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Third World Network

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12 April 2023

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

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

Dear Mrs. Hiner:

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

For any further questions, 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"

Post hearing 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

TABLE OF CONTENTS

1. Introduction

This post hearing brief supplements the detailed prehearing brief submitted by Third World Network that addresses points raised by the pharmaceutical industry during the public hearing held in March 2023. This post hearing brief provides additional information and should be read together with the prehearing brief.

2. Unmet demand for COVID diagnostics and therapeutics: examples of ways to estimate it

During the public hearing, representative of Social Watch presented on ways to estimate unmet demand using paxlovid as an example. This is elaborated below, without prejudice to further submissions on this subject.

Diagnostics

According to the United Nations, developing countries (not including least developed countries) had only 14% of the COVID-19 reported tests per million population of developed countries at the end of 2022 (468,767 COVID tests/million population in developing countries compared to 3,340,753/million population in developed countries).[1] This indicates that if affordable COVID tests are readily available, developing countries would use 7 times more COVID tests than they are now (assuming similar infection rates etc).

Therapeutics – Paxlovid example

An example of a way to estimate unmet demand for Paxlovid (which is only recommended for patients with specific risk factors) is below. Paxlovid is strongly recommended by the World Health Organization (WHO) for mild and moderate COVID-19 patients at highest risk of hospital admission because it reduces the risk of hospitalization by 85% and 'WHO is extremely concerned that -- as occurred with COVID-19 vaccines -- low- and middle-income countries will again be pushed to the end of the queue when it comes to accessing this treatment. In addition, a licensing agreement made by Pfizer with the Medicines Patent Pool limits the number of countries that can benefit from generic production of the medicine.'[2]

As Doctors without Borders notes, this Pfizer-Medicines Patent Pool (MPP) Paxlovid voluntary licence excludes most of Latin America[3] and excludes 47% of the world's population[4] and Pfizer has filed patent applications for Paxlovid in all the Latin American countries excluded from the MPP licence.[5] These Latin American countries which have been excluded from the Paxlovid MPP licence have had about 68 million confirmed COVID cases so far which is noted to be an underestimate due to limited testing (and reporting of at home tests).[6]

Estimating demand for Paxlovid based on US government treatment guidelines:

The WHO's guidelines on COVID therapeutics strongly recommends Paxlovid for those at highest risk of hospitalization which includes the elderly, immunosuppressed and those with chronic diseases as well as those who have not been vaccinated against COVID.[7] According to the US government, eligibility for Paxlovid includes those older than 50 years old or those who have one or more of the listed risk factors[8] which include:[9]

- Asthma
- Diabetes
- HIV
- Tuberculosis
- being on dialysis
- obesity
- pregnancy

[1] https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/LDC-testing-31-Dec-22.pdf
[2] 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
[3] https://medicinespatentpool.org/licence-post/pf-07321332
[4] https://msfaccess.org/msf-responds-medicines-patent-pool-deal-35-manufacturers-produce-covid-19-treatment
[5] https://msfaccess.org/latin-america-how-patents-and-licensing-hinder-access-covid-19-treatments
[6] https://ourworldindata.org/covid-cases
[7] https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2023.1
[8] https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Paxlovid/Documents/paxlovid-information-sheet.pdf
[9] https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html#anchor_1618433687270

- smoking

Although the risk factors above often overlap (e.g. an overweight unvaccinated elderly smoker), the rate of prevalence of the risk factors above in developing country populations can give an idea of the proportion of people with COVID who would be eligible for Paxlovid under US government guidelines, if the same guidelines were used in developing countries because affordable generic versions of Paxlovid were available to them.[10]

Examples of developing countries excluded from Pfizer's voluntary licence with the Medicines Patent Pool and where Pfizer has applied for Paxlovid patents[11] are Argentina and Thailand. Since Paxlovid was available for COVID patients in countries which could afford it throughout 2022,[12] the table below uses the confirmed number of COVID cases in Argentina and Thailand in 2022 [13] and gives examples of the number of those patients who would have had some of the risk factors that make COVID patients eligible for Paxlovid in the USA.[14] This is not a comprehensive list of all the risk factors under US treatment guidelines for Paxlovid so is an underestimate (e.g. it does not use the lower: older than 50 years old threshold and does not include those with tuberculosis, heart conditions etc) and is an underestimate since the number of COVID cases in 2022 in these countries is an underestimate. (These should not simply be totalled up for each country since one patient may have multiple risk factors, but it gives an idea of the number of COVID patients in these countries in 2022 who would have benefited from Paxlovid, if an affordable generic version had been available).

