxman Act intended that it would begin—and common sense dictates is must begin—not later than when the innovator's basic patents on the drug's active ingredient and the approved uses have expired and competing generic companies have demonstrated that they do not infringe any patents that then remain.

Second, it keeps in place the policy-driven disincentive to making early and entirely speculative challenges to basic patents of innovators that has been a part of the Hatch-Waxman Act since 1984.

Third, it reverses the impact of S. 1 that would otherwise provide an incentive to attack *all* innovator patents at the earliest date the law permits.

The remainder of this testimony will review the operation of Hatch-Waxman today, the changes to Hatch-Waxman under S.1, the negative impact of these changes on consumers and innovation, and what Congress should do to remedy the defects in S.1.

Operation of the Hatch-Waxman Act and Impact of S.1

To understand the impact of S. 1 on the Hatch-Waxman Act requires an examination of how patents work to protect new medicines from generic competition and how the "patent challenges" provided under the Hatch-Waxman Act were designed to facilitate generic drug entry once the basic patents on a new medicine have expired.

Innovator patents operate to provide the incentive that drives the ability to invest in new and better medicines.

The decision to develop the vast majority of new medicines is undertaken because one or more patents have been sought that an innovator believes can defer generic drug entry until these patents expire. Such patents must afford the prospect of extended periods of innovator exclusivity after the new medicine is first approved for marketing. Absent the prospect of adequate patents and an adequate postapproval patent term, the development of many potential new drugs would not go forward.

The patents that can provide this type of ensured innovator exclusivity are the so-called "basic patents." They claim the active ingredient or the approved uses for the new drug. Basic patents are, thus, those that every generic competitor must infringe to get a generic drug approved since generic drugs cannot be approved unless they copy identically the active ingredient and at least one approved use.

The underlying design of Hatch-Waxman is, therefore, premised on the ability of one or more of these basic patents to reliably fuel the ability to invest in innovation. Impairing the expectation that basic patents can provide exclusivity until they expire impairs or removes altogether the ability to invest in a new medicine's development.

Hatch-Waxman's "patent challenge" provisions permit generic drug entry once the basic patents on new medicines expire.

A second fundamental design premise of Hatch-Waxman is that generic drug entry should be possible immediately after these basic patents have expired. Once the basic patents expire, the innovator's remaining patents may claim specific formulations, physical forms of the active ingredient, or like aspects of the innovator's drug. Generic companies, however, can use unpatented formulations and unpatented physical forms in making generic drugs. Generic companies that succeed in designing around these secondary patents can readily establish that they do not infringe them and proceed with marketing under the Hatch-Waxman mechanisms.

After designing around the patents remaining after the basic patents expire, generic companies can use the so-called "patent challenge" features in Hatch-Waxman. By providing a certification statement to the patent owner that demonstrates that the generic drug does not infringe any of the secondary patents, the Hatch-Waxman Act sets in motion a procedure that allows the FDA to approve the generic drug before expiration

of the challenged patents—in some cases without the need for the generic company to ever defend itself in court.

The design of Hatch-Waxman, therefore, puts all generic companies in a position to get FDA approval and secure generic drug entry on the day the basic patents expire if they bring patent challenges to the remaining patents in a timely fashion before the expiration of the basic patents.[1] Today, the only possible confounding factor in the timing of generic drug entry after the basic patents expire is whether the operation of the 180-day exclusivity will get in the way of getting to market immediately.

Whether the 180-day exclusivity confounds generic drug entry after the expiration of the basic patents depends upon whether (1) the 180-day period has been *triggered* and (2) once triggered, runs out before or after the expiration date of the basic patents. Thus, the *trigger* that starts the 180-day period—and its relationship to the expiration date of the basic patents—is the crucial factor under the Hatch-Waxman Act that determines the start of—*or delays in the start of*—free-for-all generic competition.

"Generic exclusivity" can operate to delay, not accelerate, generic drug entry.

The Hatch-Waxman Act provides a generic company that is the "first applicant" the opportunity for a 180-day generic exclusivity period. During the 180-day period, the Hatch-Waxman Act bars the FDA from approving *all* generic drug applications, except the first applicant's generic application.

The "first applicant" is the generic company that is the first to file a generic drug application with the FDA containing a certification that at least one of the innovator's patents is invalid or that the first applicant's generic drug does not infringe the patent. The patents that can be certified as invalid or not infringed are the so-called "Orange Book patents." These are the basic patents related to a new medicine and certain secondary patents that the innovator is required by law to list with the FDA.

Once the first applicant files its patent challenge, the FDA is then barred from approving a subsequently filed generic drug application until the first applicant's "generic exclusivity" claim can be resolved.[2] The resolution of the 180-day exclusivity issue

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[1] The Hatch-Waxman Act "patent challenge" mechanism operates to encourage generic companies to bring these challenges approximately 30 months before the basic patents expire. In that way, if the patent owner believes that a court should decide the patent infringement issue raised in the patent challenge statement, this 30-month period allows a court the time to review the patent challenge and render a decision before the expiration of the basic patents. The Hatch-Waxman Act also encourages the patent owner to bring a patent infringement lawsuit immediately after receiving the certification statement if the patent owner believes that a challenged patent has been infringed. If a patent infringement lawsuit is brought within 45 days after receipt of the patent challenge statement, the FDA is required to stay the approval of the generic drug for a 30-month period (unless the patent expires first).

[2] The FDA issued final regulations governing the granting of the 180-day exclusivity period in 1994. These original regulations required that a generic company "successfully defend" against a patent claim brought by the innovator company in order to gain the 180-day exclusivity. The FDA looked to the congressional intent—that the 180-day monopoly was intended to reimburse for litigation costs—and decided that only those companies that devoted the time and resources to litigate and *won* were entitled to

requires a three-pronged *waiting* period during which the FDA approval bar for competing generic companies remains in force:

- waiting to see if the first applicant will trigger the 180-day exclusivity *or not*,
- waiting for the trigger event to actually occur, and
- waiting for the 180-day period to run its course.

Waiting out the resolution of the first applicant's 180-day exclusivity issues can consume *years*.

> *When the waiting period to resolve the 180-day exclusivity continues at or after the date that the basic patents for the new medicine have expired, the 180-day exclusivity will typically delay generic drug entry.*

On the day that the basic patents have expired, one or more of the competing generic companies may already have established that they do not infringe any of the innovator's unexpired patents that remain in the Orange Book. As noted previously, the Hatch-Waxman Act provides a complete mechanism for each competing generic company to do so by bringing a timely patent challenge to the remaining patents. For each generic company that has successfully done so, the FDA can give final marketing approval to each of the noninfringing generic companies *but for* the need to wait for the 180-day period to be triggered or not and, if triggered, to run its course.

However, the parallel efforts of the first applicant to establish that these same Orange Book patents have not been infringed may or may not be complete when the basic patents expire. Indeed, the first applicant may ultimately succeed or fail altogether in establishing it does not infringe the remaining patents. Until the first applicant does one or the other, the FDA's hands remain tied.

The FDA must delay final approval for each of the competing generic companies until the uncertainty of the first applicant's "generic exclusivity" is resolved.[3] It must do so even if years tick away for the competing generic companies that had long ago demonstrated that they are not patent infringers.

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the exclusivity period. In essence, the 180 days were awarded when generic companies cleared the way for themselves and others. However, in 1997 the District Court for the District of Columbia Circuit in *Mova v. Shalala* rejected the FDA's successful defense requirement – a ruling that was upheld by the Court of Appeals for the District of Columbia Circuit in 1998. Therefore today, a generic company need not prevail in litigation, nor even partake in any litigation to be awarded the 180 days.

[3] If the basic patents in the Orange Book have not expired, this bizarre outcome does not arise. The Hatch-Waxman Act prohibits the FDA from approving any generic drug where it would infringe a valid patent. Thus, so long as the basic patents remain in force and are infringed, the FDA cannot approve either the first applicant or any competing generic companies. Thus, generic drug entry cannot be delayed by waiting for the 180-day period to be triggered unless the trigger point can be delayed by the first applicant until the date the basic patents expire.

Under Hatch-Waxman, Congress prohibited delaying or "parking" of the 180-day period after a "court decision"

Congress made certain in 1984 that the first applicant's opportunity for "generic exclusivity" could not unduly delay or "park" generic drug entry. It did so by imposing a "trigger" event that forced the 180-day period to start to run. Even if the first applicant had not begun commercial marketing of its generic drug, this trigger would ensure that the 180-day clock would begin ticking and the 180 days would come to an end. This trigger, therefore, ensured that those generic competitors that did not infringe any remaining patents could get FDA approval to market sooner rather than later.

What was the "trigger" that Congress enacted in 1984 to prevent delaying or "parking" the 180-day exclusivity period? Congress provided that, once a court determines that a challenged patent had not been infringed or was invalid, that court decision itself triggers the start of the 180-day period for the patent in question. This use of a "court decision" as the triggering mechanism was, thus, the key design feature of the 180-day exclusivity provisions because it alone prevented any further delays in the start of the 180-day period that could otherwise delay generic drug entry by competing generic drug companies.

Indeed, without such a trigger that could be pulled before the start of the first applicant's commercial marketing of the generic drug, the 180-day exclusivity could systematically operate to delay the start of competition among generic drug companies – and frustrate its *raison d'être*. With the trigger, the Hatch-Waxman Act prevented the "parking" of the 180-day exclusivity period, which operates to delay the start of the 180-day period for months or years after other generic companies have demonstrated that they infringed no unexpired patents.

The "court decision" trigger also serves a second purpose, beyond protecting consumers from delays in generic drug entry. This second purpose was to provide a clear-cut, policy-driven disincentive to making early and speculative patent challenges against all the innovator's patents appearing in the Orange Book.

Without the "court decision" trigger to start the 180-day period, generic companies could routinely bring patent challenges at four years from the original FDA approval for the new medicine – the earliest possible date permitted in the Hatch-Waxman Act. These challenges could attack every patent in the Orange Book—both the basic patents and those that would remain after the basic patents expire.

If the attack on the basic patents failed (*i.e.*, the basic patents were found valid and infringed), the first applicant could not then "park" the opportunity for the 180-day exclusivity until the basic patents expired and only secondary patents that the court found had not been infringed still remained in force.

Because Congress provided that the "court decision" of noninfringement for the remaining patents always triggers the start of the 180-day period, the 180 days will nearly

always run their course before the basic patents have expired. No incentive exists, therefore, for bringing such an early challenge that, in some cases, would be made a decade before the expiration of the basic patents. In fact, there exists a strong disincentive for doing so.

Permitting "parking" would be bad policy because it delays generic market entry and creates an incentive to bring early and entirely speculative patent challenges—both of which are bad for consumers and innovation.

Permitting "parking" of the generic exclusivity after an early patent challenge would not only encourage speculative attacks on the innovator's basic patents, but it also would virtually always operate to delay generic drug entry by competing generic companies *at just the moment that the Hatch-Waxman Act was designed to ensure that all generic companies could get FDA approval.* Competing generic companies that had also used the patent challenge mechanism to demonstrate that they too had designed around all the patents remaining after the basic patents expire would be irrationally penalized.

For a blockbuster drug, even a six-month delay in the start of competition resulting from "parking" of a first applicant's 180-day period until the expiration date of the basic patents could mean an extra $1 billion price tag for the consumers. Thus, no part of the Hatch-Waxman Act has been more essential over the past 20 years to help avoid irrational delays in generic drug entry and competition among generic drug companies than the "court decision" trigger for the 180-day exclusivity period.

S.1 does away with the "court decision" as a "trigger," which has negative consequences for innovation and consumers.

Without noting its significance or consequences, S. 1 simply erases the "court decision" trigger for the start of the 180-day period. In doing so, S. 1 permits the 180-day exclusivity period to be "parked"—in some cases for years. It permits the parking to continue until the first applicant actually begins commercial marketing—even if this occurs *years after* the "court decision" that today would trigger the 180-day period.

Where the first applicant has brought an early, speculative challenge to all the innovator's Orange Book patents, the "parking permit" can remain in effect until the innovator's basic patents have expired. The first applicant can exit the parking lot just as competing generic companies would today get final FDA approval and begin marketing competing generic drugs.

The significance of erasing the "court decision" trigger can hardly be understated. In some situations, this will mean competing generic companies will get to market months to years later than they do today. Many of these generic companies will have demonstrated conclusively that they do not infringe *any* of the innovator's patents that remain after the basic patent expires. Like the first applicant, they will be forced to use the patent challenge mechanism—and perhaps go to court to establish that they do not

infringe the remaining patents. For all this effort and expense, they will find themselves barred from the market for months to years longer than could be the case today.

An early, speculative patent challenge that would today have failed to yield a generic marketing monopoly, because the 180-day period would have expired years before the valid, basic patents of the innovator expired, would be virtually guaranteed of success. With the ability to exit the "parking lot" at the time the basic patents have expired, the first applicant could always use the 180-day period as long as it could demonstrate that it did not infringe any remaining patents.

This virtual guarantee of success brews a powerful incentive to be the first to challenge and grab hold of the virtually certain reward. Even if a generic company challenging on the fourth anniversary of innovator marketing approval must wait for a basic patent expiration 10 years later to retrieve a $100 million or $1 billion prize from the six-month generic monopoly, the opportunity to invest in speculative patent challenges and the resulting litigation can be a compelling one.

In short, removal of the "court decision" trigger in S. 1 is profoundly anticonsumer and anti-innovation. By encouraging speculative challenges, it fosters the very type of litigation its sponsors say it was intended to avoid.

S. 1 adds new "forfeiture" provisions that further compound the anticonsumer and anti-innovation consequences of the repeal of the "court decision" trigger.

S. 1 creates new "forfeiture" provisions under which the first applicant can forfeit the right to the 180-day exclusivity. These new forfeiture provisions do not serve to replace the "court decision" trigger. Instead, they operate to further negatively affect the consumers of generic drugs.

The key forfeiture provision in S. 1 is a new "failure-to-market" forfeiture. This provision provides that, in certain situations where the first applicant fails to market after a "*court decision*" on the patent challenge, the 180-day exclusivity is forfeited. However, this "court decision" forfeiture is no substitute for the existing "court decision" trigger. In fact, it operates backwards—S. 1 provides that the forfeiture of the 180-day exclusivity can be avoided whenever a court holds a challenged patent both valid and infringed

Indeed, compared with current law, this new "court decision" forfeiture is triply defective:

- First, the "court decision" forfeiture produces no immediate forfeiture. The "court decision" forfeiture takes effect only after 75 days from the first applicant's commercial marketing. In terms of delaying the onset of competition among generic companies, these 75 days to get to a forfeiture event must be tacked onto the 180-day period itself. Viewed through this calculus, the 75 days can be added to the 180 days to produce a possible 255 days—eight and one-half months—when the FDA is barred from approving competing generic drugs after the "court

decision." This, again, is 255 days during which competition among generic drug companies could be taking place under current Hatch-Waxman law.

- Second, S. 1 redefines the "court decision" not as the district court, but the appellate court decision.[4] This change in the law potentially tacks another one to two years of possible delay before the FDA is allowed to approve competing generic drug applications—even if a host of competing generic companies have already demonstrated in their certification statements made during a patent challenge that they do not infringe a single remaining patent of the innovator!

- Third is the most problematic defect in the new forfeiture provision. The forfeiture is rendered inoperative—that is, the "court decision" is simply ignored as creating the possibility for a forfeiture – for any challenged patent where the challenge is *a complete failure* and the challenged patent is found both valid and infringed.

Under this third aspect of the new forfeiture, S. 1 throws out the court decision—even the appellate court decision—as a trigger for the 180-day period. Instead, S. 1 extends any possible forfeiture until 75 days after the *expiration* of each valid, infringed patent.

As discussed previously, this last feature creates the incentive in S. 1 for generic companies to bring early and entirely speculative patent challenges *on every single innovator patent— including the basic patents*. It is what allows the incentive to operate flawlessly for the first applicant, even if the challenge to a basic patent is launched a decade prior to its expiration.

The anti-innovation implications could hardly be more clear-cut: innovators will incur greater costs to defend these patent challenges, no matter how speculative or thin. It means a new hurdle will stand in the way of developing even the most promising medicines. Unless a potential new medicine has the most defensible patents, it might be impossible to justify the investment needed to develop it.

And, however slight, the incentive creates a new risk that a basic patent might even be lost in litigation before the medicine could ever return its investment. For those medicines, it would mean cutting short the life of a drug for which its most promising uses and greatest contribution to mankind might come from the postmarketing research into new uses that no one will have the incentive to pursue.

What Congress Should Do To Fix the Loophole in S. 1

Congress should act in conference to fix the defect in S. 1. The defect will be costly to the Medicare Drug Benefit—the federal government will foot part of the bill for

[4] Under the FDA's original approach, a "court decision" was defined as: "the court that enters final judgment from which no appeal can be or has been taken." However, in 2000, the District Court for the District of Columbia ruled in *Mylan Pharmaceuticals, Inc. v. Shalala*, that "court" means district court.

the new generic monopolies that will be unleashed under S. 1 at just the moment competition among generic drug companies should be affording consumers the full value of a generic drug.

It will be costly for innovation, forcing innovators to look beyond developing the best new medicines and focus on medicines that appear to have the best patents.

Lilly would propose that Congress simply add to S. 1 one more forfeiture to close the loophole. After the basic patents have expired and one or more competing generic companies have demonstrated that they infringe no remaining Orange Book patents, the 180-day period should no longer apply—it should be forfeited by the first applicant.

After the basic patents have expired and competing generic companies have already demonstrated that the remaining patents have not been infringed, the only function that the 180-day period can serve is to delay, not accelerate, generic competition. In this situation, there is nothing the patent challenge could do to clear a patent barrier standing in the way of generic drug entry—because it is clear that no such barriers can possibly remain.

With this new forfeiture, the 180-day exclusivity could accelerate, but never delay generic drug entry. Adding this additional forfeiture would return the 180-day exclusivity to its original policy underpinnings, only rewarding those generic companies that clear way for themselves and other generic competitors.

Conclusion

Title VII of S. 1 contains provisions that would substantially modify the Hatch-Waxman Act. These changes, while intended to close loopholes, actually create a new loophole that is anticonsumer, anti-innovation, and prolitigation.

Innovation will suffer because of a new incentive to make early, speculative patent challenges to all the Orange Book patents of the innovator. Consumers will suffer because of the systematic manner in which generic drug approvals will be delayed.

As a result, the loophole created in S. 1 must be closed prior to passage. Congress should mandate forfeiture of the 180-day exclusivity once the basic patents have expired and competing generic companies have demonstrated that they do not infringe any patents that then remain. No reasoned justification for continuing the opportunity for "generic exclusivity" could possible apply once its only possible effect would be to delay generic drug competition.

TESTIMONY ON BEHALF OF ELI LILLY AND COMPANY
BEFORE THE COMMITTEE ON THE JUDICIARY – UNITED STATES SENATE
AUGUST 1, 2003
ON THE "GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT"

Offered by
Robert A. Armitage
Senior Vice President and General Counsel
Eli Lilly and Company

Appendix A

Illustrative Examples of the Impact of S. 1

The "generic exclusivity" provisions in S. 1 are complex and can be difficult to translate from statutory language into their practical effects. This appendix offers some illustrative examples of the practical impact of S. 1. It uses as a factual predicate for several of these examples past patent challenges. However, these historical examples are updated to apply the Hatch-Waxman law as it would exist if the loophole in S. 1 is not closed, *i.e.*, Congress does not enact a new forfeiture provision that applies once the basic patents of the innovator have expired and competing generic companies have demonstrated that they do not infringe any patents that then remain.

Glynase Patent Challenge: Illustrative Example of the Impact of Moving to the Appellate Court Decision in the Failure to Market Forfeiture

The Glynase patent challenge represents an example of the impact of the new S. 1 provision allowing a first applicant to wait for the appellate court decision before any possible forfeiture of the 180-day exclusivity can occur.

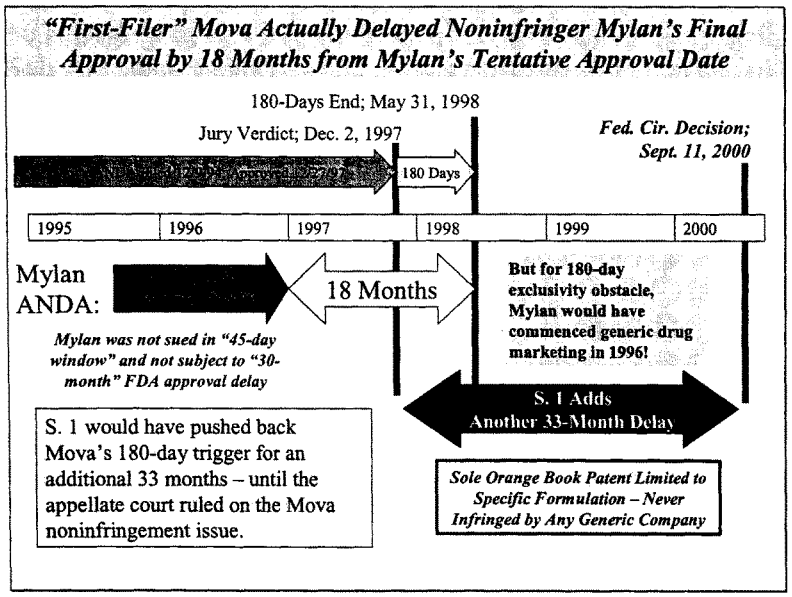
In this case, Mova was the first applicant and thus entitled to the 180-day exclusivity. The subsequent filer, Mylan, was not sued during the 45-day period after the patent owner received the patent certification statement. As a result, Mylan was given tentative FDA approval in December 1996. It was not subject to the 30-month stay in FDA approval that would have applied had a patent infringement suit been brought within the 45-day period.

The FDA was precluded from approving the Mylan generic drug application for a further 18 months after it had tentative approval solely because the first applicant Mova was still in the middle of a court challenge related to the sole Orange Book patent.

Mylan received no conceivable benefit from the patent challenge of the first applicant Mova. Both Mylan and Mova devised different means for designing around the sole Orange Book patent. Both generic companies were required to separately and independently establish that the sole Orange Book patent was not infringed.

The courts ultimately found the patent to be both valid and enforceable but not infringed by either generic company. All the basic patents had expired by the time this patent challenge was brought.

Mylan was nonetheless burdened irrationally by the imposition of generic exclusivity grounded on a patent that was ultimately held valid but that neither generic drug company infringed.



S. 1 would make Mylan's situation worse. Under S. 1, Mylan might have been forced to wait an additional *33 months* in order to gain marketing approval, the date of the appellate court decision. Even more perversely, had Mova lost its appeal and been found to infringe the patent, Mylan might have been forced to wait until September 2000 to get final approval – even though it would have been the only generic drug company not infringing the Orange Book patent.

