

Why the United States Should Support the Extension of the June 17 WTO COVID Decision to Cover Treatments and Tests: A Fact-Based Case

TO: Interested Parties

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Extending the June 17 WTO Decision would help ameliorate the lack of affordable treatments and diagnostic tests in LMICs. An extension would authorize firms in covered countries to produce under compulsory license to export generics to other countries. Scores of generic drug makers in South Africa, Argentina, Chile, and other nations that could produce quality and affordable treatments are not doing so because their domestic markets are not large enough to justify the investment. Small molecule treatments, like Paxlovid and many anti-virals now in the pipeline, have fewer IP barriers than vaccines and technology transfers are not necessary for production. Thus, key treatments could be made under compulsory license by many generics firms, such as those making HIV-AIDs drugs.

But WTO rules limiting CL production to mainly domestic use and the fear of reprisals from developed countries that threaten countries using CLs, is why countries with capacity are not now producing treatments like Paxlovid under CL. And that production is needed: LMICs are not adopting test and treat strategies because supplies of affordable diagnostics and treatments are not available. The voluntary licenses that originator firms have granted for COVID treatments to the Medicines Patent Pool exclude most middle-income countries and thus hundreds of millions of people. And the prices of treatments under voluntary license remains worryingly secret.

Extending the June 17 Decision and thus waiving the limit on exports of medicines and tests made under compulsory license would provide affordable access in middle-income countries as well as provide affordable supplies for low-income and small countries that cannot produce and now have no access to affordable generic imports. Empowering numerous existing firms with capacity to make generic versions of treatments and tests would transform the future for hundreds of millions of people in LMICs now facing indefinite waves of COVID infections without vaccines, treatments or diagnostics. U.S. leadership at the WTO will make the difference in whether this happens. U.S. support would deliver significant global health gains and geopolitical benefits.

This note compiles research conducted by and resources created by an array of public health, development, human rights and other experts and organizations into one source with links to the original work.

I. The need for expanded access to treatments and tests globally is well established.

A. COVID infection rates remain significant here and in other countries given vaccine-evading variants in regions with high vax rates plus low vax rates in Global South.

1. U.S. daily new infection rates are above 50,000. [NYT COVID tracker](#) On November 18, there were 627,000 new infections reported. [Our World in Data](#) This is a known undercount because of the severe lack of diagnostics - both PCR and antigen rapid diagnostic test.
2. “New immune-evading strains of the Omicron variant of SARS-CoV-2, behaviour changes and waning immunity mean that many countries could soon see large numbers of COVID-19 infections — and potentially of hospitalizations — say scientists... Social dynamics are back to pre-pandemic norms in many parts of the world.” [Scientists survey in Nature](#)
3. “We should anticipate that we very well may get another variant that would emerge, that would elude the immune response that we’ve gotten from infection and/or from vaccination” [Dr. Fauci](#)

4. “The Committee unanimously agreed that the COVID-19 pandemic still meets the criteria of an extraordinary event that continues to adversely impact the health of the world’s population, and that the emergence and international spread of new SARS-CoV-2 variants may present an even greater health impact.” [WHO International Health Regulations Emergency Committee](#) report.

B. With low vaccination rates in poor nations and vax-evading variants, testing and access to treatments are the only way to limit hospitalizations, economic losses and deaths.

