UNITED STATES
PATENT AND
TRADEMARK OFFICE

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

July 30, 2002

The Honorable Orrin Hatch
United States Senate
Washington, D.C. 20510

Dear Senator Hatch:

In a few months, the United States Patent and Trademark Office (USPTO) will celebrate its 200th year in existence. During that time, we have been the only Federal agency charged with administering this Nation's patent laws and determining whether inventions are patentable. USPTO plays a critical role in promoting and protecting intellectual property and the work of our Agency helps to stimulate American innovation and investment.

At your request, USPTO is providing its views on the advisability of the changes in patent laws in S. 812, the Greater Access to Affordable Pharmaceuticals Act. This letter is intended to inform you of our objections to the current language in S. 812.

First, in some cases, S. 812 would forfeit unnecessarily the core right of patent holders – the right to exclude others from practicing the invention for the entire patent term. After years of research and development and significant investment, the patent right is extinguished for the mere failure to satisfy an administrative task or respond in a timely manner. For example, if a patent holder fails to list the patent with the Food and Drug Administration within a certain time period, the patent is invalidated. Furthermore, if a patent owner fails to bring an infringement action within 45 days of receiving notice (also known as 'Paragraph IV') from a drug manufacturer that the patent is invalid or not infringed by the generic drug, then the patent right is forfeited. In this circumstance, the patent owner is barred from ever bringing an infringement case in connection with the generic drug at issue.

Second, we are concerned with the bill's disparate treatment of patents depending on issue date. The Hatch-Waxman Act gives a patent holder an automatic 30-month stay to defend a challenge to the patent by a generic drug company. S. 812 would apply this 30-month stay only to patents that issue within 30 days of the new drug application approval. This limitation is arbitrary and unrealistic. The timing of issuance bears no relation to the importance of innovation. Moreover, the patent applicant often has no control over when a patent issues. Therefore, affording certain benefits to patents that issue only within a certain time frame would be unworkable and unjust.

Finally, USPTO believes it is vital to consider each patent rigorously and uniformly to determine whether the application satisfies the standards of patentability. All patent applications are

examined with equal scrutiny and all patents must satisfy the same criteria of utility, novelty, and nonobviousness before they are issued. Each pharmaceutical patent, like all other patents, is entitled to a presumption of validity and should be judged accordingly.

USPTO does recognize that some changes to current law may be necessary to encourage appropriate access to generic substitutes and prevent abuses of the patent laws. But S. 812 clearly is not the answer. In fact, this bill would likely do the opposite of what its title suggests – by limiting access to cutting-edge drugs, decreasing innovation, and ultimately harming the quality of treatments available to patients.

Before considering any future legislative efforts, we should applaud the success of the time-tested Hatch-Waxman Act and respect the delicate industry balance it forged. In all cases, any changes should incorporate the expertise of the Committees on the Judiciary of Congress, in addition to the appropriate Government agencies. Only through a carefully conducted analysis can a result be reached that benefits consumers while promoting the progress of science and innovation.

I hope this information is helpful and I would welcome the opportunity for consultation on future endeavors.

Sincerely,

JAMES E. ROGAN
Under Secretary and Director

cc: The Honorable Patrick Leahy
The Honorable Edward Kennedy
The Honorable Judd Gregg