



March 29, 2018

Ambassador Robert Lighthizer  
United States Trade Representative  
600 17<sup>th</sup> Street NW  
Washington, D.C. 20006

Dear Ambassador Lighthizer:

As the current negotiations to modernize the North American Free Trade Agreement (“NAFTA”) advance to their final stages, ACTION for Trade writes to reiterate the core principles that we believe will be crucial to ensuring that the United States remains a leader in creating better-paying jobs, more exports, and faster economic growth.

The American Creative, Technology & Innovative Organizations Network for Trade (“ACTION for Trade”) is a coalition of like-minded business associations and companies that seeks to advance economic growth based on creativity and innovation through the protection of unique intellectual property (“IP”) in the U.S. trade agenda. In these diverse industries – which span audiovisual, music, and literary content development, production, publication, and distribution; innovative biopharmaceutical manufacturing; and technology and software development – companies rely on the strong protection of their IP around the world, new market access opportunities, and fair international trading rules in order to significantly contribute to the American economy.

Central to our companies’ ability to create new American jobs and export opportunities is the fair valuation and protection abroad of American innovation. As a result, a successfully modernized NAFTA must include strong IP protections, robust enforcement measures, and a level playing field for American companies to compete in the ever-challenging international market.

### **1. Valuing Innovation through Market-based Systems, Transparent Processes, and Accountability**

The extensive upfront, high-risk investments in innovation made by companies in the creative and innovative sectors are enabled by their ability to commercialize the protected products. Appropriately valuing those products through market-based mechanisms and free from restrictions that artificially lower their prices ensures that future investments in new innovation will continue. Harmful policies like reference pricing and ad hoc price cuts are especially prevalent in government regulation of innovative medicines and treatments. For example, current initiatives to intensify pricing regulations, particularly by Canada to its Patented Medicine Prices Review Board, will only serve to further undervalue innovative U.S. medicines.

Pricing policies that promote and appropriately value biopharmaceutical innovation are transparent, efficient, and accountable, and follow market-based principles. This includes requirements for governments to publish rules affecting pricing with a meaningful opportunity for stakeholders to submit comments prior to the rule’s finalization, the ability to appeal such rules, and the completion of these rulemaking processes in a timely manner. Regulatory processes that are transparent,

efficient, and accountable foster private sector innovation and investment. A properly modernized NAFTA will contain provisions that address these dynamics.

## **2. Copyright and Secondary Liability**

Copyright protection and enforcement are vital to the motion picture, television, music, publishing, and software industries. In turn, strong copyright protections and enforcement, which fuel American creativity, are a critical engine that drive U.S. economic growth, job creation, and trade competitiveness. The current NAFTA negotiations offer a tremendous opportunity to generate American prosperity, employment, and trade surplus, and to secure such protections and enforcement in critical markets around the world.

Our concern in NAFTA is the significant extent to which any safe harbor provisions fail to accurately reflect basic aspects of U.S. law, such as the absence of secondary liability (on which the U.S. safe harbor regime is premised). At the same time, we are also concerned that, like the text of the Trans-Pacific Partnership, any such safe harbor provisions would also provide massive copyright carve outs for Canada and Mexico, whose laws are inconsistent with even the minimum standards of U.S. law. Without strong language in NAFTA, Mexico and Canada could become “safe havens” for increased piracy and other forms of illegal content. It is critical that the final language avoid extensive and detailed loopholes contained in any safe harbor provisions that would negate the pro-creativity gains achieved elsewhere in the NAFTA text.

## **3. Patents and Regulatory Data Protection**

Unfair practices by trading partners, including restrictive patentability criteria, long patent application backlogs, unreasonable localization requirements, compulsory licensing edicts, and failures in the area of data protection, have stifled innovation by depriving U.S. businesses of the full value of their efforts.

In addition, it is important to establish regulatory data protection (“RDP”) within our trading partners’ legal regimes that is consistent with the high standard found in U.S. law. To meet that standard, America’s trading partners must provide at least 12 years of RDP for biologic medicines and at least 5 years for small molecule treatments. RDP complements patent protection for innovative medicines. Unfortunately, Canada and Mexico do not provide a level of protection that meets the standard found in U.S. law. Ensuring these patent and related protections is critical for a modernized NAFTA and the continued U.S. comparative advantage in innovation for new treatments and cures.

## **4. Enforcement**

Finally, it is no surprise that counterfeiting and commercial piracy causes a significant drain on the U.S. economy, leading to lost sales for legitimate IP owners, as well as lost tax revenues and duties to the U.S. Government. This results in decreased U.S. employment and diminishes investments in capital improvements and research and development. As a result, there is a critical need to push Canada and Mexico to develop mechanisms to combat illicit activity.

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With the most robust creative and innovative businesses in the world, the United States should prioritize rules in NAFTA negotiations to protect IP and related rights in both actual and virtual marketplaces around the world. This will ensure that the United States maintains its global lead in these industries and will help the U.S. to grow its trade surplus. We look forward to continuing to work with you to achieve these goals as NAFTA modernization advance towards completion.

Sincerely,

ACTION for Trade

Cc: Secretary Wilbur Ross, Department of Commerce  
Senator Orrin Hatch, Chairman, Senate Finance Committee  
Senator Ron Wyden, Ranking Member, Senate Finance Committee  
Representative Kevin Brady, Chairman, House Ways and Means Committee  
Representative Richard Neal, Ranking Member, House Ways and Means Committee