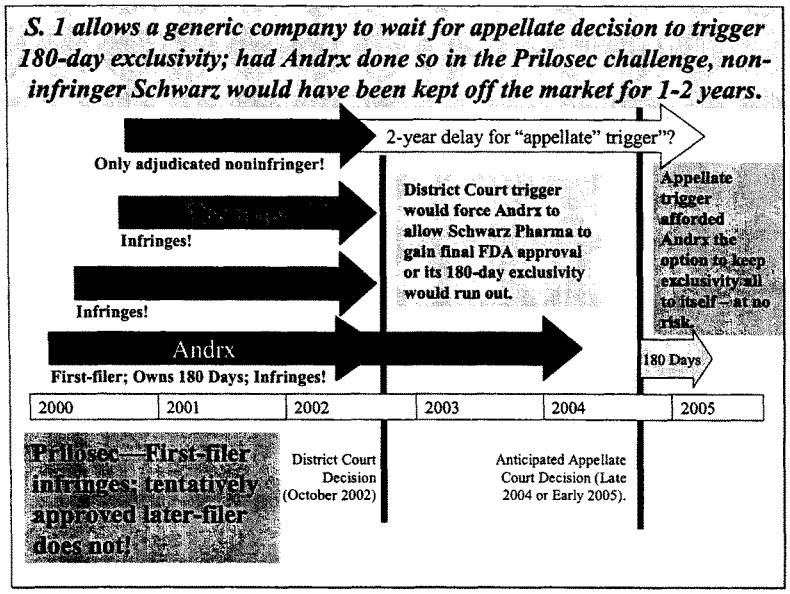
If a simple forfeiture provision were added to S. 1 that would operate to allow Mylan to certify to the FDA that its patent certification statement demonstrated to the patent owner that it did not infringe the patent and that it had not been sued for patent infringement during the 45-day period after receipt of the notice by the patent owner, Mylan would have come to market in 1996, not 2000. "First applicant" Mova could have come to market a year later.

Prilosec Patent Challenge: What if the "First Applicant" Infringes But a Subsequent Applicant Demonstrates It Does Not Infringe?

The most significant patent challenge in the 20 years since Hatch-Waxman became law in 1984 is the Prilosec patent challenge. U.S. sales of Prilosec in 2002 were in excess of $3 billion. Prilosec provides an example in which a 180-day generic monopoly could be worth $1 billion or more in profits for the first applicant.

In this challenge, four generic drug companies attempted to design around the remaining patent held by the innovator after the basic patents had expired. All four challengers were joined together in a single lawsuit that addressed the issues of validity and patent infringement.

The challenge resulted in the "first applicant" Andrx being held by the district court to infringe the patent, but one of the subsequent applicants, Schwarz Pharma, being determined not to infringe the patent.



Under current law, the "court decision" of noninfringement by Schwarz Pharma would have triggered the start of the 180-day period by Andrx. The Prilosec patent challenge was governed, however, by a prior FDA interpretation under which the final appellate court decision was the trigger for the 180-day period.

Even though Andrx could have waited for the appellate court to rule on its assertion of noninfringement, it elected not to do so. Instead, with the 180-day exclusivity worth potentially a billion dollars or more, Andrx quickly passed its 180-day exclusivity off to Schwarz Pharma so that generic competition would begin and the two companies could share in the bounty.

Had S. 1 passed, it might have dramatically undone this result. Under S. 1, the decision of the district court would not have been a trigger. Andrx would have been able to "park" its exclusivity period and wait to see if an appellate court would reverse the infringement judgment and allow it to keep the well-over-$1-billion prize that the 180-day exclusivity might represent.

Such an outcome, however, would mean that the public would still be waiting today for generic Prilosec. The long delay in generic drug entry – and the billions of dollars it would cost consumers – just might have produced a political outcry that would have moved Congress to remove the anticonsumer provisions from S. 1 that are the subject of this testimony.

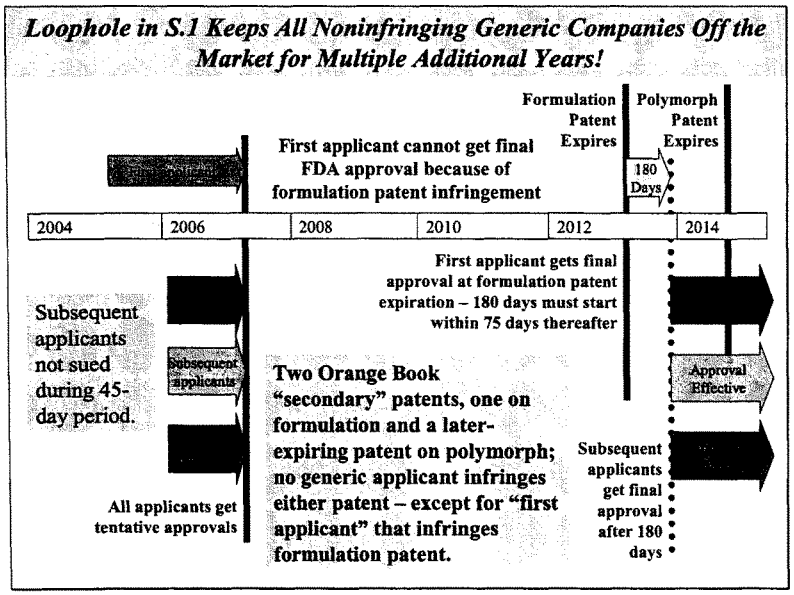
How much of Andrx's decision to allow generic drug entry after the district court decision was an economic one and how much was political is merely a matter of speculation. However, closing the loophole in S. 1 would have a less-speculative outcome – generic drug entry would have taken place after the basic patents had expired and one or more competing generic companies demonstrated that they did not infringe any remaining patents.

Hypothetical Example of the Loophole in Its Most Pernicious Incarnation

One final example illustrates the ultimate absurdity of S. 1 and the changes it will make in the 180-day exclusivity provisions. Again, it illustrates the perversity of the operation of the 180-exclusivity once the basic patents have expired and one or more competing generic drug companies have demonstrated that they infringe no remaining Orange Book patents.

Consider the situation where only two Orange Book patents exist, an earlier-expiring patent on the specific formulation for a new medicine and a later-expiring patent on a polymorph form of the drug. The first applicant challenges both patents, and under S. 1 qualifies for generic exclusivity. S. 1 will allow the first applicant to park the exclusivity after a court finds that the polymorph patent is valid, but not infringed, while the formulation patent is held both valid and infringed.

In this case the "court decision" will not result in any forfeiture until 75 days after the expiration of the formulation patent. In the example illustrated below, the expiration of the formulation patent is six years after "tentative approval" is given to the first applicant as well as three subsequent applicants.



If the group of three subsequent applicants challenge the same patents but establish so convincingly in their patent certification statements that they do not infringe either patent, such that the innovator cannot bring a patent infringement action against any of them, the noninfringers will be kept off the market under the provisions of S. 1 for six full years.

In the example above, instead of getting to market in 2007, the generics wait for six years for the start of the 180-day period and then the additional 180 days (up to 8.5 months) before they are eligible for FDA approval. If S. 1's loophole is closed through a simple provision allowing any of the three subsequent applicants to certify that they were never sued for infringement of any of the remaining Orange Book patents, then marketing approval will begin in 2007, not 2013!

Conclusion

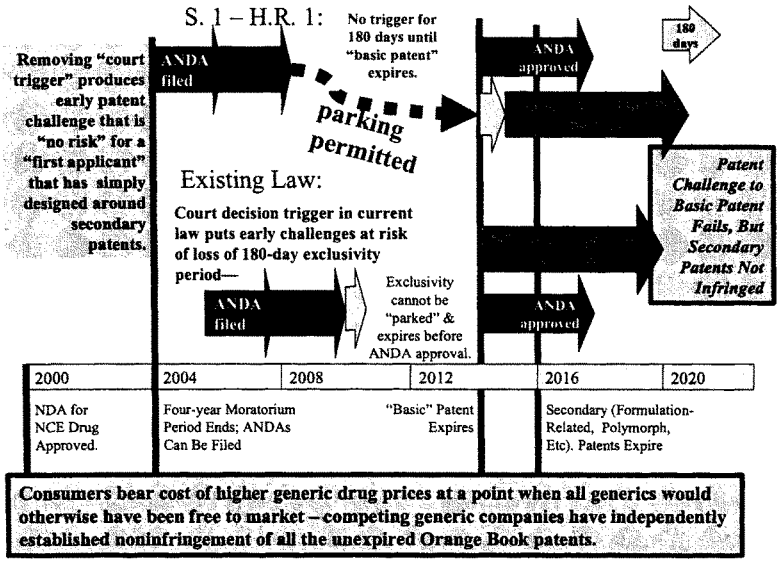
The imperative for a simple forfeiture to close the loophole could hardly be more apparent or imperative. In no case above is the 180-day exclusivity operating as an "incentive" to challenge patents that otherwise might not be challenged. In every case, the 180-day exclusivity is given to one applicant that undertook no different or greater burden than any of its generic competitors. S. 1 – without closing the loophole – would make utter nonsense of "generic exclusivity", at a huge cost to consumers.

TESTIMONY ON BEHALF OF ELI LILLY AND COMPANY
BEFORE THE COMMITTEE ON THE JUDICIARY – UNITED STATES SENATE
AUGUST 1, 2003
ON THE "GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT"

Offered by
Robert A. Armitage
Senior Vice President and General Counsel
Eli Lilly and Company

Appendix B

Illustrative Example of "Parking" Exclusivity Under S. 1 and H.R. 1 Comparison With Existing Law



Department of Justice

STATEMENT

OF

SHELDON BRADSHAW
DEPUTY ASSISTANT ATTORNEY GENERAL
OFFICE OF LEGAL COUNSEL

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

CONCERNING

EXAMINING THE SENATE AND HOUSE VERSIONS OF THE
"GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT"

PRESENTED ON

AUGUST 1, 2003

Testimony of Sheldon Bradshaw
Deputy Assistant Attorney General
Office of Legal Counsel
U.S. Department of Justice
on
H.R. 1, Medicare Prescription Drug and Modernization Act of 2003

Thank you, Mr. Chairman, for inviting me here today to provide the Administration's views on H.R. 1, the Medicare Prescription Drug and Modernization Act of 2003. My testimony today will focus on a provision in the Senate version of the bill, section 702(c), which declares that the federal courts shall have subject matter jurisdiction over certain declaratory judgment actions. Specifically, the provision in question provides that the failure of a patent owner to bring an action for patent infringement against a pharmaceutical company that files a new drug application with the FDA that is based on one of its patents within 45 days of receipt of notice of the application "shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States" to hear an action brought by the applicant under the Declaratory Judgment Act, 28 U.S.C. § 2201.[1]

On June 17, 2003, I provided this Committee with the Administration's tentative views on a similar provision contained in S. 1225, the Greater Access to Affordable Pharmaceuticals Act. At that time, the Administration had not yet formed a definitive view on whether cases brought pursuant to such a provision would satisfy the Article III case or controversy requirement. I did, however, make several general observations about the matter. I noted that, among other things, the case or controversy requirement set forth in the Declaratory Judgment Act was constitutionally compelled and that, like other Article III requirements, it could not be waived by Congress. Having now had an opportunity to examine the provision in greater detail, the Administration is of the view that, in its present form, section 702(c) is inconsistent with Article III of the Constitution. This provision, which does not appear in the House version of the bill, attempts to vest the lower federal courts with jurisdiction over disputes that, because of Article III's case or controversy requirement, the Constitution does not empower these courts to hear. Accordingly, it is the view of the Administration that this provision should either be deleted from the bill or rewritten.

Both the Senate and House versions of H.R. 1 make amendments to the process by which new drug applications are approved. The bills require that certain applicants give notice to existing owners of a patent or to holders of an approved application.[2] The notice must provide a detailed factual and legal basis for why the application does not infringe the recipient's patent or

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[1] H.R. 1, Senate Ver. § 702(c)

[2] H.R. 1, Senate Ver. §§ 702(a)(1), 702(b)(1); House Ver. §§ 1101(a)(1)(A), 11(b)(1)(A).

why the recipient's patent is invalid.[3] If the recipient of the notice sues for infringement within 45 days following receipt, it receives a significant benefit. Among other benefits, the application may not be approved until the earliest of the resolution of the infringement suit, the expiration of the relevant patents or the passage of thirty months from the date of the notice.[4]

Both the Senate and the House versions of the bill provide that if the patent holder does not bring suit within the 45-day period, the applicant may then bring a declaratory judgment action for non-infringement or patent invalidity.[5] The Senate, but not the House, version of the bill, goes further and provides that "the failure of the owner of the patent to bring an action for infringement of a patent [within the 45-day period] shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States" to hear an action brought under the Declaratory Judgment Act, 28 U.S.C. § 2201.[6] Herein lies the constitutional infirmity.

The Declaratory Judgment Act requires that a dispute be an "actual controversy" before the federal courts have subject matter jurisdiction over actions to declare the rights of the parties.[7] The Senate version of H.R. 1 purports to declare this requirement satisfied in every case by the failure of the patent holder to bring an action within 45 days, and thus to vest the federal courts with subject matter jurisdiction in all of these cases.[8] Congress, however, cannot so declare. The limitations on the federal courts' jurisdiction emanate from the Constitution, not merely from the "actual controversy" requirement of the Declaratory Judgment Act.

Under the Constitution, federal courts have jurisdiction over a dispute only if it is a "case or controversy" within the meaning of Article III.[9] This restriction on the courts' authority is fundamental to the separation of powers established by the Constitution and enjoins the courts from issuing advisory opinions. This requirement consequently operates as a limitation on Congress's power to grant the courts jurisdiction.[10] Put simply, Congress cannot expand the

---

[3] H.R. 1, Senate Ver. §§ 702(a)(1), 702(b)(1); House Ver. §§ 1101(a)(1)(A), 11(b)(1)(A).

[4] 21 U.S.C. § 355(j)(5)(B)(3).

[5] H..R. 1, Senate Ver. §§ 702(a)(2)(C), 702 (b)(2)(D); House Ver. §§ 1101(a)(1)(C), 1101(b)(2)(D).

[6] H.R. 1, Senate Ver. § 702(c)

[7] 28 U.S.C § 2201.

[8] H.R. 1, Senate Ver. § 702(c).

[9] U.S. CONST. art. III, § 2.

[10] *Federal Election Comm'n v. Akins*, 524 U.S. 11, 20 (1998).

courts' power to hear cases beyond what the Constitution itself provides.

Courts have read the Declaratory Judgment Act's "actual controversy" language to track the Constitution's "case or controversy" requirement.[11] The Supreme Court has "adjudged [the Act] constitutional only by interpreting it to confine the declaratory judgment remedy within conventional 'case or controversy' limits."[12] If the Declaratory Judgment Act were effectively amended with respect to these patent cases, satisfaction of the statutory "actual controversy" requirement would no longer be sufficient to grant the courts jurisdiction. The courts would still have to satisfy themselves that the dispute was a "case or controversy" under the Constitution. Congress cannot amend this constitutional standard. Although Congress may declare that a certain set of facts fulfills a statutory requirement, it cannot declare Article III's limitations satisfied. If it did so, it would be improperly intruding on the court's province to interpret the Constitution.[13] Just as Congress may not declare Article III's standing requirement satisfied,[14] so may it not declare Article III's "case or controversy" limitation satisfied. Congress simply cannot expand the federal court's jurisdiction beyond the bounds established by the Constitution.

Section 701(c) of the Senate version of H.R. 1 thus can have no effect. In many cases, the actions brought following the 45-day period will meet the Constitutional "case or controversy" requirement independently of section 701(c)'s declaration. As applied to these cases, the provision is constitutional, but without purpose. Currently, to determine whether Article III and the Declaratory Judgment Act are satisfied in patent disputes, federal courts have asked whether the applicant has a "reasonable apprehension" that the patent owner will sue for infringement.[15] Applying this standard, courts look to a variety of factors, including communications between the patent holder and the applicant and the actions of the patent holder with respect to other possible infringers. Indeed, in light of the statutory benefit conferred on the patent owner if it sues within the 45-day period, it is likely that a court would consider the applicant's reasonable apprehension to be diminished if the patent holder does not sue for infringement within that time. Over disputes that the courts determine are insufficiently definite and concrete to rise to a "case or

---

[11] *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-40 (1937) ("The Declaratory Judgment Act of 1934, in its limitation to 'cases of actual controversy,' manifestly has regard to the constitutional provision and is operative only in respect to controversies which are such in the constitutional sense. ... In providing remedies and defining procedure in relation to cases and controversies in the constitutional sense the Congress is acting within its delegated power over the jurisdiction of the federal courts which the Congress is authorized to establish.")

[12] *Public Serv. Comm'n of Utah v. Wycoff*, 344 U.S. 237, 242 (1952).

[13] *See City of Boerne v. Flores*, 521 U.S. 507, 529-36 (1997).

[14] *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 571-78 (1992).

[15] *See, e.g.*, *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1471 (Fed. Cir. 1997).

controversy," the Constitution prohibits Congress from granting the courts jurisdiction. Accordingly, the courts would decline to hear such cases and section 701(c) would again be rendered ineffectual.

For these reasons, it is the view of the Administration that the Senate version of H.R. 1 should be amended to delete the language purporting to confer the federal courts with subject matter jurisdiction whenever a recipient of the required notice has not sued within the 45-day waiting period.

(For the Record)

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June 11, 2003

By Facsimile and Federal Express

The Honorable Judd Gregg, Chairman
Committee on Health, Education, Labor & Pensions
United States Senate
Washington, D.C. 20510

Re: Declaratory Judgment Actions in Connection with Generic Drug Manufacturers

Dear Senator Gregg:

I write to you on behalf of the Generic Pharmaceutical Association ("GPhA") concerning a proposed amendment to the Hatch-Waxman Act, the "Greater Access to Affordable Pharmaceuticals Act," introduced in the Senate, June 10, 2003. One provision in the proposed legislation explicitly recognizes that a generic drug manufacturer that has submitted an abbreviated new drug application ("ANDA") may seek a declaratory judgment in the federal courts that a patent held by a New Drug Application ("NDA") applicant and listed in the so-called "Orange Book" is invalid, unenforceable and/or not infringed by the drug that is the subject of the ANDA. Specifically, the provision would add to 35 U.S.C. §271(e) a new subparagraph 5:

> (5) Case or Controversy. — The filing of an application described in paragraph (2), which application includes a certification under section 505(b)(2)(A)(iv) or section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, and the failure of the owner of the patent to bring an action for infringement of a patent that is the subject of the certification before the expiration of 45 days from the date the notice provided under section 505(b)(3) or section 505(j)(2)(B) is received, shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States for any action brought by the applicant under section 2201 of title 28 for a declaratory judgment that any patent that is the subject of such certification is invalid, unenforceable, or not infringed.

Questions have been raised whether such recognition of subject matter jurisdiction in these circumstances presents constitutional questions. Specifically, the question has been raised whether the provision would declare the existence of an "actual controversy" whether or not the

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ANDA applicant faces a "reasonable apprehension" of facing a patent infringement action if the ANDA were approved and the drug covered by the ANDA brought to market. The suggestion is that this "reasonable apprehension" standard is a constitutionally mandated prerequisite for federal court jurisdiction over declaratory judgment actions brought by ANDA applicants.

My purpose in writing is to explain why these constitutional concerns are unfounded. Even if a "reasonable apprehension" of facing a patent infringement suit were a constitutional prerequisite for a declaratory judgment action — and, as explained below, I consider this a questionable assumption — the listing of a patent in the Orange Book is sufficient to create such a reasonable apprehension with respect to an ANDA applicant who has served the patentee with a section IV notification, even if the patentee, for unexplained tactical reasons, chooses not to sue within the 45 day period specified by Hatch-Waxman. A patent is listed in the Orange Book only if the patentee has affirmatively identified it as covering a drug (or a method of using a drug) "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner [of the patent] engaged in the manufacture, use or sale of the drug." 21 U.S.C. §355(b)(1). Such identification is, in my view, sufficient to give rise to a reasonable apprehension of suit on the part of a generic drug manufacturer that has filed an ANDA that it will face an infringement suit with respect to such a patent.

Indeed, the proposed legislation in many ways simply makes explicit the decision that Congress made when it enacted Hatch-Waxman. Congress determined that the submission of an ANDA constitutes an "act of infringement" that in itself creates a justiciable controversy as to whether the product described in the ANDA infringes a patent covering a drug or a method of using a drug, at least at the behest of the patentee. The goal was to allow that controversy to be litigated before the ANDA applicant brought the generic drug to market. Thus, the generic manufacturer could have the matter decided before going to market and facing potentially huge damages, and the branded company would not have its market position altered unless there were a previous determination of invalidity, noninfringement or unenforceability. The proposed legislation simply allows that controversy to be litigated promptly at the behest of the ANDA applicant as well. In my view, the proposed legislation would not violate Article III of the Constitution.

Of course, if the patentee in fact acknowledges that it has no valid claim with respect to the drug described in the ANDA application, then there may be no case or controversy sufficient to satisfy Article III of the Constitution. No statute can create subject matter jurisdiction under those circumstances and patentees should have little difficulty obtaining prompt dismissals under those circumstances. *See Eli Lilly & Co. v. Zenith Goldline Pharms. Inc.*, 54 USPQ2d 1556 (S.D. Ind. 2000); *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1004 (D.C.Cir. 1999). But where an actual, concrete dispute concerning validity or infringement exists and the question concerns timing and other practical concerns, there is a "case or controversy" for purposes of

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Article III and Congress has the power to include such a dispute within the subject matter jurisdiction of the federal courts.

I. BACKGROUND

In the context of patent law, the Declaratory Judgment Act (the "Act"), 28 U.S.C. § 2201, operates to prevent competitors from having to choose "between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises" by allowing competitors to sue for a declaratory judgment to resolve whether their contemplated enterprise infringes a valid patent. *Arrowhead Indus. Water, Inc. v. Ecolochem*, 846 F.2d 731, 734-35 (Fed. Cir. 1988). In this context, the Act prevents "a patent owner [from] engag[ing] in a *danse macabre*, brandishing a Damoclean threat with a sheathed sword." *Id.* (*citing Japan Gas Lighter Ass'n v. Ronson Corp.*, 257 F. Supp. 219, 237 (D.N.J. 1966)). "The sole requirement for jurisdiction under the Act is that the conflict be real and immediate, i.e., that there be a true, actual 'controversy' required by the Act." *Id.* at 735 (*citing Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-41 (1937)).

Under 35 U.S.C. § 271(d)-(h), the Hatch-Waxman Act, ("Hatch-Waxman") a pharmaceutical manufacturer may seek expedited approval from the Food and Drug Administration ("FDA") to market a generic version of an already approved drug. *See Bristol-Myers Squibb Co. v. Royce Laboratories, Inc.*, 69 F.3d 1130, 1131 (Fed. Cir. 1995). The Hatch-Waxman Act was introduced in two titles, with two primary purposes:

a) to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962; and
b) to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval.

(USCCAN, H.R. No. 98-857, Part I, reproduced at P.L. 98-417 (14-15 and 2647-8).)

The creation in 35 U.S.C. § 271(e)(2) of "an act of infringement" sufficient to permit patent litigation to go forward based upon the filing of an ANDA was intended to allow for the expeditious resolution of patent disputes before a generic manufacturer enters the market, at the behest of a NDA-holder/patentee. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-77 (1990). Under Hatch-Waxman, the ANDA applicant must give notice to the owner of any patent listed in the Orange Book that claims the drug (or the use of the drug) with respect to which the applicant seeks to sell a bioequivalent version. 21 U.S.C. §355(j)(2)(B). The patentee can delay approval of the ANDA by filing a patent litigation suit against the ANDA applicant within 45 days of receiving this notice, 21 U.S.C. §355(j)(5)(B)(iii), but the Act requires each party to "reasonably cooperate in expediting" a court decision on "the issues of patent validity and infringement." 21 U.S.C. § 355 (j)(5)(B)(iii)(III).

The Act precludes the ANDA applicant from commencing a declaratory judgment action during this 45 day period, *id.*, thus clearly suggesting the propriety of such a suit thereafter if the patent owner does not commence an infringement action. If the ANDA applicant is not sued during the 45 day period, but the threat of suit upon market entry has not been expressly waived or disavowed, the fundamental goal of Hatch-Waxman of allowing expeditious generic market entry is plainly served by allowing generic companies the same opportunity to obtain speedy resolution of any question concerning the effect of a listed patent as the patentee-NDA-holder. This goal is furthermore served without in any way undermining the second purpose of the patent act, namely to create research and development incentives for patentees.

