

International Coalition Letter in Opposition to a TRIPS Waiver

Addressed to:

WTO Director-General Ngozi Okonjo-Iweala
TRIPS Council Chair Ambassador Dagfinn Sørli (Norway)

On behalf of the undersigned 30 organizations from 15 countries, we urge the World Trade Organization member states to oppose efforts to waive the Trade-Related Aspects of Intellectual Property Rights (TRIPS) obligations. Suspending these rights will not result in more vaccines, therapeutics, diagnostics, or other essential tools needed to halt the spread of COVID-19 in the shortest amount of time possible. Instead, the outcome is more likely to freeze investment in similar groundbreaking research and development- limiting the world's capacity to respond to the next health crisis.

Intellectual property rights are part of the solution. The development of the COVID vaccines themselves relied on decades of earlier research secured through patents. On average, 57 percent of phase 3 clinical trials fail,¹ patents that secure ownership of a successful product mitigate this investment risk by allowing innovators to recoup costs and fund future research when a new drug is successful.

This security is absolutely essential. On average, including failures, it costs \$2.8 billion for one successful new drug to make it from development through trials and eventually to a doctor's prescription note.² To the point, only one COVID vaccine and one COVID therapy have been fully approved; while 26 vaccines, 92 treatments, and 54 antivirals have failed or become inactive in the trial process, numbers that continue to grow as the pandemic continues.³ This demonstrates how pharmaceutical development is fraught with risks.

For example, Moderna, responsible for one of the most effective and widely used vaccines, struggled to raise funds to start production before late-stage clinical trials as investors believed an mRNA-based vaccine was "too risky."⁴

¹ <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2565686>

² <https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291>

³ <https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker>

⁴ <https://www.statnews.com/2021/10/26/how-moderna-nearly-lost-the-race-to-develop-a-covid-19-vaccine/>



In addition, the security of ownership offered by intellectual property rights enables the sharing of know-how and technical expertise with manufacturers through licensing agreements. Already billions of COVID-19 vaccines have been produced around the world, including in developing countries such as India and South Africa, through such licensing agreements.

As of March 2022, 10.8 billion doses of COVID vaccines have been administered across 184 countries.⁵ By June 2022, a total of “24 billion doses” are expected to have been produced “at which time vaccine supplies will most likely outstrip global demand.”⁶

In fact, forecasts estimate the world will reach capacity to produce 20 billion COVID-19 vaccines in 2022, three times the amount necessary to achieve the WHO’s call to vaccinate 70 percent of the world population and provide boosters.⁷

It’s clear that the next great challenge of eliminating the threat caused by COVID will be distributing vaccines around the world before they reach their shelf life of 6-9 months. Yet, the World Trade Organization warns several countries continue to impose tariffs, export restrictions, redundant testing requirements, or other trade barriers on inputs for COVID vaccines, therapeutics, and diagnostic tools.⁸ While many have failed to implement fast-track procedures to enable quick delivery and production of essential COVID supplies.⁹ Indeed, nearly two million doses have been destroyed due to drops in vaccine demand, vaccine hesitancy, and poor logistics causing them to expire before being used.

It has been more than a year since the first TRIPS waiver proposal, yet proponents have failed to demonstrate that there is any sizable latent production capacity for COVID vaccines and related supplies that is somehow held back due to intellectual property rights. To the contrary, chief waver proponents have asked biopharmaceutical manufacturers to delay the delivery of vaccines because of oversupply.¹⁰ Regarding

⁵ <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/>

⁶ <https://www.ifpma.org/resource-centre/as-covid-19-vaccine-output-estimated-to-reach-over-12-billion-by-year-end-and-24-billion-by-mid-2022-innovative-vaccine-manufacturers-renew-commitment-to-support-g20-efforts-to-address-remaining-barr/>

⁷ <https://catalyst.phrma.org/new-data-covid-19-vaccine-global-production-capacity-projected-to-exceed-20-billion-doses-this-year>

⁸ https://www.wto.org/english/tratop_e/covid19_e/vaccine_production_report_e.pdf

⁹ https://www.wto.org/english/tratop_e/covid19_e/global_race_infographic_e.pdf

¹⁰ <https://www.usnews.com/news/world/articles/2021-11-24/exclusive-south-africa-delays-covid-vaccine-deliveries-as-inoculations-slow>



intellectual property, they have failed to make the case that the suspension would reduce existing trade barriers that hold back production and distribution of COVID supplies. They have failed to demonstrate that existing TRIPS flexibilities are inadequate. They have also failed to address concerns related to increased risk the waiver would introduce to pharmaceutical research and development. They have even failed to reach an agreement on the conditions in which the emergency-suspension should end.

If the TRIPS waiver moves forward, instead of immediately delivering any sizable quantity of COVID supplies to those that need them, it will launch a year or more of domestic legislative initiatives to suspend current intellectual property laws that comply with TRIPS; and launch funding for production capacity upgrades and reverse-engineering initiatives (that could currently go toward ordering vaccines) for firms that do not have the capacity today to produce the COVID supplies. In that time, world demand for COVID vaccines would have been met by current production estimates.

The main organizations positioned to benefit in the short-term from a waiver are criminal syndicates that market counterfeit, substandard, and stolen medical products. The organizations have already adjusted to the pandemic by introducing fake vaccines, fake vaccination cards, and fake testing equipment¹¹— to the detriment of consumer safety and honest efforts to stop the spread of the virus.

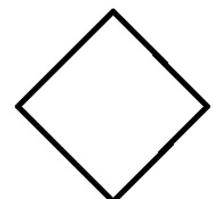
Former Director of the U.S. Patent and Trademark Office Andrei Iancu explains allowing a “free-for-all” with novel vaccine technology could easily lead to the distribution of dangerous and counterfeit vaccines that further diminish health outcomes.¹² Without the quality control embedded in licensing agreements, and reinforced by intellectual property rights, consumers will be unable to differentiate between a legitimate vaccine and fake vaccine.

The lasting effect of the TRIPS waiver, even if eventually a limited time period is agreed, will be the freezing effect on investment for discovery and development of pharmaceuticals. It introduces the additional risk that if a therapy is successful, after decades and billions invested, the World Trade Organization may exercise this power to seize it—even if record quantities are being produced and no plan exists to create more in a shorter time period once the rights are suspended. Today, thankfully, there are several candidates in the development pipeline designed to treat Alzheimer’s, diabetes, and other illnesses the health

¹¹ <https://www.interpol.int/en/News-and-Events/News/2020/INTERPOL-warns-of-organized-crime-threat-to-COVID-19-vaccines>

¹² <https://www.youtube.com/watch?v=4gTiS5Eocrw>

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regulators have called a crisis or an epidemic. In short, the waiver sacrifices a better, healthier, and more prosperous world for a passive present.

WTO member states must focus on addressing the true barriers in the way of producing and delivering as many COVID vaccines and therapeutics as possible in the shortest amount of time. The World Trade Organization has already identified many such trade barriers. Suspending TRIPS protections is not a solution to these known problems. Instead, the suspension of TRIPS will create a health crisis of counterfeit, substandard, and illicit vaccines; and another health crisis in the form of suspending pharmaceutical research and development.

Signed,

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