

THE DANGER OF WAIVING TRIPS INTELLECTUAL PROPERTY RIGHTS AT THE WTO

World Trade Organization (WTO) member states, including the United States, are considering waiving certain intellectual property (IP) rights on COVID-19 treatments, following a harmful and unnecessary decision to do the same for COVID-19 vaccines – referred to as the TRIPS waiver. Any expansion of the TRIPS waiver would have immediate and lasting consequences for global health and America's competitiveness, economic security and innovation leadership.

EXPANDING THE TRIPS WAIVER WOULD...

... compromise global public health and harm patients.

Neither the U.S. government nor American biopharmaceutical companies can ensure the safety, quality or effectiveness of medicines manufactured abroad outside of voluntary licensing agreements. Patients in low- and middle-income countries would be hurt the most since they are most likely to take these medicines without the benefit of oversight by the innovator company, who has the knowledge, know-how and safety and effectiveness data for the product.

... harm global collaboration and undermine U.S. leadership in the biopharmaceutical sector.

- Six in ten Americans are concerned that the TRIPS waiver would exacerbate unfair competition from China (64%) and Russia (58%).
- More than half of Americans are concerned the waiver could undermine both U.S. leadership in the pharmaceutical sector (54%) and the collaboration during COVID-19 (59%) to deliver lifesaving technologies.

... cede American IP to foreign countries, sending research and manufacturing jobs overseas.

Forfeiting commitments to honor IP protections on valuable American technology will harm national economic security and the workers researching, developing and producing medicines, in addition to the workers building plants, producing raw materials and transporting products.

- U.S.-based global biopharmaceutical companies invest 90% of their R&D dollars in the United States.
- The industry spent over \$20 billion on COVID-19 related clinical trials in the United States during the past two years, supporting more than 100,000 U.S. jobs.
- The U.S. biopharmaceutical industry supports 4.4 million American jobs, including more than 900,000 jobs directly in biopharmaceutical companies.

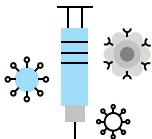
... undercut American innovation and jeopardize our ability to respond to future pandemics.

Leading COVID-19 vaccines and treatments were developed in America. More innovation is still needed. Many existing and investigational COVID-19 therapies are also useful for other diseases – ranging from cancer and HIV to autoimmune and neurological conditions such as Alzheimer's, multiple sclerosis and Parkinson's disease. The waiver discourages the investment necessary to develop new technologies to combat COVID-19 and other health emergencies.

- 28 PhRMA member companies collectively have more than 150 unique products in clinical trials right now to treat COVID-19.
- More than 2,000 clinical trials are under way across the globe to fight COVID-19: 451 investigating vaccines and 1,559 investigating therapies to fight the virus once infected.

GLOBAL PARTNERSHIPS ARE FUELING PRODUCTION OF COVID-19 VACCINES AND TREATMENTS

Biopharmaceutical manufacturers already are sharing their intellectual property (IP) and remain committed to providing timely, equitable global access to safe and effective COVID-19 vaccines and treatments.



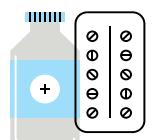
There is no supply shortage for COVID-19 medicines.

- More than 14 billion COVID-19 vaccine doses were produced by August of 2022, and there is existing capacity to produce more than enough to vaccinate the world.
- Production already exceeds demand for COVID-19 treatments for all variants, disease severity and patient settings.
- In fact, vaccine doses have been destroyed or turned away due to low demand, and treatment orders have been reduced.



Global collaboration is still fueling progress in fighting COVID-19.

- According to Airfinity, an international data provider, more than 140 voluntary licensing and manufacturing agreements for COVID-19 treatments have been signed since the start of the pandemic, covering more than half the world's population, to ensure that more than 125 low- and middle-income countries can access needed medical innovation.



Global leaders must focus efforts on the necessary systems to facilitate timely and equitable medicine distribution and administration, including:

- Improving last-mile logistics, such as cold storage and transportation
- Strengthening the health workforce
- Increasing public demand through education
- Removing trade and regulatory barriers, such as export restrictions and medicine tariffs
- Fostering collaboration through mechanisms such as voluntary licensing and technology transfers – enabled by IP rights – to accelerate innovation



The global IP system enabled America's world-leading biopharmaceutical industry to innovate and produce safe and effective vaccines and treatments in record time.

Policymakers should reject any expansion of the TRIPS waiver and focus on last-mile distribution and administration challenges around the world to make a real impact.

BACKGROUND ON THE TRIPS AGREEMENT



The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a comprehensive agreement, signed by the vast majority of countries, establishing minimum intellectual property (IP) protections.

Many WTO members provide IP protections consistent with their TRIPS obligations, establishing the certainty and predictability necessary for innovators to develop new technologies – a process that often requires many years and billions of dollars in investment. By providing a basic global floor for IP standards, TRIPS seeks to ensure that IP rights are enforced across borders and that bad actors do not free ride on the investments of innovators. TRIPS has created the policy environment necessary for the world's technological advancement over the last three decades, and countries seeking to promote and lead innovation, such as the United States, provide IP protections beyond the minimum requirements of TRIPS.

TRIPS is especially important for innovative U.S. industries, such as the biopharmaceutical industry, that rely on strong IP protections to incentivize research, development and manufacturing of cutting-edge technologies, including lifesaving medicines.

Without the strong IP protections provided by TRIPS, modern medical innovation – including vaccines and therapies to combat COVID-19 – would be significantly stymied, and many of the treatments and cures benefiting patients in countries throughout the world today would not exist.

Despite the importance of TRIPS, WTO member states recently agreed to waive certain IP rights under 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 vaccines, as well as the fact that a global surplus of vaccines existed – and still does.

To date, more than 14 billion vaccine doses have been produced, and doses are being refused or destroyed by many of the same governments that demanded the TRIPS waiver.

As public health experts agree, the real barriers to global access to vaccines are last-mile distribution and administration challenges – such as cold storage, transportation and health workforce barriers. Unfortunately – and with tragic consequences for people in countries throughout the world – rather than address these barriers, many governments and public officials prioritized the domestic political objectives of attacking IP rights and championing the TRIPS waiver. Having produced more than enough doses to vaccinate the world, the innovative biopharmaceutical industry encourages serious policymakers to reject any expansion of the TRIPS waiver and instead focus on solving these distribution and administration challenges.