



Three Reasons to Support the TRIPS Decision Extension

Contributing to COVID-19 Test and Treatment Access through Overdue Action at WTO

Backgrounder

November 2023. Contact: Peter Maybarduk, pmaybarduk@citizen.org; Brook Baker, b.baker@neu.edu.

More than a year ago, the World Trade Organization (WTO) belatedly relaxed a narrow band of requirements for “compulsory licensing” of vaccine patents, by which countries may authorize competition to support affordable and diverse vaccine supply. It was a very modest and overdue change considering the urgent needs of global vaccine access and deadly inequity. WTO members committed to keep negotiating whether to extend this decision on COVID-19 vaccines to therapeutics and diagnostics, which typically are simpler to manufacture.

Extending the WTO decision to tests and treatments would support access to medicine by making it easier to export affordable generic versions of patented COVID-19 medicines to developing countries in need. It would help countries aggregate markets and attract generic entrants.

This October, the U.S. International Trade Commission (USITC) published a long-awaited [report](#) on this issue. Access to medicines experts from around the world testified to challenges to treatment access posed by the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). USITC’s 497-page report includes pharmaceutical industry talking points as well. To help sort through the noise, this memo provides three reasons the U.S. government should now support the TRIPS decision extension:

- 1. People worldwide still need COVID tests and treatments. Price is a problem.**
- 2. The extension decision will have essentially no adverse impact on U.S. jobs or the economy.**
- 3. Voluntary measures should be complemented with tools that return power to health agencies.**

1. People worldwide still need COVID tests and treatments. Price is a problem.

The majority of people in most developing countries still lack access to COVID-19 therapeutics and diagnostics. **Sustaining the global fight against COVID-19 today, and expanding test-to-treat, requires funding, affordability, and timely supply.**

- The USITC report notes that “the disparity among countries of different income groups is wide in terms of access and availability to COVID-19 diagnostics and therapeutics.” The report states that “high prices and the lack of price transparency appear detrimental to many countries seeking access.”¹
- COVID deaths are estimated to be [four times higher](#) in poorer countries. Given low vaccine coverage in poor nations, access to tests and treatments is vital to preventing hospitalizations and death.

¹ USITC, COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities, p.16–7.

Manufacturers prioritized high-priced sales to rich countries. Developing countries went without.

- High-income countries, representing 16% of global population, purchased [over 70%](#) of therapeutics.
- The number of people with high-risk COVID-19 infections in low- and middle-income countries (LMICs) exceeded procured supply of Paxlovid by at least eight million courses in 2022. This shortfall late in the COVID-19 emergency left unmet [at least 90% of health need](#) for the WHO-preferred treatment.
- [Recent evidence](#) from Zambia shows that when treatment supply is available combined with support for implementation, more cases are reported, and COVID test-to-treat strategies succeed.

COVID still is a threat.

- New variants, spikes in infections, and waning immunity particularly endanger at-risk populations.²
- Given COVID's unpredictability, it is shortsighted to dismiss access needs for potentially new and better treatments [in the pipeline](#). [WHO](#) and [FDA](#) continue to issue guidance on management of COVID-19.³

2. The extension decision will have essentially no adverse impact on U.S. jobs or the economy.

The extension decision is very narrow and will not negatively impact innovation or R&D spending.

- Makers of widely used COVID products recouped R&D investments many times over through [massive pandemic profits](#). [Over 80%](#) of COVID-19 therapeutics are repurposed, indicating that R&D spending was likely low for initial COVID therapeutics.
- Public investment derisks key investments in candidate coronavirus treatments, for example, hundreds of [millions of dollars](#) already awarded through Project NextGen.
- Products imported under the extension decision cannot be re-exported.⁴ This prevents the sale of goods to developed country markets, further protecting the pharmaceutical industry's most profitable markets.

The decision may expand markets, but it will not negatively impact U.S. manufacturing jobs.

- U.S. manufacturers are not supplying large quantities of COVID tests or treatments to LMICs. Even the products they do sell sometimes are manufactured by contract manufacturers in other countries.⁵ U.S. jobs fundamentally will not be affected by the decision, because any new licenses will supply medicines in LMICs, particularly those excluded from voluntary licenses.
- Prohibitively expensive pricing early in the pandemic suppressed demand, constraining in turn the market for treatments and potentially negatively impacting production jobs.

Pharma deploys exaggerated innovation talking points against every effort to rein in exorbitant drug prices.

