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May 05, 2023

Katherine M. Hiner
Acting Secretary to the Commission
U.S. International Trade Commission
500 E. Street, SW
Washington, D.C., 20436

RE: Written Comments for Investigation No. 332-596: *COVID-19 Diagnostics and Therapeutics and Flexibilities Under the TRIPS Agreement*

Dear Acting Secretary Hiner,

Public Citizen submits the following comments regarding the U.S. International Trade Commission's Investigation No. 332-596: *COVID-19 Diagnostics and Therapeutics and Flexibilities Under the TRIPS Agreement*. This submission does not contain CBI. Public Citizen is a nonprofit consumer advocacy organization with 500,000 members and supporters. Public Citizen's Access to Medicines Program works with partners across the United States and around the world to make medicines available for all through tools in policy and law.

Sincerely,

Peter Maybarduk
Public Citizen Access to Medicines Director

Summary for Inclusion in the Report

The intellectual property provisions of the TRIPS Agreement constrain generic competition and rapid, widespread production of therapeutics and diagnostics. This contributes to inequitable global access to COVID-19 medical tools. Extending the June 17, 2022 World Trade Organization Ministerial Decision on the TRIPS Agreement (the 'TRIPS Decision') to therapeutics and diagnostics would simplify efforts to ensure adequate, affordable supply of these medical tools in the years ahead.

There is massive unmet global health need for COVID-19 therapeutics and diagnostics. The world's failure to quickly scale test-to-treat programming has cost many lives. Yet country orders for these medical tools, and other signals of market demand, were distressingly anemic in 2022. For example, the estimated health need for Paxlovid in low- and middle-income countries (LMICs) exceeded market demand by 8,219,833 courses; only 10% of health need was met by the expressed demand of LMICs in 2022. It is important to understand why.

Global demand for COVID therapeutics and diagnostics is constrained by supply challenges - high prices, opaque purchase agreements, and delayed and unpredictable supply. Many patented tools are unaffordable for LMICs, even with industry's tiered and not-for-profit pricing. The secrecy of supply agreements also complicates country procurement decisions. It is challenging for budget constrained LMICs to compete with high-income countries to purchase products in initially limited and/or unreliable supply. An extension of the TRIPS Decision could help facilitate affordable and reliable generic supply.

In addition to supply challenges, LMICs are faced with other access barriers, making it critically important to ensure that countries are able to access affordable supply of diagnostics and therapeutics. Competing health priorities and strained resources limit the ability of governments to prioritize their country's COVID-19 response. There are also knowledge gaps regarding the available health technologies and the value of testing and therapeutics.

Without diverse, affordable, and reliable supply, demand for diagnostics and therapeutics will continue to be far less than health need. Or, put differently, supply will be inappropriate: even where raw production numbers appear high, a late supply of expensive, single-source drugs, sold under concealed conditions, does too little for public health. Patent holders' licensing arrangements can mitigate the problems of monopoly supply over time, but they have fallen far short of unleashing the world's capabilities to manufacture and provide timely and affordable medicines. Voluntary licenses typically contain geographic restrictions, resulting in market fragmentation and gaps in access, particularly for upper middle-income countries.

TRIPS flexibilities including compulsory licensing are critical to fill these gaps and are much more easily applied to therapeutics and diagnostics than to vaccines. But TRIPS rules still needlessly complicate compulsory licensing, making it harder to clear paths to expansive, affordable, global supply. Simplifying TRIPS rules, including through the proposed extension, would help clear paths to generic entry and make it easier for health agencies to meet the extreme, ongoing health needs of the COVID-19 pandemic.

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Intellectual Property Barriers Suppress Market Demand for COVID-19 Diagnostics and Therapeutics

COVID-19 diagnostics and therapeutics are critical to preventing hospitalizations and deaths and ending the pandemic. However, there are extreme disparities in access to these tools across the world. According to the purchase data collected by the Duke Global Health Innovation Center, 74.1% of COVID-19 therapeutics have been purchased directly by high-income countries.[1] However, this data includes 13 million therapeutics (Paxlovid 4 million UNICEF and 6 million Global Fund; molnupiravir 3 million) that are a part of options agreements, and fewer than 300,000 courses have actually been procured by LMICs.[2] So, the reality of the situation is much worse. Additionally, while low- and lower-middle income countries comprise 76.3% of the world population, only 36.9% administered worldwide have been used in these countries.[3] Despite the lack of robust access to diagnostics and therapeutics in non-HICs, the COVID death toll has been estimated to be four times higher in poorer nations than in rich countries.[4] Based on this data, there is clearly great need in LMICs for COVID-19 technologies.

As the USITC considers key demand factors and unmet demand for COVID-19 diagnostics and therapeutics, it is important that the Commission bases the report's definition of demand on population need rather than market demand. Population-based need is determined by the number of infections that would require treatment to maximize the prevention of hospitalizations and deaths.[5] If therapeutic courses and tests were available, population-based need would indicate the maximum level at which they would benefit the population. As the future of the pandemic remains uncertain, it is essential that the health needs of populations are prioritized. However, the number of COVID-19 therapeutic courses and tests being delivered or requested by countries, particularly non-HICs, is significantly fewer than the health need.

Quantifying Market Demand vs. Population-Based Need: Paxlovid in 2022

Pfizer's oral antiviral Paxlovid (nirmatrelvir-ritonavir) has been deemed by the WHO as the best therapeutic choice for high-risk patients with non-severe disease.[6] Despite the potential of Paxlovid to be a game-changer in the pandemic and prevent significant numbers of hospitalizations and deaths, there

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[1] Duke Global Health Innovation Center. (2021). Launch and Scale Speedometer. Duke University. Retrieved from: https://launchandscalefaster.org/covid-19

[2] World Health Organization Therapeutics Dashboard, available at https://partnersplatform.who.int/en/therapeutics-dashboard [accessed February 27, 2023]

[3] FIND COVID-19 Test Tracker, available at https://www.finddx.org/tools-and-resources/dxconnect/test-directories/covid-19-test-tracker/ [Accessed February 21, 2023]

[4] Oxfam. Pandemic of Greed: A Wake-Up Call for Vaccine Equity at a Grim Milestone. 3 March 2022, available at https://oi-files-d8-prod.s3.eu-west-2.amazonaws.com/s3fs-public/2022-03/Pandemic%20of%20greed-Oxfam%20media%20briefing-March2022.pdf

[5] Airfinity. 'WTO TRIPS COVID-19 Tx'

[6] WHO. Therapeutics and COVID-19: Living Guideline, 13 January 2023, available at https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2023.1

has been limited supply of the branded product in LMICs.[7] To illustrate this disparity, we quantified the number of need-based doses that exceeded demand for Paxlovid in LMICs in 2022. This analysis has been updated from our previous submissions, and we continue to encourage the Commission to update, expand, and refine these estimations.

Demand Estimation

The Duke Global Health Innovation Center's Launch and Scale Speedometer (the 'Duke Dashboard') tracks purchases of COVID-19 therapeutics and maintains a dashboard that details data on these purchases.[8] This dashboard is updated regularly and aims to provide a comprehensive record of purchases of COVID-19 therapeutics. However, this data is limited to purchase agreements that are publicly available, and may exclude relevant purchase agreements or information. For example, the Duke Dashboard includes the European Commission's joint procurement contract, announced in late November 2022, for almost 3.5 million Paxlovid courses that participating countries, mostly high-income, will be eligible to purchase.[9] But details on this agreement are scant. While the majority of the courses are likely to be procured throughout 2023, there may be a small number of courses that were procured by European developing countries during December 2022. The Commission could bridge these gaps in the data by inquiring directly with Pfizer and the European Commission about details of the procurement agreements that have been made with LMICs.

As of February 2023, the Duke Dashboard reported that 48,186,517 courses of Paxlovid have been purchased worldwide, with over 70% of the courses having been purchased directly by high-income countries. Lower middle-income countries (Egypt and Ukraine) purchased a total of 320,000 courses and upper middle-income countries (Mexico and Thailand) purchased a total of 350,000 courses.

