POST-HERING STATEMENT OF THE
NATIONAL FOREIGN TRADE COUNCIL
AND RESPONSES TO COMMISSIONER QUESTIONS

INVESTIGATION NO. 332-596 – COVID 19 DIAGNOSTICS AND THERAPEUTICS: SUPPLY, DEMAND, AND TRIPS AGREEMENT FLEXIBILITIES

Submitted by:

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I. Introduction

The National Foreign Trade Council (NFTC) appreciates the opportunity to respond to several issues raised during the hearing in conjunction with the U.S. International Trade Commission (ITC or Commission) Investigation No. 332-596 on *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*.

In its hearing statement and testimony, NFTC provided an overview of the carefully crafted balance between the right to protections for innovation and qualifications on that right that negotiators created for patents in the World Trade Organization's (WTO) *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS). This balance was clarified and expanded by the addition of TRIPS Article 31bis in 2017.

Despite the existence of built-in flexibilities in TRIPS, certain developing countries with sophisticated generic pharmaceutical manufacturing sectors are leveraging the COVID-19 pandemic to press for further shifting the TRIPS protections in favor of a few foreign generics producers by expanding the scope of the TRIPS waiver for COVID-19 vaccines to "diagnostics and therapeutics." NFTC provides the following facts and clarifications to address points raised by proponents of expanding the waiver and by Commissioners during the question and answer period at the hearing.

II. The Scope of Both the Current Vaccine Waiver and Proposed Diagnostics and Therapeutics Expansion Are Unclear

In asking the ITC to address in its report potential definitions for "diagnostics" and "therapeutics" and the universe of existing COVID-19 diagnostics and therapeutics covered by patents and in development, USTR has given the ITC a challenging task. During the hearing, Commissioner Schmidtlein asked witnesses for advice on how the Commission might define diagnostics and therapeutics.[1] One suggestion was to focus on those products that expressly indicate in the FDA registration that the product is intended to treat COVID-19. How this would apply to countries that do not rely on the FDA was unclear. Pro-waiver witnesses countered that the evolving nature of both the COVID-19 virus and the recommended treatments called for a much more flexible approach that would allow the TRIPS waiver to cover any products that ultimately become successful at treating COVID-19, which made the task of fixing a specific definition or scope for the purposes of this investigation virtually impossible. For diagnostics, Ms. Miller of

[1] See Hearing Transcript at 81-90, 328-329.

AdvaMed also indicated that it is virtually impossible to separate the COVID and non-COVID elements of testing.

NFTC defers to experts from sector-specific industry associations for specific recommendations on how to define diagnostics and therapeutics. In general, NFTC recommends that the ITC choose a definition that is as narrow and specific as possible insofar as the ITC is recommending a specific definitional approach to USTR for use in the final negotiated text. However, insofar as the ITC is tasked with identifying potential economic impacts of a waiver, it should account for the full range of possible definitions that may ultimately be adopted by WTO members. NFTC strongly disagrees with witnesses that argued for an open-ended approach that would allow any product or combination of products developed in the future to be covered by the expanded waiver.

It is important for the ITC to recognize that there is no definition that, as a practical matter, will not have an impact beyond COVID-19. First, as NFTC noted in its testimony and pre-hearing statement, most COVID-19 therapeutics – including those identified as COVID-19 products in the FDA registration -- are drugs that also treat other conditions or may be developed for additional purposes in the future. While NFTC agrees that the text of the TRIPS waiver is limited to use to combat COVID-19, there is no way to definitively define or enforce this condition.

