

Congress of the United States

Washington, DC 20515

November 18, 2013

The Honorable Paul Ryan
Chairman
House Budget Committee
207 Cannon House Office Building
Washington, DC 20515

The Honorable Chris Van Hollen
Ranking Member
House Budget Committee
B-71 Cannon House Office Building
Washington, DC 20515

Senator Patty Murray
Chairman
Senate Budget Committee
624 Dirksen Senate Office Building
Washington, DC 20510

Senator Jeff Sessions
Ranking Member
Senate Budget Committee
624 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairmen Ryan and Murray, and Ranking Members Van Hollen and Sessions:

As you begin the difficult task of negotiating a Budget Conference Agreement, we write to request your assistance in addressing the damage done by the application of sequestration to fee-based federal agencies and programs.

Over the last several years, Congress has passed groundbreaking legislation to promote American innovation such as the America Invents Act and the FDA Safety and Innovation Act. These bills renewed and increased the fees that users pay to the US Patent and Trademark Office (USPTO) and the Food and Drug Administration (FDA) in exchange for services such as patent and trademark review and approval and drug and medical device regulatory review and approval. The fee increases were enacted with input and support from industry and stakeholder groups, who acknowledged the need to provide additional resources to enable the government to perform these important duties.

Unfortunately, sequestration has been applied to these and other fee-based programs, meaning that the higher fees paid by users are not being used for their intended purpose. In Fiscal Year 2013, almost \$150 million in inventors fees were diverted from the USPTO, and FDA has been denied access to nearly \$85 million in industry-paid user fees. By applying sequestration to fee-based agencies, we are going back on the deal we made with those users when we asked them to pay higher fees in exchange for improved service.

We believe that funding for these fee-based agencies is fundamentally different from other government spending and does not contribute to the budget deficit, and thus should not be subject to sequestration. For example, the USPTO is funded entirely by fees paid to the agency by those seeking patents. Congress explicitly intended for these fees to be used solely to carry out the USPTO's operations – not the government at large – to strengthen the intellectual property system the users depend on by enabling the USPTO to function more effectively and to reduce the backlog in patent applications.

The FDA uniquely relies on two-sources of revenue: Congressionally-directed appropriations and user fees. User fees are 100% industry-paid and are targeted specifically for the approval of safe and effective drugs and devices. First introduced in response to dangerously slow approval times for drugs and devices, these fees have come to represent an important collaboration between the FDA and industry.

Congress has recognized the uniqueness of user-fee funding structures in the past. The Statutory Pay-As-You-Go Act of 2010 sought to exempt from sequestration "activities financed by voluntary payments to the Government for goods or services to be provided for such payments" (2 U.S.C. 905 (g)(1)(A)). It is our view that user fees voluntarily paid to the USPTO and FDA fit this description, but the Office of Management and Budget (OMB) has determined otherwise.

A robust intellectual property system is universally recognized as crucial to American economic growth. A strong drug and medical device regulatory regime is essential to protecting the health of patients and ensuring access to innovative new technologies. To achieve these goals, the USPTO, FDA, and other fee-based agencies must have access to all of their user fee revenue.

We ask that your final Budget Conference Agreement clearly state that it is the intent of Congress that user fee revenue should not be subject to sequestration and prevent OMB from applying sequestration to revenue from fees. Such protections are vitally important to our economy and necessary promote American leadership in innovation and protect public health. Thank you for your assistance in this matter.

Sincerely,

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