Two ACT-A partners have entered into an agreement with Pfizer for 10 million courses for LMICs (6 million Global Fund; 4 million UNICEF), which are included in the Duke Dashboard.[10] To our best knowledge, these agreements function as options agreements rather than fully paid-up advanced purchase agreements. The courses available to ACT-A partners are offered to eligible countries and countries then confirm the number of courses that they want to receive, at a price that is based upon the country's income status. With this model, we considered the market demand to be the number of courses that were confirmed by countries, rather than the total amount optioned by ACT-A partners. Using the WHO Therapeutics Dashboard in February 2023, we determined that 2,132,304 courses of Paxlovid have been offered to LMICs by ACT-A, but only 135,120 courses were confirmed.[11] Therefore, although ACT-A partners entered

[7] Just a Quarter of Pfizer's COVID-19 Treatment Orders Will Go to Developing Countries, available at https://www.oxfam.org/en/press-releases/just-quarter-pfizers-covid-19-treatment-orders-will-go-developing-countries

[8] Duke Global Health Innovation Center Launch and Scale Speedometer, available at https://launchandscalefaster.org/covid-19/therapeutics [accessed February 17, 2023]

[9] European Health Union: Commission secures almost 3.5 million COVID-19 treatments through joint procurement contract, available at https://ec.europa.eu/commission/presscorner/detail/en/IP_22_6491

[10] 6 million courses for the Global Fund and 4 million courses for UNICEF

[11] World Health Organization Therapeutics Dashboard, available at https://partnersplatform.who.int/en/therapeutics-dashboard [accessed February 27, 2023]

into an agreement with Pfizer for 10 million courses, we considered the true market demand to be 135,120 courses.

Through the Knowledge Ecology International Paxlovid Procurement Announcement Tracker,[12] we identified one purchase agreement from an upper middle-income country, Malaysia, that has not yet been incorporated into the Duke Dashboard, but is relevant to our analysis.[13,14]

In addition to bilateral and multilateral Paxlovid purchase agreements, it has been reported that Pfizer donated 100,000 Paxlovid courses to the COVID Treatment Quick Start Consortium, an initiative that aims to scale-up access COVID-19 antivirals in 10 partner countries.[15] Zambia was the first country to have received a shipment, getting 1,000 courses near the end of 2022.[16]

Based on the available data, market demand in non-HICs, or the number of treatments that were being ordered or requested, could be defined as the number of courses that were confirmed by ACT-A countries (identified through the WHO Therapeutics Dashboard) combined with non-HIC originator supply deals (identified through the Duke dashboard and the Knowledge Ecology International Paxlovid Procurement Announcement Tracker) and donated courses (COVID Treatment Quick Start Consortium).

It is important to note that we did not exclude purchase agreements that were completed prior to 2022. Additionally, it could be argued that purchases made in late 2022 were reflective of projected health need in 2023. As a result, this estimation of demand could overrepresent the true market demand, when compared to health need, in 2022. Regardless, as Pfizer began negotiating purchase agreements in late 2021 and this analysis was completed in early 2023, we believe that it was a fair estimation of market demand for 2022. We encourage the Commission to explore and refine how "market demand for Paxlovid in 2022" should or should not be limited.

To date, LMICs have ordered or requested 916,120 courses of Paxlovid (Table 1).

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[12] Knowledge Ecology International. Paxlovid Procurement Announcements, available at https://docs.google.com/spreadsheets/d/1fE1sB6VwrrqGTXReJb29IH_b-B6yeOhFRzsg0_D1GrQ/edit#gid=0

[13] The Duke Global Health Innovation Center has indicated that the Malaysia Paxlovid purchase agreement will be included in the dashboard with the next data update.

[14] The Star. 'Covid-19 Watch: 110,000 high-risk patients to get first batch of oral antiviral Paxlovid, says Khairy,' available at https://www.thestar.com.my/news/nation/2022/03/05/covid-19-watch-110000-high-risk-patients-to-get-first-batch-of-oral-antiviral-paxlovid-says-khairy

[15] Reuters. Pfizer donates Paxlovid to group targeting COVID in poorer countries, available at https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-donates-paxlovid-group-targeting-covid-poorer-countries-2022-09-07/

[16] COVID Treatment Quick Start Consortium. Loas, Malawi, Rwanda and Zambia Have Received Oral Antiviral Treatments for High-Risk Patients Through COVID Treatment Quick Start Consortium, available at https://www.covidcollaborative.us/assets/uploads/img/16-March-2023-Press-Release-Laos-Malawi-Rwanda-and-Zambia-Have-Received-Oral-Antiviral-Treatments-for-High-Risk-Patients-Through-COVID-Treatment-Quick-Start-Consortium.pdf

Table 1: Market demand for Paxlovid in non-HICs[17] (courses)

Mexico	300,000
Ukraine[18]	300,000
Courses confirmed from ACT-A	135,120
Malaysia	110,000
Thailand	50,000
Egypt	20,000
Zambia	1,000
Total	**916,120 courses**

Source: Duke Global Health Innovation Center Launch and Scale Speedometer; WHO Therapeutics Dashboard; COVID Treatment Quick Start Consortium; KEI Paxlovid Procurement Announcement Tracker

Need Estimation

To determine the population-based need for Paxlovid in 2022, we consider the total number of infections in LMICs that would have benefitted from the use of Paxlovid had it been available. Paxlovid is indicated for patients with non-severe COVID-19 at the highest risk of hospitalization. While reliably identifying those at the highest risk is challenging, the WHO has determined that patients with older age, immunosuppression, and/or chronic diseases are the typical characteristics of high-risk patients.[19] The lack of COVID-19 vaccination is an additional risk factor that is particularly significant in the non-HIC setting due to the low vaccination rates. Airfinity, a health analytics company, estimated the population need for Paxlovid using the total infections in populations over 65 years old as the measure for high-risk infections.[20] Age is a faulty proxy for high-risk population groups and could result in significant underestimations, particularly in low- and middle-income countries where shorter life expectancies result in a smaller percentage of the population over the age of 65, when compared to high-income countries. This estimate does not capture key population groups that would benefit from Paxlovid, including WHO categories, such as those with chronic diseases under the age of 65. Additionally, due to data constraints, the estimation only spans from the beginning of 2022 through late November 2022. Both of these factors make this figure a significant underestimate of population need.

Airfinity found that from the beginning of 2022 through November 2022, the population need in non-HICs surpassed nine million doses of Paxlovid. When compared to the previous calculation of market demand,

[17] The data in Table 1 is limited to the purchase agreements identified through the described methods. This may not include other purchase agreements between Pfizer and LMICs that are not publicly available.

[18] Ukraine reportedly entered into a supply agreement with Pfizer for 300,000 courses in December of 2021. Pfizer has since reported that they donated 200,000 courses to Ukraine as part of their humanitarian response. It is unclear whether these donated courses are in addition to the 300,000 courses that Ukraine procured in December 2021 or in lieu of the purchased courses. If the 200,000 courses were added to Ukraine's market demand for Paxlovid (resulting in a new total of 500,000 courses for Ukraine), the total market demand of LMICs in this scenario would be 1,116,120 courses, or 12.2 percent of health need.

[19] Therapeutics and COVID-19: Living Guideline, 13 January 2023, available at https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2023.1 [accessed February 27, 2023]

[20] Airfinity. 'WTO TRIPS COVID-19 Tx'

we estimate that only one tenth of population need for Paxlovid could have been met by the expressed demand, and population need exceeded market demand by over eight million courses of Paxlovid (Table 2). This is more than eight million individuals that could have benefitted from a course of Paxlovid, potentially avoiding hospitalization or loss of life.

Table 2: Difference between market demand and population-based need for Paxlovid in LMICs (2022)

Market Demand	Population-Based Need	Need-based courses in excess of demand
916,120 courses	9,135,953 courses	**(8,219,833) courses**

Source: Airfinity; Launch and Scale Speedometer; WHO Therapeutics Dashboard

If the Commission were to replicate this analysis for Paxlovid, other therapeutics, or diagnostics, we encourage an independent calculation of the population need that is based on the *total* number of infections in LMICs that would have benefitted from the use of the technology had it been available. If an independent calculation is not feasible, more complete, and up to date Airfinity data could be used. Also, additional information from Airfinity on their data and calculations could provide a better estimate.

The ACT-A Council Working Group on Diagnostics and Therapeutics also released a report that projected the need for all antivirals in 2023. They estimated an unconstrained need in LMICs for 223 million antiviral treatments in 2023, compared to demand for 31 million treatment courses.[21] This would result in 192 million COVID-19 infections in LMICs that would benefit from antivirals, but will ultimately not have access. Unconstrained need is defined by the Working Group as the "total number of cases in LMICs in the next 12 months, regardless of a country's testing capacity, interest in the product, or capacity to roll it out." It is also acknowledged by the Working Group that actual demand will continue to be much lower than estimated. The methods used by this Working Group could potentially serve as a resource for the Commission in projecting need versus demand.