II. DECLARATORY JUDGMENT REQUIREMENTS

The Declaratory Judgment Act states:

> In a case of **actual controversy** . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is sought.
>
> For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act.

28 U.S.C. § 2201(a)-(b) (2003) (emphasis added). The reference to an "actual controversy" reflects the requirement of Article III that a federal court has subject matter jurisdiction only over "cases and controversies." *See Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-40 (1937); *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991). The determination of whether a case or controversy is present is highly factual in nature. *See Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941).

However, in patent litigation, the Federal Circuit "has evolved a pragmatic two-part test for determining declaratory justiciability." *BP Chemicals Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993). Under this test, an "actual controversy" in a patent invalidity or non-infringement declaratory judgment action is present where there is (1) an explicit threat or action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit if it commences or continues the activity in question, and (2) the plaintiff must actually have either produced the patented product or prepared to produce the patented product. *See id.; GAF Bldg. Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 481 (Fed. Cir. 1996) ("We *normally* apply a two-part test to determine whether an 'actual controversy' exists in an action for declaratory judgment of patent invalidity or noninfringement.") (emphasis added); *Minnesota Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 790 (Fed. Cir. 2002) (Gajarsa, J., concurring) (hereinafter "*3M*, Gajarsa concurrence").

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I consider it very doubtful that this "pragmatic two-part test" is an essential aspect of Article III's "actual controversy" requirement. The Supreme Court has recognized that the Courts of Appeals "have significant authority to fashion rules to govern their own procedures," *Cardinal Chemical Co. v. Morton Int'l Inc.*, 508 U.S. 83, 99 (1993), and the "reasonable apprehension" standard is thus best seen as simply a prudential rule of decision, reflecting the fact that the inquiry into whether an "actual controversy" exists is highly fact-specific and looks to the totality of the circumstances. *Maryland Casualty Co. v. Pacific Coal & Oil*, 312 U.S. 270, 273 (1941). Because nothing in the proposed legislation purports to alter the "case or controversy" requirement of Article III, it carries no Article III implication. Congress is, after all, free to modify whatever prudential or pragmatic rules the Courts of Appeals may develop so long as it does not run afoul of the "case or controversy" requirement. *Aetna Life Ins. v. Haworth*, 300 U.S. 227, 240-241 (1937) (describing case or controversy requirement).

I find support for this view from the number of cases in which courts have found or presumed that a declaratory judgment at the behest of an ANDA applicant is a proper means to determine whether the applicant's proposed drug infinges a listed patent. *See, e.g. DuPont Merck Pharm. Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397 (Fed. Cir. 1995); *Zenith Labs. Inc. v. Bristol-Myers Squibb Co.*, 30 USPQ.2d 1285 (Fed. Cir. 1994); *Dr. Reddy's Labs., Ltd. v. Aalpharma Inc.*, 2002 U.S. Dist. LEXIS 17287 (S.D.N.Y. Sept. 19, 2002); *Geneva Pharms, Inc. v. GlaxoSmithKline PLC*, 189 F. Supp. 2d 377 (E.D. Va. 2002) (in an ANDA context, court must have found subject matter jurisdiction in order to rule on summary judgment in a declaratory judgment action); *Zenith Labs. Inc. v. Bristol-Myers Squibb Co.*, 30 USPQ.2d 1285, 1286-87 (Fed. Cir. 1994) (in an ANDA context, accepting district court's determination of subject matter jurisdiction in a declaratory judgment action without comment). As noted above, the relatively rare cases in which courts have declined to entertain declaratory judgment actions, the patentee affirmatively led the applicant to conclude that there was no actual concrete dispute to resolve. But where there is an actual, concrete dispute susceptible to judicial resolution as to whether a patent is invalid or not infringed, then there is a "case or controversy," whether or not the patentee has affirmatively taken steps to cause a "reasonable apprehension" of suit.

However, as explained below, even if the Federal Circuit's "pragmatic" test were constitutionally mandated, in my view the listing of a drug in the Orange Book and the filing of an ANDA containing a paragraph IV certification for a generic version of that drug gives rise to a situation that comfortably satisfies that test except in very rare circumstances. First, I outline the legal principles that have guided courts' application of this test. Then I will apply those principles to the circumstances addressed in the proposed bill.

A. Reasonable Apprehension

In order to establish the "reasonable apprehension" element of the Federal Circuit's pragmatic test, courts evaluate the following question: "did the acts of the defendant indicate an

intent to enforce its patent?" *DuPont Merck Pharm. Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397, 1401 (Fed. Cir. 1995). While an express charge or threat of infringement is not necessary to establish a case or controversy, the plaintiff must have a reasonable apprehension of a lawsuit. *See Goodyear Tire v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987). The Federal Circuit has also stated that it "cannot read the Declaratory Judgment Act so narrowly as to require that a party actually be confronted with an express threat of litigation to meet the requirements of an actual case or controversy." *Dr. Reddy's Labs., Ltd. v. Aalpharma Inc.*, 2002 U.S. Dist. LEXIS 17287, at *18 (S.D.N.Y. Sept. 19, 2002) (stating that the extensive litigation history between the two parties in connection with the manufacture of generic drugs provided additional support for plaintiff's reasonable apprehension) (*citing Goodyear Tire*, 824 F.2d at 959). "Conduct producing a reasonable apprehension that a patent lawsuit may be filed can be subtle." *Id.* (*citing EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811 (Fed. Cir. 1996)).

Also "[r]elevant to the issue of reasonable apprehension can be the fact that the parties are engaged in litigation at the time the perceived threat is made or the fact that the patent holder has stated an intent to enforce its patent rights." *Id.* (listing the significant legal history among the parties in connection with multiple generic drug litigations as a factor supporting a "reasonable apprehension" finding). Further, the defendant does not need to know every detail of the plaintiff's product or process or have a concrete infringement position in order for the plaintiff to have a reasonable apprehension of an infringement suit. *See id.* at *26-27 (stating that "[r]egardless of any statements made by [defendant] in its responsive pleadings . . . [plaintiff] was still in reasonable apprehension of an infringement suit by [defendant], given [defendant's] threats to the generic [drug] industry").

The "reasonable apprehension" prong of the "actual controversy" requirement may also be satisfied by a threat of litigation directed to an entire product industry and need not be directed to a specific competitor. *See DuPont Merck*, 62 F.3d at 1401 (finding that defendant's threat to bring patent infringement suits against generic drug manufacturers who attempt to market their products during the twenty-year period after the patent was first filed created a reasonable apprehension that plaintiff would face an infringement suit). Further, statements or threats directed to a specific competitor or to an entire industry can satisfy the reasonable apprehension requirement even if such statements or threats are made prior to issuance of the patent, provided the patent has issued at the time the declaratory judgment complaint is filed. *See Gaf Bld. Materials Corp. v. Elk Corp.*, 90 F.3d 479, 482 (Fed. Cir. 1996).

B. Production or Preparation of the Patented Product

In order to establish the second prong of the Federal Circuit's pragmatic test, a court must evaluate the following question: "did the plaintiff engage in an actual making, selling, or using activity subject to an infringement charge or make meaningful preparation for such activity?" *DuPont Merck*, 62 F.3d at 1401. The second prong is satisfied generally by the showing of

"present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Dr. Reddy's Labs.*, 2002 U.S. Dist. LEXIS 17287, at *28. In ANDA litigation, the "concrete steps" prong is satisfied by the filing of an ANDA and its associated research and development costs. *DuPont Merck*, 62 F.3d at 1401 ("concrete steps" prong satisfied by "money [spent] in preparation for the potentially infringing activity of submitting ANDAs"); *Dr. Reddy's Labs.*, 2002 U.S. Dist. LEXIS 17287, at *28-29; *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1008 (N.D. Ill. 2001) ("Defendant has filed and the FDA has accepted for filing the ANDA, which, as both parties recognize, means that defendant is ready or has at least made meaningful preparations to be ready to market the allegedly infringing product."); *Glaxo Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997) (finding an actual controversy where alleged future infringer was taking active steps to obtain FDA approval of its ANDA).

C. The Proposed Legislation Applies in Circumstances in Which an Actual Controversy Exists Under the Federal Circuit's Pragmatic Test.

1. Reasonable Apprehension

In the context of ANDA litigation, the "reasonable apprehension" prong of the "actual controversy" test can be met simply by the filing of an NDA and concomitant listing of a patent in the Orange Book. *See 3M*, Gajarsa concurrence, 289 F.3d at 791. The Federal Food, Drug, and Cosmetic Act ("FDCA") requires that an NDA applicant file "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which **a claim of patent infringement could reasonably be asserted** if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1) (emphasis added). Filing patent information as part of an NDA pursuant to this statute — which results in the patent's being listed in the Orange Book — requires the patentee to claim that an infringement suit could "reasonably be asserted" against one who "engages in the manufacture, use or sale of the drug." *See 3M*, Gajarsa concurrence, 289 F.3d at 791. This action on the part of an NDA applicant is "conduct giving rise to a reasonable apprehension of the plaintiff's part that it will face an infringement suit or the threat of one" that satisfies the first prong of the declaratory judgment requirements. *Id.* (*citing Cordis*, 835 F.2d at 862). Accordingly, the proposed express recognition that there is an "actual controversy" where the ANDA applicant sends a notice with respect to a patent listed in the Orange Book is consistent with a "reasonable apprension" requirement.

2. Production or Preparation of the Patented Product

The second prong of the Federal Circuit's pragmatic test can be satisfied by the filing of an ANDA. *See id.* 35 U.S.C. § 271 (e)(2)(A) defines the submission of an ANDA under the

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FDCA "for a drug claimed in a patent or the use of which is claimed in a patent" as an "act of infringement." *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (defining the submission of an ANDA as an "artificial act of infringement"). As an act of infringement, the filing of an ANDA "clearly meets the [second prong] as a 'present activity which could constitute infringement.'" *3M*, Gajarsa concurrence, 289 F.3d at 791.

The "concrete steps" prong of the declaratory judgment requirement is also satisfied by the expenditure of money and resources in preparation for filing an ANDA. *See Kos Pharms., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 318 (S.D.N.Y. 2003)(describing the preparation and filing of an ANDA as "concrete steps" and "meaningful preparation" for marketing a product).

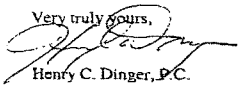
Accordingly, the proposed bill satisfies any "production or preparation" requirement of the actual controversy test.

IV. CONCLUSION

For the foregoing reasons, I consider the proposed amendment to Hatch-Waxman to be entirely consistent with Article III. In virtually every instance in which it would apply, there will be a controversy between the NDA filer and the ANDA applicant that is "definite and concrete, . . . real and substantial." *Aetna Life Ins.*, 300 U.S. at 241. If the NDA filer truly does not intend to assert a patent against an ANDA applicant, it can quickly moot any declaratory judgment action by stipulating to that effect. To the (doubtful) extent that the Federal Circuit two-part test is constitutionally mandated, the proposed legislation applies in circumstances that satisfy that test.

The proposed legislation also advances the goals of Hatch-Waxman. It completes the mechanism that the Act established to ensure that generic drugs quickly reach the market by permitting both the NDA filer and the ANDA applicant to trigger the resolution of any controversy as to whether the generic drug that the latter seeks to market in fact infringes a patent which could reasonably be asserted against it.

Very truly yours,



Henry C. Dinger, P.C.

STATEMENT OF

JON W. DUDAS

DEPUTY UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY
AND
DEPUTY DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

AUGUST 1, 2003

Chairman Hatch, Ranking Member Leahy, and Members of the Committee:

Thank you for this opportunity to share our thoughts today on patent-related provisions of pending legislation intended to promote access to affordable prescription drugs.

Mr. Chairman, as you know, the Administration has placed a high priority on ensuring that our senior citizens and other patients have access to essential prescription drugs at prices they can afford. The Administration has worked and continues to work with Congress to reach that goal.

The legislation before us today would, in part, make revisions to the almost 20-year old law that bears your name. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments, is a landmark statute that was achieved through a careful balancing of public and private interests. In order to stimulate innovation and provide for recovery of substantial research and development costs, brand name drug manufacturers are provided meaningful patent protection and a period of marketing exclusivity for their new drugs. In return, the public is assured that lower-priced generic equivalents are available on a timely basis after the expiration of the innovator's exclusive rights.

Although the passage of time has revealed the need for possible improvements in the statute, Hatch-Waxman has worked remarkably well over the years. As a result, any proposed revisions to Hatch-Waxman should be carefully considered in light of the potential effects on the delicate balance achieved almost 20 years ago. It is in this context that I offer the following observations regarding the Senate and House passed versions of "The Greater Access to Affordable Pharmaceuticals Act," as included in H.R. 1, the "Prescription Drug and Medicare Improvement Act of 2003."

Actual Controversy

The Senate version would amend section 271(e) of title 35 of the U.S. Code to establish an "actual controversy" between the generic and the patent owner if the patent owner failed to file an infringement action within the statutory window after the patent owner was notified of the generic's attempt to seek approval under a paragraph IV certification. As set forth in the bill, this would be sufficient to confer subject matter jurisdiction for a declaratory judgment action that any patent is invalid or not infringed.

This proposed amendment to establish an "actual controversy" for declaratory judgment subject matter purposes raises several significant concerns. First, the constitutionality of overriding the actual controversy requirement by legislating what constitutes an "actual controversy" sufficient to confer subject matter jurisdiction for a declaratory judgment action is questionable. I will defer further comment on this issue to my colleague from the Department of Justice.

Setting aside the constitutional concerns, the proposed amendment to establish an "actual controversy" for declaratory judgment subject matter purposes could undermine the patent system. In these cases the proposed amendment provides the generics with automatic grounds for a declaratory judgment action. This right to a declaratory judgment action could result in unnecessary harassment of patent owners. This is problematic for a number of reasons.

First, the patent owner would have to bear significant litigation costs, which ultimately may be passed on to the consumer in the form of higher drug prices. Second, a statutory entitlement to a declaratory judgment action may create patent uncertainty. By lowering the threshold for challenging a patent, the patent owner would be subject to extra litigation, which often places a "cloud" on the patent's validity. This uncertainty would make it more difficult and risky for patent owners to market, commercialize, and license their pharmaceutical innovations, thereby reducing access to valuable new medicines and therapies. Furthermore, in assessing any amendment to title 35, it is necessary to ensure that such amendment is consistent with our obligations under applicable international trade agreements.

Circumstances for Denying Treble Damages

The Senate version would also amend section 287 of title 35 to permit a court to refuse to award treble damages to a patentee who failed to list certain patents in the Orange Book. While the proposal is aimed at punishing the patentee for not listing necessary patents in the Orange Book, it appears to be a relatively harsh and unjustified penalty. Listing patents in the Orange Book triggers several benefits for the patent owner under the existing Hatch-Waxman regime, namely, patent certifications by generic applicants and the ability to obtain a 30-month stay. Penalties for failure to list patents in the Orange Book should be confined to a denial of such benefits.

Currently, the authority for punitive relief in patent cases is statutory. Whether damages are found by the jury or assessed by the judge, the court may increase the damages up to three times the amount found or assessed. The purpose of an increased damage award is to deter willful patent infringement by punishing the willful infringer. The failure of the patent owner to perform a ministerial task administered by another agency has absolutely nothing to do with whether the accused infringer acted in good faith. For these reasons, providing the court with discretion to deny treble damages for failure to list certain patents is unwise.

Conclusion

While we strongly support efforts to make modern health care affordable to all, we must make sure that those efforts do not jeopardize the benefits of medical innovation by adversely impacting the intellectual property rights of owners who have dedicated significant resources to researching, developing, and commercializing new therapies. Because there are no assurances that the proposed amendments discussed above will make prescription drugs more affordable, we caution against their adoption. We hope that any final amendment to Hatch-Waxman maintains the careful balance of public and private interests intended under the original Act.

We strongly support the initiative undertaken by the FDA to clarify the existing regulations regarding the types of patents that may and may not be listed in the Orange Book. The source of confusion centering around the term "drug" as used in the Hatch-Waxman Act has led to different interpretations as to whether patent owners should list new patents covering new variations, indications, or formulations of previously patented drugs.

Thank you.

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June 20, 2003

The Honorable Judd Gregg
Chairman, Committee on Health, Education, Labor, and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510-6300

The Honorable Orrin G. Hatch
Chairman, Committee on the Judiciary
United States Senate
224 Dirksen Senate Office Building
Washington, DC 20510-6300

Dear Chairmen Gregg and Hatch:

On June 6 of this year, I wrote to Chairman Gregg to express concern about certain provisions of what is now the "Greater Access to Affordable Pharmaceuticals Act," 149 Cong. Rec. S8249-8252 (June 19, 2003). My concern was that the provisions are likely to run afoul of Article III of the Constitution, which defines the subject matter jurisdiction of the federal courts.

I have since reviewed a letter, dated June 14, from Professor John Yoo to Chairman Hatch, which suggests that the provisions would not violate Article III. Although I have considerable respect for Professor Yoo's abilities as a scholar and legal expert, I am not persuaded by his analysis in this case.

The attached memorandum lays out the reasons why Professor Yoo's analysis does not alleviate my concerns about the proposed legislation. Attached also are copies of my letter of June 6 and of the memorandum that accompanied that letter.

Please contact me at your convenience if you wish to discuss the conclusions in the memoranda with me.

Yours sincerely,

Boyden Gray/ek

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June 20, 2003

MEMORANDUM TO THE SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE AND THE SENATE JUDICIARY COMMITTEE

On June 6, 2003, we submitted a memorandum to the Senate Health, Education, Labor, and Pensions Committee analyzing several provisions of what is now the "Greater Access to Affordable Pharmaceuticals Act," 149 Cong. Rec. S8249-8252 (daily ed. June 19, 2003) (the "Bill").[1] The Bill purports to expand the subject matter jurisdiction of the federal courts by authorizing certain suits for declaratory relief. In particular, the Bill defines the *absence* of an infringement suit by the holder of a pharmaceutical patent against the filer of an abbreviated new drug application ("ANDA") as an "actual controversy" that is "sufficient to confer subject matter jurisdiction in the courts of the United States."[2] The intended practical effect of the Bill is to permit ANDA filers to bring declaratory judgment actions against pharmaceutical patent holders even when the filers lack any "reasonable apprehension" that they will be sued for infringement — even though the Federal Circuit and at least nine other U.S. Courts of Appeals require such a "reasonable apprehension" as a prerequisite for bringing suits of this kind today. We concluded that the Bill is likely to run afoul of Article III of the Constitution, which limits the jurisdiction of the federal courts to an enumerated list of "Cases" and "Controversies" that Congress may not expand. *See* U.S. Const. art. III, § 2 (listing types of "Cases" and "Controversies"); *Verlinden B.V. v. Central Bank of Nigeria*, 461 U.S. 480, 491 (1983) ("Congress may not expand the jurisdiction of the federal courts beyond the bounds established by the Constitution.").

We have since reviewed a letter, dated June 14, from Professor John Yoo to Chairman Orrin G. Hatch of the Senate Judiciary Committee (the "Yoo Letter").[3] Opining that the Bill would not

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[1] Our June 6 memorandum analyzed provisions from a discussion draft. Despite some subsequent changes, these provisions appear to be essentially identical to the corresponding provisions of the Bill, which the Senate added as an amendment to S. 1 on June 19. 149 Cong. Rec. S8200-01, S8249 (daily ed. June 19, 2003). In this memorandum, we do not analyze any of the subsequent changes to the provisions.

[2] 149 Cong. Rec. S8250 (daily ed. June 19, 2003). The specific provision that contains this language would amend 35 U.S.C. § 271(e) by adding paragraph (e)(5).

[3] The Yoo Letter was submitted to the Senate Judiciary Committee on June 17 along with testimony by Kathleen D. Jaeger of the Generic Pharmaceutical Association. The Yoo Letter begins on page 7 of Ms. Jaeger's written testimony.

violate Article III, Professor Yoo's letter asserts that the Bill is "simply a restatement of the proper interpretation of current law."[4]

We respectfully disagree. Professor Yoo's letter spends much effort reasoning from first principles to describe how he believes Article III *should* apply in the context of patent declaratory judgment actions. However, he does not accurately describe what the courts have held Article III and the Declaratory Judgment Act actually do require in these cases. The letter gives no indication that there is a decades-old virtual consensus in the United States Courts of Appeals that, in the absence of a potential patent infringer's "reasonable apprehension" that he or she will be sued, there is no actual case or controversy that can support an action for a declaratory judgment. The U.S. Court of Appeals for the Federal Circuit — the court that has exclusive jurisdiction to hear patent appeals nationwide,[5] and the court that would decide almost every appeal from the new declaratory judgment actions created by the Bill — has consistently so held since its creation since 1982.[6] Professor Yoo attempts to marginalize the "reasonable apprehension" test by implying that it is the creation of the Federal Circuit alone.[7] But over the last three decades, *at least nine other Courts of Appeals* have applied the same test in intellectual property cases, including patent cases.[8] To our knowledge, no Court of Appeals has rejected this

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[4] Yoo Letter at 11. *See* Yoo Letter at 8 (proposed legislation "merely clarifies the proper application of existing law").

[5] 28 U.S.C. §§ 1292(c), 1295(a). *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996) ("Congress created the Court of Appeals for the Federal Circuit as an exclusive appellate court for patent cases"); 15A Charles Alan Wright et al., Federal Practice and Procedure § 3903.1 (2d ed. 1992) (most patent appeals now go to Federal Circuit, although "the regional circuits retain jurisdiction of appeals in a few cases presenting patent issues").

[6] *See* Memorandum at 2 & n.2; *see also, e.g., C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 879-82 (Fed. Cir. 1983).

[7] *See* Yoo Letter at 11 (adverting to Federal Circuit case law and to "two-part test" "developed" by Federal Circuit); *id.* at 12 (adverting to "Federal Circuit's two-prong test" and "Federal Circuit's approach").

[8] *See, e.g., Sweetheart Plastics, Inc. v. Illinois Tool Works, Inc.*, 439 F.2d 871, 874 (1st Cir. 1971); *Starter Corp. v. Converse, Inc.*, 84 F.3d 592, 595 (2d Cir. 1996); *Interdynamics, Inc. v. Firma Wolf*, 698 F.2d 157, 166-67 (3d Cir. 1982); *State of Texas v. West Publ'g Co.*, 882 F.2d 171, 175 (5th Cir. 1989); *Trippe Mfg. Co. v. Am. Power Conversion Corp.*, 46 F.3d 624, 626-27 (7th Cir. 1995); *Sherwood Med. Indus., Inc. v. Deknatel, Inc.*, 512 F.2d 724, 727 (8th Cir. 1975); *Hal Roach Studios, Inc. v. Richard Feiner and Co.*, 896 F.2d 1542, 1555-56 (9th Cir. 1990); *Societe de Conditionnement en Aluminium v. Hunter Eng'g Co.*, 655 F.2d 938, 944 (9th Cir. 1981); *Cardtoons, L.C. v. Major League Players Baseball Ass'n*, 95 F.3d 959, 965-66 (10th Cir. 1996); *United Christian Scientists v. Christian Science Bd. of Dirs., First Church of Christ, Scientist*, 829 F.2d 1152, 1158 n.25 (D.C. Cir. 1987). The circuit courts have also applied the "reasonable apprehension" test to other kinds of declaratory judgment actions. *See Atlas Air, Inc. v. Air Line Pilots Ass'n*, 232 F.3d 218, 227 (D.C. Cir. 2000) (applying reasonable apprehension test to declaratory judgment action presenting labor law issues); *Federal Express*

test. Although Professor Yoo's letter is correct that "the Supreme Court has never passed on the . . . 'reasonable apprehension' test,"[9] it is hardly the case that the test represents some transient doctrinal aberration. There is no reason to assume, as the letter appears to do,[10] that the Supreme Court would lightly uproot three decades' worth of virtual unanimity among the U.S. Courts of Appeals.