1. Barely 20% of people in the poorest nations are fully vaccinated, with populations at greater risk of infection and adverse outcomes. Treatment is even more important in areas of low vaccine coverage but high-income countries account for over 70% of courses secured via identified treatment supply deals with originator companies. [Duke Global Health Innovation Center](#)
2. “Oral antivirals can prevent hospitalization and save the lives of patients most at risk of developing severe illness.”(p.23) “The world lacks a complete understanding of the full evolution of the pandemic and emerging variants” and “risks compromising the rollout of new lifesaving outpatient oral antivirals, which are most effective at reducing hospitalisation and death when given within 5 days of symptom onset, and thus reliant on targeted and effective testing to identify early those at risk of severe disease progression” “Without sufficient testing, treatment and vaccines, the global community runs the risk of undoing the hard-earned public health gains achieved...”(p.1) (p.2) “...the pandemic is not over and issues of access to COVID-19 therapeutics and diagnostics must be addressed.(p.32) [ACT-Accelerator Working Group on Diagnostics and Therapeutics Report](#)
3. “...access to timely and accurate testing, with linkage to clinical care and therapeutics, needs to be maintained” ... “States Parties should provide access to COVID-19 treatments for vulnerable populations, particularly immunosuppressed people, and improve access to specific early treatments for patients at higher risk for severe disease outcomes.” [WHO International Health Regulations Emergency Committee](#) meeting regarding the coronavirus disease pandemic

II. Countries have not adopted test and treat strategies globally because affordable, timely and reliable supply for all LMICs has not been available.

- A. The industry argument that there must be sufficient supply of treatments and tests because there has not been demand from developing countries for greater supplies of these COVID-19 products conflates the economic concept of demand with the human concept of need.** That developing countries have not purchased large volumes of treatments and tests to date is NOT evidence that there no need for great volumes of such goods. Rather developing countries are not purchasing these goods and thus demonstrating “market demand” because there have not been reliable supply and/or prices of available product are prohibitive.

TREATMENTS:

1. “...hindering the introduction of oral antivirals” is “limited access to the products themselves and a complex and evolving landscape of treatments and costs” (p.30) For both testing and therapeutics, the ACT-A report notes the challenge of manufacturing being highly concentrated and the need for diversified production in particular local production.
2. High-income countries currently account for over 70% of courses via identified supply deals of all existing COVID-19 treatments. The US alone accounts for nearly 50% of these courses. Duke 74% of Paxlovid treatment courses and 82% of other leading treatment courses have been purchased by high-income countries, despite high-income countries only accounting for 16% of the world’s population (11/4/22) [Duke Global Health Innovation Center](#)
3. “High income countries account for 76% of total known supply deals” ([Airfinity](#) full report behind paywall 7/24/2022)\

4. “Limited supplies and high costs have restricted the flow of COVID-19 antivirals to low- and middle-income regions.” [Nature, “Donated COVID drugs start flowing to poor nations — but can’t meet demand,”](#) 9/2022
5. Low- and middle-income countries have been waiting months for deals Pfizer made with [UNICEF](#) ([reportedly](#) delayed due to renegotiation of some terms) and the [Global Fund](#) to begin delivering doses. The lack of pharmaceutical companies’ transparency on the real costs of R&D and manufacturing hinders any public scrutiny on pricing.
6. Pfizer has charged more than [\\$500](#) per treatment course in some high-income countries and [\\$250](#) in some middle-income countries. But it is estimated that with generic alternatives the cost of a 5-day treatment [can be as low as \\$73](#).
7. U.S. treatment pre-purchases limited global access to date. [Starting with remdesivir](#) in 2020 and continuing through later treatments, the U.S. government along with governments in other wealthy countries have bought up much of the world stock of treatments. In 11/2021, the [U.S. government secured 20 million doses](#) of Paxlovid. It was only in September 2022 that Pfizer agree to sell just [six million Paxlovid courses](#) to the Gates-funded Global Fund for use in 132 (!!) low- and middle-income nations after agreeing to sell [4 million doses](#) to UNICEF in March 2022. The two organizations are the main suppliers of the COVID-19 treatment for low- and middle-income countries. Pfizer [refused the reveal the price](#) it was charging.

