

# United States Senate

WASHINGTON, DC 20510

September 12, 2011

Ambassador Ron Kirk  
United States Trade Representative  
Office of the United States Trade Representative  
600 17th Street NW  
Washington, DC 20508

Dear Ambassador Kirk,

We understand that the U.S. is hosting the next round of Trans-Pacific Partnership (TPP) free trade agreement negotiations in Chicago this week. While the views of individual members of Congress may differ as to the desirability of these negotiations, we are united in urging you to propose a strong minimum term of regulatory data protection for biologics consistent with U.S. law.

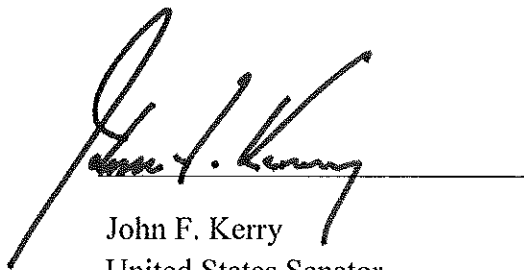
As you are aware, U.S. law provides for a 12-year term of regulatory data protection for biologics and we believe that should serve as the baseline for the administration's objectives for this aspect of the negotiation. This 12-year term was the result of careful deliberations in which the U.S. Congress arrived at a bipartisan consensus taking into account and weighing many factors. It is our view that the agreed upon term of protection best supports the Congress' goals of maintaining the nation's competitiveness as the leading innovator of biologics products, increasing the number of high-value jobs, and improving access to safe and affordable medicines by creating a clear pathway for the regulatory approval of biosimilar drugs.

Because intellectual property rights are a cornerstone for job creation and American competitiveness, we urge you to ensure that the U.S. negotiators are given clear instructions to attain this negotiating objective.

Sincerely,



Orrin G. Hatch  
United States Senator



John F. Kerry  
United States Senator

Tom

Kay L. Hagan

Ray Bent

Barbara M. Kelle

Art P. Brown

Rabit Mering

MM

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