Nor is there any basis for Professor Yoo's suggestion that the "reasonable apprehension of suit" test is simply a prudential "exercise of [the court's] discretionary powers under the Declaratory Judgment Act, rather than as a true test of Article III justiciability."[11] Professor Yoo cites no case law at all to support this suggestion. Indeed, the U.S. Courts of Appeals have held just the opposite.[12] As our original memorandum explained (at pp. 1-2 & nn.1-2), the requirement of an "actual controversy" in the text of the Declaratory Judgment Act is mandated directly by Article

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Corp. v. Air Line Pilots Ass'n, 67 F.3d 961, 964 (D.C. Cir. 1995) (same); *Spokane Indian Tribe v. United States*, 972 F.2d 1090, 1092 (9th Cir. 1992) (applying test to action arising under Indian Gaming Regulatory Act); *GTE Directories Publ'g Corp. v. Trimen Am., Inc.*, 67 F.3d 1563, 1569 (11th Cir. 1995) (applying test to action presenting state law issues).

9 Yoo Letter at 12.

10 *See id.* at 13 (encouraging Congress to pass legislation at odds with circuit court precedent "in order to spark Supreme Court review of whether these courts have properly interpreted Article III of the Constitution").

11 *Id.* at 12.

12 *See, e.g.*, *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1471 (Fed. Cir. 1997) (standard incorporating reasonable apprehension requirement "respects the constitutional requirement of an actual controversy"); *Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha*, 57 F.3d 1051, 1053 (Fed. Cir. 1995) ("The purpose of the declaratory action is to permit a threatened party to resolve its potential liability, but only when the relationship has progressed to an actual controversy, as required by Article III of the Constitution. . . . [T]o create an actual controversy there must be more than ongoing license negotiations. There must be action by the patent holder sufficient to create an objectively reasonable apprehension that suit will be brought against the declaratory plaintiff."); *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978, 981 (Fed. Cir. 1993) (reasonable apprehension required to establish "actual controversy," which is a "constitutional requirement"); *Interdynamics, Inc.*, 698 F.2d at 166 (reasonable apprehension is "prerequisite[] to establishment of an actual controversy," which "is identical to the constitutional requirement of 'cases' and 'controversies'") (internal quotation marks omitted); *Hunter Eng'g Co.*, 655 F.2d at 944 ("An action for a declaratory judgment that a patent is invalid, or that the plaintiff is not infringing, is *a case or controversy* if the plaintiff has a real and reasonable apprehension that he will be subject to liability if he continues to manufacture his product.") (emphasis added); *Int'l Harvester Co. v. Deere & Co.*, 623 F.2d 1207, 1210 (7th Cir. 1980) (reasonable apprehension is "prerequisite[] to establishment of an actual controversy," which is "a jurisdictional prerequisite of constitutional dimension") (internal quotation marks omitted); *Trippe Mfg. Co.*, 46 F.3d at 627 (same).

III of the Constitution itself, because Congress has no power to authorize the federal courts to hear matters that do not comprise actual "Cases" or "Controversies" within the meaning of Article III.[13] The "reasonable apprehension" test reflects the understanding of at least ten U.S. Courts of Appeals as to what constitutes an actual controversy in the specific context of a declaratory judgment action concerning patents and other intellectual property. The test thus represents these courts' articulation of what Article III itself requires in these cases.

The cases that Professor Yoo does cite do not sustain any argument for ignoring the reasonable apprehension requirement. Most of these cases stand for uncontroversial propositions: that an actual case or controversy is necessary to sustain Article III jurisdiction over a declaratory judgment action, or that a reasonable apprehension of suit by a patentee, but not actual litigation by a patentee, is a prerequisite to suit by a potential infringer for a declaration of non-infringement. And some of Professor Yoo's cases actually undermine the proposed legislation. *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227 (1937), *quoted in* Yoo Letter at 9-10, illustrates the basic proposition that the mere absence of a dispute between parties cannot constitute a case or controversy for Article III purposes. Rather, a live dispute between actual parties who have "taken adverse positions" is a precondition to an Article III case or controversy.[14] And *EMC Corp. v. Norand Corp.*, 89 F.3d 807 (Fed. Cir. 1996), *quoted in* Yoo Letter at 11, puts the point even more starkly: "[a] certain minimum degree of adverseness must be present in order to establish the requisite controversy. Thus, *more is required than the existence of an adversely held patent.*"[15]

Unlike the holdings of these constitutional decisions, the Bill would authorize declaratory relief in a wide range of cases in which no live dispute exists. The Bill would do so by providing that

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[13] *See Textron Lycoming Reciprocating Engine Div., Avco Corp. v. United Auto., Aerospace, Agric. Implement Workers of Am., Int'l Union*, 523 U.S. 653, 661 (1998) (Declaratory Judgment Act, "in its limitation to 'cases of actual controversy,' manifestly has regard to the constitutional provision [Art. III, § 2] and is operative only in respect to controversies which are such in the constitutional sense") (brackets in original; internal quotation marks omitted). Professor Yoo concedes this point. *See* Yoo Letter at 12 (describing the "actual controversy" limitation as "required by both the statute and the Constitution").

[14] In *Haworth*, the Court held that there was a justiciable controversy in the constitutional sense because, among other things, "the parties had taken adverse positions with respect to their existing obligations." 300 U.S. at 242. The Court concluded that the parties' dispute was "manifestly susceptible of judicial determination. It calls, not for an advisory opinion upon a hypothetical basis, but for an adjudication of present right upon established facts." *Id.* at 242.

[15] *EMC Corp.*, 89 F.3d at 811 (emphasis added; internal quotation marks omitted). *See id.* (test that includes reasonable apprehension requirement is "designed to police the sometimes subtle line between cases in which the parties have adverse interests and cases in which those adverse interests have ripened into a dispute that may properly be deemed a controversy"). *See also E. Edelmann & Co. v. Triple-A Specialty Co.*, 88 F.2d 852, 853 (7th Cir. 1937) (actual controversy existed where declaratory defendant, charging that plaintiff was infringing defendant's patents, threatened suit against plaintiff and others), *cited in* Yoo Letter at 10.

the absence of a lawsuit would "establish an actual controversy." In many cases where patent owners have failed to bring suit, the parties have *not* "taken adverse positions." Yet the Bill purports to *create* an actual controversy out of a nonentity -- the absence of a lawsuit -- by making the absence of a suit the *sufficient precondition* of an actual controversy. (See pp. 2-3 of our original memorandum.) Professor Yoo does not explain how such a provision could possibly be consistent with the limits on federal court jurisdiction established by Article III.

Instead, Professor Yoo's letter repeatedly defines the relevant legal question backwards, asking whether "the absence of a suit during the 45-day period is sufficient *per se* to destroy an actual controversy in a declaratory judgment act [*sic*] by a generic drug manufacturer." Yoo Letter at 13. That is a straw man: the very purpose of the "reasonable apprehension of suit" test is to identify actual Article III cases and controversies in circumstances where no litigation has been brought. Many declaratory judgment actions brought "in the absence of a suit" *do* meet that test under current law. For this reason, the only possible practical effect the Bill could have would be to expand the jurisdiction of the federal courts to hear declaratory judgment actions that *would not* pass the "reasonable apprehension" test. It follows that the relevant constitutional question is whether this attempt to expand federal court jurisdiction violates the actual case or controversy requirement of Article III – *not* whether an actual controversy is "destroyed" by the mere absence of suit.

Professor Yoo's letter ultimately falls back on the suggestion that Congress should simply "reject" the consistent holdings of the U.S. Courts of Appeals and try to goad the Supreme Court into a "review of whether these courts have properly interpreted Article III of the Constitution."[16] But there is no reason to expect the Supreme Court to uproot three decades' worth of consistent Court of Appeals decisions – especially when there does not seem to be any split between the circuits of the kind that could warrant Supreme Court review. Given their clear conflict with prevailing law, to adopt the declaratory judgment provisions of the Bill as they stand would be to provide no remedy at all.

Please contact us at your convenience if you wish to discuss these matters further.

C. Boyden Gray
Jonathan J. Frankel
Andrew R. Varcoe

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16 Yoo Letter at 13.

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June 6, 2003

The Honorable Judd Gregg
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510-6300

Dear Chairman Gregg:

I am writing to express concern about certain provisions of a discussion draft, dated June 4, 2003, of a bill entitled the "Greater Access to Affordable Pharmaceuticals Act." In particular, I am writing about provisions of the draft bill that purport to authorize certain suits for declaratory relief, and to expand the subject matter jurisdiction of federal courts, in patent cases. In their present form, these provisions are likely to run afoul of Article III of the Constitution, which limits federal courts' subject matter jurisdiction to "Cases" and "Controversies."

The attached memorandum provides a brief analysis of the specific provisions about which I am concerned. Please contact me at your convenience if you wish to discuss the conclusions in the memorandum with me.

Sincerely,

Boyden Gray /ak

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June 6, 2003

MEMORANDUM TO THE SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE

This Memorandum analyzes provisions of the "Greater Access to Affordable Pharmaceuticals Act" (discussion draft, dated June 4, 2003) (the "Bill") that purport to expand the subject matter jurisdiction of federal courts by authorizing certain suits for declaratory relief. In their present form, these provisions are likely to run afoul of Article III of the Constitution, which defines and limits the subject matter jurisdiction of federal courts.

Under Article III, § 2, of the Constitution, the federal courts have jurisdiction over a dispute "only if it is a 'case' or 'controversy'" within the meaning of the Article. *Raines v. Byrd*, 521 U.S. 811, 818 (1997). "This is a bedrock requirement. . . . No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *Id.* (citations and internal quotation marks omitted). Because this is a constitutional limitation, Congress may not give the federal courts subject matter jurisdiction over matters that do not qualify as actual "cases" or "controversies" within the meaning of Article III. *See Fed. Election Comm'n v. Akins*, 524 U.S. 11, 20 (1998) ("Article III, of course, *limits* Congress' grant of judicial power to 'cases' or 'controversies.'") (emphasis added).

The case-or-controversy requirement of Article III applies to declaratory judgment actions, which are governed by the Declaratory Judgment Act, 28 U.S.C. § 2201. *See Altvater v. Freeman*, 319 U.S. 359, 363 (1943) ("The requirements of case or controversy are of course no less strict under the Declaratory Judgment Act than in case of other suits.") (citations omitted). The Declaratory Judgment Act expressly recognizes the constitutional requirement by authorizing courts to issue declaratory judgments only in cases "of actual controversy," but the limitation runs deeper than the statutory text; it is "imposed by Art. III of the Constitution" itself and not merely by congressional dictate. *Steffel v. Thompson*, 415 U.S. 452, 458 (1974).[1]

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[1] *See Textron Lycoming Reciprocating Engine Div., Avco Corp. v. United Auto., Aerospace, Agric. Implement Workers of Am., Int'l Union*, 523 U.S. 653, 661 (1998) (Declaratory Judgment Act, "in its limitation to 'cases of actual controversy,' manifestly has regard to the constitutional provision [Art. III, § 2] and is operative only in respect to controversies which are such in the constitutional sense") (brackets in original; internal quotation marks omitted); *Lawson v. Callahan*, 111 F.3d 403, 405 (5th Cir. 1997) ("actual controversy" requirement of Act is "identical" to case-or-controversy requirement of Article III); *GAF Bldg.*

Because the requirement of an "actual controversy" is mandated by the Constitution itself, Congress cannot expand federal court jurisdiction simply by amending the "actual controversy" language in the Declaratory Judgment Act. If Congress passed a law purporting to authorize declaratory judgment actions in a case that presented no actual "controversy" within the meaning of Article III, the law would be invalid, and a federal court would lack jurisdiction to hear the case.

The constitutional requirement of an actual controversy applies to declaratory judgment actions filed in patent cases no less than to other declaratory judgment actions. In patent cases, Article III requires a plaintiff to at least have a "reasonable apprehension" that the patentee is likely to sue him for infringement of the patent. *See, e.g., Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1471 (Fed. Cir. 1997). "An action for a declaratory judgment that a patent is invalid, or that the plaintiff is not infringing, is *a case or controversy* if the plaintiff has a real and reasonable apprehension that he will be subject to liability if he continues to manufacture his product." *Societe de Conditionnement en Aluminium v. Hunter Eng'g Co.*, 655 F.2d 938, 944 (9th Cir. 1981) (emphasis added).[2]

Because the case-or-controversy requirement in patent declaratory judgment cases is dictated by the Constitution itself, Congress cannot override this requirement by purporting to confer subject matter jurisdiction to hear declaratory judgment actions in cases where the plaintiff has no reasonable apprehension that the patentee is likely to sue. But the Bill does exactly this. Indeed, the Bill takes the *absence* of a live case or controversy and *defines* it as an "actual controversy" under the Declaratory Judgment Act. The Bill authorizes a declaratory judgment suit by a new drug applicant in a case where a patent owner has *failed* to sue the applicant for patent infringement within 45 days of receiving notice of the applicant's new drug application.[3] The

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Materials Corp. v. Elk Corp. of Dallas, 90 F.3d 479, 481 (Fed. Cir. 1996); *Societe de Conditionnement en Aluminium v. Hunter Eng'g Co.*, 655 F.2d 938, 942 (9th Cir. 1981); 10B Charles Alan Wright et al., Federal Practice and Procedure § 2757 (3d ed. 1998) ("the requirement of an actual justiciable controversy [in § 2201] is necessary to satisfy the constitutional limitations on the judicial power").

[2] *See, e.g., GAF Bldg. Materials Corp.*, 90 F.3d at 481; *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991); *G. Heileman Brewing Co. v. Anheuser-Busch, Inc.*, 873 F.2d 985, 990 (7th Cir. 1989); *Windsurfing Int'l Inc. v. AMF Inc.*, 828 F.2d 755, 757 (Fed. Cir. 1987); 10B Charles Alan Wright et al., Federal Practice and Procedure § 2761 (3d ed. 1998).

[3] Two provisions of the Bill purport to authorize suit in these circumstances. The first of these two provisions appears in section 2(a)(2)(C) of the Bill, at page 4, line 18, through page 5, line 10. This provision would amend section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 355, by adding a new provision, section 355(j)(5)(C)(iii), that would be part of a new subparagraph, subparagraph (j)(5)(C). The second provision appears in section 2(b)(2)(C) of the Bill, at page 9, lines 4-19. This provision would also amend 21 U.S.C. § 355 by adding section 355(c)(4)(C), which would be part of a new paragraph, paragraph (c)(4). The second provision appears to contain a drafting error; it refers to a subparagraph (2)(B) even though section 355(c) contains no such subparagraph, both in its current form and in the form proposed by the Bill.

Bill goes on to provide that the patent owner's *failure* to sue in such circumstances "shall establish an actual controversy . . . sufficient to confer subject matter jurisdiction" in federal courts over a declaratory judgment action.[4] The obvious constitutional problem with these provisions is this: in the absence of a live, actual controversy, a federal court simply cannot exercise jurisdiction over a case, *even if* Congress purports to define the absence of such a controversy as an "actual controversy." "Congress may not expand the jurisdiction of the federal courts beyond the bounds established by the Constitution." *Verlinden B.V. v. Central Bank of Nigeria*, 461 U.S. 480, 491 (1983).

This is obviously a brief analysis, but we believe that it identifies a major defect of the proposed legislation that would, at the very least, result in counterproductive litigation. Please contact us at your convenience if you wish to discuss these conclusions further.

C. Boyden Gray
Jonathan J. Frankel
Andrew R. Varcoe

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[4] This provision appears in section 2(c) of the Bill, at page 10, line 23, through page 11, line 17. This provision would amend 35 U.S.C. § 271 by adding section 271(e)(5).

News Release

JUDICIARY COMMITTEE

United States Senate • Senator Orrin Hatch, Chairman

August 1, 2003

Contact: Margarita Tapia, 202/224-5225

Statement of Chairman Orrin G. Hatch
before the United States Senate Committee on the Judiciary
Hearing on

"EXAMINING THE SENATE AND HOUSE VERSIONS OF THE 'GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT'"

Good Morning. Today, we will explore important features of the Senate and House versions of the "Greater Access to Affordable Pharmaceuticals " legislation. In the Senate, this was the Gregg-Schumer Amendment to the Medicare bill, S. 1.

I seem to recall that this measure was adopted by the Senate by an overwhelming 94 to 1 vote. There is always somebody who does not get the message!

Similar, but not identical legislation was included in the House Medicare Bill, H. 1.

A chief purpose of this hearing today is to help the Medicare conferees and others evaluate the relative merits of the Senate and House provisions.

I want to commend my colleagues, Senators Gregg, Schumer, McCain, and Kennedy for all of their work on this legislation. I believe that this legislation represents a major improvement over last year's vehicle, S. 812.

I am pleased that the sponsors of this legislation have now adopted a version of the 30-month stay provision that I first suggested last May, and argued for on the floor last July. The one-and-only-one 30-month stay for all patents filed when the NDA is submitted was also a centerpiece of the Federal Trade Commission report released last summer. The proponents of this legislation were wise to reject all of the various previous legislative proposals in this area.

I want to commend again Chairman Muris and the FTC for the agency's constructive contribution to this important debate.

In addition to a recommendation pertaining to the 30-month stay, the FTC Report contained a second recommendation calling for the reporting of any potentially anticompetitive agreement between pioneer and generic drug firms to the FTC and the Department of Justice.

My colleague, Senator Leahy, developed just such legislation, the *Drug Competition Act,* that was included in the Senate Medicare bill. I have worked with Senator Leahy in developing this bill and support it.

Today, I want to spend some time examining some key differences between the Senate and House versions of the bill. For example, there are some differences between the House and Senate versions of the Leahy language that must be ironed out.

One of the most significant differences between the Senate and House bills centers on the manner in which the declaratory judgment provisions are drafted. These provisions were the subject of a spirited written debate between two esteemed lawyers - both of whom are friends of mine – Boyden Gray, former White House Counsel and John Yoo, a former member of my staff.

Today we will hear testimony from the Department of Justice that the Administration has concluded that the Senate declaratory judgment provision is constitutionally infirm.

Moreover, the Patent and Trademark Office will tell us that the Senate language "could result in unnecessary harassment of patent owners." In addition, PTO believes that the manner in which the Senate bill treats the award of treble damages is unwise.

On the other hand, we will hear from the FTC that it believes a key feature of the House declaratory judgment provision, the right to confidential access, may not be necessary and, as a matter of policy, the Senate declaratory judgment provision may have some advantages.

Consistent with its 2002 Report, the FTC takes exception with the manner in which both the Senate and House language eliminate the current *district court decision* triggering mechanism for 180-day marketing exclusivity.

We will also hear from the FDA about how the provisions of these bills would interact with the agency's recently issued final rule on patent listing. The FDA disagrees with the FTC on the matter of the court trigger and supports an appellate court triggering scheme.

It is my hope that after we have heard from our panel of government experts the conferees and other interested parties will gain knowledge about the strengths and weaknesses of the House and Senate bills'. Our goal should be to forge a conference report that preserves the best features of these measures or results in the crafting of better language.

Finally, we will also hear today from a private sector expert who will talk about the ramifications of an identical section of the Senate and House bills. These are the provisions related to the award of 180-day marketing exclusivity where pioneer patents are found to be invalid or not infringed by generic competitors.

Both bills adopt a *first-to-file* regime. I am a proponent of what I will call a *successful*

challenger system. It seems to me that the first successful challenger – be it the first generic not to be sued, the first to win in court, or the first to be granted a covenant not to be sued by the pioneer firm – is more deserving than a mere first filer. As I explained in my June 26th *Congressional Record* statement, it appears to me that the 180-day marketing exclusivity provisions in the pending legislation contain perverse incentives that may result in unfortunate, if unintended, consequences.

I plan to ask the Congressional Budget Office to review the provisions of the 180-day marketing exclusivity provisions and consider whether these new rules may actually prove costly to consumers. It is possible a consensus will emerge to revisit this issue. Frankly, it seems to me that simply adding a new forfeiture event, in cases where a challenger is not sued, succeeds in court, or obtains a covenant not to be sued, could materially improve the legislation.

It is also possible that the Medicare conference will not be the best time or place to reconsider these issues. I can accept that. But I also believe that we have not heard the last word on these new 180-day rules.

Let me close by stating that it is my hope the Congress will enact a Medicare drug benefit this year. I plan to work in a constructive fashion toward the success of this legislation. In that spirit, I hope that today's hearing will help inform the discussion of reconciling the House and Senate versions of the important provisions addressing generic drug competition.

I look forward to hearing from our witnesses today.

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United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510-6275

August 1, 2003

Mr. Douglas Holtz-Eakin
Director
Congressional Budget Office
Washington, D.C. 20515

Dear Mr. Holtz-Eakin:

This letter is to request your prompt evaluation of the potential effects of section 703 of S. 1, the "Prescription Drug and Medicare Improvement Act of 2003, that has recently come to my attention.

Section 703 creates new procedures for the application of "180-day marketing exclusivity" for certain generic products for generic manufacturers who are the first to file a "Paragraph IV" challenge to the patents of their particular branded counterparts. Rather than beginning on the date of a court decision, if Section 703 passes as currently drafted, it appears the exclusivity period will begin in many cases on the date of first commercial marketing of such a generic competitor. Subject to the specified forfeiture provisions, it appears the 180-day period would typically begin later than under current law, allowing more generic companies to take advantage of it. Under current law, in many cases the exclusivity period expires before the expiration date of the patent(s) on the active ingredient or approved uses of the product. It is these patents that typically prevent generic competition before they expire.

It is very possible that enactment of this new policy would create an increased incentive for generic companies to file Paragraph IV challenges to all manufacturer patents as soon as permissible under the statute, since they will no longer have to be as concerned about premature expiration of the exclusivity period. Moreover, the number of products where full generic competition may be delayed because of 180-day exclusivity periods appear likely to increase, since effective exclusivity grants would no longer be limited to the rare cases where an active ingredient patent (or approved use patent) was found to be invalid or not infringed. This could have significant budgetary effects, since generic manufacturers with market exclusivity commonly price the generic product close to the price of their branded counterpart. By contrast, within six months of the onset of competition from multiple generic companies, generic prices could be as low as 30-40 percent of the branded price, or lower.

In the CBO cost estimate of S. 1, you made specific note of the change in exclusivity policy, but did not make clear whether your scoring of Section 703 took into account the potential effects just described. Since you provided a single line item score for all of the

intellectual property provisions taken together, it is impossible to know whether, and to what extent, you considered any effects of potentially markedly increasing the frequency of generic exclusivity periods for products which, under current law, would experience multi-company generic competition upon expiration of the patent on their active ingredients or approved uses.

I ask CBO to provide its assessment of how the changes in the 180-day marketing exclusivity policy would likely affect the frequency and monetary value of marketing exclusivity awards. Please describe how your scoring takes this policy change into account and provide me with a specific breakdown of the cost effects of the marketing exclusivity provisions. If you not have undertaken this analysis, I would greatly appreciate you doing so in an expeditious manner and providing me with any adjustments to the CBO cost estimate.

As you know, the conference of S. 1 and H.R. 1 will be continuing throughout this month. I would appreciate an answer to these questions as soon as possible.

Thank you very much for your prompt attention to this important issue.

