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March 20, 2023

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

RE: Prehearing Brief by Third World Network - Investigation No. 332-596

Dear Mrs. Hiner:

Kindly find attached a Prehearing Brief by Third World Network for Investigation No. 332-596 "COVID-19 Diagnostics and Therapeutics: Supply, Demand and TRIPS Agreement Flexibilities"

We had submitted the attached brief by the stated deadline of March 17, 2023. However, on March 20, 2023 we received an email from USITC (from Letitia Thorne, 332 Case Manager) stating that the Brief does not contain a signature and has to be refiled. As this is our first-time engagement in an investigation by the U.S. International Trade Commission, we were unaware that a signature was required for submission of the prehearing brief.

I thus would like to request for late acceptance and to resubmit the attached Prehearing Brief by Third World Network. We hope you will consider our request.

You can contact me by phone at +44 7972 175128 or by email at sangeeta@twnetwork.org

Thank you very much for your attention to this matter.

Sincerely,

Sangeeta Shashikant
Third World Network

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

Prehearing Brief by Third World Network

This Brief is also made on behalf of the following organizations:
Third World Network Berhad
Consumers Association of Penang, Malaysia
Campaign for Access to Medicines and Diagnostics India
TWN Trust India
Social Watch

INTRODUCTION

We strongly support the immediate and unconditional extension of the 17th June 2022 World Trade Organization (WTO) Ministerial Decision on the TRIPS Agreement (hereinafter referred to as 'TRIPS Decision') to COVID-19 therapeutics and diagnostics. In this regard, the U.S. government should without any delay support adoption of the 'Decision text on extension of the 17 June 2022 Ministerial Decision to COVID-19 Therapeutics and Diagnostics' (WT/GC/W/860; IP/C/W/694[1]) presented in the WTO by a group of developing countries in 2022.

This brief discusses the important role of diagnostics and therapeutics in dealing with COVID-19 which in the near future will remain unpredictable and a threat to public health. It highlights global health experts persistently pointing to the inability of developing countries to effectively respond to COVID-19 due to lack of timely access to affordable diagnostics and therapeutics as the patent holding pharmaceutical industry prioritize higher-priced sales to developed countries. It stresses that high prices and lack of readily available affordable generic supply has artificially suppressed demand for COVID diagnostics and therapeutics. The brief elaborates on the effect of patents on access and the critical role of compulsory license and the TRIPS Decision in facilitating affordable access, and the challenges and opportunities in use of that very essential flexibility.

The brief unpacks and analyses arguments of opponents against extending the TRIPS Decision to diagnostics and therapeutics, showing how they are based on spurious and unfounded claims. The brief further examines voluntary licenses, tier-pricing, access initiatives of international organizations and donations, and finds them to be flawed and insufficient for addressing the inequities in access faced by developing countries during COVID health emergency.

1. DIAGNOSTICS AND THERAPEUTICS ARE ESSENTIAL TOOLS TO CONTAIN THE SPREAD OF COVID-19, TO LIMIT THE DAMAGING HEALTH AND ECONOMIC EFFECTS OF COVID-19 WHICH CONTINUES TO EVOLVE WITH UNPREDICTABLE CHARACTERISTICS.

1.1. Diagnostics and therapeutics are essential tools to counter COVID-19 but inequitable access has been a major challenge for developing countries.

The World Health Organization (WHO) has identified that the key primary factors driving transmission COVID-19 are the lack of access to diagnostics and life-saving tools such as therapeutics, recognizing that they are an essential part of the comprehensive COVID-19 response strategy.[2] WHO and its COVID-19 Emergency Committee have repeatedly warned of the vast inequity in terms of access to diagnostics and therapeutics between developed and developing countries and impact of the spread of COVID-19.

The ACT-Accelerator report of September 2022[3] also noted with significant concern the consequences of limited testing in developing countries: "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 [...]days of symptom onset, and thus reliant on targeted and effective testing to identify early those at risk of severe disease progression", further adding "that realizing the full potential of these new medicines also continues to be hampered by limited access to these products for LMICs, unaffordable prices, delays in adopting test-to-treat strategies…".

[1] https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/W860.pdf&Open=True
[2] See pg. 4 Strategic preparedness, readiness and response plan to end the global COVID-19 emergency in 2022
[3] https://www.who.int/publications/m/item/act-accelerator-facilitation-council-working-group-report-on-diagnostics-and-therapeutics?utm_source=substack&utm_medium=email

The 14th meeting of the WHO International Health Regulations (IHR) Emergency Committee regarding COVID-19 pandemic which met on 30 January 2023[4], highlighted "concern about the ongoing risk posed by COVID-19, with a still high number of deaths compared to other respiratory infectious diseases, the insufficient vaccine uptake in low- and middle-income countries, as well as in the highest-risk groups globally, and the uncertainty associated with emerging variants" adding that "[w]hile eliminating this virus from human and animal reservoirs is highly unlikely, mitigation of its devastating impact on morbidity and mortality is achievable and should continue to be a prioritized goal." To achieve this end, it has been recommended, among other things, that governments enhance access to COVID-19 diagnostics and therapeutics for their populations.

Most people in most developing countries still do not have timely access to therapeutics and diagnostics primarily due to high prices, shortages when demand is high, and the commercial disinterest of major diagnostics and biopharmaceutical companies to make their tests and medicines available in many developing country markets. This concern has repeatedly been expressed by the Director General of WHO. In January 2023, he once again stressed: "[v]accines, therapeutics, and diagnostics have been and remain critical in preventing severe disease, saving lives and taking the pressure off health systems and health workers globally. Yet, the COVID-19 response remains hobbled in too many countries unable to provide these tools to the populations most in need, older people and health workers."[5]

Both, the WHO's Emergency Committee as well as the ACT-Accelerator[6] highlight concern that manufacturing is highly concentrated, stressing on the need for diversified production, in particular local production, to meet the access needs of developing countries. The WHO's 12th IHR Emergency Committee regarding COVID recommended: "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" adding that "local production ….related to ….therapeutics and diagnostics should be encouraged and supported as increased production capacity can contribute to global equitable access to therapeutics".[7]

1.2 COVID-19 remains unpredictable, with many unknowns, new immune evading variants, spikes in infections the new norm for now.

"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, the Director of National Institute of Allergy and Infectious Diseases Infections said in mid-2022.[8] More recently Bronwyn MacInnis director of pathogen genomic surveillance at the Broad Institute of MIT and Harvard, a biomedical research center in Cambridge, Mass said of the virus's mutations, '"A big question is how will that play out over time?". […]"Are there other tricks we have yet to see?"'.[9] These statements by experts in the field captures the **sentiment of uncertainty which continues to prevail with respect to COVID-19.**

Similarly, scientific literature on COVID-19 also reaffirms the unpredictability of the virus. According to a nature report "New immune-evading strains of the Omicron variant of SARS-CoV-2, behaviour

[4] https://www.who.int/news/item/30-01-2023-statement-on-the-fourteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic
[5] https://www.who.int/news/item/30-01-2023-statement-on-the-fourteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic
[6] https://www.who.int/publications/m/item/act-accelerator-facilitation-council-working-group-report-on-diagnostics-and-therapeutics?utm_source=substack&utm_medium=email
[7] https://www.who.int/news/item/12-07-2022-statement-on-the-twelfth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic
[8] https://www.cnbc.com/2022/10/07/dr-fauci-new-more-dangerous-covid-variant-could-emerge-this-winter.html
[9] https://www.wsj.com/articles/what-do-we-actually-know-about-covid-19-not-enough-ec1dcafe

changes and waning immunity mean that many countries could soon see large numbers of COVID-19 infections — and potentially of hospitalizations — say scientists."[10]

