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For U.S. International Trade Commission Investigation No. 332-596

“COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities”

March 15, 2023

Key Message

This submission argues in favour of immediately and unconditionally extending the June 17, 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 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](#)) presented in the WTO by a group of developing countries in 2022.

This submission presents analysis on (1) the importance of expanded timely access to therapeutics and diagnostics, (2) the need to cover all existing and pipeline COVID-19 therapeutics and diagnostics, (3) the assessment of quantities needed should focus on actual need not expressed market demand which has been negatively impacted by high prices and early supply constraints, (3) the impact of patents of supply, price, and distribution is clear, (4) compulsory licensing is essential public health tool, but political and other challenges, including export restrictions, negatively affect their effectiveness, (5) voluntary licenses, tiered prices, and existing access and donation initiatives are insufficient, and (7) adopting the Decision is have minimal impact on innovation incentives especially taking into account existing TRIPS flexibilities and the Decision’s allowance of exports only to developing country markets with no impact on developed country market returns and profits.

1. Timely access to affordable therapeutics and diagnostics is critical to limit the damaging health and economic effects of COVID-19 which continues to evolve with unpredictable characteristics.

The [14th meeting of the WHO International Health Regulations \(IHR\) Emergency Committee](#) regarding COVID-19 pandemic, which met on 30 January 2023, 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](#): “Vaccines, 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.”

The [ACT-Accelerator report of September 2022](#) 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...”.

Both, the WHO’s Emergency Committee as well as the [ACT-Accelerator](#) highlight concern that manufacturing is highly concentrated and 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”.

2. TRIPS Decision should cover all COVID-19 therapeutics and diagnostics

COVID-19 has very uncertain characteristics, with the possibility of new variants, accelerating infections, and increased deaths as immunity weakens. Given the pandemic’s unpredictable nature, the diagnostics and therapeutics that might be needed for acute infection and long covid are still to be discovered. Numerous new treatments are under development, which could offer better clinical outcomes and which could be useful in combination therapies to reduce the risk of drug resistance. The ITC should focus on the need for accelerated access to pipeline products as well as existing ones.

Consider that the WHO maintains a [Therapeutics and COVID-19 living guideline](#), with recommendations that change multiple times every year. These recommendations suggest different treatments and combinations for different stages of COVID-19. National treatment guidelines may follow WHO or may vary. For instance, bebtelovimab that received emergency approval in the United States has not been 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.” Further, according to [industry BIO](#), there are 469 antivirals and treatments in development, 78 of which are in “late-stage clinical” phases.

Even the U.S. Food and Drug Administration’s (FDA) treatment recommendations are updated regularly, depending on the circulating variants. On the [FDA website](#), 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.”

The number of patients who might benefit from therapies to reduce the incidence, severity, and duration of long covid could be quite significant given that an estimated percentages of people infected develop long-lasting symptoms and a wide array of impairments.

3. The true metric for supply quantities is actual need; high prices and lack of early 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. In April 2022, [WHO expressed caution over the repeat of inequity witnessed with respect to COVID-19](#), stressing that it is “extremely concerned” that developing countries “will again be pushed to the end of the queue when it comes to accessing treatment.” In December 2022, [the WHO DG 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.” 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.”

The pharmaceutical industry argues that the problem is not one of access and notes 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](#). 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. 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](#). The first [Quick Start](#) delivery of a [few thousand courses of paxlovid treatment in sub-Saharan Africa](#) did not occur until December 20, 2022 – a full year after it became available in the United States. 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-of-treatment) 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)). 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 very much linked to 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. 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](#). 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.

4. Patents have an adverse effect on supply, price, and equitable distribution 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, the 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](#), 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, tocilizumab, casirivimab and imdevimab) are widely patented¹ 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.² The same situation can be expected as COVID-19 therapeutics and diagnostics with better clinical outcomes become available.

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. 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. 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).

The objective of the TRIPS Agreement as set out in Article 7 is to ensure that IP works 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 thus '[a]ppropriate measures', 'may be needed to prevent the abuse'. Accordingly, the TRIPS Agreement has built in 'flexibilities' to enable WTO 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

¹ 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](https://www.medsPAL.org/?disease_area%5B%5D=COVID-19&disease_area%5B%5D=COVID-19+(drug+candidate)&page=1)

² See [Severe shortage of high-priced drugs to treat COVID-19 | News | Jamaica Gleaner](#); [Roche warns of global Actemra shortage as delta variant drives huge spike in demand for COVID-19 patients | Fierce Pharma](#); [Unvaccinated, untreated: Africa may not get its fair share of Covid-19 drugs - The Mail & Guardian](#); [A fact-based case for the extension of the TRIPS COVID-19 decision](#). Also see <https://msfaccess.org/latin-america-how-patents-and-licensing-hinder-access-covid-19-treatments>

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.