Given the significant disparity between market demand and population-based need, the Commission has a responsibility to fully consider population need, rather than market demand, when exploring key demand factors, unmet demand, and the market segmentation of global demand. There are a number of factors contributing to the discrepancy between population-based need and market demand that should be explored by the Commission. We will discuss some of these factors below.

Demand is Constrained by High Prices, Opaque Purchase Agreements, and Delayed and Unpredictable Supply

High Prices and Opaque Purchase Agreements

The lack of a robust generics market for diagnostics and therapeutics, in part due to patents, has resulted in prices that are unaffordable for many governments. When diagnostics and therapeutics are

[21] ACT Accelerator. Report of the Access to COVID-19 Tools Accelerator Facilitation Council Working Group on Therapeutics and Diagnostics, available at https://www.who.int/publications/m/item/act-accelerator-facilitation-council-working-group-report-on-diagnostics-and-therapeutics

unaffordable, demand will be suppressed. For instance, a South African senior health official cited the "extremely expensive" price of Paxlovid as a reason that the South African government was not intending to buy the treatment for public sector patients.[22] The Medical Director at Socios en Salud (Partners in Health – Perú) also commented that the organization does not plan to use Paxlovid in the COVID-19 treatment regime if it is too expensive.[23] Additionally, according to a People's Vaccine Alliance report, tensions arose between procurers and manufacturers of antigen RDTs during the early stages of the pandemic because constrained budgets and challenges forecasting procurement resulted in the initially agreed upon volumes exceeding funding amounts.[24]

In 2019, per capita health spending averaged US$36 in low-income countries, US$125 in lower middle-income countries, US$516 in upper middle-income countries, and US$3,243 in high-income countries.[25] For low- and middle-income countries, the prices for diagnostics and therapeutics purchased from the manufacturer would exceed or consume a significant portion of their per capita health spending. Panama, whose classification has shifted from high-income to middle-income and back to high-income in recent years, obtained Paxlovid for US$250, the lowest reported price in a bilateral deal with Pfizer.[26,27] While this price is significantly reduced from the prices paid by some high-income countries, it is nearly 50 percent of the average per capita health spending in upper middle-income countries and 200 percent of the average per capita health spending in lower middle-income countries.

In addition to exorbitant pricing, the lack of transparency in supply agreements prohibits countries from having a sense of the full pricing landscape and complicates the decision-making environment for purchasers. Pfizer has offered Paxlovid to some lower-income countries at a not-for-profit price, which has been speculated to be as high as US$100.[28] Pfizer also has described a tiered pricing scheme whereby prices are negotiated based on a country's income level. But specifics on these prices have not been disclosed.

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[22] S. Africa not planning to buy Pfizer's COVID pill for public sector, available at https://finance.yahoo.com/news/africa-not-planning-buy-pfizers-073311851.html

[23] Matahari Global Solutions. Mapping COVID-19 Access Gaps: Results from 14 Countries and Territories, available at https://app.box.com/s/ewdjytgt0tk0fdgmqnlm4l30hmdyevxw

[24] People's Vaccine Alliance, 'Study on the Availability and Affordability of Diagnostics for COVID-19 and MPOX in Low and Middle-Income Countries' (2022), available at https://peoplesvaccine.org/wp-content/uploads/2023/02/Study-on-the-Availability-and-Affordability-of-Diagnostics.pdf

[25] World Health Organization. Global Health Expenditure Database, available at https://apps.who.int/nha/database/Select/Indicators/en

[26] Consejo de Gabinete aprueba la compra del antiviral Paxlovid de Pfizer, available at https://www.laestrella.com.pa/nacional/220125/consejo-gabinete-aprueba-compra-antiviral-paxlovid-pfizer

[27] Prices for Brazil ($250 asked), China ($282-340), and Thailand ($300) have also been reported.

[28] Pfizer to Supply Global Fund Up to 6 Million PAXLOVID™ Treatment Courses for Low-and-Middle-Income Countries, available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-supply-global-fund-6-million-paxlovidtm-treatment; Pfizer Expands 'An Accord for a Healthier World' Product Offering to Include Full Portfolio for Greater Benefit to 1.2 Billion People in 45 Lower-Income Countries, available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-expands-accord-healthier-world-product-offering

Without this disclosure, prices paid for COVID-19 diagnostics and therapeutics are largely unknown and are reported for only a subset of purchase agreements made. The reported prices are unaffordable for most countries. For low- and middle-income countries that are particularly price sensitive, understanding the full pricing landscape would be a key decision-making factor. These countries are left waiting for a more affordable price or for generics to become available, lowering the number of orders placed (i.e., market demand) below the level of public health need. For example, test-to-treat programs launched by ACT-A partners in early 2021 cited the "complex and evolving landscape of treatments and costs" as a barrier that hindered the introduction of oral antivirals in LMICs. These pilot programs demonstrated that full price transparency and affordable treatments are instrumental factors in generating demand and uptake of therapeutics.[29]

Additionally, the price to the consumer can suppress demand even when country-level procurement costs are non-prohibitive. Recent economic challenges, such as rising inflation, have made it even more difficult for individuals to afford getting tested for COVID-19. In addition to the cost of the test itself, related costs, such as paying for transportation to the hospital or laboratory, are unaffordable for many people in LMICs and have lowered the demand for diagnostics at the community level.[30] As of early 2022 in Zimbabwe, when free tests ran out at the poorly supplied walk-in testing centers, individuals were left to purchase rapid tests in pharmacies for up to US$15 – an unaffordable price for a majority of the population in the country.[31] It is essential that countries are able to procure COVID-19 technologies at a price that allows for public health needs to be met, without exorbitant prices being passed along to individuals.

As rising inflation and increasing levels of public debt in 2022 have put pressure on countries' health spending capacities,[32] diverse and affordable supply is key to bring prices down and generate robust global demand for COVID-19 health technologies.

Delayed and Unpredictable Supply

Low- and middle-income countries have continually fallen to the bottom of the supply chain for COVID-19 technologies. The vaccine apartheid has been widely documented throughout the pandemic, with high-income countries quickly purchasing and stockpiling enough supply to vaccinate their populations multiple times over while low- and middle-income countries received only a fraction of the doses

[29] Report of the Access to COVID-19 Tools Accelerator Facilitation Council Working Group on Therapeutics and Diagnostics, available at https://www.who.int/publications/m/item/act-accelerator-facilitation-council-working-group-report-on-diagnostics-and-therapeutics

[30] UNICEF. Access to COVID-19 Tools Accelerator, Humanitarian Situation Report No. 4, End of Year Report 2022

[31] In Africa At-home COVID Tests are Scare and Expensive, Help May Not Come Until Next Year, available at https://www.pbs.org/newshour/world/in-africa-at-home-covid-tests-are-scarce-and-expensive-help-may-not-come-until-next-year

[32] The World Bank. From Double Shock to Double Recovery – Implications and Options for Health Financing in the Time of COVID-19, available at https://openknowledge.worldbank.org/bitstream/handle/10986/35298/September%202022.pdf?sequence=12&isAllowed=y

needed.[33] Developed countries had the financial capacity to secure advance purchase agreements for vaccines even when the product was still in the research phase.[34] As a result, by August 2021, enough vaccine doses were committed to vaccine the entire global population; however, 39% of these purchase commitments were for countries that comprise just 12.9% of the world's population.[35] These same challenges have been seen in diagnostic and therapeutic supply to LMICs.

For example, soon after clinical studies showed promising results for Paxlovid at the end of 2021, high-income countries began entering into advance purchase agreements with Pfizer for millions of courses. Before any low- and middle-income countries were able to secure supply agreements, nearly 30 million courses – the amount that Pfizer could produce in the first half of 2022 – had already been purchased by HICs.[36] By early September of 2022, it was reported that many LMICs still had no access to the drug.[37] Indeed, Pfizer was still negotiating secretly with ACT-A partners on the terms and conditions of procurement, not finalizing such negotiation until late Q3 2022. Similarly, HICs were able to outbuy LMICs in diagnostics, resulting in restricted supply of diagnostic tools such as PCR machines, test reagents, and consumables before manufacturers could scale up production.[38]

Supply of COVID-19 diagnostics and therapeutics to LMICs has been largely unreliable throughout the pandemic. This unreliable supply has exacerbated the effects of the pandemic in LMICs while also hindering the demand for these technologies. When advance purchase agreements consume the supply for six months and more, as with Paxlovid, LMICs were left to purchase therapeutics that would be unavailable for months, even if Pfizer had finalized its procurement route for LMICs earlier than the fall of 2022. With the unpredictability of COVID-19 case surges and entry of variants, it is challenging for countries with constrained spending capacities to enter into a supply agreement for products with unreliable supply.