Precariousness of the COVID situation is reflected in the recent Washington post report following its interviews with various scientific experts: "Scientists, still in the dark about what the virus will do in the long term, warn it is too early to sound the all clear. Despite the success of a global effort to decode the SARS-CoV-2 virus and create vaccines and treatments to combat it, there remains uncertainty about how the virus will behave, the path of its mutations and Covid-19's long-term effects.[…] **The unknowns could have public-health consequences in the years ahead, virus experts said"**.[11]

1.3. As COVID-19 is unpredictable, the diagnostics and therapeutics landscape are constantly changing.

As mentioned above, COVID-19 has very uncertain characteristics, with the possibility of new variants, accelerating infections, and increased deaths as immunity weakens. **Given the pathogen's unpredictable nature, the diagnostics and therapeutics that are effective and needed is constantly evolving.** For instance in the US due to resistance to circulating variants, monoclonal antibodies (mAbs) are not recommended presently. The US FDA website notes that "[s]ome variants can cause resistance to one or more of the mAb therapies authorized to treat COVID-19. Due to the high frequency of variants circulating within the United States that are not susceptible to the following mAbs, the products below [referring to REGEN-COV (casirivimab and imdevimab), sotrovimab, bamlanivimab and etesevimab, bebtelovimab, evusheld (tixagevimab co-packaged with cilgavimab) are not currently authorized in any U.S. region until further notice by FDA".[12] **Further numerous new treatments are under development (for e.g. for acute infection, long COVID) which could offer better clinical outcomes.**

Consider that the WHO maintains a Therapeutics and COVID-19 living guideline[13], with recommendations that change multiple times every year. Thus far there have been 13 versions of this guideline. These recommendations suggest different treatments and combinations for different stages of COVID-19 and the recommendations change as new variants circulate and evidence emerges. National treatment guidelines may follow WHO or may vary. For instance, bebtelovimab had received emergency approval in the United States, but it was not recommended by WHO. WHO's COVID-19 living guideline also notes "[t]he unprecedented volume of planned and ongoing studies for COVID-19 interventions – over 5000 RCTs as of May 2022." According to industry BIO, there are 469 antivirals and treatments in development, 78 of which are in "late-stage clinical" phases.[14]

Even the U.S. Food and Drug Administration's (FDA) treatment recommendations are updated regularly, depending on the circulating variants. On the FDA website[15], in response to the question "What treatments are available to treat COVID-19," there is a reference to all products that have received emergency use approval and full approval. The FDA website adds: "many more therapies are being tested in clinical trials to evaluate whether they are safe and effective in combating COVID-19" and that "The FDA is continually monitoring how authorized and approved treatments for COVID-19 are affected by changing variants. If data shows the authorized dose of a treatment is unlikely to be effective against a current variant, the FDA may announce that the therapy is no longer authorized for use at this time. When that happens, the U.S. government recommends that the product be stored in case that treatment works on a future variant."

[10] https://www.nature.com/articles/d41586-022-03157-x?utm_medium=affiliate&utm_source=commission_junction&utm_campaign=CONR_PF018_ECOM_GL_PHSS_ALWYS_DEEPLINK&utm_content=textlink&utm_term=PID100062364&CJEVENT=70ad39a447f311ed8010019d0a18050f
[11] https://www.wsj.com/articles/what-do-we-actually-know-about-covid-19-not-enough-ec1dcafe
[12] https://www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs
[13] https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2022.4
[14] https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker
[15] https://www.fda.gov/consumers/consumer-updates/know-your-treatment-options-covid-19

2. HIGH PRICES AND LACK OF AFFORDABLE SUPPLY OPTIONS HAS ARTIFICIALLY SUPPRESSED DEMAND FOR COVID DIAGNOSTICS AND TREATMENTS.

Timely affordable access to supplies of pharmaceuticals to test and treat COVID-19 patients has been a constant struggle for developing countries.

For example Casirivimab +imdevimab was recommended by WHO for patients with non-severe COVID-19 at highest risk of hospitalization in September 2021. While the recommendation for its use has changed, it is worth noting that WHO expressed concern about "shortage of casirivimab and imdevimab globally and these medications are expensive".[16] The combination therapy held by company Regeneron has a very high price tag. i.e. of US$820 in India, $2,000 in Germany and $2,100 in the US.[17]

Price of tocilizumab another WHO recommended COVID-19 treatment is also very high[18] ranging from US$410 in Australia, $646 in India, to $3,625 in the USA per dose of 600mg for COVID-19. The actual cost to manufacture tocilizumab is actually estimated to be as low as $40 per dose of 400mg, given that the manufacturing costs of monoclonal antibodies are often below $100 per gram when produced on a large-scale.[19] Roche itself has indicated it will not be able to meet the demand.[20] Shortages of Tocilizumab were reported to be widespread while the limited supply is being snapped up by rich countries.[21]

In its guideline as at 13/1/2023 WHO strongly recommends treatment with IL-6 receptor blockers (tocilizumab or sarilumab) for patients with severe or critical COVID-19. However WHO also notes that "[c]urrently, access to these drugs [referring to tocilizumab and sarilumab] is challenging in many parts of the world, and without concerted effort is likely to remain so, […] It is therefore possible that this strong recommendation for IL-6 receptor blockers could exacerbate health inequity. On the other hand, given the demonstrated benefits for patients, it should also provide a stimulus to engage all possible mechanisms to improve global access to these treatments".[22]

The same WHO guideline strongly recommends baricitinib for patients with severe or critical COVID-19. But notes that it is "expensive" and access "is challenging in many parts of the world and, without concerted effort, is likely to remain so," adding that "It is therefore possible that this strong recommendation could exacerbate health inequity…. On the other hand, given the demonstrated benefits for patients, it should also provide a stimulus to engage all possible mechanisms to improve global access to these treatments".[23]

With respect to nirmatrelvir + ritonavir (brandname: paxlovid), which WHO guideline strongly recommends for patients with non-severe COVID-19 at highest risk of hospitalization, it observes that "Obstacles to access in low- and middle-income countries (LMICs) may prove formidable due to cost and availability" adding that since the "recommendation involves ideally administering treatment with

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[16] https://www.who.int/news-room/questions-and-answers/item/coronavirus-disease-(covid-19)-casirivimab-and-imdevimab---monoclonal-antibody-therapy

[17] https://timesofindia.indiatimes.com/business/india-business/health-activists-seek-lower-prices-of-roches-high-priced-antiviral-cocktail/articleshow/86488235.cms

[18] https://prezly.msf.org.uk/tocilizumab-second-drug-ever-recommended-by-who-for-covid-19-will-remain-unaffordable-and-inaccessible-for-most-of-the-world

[19] https://msfaccess.org/tocilizumab-second-drug-ever-recommended-who-covid-19-will-remain-unaffordable-and-inaccessible

[20] https://mg.co.za/africa/2021-08-26-unvaccinated-untreated-africa-may-not-get-its-fair-share-of-covid-19-drugs/

[21] See Severe shortage of high-priced drugs to treat COVID-19 | News | Jamaica Gleaner at https://jamaica-gleaner.com/article/news/20210904/severe-shortage-high-priced-drugs-treat-covid-19; Roche warns of global Actemra shortage as delta variant drives huge spike in demand for COVID-19 patients | Fierce Pharma at https://www.fiercepharma.com/pharma/roche-warns-global-actemra-supply-shortage-as-delta-variant-drives-unprecedented-demand-for; Unvaccinated, untreated: Africa may not get its fair share of Covid-19 drugs at https://mg.co.za/africa/2021-08-26-unvaccinated-untreated-africa-may-not-get-its-fair-share-of-covid-19-drugs/; Crushing costs of Covid care leave grieving Mexican families facing ruin at https://www.theguardian.com/global-development/2021/jan/31/mexico-coronavirus-care-costs