5. Compulsory licensing to increase supply and price competition is an essential tool for public health, but their use is challenging

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 license (CL) to overcome patents barriers as provided for in Article 31 of TRIPS. In 2001, the right to use CLs was reaffirmed in the Doha Declaration on TRIPS and Public Health adopted by WTO Members. Paragraph 3 of the Doha Declaration recognizes “concerns about its [intellectual property] effects on prices”, while paragraph 4 clarifies that the “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. 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 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. There are [multiple other examples of use of CLs to override patents](#) that has resulted in access and scale-up of treatment.³

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, to allow [domestic manufacture for 3,000 COVID-19 patients](#).⁴ 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.

The United States is far and away the most frequent user of CLs, 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. The compulsory licenses were granted for a diverse set of products, 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](#) and this is not an exhaustive list. Section 1498 allows the federal government to authorize third parties to use

³ See [Country experiences in using TRIPS safeguards: Part 1, WHO](#) ; [Malaysia’s experience in increasing access to antiretroviral drugs: exercising the “government use” option. Penang: Third World Network 2006](#); 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>

⁴ Reuters. [Online]. 2020 Oct 7 [cited 2021 May 17]. Available from: <https://www.reuters.com/article/us-health-coronavirus-remdesivir-richter-idUSKBN26S283>

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 be 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 case⁵.

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) and [with court actions by pharmaceutical corporations](#)⁶ from using CLs for access to medicines.⁷ While more recently, the Office of the U.S. Trade Representative [has acknowledged](#) 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.

Another challenge to the use of CLs is TRIPS-plus provisions in North-South Free Trade Agreements, such as data exclusivity, which may hinder the effective use of CLs by preventing the grant of marketing approval to generic therapeutics.⁸ Mandatory patent term extension provisions might lengthen the duration of patent protection and thus the necessity of issuing CLs. In a different manner, investor-state-dispute-settlement rights and definitions of protected investments in Investment Treaties can give rise to private arbitration claims by pharmaceutical investors who claim that CLs impinge their investor rights. The United States and other countries should suspend the enforcement of any provisions in such FTAs and Investment Treaties/Clauses that affect the use of CLs, [including for COVID-19 purposes](#).

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 31bis](#) of TRIPS (previously known as the 30th August 2003 WTO Decision⁹) 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”](#). 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 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/>

⁶ 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.

⁷ See Timeline of US pressure on India IP law (2015): [a timeline of us attacks on india's patent law & generic - january 2015](#); [Novartis letter to Colombia on compulsory license](#); [Switzerland pressured Colombia over compulsory license](#); [USTR pressure on Colombia over the use of compulsory license and other regulatory measures](#) and <https://www.keionline.org/wp-content/uploads/2018/03/Lighthizer-letter-to-Colombia-Feb-14-2018-re-OECD.pdf>; [Pressure on Malaysia over the use of compulsory license](#)

⁸ see pgs. 24-26 [Report of the UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES](#); [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](#)

⁹ https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

6. Voluntary licenses, tiered pricing, and existing access and donation solutions are not sufficient

Voluntary licenses (VLs) 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.¹⁰ And where VLs exist, for example with respect to Merck, Pfizer, and Shionogi antivirals, they exclude supply to many developing countries. In particular, 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 of Merck’s and Pfizer’s MPP licenses (see map [here](#)). Many excluded countries have large populations and have suffered some of the most damaging rates of infection. These countries can source only from the originator companies, who have maintained monopoly control over supply, allocation, and price.

Apart from the limited country coverage, there are other [unjustified terms and conditions](#) in VLs that could delay or hinder generic production and which arguably are also anti-competitive.¹¹ For example Pfizer’s license prevents [R&D on combination regimens, coformulation, and even co-packaging](#). VLs also do not provide the prompt access that is needed in times of health emergency.¹² Whilst VLs may facilitate access for some developing countries, they are an insufficient tool on their own.

Tiered-pricing is voluntary and revocable, does not deliver affordable prices, and lacks transparency. Prices that are the result of generic competition are usually significantly lower than tiered-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 (exact price undisclosed, but estimated as at least \$90) is multiples higher than the [estimated price for generic paxlovid](#) (US\$15.08 that includes cost of production + 10% profit margin and 26.6% tax on profit) and [estimated price for generic molnupiravir](#) (US\$19.99 that includes cost of production + 10% profit margin + allowance for 27% tax on profits)

There is also no guarantee of GNI/capita indexed tiered-pricing as prices for MICs are typically set by pharmaceutical companies at their own discretion. For example, the [price of molnupiravir to Thailand was \\$300](#) a course of treatment and the price of paxlovid to [Brazil is reported to be near \\$250](#) a course of treatment and [even higher at \\$282-\\$340 in China](#). Even though these countries have GDP/capita that is a fraction of that in the U.S., they are asked to pay more than nearly half or more than half of the U.S. price (\$529/course of treatment).