Additionally, the effectiveness of current COVID-19 therapeutics is reliant on well-developed test-to-treat strategies, including diagnostic capacity and the immediate availability of therapeutics.[39] An unreliable supply of diagnostics and therapeutics prevents countries from scaling-up the implementation of test-to-treat strategies. The World Health Organization's Access to COVID-19 Tools (ACT) Accelerator initiative

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[33] Prasad S et al. Vaccine apartheid: the separation of the world's poorest and most vulnerable and the birth of Omicron. Ther Adv Vaccines Immunother. 2022 Jul 5, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9272166/

[34] Economic Commission for Latin America and the Caribbean (ECLAC), *Plan for self-sufficiency in health matters in Latin America and the Caribbean: lines of action and proposals* (LC/TS.2021/115), Santiago, 2021.

[35] Ibid.

[36] The Looming COVID-19 Treatment Equity Gap, available at https://www.devex.com/news/the-looming-covid-19-treatment-equity-gap-102816

[37] Why Paxlovid is still not available in many LMICs, available at https://www.devex.com/news/why-paxlovid-is-still-not-available-in-many-lmics-103904

[38] Boro E, Stoll B. Barriers to COVID-19 Health Products in Low-and Middle-Income Countries During the COVID-19 Pandemic: A Rapid Systematic Review and Evidence Synthesis. Front Public Health. 2022 Jul 22, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9354133/

[39] COVID Gap. Pills to People: Accelerating Equitable Global Access to Oral Therapeutics for COVID-19, available at https://www.covidcollaborative.us/assets/uploads/pdf/Covid-Gap-Oral-therapeutics-v8.pdf

has organized Global COVID-19 response and test-to-treat programs, with the support of the U.S. government, many international agencies, and private foundations and funders. This initiative aimed to ensure rapid access to COVID-19 tests, followed by timely treatment, for anyone in the world. But because of the COVID-19 response funding shortfall, the reality of this initiative is a pilot program in 10-20 countries, with hopes to expand.[40] Robust test-to-treat programs are critical in generating demand for COVID-19 diagnostics and therapeutics. Without these programs in place, countries will not have the program capacity to rapidly deploy tests and treatments, so demand will appear lower than public health need, even when supply of products become available. It remains a challenge to fight the pandemic and provide diagnostics and therapeutics, becoming even more important to find affordable solutions from a variety of potential providers.

Other Access Challenges in LMICs Constrain Demand, Making it Critically Important to Facilitate Access to Affordable Generics

In addition to supply challenges – high prices, opacity and delayed and unpredictable availability – that constrain demand, LMICs are faced with other access challenges that make affordable supply vital to achieve global access to diagnostics and therapeutics. For example, competing health priorities and strained resources in LMICs limit the ability of governments to prioritize their country's COVID-19 response, and there are knowledge gaps across developing countries regarding the available health technologies and the value of testing and therapeutics. However, these challenges are not unique to developing countries; vaccine hesitancy in high-income countries has been a major barrier to COVID-19 vaccine uptake, and many high-income countries underspend on healthcare.[41,42] These barriers are important to address, and contribute to the market demand for COVID technologies falling short of need in LMICs, but without affordable and available supply, access will not be achieved.

Strained Health System Capacity

Strained health system resources and capacity in LMICs limits the demand for COVID-19 diagnostic and therapeutic tools. For instance, competing health priorities in ACT-A countries, such as new disease outbreaks of cholera and mpox, limited community interest in ACT-A's efforts to promote trust in COVID-19 tools.[43] Additionally, humanitarian crises such as conflicts and natural disasters impacting regions including Eastern and Southern Africa, the Middle East, and North Africa have exacerbated the challenge for many countries to implement a robust COVID-19 response.[44] During procurement of the vaccine, it was reported that gaps in cold chain and service delivery and insufficient workforce capacity in low- and lower-middle income countries contributed to the discrepancy between the number of available vaccine doses and the amount that ended up in low-income countries.[45] For diagnostics and therapeutics, strained

[40] E.g., The QuickStart Consortium, with partner countries including Ghana, Kenya, Laos, Malawi, Nigeria, Rwanda, South Africa, Uganda, Zambia, and Zimbabwe; https://dukeghic.org/our-work/quick-start/
[41] Aw, Junjie et al. "COVID-19 Vaccine Hesitancy-A Scoping Review of Literature in High-Income Countries." Vaccines vol. 9,8 900. 13 Aug. 2021
[42] Chen, Simiao et al. "Macro-level efficiency of health expenditure: Estimates for 15 major economies." Social science & medicine (1982) vol. 287 (2021): 114270.
[43] UNICEF. Access to COVID-19 Tools Accelerator, Humanitarian Situation Report No. 4, End of Year Report 2022
[44] UNICEF. Access to COVID-19 Tools Accelerator, Humanitarian Situation Report No. 4, End of Year Report 2022
[45] Usher AD. The global COVID-19 treatment divide. Lancet. 2022 Feb 26

health system capacity limits the prioritization LMICs can place on procuring and distributing COVID-19 tools.

Additionally, many LMICs were unprepared to quantify and forecast national needs for diagnostics.[46] It is challenging for countries to make the decision to disburse significant funds for diagnostic tools when there is not a system in place to forecast the amount that is needed. Similarly, when diagnostics are unavailable or underutilized, infections will go unreported. For example, in October of 2021, the WHO reported that only one in seven COVID-19 infections are detected in Africa.[47] Without an accurate estimate of infection-level in a population, the demand for therapeutics will be lower than the true population-based need.

A People's Vaccine Alliance report also highlighted that the demand for COVID-19 diagnostics in low- and middle-income settings is impacted by individuals' demand factors, such as the challenges associated with receiving a positive test.[48] LMICs often do not have the resources or capacity to operate social safety net programs that will address these challenges, such as issues with forgoing wages for many days to isolate due to a positive test. This suppressed demand at the community level will make it challenging for countries to request products at the level needed to meet true public health need.

Knowledge Gaps

Market demand also cannot reach the levels of population health need when there are gaps in knowledge that hinder the use of diagnostics and therapeutics. Matahari Global Solutions, a global health consultancy firm, conducted interviews in 14 countries and reported instances in countries such as Haiti, Madagascar, and Nigeria where health care workers did not have any knowledge of the existence of Paxlovid.[49]

When health care workers and communities are aware of the existence of diagnostics and therapeutics, the demand for these products can still be artificially suppressed by gaps in knowledge of the importance of these tools in combatting the pandemic. According to a 2022 situation report by UNICEF, the level of awareness of the value of diagnostics constrained the provision of diagnostics globally.[50] In September 2022, the ACT-A Working Group on Diagnostics and Therapeutics reported that government officials, health workers, and communities in many LMICs are unaware of the importance of test-to-treat strategies

[46] People's Vaccine Alliance, 'Study on the Availability and Affordability of Diagnostics for COVID-19 and MPOX in Low and Middle-Income Countries' (2022), available at https://peoplesvaccine.org/wp-content/uploads/2023/02/Study-on-the-Availability-and-Affordability-of-Diagnostics.pdf
[47] WHO. Six in Seven COVID-19 Infections Go Undetected in Africa, available at https://www.afro.who.int/news/six-seven-covid-19-infections-go-undetected-africa
[48] People's Vaccine Alliance, 'Study on the Availability and Affordability of Diagnostics for COVID-19 and MPOX in Low and Middle-Income Countries' (2022), available at https://peoplesvaccine.org/wp-content/uploads/2023/02/Study-on-the-Availability-and-Affordability-of-Diagnostics.pdf
[49] Matahari Global Solutions. Mapping COVID-19 Access Gaps: Results from 14 Countries and Territories, available at https://app.box.com/s/ewdjytgt0tk0fdgmqnlm4l30hmdyevxw
[50] UNICEF, Access to COVID-19 Tools Accelerator, Humanitarian Situation Report No. 4, End of Year Report 2022

and COVID-19 therapeutics.[51] Without knowledge of the value of these tools, they will be underutilized and there will be limited community buy-in for initiatives such as test-to-treat.