Sincerely,

Orrin G. Hatch
Chairman

Generic Pharmaceutical Association

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July 31, 2003

The Honorable Orrin G. Hatch
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20515

Dear Senator Hatch:

As House and Senate conferees continue work on a comprehensive Medicare reform bill, the Generic Pharmaceutical Association ("GPhA") would like to share its views on the Hatch-Waxman reform provisions attached to S. 1, the Prescription Drug and Medicare Improvement Act of 2003, and H.R. 1, the Medicare Prescription Drug and Modernization Act of 2003. We would like to applaud the Congress for taking swift action on an issue that will encourage timely competition in the pharmaceutical marketplace and increase consumer access to affordable pharmaceuticals.

As you are aware, GPhA has been working for years to secure passage of legislation to close some of the unintended loopholes in the 1984 Hatch-Waxman Act and to further the important goals of that law. In the nearly two decades since its enactment into law, the Hatch-Waxman Act has substantially increased competition in the market for prescription drugs and has saved the American consumer and the federal government billions of dollars.

This carefully crafted legislation was intended to strike a balance between ensuring timely generic competition to increase access to lower-cost medicines and encouraging continued investment in research and development by the brand industry. More specifically, two aspects of the Hatch-Waxman Act have been essential for early market entry of lower-priced generic alternatives.

First, in exchange for certain patent extensions and other exclusivities, the Hatch-Waxman Act simplified the requirements for the approval of generic drugs. It established a framework under which a generic drug company can seek approval of its product and obtain the necessary FDA approvals *prior to* the expiration of valid brand company patents. In this way, generic manufacturers could be in a position to market their products as soon as they had received approval from FDA, where applicable patents had expired.

Second, Congress recognized that high drug prices could only be lowered with increased competition, which, in turn, would happen only if companies sought to market products prior to patent expiration. At the same time, Congress recognized that mounting the first patent challenge is an extremely expensive and risky proposition. Thus, a critical part of the balance struck in the Hatch-Waxman Act is the 180-day generic exclusivity period, which was created to encourage generic drug manufacturers to expend the significant resources necessary to initiate patent challenges on questionable drug patents blocking generic market entry.

By all accounts, the law has worked reasonably well up to the last several years. But more recently, as President Bush noted in an October 2002 speech in the Rose Garden, "[s]ome brand name drug manufacturers may have manipulated the law to delay the approval of competing generic drugs." These maneuvers were not contemplated twenty years ago, and we agree with the President that "the careful balance of the law is being undermined."

GPhA strongly believes the Hatch-Waxman reform provisions contained in S.1 would remove some of the most serious market barriers to generic competition and provide relief to Americans struggling with skyrocketing prescription drug costs, while preserving incentives for medical innovation. The language in S.1 represents a bipartisan compromise reached after both sides made important concessions to arrive at a proposal that will benefit American consumers, and must not be weakened or diluted. The compromise must be protected to ensure that this measure successfully achieves the President's stated objective "to close the loopholes, to promote fair competition and to reduce the cost of prescription drugs in America."

INTRODUCTION

As the Committee is aware, the Hatch-Waxman Act has greatly increased public access to generic drugs and has expanded competition in the pharmaceutical arena. In the United States, one out of every two prescriptions is filled with a generic pharmaceutical. Yet last year, generics accounted for *less than eight cents of every dollar* that consumers and health care purchasers spent on prescription pharmaceuticals, demonstrating the significant value generic drugs bring to the American health care system. Generic pharmaceuticals are not only a vital cost-containment tool -- they also provide the financial headroom so that Americans can afford innovative drug agents and other medical interventions.

Additional savings can be achieved by eliminating the abuses of the Hatch-Waxman system by brand companies. Such abuses have become increasingly common in recent years and include the use by some brand companies of questionable patents and multiple 30-month stays to block generic competition. And, accordingly, the balance has shifted in favor of the brand industry and away from consumers. The current legislative reforms discussed herein are intended to restore the original 1984 balance between access and innovation.

The 1984 Act sets forth a procedure that allows for early litigation of patent disputes, in order that patent issues can be resolved quickly and before generic market entry. This procedure begins when a brand company submits patent information to the FDA for listing in the Agency's "Orange Book." If a generic company submits an ANDA seeking FDA approval for its product prior to the expiration of the listed patent because the patent is invalid, unenforceable or not infringed (*i.e.* by filing a so-called "Paragraph IV certification"), the brand company has the option of initiating an immediate patent infringement action. If the brand company brings suit, it automatically obtains a 30-month stay of FDA approval of the generic company's application. While this procedure was intended to establish an orderly process for resolving patent disputes, some brand companies have used these procedures to tie up generic competitors in litigation and to extend their monopolies beyond the period of their patent protections – for example, by improperly listing patents in the Orange Book or by seeking multiple 30-month stays of a single ANDA.

HISTORY

Abuses of the Hatch-Waxman Act by some brand companies have been well recognized, and there have been a number of legislative and regulatory proposals to address them. These issues have been the subject of numerous hearings and reform efforts. On May 1, 2001, for example, Senators Schumer and McCain introduced S. 812 and on May 24, 2001, the Senate Judiciary Committee held a hearing on "Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements." On June 13, 2001, the House Energy and Commerce Subcommittee on Health held a hearing entitled "Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals." Then, in April 2002, the Senate Committee on Commerce, Science and Transportation held a hearing on similar issues.

In June 2002, the Senate Committee on Health, Education, Labor and Pensions (HELP) held a hearing on S. 812 and the Committee subsequently passed the legislation on July 11, 2002. On July 30, 2002, the Federal Trade Commission issued its report documenting various abuses of the Hatch-Waxman Act, including, significantly, the abuses of the 30-month stay provision. Immediately following the FTC's report, on July 31, 2002, the Senate passed S. 812 by a vote of 78 to 21. In the House, the Energy and Commerce Subcommittee on Health conducted a hearing on legislative reform of Hatch-Waxman on October 9, 2002.

GPhA strongly supported S. 812. If enacted, it would have closed many of the loopholes identified during the Congressional hearings and by the FTC. Unfortunately the House did not pass a comparable bill.

With S.812 as a backdrop, earlier this year, Senators Gregg and Schumer entered into discussions that led to the introduction in June of bipartisan compromise legislation (S.1225). After negotiations, the Gregg-Schumer bill was included as part of S. 1. The Gregg-Schumer bill offers a different approach than S. 812 on some key provisions. For example, S. 812 contained two statute of limitations provisions to facilitate timely resolution of patent disputes and rapid entry of generic drugs onto the market. The first

statute of limitations provision would have required the brand company to initiate litigation as to the validity of the patent within 45 days after receiving generic competitor's notice, or to lose its right to bring a patent infringement lawsuit against that generic company. S. 1, by contrast, would permit generic competitors to file declaratory judgment actions after the expiration of the brand company's 45-day window. The second statute of limitations provision in S. 812 would have required brand companies to file applicable patents in the system and, if they failed to do so, a brand company would have been precluded from enforcing against a generic competitor outside the system a patent that should have been listed within the system. S. 1, on the other hand, would provide courts with the discretion to forego imposing enhanced patent infringement damages against a generic competitor for a patent that should have been subject to the Hatch-Waxman generic approval system. In addition, while S. 812 contained a provision permitting the generic manufacturer to initiate an independent action to challenge an inappropriate Orange Book listing, the Gregg-Schumer bill addresses this issue by providing for a counterclaim mechanism to challenge inappropriately listed patents.

The generic industry has worked diligently with the legislation's sponsors, House and Senate leadership, and multiple coalitions representing consumers, employers, Governors, insurers, labor unions and others to resolve these issues so that fair, effective, bipartisan legislation could be enacted this year — to provide benefits to consumers and health care purchasers at the earliest possible date. Indeed, the Senate Health, Education, Labor and Pensions Committee addressed the compromise bill merely six weeks ago in a hearing. Two days later, by a vote of 94 to 1, the Senate passed the Gregg-Schumer bill as an amendment to its Medicare prescription drug benefit bill. The House included provisions similar to the S.1225 in H.R. 1, which it passed several days later. Conferees appointed by each Chamber are now working to reconcile the limited differences between the bills, even as this Committee conducts another hearing on the issue.

DIFFERENCES BETWEEN HATCH-WAXMAN REFORM PROVISIONS IN S. 1 AND H.R. 1

In many respects, the Hatch-Waxman reform language in S. 1 and H.R. 1 is identical, or contains small differences with no substantive impact. Both bills contain important provisions to limit the abuses of the 30-month stay provision and to resolve certain issues that will allow the 180-day generic exclusivity provision to be available to generic companies that contest questionable patents. We urge the Conferees to accept the identical provisions that both chambers have adopted without modification. Where there are small differences, such as is the case with respect to the provisions drawn from Senator Leahy's bill on notification of settlements, we expect that the differences will be easy to reconcile. As to the three areas where there are significant differences between the Senate and the House, discussed below, we strongly urge the Conferees to adopt the provisions contained in the S. 1 for the following reasons.

Declaratory Judgments: As previously stated, it has always been critical to the goal of generic competition to have patent issues resolved in a timely fashion. The 30-

month stay provision in current law gives the brand companies an important incentive to do just this, since a brand company that files suit within 45 days of being informed of a Paragraph IV certification receives an automatic 30-month stay of any generic approval. S. 812 also included a strong incentive to the brand companies to challenge patents early. That bill provided that if the brand company intended to assert its patent rights, it must do so within 45 days of being notified of a Paragraph IV certification; otherwise the company would have relinquished its rights to enforce the patent at a future date.

S. 1 (section 702(a)(2)(C)(i)) has adopted a compromise approach. Under S. 1, the brand company that does not sue within 45 days will not lose its right to assert patent infringement. But the drafters recognized the vulnerable position that a generic company could be in if it had no ability to litigate patent issues early, and therefore S. 1 provides that if the brand manufacturer does not sue within 45 days, the generic manufacturer may bring a declaratory judgment against the brand company to adjudicate the validity of the patent before it begins marketing its drug. This provision is helpful in preserving the Hatch-Waxman goal of providing that patent infringement issues be litigated early so that the generic manufactures may be positioned to begin marketing their drugs once all valid patents have expired. H.R. 1 (section 1101(a)(2)(C)(II)) restates the statutory provision precluding a generic company from bringing a declaratory judgment action until the expiration of the 45-day period provided for the brand company to initiate an action. In addition, however, the provision would condition the right of the generic company to bring a declaratory judgment action on its willingness to provide the brand company access to confidential and proprietary business information contained in its ANDA.

GPhA strongly supports the Senate approach, which would advance the goal of timely resolution of patent disputes. Even without the Senate language, a generic company could bring an action for declaratory judgment against a patent holder, but generic companies may face the argument by the brand firm that such an action is premature and, thus, that the case should be dismissed for lack of subject matter jurisdiction. This is the approach that the court took in the recent case concerning the company, Dr. Reddy's Laboratories, involving the drug Sertraline, where it dismissed Dr. Reddy's declaratory judgment action, substantially delaying generic product's entry to the market. The Senate provision is intended to resolve the current uncertainty in favor of competition and consumers by providing the generic company the express statutory right to bring such an action.

GPhA recognizes that the brand companies have argued that the creation of a right to a declaratory judgment action in this context raises constitutional issues. We certainly are aware of the case and controversy limitations of Article III, but the provision in S. 1 is a far cry from the kind of statutory provision that would require the federal courts to resolve a theoretical issue or an issue where there is no controversy and that therefore might be barred by Article III. In the situation covered by S. 1, the brand company would already have publicly stated to all generic companies that its patent applies to the drug for which generic companies seek approval by filing the patent in the Orange Book. For strategic, commercial reasons, it may wish to delay litigation of that patent, but that business decision does not eliminate the apprehension created by the

patent listing. Thus, the brand company's commercial decision should not be a barrier to a generic company's ability to obtain an early resolution of patent issues that clearly are the subject of a dispute between the generic and brand companies.

Professor John Yoo, currently Professor of Law at Boalt Hall School of Law, has analyzed this issue and submitted his conclusions to the Senate Judiciary Committee. Professor Yoo, who served as counsel to that committee and more recently as deputy assistant attorney general in the Office of Legal Counsel at the Department of Justice, has concluded that S.1's application of the Declaratory Judgment Act falls within Article III's case or controversy requirement. As the Supreme Court has explained in upholding the constitutionality of the Declaratory Judgment Act, "[t]he controversy must be definite and concrete, touching the legal relations of parties having adverse legal interests. . . . It must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." Aetna Life Insurance Co. v. Haworth 300 U.S. 227, 240-41 (1937).

As Professor Yoo has observed, there are obvious adverse legal interests between the patent holder and the generic drug manufacturer over the validity and application of a patent. The generic drug manufacturer has invested a substantial amount of resources to file an ANDA and to prepare and manufacture the generic drug. The enforcement of the patent could prevent the generic drug company from producing and selling its product, nullifying its investments in research and production, and potentially subjecting any profits to the uncertainty of a future lawsuit. In filing an ANDA, the generic drug company declares its intention and ability to produce the drug, which renders the dispute anything but hypothetical. Were the pioneer drug company to bring a patent infringement action, the case clearly would fall within Article III's arising under jurisdiction. There is nothing unconstitutional about Congress's desire to make clear that such suits fall within the Article III case or controversy requirement. Indeed, to the extent that there is ambiguity in the manner in which the lower federal courts have applied the Declaratory Judgment Act in patent cases involving generic drugs, it is important for Congress to step in and clarify the law.

As previously noted, H.R. 1 does not include the Senate provision, but instead includes a provision that would give brand companies access to the generic competitor's proprietary and confidential business information. This provision would not assist the generic companies in obtaining early resolution of patent disputes; rather, the provision provides brand companies with access to sensitive, proprietary information, and it may provide the brand industry with additional grounds to significantly delay generic competition. Moreover, current industry practice provides for relevant proprietary and confidential information to be conveyed, when necessary, either under contractual arrangements by the litigants or under an appropriate judicially enforceable protective order. We are concerned that the provision lacks a sufficient enforcement mechanism, and that it would provide brand companies with additional gaming opportunities, preventing timely introduction of generic pharmaceuticals.

In summary, GPhA strongly supports the declaratory judgment provision in the Senate bill. In the alternative, GPhA would prefer current law to the "right of confidential access to application" provision in the House bill.

Treble Damages: Under the Hatch-Waxman Act, when a generic files its ANDA, it must certify as to whether it accepts the validity of patents listed in the Orange Book. The Hatch-Waxman Act provides that with respect to patents that it claims are invalid under Paragraph IV, the brand that files suit for infringement within 45 days of the Paragraph IV certification will benefit from a 30-month delay in approval of the ANDA.

Without the opportunity to obtain multiple 30-months stays, brand companies may chose not to list their relevant patents in the Orange Book (which would violate Hatch-Waxman's requirement that they do so) and to bring a patent infringement suit after the ANDA is approved, which could significantly delay marketing the generic drug S. 812 addressed this concern by providing that if a brand company improperly did not list a patent in the Orange Book, the brand company would relinquish its right to enforce the patent against generic companies outside the Hatch-Waxman structure.

S. 1 rejects the statute of limitations concept, but contains a provision that would give the brand companies an incentive to list patents in the Orange Book. The bill recognizes that the generic company is at a serious disadvantage if the brand company disregards the law by failing to list its patent in the Orange Book but nevertheless sues the generic company for patent infringement. If a patent is not in the Orange Book, the generic company might not even be aware of its existence. Even if the generic company knew about the patent, the fact that it is not listed indicates to the generic company that the brand does not believe that the patent applies to its drug. The generic company is entitled to rely on this representation and there should be no penalty damages in a patent suit. Under the Senate provision, courts would have the discretion not to award enhanced damages against a generic company if the patent at issue had not been appropriately filed with FDA. The House bill lacks a similar provision. Accordingly, GPhA supports the damage penalty provision in the Senate bill.

AntiBundling: The Food and Drug Administration has had a long-standing policy concerning the bundling of products in a single application. Permitting bundling of applications that raise similar issues into a single application conserves both industry and FDA resources and leads to more expeditious resolution of issues pertaining to an application. The pertinent FDA regulations and guidance document, which essentially permits bundling of different strengths and other variations but not of different dosage forms (*e.g.*, tablet, liquid, capsule), have been in effect for over ten years. To date, the agency has implemented these industry policies with no known adverse issues.

GPhA opposes inclusion of the antibundling provision in H.R. 1, as drafted. If, as has been represented to GPhA, the House bill merely codifies current policy, then it is unnecessary at best. GPhA is concerned that the provision ultimately will be interpreted differently than FDA's current policy. Specifically, that the provision could be construed as disallowing the filing of a single ANDA under circumstances permitted today by

FDA's guidance. More significantly, however, GPhA fears that this provision could be misinterpreted and be turned into a commercial tool for delaying generic market entry.

If the House bill is modified so that it simply codifies the agency's current policy, which the House sponsors have indicated is their intent, GPhA would not oppose the provision. Yet, GPhA would still view the provision as unnecessary and would agree with those who believe that it is better to address issues of this nature in guidance or regulations. In that way, the agency will retain appropriate discretion to apply a policy that is tailored to particular circumstances. Therefore, GPhA urges the Conferees to support a Conference Report that does not include the House's antibundling provision and that permits the Agency to retain the flexibility to modify its current policy, if appropriate.

180-Day Provision: We also would like to comment on the 180-day provision, which is identical in both bills, because retaining the provision in its current form is essential to the support of the GPhA of this legislation.

Both the Senate and House bills contain identical provisions pertaining to 180-day generic exclusivity, which provides an important incentive to generic companies to challenge suspect patents, thereby giving the public access to less-expensive generic drugs more expeditiously. For the Hatch-Waxman scheme to be effective, there must be a valid mechanism and meaningful incentive to challenge suspect patents. Otherwise, the brand companies will be able to use questionable and invalid patents to block generic competition. For this reason, GPhA believes that an effective 180-day exclusivity provision is essential to any viable Hatch-Waxman reform.

In recent years, judicial decisions have undermined the effectiveness of the 180-day provision. One court has interpreted language in the Hatch-Waxman Act to require the 180-day exclusivity to begin when a district court decision invalidates a patent, and another court has interpreted the provision in the Act in a manner that leads to this result.[1] The FDA's acquiescence to these decisions has placed the generic companies in the untenable position of choosing between, on one hand, using the 180-day exclusivity and beginning marketing after the district court decision, thus risking potentially devastating damages if the district court is reversed, and, on the other, waiting to begin marketing until after the appellate court decision, but losing all of the 180-day exclusivity.

The Senate and House bills have clarified the Hatch-Waxman Act's generic exclusivity provisions and both preserve the incentive to challenge invalid patents. GPhA strongly urges the Conferees to leave in place, without modification, this provision and all other provisions where the Senate and House bills are identical. Indeed, we believe that any modifications to the agreed-upon language would destroy this pro-consumer, bipartisan piece of legislation. For example, abandoning the product-by-

[1] Mylan Pharmaceuticals, Inc. v. Shalala, 81 F. Supp. 2d 30 (D.D.C. 2000); Tor Pharm. Inc. v. Shalala, 1997 U.S. Dist. LEXIS 21983(D.D.C. September 15, 1997), appeal withdrawn and remanded, 1998 U.S App. LEXIS 4681 (D.C. Cir. Feb 5, 1998), vacated No. 97-1925 (D.D.C. Apr. 9, 1998).

product exclusivity approach endorsed by the FDA and others, which is incorporated into both bills, would render the proposed statutory scheme unworkable to the detriment of American consumers. Similarly, the notion of reinserting a "court-decision trigger" for the 180-day generic exclusivity, as some have suggested, would be superfluous because the concept already is included in both bills as part of a comprehensive "failure to market" forfeiture provision. Removing the concept from this forfeiture provision and including it somewhere else would undermine the strength of the 180-day exclusivity period itself. Doing so could render the provision meaningless and in turn, guarantee fewer challenges to suspect patents meaning unnecessarily high drug prices for years to come.

For these reasons, GPhA again urges the Conferees to leave in place, unmodified, the 180-day exclusivity provisions as set forth in both S. 1 and H.R. 1 – provisions that have undergone considerable debate and thought, and reflect a compromise concept.

* * * *

In summary, in most respects, the Senate and House bills are identical. We urge the Conferees to leave those provisions intact without modifications. With respect to the three areas where the bills differ, GPhA urges the Conferees (1) to adopt the Senate provision on declaratory judgments; (2) to adopt the Senate position on allowing consideration of Orange Book listings in deciding on enhanced damages; and (3) to adopt the Senate position that a bundling provision is neither necessary nor appropriate.

As always, should you or your staff have any questions, we would be pleased to discuss them with you. We look forward to working together with you as the work of the Conference progresses.

Sincerely yours,

Kathleen Jaeger
President and CEO

PhRMA

Bruce N. Kuhlik
SENIOR VICE PRESIDENT
GENERAL COUNSEL

July 30, 2003

The Honorable Orrin G. Hatch
Chairman, Committee on the Judiciary
United States Senate
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Chairman:

On behalf of the Pharmaceutical Research and Manufacturers of America, I am pleased to respond to your letter to Alan Holmer dated July 25, 2003, which requests our views specifically on the differences between title VII of S. 1, the Prescription Drug and Medicare Improvement Act of 2003, and title XI, subtitles A and B, of H.R. 1, the Medicare Prescription Drug and Modernization Act of 2003.

These provisions include amendments to the Federal Food, Drug, and Cosmetic Act and the Patent Code relating to the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the "Hatch-Waxman Act"). There are three important substantive differences between the Senate and House Hatch-Waxman provisions. With respect to each difference, the House bill is more favorable to the preservation of necessary incentives for continued pharmaceutical innovation.

1. **Declaratory judgments**

The Senate bill affirmatively authorizes a generic applicant to bring a declaratory judgment action if it is not sued within 45 days of providing a paragraph IV notice, and it amends title 35 to purport to establish a "case or controversy" for jurisdictional purposes (page 995 lines 3-23; page 1003 lines 1-21; page 1005 lines 3-22).[1]

The House bill provides that a generic applicant cannot bring a declaratory judgment action unless it has provided to the patent holder a confidential right of access to the abbreviated new drug application ("ANDA") for purposes of assessing any assertion of non-infringement; the House bill does not amend title 35 to change any of the jurisdictional provisions relating to declaratory judgments (page 647 line 17 through page 649 line 21; page 657 line 16 through page 659 line 20).

[1] Both bills make corresponding changes in the section 505(b)(2) provisions of the Act, which also are included in the parenthetical page and line references in this letter).

Pharmaceutical Research and Manufacturers of America
1100 Fifteenth Street, NW, Washington, DC 20005 • Tel: 202-835-3469 • FAX: 202-728-3932 • E-MAIL: bkuhlik@phrma.org

The Senate bill is unconstitutional because it attempts to establish jurisdiction where there is no reasonable apprehension of suit and therefore no genuine case or controversy. This would lead to unnecessary litigation and would force patent holders into court when there is no immediate dispute and where they lack sufficient information to make a fully informed decision as to whether there is in fact a basis for claiming infringement. The House bill does not include these questionable provisions. It does require generics to provide a right of confidential access to their ANDAs (as a prerequisite to a declaratory judgment action), in order to allow innovators to have a broader set of facts on which to evaluate claims of non-infringement. Under current law, generics often provide only sketchy information in their paragraph IV notices.

I am enclosing two letters and memoranda from former White House Counsel Boyden Gray analyzing the constitutionality of the Senate declaratory judgment provision and concluding that the provision violates the "case or controversy" requirement of Article III.