Tiered-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. 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.

¹⁰ 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>

¹¹ 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.

¹² For example, in November 2021, Pfizer and the Medicines Patent Pool 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 the conditions attached to the VL, as at March 2023 generic supply is only available from one generic company.

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.¹³

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](#), is targeted at 10 countries in Africa and 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. In the case of [UNICEF](#) as at 5 March 2023, it has only supplied 528 originator paxlovid treatments to Tajikistan and 60, 478 originator molnupiravir (lagevrio) treatments to 10 countries/territories. [Effectiveness of the latter treatment is very much in question](#), especially in view of the [refusal of the European Medicines Agency to grant marketing approval](#) for molnupiravir.

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.

7. Exaggerated concerns about the Decision’s negative impact on innovation incentives are unfounded given continued protection of highly remunerative developed country markets, especially given many CL-for-export pathways that already exist.

As discussed above, compulsory licensing is 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 and more equitable distribution of public health programs that limit the spread of the infectious disease and save lives. Exaggerated industry claims that CLs discourage innovations are baseless and spurious even more so with respect to the quite limited economic impacts of the proposed extension of the WTO Decision to cover therapeutics and diagnostics as well as vaccines.

Economic analysis consistently finds that the [pharmaceutical industry is highly, even disproportionately profitable](#) compared to other major industries. Contrary to industry talking points, most of industry’s excess profits are returned to investors and senior management through [dividends and stock buybacks which typically out-pace industry investments in expanded research and development](#). Again, contrary to industry talking points, analysis from the [National Bureau of Economic Research](#) 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.

Waiver of limitation of exports (Article 31(f) of TRIPS) is the main feature of the TRIPS Decision text which is time-bound and only applicable to ‘developing countries.’ The TRIPS Decision text is also very specific to COVID-19-related health technologies and cannot be used to promote manufacture and export/import for any other health need. Thus, industry’s hyperbolic concern about dual or multi-use products is unavailing. Most significantly, 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.

¹³ See pg. 35 of [The United Nations Secretary-General's High-Level Panel on Access to Medicines Report](#).

The Decision will not affect the exclusive rights of pharmaceutical companies in richer developed country markets, where [pharmaceutical companies tend to make most of their sales and the vast majority of their profits](#) (over 70% of pharmaceutical sales value is in developed country markets and 87.5% of IP-protected original brand global sales value). The U.S. is far and away the largest market, faces the highest prices and profit margins on IP-protected products, and is expected to spend an additional \$119 billion on new and existing brands by 2026. Thus, arguments that extension of the TRIPS Decision will significantly impact sales, profits, and innovation incentives are 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.

A further reason why the industry's concerns about the economic impacts of extension of the Decision to diagnostics and therapeutics is unwarranted is that the door to CLs, including for exports, is already [open through a variety of TRIPS-compliant channels](#). Although the extended decision would open the door wider for an easier CL mechanism for exporting unrestricted quantities to developing countries, in many ways the extended Decision would merely supplement existing pathways, which include:

- Using Article 73, Members can declare a national security exception to all relevant intellectual property protections (patents, trade-secrets/confidential information, data protection, copyright, and industrial design) in light of the COVID-19 pandemic (see, analyses by [Carlos Correa](#), [Alexander Beyleveld](#), and [Fred Abbott](#)).
- Using Article 31(k),¹⁴ Members can issue unlimited quantities to remedy anti-competitive practices, which could include excessive pricing, refusal to license, and essential facilities doctrine,¹⁵ and can also reduce adequate remuneration accordingly. Although a process to determine anticompetitive behaviour must be followed, it need not be judicial or require judicial appeal.¹⁶
- Using Article 44.2,¹⁷ Members can, under domestic law, limit judicial remedies for infringement of patents to payment of adequately remuneration. Granting judicial licenses is widely used in the U.S. under the [E-Bay decision](#) and has been done without reference the requirements of Article 31(f). As Jamie Love has pointed out, some US E-Bay decisions have allowed for unlimited export¹⁸ whereas others have involved [trade secrets](#) as well as patents.