Risk factor	**Argentina**		**Thailand**	
	Prevalence of risk factor in Argentine population	**Number of Argentine COVID patients in 2022 with this risk factor**	**Prevalence of risk factor in Thai population**	**Number of Thai COVID patients in 2022 with this risk factor**
>64 years old[15]	12%	501,600	15%	375,000
Diabetes	10.2% [16]	426,360	9.6% [17]	240,000
HIV[18]	0.31%	12,958	0.73%	18,250
Obesity (BMI >30 kg/m^2)[19]	28.3%	1,182,940	10%	250,000
Pregnant[20]	641,322 births per year	58,520	1,002,415 births per year	28,000
Smoking[21]	24.5%	1,024,100	22.1%	552,500

[10] This assumes the incidence of these risk factors is the same in those with COVID as the general population.
[11] https://www.medspal.org/?keywords=paxlovid&page=1 and https://www.medspal.org/?keywords=paxlovid&page=5
[12] See below
[13] 4.18million and 2.5 million respectively, https://ourworldindata.org/covid-cases which notes this is an underestimate of the true number of infections in 2022 due to limited testing.
[14] This assumes the incidence of these risk factors is the same in those with COVID as the general population.
[15] https://data.worldbank.org/indicator/SP.POP.65UP.TO.ZS
[16] https://www.who.int/publications/m/item/diabetes-arg-country-profile-argentina-2016
[17] https://www.who.int/teams/noncommunicable-diseases/surveillance/data/diabetes-profiles
[18] https://www.unaids.org/sites/default/files/media_asset/data-book-2022_en.pdf and total population from https://data.worldbank.org/indicator/SP.POP.TOTL
[19] https://apps.who.int/gho/data/node.main.A900A?lang=en which is 2016 data which is likely to be an underestimate for 2022 based on previous historical trends for Argentina and Thailand
[20] https://data.worldbank.org/indicator/SP.DYN.CBRT.IN?locations=AR which is an estimate since it is the number of live births so does not count pregnancies which end in miscarriages or factor in twins etc.
[21] This is an estimate because https://data.worldbank.org/indicator/SH.PRV.SMOK is % of current tobacco use among adults whereas the CDC uses current and former smokers in its risk factors

Furthermore, long COVID (which can affect 10-43% of those with COVID[22]) can be debilitating including preventing people from being able to return to work and thus reducing economic growth and consumer spending (e.g. on US products),[23] especially in developing countries unable to afford unemployment/sickness benefits. A recent study found that Paxlovid reduces the chances of long COVID by 26%,[24] so if Paxlovid were widely taken to prevent long COVID, that would increase demand further, if more affordable generic versions were available.

Paxlovid affordability:

It is difficult to know the prices charged by Pfizer for Paxlovid in each country e.g. the WHO has criticized Pfizer for its lack of transparency in Paxlovid pricing and called for greater price transparency[25]. The lowest known Pfizer price for Paxlovid is US$250 per treatment course,[26] but generic versions of Paxlovid could be made for US$15 per treatment course (including 10% profit margin and 26.6% tax on profit)[27].

At US$250 per treatment course (assuming this is the price Pfizer offers them), Paxlovid is still unaffordable for many developing countries e.g.:

- Thailand's total annual health spending per person (including by government and patients and insurance) is US$305 per person per year.[28] So the cost of treating one incidence of COVID with Paxlovid at the Pfizer price would use up 82% of the total health spending for that person for the year. (Whereas at a generic price of US$15/treatment course, it would only use 5% of the annual health spending for that patient to pay for enough generic Paxlovid to treat a COVID case).

- Argentina's total annual health spending per person (including by government and patients and insurance) is US$864 per person per year.[29] So the cost of treating one incidence of COVID with Paxlovid at the Pfizer price would use up 29% of the total health spending for that person for the year. (Whereas at a generic price of US$15/treatment course, it would only use 1.7% of the annual health spending for that patient to pay for enough generic Paxlovid to treat a COVID case).