Intensifying these access barriers that have constrained demand, the World Health Organization has been unable to operate at speed to publish clinical guidance on the use of outpatient antivirals and to prequalify both originator and generic medicines. By the time the WHO published antiviral guidance and the emergency use of Paxlovid and molnupiravir, high-income countries were already several months into their deployment of test-to-treat strategies. WHO was similarly slow in publishing guidance on self-testing, a backbone of test-to-treat programming, and has still not finalized guidance on test-to-treat program implementation.

Industry-Led Initiatives Have Fallen Short of Overcoming IP Barriers to Global Access

Intellectual property protections have contributed to challenges in developing timely, robust generics markets for diagnostics and therapeutics. Without diverse, affordable, and reliable supply, demand for diagnostics and therapeutics will continue to be suppressed globally. An extension of the TRIPS Decision to diagnostics and therapeutics would promote the entry of generic manufacturers to the market for COVID-19 health technologies, inducing demand and increasing access to supply at more affordable prices.

While the relationship between IPRs within trade agreements and access to medicines is complicated and difficult to demonstrate empirically due to the short time periods and small markets, the issue of TRIPS and access to medicines is really one of generic competition. It has been widely demonstrated that increasing generic competition puts downward pressure on price and effectively increases access. If countries could purchase reliable supply of COVID-19 therapeutics and diagnostics at an affordable price, global demand for these technologies would rise. The IP protections within the TRIPS Agreement have the chief function of blocking competition, hindering generic manufacturing of the COVID-19 technologies that are essential to controlling and ending the pandemic. The current tools deployed to overcome IP barriers to generic competition are inadequate in increasing global access and generating market demand that meets population health need.

Voluntary Licensing

Licensing is one mechanism to increase access to generic COVID-19 therapeutics and diagnostics within LMICs. While voluntary licensing measures are successful in accelerating affordable and reliable supply of generic products to certain markets, the agreements typically exclude many upper middle-income countries. Timely access to generics is critical and could be achieved in more markets with an extension of the TRIPS Decision.

[51] Report of the Access to COVID-19 Tools Accelerator Facilitation Council Working Group on Therapeutics and Diagnostics, available at https://www.who.int/publications/m/item/act-accelerator-facilitation-council-working-group-report-on-diagnostics-and-therapeutics

The Medicines Patent Pool (MPP) aims to solve the challenges faced by LMICs in accessing COVID-19 diagnostics and therapeutics by negotiating deals that are acceptable to both patent holders and generics firms. MPP works to negotiate deals that will facilitate generic access in as many countries as possible. However, patent holders limit the number of countries that they will agree to license for a particular product, typically excluding many upper middle-income countries. Patent holders have signed agreements through the Medicines Patent Pool (MPP) for 15 COVID-19 technologies, including licenses for three oral antiviral treatments and four diagnostics.[52]

MPP and Pfizer signed a licensing agreement in November 2021 for nirmatrelvir, and the MPP then signed agreements with 35 companies to manufacture nirmatrelvir in March 2022.[53] One of these companies, Hetero in India, received WHO prequalification for their generic Paxlovid in late December 2022.[54] Through the MPP license, the Clinton Health Access Initiative (CHAI) has announced that generic Paxlovid will be available to LMICs for US$25 per course.[55] Considering the prices that have been reportedly paid for the brand-name drug, this agreement between CHAI and generic manufacturers is significant and will play a large role in ensuring affordable access to Paxlovid for LMICs. However, countries not included in the MPP licensing agreement will not be able to benefit from the generic pricing and may face challenges accessing generic Paxlovid until 2041.[56]

Pfizer's MPP agreement for Paxlovid excludes most of Latin America, a region that was devastated by the pandemic. Despite comprising only 8.4% of the world's population, by end-August 2021 Latin America and the Caribbean countries accounted for 20.1% of COVID-19 infections and 32% of deaths.[57] In November 2022, dozens of leading Latin American health groups wrote Pfizer, asking for Pfizer to expand the territory of its MPP license to include Latin America to help meet health need.[58] Pfizer has still not responded to this request.

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[52] MPP Products Licensed, available at https://medicinespatentpool.org/progress-achievements/licences

[53] 35 generic manufacturers sign agreements with MPP to produce low-cost, generic versions of Pfizer's oral COVID-19 treatment nirmatrelvir in combination with ritonavir for supply in 95 low- and middle-income countries, available at https://medicinespatentpool.org/news-publications-post/35-generic-manufacturers-sign-agreements-with-mpp-to-produce-low-cost-generic-versions-of-pfizers-oral-covid-19-treatment-nirmatrelvir-in-combination-with-ritonavir-for-supply-in-95-low-and

[54] India-based Hetero's Paxlovid generic gets WHO backing, available at https://www.reuters.com/business/healthcare-pharmaceuticals/india-based-heteros-paxlovid-generic-gets-who-backing-2022-12-27/

[55] Press Release: CHAI Announces Agreements with Leading Generic Manufacturers to Make Affordable COVID-19 Treatment Available in Low- and Middle-Income Countries, available at https://www.clintonhealthaccess.org/news/chai-announces-agreements-with-leading-generic-manufacturers-to-make-affordable-covid-19-treatment-available-in-low-and-middle-income-countries/

[56] Latin America: How Patents and Licensing Hinder Access to COVID-19 Treatments, available at https://msfaccess.org/latin-america-how-patents-and-licensing-hinder-access-covid-19-treatments

[57] Economic Commission for Latin America and the Caribbean (ECLAC), *Plan for self-sufficiency in health matters in Latin America and the Caribbean: lines of action and proposals* (LC/TS.2021/115), Santiago, 2021.

[58] AIS Peru. Peticion a Pfizer para acceder a tratamiento para el covid 19, available at https://aisperu.org.pe/peticion-a-pfizer/

When China lifted its 'zero-COVID' policy, the country instantly struggled with life threatening treatment shortages. China's government is responsible for the mistakes of this period and their disastrous consequences. Nonetheless and for purposes of this inquiry, it also is the case that there was not sufficient Paxlovid supply in China. People smuggled Paxlovid in suitcases across the border and purchased from the black market.[59] Pfizer had an advance opportunity to mitigate this harm, by including China in the territory of its license with the Medicines Patent Pool more than a year earlier, in November 2021. Pfizer declined. Pfizer waited nine more months before signing a bilateral deal with Chinese manufacturer Zhejiang Huahai (which also is an MPP sublicensee, authorized to sell nirmatrelvir outside China under the terms of the MPP license).[60] Had those nine months not been lost, and had Pfizer worked quickly to support rapid generic production and distribution, perhaps generic nirmatrelvir could have been available when zero-COVID was lifted, and more lives saved.

The restricted geographical reach of the voluntary licenses also limits economies of scale and the markets available for generics, resulting in a less attractive opportunity for generic manufacturers. For example, in the Paxlovid agreement between CHAI and generic manufacturers, the price of US$25 will only apply if volume requirements are met – any single order must be for a quantity of at least 50,000-treatment courses and the aggregate of all orders must meet or exceed one million treatment courses.[61] If larger markets were available to generic manufacturers, increasing the global demand for the drug, the market opportunity may be sufficiently enticing and these stipulations would not be necessary for generic manufacturers to enter the market. An extension of the TRIPS Decision would play an important role in expanding the available markets for generic products, increasing both the supply of and demand for generic diagnostics and therapeutics. The delayed access of diagnostics and therapeutics will continue to cost lives and put additional strain on health systems.

Tiered Pricing

Tiered pricing is another voluntary mechanism that theoretically provides access to affordable technologies for countries that are left out of voluntary licensing agreements. The Pfizer CEO commended their tiered pricing system as a "critical step that will boost equitable access for high-risk patients in low-and-middle income countries."[62] Yet tiered prices are set by and acceptable to the manufacturer, and do not necessarily ensure that therapeutics and diagnostics are affordable for the purchaser.[63] In a study of price reduction strategies for antiretroviral drugs, researchers found that for 15 of 18 ARVs, differential

[59] TIME. As COVID-19 Barrels Through China, Some Are Turning to Black Market Amid Drug Shortages, available at https://time.com/6247596/covid-china-contraband-treatments/

[60] Reuters. Pfizer CEO rules out generic COVID drug Paxlovid for China, available at https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-not-talks-licensing-generic-covid-pill-china-2023-01-10/

[61] FAQ: What you need to know about CHAI's generic Paxlovid deal, available at https://www.clintonhealthaccess.org/news/frequently-asked-questions-for-nir-r-agreement-announcement/

[62] Pfizer to Supply Global Fund Up to 6 Million PAXLOVID Treatment Courses for Low-and-Middle-Income Countries, available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-supply-global-fund-6-million-paxlovidtm-treatment

[63] Moon S, Jambert E, Childs M, von Schoen-Angerer T. A win-win solution?: A critical analysis of tiered pricing to improve access to medicines in developing countries. Global Health. 2011 Oct 12, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3214768/

pricing schemes were 23-498% more expensive than generic products.[64] Panama reportedly paid US$250, Thailand US$300, China US$282-340, and Brazil US$250 (asked) for Paxlovid under the tiered pricing scheme. These differential prices are ten times higher than the generic price negotiated by CHAI ($25). The not-for-profit price, which has been speculated to be as high as US$100, is still four times higher than CHAI's generic price.