¹⁴ “Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;”

¹⁵ Brook K. Baker, A FULL DESCRIPTION OF WTO TRIPS FLEXIBILITIES AVAILABLE TO ARIPO MEMBER STATES AND CRITIQUE OF ARIPO'S COMPARATIVE STUDY ANALYZING AND MAKING RECOMMENDATIONS CONCERNING THOSE FLEXIBILITIES, 28 (March 5, 2019) <https://www.bu.edu/gdp/files/2020/05/ARIPO-Member-States-obligations-and-flexibilities-under-the-WTO-TRIPS-Agreement-March-2019.pdf>.

¹⁶ See generally, Ong, B. (2015). Compulsory Licences of Pharmaceutical Patents to Remedy Anti-Competitive Practices Under Article 31(k) of the TRIPS Agreement: Can Competition Law Facilitate Access to Essential Medicines?. In: Hilty, R., Liu, K.C. (eds) Compulsory Licensing. MPI Studies on Intellectual Property and Competition Law, vol 22. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-54704-1_13.

¹⁷ “Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.”

¹⁸ *Edwards Lifesciences Ag v. Corevalve, Inc.*, 699 F.3d 1305 (Fed. Cir. 2013).

- Using Article 30,¹⁹ Members can explore creating an additional exception to Article 31(f) as had been previously advocated during the negotiation of the August 30 Waiver Decision²⁰ and as has been incorporated domestically in some cases, e.g., Uganda.²¹
- Using Article 6,²² Members can adopt international exhaustion rules and import products produced under a compulsory license without deference to any narrow “consent” rule.²³
- Issuing a regular compulsory license under Art. 31, Members automatically allow licensees to export non-predominate quantities to other countries,²⁴ which might be a credible alternative for producers in larger countries or that are producing smaller quantities; if relying on “emergencies or matters of extreme urgency grounds” – clearly justified with respect to COVID-19 – there would be no obligation of prior negotiations.
- Issuing an Art. 31 *bis* CL, Members can allow production for export compulsory license with all required [notifications and limitations](#). Key limitations include that non-LDC importing countries would have to notify the WTO of their insufficient domestic manufacturing capacity (LDCs automatically eligible), differentiate the appearance of their product (not an issue for vaccines), take some measures against the risk of diversion (though not nearly as stringent as adopted in the June 22 WTO TRIPS Decision), strictly limit export to notified quantities, and file additional notifications. On the other side, compared to the Decision, there would be no limitations on countries eligible to produce and export or to import and use (though some countries have unwisely opted out of importation rights or limited them to national emergency situations), there is only a single remuneration in the case of CLs being issued in both the exporting and importing country, and there is some right of regional export/import in regional groups with LDC members.²⁵
- Last, but by no means least with respect to overcoming patents, existing voluntary licenses negotiated by the Medicines Patent Pool for outpatient COVID-19 antivirals all include provisions specifically allowing sublicensees to supply countries that have issued compulsory licenses (on the condition that the sub-licensees had not taken a technology know-how package). These sublicensees would thereby have an easy path to export unlimited quantities because they would not need a CL in the country of production and export because of the licensor’s assent.

In summary, if the Decision is adopted and implemented to cover diagnostics and therapeutics, it will open an existing 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’ 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 and sales and Decision only supplements rights to issue CLs for export that already exist.

¹⁹ “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

²⁰ Brook K. Baker, *Ending drug registration apartheid – taming data exclusivity and patent/registration linkage*, 34 AM. J. LAW & MED. 303-344 (2008)

https://www.researchgate.net/publication/23165526_Ending_Drug_Registration_Apartheid_Taming_Data_Exclusivity_and_PatentRegistration_Linkage.

²¹ Uganda, Industrial Property Act (2014), section 44(e).

²² “For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”

²³ Carlos Maria Correa, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS*, 71 (Oxford University Press, 2d ed., 2020).

²⁴ Art 31(f): “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”

²⁵ This list draws substantially on Brook K. Baker, *TRIPS-Compliant Measures for Overcoming Intellectual Property Barriers to COVID-19 Countermeasures* (2022),

<https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1078&context=research>.

Conclusion

ITC in its report to the U.S. Trade Representative (USTR) should accurately capture the expansive unmet need for COVID-19-related diagnostics and therapeutics in developing countries due to high prices and lack of timely, affordable supply, enabled by the patent monopolies 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 shown above, voluntary licenses, donations, tiered-pricing are insufficient to address public health needs in developing countries.

ITC should highlight the important role of compulsory licensing in facilitating timely affordable access and scale-up of testing and treatment, noting its wide use by developed countries including the US. Extension of the TRIPS Decision to therapeutics and diagnostics will effectively waive only 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, but it will not negatively impact R&D incentives. Importantly, the ITC should recognize that given the narrow scope of TRIPS Decision (only for COVID-19 and for export to developing countries), the sales and profits of pharmaceutical companies in developed countries will not be adversely affected nor will pharmaceutical manufacturing jobs in the United States.