

A WTO TRIPS AGREEMENT WAIVER TO PROMOTE THE DISSEMINATION OF COVID-19 DIAGNOSTICS AND THERAPEUTICS IS UNNEEDED AND WOULD IMPOSE HARM

Submission for U.S. International Trade Commission fact-finding investigation, *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities* (Inv. No. 332-596).

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INTRODUCTION

We are pleased to respond to the solicitation for written submissions to help inform the U.S. International Trade Commission (the Commission), as it considers its response to the Office of the U.S. Trade Representative’s request that the Commission conduct an investigation and prepare a report that analyzes the universe of existing COVID-19 diagnostics and therapeutics (hereinafter “medicines”) in relation to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). We trust that the views we express may prove helpful to the Commission.

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We wish to address the following: To what extent would a waiver of TRIPS intellectual property (IP) protections—in particular, patent protections—be useful in improving access to COVID-19 medicines?

We raise two key points for the Commission’s consideration:

1. The case of harm due to TRIPS IP protections for COVID-19 medicines has not been proven.
2. There is substantial evidence that a TRIPS waiver for COVID-19 medicines would impose harm.

Hence, there is no need for a waiver of such protections.

THE CASE OF HARM DUE TO TRIPS IP PROTECTIONS FOR COVID-19 MEDICINES HAS NOT BEEN PROVEN

Waivers of TRIPS IP protections would be unprecedented. Accordingly, a waiver of such protections for COVID-19 medicines should not be granted without sound justification.

We are unaware of any evidence that anyone was harmed from lack of access to patents covering COVID-19 vaccines prior to the June 2022 TRIPS waiver applicable to those vaccines.¹

Instead, the evidence suggests something quite different: key factors explaining the low vaccination rates in developing countries and associated harm from lack of access to vaccines were due to misinformation about COVID-19² and limitations on logistics, transportation, storage (e.g., refrigeration needed to store vaccines), and production (e.g., limitations due to the challenges inherent in producing complex biologics and pharmaceuticals).

Data show that 635 million doses were purchased with World Bank financing, but only 503 million doses were delivered with that financing.³ These figures prove that limitations on COVID-19 vaccinations were less about a patent-specific constraint on the supply of vaccines to developing countries and more about infrastructure constraints on getting the shots in people's arms. Indeed, if all purchased doses have been delivered, we would expect that patents is the problem limiting the supply of vaccines.

There is bipartisan agreement by knowledgeable former senior officials that patent protection has not been responsible for any limitations on COVID-19 vaccine distribution. Former Secretary of Commerce Gary Locke (Obama administration), joined by former Patent and Trademark Office directors David Kappos (Obama administration) and Andrei Iancu (Trump administration),⁴ authored a November 2021 report dealing with the international dissemination of COVID-19 vaccines. They explained why patent protections had no effects on the distribution of COVID-19 vaccines:

The truth is that every qualified manufacturing facility on the planet is churning out as many Covid-19 shots as is safely possible. In fact, researchers at Duke University's Global Health Innovation Center estimated that global manufacturers are on track to produce enough vaccines to inoculate 70 percent of the world's adult population by the end of 2021. Far from stymieing vaccine distribution, IP protections have made this previously unthinkable pace of production

¹ See World Trade Organization, "Draft Ministerial Decision on the TRIPS Agreement," June 17, 2022, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True>. This was the first WTO waiver of IP protections in the history of the TRIPS Agreement.

² An empirical study indicates that misinformation may have had a substantial impact on decisions not to vaccinate, particularly in lower per-capita income countries. See Singh et al., "Misinformation, Believability, and Vaccine Acceptance over 40 Countries: Takeaways from the Initial Phase of the COVID-19 Infodemic" *PLoS ONE* 17, no. 2 (February 2022): e0263381.

³ World Bank, "World Bank Support for Country Access to COVID-19 Vaccines," accessed May 4, 2023, <https://www.worldbank.org/en/who-we-are/news/coronavirus-covid19/world-bank-support-for-country-access-to-covid-19-vaccines>.

⁴ The Patent and Trademark Office (PTO) is supervised by the commerce secretary.

possible by ensuring that those facilities licensed to produce the vaccines worldwide can meet the rigorous standards of the vaccines' developers.