[22] https://app.magicapp.org/#/guideline/nBkO1E/rec/jDBZ3n

[23] https://app.magicapp.org/#/guideline/nBkO1E/rec/jDBZ3n

nirmatrelvir-ritonavir within 5 days of symptom onset, increasing access and ensuring appropriate use of diagnostic tests is essential for implementation. Thus, availability and use of appropriate SARS-CoV-2 diagnostic tests is needed to improve access to drugs, especially those targeting the early phase of disease."[24]

Alarmed by the lack of access to affordable COVID-19 diagnostics and therapeutics in developing countries, in April 2022, WHO expressed caution over the repeat of "inequity" witnessed with respect to COVID-19 vaccines , saying that it is "extremely concerned" that developing countries "will again be pushed to the end of the queue when it comes to accessing treatment."[25] In December 2022, the WHO Director General again emphasized: "[a]ccess to diagnostics and life-saving treatments for COVID-19 remains unacceptably unaffordable and unequal", adding that "[t]he burden of post-COVID-19 condition is only likely to increase."[26] Advocating that WTO Members support the extension of the TRIPS Decision to therapeutics and diagnostics, the WHO Director General stressed the imperative to "implement all the available tools they have to make local production possible and improve access." [27]

The pharmaceutical industry argues that the problem is not one of access, pointing to the low demand for therapeutics and diagnostics as measured by the volume of orders placed for treatments and tests. **But demand for tests and treatments in developing countries has been artificially suppressed.**

a. **First, rich countries hoarded initial supplies and big biopharmaceutical and diagnostic manufacturers prioritized higher-price sales to powerful developed countries and blocs.**[28] With only 20% of people in poor nations fully vaccinated, treatments are the only way to limit hospitalizations, deaths and economic losses. Yet developed countries have grabbed more than 70% of treatments so far produced, according to the Duke Global Health Innovation Center, despite accounting for only 16% of the world's population.[29] For example, virtually all of the first six months supply of nirmatrelvir+ritonavir (brandname: paxlovid) was committed to developed countries, most especially the United States, which reserved 20 million courses of treatment.[30] The first Quick Start[31] delivery of a few thousand courses of paxlovid treatment to sub-Saharan Africa did not occur until December 20, 2022 – a full year after it became available in the United States.[32] According to the Access to COVID-19 Tools Accelerator (ACT-A) and WHO, as of February 2023, 158,000 units of paxlovid had been ordered by the WHO Partner's Platform and the Test & Treat Coordination Working Group Partner Pilot of which only 40% had actually been delivered.

b. **Second, absent generic production, the prices for diagnostics and treatments that do become available are not affordable to developing countries.** As described below, the tiered pricing schemes used by pharmaceutical corporations in direct sales in developing countries still result in untenably high prices. Pfizer has charged more than $500 for each course of paxlovid in some developed countries and $250 in some developing countries, multiple times higher than the price negotiated by the Clinton Foundation for generic paxlovid ($25/course-

[24] https://app.magicapp.org/#/guideline/nBkO1E/rec/jDBZ3n
[25] https://www.who.int/news/item/22-04-2022-who-recommends-highly-successful-covid-19-therapy-and-calls-for-wide-geographical-distribution-and-transparency-from-originator
[26] https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-who--wipo--wto-joint-technical-symposium-on-the-covid-19-pandemic--response--preparedness--resilience---16-december-2022
[27] https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-who--wipo--wto-joint-technical-symposium-on-the-covid-19-pandemic--response--preparedness--resilience---16-december-2022
[28] https://launchandscalefaster.org/covid-19/therapeutics
[29] "A fact-based case for the extension of the TRIPS COVID-19 decision" at https://peoplesvaccine.org/wp-content/uploads/2022/11/A-fact-based-case-for-the-extension-of-the-TRIPS-COVID-19-decision.pdf
[30] https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/26/fact-sheet-biden-administration-increases-access-to-covid-19-treatments-and-boosts-patient-and-provider-awareness/
[31] https://www.covidcollaborative.us/initiatives/quickstart-consortium
[32] https://www.bloomberg.com/news/articles/2022-12-19/clinton-backed-initiative-ships-pfizer-covid-drugs-to-africa

of-treatment)[33] and the estimated cost-of-production plus profit analysis produced by Harvard Researcher Melissa Barber of $15.08 (estimated generic price – (cost of production + 10% profit margin and 26.6% tax on profit))[34]. Even when supplies do become available, prices based on monopoly control that are more than ten times the generic price (based on cost and set profit margin) mean developing countries simply cannot afford to provide their populations with access to key COVID tests and treatments.

Demand is dependent on availability and affordability of treatments and diagnostics. As Professor Joseph Stiglitz has repeatedly noted, test and treat programs in developing countries will be limited no matter how dire the need unless ample supplies of affordable diagnostics and treatments are readily available.[35] **The ITC's assessment of "unmet demand" should reflect people's actual needs – based on infection rates (including if and when it accelerates again) and the target populations that would be treated – were testing and affordable courses of treatments readily available. It should also take into account the likelihood that future treatments might be beneficial to treat other than "highest risk" populations, and people at risk of or experiencing long COVID.[36] To be able to assess the need for the extension of the June COVID WTO Decision, it is essential that the ITC measure demand based on need, not on the artificially suppressed volume of orders placed for medical intervention that have been unavailable and/or unaffordable.**

3. PATENTS HAVE AN ADVERSE EFFECT ON PRICES AND SUPPLY OF COVID-19 DIAGNOSTICS AND THERAPEUTICS.

Patents have a huge effect on supply, prices and distribution. Patents accord the patent holder a 20-year monopoly, enabling them to charge high prices and prevent other manufacturers from producing and supplying more affordable generic versions of the needed diagnostics and therapeutics. For example, prices for first line HIV treatment was $10439 per person per year, beyond the reach of developing countries. However, with the entry of generic competition, (i.e. production and supply by manufacturers in developing countries where patents had not been granted), prices fell drastically. Improved antiretroviral regimens with an annual cost over $45,000 in the U.S. are now available for less than $45 a year in South Africa[37], a thousand-fold price decrease enabling HIV treatment to be scaled-up there and in many other developing countries.

Existing COVID-19 therapeutics (e.g. nirmatrelvir, baricitinib, molnupiravir, tocilizumab) are widely patented[38] in the developing countries, especially those with generic manufacturing capacity. With high prices and supply to rich countries prioritized, these treatments have been and continue to be unavailable to most developing countries.[39] The same situation can be expected as COVID-19 therapeutics and diagnostics with better clinical outcomes become available.

