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Judge Paul Michel (Ret.), Board Member
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Frank Cullen, Executive Director

December 4, 2023

The Honorable Joseph R. Biden
President of the United States
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear President Biden,

We are writing to urge you to oppose the World Trade Organization's proposed waiver of intellectual property rights for Covid-19 therapeutics and diagnostics. The waiver would imperil American medical research and economic growth while hindering our global competitiveness.

The Council for Innovation Promotion is a bipartisan advocacy group chaired by two former directors of the U.S. Patent and Trademark Office, appointed by presidents of different parties. We have convened the undersigned group of trade, health, and university technology transfer experts and former senior government officials to impress upon you the seriousness of this matter.

U.S. innovation and global economic competitiveness depend on strong intellectual property rights, which are the most important engine of our technological and scientific prowess.

At the instruction of your administration, the International Trade Commission has completed its fact-finding review concerning the proposed waiver. The ITC report concludes that there are indeed disparities among countries regarding access to Covid-19 treatments and diagnostics, but underscores that these disparities stem from non-IP barriers. On these grounds, we respectfully implore you to oppose the expansion of the TRIPS waiver.

A careful examination of all available evidence should lead you to this decision. The ITC report does not assert that intellectual property protections have contributed to

disparities in access, nor does it conclude that waiving intellectual property rights would reduce existing gaps. Rather, to effectively address this genuine global problem, we must tackle its root causes, which encompass -- among other non-IP factors -- last-mile administration and distribution challenges.

Bolstering the accessibility of Covid-19 treatments and diagnostics worldwide is an important goal and deserves our attention. However, it's essential to consider that the proposal for WTO waivers originated in 2020, a time marked by considerable uncertainty regarding the trajectory of the pandemic -- and access to vaccines, diagnostics, and treatments. Presently, both the World Health Organization -- and you, in your capacity as President of the United States -- have officially determined the pandemic emergency is over.

In this current context, we share concerns that a new waiver -- like last year's decision to pare back patent protections for Covid-19 vaccines -- would actually undermine public health. Such a move would stifle crucial medical research and development, leaving the entire world more vulnerable to future pandemics.

The development of mRNA technology, for which Hungarian-American scientist Katalin Karikó and American scientist Drew Weissman recently won the Nobel Prize, perfectly encapsulates the link between strong intellectual property protections and life-saving innovation. Karikó and Weissman never would have been able to advance their groundbreaking discoveries if the University of Pennsylvania had been unable to secure and license patents on their research. Intellectual property protections provide the necessary certainty for companies to turn promising lab discoveries into real-world products.

The same holds true for Pfizer and Moderna, who were only able to complete the final leg of mRNA research that created the Covid-19 vaccines through exclusive licenses granted by UPenn. Neither company would have marshaled the billions of dollars required for this endeavor without a basic guarantee they could recoup their investment.

Nor would Pfizer have ever invested in Paxlovid, one of the cutting-edge therapeutics potentially subject to this new waiver. It can cost more than \$2 billion

to bring a single drug to market.

Voiding global IP protections for American-made Covid-19 therapeutics and diagnostics would discourage U.S. bioscience firms from developing treatments for new Covid-19 variants -- and other diseases that will inevitably cause future public health crises. If governments and other international member organizations routinely waive these patent protections, American companies will justifiably hesitate to make such investments again.

It would also endanger America's biotech sector and other IP-intensive research industries, which currently support millions of jobs and generate trillions in economic growth. Your administration has taken laudable steps toward strengthening our nation's bioscience industry through programs like the National Biotechnology and Biomanufacturing Initiative. But this proposed waiver would seriously threaten that key program and other similar initiatives.

Moreover, contrary to what some advocates argue, there's no sound public health justification behind the waiver. American pharmaceutical companies manufacturing Covid-19 diagnostics and therapeutics have already entered into more than 400 voluntary licensing agreements with partners on every continent. Pfizer and Merck have also licensed their patents to the United Nations-backed Medicines Patent Pool (MPP), enabling generic producers across the globe to manufacture their antivirals.

That means around 100 low- and middle-income countries can *already produce* effective antiviral therapies for Covid-19. While barriers to access remain a serious problem in much of the developing world, these obstacles primarily stem from logistical challenges -- such as lack of cold storage for treatments and understaffed healthcare workforces. In September 2022, these countries had disbursed just under 30% of the Covid-19 treatments they had available.

We firmly support efforts from your administration and other policymakers to resolve these types of challenges. But needlessly waiving intellectual property

rights for life-saving treatments would do nothing to accomplish that goal.

As a group, we have spent decades shaping policy in Washington and our respective states on both sides of the political aisle. Some of us had the honor of serving alongside you in the Obama administration. Today, we are all united by a common cause -- ensuring that the United States can marshal its scientists' ingenuity to fight the pandemics of today and the public health crises of tomorrow. We urge you to oppose the WTO's proposed waiver, which poses a grave threat to this mission.

Sincerely,

The Honorable Andrei Iancu

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Under Secretary of Commerce for Intellectual Property and Director, U.S. Patent and Trademark Office (2018-2021)

The Honorable David Kappos

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cc:

Secretary Antony Blinken, U.S. Department of State

Secretary Gina Raimondo, U.S. Department of Commerce

Secretary Xavier Becerra, U.S. Department of Health and Human Services

Ambassador Katherine Tai, Office of the U.S. Trade Representative

Director Kathi Vidal, U.S. Patent and Trademark Office

NOTE: The views expressed herein are personal to the signatories, and do not represent the views of firms, companies, institutions, clients, or any others with whom they may be affiliated.