

The Importance of Strong Trade Policy in Driving Biopharmaceutical Innovation

A once-in-a-century global pandemic has reinforced the value of the scientific advances America's innovative and indispensable biopharmaceutical industry made possible. The industry has been working around the clock for more than a year to research, develop and deliver safe and effective therapeutics and vaccines to combat COVID-19. To enhance patient access to innovative medicines during this pandemic and beyond, governments should institute and strengthen policies that incentivize the research, development, manufacturing and trade of new medicines for patients.

The majority of the world's medical innovation occurs in the United States because it supports a market-based policy environment that protects intellectual property, encourages and recognizes the value of medical innovation and facilitates the flow of resources necessary to fuel research and development. As a result, in 2020 alone, America's biopharmaceutical sector generated \$60 billion in exports and supported more than 4 million American jobs.^{1,ii} 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 benefiting from today's discoveries and encouraging tomorrow's new medicines and cures.

Unfortunately, some foreign governments use unfair trade practices to undermine American inventions and disadvantage U.S. companies in foreign markets. In some cases, as with Australia and South Korea, the United States has an existing trade agreement, but our trading partner has not implemented or enforced key commitments. In other cases, as with Japan and India, the country regularly takes actions that fail to value U.S. innovation or that are designed to favor local companies at the expense of U.S. innovators. In either scenario, the U.S. government must hold its trading partners accountable. Millions of jobs in America — and many more millions of patients' lives around the world — hang in the balance.

Some governments are seeking to waive international commitments to honor intellectual property rights for COVID-19 vaccines under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This harmful approach fails to examine and address the real barriers to equitable vaccine distribution and could undermine the global pandemic response.

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 therefore should:

- 1. Enforce existing trade agreements** by ensuring that our trading partners value U.S. innovation and implement and enforce their trade obligations.
- 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. Uphold sound patent law** by not allowing trading partners to infringe or misinterpret rules or diminish or modify globally-defined patentability criteria.
- 4. Challenge illegal localization barriers** by opposing requirements designed to block foreign imports and enrich local competitors.
- 5. 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.

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. In times of crisis like the COVID-19 pandemic, the world needs innovation more than ever. Patents and other intellectual property protections have enabled a rapid response to the coronavirus and can help address future challenges. By adopting these policies, U.S. trading partners can help to deliver life-saving treatments, vaccines and cures to every corner of the world.



i US Census Bureau. U.S. international trade data. [US Census Bureau website](#). Accessed July 2021.

ii TEconomy Partners; for PhRMA. The Economic Impact of the US Biopharmaceutical Industry 2017: National and State Estimates. Columbus, OH: TEconomy Partners.