Amount of Paxlovid available:

Paxlovid got emergency use authorisation in the USA in December 2021.[30] Pfizer said it could produce 120million Paxlovid doses in 2022, but Reuters noted that it is unclear how many it had produced by December 2022.[31]

[22] E.g. see https://www.wsj.com/articles/over-2-million-americans-arent-working-due-to-long-covid-says-brookings-11661364528 and https://www.washingtonpost.com/business/what-experts-know-about-long-covid-and-who-gets-it/2022/04/18/872f7aa0-bf76-11ec-b5df-1fba61a66c75_story.html

[23] E.g. see https://www.cnbc.com/2022/12/08/long-covid-is-distorting-the-labor-market-hurting-the-us-economy.html and https://www.wsj.com/articles/over-2-million-americans-arent-working-due-to-long-covid-says-brookings-11661364528

[24] https://www.cnbc.com/2023/03/24/pfizer-covid-drug-paxlovid-may-reduce-the-risk-of-long-covid-study.html

[25] 'WHO has strongly recommended that Pfizer make its pricing and deals more transparent', https://www.ungeneva.org/en/news-media/news/2022/04/who-recommends-covid-19-drug-and-urges-transparency-around-pricing

[26] https://scholar.harvard.edu/sites/scholar.harvard.edu/files/melissabarber/files/estimated_cost-based_generic_prices_for_nirmatrelvir_ritonavir_paxlovid.pdf

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

[28] https://apps.who.int/nha/database/country_profile/Index/en

[29] https://apps.who.int/nha/database/country_profile/Index/en

[30] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19

[31] https://www.reuters.com/business/healthcare-pharmaceuticals/chinas-111inc-app-starts-retail-sales-pfizers-paxlovid-covid-treatment-2022-12-13/

Furthermore, as of 31 March 2023, 71% of the known purchases of Paxlovid were by high income countries (e.g. the US (with 4.2% of the global population[32]) alone in November 2021 bought 49% of the Paxlovid purchased by all countries until 31 March 2023).[33]

The first generic version of Paxlovid produced under an MPP licence was only approved by the WHO (pre-qualification) a year after Pfizer got approval in the USA, on 26 December 2022.[34]

In summary:

The methodology above is an example specific to Paxlovid based on the US government's treatment guidelines for that therapeutic. However future therapeutics which may already be in the pipeline may be more effective and recommended for a broader range of people with COVID, so the demand for such a therapeutic would be for everyone with COVID. Therefore, the methodology to estimate unmet demand can vary depending on who the therapeutic is effective for (e.g. mild cases of COVID or those hospitalized with COVID) and which sectors of the population it is recommended for (e.g. the elderly, those who are pregnant, those with cancer, or everyone with COVID etc). Further, consideration of unmet demand should also consider situations where a voluntary license exists but the licensee of the VL is able unable to supply (e.g. as shown above, it takes more than a year for a licensee to meet all the terms of the voluntary license), and thus even countries that may be supplied under a VL, may fall within the category of "unmet demand".

3. The "last mile" problem is exaggerated by the pharmaceutical industry

Opponents of extension of the June 2022 TRIPS Decision[35] (TRIPS Decision) dispute that intellectual property (IP) impacts access, instead arguing that "last mile" factors such as registration, delivery and distribution are the main challenges affecting timely and affordable access.

This argument is baseless for several reasons. Concerns about the effects of IP on production, supply options, prices and access are well established.[36] Recognizing these concerns, in 2001, WTO Members adopted the Doha Declaration on TRIPS and Public Health which confirmed that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health", and "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." Further **the "last mile" challenge only arises if there is**

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[32] https://data.worldbank.org/indicator/SP.POP.TOTL

[33] https://launchandscalefaster.org/sites/default/files/documents/2023%20vaccine%20info/Duke%20Global%20Health%20Innovation%20Center%20Extracted%20Therapeutics%20Data%203.31.2023.xlsx from https://launchandscalefaster.org/COVID-19

[34] https://www.hetero.com/press-release-2022-6 and https://timesofindia.indiatimes.com/india/hetero-emerges-1st-in-world-to-bag-who-pq-for-generic-version-of-pfizers-covid-19-oral-drug-paxlovid/articleshow/96512620.cms

[35] https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True

[36] See Report of the UN Secretary General's High Level Panel on Access to Medicines https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf; 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

production and supply, meaning that the first barrier is IP; only if affordable diagnostics and therapeutics are available does the issue of registration, delivery and distribution arise.

