Testimony of

Mr. Jon Dudas

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STATEMENT OF

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AND
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BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

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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.