Waiving IP protections would not lead to the manufacture of a single additional dose of a vaccine. One key reason is that there is currently no capacity to make more; production facilities are running at full tilt, and the supply of key ingredients in the manufacturing process has already been fully tapped. Before the pandemic, the world collectively produced about 5 billion vaccine doses annually for maladies such as the measles, polio, and chickenpox. People still need those shots, but now we need 14 billion doses of the Covid-19 vaccines, too.⁵

Consistent with this analysis, former PTO Director Iancu pointed out that there is no evidence that COVID-19 patentees have unreasonably refused licenses to their IPs, or that more facilities could have manufactured a vaccine more rapidly if they had had the intellectual property. He noted:

The issues about making more vaccines and distributing them to every country are far more complex than those proposing to waive intellectual property rights on these vaccines would have us believe. Manufacturing and distributing these vaccines is extremely complicated, posing issues well beyond patents.

Almost every factory on the planet that can make these vaccines is already doing so. One of the biggest, the Serum Institute in India, has contracts with AstraZeneca and others to make millions of doses. Under deals like these, manufacturing plants in India will produce 3.6 billion doses of vaccine this year, second only to the United States.

Other companies have licensed their manufacturing process to subcontractors, and even to competitors. Johnson & Johnson and Merck are teaming up to expand manufacturing capacity of the J&J vaccine. Novartis and Sanofi are using their facilities to help increase the production of the Pfizer/BioNTech vaccine.⁶

In short, there's robust collaboration and cooperation within the industry to ensure that vaccines are made quickly and safely. And patents actually facilitate such cooperation, because each entity can rest assured that its proprietary technology is protected in the long run.

Consistent with the nature of these constraints on vaccine availability, there is no evidence that any unmet demand for COVID-19 diagnostics and therapeutics is due to lack of access to patented technology. Hence, there is no case for a TRIPS waiver of IP protection for COVID-19 medicines.

⁵ Gary Locke, Andrei Iancu, and David J. Kappos, *The Shot Heard around the World: The Strategic Imperative of U.S. Covid-19 Vaccine Diplomacy* (Washington, DC: Center for Strategic and International Studies, November 2021; internal citation omitted).

⁶ Andrei Iancu, "No Evidence that Patents Slow Access to Vaccines," *STAT*, April 13, 2021.

THERE IS SUBSTANTIAL EVIDENCE THAT A WAIVER OF TRIPS IP PROTECTIONS FOR COVID-19 MEDICINES WOULD IMPOSE HARM

A patent waiver would reduce incentive for future R&D, which in turn would decrease the probability of preparedness for the next pandemic. As the Bloomberg School of Public Health at Johns Hopkins University stated, “thanks to decades of research and innovation, mRNA vaccine technology was ready.”⁷

It is worthwhile to review the history of mRNA vaccine technology to fully appreciate the essential role of private sector research and development. Although public investment is important, without strong incentives for private investment, key risk-taking required to produce the vaccines would not have occurred.⁸ An estimated \$31.9 billion of US public investment went toward developing, producing, and purchasing mRNA vaccines during the pandemic. But most (92 percent) of that \$31.9 billion went toward securing a guarantee for two billion vaccine doses if the vaccine was effective. Only \$2.7 billion of those funds or 8 percent supported mRNA R&D, clinical trials, and manufacturing investment. Billions of additional dollars were invested by private sector companies that took the risk on mRNA vaccine technology. Pfizer’s COVID-19 vaccine was the first mRNA product to achieve full FDA approval in the United States.

As is well-documented in the literature and most recently by author Jonathan Barnett,⁹ investors put resources into R&D because of the profit incentive. Removing the profit incentive diminishes the incentives for R&D. Without those incentives and the competitive research system those incentives bring about, it is extraordinarily difficult to argue that the world would have had the mRNA vaccine in the record time that was achieved.

More generally, a 2020 Council of Economic Advisers report¹⁰ highlights and documents the role of the US patent-based incentive system in bringing forth pharmaceutical products that benefit the entire world and the threats to that role posed by foreign price controls. A TRIPS waiver of pharmaceutical patent rights is the ultimate form of underpricing, because it would give third parties access to the costly development of technology *for a price of zero*. Zero pricing would do great damage by reducing incentives for the costly R&D needed to develop future lifesaving innovative vaccines and drugs. Once an unexpected waiver for a major class of drugs and vaccines is granted, the longstanding TRIPS-based understanding that IP rights on future pharmaceutical innovations will be protected is effectively

⁷ See Chris Beyrer, “The Long History of mRNA Vaccines,” Johns Hopkins Bloomberg School of Public Health, October 6, 2021.