The challenge of "last mile" in developing countries is exaggerated by the pharmaceutical industry, an attempt to downplay the effect of IP. In 2000 as developing countries lacked access to HIV treatment, industry also claimed that the "last mile" was the main challenge hindering access and not the price tag of more than $10,000 per patient per year. However, once generic versions were introduced into the market by manufacturers in developing countries (where the medicines had not been patented), prices dropped drastically, to US$61 per patient per year for HIV treatment,[37] enabling scale-up of HIV treatment. 28.7 million people were accessing antiretroviral therapy in 2021 of which at least 26 million are in developing countries.[38]

Similar progress in the scale-up of hepatitis C treatment has been observed in countries where affordable generic hepatitis C treatment is readily available. For example, Egypt has one of the largest burdens of hepatitis C infection. Nearly 50 million adults and 9 million children aged 12–18 years were screened, and 2.23 million additional persons received treatment in 2018, an increase from 30,000 patients treated in 2014.[39] This was only possible due to readily available affordable generic direct acting anti-virals (DAAs) that can cure hepatitis C (HCV) patients, enabling the government to launch a country-wide campaign to eliminate HCV by making treatment freely available in the public sector. Generic sofosbuvir/daclatasvir (fixed-dosed HCV treatment) is available for $16 per 28-day supply or $48 per course of treatment from a local manufacturer in Egypt. WHO's Report on HCV concludes that the "approach shows the feasibility of universal access based on rapid, widespread testing and affordable treatment"[40].

Similarly, Pakistan also has a high burden of HCV, with more than 10 million estimated HCV infections. It was able to increase the number of people treated from about 6500 in 2015 to 200,000 by the end of 2018, 40% of whom accessed treatment in the public sector. The reported price of a locally produced generic fixed-dose combination of sofosbuvir/daclatasvir is $7 per pack in the public sector, or less than $30 per treatment course.[41]

The HIV and HCV examples clearly show that developing country governments are able to roll out test and treat programmes if patents are not a barrier and affordable supplies are readily available. Further, the wide vaccination of smallpox and polio, and consequently their eradication in most parts of the world is a strong indication that if affordable supplies are available through diversified production, international and local support systems are in place in developing countries to roll out test and treat programmes. In the case of polio, the first vaccine was developed in 1950 and it was not patented. In a 1955 interview, when US physician Jonas Salk was asked who owned the patent for the inactivated poliovirus vaccine (IPV), he famously replied: "Well, the people, I would say. There is no patent. Could you patent the sun?". Local production of polio vaccine was diversified, allowing for readily available supply and rapid immunization in developing countries, and consequently eradication of polio in most countries.[42]

[37] https://www.msf.org/untangling-web-antiretroviral-price-reductions-14th-edition
[38] https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf
[39] See pg. 12 of https://www.who.int/publications/i/item/9789240019003
[40] See pg. 15 of https://www.who.int/publications/i/item/9789240019003
[41] See pg. 16 of https://www.who.int/publications/i/item/9789240019003
[42] See https://www.who.int/news-room/spotlight/history-of-vaccination/history-of-polio-vaccination

4. Developing Countries have the ability to innovate/manufacture therapeutics and diagnostics

There is production capacity for diagnostics and therapeutics including biotherapeutics in developing countries. For example, WHO-prequalification lists for diagnostics and therapeutics as well as Medicines Patent Pool licenses include manufacturers from many developing countries such as Thailand, India, Indonesia, Brazil and South Africa.[43] Also see the list of diagnostic manufacturers in developing countries at https://www.path.org/programs/diagnostics/covid-dashboard-global-availability-covid-19-diagnostic-tests/

