PATENT COALITION

The Honorable Robert E. Lighthizer United States Trade Representative 600 17th Street, NW Washington, DC 20508

January 23, 2020

Dear Ambassador Lighthizer:

As members of the Patent Coalition and others who share the Coalition's concerns, we write to express our dismay that important intellectual property protections negotiated as part of the United States-Mexico-Canada Agreement (USMCA) have been dropped from the final package. We regret that this historic opportunity to protect American innovators against intellectual property theft by foreign competitors has been lost, and we hope that this development will not become a precedent for future trade agreements.

The United States is a global leader in the field of biologics. Nearly 60% of all new drugs worldwide originate in the U.S., and we benefit from the medical advances, job opportunities, and economic growth that come with a vital biotech sector. An astounding 71% of all biologic medicines being developed come from small, emerging biotech companies. More than half (54%) of these biologics are being developed solely by emerging companies, while the remaining are done through partnerships with larger pharmaceutical companies.

These innovators face incredibly long odds. Approximately 90% of all clinical trials will ultimately fail, which means only a small percentage of these projects will ever be approved for patients. However, each project still represents huge private investments for the companies that undertake the necessary research and development. Strong intellectual property protections stand behind this important, life-saving work. That's why, in 2009, Congress adopted a 12-year data exclusivity period for the U.S. that was based on extensive analysis and endorsed with strong bipartisan support. This exclusivity does not prohibit a competitor from doing its own research, development, and application for review and approval in the U.S., Mexico, or Canada.

We are especially concerned about the signal this will send to China and other countries: that the U.S. will not stand behind our companies who develop cutting edge technologies and cures. This failure could result in more piracy of U.S. innovations, and damage U.S. leadership in these sectors. While policy makers often complain that other countries are "free riding" on our investments in innovation, the failure to insist that our trade agreements protect intellectual property will only encourage that conduct to continue.

The Honorable Robert E. Lighthizer January 23, 2020 Page Two

We regret that the important protections you negotiated for biologics were omitted from the final package. It should not be a model for future trade agreements.

Thank you for your consideration.

Sincerely,

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