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[33] https://www.reuters.com/business/healthcare-pharmaceuticals/generic-drugmakers-sell-pfizers-paxlovid-25-or-less-low-income-countries-2022-05-12/

[34] https://scholar.harvard.edu/files/melissabarber/files/estimated_cost-based_generic_prices_for_nirmatrelvir_ritonavir_paxlovid_january_2023_update.pdf

[35] https://www.scientificamerican.com/article/the-international-community-must-prioritize-covid-treatment-and-test-access/\; https://asia.nikkei.com/Opinion/Delays-on-WTO-deal-for-COVID-treatments-are-costing-lives-in-Asia

[36] https://www.medrxiv.org/content/10.1101/2022.11.03.22281783v1

[37] https://www.groundup.org.za/article/good-news-hiv-medicine-prices-have-decreased-dramatically/

[38] See, Medicines Patent Pool MedsPaL data base on COVID-19 therapeutics: https://www.medspal.org/?disease_area%5B%5D=COVID-19&disease_area%5B%5D=COVID-19+(drug+candidate)&page=1

[39]See See Severe shortage of high-priced drugs to treat COVID-19 | News | Jamaica Gleaner at https://jamaica-gleaner.com/article/news/20210904/severe-shortage-high-priced-drugs-treat-covid-19; Roche warns of global Actemra shortage as delta variant drives huge spike in demand for COVID-19 patients | Fierce Pharma at https://www.fiercepharma.com/pharma/roche-warns-global-actemra-supply-shortage-as-delta-variant-drives-unprecedented-demand-for; Unvaccinated, untreated: Africa may not get its fair share of Covid-19 drugs at https://mg.co.za/africa/2021-08-26-unvaccinated-untreated-africa-may-not-get-its-fair-share-of-covid-19-drugs/; Crushing costs of Covid care leave grieving Mexican families facing ruin at https://www.theguardian.com/global-development/2021/jan/31/mexico-coronavirus-care-costs. Also see "Latin America: How patents and licensing hinder access to COVID-19 treatments" at

In the case of diagnostics, supply constraints due to concentrated production and high prices as developed countries outbid developing countries is a key obstacle to access to COVID-19 diagnostics. Diagnostic companies typically file many patents, with patent thickets being a key concern.[40] For example, the estimated cost of production for Cepheid's GeneXpert COVID-19 diagnostic test is just US$3-5 per test, yet Cepheid is charging US$14.90 in developing countries, at least 3 times the estimated cost of production.[41] This high price vastly limits access to this test in resource limited settings. Wider access to point of care molecular diagnostics such as the GeneXpert system would mean more people could be tested for COVID-19 by the sensitive PCR technology in decentralised settings. Notably, Cepheid developed GeneXpert and its assays over the past two decades largely through significant public and philanthropic funding (at least US$252 million).[42]

Article 7 of TRIPS sets out the objectives of the TRIPS Agreement as being to 'the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.' Article 8(2) of TRIPS recognizes that there may be abuse of the IP system by its right holders, and "[a]ppropriate measures", "may be needed to prevent the abuse". There is extensive literature about the abuse of the IP system by the right holders especially in the context of patents and the resulting negative consequence on public health.[43] Accordingly, the TRIPS Agreement has built in "flexibilities" to enable WTO Members to take measures to protect public health. One of the flexibilities provided for within the WTO and TRIPS framework is temporary waivers from TRIPS's requirements. There is no reason that this flexibility via the limited waiver of one aspect of TRIPS that would facilitate export of compulsory licensed treatments and tests cannot be extended beyond vaccines to include diagnostics and therapeutics.

4. COMPULSORY LICENSE (CL), AN ESSENTIAL FLEXIBILITY FOR PUBLIC HEALTH

While there are multiple determinants of access, **lifting the patent barrier is a prerequisite for enabling generic manufacturing, expanding supply options, reducing prices and promoting access.** One of the most important flexibilities in the TRIPS Agreement is the flexibility to issue a compulsory licence (CL) to overcome patents barriers, as provided for in Articles 31 of TRIPS. In 2001, the right to **use CL was reaffirmed in the Doha Declaration on TRIPS and Public Health adopted by WTO Members**.[44] Paragraph 3 of the Doha Declaration recognizes "concerns about its [intellectual property] effects on prices", while paragraph 4 clarifies: "TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

Compulsory licensing has enabled governments (developed and developing countries) to address their public health needs. For instance, in 2017 Malaysia issued a CL to access affordable hepatitis C treatment that could avoid liver cancers and cure patients.[45] The treatment was approved by US FDA in 2013 but was unavailable in Malaysia due to the high costs of around US$70,000. Use of a CL

https://msfaccess.org/latin-america-how-patents-and-licensing-hinder-access-covid-19-treatments and A fact-based case for the extension of the TRIPS COVID-19 decision" at https://peoplesvaccine.org/wp-content/uploads/2022/11/A-fact-based-case-for-the-extension-of-the-TRIPS-COVID-19-decision.pdf

[40] https://msfaccess.org/sites/default/files/2021-07/IP_IssueBrief_Local-diagnostics-local-health-needs_ENG_13.7.2021.pdf

[41] https://peoplesvaccine.org/wp-content/uploads/2022/11/A-fact-based-case-for-the-extension-of-the-TRIPS-COVID-19-decision.pdf

[42] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0256883

[43] See for e.g. "Overpatented, Overpriced Curbing Patent Abuse" at https://www.i-mak.org/wp-content/uploads/2023/01/Overpatented-Overpriced-2023-01-24.pdf

[44] https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[45] https://www.twn.my/title2/intellectual_property/info.service/2023/ip230202.htm

allowed affordable generic versions to be imported from Egypt, another developing country, costing less than US$300 (99.7% reduction in price), enabling the roll-out of free HCV treatment in Malaysia. In 2012 a CL was issued in India to override patent barriers on a kidney and liver cancer treatment (which had been approved by the US FDA in 2005) allowing the manufacture and supply of a generic version with a 97% price reduction.[46] There are multiple other examples of use of CLs to override patents that has resulted in access and scale-up of treatment.[47]

Notably, developed countries such as the US are prolific users of CLs for various purposes including to address COVID related access needs. For example, in late 2020, Hungary granted a CL on remdesivir[48], to allow domestic manufacture for 3,000 COVID-19 patients.[49] In 2020 Israel issued a CL to import generic versions of lopinavir/ritonavir from India (where there were no patents) for the sole purpose of medicinal treatment of COVID-19 patients due to the shortages. Thereafter patent holder AbbVie issued a commitment not to enforce patents on lopinavir/ritonavir globally.[50]

The United States is one of the most frequent users of CL including for COVID-19. At least 166 U.S. contracts disclosed to the U.S. Securities and Exchange Commission (SEC) contain broad compulsory licenses to use patented inventions without the consent of patent holders when the use is "by or for" the U.S. government, under 28 U.S. Code § 1498.[51] The compulsory licenses were granted for a diverse set of purposes, and many by different federal government agencies.

With respect to COVID-19, a review of 62 contracts revealed 59 authorizations for non-voluntary use of third party patents under 28 USC 1498[52] and this is not an exhaustive list. Section 1498 allows the federal government to authorize third parties to use patented inventions without the consent of the patent holder. The best known case involves Moderna vaccine, wherein the U.S. government has argued on the basis of section 1498 that it should liable for any infringement of Arbutus Biopharma Corp and Genevant Sciences GmbH's patents that took place under Moderna's contract to provide shots for the government's nationwide vaccination effort. The federal government's authorization has been highlighted by Moderna in court filings relating to the infringement case[53].