It is noteworthy that at a certain stage of COVID-19 many monoclonal antibodies (mAbs) were recommended by the WHO, but none of these were available to, and/or affordable for, developing countries. However, as COVID-19 evolves and new mABs are recommended for COVID-19, there is great potential to scale up treatment, if supply of affordable biosimilars were readily available by lifting the patents barriers in developing countries and facilitating production and exports. For instance, India approved its first biosimilar much before the United States and Europe, in 2000 for hepatitis B. Since then several biosimilars have been developed in India by various biopharmaceutical companies. Recently, an Indian biopharmaceutical company obtained the USFDA marketing approval for herceptin (active drug is trastuzumab) used to treat certain breast and stomach cancers.[44] Introduction of biosimilars can create competition that drives down mAb prices and facilitate access. This is particularly evident in India, where biosimilars are discounted on average by 57 per cent, and increasing competition has resulted in some biosimilars being 70 per cent less expensive than the mAbs that they copy.[45]

5. Extending the TRIPS Decision does not mean the entire TRIPS Agreement is waived and that technology is given away

The TRIPS Decision does not waive the entire TRIPS Agreement or the national IP system. The only waiver is in paragraph 3(b) of the Decision. And it only waives one condition attached to the use of compulsory license, lifting the export restrictions in Article 31(f) of the TRIPS Agreement when a compulsory license is used. The remaining aspects of the TRIPS Decision are clarifications of what is already allowed by the TRIPS Agreement.

Adopting the Decision also does not automatically activate compulsory license. The use of compulsory license under Article 31 of the TRIPS Agreement requires further action by a developing country government. **In addition, even if a compulsory license is utilized, it does not mean that the Decision will be utilized** as the Decision is mostly useful if there is a need for a manufacturing developing country to export more than 50% of its production to another developing country with insufficient capacity. Hence extension of the TRIPS Decision to COVID therapeutics and diagnostics mainly makes available an option to developing countries should they need to use it, to produce and export the majority of the production to another developing country.

[43] See https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists, https://tinyurl.com/3cemnav5 and https://medicinespatentpool.org/progress-achievements/licences
[44] https://journals.lww.com/jpbs/Fulltext/2019/11010/Biosimilars_in_India__Current_Status_and_Future.2.aspx
[45] See https://www.iavi.org/phocadownload/expanding/Expanding%20access%20to%20monoclonal%20antibody-based%20products_Supplement%205.pdf

A compulsory license is merely the grant of legal permission to exploit (i.e. manufacture, export, import) the patented production without the consent of the patent holder. No technology transfer is required from the patent holder to the developing country manufacturer. Developing country manufacturers would use their own technology and processes to manufacture more affordable generic versions of the product. An unofficial English translation of the compulsory license issued by Israel to import lopinavir/ritonavir (HIV treatment) from India to treat COVID-19, due to shortages, is reproduced below, as an example of a compulsory license.

Wednesday, 22nd of Adar, 5780
March 18, 2020

To
The Emergency Department, Ministry of Health
K.S. Kim International Ltd., Company ID# 51-389054-1

A Permit to the State to Exploit an Invention Pursuant to Chapter Six, Article Three of the Patents Law 5727-1967

In accordance with the power vested in me under Cabinet Decision #4888 from March 13, 2020[1] pursuant to Section 112 of the Patents Law 5727-1967[2] (hereinafter – the Law), I hereby grant permission, in accordance with Sections 104 and 105 of the Law, to the Emergency Department at the Ministry of Health and to K.S. Kim International Ltd. to exploit the invention protected in patents numbers 173939, 207260, 185390 by way of importation of the lopinavir 200mg/ritonavir 50mg medication manufactured by Hetero, for the sole purpose of medicinal treatment of Corona patients (Novel Coronavirus 2019, pursuant to a Notice of a Dangerous Infectious Disease, under the Public Health Ordinance, 1940, dated 27.1.20). The permission to exploit is necessary in the interest of the maintenance of essential supplies and services.