Pfizer entered into supply agreements based on tiered pricing with the Global Fund and UNICEF, both partners of ACT-A, for 6 million and 4 million treatment courses of Paxlovid, respectively.[65] However, these agreements were largely options agreements, not advance purchase agreements, with the courses available to low-income countries at the (still high) not-for-profit price and courses available to middle-income countries at a (quite high) tiered price. While there potentially was some funding available to cover procurement costs for the very lowest income countries, it is not at all our understanding that every LMIC country would have been able to receive the treatments at no cost. According to the WHO Therapeutics Dashboard, as of February 2023, 2,132,304 courses of Paxlovid had been offered to LMICs by ACT-A, but only 135,120 courses were confirmed.[66] The discrepancies between the courses optioned, the courses offered, and the courses procured are significant and suggest that the alleged surplus of supply does not exist for patients in LMICs. It can be inferred that the prices offered through these options agreements were still too high to induce substantial demand that meets population need, particularly when there is imminent generic supply at a fraction of Pfizer's tiered pricing.

The current voluntary measures in place provide some routes for some low- and lower middle-income countries to access COVID-19 products at a more accessible price, either through industry's tiered not-for-profit pricing that is still quite high or through the voluntary licensing enabled generic supply. However, most upper middle-income countries will continue to be left without access to tools that will meet population needs during the pandemic. These countries are largely excluded from voluntary licensing agreements and are left with unaffordable prices through tiered pricing schemes, resulting in a fragmented market limiting scale and opportunities for generic diagnostic and therapeutic suppliers. As many upper middle-income countries have been devastated by the pandemic and exhibit extreme income disparities, the lack of access to affordable COVID-19 diagnostics and therapeutics is consequential. When voluntary mechanisms fail to achieve global access, there is a need for compulsory solutions that will enable countries to address the health needs of their populations.

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[64] Waning, Brenda, et al. "Global strategies to reduce the price of antiretroviral medicines: evidence from transactional databases." Bulletin of the World Health Organization 87.7 (2009)

[65] Pfizer to Supply Global Fund Up to 6 Million PAXLOVID Treatment Courses for Low-and-Middle-Income Countries, available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-supply-global-fund-6-million-paxlovidtm-treatment

[66] World Health Organization Therapeutics Dashboard, available at https://partnersplatform.who.int/en/therapeutics-dashboard [accessed February 27, 2023]

When Industry-Led Initiatives Fail, TRIPS Flexibilities Can Help Achieve Global Access

Compulsory licensing is a flexibility under the TRIPS Agreement that can expand generic markets and provide access to COVID-19 therapeutics and diagnostics where pharmaceutical companies have chosen to not license voluntarily. Licensing in this understanding is simply a proxy for generic market competition, which we know to be the most effective means of reducing price and ensuring prices continue to fall over time. A number of countries have successfully issued compulsory licenses to promote public health objectives and improve access to medicines.

Compulsory licenses are part and parcel of the international intellectual property rules established through the TRIPS Agreement. They are intrinsic and fundamental to any patent system. Without compulsory licensing, government use of patents and other flexibilities, intellectual property would not be sustainable as a legal system. Intellectual property in that case would amount to monopoly control of new inventions, across technological fields, without exception or possibility of government intervention to protect the public or interests of the state. These conditions would be unacceptable for any government. The U.S. Secretary of Health and Human Services under President George W. Bush, Tommy Thompson, invoked the government's right to authorize generic competition with Bayer's patented Cipro during the anthrax scare, resulting in the negotiation of nearly a 50% price reduction.[67] The availability of government's compulsory authorities, and a realistic prospect that they may be used, is part of what helps induce better deals with pharmaceutical companies.[68]

Challenges Faced by Developing Countries Issuing Compulsory Licenses

Allowing developing countries to use compulsory licensing more effectively is part of how countries that are not already tended to in negotiated agreements can be supported in meeting the health needs of their population. However, developing countries are discouraged from using this mechanism by pharmaceutical companies and some high-income countries. The extension of the TRIPS Decision to diagnostics and therapeutics would provide an easier route to export, overcoming the restrictions of Art. 31(f) and the challenges of Art. 31bis, and would provide assurance to developing countries that all World Trade Organization (WTO) members support the use of compulsory licensing to meet access needs within the COVID-19 pandemic.

An MSF Access Campaign briefing describes the challenges that developing countries have faced when using compulsory licensing prior to the pandemic, including lawsuits from pharmaceutical companies, threatened trade sanctions through the USTR Special 301 Reports, and warnings from the European

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[67] The New York Times. A NATION CHALLENGED: CIPRO; U.S. Says Bayer Will Cut Cost of Its Anthrax Drug, available at https://www.nytimes.com/2001/10/24/business/a-nation-challenged-cipro-us-says-bayer-will-cut-cost-of-its-anthrax-drug.html

[68] *See* KEI Briefing Note 2022:1, 'Selected U.S. Government COVID Contracts with Authorization and Consent to Non-Voluntary Use Of Third Party Patents,' available at https://www.keionline.org/wp-content/uploads/KEI-bn-2022-1.pdf

Commission. [69] Compulsory licensing actions relating to Latin American countries, compiled by Knowledge Ecology International, further demonstrate pressure and threats from HICs and pharmaceutical companies to discourage the use of compulsory licensing by LMICs.[70] We can attest to these pressures and more from our own experiences providing technical assistance. (We would be happy to provide the commission with further details). We will briefly describe two publicly documented examples of pressure faced by upper middle-income countries Colombia and Ecuador (both excluded from Pfizer's MPP license for nirmatrelvir).

Glivec (imatinib), a treatment for chronic myeloid leukemia, was sold in the Colombian market alongside 13 generic alternatives until Novartis, the manufacturer, was issued a patent and requested its competitors to leave the market. As the price for the branded product was much higher than the generic alternatives that were forced out of the market, the Colombian Ministry of Health attempted to negotiate a voluntary license but was unsuccessful.[71] Subsequently, an application for a compulsory license was initiated and Novartis declined to negotiate a lower price for the drug.[72] In response to the compulsory license process being initiated, the Colombian government received pressure at both the national and international levels. For example, the Secretariat for Economic Affairs of Switzerland wrote to the Colombian Ministry of Health to express concern over the compulsory license application, equating a compulsory license to "an expropriation of the patent owner."[73] This letter also highlighted Switzerland's economic relations with Colombia, investment in the country, creation of Colombian jobs, and humanitarian aid and peace contributions. Then, reportedly, and infamously, a representative of influential U.S. Sen. Orrin Hatch threatened that U.S. financial support for the Colombian peace process would be withdrawn if the compulsory license was issued.[74,75]

Ecuador faced pressure after President Rafael Correa issued Decree 118 to improve access to medicines and support public health programs through a protocol that established procedures for the compulsory licensing of pharmaceutical products. The protocol limited public interest licensing to medical conditions that are priorities for public health, and required both the payment of royalties to patent holders and interagency cooperation to grant licenses. Nonetheless, cables from the U.S. Embassy in Ecuador to the U.S. Department of State show that the Embassy and multinational pharmaceutical companies worked to

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[69] Medecins Sans Frontieres. Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies, available at https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf

[70] KEI. 'Latin America, Compulsory Licensing,' available at https://www.keionline.org/cl/latin-america-compulsory-licensing

[71] This information was provided by Luz Marina Umbasia Bernal, an intellectual property and access to medicines expert in Colombia, Legal Advisor at GHP Corp in Colombia and Legal Fellow at Public Citizen's Access to Medicines Program.