5. CHALLENGES IN USING COMPULSORY LICENSES

5.1 Pressure of trading partners (especially the United States and pharmaceutical corporations)

Despite importance of using CLs to address public interest concerns at the national level, there are significant challenges to their use. Developing countries have been systematically harassed, bullied and threatened with trade sanctions by trading partners (especially the United States)[54] and with court

[46] https://www.twn.my/title2/resurgence/2012/259/cover07.htm
[47] See Country experiences in using TRIPS safeguards: Part 1, WHO at http://apps.who.int/iris/bitstream/handle/10665/272977/Country-experiences-TRIPS-Part1.pdf?sequence=1&isAllowed=y; "Malaysia's experience in increasing access to antiretroviral drugs: exercising the "government use option" at https://www.twn.my/title2/IPR/pdf/ipr09.pdf; Compilation of various materials including articles, case reports and press releases, pertaining to the use of CL in US, Europe, South and Central America and the Caribbean, Asia Pacific and America https://www.keionline.org/cl
[48] https://www.keionline.org/35558
[49] "Hungary's Richter has manufactured Remdesivir for 3,000 COVID-19 patients" at https://www.reuters.com/article/us-health-coronavirus-remdesivir-richter-idUSKBN26S283;
[50] https://www.ft.com/content/5a7a9658-6d1f-11ea-89df-41bea055720b
[51] https://www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2022-2-FAR-52.227-1-SEC-exhibits.pdf
[52] https://www.keionline.org/bn-2022-1
[53] See https://www.keionline.org/38327 and https://www.reuters.com/legal/us-backs-moderna-says-government-should-face-covid-19-vaccine-lawsuit-2023-02-15/
[54] The Pharmaceutical Research and Manufacturers Association (PhRMA) and the Biotechnology Innovation Organization (BIO), the industry's trade association in the US annually submit complaints to the US Trade Representative (USTR) relating to compulsory license measures considered and taken by foreign governments. At the behest of pharmaceutical corporations, the annual USTR Special 301 Report on IP enforcement has over the years threatened trade sanctions against developing countries for issuing compulsory licenses to allow lower-priced versions of desperately needed medicines while the medicine was still under patent.

actions by pharmaceutical corporations[55] from using CLs for access to medicines.[56] While more recently, the Office of the U.S. Trade Representative has acknowledged[57] the right of all countries to use CLs, the **USTR has to do much more to eliminate political and trade pressures that undermine the use of TRIPS flexibilities especially CLs** and instead to encourage their use in support of equitable access. **A first step would be for the USTR to unconditionally support extending the TRIPS Decision to therapeutics and diagnostics.**

5.2 TRIPS plus in North-South FTAs especially with the United States

Another challenge to the use of CLs is TRIPS-plus provisions in North-South Free Trade Agreements, such as data exclusivity, which hinders the effective use of CLs by preventing the grant of marketing approval to generic therapeutics.[58] **The United States should suspend the enforcement of any provisions in such FTAs that affect the use of CLs, including for COVID-19 purposes.**

5.3 Restriction on Exports due to Article 31(f) of TRIPS

To benefit from the use of CLs, affordable generic supply has to be readily available, especially for countries with small domestic markets or where local manufacturing may not be viable or is delayed. This in turn requires economies-of-scale, as well as importing and exporting countries (including manufacturers in exporting countries) being able to manufacture, import and export to meet public health needs without being bogged down and deterred by labyrinth administrative and procedural requirements. **The unworkable and flawed Article 31*bis* of TRIPS (previously known as the 30th August 2003 WTO Decision[59]) is especially problematic in this regard.** In 20 years, it has only been used once, and was considered "unnecessarily complex and does not adequately represent the interests of those who require treatment".[60]

Hence the need for extension of the TRIPS Decision on therapeutics and diagnostics, which waives only one aspect of the TRIPS Agreement – the limitations on exports of products made under CLs (Article 31(f) of TRIPS).

5.4 Arguments that CL discourages innovations are baseless and spurious

Compulsory licensing is so obviously a critical tool for addressing public health concerns, widely utilized by developed and developing countries alike, with positive effects on affordability and availability, and eventual scale-up of public health programs that limit the spread of the infectious disease and save lives. **Exaggerated claims that CLs discourage innovations are baseless and spurious.** Scherer studied 70 companies and found those whose patents had been compulsorily licensed actually significantly increased their research and development compared to companies of comparable size who had not been subject to compulsory licences.[61] It concludes that there is **no evidence that the**

[55] https://www.keionline.org/37566

[56] See Timeline of US pressure on India IP law (2015): https://msfaccess.org/sites/default/files/2018-10/IP_Timeline_US%20pressure%20on%20India_Sep%202014_0.pdf; 13 NGOs Call on USTR To Support Colombia in Special 301 Following Pressure Over Legal Access to Meds Efforts at https://www.keionline.org/27256 and see https://www.keionline.org/wp-content/uploads/2018/03/Lighthizer-letter-to-Colombia-Feb-14-2018-re-OECD.pdf; Switzerland pressures Colombia to deny compulsory license on imatinib at https://www.keionline.org/22864#:~:text=However%2C%20in%20a%20letter%20of

[57] https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/december/us-support-extension-deadline-wto-trips-ministerial-decision-requests-usitc-investigation-provide-0

[58] see pgs. 24-26 Report of the UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES at https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf; Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover at https://digitallibrary.un.org/record/652915?ln=en; Intellectual Property in Free Trade Agreements at https://www.twn.my/title2/books/SanyaFTA.htm

[59] https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

[60] "Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable" at https://msfaccess.org/neither-expeditious-nor-solution-wto-august-30th-decision-unworkable. Also see https://www.biospace.com/article/releases/apotex-inc-life-saving-aids-drug-for-africa-gets-final-clearance-/

[61] see pg. 72 of Intellectual Property in Free Trade Agreements at https://www.twn.my/title2/books/SanyaFTA.htm

granting of compulsory licences has led to a reduction in R&D investment.[62] Analysis from the National Bureau of Economic Research[63] suggests that "when patent rights have been too broad or strong, they have actually discouraged innovation", and further finds that compulsory licensing can indeed encourage innovation.

Boldrin and Levine identified 23 empirical studies which examined whether stronger patent protection had in fact increased innovation. These **studies found weak or no evidence that strengthening patent protection increase innovation, stronger patent regimes merely increase patenting.**[64] Recent patent disputes among mRNA innovators illustrate how patents held by one company can impede important medical advances with costly and time-consuming legal disputes that threaten to detract all parties from innovation work.

Patents are not a strong measure of medically beneficial innovation. A study by Robin Feldman found that most patents over a 10-year period (2005-2015) were for existing products.[65]

6. CONCERNS OVER EXTENSION OF TRIPS DECISION ARE UNFOUNDED

Opponents of the TRIPS Decision have raised various arguments against its extension to diagnostics and therapeutics. This section unpacks those assertions, proving them to be baseless and unfounded.

6.1 Scope of the TRIPS Decision is narrow and conditioned

The TRIPS Decision is time-bound and **only applicable to 'developing countries'**. The main feature of the Decision text is a waiver of Article 31(f) of TRIPS (see paragraph 3(b) of the TRIPS Decision). This limited waiver is subject to several conditions (see paragraph 3(c), paragraph 5 of the TRIPS Decision). Remaining elements of the TRIPS Decision are simply reaffirming what is already allowed by the TRIPS Agreement.

6.2 The TRIPS Decision text is also very specific to COVID-19 and cannot be used for any other purpose.

Any concern that therapeutics licensed for COVID-19 will be used for the treatment of other diseases is completely unfounded. While under Article 31 of TRIPS, compulsory license may be issued for any purpose, the **TRIPS Decision text is very specific to COVID-19**. **Normally when a compulsory license is issued it is for a very specific purpose and duration.** Article 31(c) of TRIPS makes clear that "the scope and duration of such use shall be limited to the purpose for which it was authorized". This means compulsory licensee will have to operate within the parameters of the CL granted. And in situations where the TRIPS Decision is invoked, within the parameters of the Decision.

Further **if there are concerns with the CL issued under Article 31 of TRIPS a patent holder has options under Article 31(g) and (i) of TRIPS**. Article 31(g) of TRIPS provides that the competent authority shall have the authority to review, on request of the patent holder, the continued need for the CL. Article 31(i) of TRIPS requires that the "legal validity of *any* decision relating to the authorization of such use shall be subject to judicial review or other independent review" meaning that legal avenues are available to a patent holder, that has concerns with respect to the CL granted.