Moreover, there is significant uncertainty about exactly what authority is provided in the vaccine waiver. The South Centre published a report outlining areas where the June 2022 vaccine waiver text in its view allows for broad flexibilities in application.[2] Predictably, the paper argues that developing countries should implement the waiver authority using the most expansive interpretation possible. For example, the paper identified the following interpretational issues, among others, in the June 22 vaccine waiver text (note the positions stated below are the views of the South Centre and are not agreed to by WTO members):

- The phrase “to the extent necessary to address the COVID-19 pandemic” should not mean that eligible Members must prove that the grant of a compulsory license, if made in relation to COVID-19, was “necessary”. In other words, a “necessity test” does not apply in respect of an authorization as such but only in relation to its (limited) purpose.[3]
- In the absence of a legal definition of the term “pandemic,” or a specific limitation to pandemics declared by the World Health Organization (WHO), the June 22 text leaves open the possibility that Members may have diverse views on how long the COVID-19 pandemic exists and whether the flexibilities provided by the TRIPS waiver continue should the pandemic become an endemic.[4]
- Footnote 1, which clarifies that the “subject matter of a patent” includes ingredients and processes necessary for the manufacture of the COVID-19 vaccine is illustrative and

[2] Carlos M. Correa and Nirmalya Syam, *THE WTO TRIPS DECISION ON COVID-19 VACCINES: WHAT IS NEEDED TO IMPLEMENT IT?* The South Centre, Research Paper 169, November 8, 2022. (Exhibit 1)
[3] Exhibit 1 at 4.
[4] Exhibit 1 at 4.

does not exclude equipment nor any products needed, for example, to stock or administer the vaccines.[5]

- It is unclear what is intended by the provision in the June 22 text allows that allows for export of compulsorily licensed products to "international or regional joint initiatives," which leaves open the possibility of exporting to any mechanism, "whether institutionalized or not, transitory or permanent, which operates in a developed or developing country, with the purpose (unique or not) of facilitating access of COVID-19 vaccines to "eligible members."[6]
- The requirement to use "all reasonable efforts" to prevent re-exportation of compulsory licensed products only provides for a "best efforts" obligation that does not impose a commitment to effectively "prevent" re-exports so long as some actions are taken to that end.[7]
- The June 22 text provided narrow exception to the re-exportation limitation in "exceptional circumstances" for "humanitarian and not-for-profit purposes." This text allows Members to implement this provision based solely on the existence of "humanitarian and not-for-profit purposes." Thus, an exporting country would only need to demonstrate that the purpose of the exports as humanitarian or not-for-profit without showing there are any additional exceptional circumstances.[8]
- The obligation for Members to prevent imports "diverted to their markets inconsistently with its [the Decision] provisions" applies only to diversion to non-eligible members (i.e., developed countries). There is no obligation to prevent re-exports from one eligible member to another.[9]
- The protection of test data as required under the TRIPS Agreement is not based on the grant of exclusive rights ("data exclusivity"). Rather, Article 39.3 only obliges to protect such data —when some conditions are met— under the discipline of unfair competition which does not generate any exclusive rights.[10]

The issues identified above indicate that many questions remain about exactly what was agreed to in the June 22 vaccine waiver text. It is worth noting that the position taken by the South Centre regarding an expansive interpretation of the vaccine waiver conflicts with the testimony of Ms. Shashikant provided at the ITC hearing that the vaccine waiver will have little impact because it is quite narrow.[11]

The uncertainty regarding the underlying language of the June 22 vaccine waiver combined with the even greater uncertainty about what products would fall within the scope of diagnostics and therapeutics means there are no real guardrails to limit the adverse impact if the current waiver were to be expanded. There is simply no common understanding of what the June 22 vaccine

[5] Exhibit 1 at 5.
[6] Exhibit 1 at 9.
[7] Exhibit 1 at 10.
[8] Exhibit 1 at 11.
[9] Exhibit 1 at 11.
[10] Exhibit 1 at 13.
[11] See, ITC Hearing Transcript (Day One), Shashikant at 46 ("Tr.").

waiver does or what products could fall within the diagnostics and therapeutics categories. Such a broad expansion of the vaccine waiver would put at risk the IP protection of a much broader range of innovations well beyond pharmaceutical products. This is particularly the case given that the usual dispute settlement mechanisms for enforcing rights and obligations at the WTO are currently inoperative.