- Many drugmakers spend more enriching shareholders through stock buybacks [than supporting R&D](#).

² In their September 2023 [COVID-19 Epidemiological Update](#), WHO stated that "COVID-19 remains a major threat, and WHO urges Member States to maintain, not dismantle, their established COVID-19 infrastructure. It is crucial to sustain, inter alia, early warning, surveillance and reporting, variant tracking, early clinical care provision, administration of vaccine boosters to high-risk groups, improvements in ventilation, and regular communication."

³ The FDA states that "many more therapies are being tested in clinical trials to evaluate whether they are safe and effective in combating COVID-19." It also references that "the FDA continues to work with developers, researchers, manufacturers, the National Institutes of Health and other partners to help expedite the development and availability of therapeutic drugs and biological products to prevent or treat COVID-19."

⁴ Paragraph 3(c), [MINISTERIAL DECISION ON THE TRIPS AGREEMENT](#), 17 JUNE 2022.

⁵ According to the USITC report, the number of manufacturers producing virus-directed COVID therapeutics is substantially higher in UMICs and LMICs compared to HICs, p.148.

- Drug corporations use the same arguments to challenge President Biden’s hugely popular effort to address high drug prices via the Inflation Reduction Act. As the U.S. makes commendable efforts to address pricing and access issues at home, so too should developing countries.

3. Voluntary measures should be complemented with tools that return power to health agencies.

Licensing, especially through health organizations like the Medicines Patent Pool, is an essential tool for accelerating affordable and reliable supply of generic products. However, as documented by USITC, drug corporations exclude many countries from their licenses, and importantly, fail to license many medicines at all.

- Pfizer [excluded more than 50 countries](#) from its Medicines Patent Pool license for nirmatrelvir-ritonavir (Paxlovid), accounting for over half of the world’s population.
- [Unreasonable terms and conditions](#) in voluntary licensing agreements may inhibit generic production. For example, some MPP licensees for COVID antivirals have taken on technology transfer conditions that [exclude supply to certain territories](#), leaving many without an avenue for affordable access.
- Notably, drug corporations’ licenses undertaken outside health-oriented licensing bodies tend to be far less transparent and include more onerous terms.

In absence of a robust generics market for diagnostics and therapeutics, supply that did become available to upper-middle-income countries excluded from voluntary schemes often remained unaffordable.⁶ Secrecy in drugmakers’ supply agreements further suppressed demand and kept prices high.

Compulsory licensing helps ensure affordability and timely supply where voluntary licensing proves insufficient.

- USITC found compulsory licenses are “associated with increased generics and lower prices, and increased access to pharmaceuticals.” The report cites evidence that patent protection “has little to no positive effect for innovation in developing countries and negative effects for access and affordability.”⁷
- Helpfully, the Biden-Harris administration [acknowledged](#) countries’ health interest in compulsory licensing to support production and access, and stepped down [trade pressures](#) against their use.
- Compulsory licenses return power to health agencies to meet access needs and make policy decisions based on health requirements rather than on the goodwill of for-profit corporations.
- At least six countries have issued compulsory licenses for COVID-19 drugs or vaccines, with four more countries that have begun the process but no license has been executed.⁸
- The U.S. also authorized use of inventions without permission of patent holders for COVID-19 vaccines, drugs, tests and other technologies [in dozens of cases](#). The Department of Justice acknowledged this in its [intervention](#) in the Arbutus Biopharma, Genevant Sciences, and Moderna patent infringement case.

COVID-19 health needs, particularly for treatments, still are unmet in developing countries. Early hoarding of medical tools by wealthy countries and opaque practices of drug corporations contributed to this failure. Time was lost debating the initial TRIPS waiver. WTO quickly should extend its decision to include therapeutics and diagnostics. There still is opportunity to build a healthier and more resilient future, including by making it easier for countries to access affordable, timely and diverse supply of therapeutics and diagnostics.

⁶ Pfizer’s paxlovid was priced at over \$500/course in some developed countries and \$250 in some developing countries, these prices are substantially greater than the price negotiated by the Clinton Foundation for generic paxlovid (\$25/course), https://healthgap.org/wp-content/uploads/2023/03/Health-GAP-US-ITC-Submission_baker.pdf

⁷ *ibid.* p.16, 64–5.

⁸ South Centre, <https://www.southcentre.int/covid-19-compulsory-licenses-table-march-2021/> ; Medicines Law & Policy, <http://tripsflexibilities.medicineslawandpolicy.org/>