The Honorable Katherine Tai
United States Trade Representative
600 17th Street NW
Washington, DC 20508

February 20, 2024

Dear Ambassador Tai,

As global access to medicines advocates, we write to welcome your decision to respect developing countries' use of health rights under patent rules and to step down U.S. pressure against compulsory licensing of pharmaceuticals, including in the U.S. Trade Representative's Special 301 Report, published annually about trading partners' intellectual property practices. This laudable policy shift will help protect health and fight disease, particularly in developing countries. In addition to refraining from criticizing compulsory and government use licenses, you have also wisely decided not to pursue intellectual property protections and enforcement provisions beyond World Trade Organization (WTO) requirements in bilateral and plurilateral trade agreements.

Compulsory licensing and the government use of patents are critical tools by which countries can overcome high-price patent monopolies that restrict access to lifesaving medicines against conditions ranging from HIV to cancer. Through the grant of a compulsory license, a country can authorize affordable generic competition, typically in exchange for payment of a reasonable royalty to the patent holder. These tools help national health agencies make procurement decisions based on their peoples' health needs, rather than a country's limited ability to pay.

In our work, we all have witnessed developing country health agencies weigh health needs against the criticism and consequences they expect from Washington on behalf of patent-based prescription drug corporations. Your decision to stop criticizing the practice of compulsory licensing demonstrates respect for trading partners' sovereignty and choices to protect health. It gives practical meaning to the U.S. government's often stated position that it respects partners' rights to improve access to medicines through flexibilities in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and to take advantage of the Doha Declaration's reaffirmations of countries' rights to adopt and use compulsory and government use licenses.

This decision also is supported by U.S. domestic policy. President Biden announced in December a framework for the federal use of "march-in rights," or compulsory licensing for publicly funded medicines in the United States. The White House says its policy will:

> "… put drug companies on notice if products developed using federal funds are not made available to the public on reasonable terms, including based on price. The proposal would promote the federal government's ability to license a patent — such as those used to create life-saving drugs — to a competitor with the goal of increasing competition and bringing costs down for families."

We are disappointed by the apparent failure of WTO members including the U.S. to extend the COVID-19 TRIPS waiver decision to diagnostics and therapeutics. USTR had helpfully signaled the Biden

administration's support for the initial waiver on vaccines, acknowledging countries' health interest in compulsory licensing to support production and access. We encourage you to clarify, in this year's Special 301 Report and elsewhere, that U.S. respect for the use of TRIPS flexibilities including compulsory licensing is not limited to pandemics or urgent circumstances, but rather recognizes that flexibilities are available to countries at all times to meet public interest and development needs.

Further, despite the positive changes on compulsory licensing and in trade agreements, the Special 301 Report continues to list countries for other WTO-compliant public health policies, indicating U.S. government concern and thereby seeking to deter certain policies that can support health taking root. The 2023 Special 301 Report raised concerns about standards for patenting, data exclusivity and patent-registration linkage, and technology transfer, among others, all of which are policies that support access to medicines. The Report has also expressed concern about policies promoting local production at a time when the need for expanded domestic and regional manufacturing capacity is being recognized in multiple forums and frequently by this administration.

We urge the U.S. government to embrace the principle of respect by refraining from criticizing countries for adopting and using other TRIPS-compliant policies that support health and access to medicines. We ask that USTR state that policy more publicly and forcibly in this year's Special 301 Report or elsewhere. A public statement from you will go a long way to creating an environment in which health authorities feel free to properly consider the measured use of TRIPS flexibilities when industry's supply, pricing, and distribution practices frustrate achievement of their duties to promote and protect health. It is also possible that more policy space to use flexibilities will result in broader and better use of the voluntary measures that the U.S. supports.

We appreciate these acknowledgments of access to medicines and hope the U.S. government will build on this progress for health.

Sincerely,

AIDS Healthcare Foundation

Amnesty International

Drugs for Neglected Diseases Initiative

Harm Reduction International

Health GAP

NETWORK Lobby for Catholic Social Justice

PIJIP Project on IP and Access to Medicine, Washington College of Law

Public Citizen

Treatment Action Group

Universities Allied for Essential Medicines

Yale Global Health Justice Partnership

Cc:

Gina M. Raimondo, Secretary of Commerce

Stephanie Psaki, U.S. Coordinator for Global Health Security, The White House

Loyce Pace, Assistant Secretary for Global Affairs, Department of Health and Human Services