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For U.S. International Trade Commission Investigation No. 332-596
"COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities"

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Key Message

Speaking on behalf of Health Global Access Project, Inc., I advocate that the findings and ultimate recommendation of this ITC Investigation support a decision and vote by the United State Trade Representative to immediately and unconditionally extending the June 17, 2022 World Trade Organization (WTO) Ministerial Decision on the TRIPS Agreement ('TRIPS Decision') to cover COVID-19 therapeutics and diagnostics. This testimony makes seven key points.

Timely access to affordable therapeutics and diagnostics is just as critical abroad as it is in the U.S. to limit the continuing and damaging health, social, and economic effects of COVID-19. Timely and broad access to covid testing and outpatient antiviral treatment in the U.S. has prevented disease progression and saved thousands of lives. The U.S. has stockpiled almost 24 million treatment courses of Paxlovid and over 6 million Americans had accessed Paxlovid as of December 2022. Access to these same products should be available to all developing countries.

TRIPS Decision should cover existing and pipeline COVID-19 therapeutics and diagnostics, even those with multiple uses. COVID-19 has very uncertain characteristics, with the possibility of new variants, accelerating infections, and increased deaths as immunity weakens. Given the pandemic's unpredictable nature, better tests and treatment for acute infection and long covid are still being discovered. New treatments could also be useful in combination therapies that reduce the risk of drug resistance. Concerns about expanding access to therapeutics with alternative uses are overblown because of the COVID-19 specific field-of-use restriction in the WTO Decision.

In assessing the sufficiency of existing manufacturing capacity, the ITC should focus on actual testing and treatment needs not expressed demand which has been artificially suppressed by high prices, stockpiling by high-income countries, a lack of global support for rollout of test-to-treat programming. Richer countries gobbled up the first six months of production of Pfizer's Paxlovid. Similarly developing-country access to diagnostics has been supressed given huge demand in high-income countries. In both instances, the issue of affordability loomed large, especially in the absence of global funding for purchasing and test-to-treat service delivery. Quantities needed may also increase as treatment indications expand, including for long covid.

There is no doubt that patents have an adverse effect on supply, price, and equitable distribution of COVID-19 diagnostics and therapeutics. Twenty-year patents allow patent holders to decide what quantities are produced, what prices are charged, and who are favoured and

disfavoured buyers. The history of the AIDS movement has shown that facilitating robust generic competition has dramatically expanded supplies, reduced prices a 1000-fold in some cases, and hugely increased the number of people on treatment in developing countries. For small molecule medicines, patents are the key barrier that must be overcome to allow generic production, affordable pricing, and more secure and equitable distribution.

Compulsory licensing to increase supply and price competition is an essential tool for the pandemic response and has been widely used in the U.S., but is challenging to use in developing countries because of long history of rich country opposition. A Knowledge Ecology International study has found dozens of cases where the U.S. used 28 U.S.C. section 1498 to protect biopharmaceutical companeis from infringement claims on covid countermeasures purchased by the U.S. Historically, CLs were broadly used to increase access to HIV antiretrovirals. Nonetheless, there has also been a trenchant history of opposition to the use of CLs by U.S. and European authorities. Use of CLs is also hindered by restrictions on rights to export and thus to aggregate markets that are attractive to generic producers.

Voluntary licenses, tiered pricing, and existing access and donation solutions are not sufficient. There have been some voluntary licenses on COVID-19 therapeutics, including with the Medicines Patent Pool, but most of them exclude 30% of the world's population who live in commercially attractive developing-country markets. Excluded countries are left to predatory tiered pricing policies that often result in disproportionately high prices on a GNI/capita basis. For example, the price of Paxlovid in select developing countries is nearly half or more than in the affluent U.S. Although the cost of production of Paxlovid is estimated at $15 a course of treatment and will be available for $25 from WHO prequalified producers, tiered prices are as high as $340 in some developing countries compared to $529 in the U.S.

Concerns about the Decision's alleged, negative impact on innovation incentives are hugely overblown given the Decision's continued protection of highly remunerative developed country markets and given several CL-for-export pathways that already exist. Over 87.5% of global pharmaceutical sales of IP-protected brands, by value, occurs in developed country markets that will continue to have full patent protection under the extended Decision. Moreover, the Decision only affects COVID-related products and thus does not impact the bulk of profits earned on other IP-protected medicines in developing countries. Thus, the impact of the Decision on innovation incentives is de minimus. Finally, although the Decision would make it easier to export CL-enabled generic medicines to other developing countries, such flexibility already exist to some extent under MPP licenses and Articles 31 and 31bis of the TRIPS Agreement.