2. Treble damages

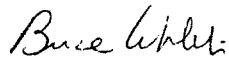
The Senate bill provides that a court may refuse to award treble damages in a case involving willful infringement if it determines that the patent in issue should have been, but was not, listed in the Orange Book (page 1017 line 17 through page 1018 line 2). There is no corresponding provision in the House bill. The Senate provision establishes an inappropriate and unnecessary defense for willful infringers. At a time when the number of willful infringement cases already is growing, providing a defense to treble damages will simply encourage more of these cases. Moreover, there is no need for such a defense as a way of encouraging patent filings in the Orange Book, since innovators already have ample incentives for these filings (generics typically claim there are too many, not too few patents in the Orange Book), and FDA's recent clarification of the filing rules establishes a common understanding of exactly which patents do need to be filed.

3. Amendments and supplements

Under both bills, the 30-month stay applies only to patents submitted to FDA for listing in the Orange Book before the ANDA is submitted. This new system will be subject to gaming by generic applicants if they are able to file amendments or supplements to old ANDAs for new products. This would allow them to avoid the 30-month stay for patents filed before the amendment or supplement but after the old ANDA had been filed. The House bill prevents this by making clear that generic applicants must file new ANDAs to seek approval of new products and cannot use amendments or supplements for this purpose (page 643 lines 17-24; page 653 lines 14-22). There is no corresponding provision in the Senate bill.

Thank you for the opportunity to provide this analysis. Please do not hesitate to contact me if you have any further questions.

Sincerely yours,



Bruce N. Kuhlik

Enclosures

U.S. SENATOR PATRICK LEAHY

CONTACT: David Carle, 202-224-3693 VERMONT

Statement of Senator Patrick Leahy
"Examining the Senate and House Versions of
The 'Greater Access to Affordable Pharmaceuticals Act'"
Senate Judiciary Committee
August 1, 2003

The Senate has been struggling with the myriad issues surrounding Medicare reform, and indeed the provision of quality, affordable health care generally, for years. Our latest effort is now in conference: The "Greater Access to Affordable Pharmaceuticals Act" is a critical part of the Medicare legislation, and I have high hopes for its ultimate effect on the health and lives of a great many Americans.

Like any complicated and contested bill, the Act has presented many challenges to its drafters and supporters as it has progressed through the legislative process. Now that it is in conference, the final decisions need to be made, and the last compromises worked out, so that we can continue to move forward. I sincerely hope that the tremendous quantity of time, and the heroic quality of effort, that have been put into this bill are not dissipated in conference. The stakes are too high, when we are dealing with the health and well-being of our citizenry, to risk a final bill that is anything less than a genuine improvement in our system of healthcare.

I do understand that there are more than a few differences between the House and Senate versions of the Act, and I know that feelings are running high on several of those, most notably on the declaratory judgment provision that concerns patent suits between companies anxious to enter the market with a generic version of a drug and the brand name drug companies that hold a patent on that drug. I will not enter that fray today, except to say that while we should take seriously the constitutional limitations on our actions in Congress, we should also not hesitate to legislate what is necessary within the confines of our constitutional powers and prerogatives.

One matter quite close to me is the Drug Competition Act, which was included as an amendment in the Greater Access to Affordable Pharmaceutical Act. The Drug Competition Act closes a truly problematic loophole in the current law. Under that law, the first generic manufacturer that gets permission to sell a generic drug before the patent on the brand-name drug expires enjoys protection from competition for 180 days – a head start on other generic companies. In itself, that was an excellent idea, and likely to promote generic drugs in the marketplace. That was a good idea – but the unfortunate loophole exploited by a few is that secret deals can be made that allow the manufacturer of the generic drug to claim the 180-day grace period – to block other

generic drugs from entering the market – while, at the same time, getting paid by the brand-name manufacturer not to sell the generic drug.

The Drug Competition Act simply requires generic and brand name drug companies that enter into agreements that touch on that 180-day exclusivity period to report those deals to the antitrust enforcers at the Department of Justice and the Federal Trade Commission. Thus, it will ensure that law enforcement agencies can take quick and decisive action against companies that are driven more by greed than by good sense. The FTC and Justice can look at every deal that could lead to abuse, so that only the deals that are consistent with the intent of that law will be allowed to stand. The Drug Competition Act accomplishes precisely that goal, and helps ensure effective and timely access to generic pharmaceuticals that can lower the cost of prescription drugs for seniors, for families, and for all of us.

Indeed, last July, the Federal Trade Commission released a comprehensive report on the barriers to entry of generic drugs into the pharmaceutical marketplace. The FTC had two recommendations to improve the current situation and to close the loopholes in the law that allow drug manufacturers to manipulate the timing of generics' introduction to the market. One of those recommendations was simply to enact our bill, as the most effective solution to the problem of "sweetheart" deals between brand name and generic drug manufacturers that keep generic drugs off the market, thus depriving consumers of the benefits of quality drugs at lower prices. I am pleased to see Chairman Muris here this morning, and want to thank him for his support of the Drug Competition Act.

The Drug Competition Act bolsters our efforts to bring quality healthcare at lower costs to more of our citizens. It enjoyed the unqualified support of the Senate last year, and I sincerely hope that this common sense legislation is a part of any final agreement with the House on the larger drug bill. I do know that the House version has deleted the reference to the Department of Justice, limiting referrals of these secret deals simply to the FTC, but I understand that that is simply a jurisdictional issue, and not a substantive concern. I believe that the Department of Justice can be restored to its co-equal role with the Federal Trade Commission in overseeing this situation while the larger bill is in conference.

I have also heard the very thoughtful and positive suggestion that other deals that effect the 180-day period should be included, and that the bill not be limited to generic manufacturers' deals with brand name companies. Instead, it has been suggested that generic-generic deals, as well as brand name-brand name deals, be included as well in the agreements that must be reported to the antitrust enforcement agencies, and I whole-heartedly concur in that suggestion. No companies should be allowed to abuse the incentives designed to encourage the entry of generic drugs to the marketplace, and this would be a worthwhile enhancement of the Drug Competition Act's purpose in stopping such misbehavior.

I look forward to hearing what all the witnesses have to say this morning, and I thank

Chairman Hatch for convening a hearing on an issue that has such an impact on the physical health and fiscal well-being of all our citizens.

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Prepared Statement of
The Federal Trade Commission

Before the

Committee on the Judiciary
United States Senate

Washington, D.C.

August 1, 2003

Introduction

Mr. Chairman, I am Tim Muris, Chairman of the Federal Trade Commission. I am pleased to appear before the Committee today to testify on behalf of the Commission regarding the Senate's and House of Representatives' versions of the "Greater Access to Affordable Pharmaceuticals Act." This statement supplements the Commission statement dated June 17, 2003 (attached) in which the Commission described the Hatch-Waxman provisions that govern the generic drug approval process, its vigorous enforcement of the antitrust laws with respect to generic drug competition, and the Commission's industry-wide study of generic drug entry prior to patent expiration entitled: Generic Drug Entry Prior to Patent Expiration: An FTC Study.[1]

Earlier this year, both the Senate and House passed versions of the Greater Access to Affordable Pharmaceuticals Act that reform the Hatch-Waxman generic drug approval process. The reforms are nearly identical to the FTC Study's recommendations. With one important exception highlighted below, the language in both bills is very similar. This testimony will describe the legislative changes to Hatch-Waxman in both the Senate and House bills, compare them to the FTC Study's recommendations, and explain the Commission's concern about the "failure to market" forfeiture event provision in both bills.

Limits Brand-Name Companies to Only One 30-Month Stay

Both the Senate and House bills amend Hatch-Waxman to allow only one 30-month stay per drug product, per Abbreviated New Drug Application (ANDA) for patents listed in the Orange Book prior to the generic company filing its ANDA. The FTC Study recommended this exact change. This provision, had it been in effect previously, would have eliminated all eight instances the FTC Study identified in which a brand-name company's later listing of patents resulted in the start of an additional 30-month stay of FDA approval.

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

Under both bills, a district court decision of patent invalidity or non-infringement terminates the 30-month stay. This change codifies current FDA interpretation. If the generic applicant includes more than one paragraph IV certification in its ANDA, the district court decision on the last patent terminates the 30-month stay for which the generic applicant submitted a paragraph IV certification. Both bills clarify that if the district court finds the patent infringed, the FDA cannot approve the ANDA unless an appeals court overturns the district court's decision. The Commission supports these changes.

A New Counterclaim to Correct Orange Book Patent Listing Information

Consistent with an FTC Study recommendation, both the Senate and House bills provide generic applicants a new tool to correct patent information listed in the Orange Book. Under both bills, if a brand-name company initiates a patent infringement suit against a generic applicant, the generic applicant may assert a counterclaim seeking an order requiring the brand-name company to correct or delete the patent information listed in the Orange Book. The generic applicant may argue that the patent claims neither the drug for which the brand-name drug was approved, nor an approved method of using the drug.

The patent listing statute also requires that the patent holder list patents only "for which a claim of patent infringement could reasonably be asserted." The bills, however, do not include this prong as a basis for the counterclaim. The Commission suggests that Congress consider modifying the counterclaim provision to parallel the bases for listing patents in the Orange Book.

Declaratory Judgment/Case or Controversy Provisions

The Senate bill adds a provision clarifying that if the brand-name company fails to bring an infringement action within 45 days of receiving notice of an ANDA containing a paragraph IV certification, the generic applicant can bring a declaratory judgment action that the patent is invalid or not infringed. To overcome possible jurisdictional limits to bringing such an action, the bill adds a provision stating that the failure of the patent owner to bring an action for patent infringement before the expiration of the 45-day period shall establish a controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States.

The House bill does not include a similar provision establishing a controversy between the parties. Rather, the bill allows a generic applicant to bring a declaratory judgment action after the expiration of the 45-day period (assuming the brand-name company has not sued for patent infringement) only if the generic applicant provides a "right of confidential access" to its ANDA. This right would allow the brand-name company to make an informed decision about whether it should sue for patent infringement during the 45-day period.

Without addressing the constitutional issues involved, the Senate provision may help ensure that a federal court has subject matter jurisdiction to resolve the patent issues. In addition,

the Commission does not believe that the House's "right of confidential access" to a generic applicant's ANDA is necessary. A generic applicant currently has incentives to provide brand-name companies with sufficient information about whether its ANDA infringes the brand-name company's patents to ensure that the dismissal or adjudication of any suit precludes future infringement suits.

The 180-Day Exclusivity Provision

Both bills change how the FDA administers Hatch-Waxman in two fundamental ways. First, the FDA will be able to grant the 180-day exclusivity provision on a product basis. This change eliminates the exclusivity problems the FDA encountered by awarding exclusivity to generic applicants on a patent basis (*i.e.*, some drug products have multiple patents on which different generic applicants have been first to file an ANDA containing a paragraph IV certification). Second, both bills institute a "multiple first applicant" system in which all ANDAs filed on the first day an ANDA is filed for a particular drug product would be eligible for the 180-day exclusivity period. Both of these provisions should provide certainty to the FDA and industry about the administration of the 180-day exclusivity provisions.

Filing of Patent Settlement Agreements with the FTC

The Senate and House bills require brand-name companies and generic applicants to file patent settlement agreements with the FTC within 10 days of execution. The filing of agreements is the main requirement of the Drug Competition Act (S. 946, 108th Congress) which the Commission endorsed in the FTC Study. The House bill also requires the filing of agreements between generic applicants. This provision recognizes the possibility of anticompetitive agreements in light of the "multiple first applicant" system described above. The Commission supports this provision.

Triggers for the 180-Day Marketing Exclusivity

Both the Senate and House bills eliminate the current court decision trigger for the 180-day exclusivity. Only commercial marketing by the first generic will trigger the 180-day exclusivity period. Both bills adopt the FTC Study's Minor Recommendation #1 that clarifies marketing of the brand-name drug product by the first generic applicant constitutes commercial marketing to trigger the 180-day period.

The bills also contain a forfeiture provision that attempts to safeguard against the possibility that first generic applicants will delay the start of commercial marketing. When a forfeiture event occurs, the 180-day exclusivity would not roll to the next generic applicant. The forfeiture events include: (a) failing to market within prescribed time periods (described more below); (b) withdrawing the ANDA application; (c) changing a paragraph IV to a paragraph III certification; (d) failing to obtain tentative approval within 30 months; and (e) entering into an agreement with the brand-name company, or another generic applicant, that an FTC or court

decision, from which no appeal can be taken, finds violates the antitrust laws.

The Commission believes that the bills ensure that the first generic applicant will receive the 180-day exclusivity, unless it faces significant problems obtaining final approval of its ANDA. The 180-day exclusivity near-guarantee arises because the "failure to market" forfeiture provision is triggered when the first generic applicant fails to market within 75 days of *the later of* (a) receiving final approval of its ANDA (which, for purposes of this provision, will not extend beyond 30 months)[2] or (b) an appeals court decision on the patents that were subject to paragraph IV certifications by the first applicant. The appeals court decision can relate to any generic applicant's ANDA, not just the first generic applicant to file.

The Commission has two concerns about this provision's likely effect on generic entry, and the Commission offers suggestions to address these concerns. First, the provision may cause first generic applicants to delay commercial marketing as compared to the current regulatory structure. Under the current rule, the 180-day exclusivity is triggered by *any district* court decision, not an appeals court decision. This rule has the effect of encouraging the first generic applicant to market as soon as possible thereafter or risk loss of the exclusivity period. Moreover, the FTC Study found that appeals courts overturn less than 10 percent of district court decisions of patent invalidity or non-infringement in the Hatch-Waxman context.

The FTC Study found that an appeals court decision, on average, occurs approximately 12 months after a district court decision (25 months, 15 days for a district court decision versus 37 months, 20 days for appeals court decision). Thus, the bills' effect could be to further delay generic entry, on average, by 10 months (75 days plus 7 months, 20 days (which is the time between *the later of* (a) the latest approval ANDA date of 30 months and (b) the average time for an appeals court decision)). If the 180-day period starts only after an appeals court decision, then consumers may wait longer for the price reductions caused by generic entry.

Second, the district court decision trigger for the 180-day exclusivity is important to encourage subsequent generic entry. The FTC Study's Minor Recommendations #2 and # 3 suggested that a district court decision in a case involving a subsequent generic applicant trigger the first applicant's 180-day period. If a subsequent generic applicant is "ready to go," the first applicant's exclusivity should not block its entry. On balance, the Commission stated that this result was right because it provided the first applicant a reasonable period for which to begin commercial marketing, but reduced the potential that the first applicant's failure to market commercially would block another generic that was ready to compete.

To address these issues, the Commission suggests that the failure to market provision be amended so that the generic applicant forfeits the 180-day exclusivity if it does not begin commercial marketing within 75 days of the later of (a) receiving final approval of its ANDA (which, for purposes of this provision, will not extend beyond 30 months) or (b) a district court

[2]The 30-month savings clause ensures that the generic applicant does not attempt to game or delay final FDA approval.

decision on the patents that were subject to paragraph IV certifications by the first applicant.

In theory this rule could deprive the first generic applicant of its ability to market exclusively for 180 days and, therefore, arguably dampen a company's incentive to become the first applicant to challenge complex patents, especially if the potential damages for infringement could bankrupt the company. The Commission, however, does not believe that this will be the case. Because we are suggesting changes that modify the bills to resemble more closely the FDA's current rules, the Commission staff examined FDA data to determine whether the number of ANDAs containing paragraph IV certifications has decreased since the current rules became effective in March 2000. From January 1992 through December 2000, generic companies filed ANDAs with paragraph IV certifications for 104 brand-name drug products. During the two and one-half year period beginning January 2001 through the end of June 2003, generic applicants have filed ANDAs containing paragraph IV certifications for over 80 different brand-name drug products. The data suggest that, despite the FDA's rule change to a district court decision, generic companies retained the incentive to submit ANDAs with paragraph IV certifications.

The Commission also suggests an amendment to the language of the "failure to market" forfeiture provision to accommodate Minor Recommendation #3 of the FTC Study. In this recommendation the Commission sought to ensure that court decisions dismissing a declaratory judgment action for lack of subject matter jurisdiction trigger the first applicant's 180-day period. The need for this amendment could occur, for example, if a subsequent generic applicant develops a clearly non-infringing product and the brand-name company does not sue the applicant for patent infringement. Without such a change to the language of the bills, the subsequent generic applicant would be blocked from marketing until the first applicant begins commercial marketing. This change is necessary to ensure that the 180-day period does not unreasonably block a subsequent generic applicant's market entry after allowing the first applicant a reasonable time to begin commercial marketing.

Conclusion

Thank you for this opportunity to share the Commission's views on the Senate and House of Representatives versions of the "Greater Access to Affordable Pharmaceuticals Act." The Commission looks forward to working closely with the Committee, as it has in the past, to ensure that competition in this critical sector of the economy remains vigorous.

Full statement for the record

Judiciary Hearing
Examining Differences between House and Senate Versions of the "Greater Access to Affordable Pharmaceuticals Act"
Statement of Senator Charles E. Schumer
August 1, 2003

Let me first thank you, Mr. Chairman, not only for holding this hearing today, but for your leadership on this issue. As I've said throughout the course of working on this issue, I think that the Hatch-Waxman Act was one of the greatest pro-consumer pieces of legislation in the past 25 years. Your leadership in authoring the bill back in 1984 has led to consumer savings of billions of dollars and significantly increased access to life-saving drugs for so many Americans, while preserving strong incentives for innovation.

But as we both know, the law has been abused in recent years, and I especially want to thank you for recognizing that and calling the multiple hearings you have had over the past few years to bring the issue to light and move the ball forward to get us to where we are today.

I also want to thank Senator Leahy, who along with you, Mr. Chairman, drafted the Drug Competition Act – another piece of legislation which is key to ending the anti-competitive behavior in the pharmaceutical industry. I have always supported this legislation, and am very happy to see that it has been included in both the Senate and House versions of the Medicare bill as well. It is this bill, along with the Gregg-Schumer bill, which we are here to discuss today, that will ensure that as the federal government implements a Medicare drug benefit, precious taxpayer money will not be wasted due to anti-competitive gaming.

I would also like to thank Senator Gregg for his leadership in approaching me and bringing together Senators McCain and Kennedy – with whom I have worked on this issue for the past few years – to craft the strong bipartisan compromise which is now a part of the Medicare bill in conference. In redrafting the bill this year, we made modifications to address the concerns that kept the bill's critics from supporting it last year, including those of the Chairman, who has always given me good advice in this area.

I was of course also very pleased to see similar provisions included in the House bill – though I do have some serious concerns about the areas in which there are significant differences in approach, which I will touch on in a minute. The Senate bill, which passed *nearly unanimously* in the Senate, is an effective, efficient approach to achieving the goals of the original Schumer-McCain bill. Specifically, the Gregg-Schumer bill in S. 1 will remove barriers to access and increase competition in the pharmaceutical marketplace – simply put, it will get lower cost generics into the pharmacies and into the hands of consumers as quickly as possible. On the contrary, I do not believe that the House bill will effectively achieve these goals.

Before I get into details on the differences between the bills, I just want to say that we've come a long way in the past few years on this issue. With these bills in conference, we are on the verge of making some real progress for consumers. We are all familiar with the abuses – and

over the past year or two, support for this legislation has only continued to swell. In past hearings we have heard from the FDA, the FTC, and witnesses representing consumers and States, all of whom shared their concerns about ways in which the pharmaceutical industry was taking advantage of loopholes in the law at the expense of the consumer.

For years, the carefully-crafted balance of Hatch-Waxman worked as it was intended to bring low-cost generic drugs to market quicker while continuing to provide ample reward for innovation. But as the profits have spiraled higher – and as the pharmaceutical industry began to see their multi-billion dollar monopolies coming to an end – without new blockbusters ready to replace the old – they have changed their approach to innovation. Instead of innovating new drugs, they have been innovating new patents.

Find a good lawyer, and he will find a good loophole. And some of the generic companies are just as much to blame for making deals with the brand companies to stay off the market. We've heard example after example of how abuse of these loopholes has cost consumers literally billions of dollars, and I will not spend time here going over those again. At this point we clearly have agreement that there's a problem that needs to be fixed.

But, as they say, the devil is in the details – and I'm sure my friend Chairman Hatch would agree there is perhaps no other statute for which this phrase is more true. Change an "an" to a "the" and you go from huge savings to huge cost. Senator Gregg and I saw multiple examples of this as we worked out the technical details of the bill with the FDA – and I'd like to thank Mr. Troy and Dr. McClellan for their invaluable help as we worked out the final bill.

The bill that Senator Gregg, McCain, Kennedy and I put together is extremely carefully crafted – it is fair and balanced, and I will not stand by and watch it watered down in conference. Though there are only a few areas of difference between the two bills, the differences could mean seriously different outcomes for consumers, and so they cause me serious concern.

The first issue is the difference between the declaratory judgment provisions. First, I understand that some have raised questions about the constitutionality of the Senate approach, and I understand the Department of Justice is here to testify to that effect. Quite frankly, I'm floored. Last fall the President went to the Rose Garden and made it his mission to "close the loopholes" and "to promote fair competition" – this is precisely what the declaratory judgment provision will achieve.

I'm sure we will hear Chairman Muris of the FTC, who is here today, testify yet again of the importance of timely resolution of patent disputes to ensuring robust competition – the importance of which was also clearly communicated in the FTC report released last summer. To hear the Department of Justice sitting here today suggesting that we delete a provision which is at the very heart of promoting timely, robust competition – well, I'm sorry to say Mr. President, but you can't have it both ways.

I just don't agree that these constitutional arguments have merit, and I have heard very convincing arguments on the other side. I have letters here from two extremely well-respected

constitutional experts – Henry Dinger with Goodwin Procter, who has decades of experience with constitutional questions such as this and from John Yoo, formerly of the Office of Legal Counsel under this Administration and currently a fellow at the American Enterprise Institute and a constitutional scholar and professor at UC Berkeley – both of whom make perfectly clear that there is simply NO constitutional issue with this provision.

I want to stress the importance of the Declaratory Judgment provision in this bill – it is key to making the system work. There is not currently a clear pathway for a generic company to get a declaratory judgment to show that they do not infringe a patent.

We saw yet another example of this just three weeks ago when the District Court for the District of New Jersey dismissed Dr. Ready's case for declaratory judgment that their generic does not infringe a patent on Pfizer's blockbuster drug Zoloft. Basically, Dr. Reddy's challenged the patent, Pfizer did not choose to sue within the 45 days, and Dr. Reddy's wanted assurances from the court that they were clear to go to market without the risk of Pfizer suing later.

The court dismissed the case for lack of subject matter jurisdiction, and now Dr. Reddy's has to go back to the drawing board and generic competition will be significantly delayed. On a drug with sales of $2.4 billion per year, this decision could cost consumers hundreds of millions of dollars.

At the very heart of the Hatch-Waxman Act is the goal of ensuring that patent disputes are resolved before generics come to market. The Act protected this right of the brand companies by granting them an automatic 30-month stay with each generic challenge. And they abused this protection. Now that we have gotten rid of the potential for that abuse, we must take steps to ensure this core goal of Hatch-Waxman is achieved. The amendment to Title 35 in the bill is what ensures this aim is satisfied.

Without a clear right for the generics to bring a suit for declaratory judgment, the brand companies are in a position to leave the generics in the dark – the brand company can list a new patent, and sit back and wait – and wait and wait and wait. Because the brand company is no longer getting an automatic 30 month delay for every patent it lists, the best weapon it has is to leave the generic wondering whether or not they will be sued in the future.

Sure the generic could just go ahead and go to market at risk, but then the brand company could pounce, and if they win the suit they could collect *triple* their lost profits. Mr. Chairman, I ask you, what generic company in it's right mind – with shareholders keeping close watch – would be willing to take that risk? As we change the system of incentives in the Hatch-Waxman regulatory scheme – and as the original author I'm sure you would agree with me on this – we must ensure we preserve its core goals.