TESTS:

8. COVID testing rates in LMICs are extremely low, as this [UN tracker displays](#). In summer 2022, despite a marked decline in testing across countries, high-income countries continued to test people 50 times more frequently than low- and middle-income countries, with low- and middle-income countries conducting just 0.04 tests per 1,000 people. [WHO](#)
9. “...There's another gouging going on. There's a lot of companies charging a lot of money for testing that's way, above any, markup. It's profiteering, it's absolute profiteering. The governments came in well and put in place government-supported testing machines when we got lots of testing. And they deserve credit for that. Now, the market in a way should define the cheap testing regime, but it doesn't. Because the testing costs have shot back up. It is very hard to get tested in some countries for less than \$100. Who's going to pay \$100 for a test? That's a problem. We need to find better ways of doing systematic population-based testing that's free for people.” WHO’s Mike Ryan [talking](#) about the difficulties facing countries.
10. Timely and accurate diagnostic testing for SARS-CoV-2 continues to be an essential part of the comprehensive COVID-19 response strategy. WHO’s COVID-19 [Global Preparedness, Readiness and Response plan](#)). Testing is essential to reduce transmission, track the evolution of the epidemic and the SARS-CoV-2 virus and effectively implement test and treat strategies and treatments.

B. Voluntary licensing won’t create sufficient affordable supply, especially for middle-income nations.

Voluntary licensing will not deliver reliable access in all low- and middle-income. COVID-19 voluntary licenses have significant geographic restrictions that exclude scores of countries and hundreds of millions of people, thus limiting their usefulness.

1. Gilead issued some bilateral licenses for remdesivir and the Medicines Patent Pool (MPP) negotiated three voluntary licenses agreements with MSD (molnupiravir), Pfizer (nirmatrelvir+ritonavir aka Paxlovid), and Shionogi (ensitrelvir fumaric acid.) All of the licenses exclude a significant number of countries, many of which have large populations and have suffered some of the highest COVID infection rates. These countries can only source only from the rightholders at whatever price is demanded if there is supply available.
2. Pfizer’s [deal](#) with the MPP licensed 35 firms in 12 countries to make generic Paxlovid that can be sold in only 96 nations. This arrangement [bars](#) sale of those generics in the other [100 countries of the world](#) with 47 percent of the world’s population and the [highest COVID infection rates](#) where apparently Pfizer thought for-profit sales for the few who could afford it may be lucrative. Pfizer has

even barred sales in the DR although it licensed a generics firm to produce there. Pfizer's deal only allows sales in the poorest countries. In the Americas, that means only Guatemala, Haiti, Honduras, Nicaragua and Venezuela. Most African, Middle Eastern and Asian nations that are not Least Developing Countries are likewise excluded. That's why it's critical for companies all over the world to be able to make the treatment using a compulsory license and then export it easily.

3. The Clinton Health Access Initiative says it could make [generic Paxlovid available](#) to low- and middle income countries for less than \$25 a course of treatment. But its deal with Pfizer can proceed only if certain conditions can be met, including [large minimum volume requirements](#) and although eligible nations have not been declared, there are indications that it will be only low- and lower-middle-income countries, meaning that again hundreds of millions of people in middle-income countries will continue to be excluded.

- C. **The extension will promote access to the next generation of treatments and combination drugs, which may be more effective than current options as we struggle to manage COVID over the next five years.** Currently hundreds of treatments are in the pipeline, including at least [78 in phase-3](#) clinical trials or later, according to BIO. This includes Shionogi's ensitrelvir. "The unprecedented volume of planned and ongoing studies for COVID-19 interventions – over 5000 RCTs [randomized clinical trials] as of May 2022 – implies that more reliable and relevant evidence will emerge to inform policy and practice," according to the WHO Living Guideline.

1. For the treatment of severe/critical disease among hospitalized patients, arguably the most promising candidate is sabizabulin, an oral drug with anti-inflammatory and antiviral properties which led to roughly 50% lower risk of death in phase 3 trial. The drug is currently under evaluation for approval in the U.S, EU and the UK. Tentative price is \$ 3000 per day of treatment. (Total: \$36,000 for [full treatment course](#) of 12 days).

III. Extending the Decision's permission to produce under CL for export is needed to overcome IP barriers now thwarting generic production of treatments and tests.