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[62] F. M. Scherer, Comments in Robert Anderson and Nancy Gallini (Eds.), Competition policy and intellectual property rights in the knowledge-based economy, University of Calgary Press, Alberta 1998 cited in Resource Book on TRIPS and Development, UNCTAD-ICTSD (pg. 488) at https://unctad.org/system/files/official-document/ictsd2005d1_en.pdf

[63] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2712428

[64] 'Against Intellectual Monopoly', Boldrin & Levine, 2007, http://www.dklevine.com/general/intellectual/againstnew.htm

[65] May your drug price be evergreen at https://academic.oup.com/jlb/article/5/3/590/5232981

6.3 Extension of the TRIPS Decision will not affect the sales and profits of pharmaceutical companies or pharmaceutical R&D

(a) Pharmaceutical companies tend to **make most of their sales and profits from developed country markets**.[66] For instance, in 2022, Pfizer signed a supply agreement with the US amounting to US$12.6 billion.[67] This deal alone accounts for 67% of Pfizer's sales for paxlovid in 2022 which reportedly was US$18.9billion.[68] These sales that takes place in developed countries will not be affected as the TRIPS Decision may only be used by developing countries.

Second point to note is that paragraph 3(c) of the TRIPS Decision is clear that products manufactured under the Decision that have been imported under the Decision cannot be re-exported and that "[m]embers shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products manufactured under the authorization in accordance with this Decision, and diverted to their markets inconsistently with its provisions". **This condition sufficiently ensures that products manufactured during the Decision cannot be diverted into developed country markets**, thus protecting the sales of pharmaceutical industry in those markets.

(b) **Use of CL is in any case subject to payment of royalties to the patent holder.** Article 31(h) of TRIPS conditions the use of CL to the right holder being paid "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization". Payment of adequate remuneration is reaffirmed in paragraph 3(d) of the TRIPS Decision text.

(c) Analysis of the COVID-19 therapeutic patent landscape suggest, more than 80% of the COVID-19 therapeutics were repurposed, i.e., drugs that have been approved for treatment of a different disease[69], strongly indicating that R&D expenditure has been minimal and most of the compounds are benefitting or have benefitted from a 20 year patent monopoly. **As such most new patent applications/grants for COVID-19 are very likely to be for "new use" and secondary patents aimed at patent evergreening, essentially an abuse of the patent system.** Unfortunately such anti-innovation, anti-competitive strategies are a common feature in the pharmaceutical sector[70].

Further any investment in R&D that may have been made has definitely been recouped given the bumper profits made in 2021/22. In 2022, molnupiravir, generated $5.68 billion in sales for Merck[71] while Pfizer made $18.9billion from paxlovid. In 2023, both are expected to make more billion dollar sales. As explained in (a), the revenue of pharmaceutical companies are unlikely to be affected as their primary markets are the developed country markets and the TRIPS Decision will not impact those markets. And in any case, given the massive super profits of the pharmaceutical industry in the past two years, it is evident that any R&D investment would surely have been recouped.

Arguments that extension of the TRIPS Decision will affect innovation incentives are thus baseless. Likewise, adoption of the Decision will not adversely impact pharmaceutical manufacturing jobs in the United States, which are again largely focused on manufacturing for sales in developed country markets. Instead, the Decision, if adopted and implemented, will ensure timely affordable access to developing countries and limit the negative effects of COVID-19. It will open the door wider to facilitate accelerated export of vital COVID-19 diagnostics and therapeutics to developing countries, thereby speeding up and expanding supply, lowering prices, and ultimately facilitating more equitable access to tests, treatments, and test-to-treat health service delivery. This will not cut into pharmaceutical firms'

[66] See https://launchandscalefaster.org/sites/default/files/documents/2023%20vaccine%20info/Duke%20Global%20Health%20Innovation%20Center%20Extracted%20Therapeutics%20Data%202.17.2023.xlsx
[67] See https://www.reuters.com/world/us/us-pay-pfizer-nearly-2-bln-more-paxlovid-courses-2023-2022-12-13/
[68] See https://www.cnbc.com/2023/01/31/the-covid-pandemic-drives-pfizers-2022-revenue-to-a-record-100-billion.html
[69] https://www.wipo.int/edocs/pubdocs/en/wipo-pub-1075-en-covid-19-related-vaccines-and-therapeutics.pdf
[70] See https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html; "Overpatented, Overpriced Curbing Patent Abuse" at https://www.i-mak.org/wp-content/uploads/2023/01/Overpatented-Overpriced-2023-01-24.pdf
[71] See https://www.reuters.com/business/healthcare-pharmaceuticals/merck-fourth-quarter-tops-expectations-strong-covid-pill-sales-2023-02-02/

profits or jobs in the sector, as the Decision does not apply to developed countries where the firms are now making most of their profits on sales.

6.4 Extension of the TRIPS Decision will not affect future pandemic response

Arguments that future global pandemic preparedness and response will be affected if the TRIPS Decision is extended is another frivolous attempt by the pharmaceutical industry to undermine the use of TRIPS flexibilities.

(a) **Pharmaceutical R&D especially for neglected and emerging diseases is mostly driven by public funds**. Amin, T., et al. have noted[72]:

"Since 2002, epidemics caused by severe acute respiratory syndrome (SARS), swine flu (H1N1), Middle East respiratory syndrome (MERS), Zika, Ebola, and other viral diseases have killed nearly 600,000 people worldwide. Yet, in the aftermath of these outbreaks, and despite clear warnings that another viral pandemic could emerge, the pharmaceutical industry failed to sustain investment into new treatments and vaccines.

In 2018, global funding for basic research and product development for neglected diseases was just $4 billion. Of this funding, 64% came from public tax dollars. Another 19% came from philanthropic organizations. The private pharmaceutical sector contributed just 17% —$650 million — a drop in the ocean considering that the revenue of the top 20 pharmaceutical companies was more than $661 billion in 2019.

The lack of investment by the pharmaceutical industry is not limited to neglected diseases and pandemic preparedness. Many of the largest pharmaceutical companies have stopped investing in the development of new antibiotics to treat drug-resistant infections, which is already a global health crisis that is costing lives and threatening modern medicine, including routine surgery and chemotherapy. Rather than conducting research and developing genuinely new drugs that could help solve some of the biggest public health issues now and in the future, companies spend more time finding ways to keep existing drug franchises profitable. This includes filing hundreds of patents on a single drug under the guise of medical innovation"

(b) **Compulsory license has played a significant role in COVID-19 response and it has not affected pharmaceutical R&D or profits**.