We must ensure that if there are issues of potential patent dispute which the brand company decides to take its sweet time in addressing, that at least its generic competitor will be able to go to a court and say, "look, I want to go to market and get this product to consumers, will you give me clearance to go?" Without a strong declaratory judgment provision to amend Title

35, we are not reducing delays, we are simply changing the nature of those delays and leaving wide open the potential for gaming and abuse.

The provision in the Senate bill that amends Title 35 does no more than define the statutory term "actual controversy" for the courts. It simply directs a federal court to interpret its discretionary jurisdiction under the "actual controversy" requirement of the Declaratory Judgment Act as broadly as possible when generic drug applicants seek declaratory relief about certain brand drug patents. All within the limits imposed by the "case or controversy" requirement of the Constitution, of course.

The approach taken in the Senate bill is fair and workable and in Title 35, it parallels the creation of the artificial act of infringement that was created by Hatch-Waxman in 1984. I will not sit by and watch the provision be gutted.

The House bill, instead of enhancing the ability of a generic to seek a declaratory judgment, actually takes a step backward. It makes the right of the generic to bring an action for declaratory judgment *contingent* on the generic handing over sensitive, proprietary information about its product, all without any kind of protective order from a court and with no enforcement of any kind to prevent the brand company from using this information inappropriately. I don't know of any precedent for this type of disclosure, nor do I know of any company who would simply turn over highly-sensitive proprietary information with no assurances that the information will be protected.

The second major difference between the bills is that the House version is devoid of a mechanism to enforce the brand companies to list patents appropriately. Under the current scheme, brand companies have an incentive to list as many patents as they possible can in the FDA's Orange Book. By eliminating multiple, automatic 30-month stays, brand companies no longer have this incentive – which is good. They won't list patents that don't belong in the Orange Book. And if they do, the Gregg-Schumer bill allows a generic to bring a counter-claim to have them delisted.

But under this new scheme, another way for the brand companies to keep the generics in the dark is to choose *not to list their patents at all.* This way, the patent dispute is outside of the system – the enhanced declaratory judgment will not apply, and the system will not work. The Gregg-Schumer bill includes a provision to ensure that brand companies comply with the new rules by saying that if a brand company does not list a patent which should have been listed, the court may decide not to award treble damages if the generic chooses to go to market.

Without such a provision, who will enforce that the brand companies comply with the new rules? After all, the FDA has never taken enforcement action with regard to patent listing and we have every reason to believe they will not start. In fact Mr. Troy has repeatedly testified that this is not their job, so an independent enforcement action is key to making these new rules work.

Finally, there is a provision in the House bill which is commonly referred to as the "anti-

bundling" provision. Quite frankly, I can't figure out why it's in there. What I hear is that it is intended to codify existing FDA guidance on what can and can't be included in a generic application. Well, it is my understanding that the FDA's guidance is very clear on this point and its system has been working just fine – I don't know of a single example of how these procedures have been problematic in the drug approval process.

As I mentioned earlier, this statute is extremely complex, and as we have plainly seen, any change we make to the statute runs the risk of being interpreted overly broadly or of opening new loopholes. I have talked to many in the industry who have assured me that the drafting of this "anti-bundling" provision leaves it open for serious gaming by the brand companies. Why we would want to take a risk of opening up new loopholes that could cost consumers millions when there is no evidence that this is an area in need of clarification is beyond me. I feel strongly that we should leave this one to the FDA.

Before I close, Mr. Chairman, I would just like to again ask the brand pharmaceutical companies – why do you continue to ruin your goodwill by playing these games and by continuing to attempt to gut this bill? You make a great product, and you save people's lives. That is not disputed. Nor do I believe you should be deprived of a good solid rate of return on your investment. To the contrary, you should make a solid profit on a good product. But now the spotlight is on you, and it has been in recent weeks and months. It is time to redeem yourselves in the eyes of American consumers who struggle to afford the wonderful medications that you produce.

I ask you to work with us to get this bill done, to get a strong bill passed which will encourage everyone to play by the rules. All of those who have supported our efforts over the years – major corporations, State governments, the State Attorneys General, labor unions, insurers – we will all have our eyes on this conference. So I urge you stop with the games and to work with us to make effective revisions in the law that will once again level the playing field as it was intended to be with the original enactment of the Hatch-Waxman Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

DANIEL E. TROY, CHIEF COUNSEL

U.S. FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

AUGUST 1, 2003

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Daniel E. Troy, Chief Counsel for the United States Food and Drug Administration (FDA or the Agency). I am joined by Gary Buehler, R.Ph., Director, Office of Generic Drugs, Center for Drug Evaluation and Research. I am pleased to be with you today to discuss FDA's implementation of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments and recent Congressional action on amendments to Hatch-Waxman.

This testimony will discuss a number of issues that affect the timely introduction of generic drugs into the U.S. marketplace. It will focus in particular on whether certain "later-listed" patents or inappropriate patent submissions by the sponsors of innovator drug products have resulted in the delay of generic drug approvals. On June 18, 2003, FDA published its final rule intended to speed access to and increase the availability of generic drugs by limiting the use of 30-month stays by brand-name drug sponsors and by clarifying the types of patents that must and must not be submitted to FDA for listing in the Orange Book.

The Hatch-Waxman Amendments were intended to balance two important public policy goals. First, Congress wanted to ensure that brand-name (also known as innovator) drug manufacturers would have meaningful patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the statutory patent protection and marketing

exclusivity for these new drugs has expired, consumers would benefit from the rapid availability of lower priced generic versions of innovator drugs.

Since its enactment in 1984, Hatch-Waxman has governed the generic drug approval process. In general, the law has been working well. Since 1984, over 10,000 generic drugs have entered the market, and generics now account for close to 50 percent of prescriptions filled. Attention has recently focused on two key provisions of the law that allow for 180 days of marketing exclusivity to certain generic drug applicants, and for the 30-month stay on generic approvals. Both of these provisions are discussed in detail below.

FDA's objective is to enhance the ability of innovators, generic firms and the Agency to achieve the goals embodied in Hatch-Waxman. While the new rule will improve FDA's implementation of the law, this is only one part of a set of FDA initiatives that will reduce drug costs by encouraging innovation and speeding up the drug development and approval process, while maintaining FDA's high standards for safety and effectiveness. Our reforms in the generic approval process will generally shave months off the time to availability of generic drugs across the board. Similarly, new pathways for approving inhaled and topical generic drugs will potentially affect many products. This broad improvement in the availability, of both new drugs and generic drugs, will have a positive impact on all patients, not just those affected by imperfections in the operation of Hatch-Waxman.

STATUTORY PROVISIONS

The Hatch-Waxman Amendments amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and created a statutory generic drug approval process with section 505(j). Section 505(j) established the abbreviated new drug application (ANDA) approval process, which permits generic versions of previously approved innovator drugs to be approved without submitting a full new drug application (NDA). An ANDA refers to the previously approved NDA (the "listed drug") and relies on the Agency's finding of safety and effectiveness for the listed 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 relating to the drug product that is the subject of the NDA. FDA is required to publish the patent information submitted once the drug is approved. The statute establishes a process that requires that ANDA applicants certify to the patents listed, provide notice to the NDA holder and patent owner, and, if patent infringement litigation is filed, it imposes a 30-month stay on the approval of an ANDA. The Hatch-Waxman Amendments also created a period of market exclusivity for certain generic applicants.

"ORANGE BOOK" LISTINGS

Only certain types of patent information can be submitted to FDA. FDA publishes patent information on approved drug products in the Agency's publication Approved Drug Products

with Therapeutic Equivalence Evaluations, also known as the "Orange Book." The Orange Book is available on FDA's website and is updated every few weeks. The book is also printed yearly by the Government Printing Office, updated monthly, and is available to the public. It lists all approved drug products with their therapeutic equivalence codes in addition to the products' patent and exclusivity information (if such information exists). Concerns have been expressed over FDA's role in the listing of patents in the "Orange Book." Under the FD&C Act, pharmaceutical companies seeking to market innovator drugs must submit 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. FDA's final rule published on June 18, 2003, clarified the types of patents that must be listed in the Orange Book.

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 current required text of the declaration is described in FDA's regulations. The final rule replaces the signed declaration with a declaration form that must be used for the submission of patent information.

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 may result in a considerable delay in the approval of ANDAs when an innovator company submits a new patent listing to FDA. Therefore, ANDA applicants often closely scrutinize these listings. FDA's 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 will then ask 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 does not change the patent information 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 for listing 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. Until the final rule effective date, pending generic drug applications may be subject to multiple overlapping 30-month stays if new patents are listed for the innovator drug and those patents result in litigation.

FDA does not undertake an independent review of the patents submitted by the NDA sponsor. The statute requires FDA to publish patent information upon approval of the NDA. This strongly suggests – and FDA has long held – that the Agency's role in the patent-listing process is intended to be ministerial. Issues of patent claim and infringement are matters of

patent law, and FDA lacks the authority, the resources, and the capability to 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. As such, FDA has implemented the statutory patent listing provisions by informing interested parties of what patent information is to be submitted, who must submit the information, and when and where to submit the information. Generic and innovator firms may resolve any disputes concerning patents in private litigation.

Over the past few years, new patents have occasionally been submitted to FDA for listing in the "Orange Book" shortly before patents already listed in the "Orange Book" were scheduled to expire. These new patents have been submitted to FDA within the required 30-days of issuance by the Patent and Trademark Office. If the NDA sponsor complies with the requirements of the statute and regulations in submitting a patent for listing in the "Orange Book," the Agency may not reject a patent merely on the basis that, but for the filing of the patent, ANDAs would be eligible for final approval.

It has been suggested that FDA should review drug patents to determine if they should be listed in the "Orange Book" as protection for innovator drug products -- that is, FDA should assess whether a submitted patent properly claims the approved drug product and could support a claim of patent infringement. The Agency believes that, even if it had the authority and expertise (which it does not), such a review would not speed the availability of generic drugs. Rather, it would instead add a layer of complexity and delay, leading to litigation

between FDA and the generic or innovator, in addition to any litigation between the generic and innovator.

Moreover, FDA review of patents would be unlikely to speed approval and marketing of generic drugs in a meaningful way. Even if FDA were to decide not to list a patent, the innovator company could obtain an injunction against approval or marketing of the generic drug until the patent listing question is resolved. In such a case, FDA's review of the patents would have done nothing to speed approval of generic drugs. Patent reviews would lead to substantial litigation that will impose a new and substantial burden on FDA's Office of the Chief Counsel and Department of Justice litigation resources. Finally, the Agency does not have the resources or expertise to review patents.

DELAYS IN GENERIC DRUG APPROVALS – 30-MONTH STAYS

Patent listings are important in the generic drug approval process because challenges to listed patents can lead to stays in approval. The FD&C Act requires that generic drug applicants include, in their ANDAs, a certification for each patent listed in the "Orange Book" for the innovator drug. Similar information is required for applicants filing 505(b)(2) applications under section 505(b)(2) of the FD&C Act. 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 when the patent expires.

A paragraph IV certification, however, 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 before the expiration of the patent. Under the current regulations, 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. Until the effective date of FDA's final rule, all patents submitted and listed in the Orange Book that are the subject of a paragraph IV certification require notice to the NDA holder and patent owner. 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. Accordingly, the ANDA applicant who submits an application containing a paragraph IV certification may be sued for patent infringement. If the NDA holder 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 that notice.

This 30-month stay will delay approval of the generic drug product unless the court reaches a decision earlier in the patent infringement case or otherwise orders a longer or shorter period for the stay. A court may modify the length of a stay, under the FD&C Act, "if either party in the action failed to reasonably cooperate in expediting the action." (21 U.S.C. 335(j)(5)(iii))

Under FDA's traditional interpretation of the Hatch-Waxman Amendments, multiple 30-month stays have been possible. Submission of newly issued patents after an ANDA application has been filed with FDA has required the appropriate certification and notice to the NDA holder and patent owner with the possibility of a 30-month stay if patent infringement litigation resulted. As a result, there have been a number of instances where there has been more than a single 30-month stay. These include paroxetine hydrochloride (Paxil) and gabapentin (Neurontin).

A recent review of FDA's records indicates that of the 442 active ANDAs that contained paragraph IV certifications, only 17 have had multiple 30-month stays, representing 3.8 percent of all applications with patent challenges. However, we note that a significant number of these products have high dollar value annual sales, and we are aware of some instances where multiple stays have resulted in the delay of a generic drug approval for a number of years.

180-DAY EXCLUSIVITY

The Hatch-Waxman Amendments provide 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 thereby runs 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.

This is true even if the later ANDAs are otherwise ready for approval and the sponsors are willing to begin marketing immediately. Therefore, an ANDA applicant who is eligible for exclusivity can often delay all generic competition for the innovator product.

Only an ANDA 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.

The 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. As described in a June 1998 guidance for industry, FDA currently is addressing on a case-by-case basis those 180-day exclusivity issues not addressed by existing regulations.

One of the most fundamental changes to the 180-day exclusivity program, resulting 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 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

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

finds that the patent at issue is invalid, unenforceable, or will not be infringed by the generic drug product. FDA had previously 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 begins 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.

FEDERAL TRADE COMMISSION STUDY

In response to reports of brand-name and generic drug companies engaging in anti-competitive behavior, the FTC conducted a study to determine if the 180-day exclusivity and the 30-month stay provisions of the Hatch-Waxman Amendments have been used

strategically to delay consumer access to generic drugs. In July 2002, FTC published the findings of their study and provided two primary recommendations.

FTC recommended that only one automatic 30-month stay per drug product per ANDA be permitted to resolve infringement disputes over patents listed in the "Orange Book" prior to the filing date of the generic applicant's ANDA. FDA agrees with FTC's conclusion that, recently, more ANDAs have been subject to 30-month stays, there have been more multiple 30-month stays than in years past, and more patents on average are now being litigated per generic drug application than in the past.

FTC's second recommendation was to pass legislation to require brand-name companies and first generic applicants to provide copies of certain agreements to FTC. This is a response to FTC's finding that brand-name companies and first generic applicants have on occasion entered into agreements to delay generic competition. FDA has no objection to this recommendation.

FDA agrees with many of the conclusions of the FTC study and has found the factual information provided in the report to be extremely valuable in our own deliberations regarding the generic drug approval process. One example of this is the compilation of information on the disposition of litigation surrounding patents filed after NDA approval. Finally, we note that FTC's report recognized that FDA does not have the capacity to review the appropriateness of patent listings.

FDA RULEMAKING

On June 12, 2003, President Bush, HHS Secretary Thompson and FDA Commissioner McClellan announced a new regulation to be effective on August 18, 2003, that will streamline the process for making safe, effective generic drugs available to consumers. This rule was first proposed on October 24, 2002, in response, in part, to the FTC recommendations and other changes the Agency identified as being useful in improving generic competition. The new rule will limit an innovator drug company to only one 30-month stay of a generic drug applicant's entry into the market for resolution of a patent challenge. The changes in the regulations will save consumers an estimated $35 billion over ten years by making generic alternatives to certain more costly brand-name drugs available more quickly, by avoiding time-consuming legal delays. The new regulations were published as a final rule in the *Federal Register* on June 18, 2003.

The rule provides a full opportunity for only one 30-month stay per ANDA or 505(b)(2) application; prohibits the submission of patents claiming packaging, intermediates, or metabolites; requires the submission of certain patents claiming a different polymorphic form of the active ingredient described in the NDA; adds a requirement that, for submission of polymorph patents, the NDA holder must have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA; makes changes to the patent information required to be submitted and provides declaration forms for submitting that information to FDA, both with the NDA and after NDA approval;

and does not require claim-by-claim listing on the declaration form except for method-of-use patents claiming approved methods of use.

30-Month Stay Provisions

The final rule limits brand-name companies to only one 30-month stay. The rule accomplishes this by establishing when generic companies must provide notice of a paragraph IV patent challenge to a brand-name sponsor and the patent owner (which initiates the process that may result in a 30-month stay). Notice of a paragraph IV certification must be provided with an initial paragraph IV certification, and when a previous certification and notice did not result in a full opportunity for a single 30-month stay.

If an ANDA or 505(b)(2) application is amended to include a paragraph IV certification, notice must be provided to the NDA holder and patent owner only if the application did not already contain a paragraph IV certification or there was not a full opportunity for a 30-month stay. If an ANDA or 505(b)(2) applicant changes its paragraph IV certification before the 45-day period after notice to the NDA holder and patent owner has expired, and the NDA holder or patent owner has not initiated patent litigation, such paragraph IV certification and related notice are not considered to have satisfied the requirement of providing one notice of a paragraph IV certification and a full opportunity for a 30-month stay.

Generic drug applicants will still have to file paragraph IV certifications to FDA, and the ability of brand-name firms to obtain patents and to defend patent rights in court is undiminished. They will not, however, be able to forestall approval of a generic version of a

drug by submitting later-issued patents. These later submissions will no longer result in multiple 30-month stays.

Requirements for Drug Patent Submissions

Under the final rule, drug manufacturers will not be allowed to submit patent information for listing in the Orange Book for drug packaging, drug metabolites, and intermediate forms of a drug. Permitted submissions include patent information on drug product (active ingredients), drug substance (formulation/composition), and approved uses of a drug.

In addition, patent submission declarations will be more detailed. There are mandatory forms that must be used to submit patent information to FDA. The forms include a series of questions with check-off boxes to be completed that provide details on the type of patent information submitted. The questions request information on whether the patent is one of the type permitted under the regulations, whether the patent is a product-by-process patent and the product claimed is novel, whether the method of use is an approved method of use and the relevant indication included in the approved labeling, and other relevant information.

The declarations must be filed with the NDA, amendment, or supplement, and for patent information submitted after NDA approval. The check-off questions are designed so that FDA does not have to do anything more than quickly review the form to determine whether the patent information is eligible for listing. A signed attestation is required on the declaration form that requires that the submitter attest to the familiarity with the regulations and the information submitted. A warning is included that a willfully and knowingly false

statement in the attestation can lead to criminal charges. These changes will significantly reduce opportunities to submit inappropriate patents for listing in order to delay approval of generic drugs and prevent fair competition

INITIATIVE ON IMPROVING ACCESS TO GENERIC DRUGS

Concurrent with FDA's June 12, 2003, announcement on publication of its final rule, President Bush announced an initiative on Improving Access to Generic Drugs, which includes the following components:

- A proposed increase of $13 million in fiscal year 2004 in FDA resources devoted to improving access to generic drugs.

The proposed addition in the President's fiscal year 2004 budget of an additional $13 million in spending for FDA's generic drug programs would be the largest annual infusion of resources into the generic drug program ever, increasing the program's size by about one-third. FDA would be able to hire about 40 additional staff in generic drugs and expand the new chemistry review division in the Office of Generic Drugs. This expansion should help reduce the average review time by at least two months, increase the percentage of reviews that are completed within 180 days, approach the goal of reviewing 100 percent within 180 days and further reduce the time it takes FDA to review.

- New processes to reduce the time and cost of generic drug approvals.

Beginning in the next fiscal year, FDA will make significant changes in its processes for approving generic drugs. In particular, FDA will implement early communications with

generic drug manufacturers to discuss their applications. FDA will increase the number of guidances available for generic manufacturers regarding what is required to prepare and submit quality, complete applications. FDA will also institute regular meetings with generic trade associations to discuss the process for improving the quality of applications and to impart information on changes in policies and procedures. Studies of FDA processes for new drugs indicate that early communications and more explicit guidances can often improve drug applications and allow deficiencies to be corrected while an application is under review, rather than having to wait for additional review cycles to fix problems. This can significantly reduce the time it takes to approve a drug.

- Enhanced public education and scientific study of generic drugs.

FDA will expand its educational programs and partnerships involving generic drugs to help health care practitioners and consumers get accurate information about the availability of generic drugs for health care needs. FDA will also undertake additional scientific studies of certain types of generic drugs where adequate bioavailability methods have not been adequately developed, to make it easier to approve these generic drugs. FDA will also enhance the monitoring of the safety of generic drugs currently on the market.

These steps to improve access to generic drugs are expected to reduce the average time for most generic drug approvals by three months or more. Because this approach to increase availability will apply to all generic drugs, it can have a substantial impact on health care costs. In particular, faster access and a lower-cost approval process for the hundreds of generic drugs expected to come on the market would be expected to save consumers many

billions. Improved consumer education and generic drug science is also intended to lead to additional savings from greater confidence and use of generic drugs.

OTHER SIGNIFICANT BARRIERS TO GENERIC DRUG AVAILABILITY

Although patent-related challenges have delayed approval of generic drugs in a number of high-profile cases, there are a number of other important barriers to generic competition. These barriers, which usually result from insufficient scientific knowledge and standards, are likely to become even more significant as scientific advances in drug development lead to new forms of therapy.

Currently, some classes of drug products entirely lack generic versions because scientific methods for evaluating their bioequivalence are not available. Examples include the nasal and inhaled corticosteroids used for allergy and asthma treatment. Prospective manufacturers of inhaled or topical generic drugs face uncertainty and high development costs, and thus few such products have been developed. Other widely used drugs, such as conjugated estrogens (available since the 1940s), lack generic competition due to scientific uncertainty about the composition of the active ingredient (s). Disputes over composition and bioequivalence standards also have caused delays in approval of many generic drugs while innovator challenges to the standards are evaluated. Scientific research to support the development of additional standards in these areas would enable FDA to approve drugs in additional classes, and also to address scientific challenges to pending generic drug approvals more expeditiously.

Innovations in drug therapy are leading to new methods of drug delivery, including via liposomes, implantable systems, transcutaneous or transmucosal products, and inhalation methods. At the same time, due to innovations in chemistry, drugs with very complex molecular structures are possible. If generic copies of such innovative therapies are eventually to be made available, standards must be developed to accommodate these products within the Hatch-Waxman framework. This includes work on issues of composition, formulation and bioequivalence. Scientific research in each of these areas is needed to support new standards.

A significant portion of the FY 2004 budget increase for the generic drug program noted above will allow for additional bioequivalence research on inhalers, topical generics, and other dosage forms, so that in the future, new classes of generics can be made possible. This is a long-term research activity that will take time and a lot of effort, but FDA is dedicated to opening up these new product areas.

RECENT CONGRESSIONAL ACTION ON GENERICS LEGISLATION

Both the Senate and the House have added generic drug access provisions to their versions of the Medicare bill, which have passed both chambers and are currently in conference. We are pleased that both versions of this legislation include key ideas embodied in FDA's regulation to improve access to generic drugs, and do not include certain other problematic provisions contained in legislation (S. 812) that passed the Senate last year.

Summary of the Generic Drug Amendment to the Senate Medicare Bill (S. 1)

The Senate bill amends the existing statutory 30-month stay in the following ways:

- requires the ANDA[2] applicant to provide notice to the patent owner and NDA holder within 20 days after the applicant is notified that FDA has filed its ANDA when the applicant has submitted a certification that can trigger a lawsuit and resulting 30-month stay;
- limits the patents eligible for the 30-month stay to those submitted to the Agency prior to submission of the ANDA, disallowing later-submitted patents from triggering additional 30-month stays;
- permits approval of an ANDA if, before any 30-month stay expires, a district court finds the patent invalid or not infringed, or if a district court judgment finding the patent infringed is overturned on appeal, upon judgment of the court of appeals.

