

# The Importance of Strong Trade Policy in Driving Biopharmaceutical Innovation

The United States leads the world in medicine research, development and manufacturing, and international trade delivers those medicines to patients around the globe. But trade barriers imposed in many countries impede the ability of U.S. biopharmaceutical companies to export even more American-made medicines and employ even more scientists, researchers and factory workers. These barriers include inadequate intellectual property (IP) protection of American innovation and a variety of policies that discriminate against American products.

America's innovative biopharmaceutical sector continues to be one of the most manufacturing- and export-intensive in America. In 2021, U.S. biopharmaceutical goods exports exceeded \$80 billion, and in 2020, the sector was the largest goods exporter among America's most R&D-intensive industries, which also includes navigational equipment, semiconductors, medical equipment and communications equipment.<sup>i</sup> Additionally, the U.S. biopharmaceutical industry is among the top five employers of U.S. manufacturing jobs, with more Americans directly employed in biopharmaceutical manufacturing than in manufacturing in each of the following: iron and steel, aerospace, petroleum and coal, and electric equipment and appliances.<sup>ii</sup>

Trade policy is a vital tool for ensuring that foreign countries protect U.S. intellectual property, value U.S. innovation, provide non-discriminatory and transparent administrative processes, and commit to adopt policies that will expand global access to innovative treatments. Through the negotiation and enforcement of ambitious trade agreements, the United States can significantly expand its exports and U.S. trading partners can become stronger and more reliable partners in promoting and benefitting from today's discoveries and encouraging tomorrow's new medicines and cures.

Importantly, the U.S. government itself must not encourage foreign competitors to take unfair advantage of American innovation. The United States Trade Representative (USTR) recently agreed to waive obligations to protect IP under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for COVID-19 vaccines – a harmful and unnecessary decision. This “TRIPS waiver” decision was made despite the fact that TRIPS protections were essential to incentivize the development of American vaccines, as well as the fact that a global surplus of vaccines existed at the time of the decision – and still does.

USTR's decision to forfeit American IP to countries looking to undermine U.S. leadership in biomedical innovation runs counter to the President's stated objectives concerning the growth of American infrastructure, innovation and employment. Any further effort by USTR to cede American IP to foreign countries is an effort to undercut American innovation and send American research and manufacturing jobs overseas.

Biopharmaceutical innovators depend on strong regulatory systems, robust intellectual property protections and enforcement, and fair and transparent access to overseas markets through the operation of competitive markets or other procedures that appropriately recognize the value of innovative medicines.

America's trade policy should:

- 1. Negotiate new and enforce existing trade agreements** to ensure that our trading partners value U.S. innovation, protect American intellectual property and allow fair market access for U.S. medicines.
- 2. Eliminate government pricing policies that do not appropriately value U.S. innovation** by holding decision-makers accountable to frameworks established under trade agreements.
- 3. Protect American innovation** by ensuring trading partners do not hinder or prevent biopharmaceutical innovators from seeking patents, maintaining or effectively enforcing patents, and protecting regulatory test data.

**4. Reject compulsory licensing**, or the elimination of certain patent rights, by preventing foreign governments from expropriating – or threatening to expropriate – American innovations. Too often compulsory licensing is used as a tool to implement industrial policy or as undue leverage in pricing negotiations between governments and right holders.

**5. Challenge discriminatory localization barriers** by opposing requirements in other countries designed to block U.S. exports and enrich local competitors.

The U.S. government must firmly enforce existing trade obligations and ambitiously negotiate new trade commitments that ensure effective regulatory regimes, the protection of intellectual property and transparent and non-discriminatory pharmaceutical pricing and reimbursement regimes that provide procedural fairness and full market access for American products. The world needs innovation now more than ever. By adopting ambitious policies, U.S. trading partners can help to deliver life-saving treatments and cures to every corner of the world.

i U.S. Census. USA Trade Online: Foreign Trade Data by NAICS.

ii [Labor Force Statistics from the Current Population Survey](#).