Several countries have enacted progressive CLs provisions[73] to make it easier to use CL, while others have actually issued CL to address shortages of COVID-19 therapeutics, such as Hungary, Israel (as discussed in section 4 above) as well as Indonesia[74] and Russia[75]. The right to issue CL for government use to address public health needs is the basis for US's intervention in the Arbutus Biopharma Corp, Genevant Sciences and Moderna patent dispute.[76]

None of these instances of relying on CL has adversely impacted pharmaceutical profits or R&D as evidenced by the thriving R&D pipeline for COVID-19 therapeutics (discussed above) and record-breaking profits of the pharmaceutical companies in 2022:

[72] See "Covid-19 has exposed the limits of the pharmaceutical market model" at https://www.statnews.com/2020/05/19/covid-19-exposed-limits-drug-development-model/?utm_content=bufferfdaeb&utm_medium=social&utm_source=twitter&utm_campaign=twitter_organic
And G-Finder Global Funding for Innovation for Neglected Diseases at https://s3-ap-southeast-2.amazonaws.com/policy-cures-website-assets/app/uploads/2020/02/07161934/GF-6pSummary2019.pdf
[73] See pg 3-4, MSF Briefing Document May 2021 at https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf
[74] See https://makemedicinesaffordable.org/indonesia-issues-government-use-licenses-for-remdesivir-and-favipiravir/
[75] See https://makemedicinesaffordable.org/gilead-sues-russia-private-company-challenges-a-countrys-right-to-protect-public-health/
[76] https://ipwatchdog.com/2023/03/08/pharma-companies-u-s-government-spar-application-section-1498-patent-infringement-claims-modernas-covid-19-vaccine/id=157459/#

- Pfizer's revenue for 2022 was US$100.3 billion, US$57 billion of which was driven by its vaccine and antiviral pill paxlovid. In 2022, US$18.9 billion revenue was generated from sales of paxlovid.[77]
- Gilead's remdesivir (brand name veklury) generated revenue of US$3.9billion in 2022[78].
- Merck's molnupiravir generated revenue of US$5.68billion in 2022.[79]

6.5 Extension of the TRIPS Decision will not affect the quality of diagnostics and therapeutics.

Opponents of the TRIPS Decision often assert that granting an extension will lead to oversight problems and quality risks that can hurt patients. This argument is false and merely a scaremongering tactic to oppose the extension and deter countries from using compulsory license. It is an attempt to confuse and conflate issues of intellectual property with issues pertaining to quality, safety and efficacy of a pharmaceutical product. It is important to note that the grant of patents and other IP is not based on the quality, safety and efficacy of a product. Issues concerning the quality, safety and efficacy of a pharmaceutical product are handled by the medicines/drug regulatory authority which is a distinct entity from the IP office.

Section 4 above describes CL as a critical tool to facilitate access, used in developed and developing countries including for the purpose of COVID-19. CL is simply an authorization by a government/IP office allowing the use of the patented invention without the consent of the right holder. With this grant, a manufacturer may produce a product. However to market or commercialize a pharmaceutical product, marketing approval from the national medicines/drug regulatory authority has to be obtained. Hence each country through its national medicines/drug regulatory authority will assess the quality, safety and efficacy of a generic medicine before granting marketing approval for the commercialization of a product. **The TRIPS Decision and its extension does not in any way affect or impact the marketing approval processes that are in place in each country to assess the quality, safety and efficacy of each product.**

6.6 TRIPS Decision should be extended unconditionally, without delay, and should cover all COVID-19 therapeutics and diagnostics

TRIPS Decision is an outcome of prolonged tense negotiations, and thus it should be extended immediately without any further restrictions/conditions. **Any suggestion that extension of the TRIPS Decision should be restricted to a few products, are simply flawed given the unpredictable characteristics of the COVID-19 virus.** Extension of the Decision will only affect one condition for using CLs, namely the limitation of quantities exported to other developing countries found in Art. 31(f) (limiting exports to non-predominant quantities) and only with respect to 'developing countries' that invoke Decision.

7. VOLUNTARY LICENSES (VLS) ARE NOT GUARANTEED AND ARE NOT SUFFICIENT

Voluntary licenses are often put forward as the solution to the challenge of access in developing countries. However, as the licenses are 'voluntary', **there is no guarantee that a patent holder will make available such license for supply to developing countries.** For example, in the case of baricitinib, no VL has been granted for supply to developing countries.[80]

[77] https://www.cnbc.com/2023/01/31/the-covid-pandemic-drives-pfizers-2022-revenue-to-a-record-100-billion.html
[78] https://www.gilead.com/news-and-press/press-room/press-releases/2023/2/gilead-sciences-announces-fourth-quarter-and-full-year-2022-financial-results
[79] https://www.merck.com/news/merck-announces-fourth-quarter-and-full-year-2022-financial-results/
[80] See https://msf-access.medium.com/jak-inhibitors-promising-treatment-for-people-with-severe-covid-19-illness-2b14e812a434 and https://www.msf.org.za/news-and-resources/press-release/south-africa-must-urgently-revoke-patents-key-covid-19-treatments

And where VLs exists, for example with respect to Merck, Pfizer, and Shionogi antivirals, they exclude supply to many developing countries. Medicines Patent Pool (MPP) licenses for authorized treatments (paxlovid and molnupiravir) **exclude supply to nearly half the world's population. More than 50 developing countries are excluded from one or both licenses[81],** most of which are have large populations and suffered some of the most damaging rates of infection. These countries can source only from the originator companies, who maintain monopoly control over supply, allocation, and price.

For instance in the case of paxlovid, MSF highlights that "[m]ost Latin American countries have been excluded from the deal signed by Pfizer and the Medicines Patent Pool for the new COVID-19 treatment nirmatrelvir/ritonavir. Pfizer has additionally filed patents in all of these countries. With pending patent claims that may be granted later, Latin American countries will face [access] challenges, until at least 2041".[82] In March 2022, in a joint letter to Pfizer CEO Albert Bourla, a consortium of 100 activist groups, including Amnesty International and Oxfam, urged Pfizer to expand the territory coverage of the VL, to include all developing countries.[83] This has not happened.

In MPP's license with Merck with respect to molnupiravir, many developing countries were excluded from supply including Latin America although countries excluded from the license had 30 million infections in the first half of 2021, and 50% of all infections in developing countries.[84]

Apart from the limited country coverage, there are other unjustified terms and conditions in VLs[85] that could delay or hinder generic production and which arguably are also anti-competitive.[86] For example **Pfizer's license prevents R&D on combination regimens, coformulation, and even co-packaging.**[87]

VLs also do not provide the prompt access that is needed in times of health emergency. For example, in November 2021, Pfizer and MPP signed a licence agreement to facilitate affordable access of Pfizer's oral COVID-19 antiviral treatment nirmatrelvir in combination with ritonavir. But, more than one year on, due to conditions attached to the VL, as at March 2023 generic supply is only available from one generic company. In the case of MPP license with Merck signed in October 2021, as at March 2023, only 2 generic suppliers can provide under the license due to the terms of the MPP license.

Whilst VLs may eventually (one or two years after signature) facilitate access to affordable generics for some developing countries, they are obviously an insufficient tool.

8. TIER-PRICING DOES NOT DELIVER AFFORDABLE PRICES. IT IS VOLUNTARY, REVOCABLE AND LACKS TRANSPARENCY

Tier-pricing does not equate to affordable prices. **Prices that are the result of generic competition are usually significantly lower than tier-pricing prices and most affordable**. For instance the so-called not-for-profit pricing available to certain developing countries (molnupiravir ($85/course of treatment), paxlovid (Panama, $250/course-of-treatment[88]) is multiple times higher than the estimated price for generic paxlovid (US$15.08 that includes cost of production + 10% profit margin and 26.6%

[81] See map at https://twitter.com/peoplesvaccine/status/1597542383142703104/photo/1
[82] https://msfaccess.org/latin-america-how-patents-and-licensing-hinder-access-covid-19-treatments
[83] https://healthgap.org/pfizerletter/
[84] https://www.twn.my/title2/health.info/2021/hi211101.htm
[85] Voluntary Licenses and Access to Medicines, MSF Briefing Document at https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf
[86] See also critique of MPP license for COVID-19 medicine molnupiravir wherein it is argued that the license strengthened Merck's monopoly with its limited country coverage, unjustified royalties and anti-competitive provisions amidst a weak patent portfolio held by MSD. It is a perfect example of using a voluntary license (VL) for rent seeking purposes. https://www.twn.my/title2/health.info/2021/hi211101.htm
[87] Also see https://healthgap.org/pfizerletter/ and https://infojustice.org/archives/44914
[88] https://scholar.harvard.edu/files/melissabarber/files/estimated_cost-based_generic_prices_for_molnupiravir_for_the_treatment_of_covid-19_infection.pdf

tax on profit)[89] and estimated price for generic molnupiravir (US$19.99 that includes cost of production + 10% profit margin + allowance for 27% tax on profits)[90]

Tier-pricing is voluntary and many developing countries are known to be excluded from tier-pricing schemes of pharmaceutical companies. For example, the price of molnupiravir to Thailand was $300[91] a course of treatment and the price of paxlovid to Brazil is reported to be near $250[92] a course of treatment. Even though these countries have GDP/capita that is a fraction of that in the U.S., they are asked to pay more than 40% of the U.S. price.