The Senate bill also allows an ANDA applicant to file a declaratory judgment action against a patent owner or the NDA holder if no patent infringement suit is brought within 45 days after the applicant provides notice of the certification challenging the patent. The provision seeks to make the failure to file such a suit an actual controversy under the declaratory judgment statute. If a suit is filed, the applicant may assert a counterclaim for an order to require deletion of patent information that the NDA holder should not have submitted for listing in the Orange Book.

The Senate bill amends the existing statutory 180-day exclusivity provision as follows:

- applies exclusivity on a product basis, rather than patent-by-patent basis;

[2] Also applies to applicants who submit applications under Section 505(b)(2).

- allows all ANDA applicants that challenge patents on the first day that ANDAs challenging patents are submitted for a particular listed drug to qualify for exclusivity;
- triggers 180-day exclusivity only with commercial marketing;
- provides for forfeiture of an applicant's eligibility for exclusivity if it does not market the drug within a particular period of time or after courts resolve the status of the challenged patents, if the applicant withdraws its ANDA, if the patent challenges are withdrawn, if the applicant fails to obtain tentative approval within 30 months, if the applicant enters into an anticompetitive agreement, or if all qualifying patents expire.

The bill defines bioavailabilty and bioequivalence for non-systemic drugs (those not absorbed into the bloodstream).

Lastly, the Senate bill states that a court may refuse to award treble damages in a patent litigation action if the NDA holder fails to submit a patent to FDA for listing in the Orange Book that claims a drug or a method of using a drug.

Differences between Senate and House Generic Drug Legislation

The House version of the generic drug legislation is very similar to the Senate version described above. The bills differ in the following areas:

- *Approval of a different listed drug* - The House bill prohibits ANDA applicants from amending or supplementing an application to seek approval of a generic drug

referencing a listed drug different from the listed drug identified in the original application. That prohibition does not apply to different strengths. The Senate bill lacks this language.

- *Civil action for patent certainty* - The Senate bill allows the ANDA applicant to bring a civil action for a declaratory judgment that the patent is invalid or will not be infringed if the patent owner or NDA holder does not bring suit within 45 days after notice is received. The House bill is slightly different.

- *Access to confidential ANDA information* - The House bill allows a declaratory judgment action to be brought if the 45 days expires and the notice was accompanied by a document providing a right of confidential access to the ANDA applicant's application for the purposes of determining whether a lawsuit should be brought. The provision sets forth the contents of the document, including restrictions on access to the application and the uses of information obtained through the process. The Senate bill does not contain the confidential access provision.

- *Failure to bring patent infringement action* - The Senate bill makes the failure to bring a patent infringement action within 45 days of notice an actual case or controversy sufficient to confer subject matter jurisdiction on the Federal courts. The House bill does not contain this provision.

- *Treble damages* - The Senate bill provides that in determining remedies for infringement of a patent that claims a drug or a method of using a drug, the court shall consider whether information on the patent was required to be submitted under section 505(b), and if such information was required to be submitted but was not, the court may refuse to award treble damages. The House bill lacks this provision.

- *Filing of certain agreements with FTC* - Both bills contain requirements that certain agreements between generic drug manufacturers and innovators regarding the marketing of a generic drug be filed with the FTC. The House bill requires that certain agreements between generic manufacturers also be filed with FTC, while the Senate bill does not.

Relationship Between the Legislation and the Final Rule

The legislation, included as part of the Medicare bills in the House and Senate, does not address all of the provisions in the final rule. If such legislation were to pass, based on our review, we believe that only the 30-month stay provision of the final rule would be impacted.

CONCLUSION

Greater access to generic drugs will reduce health care costs because the price of generic drugs is typically much lower than the brand-name drug. Reducing expensive lawsuits over drug patents and making the approval process more efficient will also help to lower national

health care costs by reducing the cost of bringing safe and effective generic drugs to market. Thanks to the President's leadership, we are making real progress to build on his initiatives on speeding access to generic drugs by finalizing a generic drug rule that will save consumers $35 billion over 10 years by increasing access and availability to generic drugs.

FDA continues to implement the Hatch-Waxman Amendments exclusivity provisions in the best manner possible given the text and history of the legislation, and the numerous court challenges. In doing so, FDA has tried to maintain a balance between innovation in new drug development and expediting the approval of lower-cost generic drugs, as Congress sought to do in enacting this statute. We are confident that the President's initiative and the Agency's regulatory changes will go far towards achieving these goals, and improving health care outcomes as a result.

Thank you for the opportunity to discuss these important issues with you, and I will be happy to answer any questions you may have.

June 19, 2003

The Honorable Orrin G. Hatch
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20001

Dear Senator Hatch:

It was my pleasure to appear before your committee on June 17, 2003, on behalf of the Generic Pharmaceutical Association, to address the constitutionality of an amendment to the Hatch-Waxman Act. The proposal would allow a generic drug manufacturer who has filed an abbreviated new drug application (ANDA) to seek relief under the federal Declaratory Judgment Act, 28 U.S.C. § 2201, against potential patent infringement claims. This letter follows up on my June 16, 2003 letter to the Senate Judiciary Committee and my congressional testimony of June 17, 2003 that concluded that the amendment in question is clearly constitutional.

I have reviewed a June 6, 2003 letter to Senator Judd Gregg, Chairman of the Senate Committee on Health, Education, Labor and Pensions, from C. Boyden Gray of the law firm of Wilmer, Cutler & Pickering, that raises constitutional concerns about the amendment. While I have the utmost respect for Mr. Gray, I disagree with his conclusions on this issue.

The amendment to Hatch-Waxman would recognize that "an actual controversy" between an ANDA filer and a patent holder would exist "sufficient to confer subject matter jurisdiction in the courts of the United States" if, after 45 days have passed since the ANDA has been filed, the patent holder chooses not to bring a patent infringement action. Mr. Gray argues that the bill represents an unconstitutional effort by Congress to expand Article III's requirement of a live "case or controversy" to include such suits. As his letter argues, "the Bill takes the *absence* of a live case or controversy and *defines* it as an 'actual controversy' under the Declaratory Judgment Act."

I agree with Mr. Gray that Congress cannot expand the jurisdiction of the federal courts beyond the limits established by Article III's case or controversy requirement. The hallmark of the federal judicial system is that federal courts are courts of limited subject matter jurisdiction. The absence of a lawsuit by a patent holder, however, does not compel the conclusion that a suit by a potential patent infringer is unconstitutional. Indeed, as I observed in my June 16 letter, the situation of a manufacturer uncertain as to the scope of a patent was precisely one of the cases that motivated Congress to enact the Declaratory Judgment Act. *See also* C. Wright & A. Miller, Federal Practice and Procedure § 2751. It was because the patent holder could defer the filing a lawsuit to enforce its federal right – which all agree would be an Article III case or controversy – that Congress took the step of allowing potential defendants to bring declaratory

judgment actions. In arguing that the absence of a lawsuit by the patent holder deprives the federal courts of jurisdiction, Mr. Gray is actually criticizing the constitutionality of the Declaratory Judgment Act itself. Of course, the Supreme Court settled this question in *Aetna Life Insurance Company v. Haworth*, 300 U.S. 227 (1937).

I believe that such uses of the Declaratory Judgment Act fall within Article III's case or controversy requirement. As the Supreme Court explained in *Aetna*, "[t]he controversy must be definite and concrete, touching the legal relations of parties having adverse legal interests. . . . It must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." 300 U.S. at 240-41. There are obvious adverse legal interests between the patent holder and the generic drug manufacturer over the validity and application of a patent. The generic drug manufacturer has invested a substantial amount of resources to file an ANDA and to prepare and manufacture the generic drug. The enforcement of the patent could prevent the generic drug company from producing and selling its product, nullifying its investments in research and production, and potentially subjecting any profits to the uncertainty of a future lawsuit. In filing an ANDA, the generic drug company declares its intention and ability to produce the drug, which renders the dispute anything but hypothetical. Were the pioneer drug company to bring a patent infringement action, the case clearly would fall within Article III's arising under jurisdiction.

There is nothing unconstitutional about Congress's desire to make clear that such suits fall within the Article III case or controversy requirement. Indeed, to the extent that there is ambiguity in the manner in which the lower federal courts have applied the Declaratory Judgment Act in patent cases involving generic drugs, it is important for Congress to step in and clarify the law.

Mr. Gray further argues that the amendment is inconsistent with the two part test developed by the U.S. Court of Appeals for the Federal Circuit. As the Federal Circuit has found, in order for a potential patent infringer to have a remedy under the Declaratory Judgment Act,

> First, the plaintiff must actually produce or be prepared to produce an allegedly infringing product. Second, the patentee's conduct must have created an objectively reasonable apprehension on the part of the plaintiff that the patentee will initiate suit if the activity in question continues.

EMC Corp. v. Norand Corp., 89 F.3d 807, 811 (Fed. Cir. 1996), *cert. denied*, 117 S. Ct. 789 (1997). Mr. Gray appears to believe that a pioneer drug producer's refusal to initiate a lawsuit within the 45-day period shows that there is no "objectively reasonable apprehension" of a lawsuit against the generic drug manufacturer, and hence no Article III case or controversy. This conclusion, however, seems to run counter to the cases of the Federal Circuit itself. In applying "reasonable apprehension," the Federal Circuit appears to looks at many different circumstances, short of simply filing a lawsuit. *See Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 889 (Fed. Cir. 1992); *Arrowhead*, 846 F.2d

at 736-39; *Shell Oil Co.*, 970 F.2d at 889; *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993). These cases show that even though a patent holder does not actively seek to enforce its federal patent rights in court, a potential patent infringer may still bring an action under the Declaratory Judgment Act.

As I noted in my earlier letter, even if the amendment were considered inconsistent with the case law of the Federal Circuit, it would still be constitutional on several other grounds. First, it does not appear to me that the Federal Circuit's approach is required by Article III of the Constitution, nor is it demanded by the Supreme Court's interpretation of the Declaratory Judgment Act. The Federal Circuit's two-prong test may be conceived of as an exercise of its discretionary powers under the Declaratory Judgment Act, rather than as a true test of Article III justiciability. The Supreme Court has held that the federal courts may decline to adjudicate a federal declaratory action even if case or controversy jurisdiction exists. *Public Serv. Comm'n v. Wycoff Co.*, 344 U.S. 237, 241 (1952); *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286-87 (1995). As a discretionary refusal to adjudicate declaratory judgment actions, the Federal Circuit's approach is subject to Congress's power to establish federal rules of procedure. The proposed amendment represents Congress's direction that the federal courts adjudicate Declaratory Judgment Act cases in this situation, rather than declining as a matter of prudence.

Second, the Supreme Court has never reviewed the "reasonable apprehension" approach, and therefore the Federal Circuit's test does not represent the last word of the Judicial Branch on the application of the Declaratory Judgment Act in the patent context. As I observed in my earlier letter, Congress has the authority to make its own judgments about constitutional meaning. Congress's authority to interpret the Constitution, which is fundamental to the separation of powers, certainly must include the ability to reject lower court decisions that it believes to be in error. The amendment could constitute a legitimate effort by Congress to trigger Supreme Court review of whether the Federal Circuit has properly interpreted Article III of the Constitution. Of course, this may be wholly unnecessary because the Federal Circuit has yet to hold that the absence of a suit is sufficient alone to destroy an actual Article III case or controversy in a declaratory judgment action.

Please do not hesitate to contact me if I can provide further assistance. Also, please realize that the views I express in this letter are mine alone, and do not represent those of the American Enterprise Institute, where I am currently a visiting fellow, or of the University of California at Berkeley, where I have been a law professor since 1993. I may be reached at 202-862-5819, or at yoo@law.berkeley.edu.

Sincerely,

John Yoo

Professor of Law
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(For the record)

August 1, 2003

The Honorable Orrin G. Hatch
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20001

Dear Senator Hatch:

I have been asked by the Generic Pharmaceutical Association to review the testimony provided to your committee by the Department of Justice on August 1, 2003, concerning the constitutionality of the declaratory judgment provisions of S.1. The proposal would allow a generic drug manufacturer who has filed an abbreviated new drug application (ANDA) to seek relief under the federal Declaratory Judgment Act, 28 U.S.C. § 2201, against potential patent infringement claims. This letter follows up on my June 16, 2003 and June 19, 2003 letters to the Senate Judiciary Committee and my congressional testimony of June 17, 2003 that concluded that the amendment in question is constitutional.

The Senate amendments to Hatch-Waxman would recognize that "an actual controversy" between an ANDA filer and a patent holder would exist "sufficient to confer subject matter jurisdiction in the courts of the United States" if, after 45 days have passed since the ANDA has been filed, the patent holder chooses not to bring a patent infringement action. DOJ's letter asserts that this amendment would unconstitutionally expand the jurisdiction of the federal courts beyond the limits set by Article III of the Constitution. I have reviewed DOJ's letter, and while I have the utmost respect for the attorneys who work in the Office of Legal Counsel (many of whom were my colleagues for the last two years during my service there as a deputy assistant attorney general), I disagree with their conclusion.

Both the Justice Department and I agree that Congress cannot expand the jurisdiction of the federal courts beyond Article III's case or controversy requirement. This is a principle of federal courts law that has existed ever since *Marbury v. Madison*, 5 U.S. (1 Cranch) 137 (1803). We also agree that the Declaratory Judgment Act is constitutional, and has been so upheld by the Supreme Court in *Aetna Life Insurance Company v. Haworth*, 300 U.S. 227 (1937). We also agree that **many cases** filed after the 45-day period would meet Article III's case or controversy requirement. In this class of cases, therefore, the application of the Senate's amendments to Hatch-Waxman would be clearly constitutional.

Where the Justice Department and I differ is whether Congress may extend federal subject matter jurisdiction to the remaining class of cases filed after the 45-day

period. According to the Department, the Federal Circuit's "reasonable apprehension" test – so called because the plaintiff must have a reasonable apprehension that the patent holder will sue – will exclude a certain number of cases that are filed after the 45-day period. In fact, the Department seems to believe that plaintiffs who file after the 45 days will almost never satisfy this test, because "in light of the statutory benefit conferred on the patent owner if it sues within the 45-day period, it is likely that a court would consider the applicant's reasonable apprehension to be diminished if the patent holder does not sue for infringement within that time." I believe that Congress may extend federal subject matter jurisdiction to this class of cases, and that since this category may not be large, the amendment to Hatch-Waxman could not be unconstitutional on its face but only as applied at best.

I believe that the Justice Department's opinion is in error because it does not properly understand why the Declaratory Judgment Act is constitutional, even though it permits suits to occur *before* the holder of the federal right has chosen to bring a lawsuit. The Act allows plaintiffs to bring suit against a defendant who would hold a federal right to seek a coercive remedy against the plaintiff, if the defendant had chosen to bring suit first. Declaratory judgments acts first arose in the states, but it was initially suggested that such cases could not be heard in federal courts due to the case or controversy requirements of Article III of the Constitution. *Willing v. Chicago Auditorium Ass'n*, 277 U.S. 274 (1928). In 1927, however, the Court gave res judicata effect to a state declaratory judgment, *Fidelity Nat'l Bank & Trust Co. v. Swope*, 274 U.S. 123 (1927), and in 1933 it upheld a state court declaratory judgment, *Nasville, C. & St. L. Ry. v. Wallace*, 288 U.S. 249 (1933). Immediately after *Wallace*, Congress enacted the Declaratory Judgment Act:

> In a case of actual controversy within its jurisdiction, ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

Act of June 14, 1934, ch. 512, 48 Stat. 955, codified at 28 U.S.C. §2201(a).

The legislative history of the Act shows that Congress was concerned about the uncertainty in business and legal relations, including the case in which a patent holder chose to delay litigation for patent infringement.[1] Professor Edson R. Sunderland, an advocate of the Act, testified before Congress that:

> I assert that I have a right to use a certain patent. You claim that you have a patent. What am I going to do about it? There is no way that I can litigate my

[1] *See* L. Dolak, *Declaratory Judgment Jurisdiction in Patent Cases: Restoring the Balance Between the Patentee and the Accused Infringer*, 38 B.C. L. Rev. 903, 910 (1997). A comprehensive review of the legislative history of the Act may be found Donald L. Doernberg & Michael B. Mushlin, *The Trojan Horse. How the Declaratory Judgment Act Created a Cause of Action and Expanded Federal Jurisdiction While the Supreme Court Wasn't Looking, 36 UCLA L. REV. 529 (1989).*

> right, which I claim, to use that device, except by going ahead and using it, and you [the patent holder] can sit back as long as you please and let me run up just as high a bill of damages as you wish to have me run up, and then you may sue me for the damages, and I am ruined, having acted all the time in good faith and on my best judgment, but having no way in the world to find out whether I had a right to use that device or not.[2]

The Supreme Court soon made clear that the Declaratory Judgment Act was constitutional, even though the statute extended federal jurisdiction to cases in which the holder of the federal right had not yet sought to enforce it. Finding that declaratory judgment suits met Article III's case or controversy requirement, the Court explained:

> The Declaratory Judgment Act of 1934, in its limitation to "cases of actual controversy," manifestly has regard to the constitutional provision and is operative only in respect to controversies which are such in the constitutional sense. The word "actual" is one of emphasis rather than of definition. Thus the operation of the Declaratory Judgment Act is procedural only. In providing remedies and defining procedure in relation to cases and controversies in the constitutional sense the Congress is acting within its delegated power over the jurisdiction of the federal courts which the Congress is authorized to establish. . . . Exercising this control of practice and procedure the Congress is not confined to traditional forms or traditional remedies.

Aetna Life Insurance Company v. Haworth, 300 U.S. 227, 240-41 (1937). In explaining why the Act did not include cases that were actually unripe or moot, Chief Justice Hughes wrote:

> A "controversy" in this sense must be one that is appropriate for judicial determination. . . . A justiciable controversy is thus distinguished from a difference or dispute of a hypothetical or abstract character; from one that is academic or moot. . . . The controversy must be definite and concrete, touching the legal relations of parties having adverse legal interests. . . . It must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts. . . . Where there is such a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged, the judicial function may be appropriately exercised although the adjudication of the rights of the litigants may not require the award of process or the payment of damages. . . . And as it is not essential to the exercise of the judicial power that an injunction be sought, allegations that irreparable injury is threatened are not required.
>
> *Id.* at 240-41

[2] Quoted in Dolak, *supra*, at 911.

The Justice Department's letter shows no understanding that the very purpose of the Declaratory Judgment Act is to allow relief in cases in which a potential patent infringer needs legal certainty concerning the scope of a patent before it can proceed with its activities. Indeed, the Department's approach would suggest that the Act itself is unconstitutional.

There are, however, obvious adverse legal interests between the patent holder and the generic drug manufacturer over the validity and application of a patent. The generic drug manufacturer has invested a substantial amount of resources to file an ANDA and to prepare and manufacture the generic drug. The enforcement of the patent could prevent the generic drug company from producing and selling its product, nullifying its investments in research and production, and potentially subjecting any profits to the uncertainty of a future lawsuit. In filing an ANDA, the generic drug company declares its intention and ability to produce the drug, which renders the dispute anything but hypothetical. Were the pioneer drug company to bring a patent infringement action, the case clearly would fall within Article III's arising under jurisdiction.

By failing to understand why generic drug manufacturers would suffer uncertainty from the possible enforcement of a patent, the Department errs in concluding that the amendment would be unconstitutional. The Department asserts that the amendment "can have no effect." This is because, apparently, many lawsuits brought after the 45-day period would meet Article III's case or controversy requirement anyway, and those that did not could not fall within Article III jurisdiction thanks to passage of the amendment. But then the Department observes that the lack of a lawsuit within the 45-day period would suggest that there is no "reasonable apprehension" present. The Department's opinion assumes without question that the Federal Circuit's approach to the Declaratory Judgment Act in this context – the "reasonable apprehension" test – correctly includes *all* of the possible cases that would meet Article III's case or controversy requirement, and that application of this test to those who do not sue would likely find no reasonable apprehension. Therefore, according to the Department, cases in which no suit is filed within 45 days indicate that there is no reasonable apprehension of a lawsuit, and therefore that there is no Article III case or controversy requirement.

This view is erroneous, however, because it assumes that any patent holder who does not sue within 45 days will never sue. As Congress itself believed when it enacted the Declaratory Judgment Act, patent holders might choose not to sue in such circumstances for many reasons, such as allowing the generic drug manufacturer to run up potential damages while it risks little, creating uncertainty in the market and among distributors and buyers of the generic drug, and causing uncertainty about the value of investments and research by generic manufacturers. Indeed, testimony before Congress at the time of the passage of the Declaratory Judgment Act underscored that the more time that passed, the more damages that a patent holder could potentially accumulate. By passing the Act, Congress recognized that merely by refraining to exercise their federal rights, regardless of the amount of time that passes, patent holders created sufficient legal and business uncertainty to harm manufacturers such as generic drug producers. It is this harm that brings such cases within the Article III case or controversy requirement. The

Justice Department appears to have no theory as to why any Declaratory Judgment Act case satisfies the Article III requirement, and hence cannot judge whether any new application of the Act would be constitutional or not.

In enacting the Declaratory Judgment Act, Congress did not give any indication that it required plaintiffs to show they had a "reasonable apprehension" of a lawsuit, nor has the Supreme Court ever interpreted the Act to require such a result. Rather, Congress wanted to give those who could be subject to a lawsuit by the holder of a federal right the ability to seek legal certainty for all parties involved, so that business planning and activity could occur in an environment with clear legal rules.

As applied by the Federal Circuit, the "reasonable apprehension" test creates an effect opposite of that desired by Congress. The Federal Circuit appears to employ an inherently unpredictable totality of the circumstances approach to determining whether a potential patent infringer has a "reasonable apprehension" of lawsuit. Such approaches undermine the very purpose of having clear rules in the area of federal jurisdiction, and instead invite wasteful and excessive litigation merely to determine whether a case is appropriately brought in federal court. It is certainly within Congress's authority to seek to correct misinterpretations of its enactments where, as here, the courts have acted in a way that undermines the very purposes of the statute it has passed. By adopting the amendment, Congress would simply be making clear the original purposes of the Declaratory Judgment Act, which the Supreme Court, almost immediately after the Act's passage, had upheld as constitutional. By enacting the amendments to Hatch-Waxman, Congress is appropriately acting to correct a misinterpretation of the Declaratory Judgment Act that goes too far in narrowing its scope. By employing the reasonable apprehension test, the Federal Circuit may be allowing declaratory judgment actions in only a subset of the possible range of cases that could be permitted by Article III's case or controversy requirement. By enacting this amendment, Congress would be instructing the courts that it wishes to expand the exercise of federal subject matter jurisdiction under the Declaratory Judgment Act to the full extent permitted by the Constitution.

This brings me to another reason why the amendment is constitutional. As an independent and coordinate branch of government, Congress certainly has the authority to interpret the Constitution for itself and to base its enactments on that interpretation. This is exactly what happened with the original Declaratory Judgment Act: some doubted whether the potential defendants of enforcement actions could bring a suit seeking a declaration that their actions were legal. Yet, in order to create an environment in which all parties could conduct their activities with legal certainty, Congress enacted the Declaratory Judgment Act. In doing so, Congress acted on its own interpretation of the Article III case or controversy requirement that such suits were constitutional. The Supreme Court subsequently agreed. Congress has even fuller authority where, as here, the Supreme Court as the final arbiter within the federal judiciary has never examined whether Article III or the Declaratory Judgment Act impose any special requirements in patent infringement cases.

Please do not hesitate to contact me if I can provide further assistance. Also, please realize that the views I express in this letter are mine alone, and do not represent those of the American Enterprise Institute, where I am currently a visiting fellow, or of the University of California at Berkeley, where I have been a law professor since 1993. I may be reached at 202-862-5819, or at yoo@law.berkeley.edu.

Sincerely,

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