- A. Beyond [WIPO's](#) patent landscape identifying more than 5,000 patent filings related to COVID-19, industry's count of the number of patents affected by an extension of the WTO TRIPS decision is much higher at [135,627 as of 2021](#). This number is expected to increase significantly between 2022 and 2023 due to patent filing publication delays and companies filing further patents on the same product (evergreening of patents). There are [four times more patent applications for therapeutics](#) than there are for vaccines

B. Examples of IP barriers for some therapeutics

1. **Nirmatrelvir/ritonavir (Brandname: Paxlovid):** Recommended by WHO in patients with non-severe illness at the highest risk of hospitalization. Has to be administered as soon as possible after onset of symptoms, ideally within 5 days (hence the need for diagnostics).

Patent landscape: Pfizer has applied for patents across the globe including in majority of developing countries. If patents are granted on nirmatrelvir compound it will have [exclusive rights at least until 2041](#) hindering generic production and/or supply in countries where patents are granted.

Voluntary license (VL): In November 2021, Pfizer signed a [voluntary license \(VL\) agreement](#) with Medicines Patent Pool. The license [excludes supply to the majority of Latin American countries](#) including Brazil and several other developing countries such as [Malaysia and Thailand](#). In March 2022, [MPP announced](#) that 36 generic companies from 12 countries have signed the sub-license agreements to produce generic nirmatrelvir/ritonavir.

Access Challenge:

For countries allowed to be supplied by licensee: The VL was first announced in November 2021. But it is estimated that generic supply under VLs will not enter the market until much later, [possibly 2023 or beyond](#). Pricing is not transparent, has not been announced. *For countries excluded and*

hence cannot be supplied by the licensee: 47% of the world's population is excluded from being supplied by the VLs. While some countries in the excluded territory have manufacturing capacity and sufficient market, others neither have the manufacturing capacity nor the market. This means they are dependent on countries with manufacturing capacity for supply. Extension of the 17th June decision would support the production and export of supplies for dealing with COVID-19. Recently Pfizer announced [its plan](#) to offer low prices of nirmatrelvir/ritonavir to 45 LMICs. But the announcement lacks details about the actual prices, conditions and timelines of delivery. Pfizer has not published any data on the cost of manufacturing to allow public scrutiny on its pricing strategies. In May 2022, the Clinton Health Access Initiative ([CHAI](#)) [announced](#) that it has signed agreements with selected generic companies to secure affordable prices of generic nirmatrelvir/ritonavir for 95 LMICs with a ceiling price of US\$ 25 per treatment course. In addition to this arrangement excluding scores of countries and millions of people, the [potential ceiling price would only be possibly triggered](#) if the aggregate of all orders for public sector use in the 95 LMICs during the year is anticipated to meet or exceed one million treatment courses and any single order is for a quantity of least 50,000-treatment courses.

2. Molnupiravir

Purpose: WHO recommended in patients with non-severe COVID-19 at highest risk of hospitalization (excluding pregnant or breastfeeding women, and children). Needs to be administered within 5 days of symptom onset hence increasing access and ensuring appropriate use of diagnostic tests is essential.

Patent landscape: Merck has been granted or has pending patents in at least [25 developing countries](#). These patents could block generic production and supply in countries until 2035-2038.

Voluntary License: In October 2021, Merck signed a [voluntary license](#) with MPP. However, the voluntary license [excludes supply to nearly half of the world's population](#) including in countries with robust manufacturing capacity, including Brazil. Although MPP has [signed sublicense agreements](#) with 25 generic companies in January 2022, the limitation of geographic coverage and terms results in an unethical practice prohibiting generic companies from excluded nations to supply locally. (See Article 2, particularly 2.3 of the license, <https://medicinespatentpool.org/licence-post/molnupiravir-mol>) The license also contains a [harmful](#) provision [undermining the right of generic companies](#) who sign the license to legally challenge the validity of patents of molnupiravir. (See Article 10.3(g) of the sublicense form, and Article 6.2(g) and 10.3(g) of the main license agreement, available at: <https://medicinespatentpool.org/licence-post/molnupiravir-mol>) The provision could be considered unlawful in some jurisdictions for its anti-competitive effects.