Tier-prices are sometimes known to be significantly higher in developing countries than in developed countries. An analysis revealed that baricitinib costs $886.48 (per course of treatment) in Argentina (a developing country), significantly more than in developed countries: US$371.98 in France, US$551.32 in UK, US$822.78 in the US.[93] Meanwhile the estimated generic price for baricitinib is US$2/treatment course including cost of production +10% profit margin, and 26.6% tax on profit.[94]

The **tier-pricing argument is also dubious in view of the complete lack of transparency in the prices charged by pharmaceutical companies in each country as well as their costs of production**.[95] In 2022, WHO cautioned "..availability, lack of price transparency in bilateral deals made by the producer, and the need for prompt and accurate testing before administering it, are turning this life-saving medicine into a major challenge for low- and middle-income countries'.[96] It also stressed "[l]ack of transparency on the part of the originator company is making it difficult for public health organizations to obtain an accurate picture of the availability of the medicine, which countries are involved in bilateral deals and what they are paying".[97] Pharmaceutical giant Pfizer allegedly pressured UNICEF to agree to non-disclosure requirements on pricing that would protect information on the prices of the company's anti-viral treatment for COVID-19 Paxlovid.[98]

Moreover, **tiered pricing can potentially create a disincentive structure.** "If a company has a limited supply, and has to decide who gets served first, all the incentives are tipped towards fulfilling the contracts that pay top dollar", experts have concluded.[99]

9. DONATIONS ARE UNRELIABLE WHILE ACCESS INITIATIVES BY INTERNATIONAL ORGANIZATIONS AD HOC AND USUALLY DEPENDANT ON AVAILABILITY OF AFFORDABLE GENERIC SUPPLY

Opponents of extension tend to refer to announcements by international organizations engaged in procurement and distribution of COVID-19 therapeutics and diagnostics, such as ACT-A, suggesting "access" in developing countries is no longer an issue. However, **these access schemes are often extremely limited, supplying small amounts to a few countries with the lowest incomes.** For instance, the COVID treatment Quickstart consortium[100], is targeted at 10 countries in Africa and

[89] https://scholar.harvard.edu/files/melissabarber/files/estimated_cost-based_generic_prices_for_molnupiravir_for_the_treatment_of_covid-19_infection.pdf
[90] https://scholar.harvard.edu/files/melissabarber/files/estimated_cost-based_generic_prices_for_molnupiravir_for_the_treatment_of_covid-19_infection.pdf
[91] https://www.bangkokpost.com/thailand/general/2212563/cabinet-approves-purchase-of-molnupiravir
[92] https://www.gov.br/conitec/pt-br
[93] https://scholar.harvard.edu/files/melissabarber/files/estimated_cost-based_generic_prices_for_baricitinib.pdf
[94] https://scholar.harvard.edu/files/melissabarber/files/estimated_cost-based_generic_prices_for_baricitinib.pdf
[95] See pg. 35 of The United Nations Secretary-General's High-Level Panel on Access to Medicines Report.
[96] https://www.who.int/news/item/22-04-2022-who-recommends-highly-successful-covid-19-therapy-and-calls-for-wide-geographical-distribution-and-transparency-from-originator
[97] https://www.who.int/news/item/22-04-2022-who-recommends-highly-successful-covid-19-therapy-and-calls-for-wide-geographical-distribution-and-transparency-from-originator
[98] https://genevahealthfiles.substack.com/p/pfizer-allegedly-pressured-unicef
[99] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8871493/
[100] https://www.clintonhealthaccess.org/news/partnership-to-introduce-covid-oral-antivirals-and-national-test-and-treat-programs-announced-by-new-public-private-consortium/

Southeast Asia to introduce COVID oral antivirals and national test-and-treat programs. Despite its announcement in September 2022, as discussed previously only highly limited supplies of paxlovid have been delivered out of Pfizer's announced 100,000 courses of treatment since generics were not available.

UNICEF signed a supply agreement with Pfizer in March 2022, to supply 4 million treatment courses of paxlovid at affordable prices (which are not disclosed[101]) to 95 developing countries. As at 5 March 2023, it had only supplied 528 originator paxlovid treatments to Tajikistan. This increased to 59328 originator paxlovid treatments (as at 14th March 2023) supplied only to 7 countries. 60, 478 originator molnupiravir (lagevrio) treatments (as at 14th March) has been supplied to 10 countries/territories. It is important to note that effectiveness of molnupiravir is very much in question[102], especially in view of the refusal of the European Medicines Agency to grant marketing approval for molnupiravir.[103]

Evidently, while these initiatives may provide small-scale support to a few countries, it is definitely inadequate to meet the needs of developing countries. Importantly, the **success of these initiatives also ultimately depends on affordable generics being readily and widely available.** Further donations are also inherently unreliable for they are ad-hoc.

10. CONCLUSION

ITC in its report to the U.S. Trade Representative (USTR) should accurately capture the expansive unmet need in developing countries due to high prices and lack of timely affordable supply, enabled by the intellectual property monopoly held by pharmaceutical companies. WHO and global public health experts have persistently pointed to the vast gap in COVID-19 response in developing countries, due to inequitable access to affordable therapeutics and diagnostics, which is critical to limit the spread of COVID-19 and its damaging effects. As discussed above, voluntary licenses, donations, tier-pricing are insufficient deficient tools to address public health needs of developing countries.

ITC should highlight the important role of compulsory license, in facilitating timely affordable access and scale-up of testing and treatment, noting its wide use by developed countries including the US. ITC should recommend to the USTR to eliminate political and trade pressures that undermine the use of TRIPS flexibilities especially CLs and as a first step to support extension of the TRIPS Decision to diagnostics and therapeutics. ITC should also urge the USTR to suspend enforcement of any provisions in FTAs that affect the use of CLs, including for COVID-19 purposes.

Extension of the TRIPS Decision to therapeutics and diagnostics will effectively waive one condition for using compulsory license, namely the limitation of quantities exported to other developing countries found in Art. 31(f) (which limits exports to non-predominant quantities) and only with respect to 'developing countries' that invoke the Decision. This limited waiver will enable manufacturers to achieve economies of scale, expand affordable supply options, and promptly respond to the access needs in developing countries.

Importantly ITC should recognize that given the narrow scope of TRIPS Decision (which is only for COVID-19 and for developing countries), which if extended to therapeutics and diagnostics will not affect R&D, the revenue of pharmaceutical companies, and pharmaceutical manufacturing jobs in the United States.

[101] https://genevahealthfiles.substack.com/p/pfizer-allegedly-pressured-unicef
[102] https://www.ox.ac.uk/news/2022-12-23-molnupiravir-doesnt-reduce-covid-19-hospitalisations-high-risk-vaccinated-people
[103] https://www.ema.europa.eu/en/documents/smop-initial/questions-answers-refusal-marketing-authorisation-lagevrio-molnupiravir_en.pdf