⁸ See Thomas Cueni, “How Did Private Sector Invest in mRNA Vaccines? A Part of the Story Not to Be Missed,” *Pulse*, March 9, 2023.

⁹ Jonathan Barnett, *Innovators, Firms, and Markets: The Organizational Logic of Intellectual Property* (Oxford, England: Oxford University Press, 2021).

¹⁰ As the report stresses, “[t]he U.S. Government and the biopharmaceutical industry have been critical to improving health worldwide by leading the way in the research and development (R&D) that enables drug discovery. In contrast, foreign countries often do not make equal investments in the R&D that is necessary to fuel innovation and ensure the economic viability of biopharmaceutical products.” Council of Economic Advisers, *Funding the Global Benefits to Biopharmaceutical Innovation*, February 2020, 1.

shattered. The inevitable result will be a slowdown in new treatments and cures, to the detriment of patients around the world.

There is substantial evidence that a TRIPS waiver could impose harm on companies, future innovation, and the provision of healthcare and therapies in both developing countries and industrialized countries, including the United States. In particular, it would unjustifiably harm the competitive position of US drug manufacturers, which are world leaders in developing new lifesaving vaccines and medicines. Locke, Iancu, and Kappos summarize the evidence that underscores these concerns with respect to COVID-19 vaccines—evidence that applies in equal measure to COVID-19 medicines:

While voiding IP protections would not increase vaccine production, doing so would strike a severe blow against the United States' world-leading biotech industry—and the incentives to discover cures for dreaded diseases and future pandemics. Abraham Lincoln once described the U.S. system of IP rights as adding “the fuel of interest to the fire of genius.” Today, these laws underpin our entire innovation ecosystem. They are a chief reason the United States is home to the most advanced pharmaceutical companies, scientists, and laboratories in the world. Indeed, it was U.S. laws protecting IP that created the huge competitive advantages U.S. companies enjoyed in pursuit of Covid-19 vaccines.

The United States' IP protections reflect the nation's respect for science and scientists. Americans know how important and difficult scientific research is. Ensuring that scientists can benefit from their discoveries is not greed or selfishness; it reflects appreciation for the people and institutions whose breakthroughs benefit everyone else.

Estimates of the cost of taking a drug to market—a years-long process of lab testing and clinical trials that most often end in failure—range from \$1 billion to \$2.8 billion. The entire research and development process for a single drug often lasts a decade or more. Without IP protections, companies would hesitate to make the enormous investments in research and development modern science requires.

The U.S. commitment to IP also makes science a national strength. History demonstrates that the humanitarian rewards of open inquiry outweigh the political risks—but only for societies unafraid of the scientific method, which, by definition, involves failure and risk. The United States embraces such failure and risk.

Because the United States is responsible for the lion's share of pharmaceutical innovation, relinquishing its IP will not lead to more medicines globally. It will lead to less research and development and ultimately fewer medicines—to say nothing of the impact on the U.S. economy and one of its most important industries. Today, the biopharmaceutical industry supports more than 4 million American jobs and employs people at twice the average private-sector wage. It accounts for more than \$1 trillion in annual economic output. Every single one of those jobs and every dollar of GDP this sector produces is derived from IP—and the fact that it is

protected worldwide. After U.S. drug companies' triumph against Covid-19, a forcible surrender of their new knowledge would hamstring both economic growth and scientific inquiry.¹¹

CONCLUSION

There is no evidence that IP protections have limited the availability of COVID-19 vaccines and medicines. Accordingly, a waiver of TRIPS IP protections applicable to COVID-19 medicines would be unjustified. Furthermore, such a waiver would impose harm by reducing incentives for the investment needed to generate the creation of new treatments for COVID-19 and other diseases. In sum, we submit that granting a TRIPS IP waiver for COVID-19 medicines would be an unsound public policy.

¹¹ Locke, Iancu, and Kappos, *The Shot Heard around the World*, 5 (internal hyperlinks omitted).