[-]

MP Rabbi Yaacov Litzman
Minister of Health

[1] YALKUT HA-PIRSUMIM [Government Notices] 5780, p 5068.
[2] SEFER HA-HUKIM [Book of Laws] 5727, p 148

Source: https://www.keionline.org/wp-content/uploads/A-Permit-to-the-State-to-Exploit-an-Invention-Pursuant-to-Chapter-Six-Article-Three-of-the-Patents-Law-5727-1967.pdf

6. Article 31*bis* of the TRIPS Agreement is flawed, unworkable, and affects the ability to achieve economies of scale

Article 31*bis* was adopted to waive the condition contained in Article 31(f) of the TRIPS Agreement, to enable supply to countries with insufficient manufacturing capacity. 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"[46], by the Canadian generic supplier Apotex involved in producing generic antiretrovirals (ARVs) for export to Rwanda in 2007 using procedures in the "30th August 2003 Decision" of the WTO (which is now reflected as Article 31*bis* of the TRIPS Agreement).

The complex requirements of Article 31*bis* have been made even more complicated when implemented at the national level. For example, the Canadian legislation that implements Art.31*bis* contains over 19 sections and 100 clauses and sub-clauses. Simply understanding the legislation requires legal training or support. As Tanzania's then High Commissioner to Canada, His Excellency Ombeni Sefue, has noted: "It's not that we don't want to do it. It's just that we haven't because... all the bureaucratic, administrative, and legal requirements take a lot of time...The system is too complicated..."[47]

Article 31(f) of the TRIPS Agreement is a condition of only 20 words. But to waive these 20 words, Article 31*bis* has conditions of about 4 pages.

This part discusses the requirements and difficulties in using Article 31*bis* of the TRIPS Agreement.

(a) Notification by Importing Country

Article 31*bis* of the TRIPS Agreement requires every importing country to do a general notification of its intent to use the Article 31*bis* mechanism. And every time it intends to import products it will also need to notify the WTO specifying the names and quantities of products needed, confirming that it is an eligible importing WTO Member and that where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license.

So, if there are 20 countries wanting to import, each of these 20 countries will have to follow the procedure. If the needs of the importing country change e.g. additional quantities are needed, further notification will need to be made with respect to the names and quantities of the product needed. This is cumbersome as making a WTO notification requires coordination at the national level among several different ministries/departments such as the health and trade ministries and the patent office. And every time the notification has to be made because additional products are needed or the quantity changes, further inter-ministerial coordination is required, thereby complicating/delaying those notifications.

(b) Requirements in an Exporting Country

[46] "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-/

[47] 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.

As with the importing country, Article 31*bis* has multiple requirements with respect to entities receiving export licenses and exporting countries themselves, with respect to notifications, compulsory licenses, and final product differentiation.

Article 31*bis* requires that the compulsory licence issued by the exporting WTO Member under the system is clear that "only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS".

This condition makes it impossible to effectively use the system and/or to achieve economies of scale. The manufacturer producing under the compulsory license to export may only manufacture amounts needed to meet the quantities notified by the importing country. If the amount being imported is small, it is simply not viable for the exporting manufacturer.

The exporting Member will also have to notify the TRIPS Council of the grant of the licence, including the conditions attached to it. The information provided has to include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence.

Thus, another challenge is that a manufacturer in an exporting country does not get all import orders at the same time. For instance, in July Country A wishes to import 1 million doses. Assuming a manufacturer in the exporting country is granted a compulsory license to supply this amount, the exporting Member will have to notify the TRIPS Council with relevant information including of the grant of the license, the quantities, and the country to which the product is to be supplied. Then in September, Country B wishes to import; the manufacturer and the exporting Member will have to repeat the process all over again beginning from the grant of the compulsory license. And if in December, Country A wishes to import more doses, the manufacturer and the exporting Member will have to repeat this same process.

This aspect is a major flaw in Article 31*bis* of the TRIPS Agreement. It considers the export and import of each product as a stand-alone transaction, wherein the importing country has a fixed amount that is needed which is specifically met by an exporting manufacturer and its exporting country. It fails to recognize that for a manufacturer to be willing to meet the needs of the importing country, the quantities must be economically viable for production. It also fails to appreciate that in situations such as COVID-19, the need fluctuates very rapidly depending on the severity of the infection, and there needs to be greater flexibility in the import and export of products and a sense of urgency in the supply.