[72] Novartis perdería exclusividad para fabricar Imatinib, medicamento para tratar el cáncer, available at https://www.elespectador.com/salud/novartis-perderia-exclusividad-para-fabricar-imatinib-medicamento-para-tratar-el-cancer-article-629267/

[73] *See* **Appendix A**

[74] KEI. 'Senator Hatch, before pressuring Colombia over cancer drug compulsory license, wanted one for Napster,' available at https://www.keionline.org/23081

[75] *See* **Appendix B**

undercut this emerging health policy.[76] The Embassy endeavored to organize wealthy countries with strong pharmaceutical industries to oppose Decree 118.[77] Ecuador was able to initiate its licensing protocol, however haltingly.[78] Several years later, after overcoming opposition, Ecuador paired patent licensing with price negotiation to save health agencies fully 0.4% of GDP through medicine price reductions.

Critics of compulsory licensing, in an attempt to undermine their use, conflate licensing decisions and the regulatory approval process. But intellectual property decisions are properly kept separate from regulatory decisions, which require distinct competencies and assess whether a particular medicine – and every medicine, patented or generic – is safe for consumers. A former opposition minister in Ecuador, referred to in Embassy cables as a "well-placed contact" of multinational pharmaceutical companies, raised a criticism that generics sold under a compulsory license might not contain active ingredients. (If this were true, those medicines would not be properly considered generics. They would not meet standards for regulatory approval and their proprietors would be subject to criminal penalties.) An opposition minister also reportedly investigated the business dealings of local medicine suppliers to gain leverage for the patent-based global pharmaceutical companies.[79]

Issuing Compulsory Licenses for COVID-19 Diagnostics and Therapeutics

For developing countries that are excluded from voluntary agreements for COVID technologies and have subsequently been unable to procure enough COVID-19 therapeutics and diagnostics to meet public health need, compulsory licensing could facilitate greater access to affordable and reliable generics. However, the historical pressure and opposition from pharmaceutical companies and high-income countries, combined with economies of scale issues and procedural complexities, make compulsory licensing a challenging flexibility to implement. According to the Global Humanitarian Progress Corporation (GHP Corp), five compulsory license actions are in progress in LAC for Paxlovid – Chile, the Dominican Republic, Colombia, Perú, and Costa Rica.[80] Pfizer has filed a patent application for nirmatrelvir in all five of these countries.[81] GHP Corp, alongside other civil society organizations, submitted a request to the Colombian Government for government use of Paxlovid on March 14, 2022, but did not receive a

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[76] Public Citizen. 'Wikileaks docs cite our work and shed light on Big Pharma & U.S. government team-up in other countries,' May 2011, available at https://www.citizen.org/news/wikileaks-compulsory-licensing-hiv-aids-big-pharma-ecuador-peter-maybarduk/

[77] Info Justice. 'LEAKED CABLES SHOW U.S. TRIED, FAILED TO ORGANIZE AGAINST ECUADOR COMPULSORY LICENSING,' May 2011, available at https://infojustice.org/archives/3393

[78] Ministerio de Salud Pública. 'Ecuador concedió nueve licencias obligatorias para medicamentos estratégicos,' available at https://www.salud.gob.ec/ecuador-concedio-nueve-licencias-obligatorias-para-medicamentos-estrategicos/

[79] Public Citizen. 'Wikileaks docs cite our work and shed light on Big Pharma & U.S. government team-up in other countries,' May 2011, available at https://www.citizen.org/news/wikileaks-compulsory-licensing-hiv-aids-big-pharma-ecuador-peter-maybarduk/

[80] Global Humanitarian Progress Corporation, Acceso a tratamientos COVID 19 en LAC, available at https://www.ghpcorporation.co/accesoatratamientoscovid-19

[81] Latin America: How Patents and Licensing Hinder Access to COVID-19 Treatments, available at https://msfaccess.org/latin-america-how-patents-and-licensing-hinder-access-covid-19-treatments

response.[82] After the presidential election in 2022, the civil society organizations filed another application for government use to the new Colombian government. Similarly, on Dec. 3, 2021, Knowledge Ecology International submitted a request to the government of the Dominican Republic for an open compulsory license relating to Paxlovid.[83] Pfizer responded with opposition, putting pressure on the government of the Dominican Republic to reject the request.[84]

Developing countries have faced significant barriers and challenges in using compulsory licensing as a policy tool to protect public health. The extension of the TRIPS Decision could ease some of these barriers and would send a political message that all WTO members support developing countries' use of compulsory licensing to protect the health of their populations. This would encourage more developing countries to meet the health needs of their population through access to generic COVID-19 diagnostics and therapeutics. Expanding markets available to generic manufacturers through the extension of the TRIPS Decision would also induce greater supply of affordable generics, generating market demand that could better address population heath need in LMICs.

Manufacturing Capacity in LMICs

If the June 2022 TRIPS Decision is extended to diagnostics and therapeutics, there are able and interested generic manufacturers in developing countries that could ramp up generic production of these technologies. For COVID therapeutics, indicators of manufacturing capacity, interest, and investment in LMICs include the sublicensing agreements with the Medicines Patent Pool. MPP sublicensees for development of generic Paxlovid include 38 manufacturers from 13 countries - Bangladesh, Brazil, Puerto Rico, Dominican Republic, Pakistan, India, China, Ukraine, Vietnam, and Serbia, Israel, Jordan, and Republic of Korea.[85] These manufacturers have met MPP's requirements, are confident in their ability to make the licensed therapeutics, and many are already making investments to that end. Generic production of COVID-19 therapeutics is well underway. Hetero, a pharmaceutical company based in India, already has a World Health Organization-prequalified generic for Paxlovid.[86]

In Latin America and the Caribbean (LAC), there is a well-established generic pharmaceutical industry that has demonstrated the capacity to both produce and export generic drugs. While innovative drugs are imported into the region primarily from transnational companies outside of LAC, local firms produce most

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[82] Global Humanitarian Progress Corporation, Acciones en Colombia, available at https://www.ghpcorporation.co/blank

[83] KEI Requests an Open Compulsory License Relating to Paxlovid in the Dominican Republic, available at https://www.keionline.org/37066

[84] https://keionline.org/misc-docs/1/Translation-Pfizer-opposition-KEI-CL-Paxlovid-18march2022.pdf

[85] Unitaid and the World Health Organization. Improving access to novel COVID-19 treatments: A briefing to Member States on how to navigate interfaces between public health and intellectual property, available at https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/j0198_unitaid_briefingcountries_en7178c1800570451fa6f18deccdefb99c.pdf?sfvrsn=6a905980_10&download=true

[86] Reuters. India-based Hetero's Paxlovid generic gets WHO backing, available at https://www.reuters.com/business/healthcare-pharmaceuticals/india-based-heteros-paxlovid-generic-gets-who-backing-2022-12-27/

of the region's generic drugs.[87] Argentina, Brazil, and Mexico largely self-supply generic medicines, and are the top three intraregional exporters of pharmaceutical products. Pharmaceutical products produced in Colombia, Costa Rica, Guatemala, El Salvador, Chile, Uruguay, and the Dominican Republic also comprised a significant share of the intraregional pharmaceutical exports in 2019.[88] Among the LAC countries with less pharmaceutical production capacity, many depend on other countries in the region to satisfy their demand for generic drugs and significant percentage of their imported pharmaceutical products are from other LAC countries (Belize 47%, Ecuador 42%, El Salvador 38%, Guatemala 60%, Honduras 46%, Nicaragua 52%, Paraguay 56%, and Bolivia 49%).[89] Additionally, an analysis of LAC regional capacity for vaccine manufacturing identified biologics manufacturers with the capacity to manufacture monoclonal antibodies in Argentina, Brazil, and Mexico.[90]

Conclusion

It is important that the TRIPS Decision is extended to diagnostics and therapeutics, contributing to an environment that makes it straightforward for countries to address the health needs of their population.

The COVID-19 products that are currently on the market represent a small subset of the future tools that will be developed to combat the pandemic. According to the BIO COVID-19 Therapeutic Development Tracker, 76 therapeutics are in late-stage clinical development.[91] Absent further reforms, each time a patented product comes to market, LMICs are likely be left with initially limited and opaque supply at prices much higher than they could be in a robust generics market.

Suppressed demand is a symptom of intellectual property barriers, among other challenges. Continued overreliance on voluntary action by patent holders will hinder global access to COVID-19 diagnostics and therapeutics.

