



July 15, 2013

Ambassador Michael Froman
United States Trade Representative
Office of the U.S. Trade Representative
600 17th Street N.W.
Washington, D.C. 20508

Dear Ambassador Froman:

The Biotechnology Industry Organization (BIO) writes to support the effort of the Obama Administration to develop a comprehensive, forward-looking Trans-Pacific Partnership (TPP) agreement. BIO and its members believe a successful TPP Agreement will create an environment that promotes collaboration and innovation throughout the trans-Pacific region. A key element of this environment involves a robust and forward-looking set of intellectual property (IP) standards shared by all TPP members. We look forward to working with you to achieve this important goal.

I have attached to this letter a white paper, prepared by BIO, that provides a comprehensive overview of the considerations related to an area of critical importance to our members – effective legal protections for innovative biological pharmaceutical products. The United States recently adopted a system that enables the Food and Drug Administration (FDA) to approve similar versions of innovative biological pharmaceutical products through an abbreviated regulatory process – referred to as “biosimilars” in the United States, the European Union, and by the World Health Organization (WHO). The U.S. system, as we discuss below, was developed after extensive deliberations by the United States Congress, and balances a number of critically important considerations, particularly the need to provide a continued, robust incentive for development of new biological products and new uses of existing products. We urge you to draw from this record of experience in developing the U.S. system as you engage in deliberations with other TPP countries to fashion international standards that will relate to these products and our industry.

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We, of course, stand ready to work with you to more precisely define the requirements of a viable intellectual property infrastructure for the TPP region, and look forward to your efforts to secure this important objective.

Sincerely,

James C. Greenwood
President & CEO

Attachment