









February 18, 2016

The Honorable Orrin Hatch Chairman Committee on Finance United States Senate Washington, DC 20510

Dear Senator Hatch:

We are writing on behalf of America's most innovative industries to commend your leadership in support of effective intellectual property (IP) frameworks globally and maintaining the ability of U.S. innovators to develop and disseminate solutions to society's greatest challenges. We are concerned that initiatives at certain United Nations (UN) organizations could degrade the global ecosystem for innovation, leading companies to curb investments in R&D and thus depriving people worldwide of critical advances in areas like healthcare and clean energy. Your efforts to safeguard environments that enable innovation, including effective systems for IP protection, will help to enhance development and deployment of critical new technologies globally.

In particular, we urge you to work with the Administration to support an effective interagency approach to safeguard innovation at multilateral institutions. There is a positive precedent for such an approach: recent coordination among the U.S. Department of State, Office of the U.S. Trade Representative (USTR) and the U.S. Department of Commerce at the December 2015 UN Framework Convention on Climate Change (UNFCCC) negotiations in Paris. In Paris, technical and IP experts from different parts of the Administration worked together to secure a final UNFCCC text that does not mention IP and thus removes uncertainty that could have discouraged continued investments by U.S. companies in clean technology.

Significant challenges to IP still remain in the Paris Agreement's implementation and subsequent negotiations—especially those related to the technology development and transfer chapter. Nonetheless, we are certain that the successful UNFCCC outcome on IP in Paris could not have been achieved without close interagency cooperation and collaboration among the U.S. government's technical and IP experts in dialogue with business. This allowed the U.S. delegation to develop and defend consistent negotiating positions that, ultimately, are in the interest of not only U.S. innovators, but also people everywhere who will benefit from clean innovation in the years to come. We would recommend that this coordination continue on other important debates.

Challenges to IP protection are proliferating throughout the UN system, and the approach adopted by the U.S. delegation in Paris could be applied to other UN initiatives, such as the recently announced UN High Level Panel on Access to Medicines (UNHLP). This panel, formed by the UN Development Program (UNDP) in November 2015, will analyze and make recommendations to "remedy the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."

Our member companies welcome a discussion on health innovation and treatment challenges. We are concerned, however, that the UNHLP process will not provide for an informed, balanced, and inclusive dialogue that adequately incorporates the perspectives of innovators. Concerns have already arisen from the lack of transparency regarding the selection of the panel members and experts, the limited scope of inquiry that specifically excludes the broader context needed to understand the complex issues impacting the development and deployment of health-related technologies, and the tight timeline for the Panel's work that allows little room for stakeholder engagement. Based on the lack of balance evident in the background and views of Panel and advisory group members, and as well as the lack of important context about the value of intellectual property in the Panel's supporting documents, it is unfortunately likely that the result of this process, while perhaps well-intentioned, will be ill-informed. This would be a disservice to those countries and stakeholders seeking to enhance the development and consequent dissemination of important healthcare-related technologies.

This is not, however, the only example of a UN institution constraining business involvement to the detriment of innovation. Similar exercises are currently underway in the World Health Organization (WHO) with its "Framework for Engagement with Non-State Actors" (FENSA) as well as in the UN's global Technology Facilitation Mechanism. Inter-governmental organizations that are discriminatory towards business, or that focus on a limited range of factors potentially inhibiting innovation deployment, undermine evidence-based policy-making and hobble the delivery of solutions to healthcare and other sustainability challenges.

U.S. leadership will be essential to managing diverse initiatives across the UN system, such as the UNHLP, to ensure that they do not undermine innovation. All relevant U.S. government

agencies must be aligned in such efforts, and the U.S. delegation must be appropriately staffed with officials from the agencies with IP expertise. This formula was essential to the positive outcome in the UNFCCC negotiations in Paris, and it should be retained as we tackle ongoing discussions that impact technology and healthcare innovation in the United Nations.

Thank you for your time and attention to the leadership of U.S.-financed UN initiatives that directly impact innovative industries here at home. We look forward to further discussion of how to ensure that the U.S. government can speak with one voice in support of pro-innovation policies that are at the very core of advancing human progress.

Sincerely,

Biotechnology Innovation Organization National Association of Manufacturers National Foreign Trade Council Pharmaceutical Research and Manufacturers of America U.S. Chamber of Commerce United States Council for International Business