(c) Product differentiation

Article 31*bis* of the TRIPS Agreement requires a certain degree of product differentiation in the appearance of the final product, a requirement that in some instances can complicate creating a therapeutically equivalent product. This task might be made even more difficult if the patent holder actually uses different trade dress for its medicine in different markets.

Further, such differentiation is unnecessary as the pharmaceutical sector is highly regulated. Diagnostics and therapeutics cannot be marketed if they have not received domestic regulatory approval. National regulatory authorities do not normally grant marketing approval to generic products that look the same or very similar to the originator products. In addition, any use of the originator's trademark by a generic company would amount to a trademark infringement. For these reasons, specific conditions on product

differentiation are not required. Certain types of product differentiation such as different coloured pills or shapes can also be confusing for patients and affect adherence to treatment.

The June 17, 2022 TRIPS Decision avoids the above-mentioned problems. The Decision does however contain conditions that prevent re-exportation inconsistent with the provisions of the Decision – see paragraph 3(c) of the Decision. It further requires notification "as soon as possible" to the TRIPS Council of any measure related to the implementation of the Decision (see paragraph 5 of the Decision). Generally, the Decision is more suited for health emergencies like COVID-19 and to rapidly supply affordable diagnostics and therapeutics to developing countries in need, which is essential to limit/delay the spread of COVID-19 infection.

7. Extension of the TRIPS Decision does not extend to climate technologies

It is argued by the pharmaceutical industry that granting this extension is the beginning of a slippery slope, which will be extended to climate technologies. This argument is sheer "scaremongering" on the part of the pharmaceutical industry.

The scope of the Decision is crystal clear: it is about "production and supply" "to the extent necessary to address the COVID-19 pandemic". This Decision is not applicable to, and cannot be extended to, climate technologies.

Further, it should be noted that waivers from WTO obligations are commonly granted including for the benefit of the US.[48] There are currently 3 waivers in force from specific provisions of the TRIPS Agreement.[49] **The logical endpoint of the slippery slope argument is that no waivers should ever be granted at the WTO including the ones that the US is currently benefitting from.**

In addition, to obtain a waiver from WTO obligations, procedures of Article IX of the Marrakesh Agreement must be complied with. Moreover, according to usual decision-making procedures in the WTO, there has to be consensus among WTO members. **To accept the "slippery slope" argument of the pharmaceutical industry is to suggest that WTO Members should no longer use the flexibility built into Article IX of the Marrakesh Agreement.**

8. The TRIPS Decision is clear on the scope of diagnostics and therapeutics

Several times during the US ITC public hearing, the definition of diagnostics and therapeutics was requested. The evolving nature of COVID-19 and **the reality that different types of diagnostics and therapeutics may be needed at different stages of the diseases suggests that defining needed diagnostics and therapeutics is a futile exercise.**

It is also unnecessary as the purpose of the Decision is very clear in its paragraph 1. The Decision can only be used for the purpose stated in paragraph 1 of the Decision. Article 31(c) of TRIPS is also clear that with respect to compulsory license "the scope and duration of such use shall be limited to the purpose for which it was authorized".

[48] See https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/W862.pdf&Open=True
[49] See https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/W862.pdf&Open=True

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

Generally, most sales of originator pharmaceutical companies (more than 87%) are in developed country markets (US, Europe and Japan alone (not including developed countries such as Canada, Australia, New Zealand etc) are 87.2% of sales of new medicines from 2016-2021 according to the European Federation of Pharmaceutical Industries and Associations which represents companies such as Pfizer and Eli Lilly[50]).[51] These sales are not affected as the Decision specifies in footnote 1 that it is only applicable to developing countries. Anti-diversion measures in paragraph 3(c) of the Decision are an additional safeguard to ensure that the sales in developed countries are not affected. Other markets are not very significant for the pharmaceutical companies. This was reinforced by Dennis Purcell from Aisling Capital (a venture capitalist who has been in the life sciences sector since 1980) who during Panel 6 of the ITC hearing admitted that he did not think investors invest thinking that they will make a return in lesser developed countries.

[50] https://efpia.eu/about-us/who-we-are/
[51] https://www.efpia.eu/publications/data-center/the-pharma-industry-in-figures-economy/geographical-breakdown-of-sales-of-new-medicines/