Low-, middle- and high-income countries alike underfund health systems. But that is not the point of this investigation. Because upper middle-income countries are excluded from many of the pharmaceutical companies' concessionary measures, it becomes critically important to ease their path to accessing affordable generics and support widespread test-to-treat programming, including through extending the TRIPS Decision to diagnostics and therapeutics.

We appreciate the opportunity to comment. Thank you.

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[87] Economic Commission for Latin America and the Caribbean (ECLAC), *Plan for self-sufficiency in health matters in Latin America and the Caribbean: lines of action and proposals* (LC/TS.2021/115), Santiago, 2021.
[88] Does not include Panama because it is not possible to separately identify re-exports from the Colón Free Zone. Economic Commission for Latin America and the Caribbean (ECLAC), *Plan for self-sufficiency in health matters in Latin America and the Caribbean: lines of action and proposals* (LC/TS.2021/115), Santiago, 2021.
[89] Ibid.
[90] Vargas, Veronica. Analysis of Regional Capacity for Research, Development, and Manufacturing of Vaccines in Latin America and the Caribbean. 2020.
[91] BIO COVID-19 Therapeutic Development Tracker, available at https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker

Appendix A: Letter from the Swiss Federal Department of Economic Affairs to the Colombian Health Ministry

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,
Education and Research EAER

State Secretariat for Economic Affairs SECO
Bilateral Economic Relations
Americas

CH-3003 Bern, BWAM / SECO/lea

Dr
Carolina Gómez
Asesora del Despacho del Minsitro
Ministerio de la Salud y Protección Social
Bogotá
Colombia

Bern, 26 May 2015

Patent of Imatinib / Glivec: Closing arguments

Dear Mrs Gómez

On behalf of the State Secretariat for Economic Affairs of Switzerland, I would like to seize the opportunity to present our views referring to an official request to declare of public interest the patent of Imatinib / Glivec. On May 18th, State Secretary and Director of the Federal Office of Public Health Pascal Strupler presented our concern to the Minister of Health and Social Protection, Alejandro Gaviria.

First, let me highlight our excellent bilateral economic relations with in particular agreements on free trade, investment protection and double taxation. Colombia is an important destination for Swiss investors with more than 16'000 jobs created locally and one out of two partners in Latin America benefitting from the Swiss Economic Development Cooperation (SECO). Switzerland and Colombia further cooperate in the fields of humanitarian aid, peace promotion and human rights.

Within the procedure of "closing arguments", I would like to present the concern of the State Secretariat for Economic Affairs of Switzerland regarding the request to the Ministry of Health and Social Protection of two Colombian NGOs and the Center for the study of Medicines of Universidad Nacional to declare of public interest the patent of Imatinib. This would be a first step to the issuance of a compulsory license by the Colombian Patent Office.

The Swiss firm Novartis has developed the beta crystal form of Imatinib Mesylate creating a breakthrough, life-saving cancer medicine. No other drug comprising Imatinib was available anywhere in the world before Glivec was launched. Scientists at Novartis developed the Me-

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sylate Salt of Imatinib and then the Beta crystal form of Imatinib Mesylate to make it suitable for patients to take in a pill form that would deliver consistent, safe and effective levels of medicine.

In Colombia, the drug is in the basic formulary and its price has been regulated by the authorities. The product has not been out of stock at any time and supply has been guaranteed to the Colombian health authorities.

Novartis requested before the Superintendency of Industry and Commerce a patent for Glivec covering the crystalline form Beta on July 9th, 1998. The Superintendency denied the patent on February 25th, 2003 on the grounds that it lacked inventive step. After a very long judicial process (9 years), the State Council issued its final decision on the case ordering the Superintendency to issue the patent on February 9th, 2012.

While compulsory licenses are permissible under the WTO TRIPS Agreement on the condition of compliance with the terms and conditions set out in its Art. 31, they are also considered a policy tool of last resort. A Compulsory license is tantamount to an expropriation of the patent owner and constitutes a deterrent to future research and development of innovative medicines and their placing on the market in Colombia. Accordingly, it is our view that all efforts should be undertaken by the Colombian authorities to find a mutually agreeable solution with the right holder and that all other options are exhausted before the issuing of a compulsory license is being contemplated.

The Glivec case raises important issues that are essential to the future of intellectual property law and the innovative pharmaceutical business in Colombia. The ability to rely on patents in Colombia benefits government, industry and patients alike because research-based organizations will know that investing in the development of better medicines for patients is a viable and sustainable long-term option.

Patents are the foundation of innovative drug discovery and essential to advancing medical science and treatment for patients. Without patents, there would be less incentive for investment in drug discovery research and clinical development, which over time would halt innovative drug discoveries for patients in need of new treatment options.

I thank you for taking duly into consideration the views of the Swiss government. We are available to discuss any point referring to this very important issue.

Best Regards,

State Secretariat for Economic Affairs SECO

Livia Leu

Livia Leu

Ambassador, Head of Bilateral Economic Relations
Delegate of the Federal Council for Trade Agreements

Appendix B: Letter from Members of the U.S. House of Representatives to Ambassador Froman

Congress of the United States
House of Representatives
Washington, DC 20515
May 25, 2016

The Honorable Michael Froman
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Froman:

We are writing to express our serious concern that, according to recent press reports, U.S. officials may have discouraged Colombian government officials from issuing a compulsory license on a cancer medicine, Gleevec (imatinib), produced by the Swiss pharmaceutical company Novartis. A Senate Finance Committee spokeswoman also recently suggested that the issuance of a compulsory license "may be inconsistent with international trade obligations." The press reports suggest that Colombian officials were left with the deeply troubling impression that $450 million in U.S. funding to aid peace efforts could be in jeopardy if Colombia failed to change course.

As you know, the issuance of compulsory licenses is permissible under U.S. trade agreements and the WTO Agreement. Indeed, the 2001 WTO Doha Declaration on public health recognizes this "flexibility" that WTO Members have to protect public health: "Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted." U.S. officials should respect the flexibilities that are recognized in that Declaration. In fact, that is precisely what Congress instructed our trade officials to do, most recently through the passage of Trade Promotion Authority last year. (See section 102(b)(5)(C) ("to respect the Declaration on the TRIPS Agreement and Public Health").) We therefore find it deeply troubling that U.S. officials may not be respecting the Doha Declaration.

To be sure, the issuance of compulsory licenses can raise legitimate concerns in some circumstances. For example, under Article 31 of the WTO TRIPS Agreement, compulsory licenses should be issued only on a case-by-case basis, not as part of a blanket policy. And, even where a government issues a compulsory license, that government is required to pay the patent holder "adequate remuneration". But we are not aware of any actions that Colombia has taken or is considering taking that are inconsistent with those rules. For example, Colombia appears to be considering a compulsory license on this medicine – which the World Health Organization has listed as an "essential medicine" – based on its individual merits and not as part of a blanket policy. In fact, to our knowledge, Colombia has not issued a compulsory license on any other product.

Discouraging the issuance of compulsory licenses would be inconsistent not only with the Doha Declaration and with TPA, but also with the historic May 10 Agreement of 2007. The May 10 Agreement included several critical changes to U.S. trade policy to better ensure access to affordable medicines. Our bilateral trade agreement with Colombia incorporates those changes –

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including adding to the Colombia trade agreement language from the Doha Declaration, to clarify that the intellectual property obligations in the agreement "do not and should not prevent [Colombia] from taking measures to protect public health by promoting access to medicines for all".

There are growing concerns about the very high and increasing costs of pharmaceuticals in the United States and in other nations. And the annual price of this medicine in Colombia is almost twice as much as the average annual income per person in Colombia. As policymakers struggle to address this issue, we should not seek to limit the existing, agreed upon flexibilities public health authorities have to address these concerns.

We ask that you clarify the position the Administration has taken in meetings with Colombian officials on this important issue as soon as possible, particularly given that USTR's recent Special 301 report did not mention compulsory licensing in Colombia but instead, in another section of the report, included the general statement that "the United States respects its trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement and the Doha Declaration[.]" Just as we expect our trading partners to act transparently and in accordance with the rule of law, our policies and practices should follow that same course.

Sincerely,

Sander M. Levin

James P. McGovern

Jim McDermott

Jan Schakowsky

Eddie Bernice Johnson

Peter Welch

Rosa L. DeLauro

John Lewis

Barbara Lee

Chris Van Hollen

Peter DeFazio

Lloyd Doggett

David Price

Carolyn B. Maloney

Sam Farr