Access Challenge:

To date, although limited generic supply sources maybe upcoming in some countries like India (due to bilateral license signed with Merck), access to more affordable generic version of molnupiravir in the short and medium term remains uncertain in the majority of developing countries.

3. Baricitinib

Purpose: recommended by WHO in combination with corticosteroids, in patients with severe or critical COVID-19.

Patent landscape: Eli Lilly holds patents on baricitinib in more than [50 developing countries](#), including most Latin American countries, South Africa and India. The patents would only start to expire in 2029, but the term of Eli Lilly's monopoly could be extended if additional patents are granted.

Voluntary license: No MPP license. Only bilateral VL given to select Indian manufacturers to supply India. Supply outside of India is not allowed.

Access Challenge: Patent holder Eli Lilly’s prohibitive price is US\$1,109 per 14-days treatment course in the United States. Eli Lilly has monopoly over supply and prices, thus it seems that some [developing countries, are paying much higher prices](#) for the originator version than developed countries (e.g. Argentina – 14 day treatment is \$886.48). Where patents are not a barrier [generic versions of baricitinib](#) are available for about US\$6-\$7 per treatment course i.e. nearly 158 times less than Eli Lilly’s price in the US. For e.g. in India (under bilateral voluntary license wherein supply outside of India is not allowed) and Bangladesh (due to LDC IP exemption). Overall, generic supply to developing countries with insufficient manufacturing capacity is a problem.

4. Intellectual property issues related to diagnostics: Local production of diagnostic tests can face potential intellectual property (IP) [barriers](#) in the form of patents and patent thickets on reagents, instruments, methods and software. Public health officials and advocates have struggled with these barriers in the context of HIB-AIDS and hepatitis. Diagnostic companies typically file [many patents](#). Since December 2020, WHO has recommended using quantitative immunoassays (ELISA) for the surveillance of COVID-19. Reliable tests for surveillance of COVID-19 are critical to measure incidence and mortality, and which population groups are at highest risk. Many ELISA tests available on the market can only identify one or two types of antibodies against COVID-19. In addition, most ELISA tests are not available nor suitable for developing countries. For example, the Elecsys Anti-SARS-CoV-2 ELISA test from Roche, a large Swiss-based pharmaceutical corporation, can only be used with Roche’s own device which is expensive and not adapted for use in resource limited settings. In November 2021, the [Spanish National Research Council offered an antibody test](#) technology to the WHO COVID-19 Technology Access Pool (C-TAP) and MPP. However, [one license from one technology owner is not enough](#) to open up the full platform so that developers in countries can improve their tests for COVID-19 antibodies. Overcoming intellectual property barriers on all key technology components, is [important to guarantee and improve access to COVID-19 diagnostics](#) for all.

IV. Sales of treatments in developed countries are extremely profitable, so extending the Decision to increase generic supply in LMICs won’t eliminate firms’ research funding.

Company	Q2 treatment revenue estimate	FY 2022 estimate	FY 2022 market share
Pfizer	US\$9.3 Billion	US\$ 23.3 Billion	79%
Merck	US\$ 1.3Billion	US\$ 5.8 Billion	20%
Shionogi’s S-217622	\$0	\$0.5 Billion	2%

V. Pharmaceutical firms’ and policymakers’ critique that June 17 Decision has not increased vaccine production is extremely cynical and without merit.

COVID vaccines, especially mRNA vaccines, have too many intellectual property barriers to be made under the compulsory licensing arrangements permitted by the WTO whether or not the right to produce for exports is established. As numerous health officials and generic manufacturers said during the lengthy debate leading to the June 17 Decision, without waivers for WTO-enforced IP rights, including relating to the data held by regulatory agencies with respect to how a vaccine is manufactured, production would not increase. Thus, the failure to waive WTO IP barriers is why generic COVID vaccine access has not increased and will not.