Several NGO witnesses at the hearing repeatedly stressed the importance of having the ability to compulsorily license any successful products that are developed in the future.[12] These same ambitions are also being raised in the negotiations for the WHO Pandemic treaty. Looking forward, this approach would ultimately lead to weakened IP protections for an extremely broad swath of products – the "slippery slope" concern is not merely hypothetical in this case.

It is clear that regardless of the scope of diagnostics and therapeutics that the ITC may recommend in its report, the WTO member proponents of these TRIPS waivers intend to push their use to maximum limits, despite their claims that the TRIPS waiver is only a narrow, limited tool that would have little effect on innovation.[13]

As was noted at the hearing, the advocates of expanding the waiver sought a broader waiver initially and continue to pushing for a much more expansive waiver for COVID-19, and regularly advocate for more expansive waivers of intellectual property rights at the World Health Organization, in the UN High Level Panel on Pandemic Planning, Preparedness and Response, and at the UN in climate change talks.[14] NFTC shares the concern expressed about the trajectory of IP protection in global agreements and a decision by the WTO to expand the TRIPS waiver at this juncture will simply add fuel to this fire.

III. There is No Evidence That Expansion of the TRIPS Waiver Is "Necessary"

Throughout the hearing, Commissioners probed witnesses for evidence that IP protection for COVID-19 diagnostics and therapeutics might be an access barrier for COVID-19 diagnostics and therapeutics.[15] NFTC and other industry witnesses provided data showing that current supplies of diagnostics and therapeutics exceed current demand, which is a strong indicator that limited generic manufacturing capacity is not the impediment to access to these products. In response, advocates for expanding the waiver focused on other measures, hypothetical scenarios, and experiences from addressing entirely different health situations (e.g., the AIDS/HIV epidemic and Hepatitis C) as demonstrating the need for an expanded COVID-19 waiver.

NFTC urges that the burden should fall on the proponents of expanding the waiver to provide current data and evidence from the COVID-19 pandemic to demonstrate that the expansion is necessary. Despite being given ample opportunity, none of the witnesses has been able to meet

[12] See Tr., Love at 27, Reid at 30-31, Maybarduk at 38, Baker at 367-369.
[13] See, e.g., Tr. Shashikant, Transcript at 48, Baker at 285, 322, and Thrasher at 345.
[14] Tr., Kilbride at 65.
[15] See, e.g., Tr., Karpel at 110, 120, Kearns at 141.

that burden. Instead, much of the discussion across all panels centered on whether compulsory licensing helps in lowering drug prices.[16] Importantly, this discussion ignored the fact that many of the therapeutics at issue are available at low or no cost to governments – low, middle and upper-middle-income countries alike -- through UNICEF, the Global Fund and other mechanisms – yet demand for the products remains below supply.

Indeed, if patent protection were causing significant access issues with the COVID-19 pandemic, there would be an abundance of evidence. Despite USTR's encouragement for WTO Members to participate in the ITC hearing process, only one country opted to testify – Madagascar - and their witnesses's testimony touted a potential therapeutic they have developed and did not allege patent-related access challenges obtaining diagnostics and therapeutics.

Mexico – an upper-middle-income country in Latin America, the precise category of countries some NGO witnesses argued would be the beneficiaries of an expanded waiver – joined Switzerland in communication arguing there is no need for the expansion.[17] Similarly, several developing countries are members of the Ottawa Group, which has proposed non-IP-related solutions to address the ability to scale up manufacturing production.

It is also revealing to consider which countries are pushing the waiver. The original proposal for a TRIPS waiver was made by India and South Africa before COVID-19 vaccines had even been granted emergency use in the US. The most vocal support for expanding the waiver is being driven primarily by countries (e.g., Argentina, India, India, Indonesia) who want to produce these products – not countries proclaiming that they have a critical need for access to them.[18] Indeed, many of the same countries that demanded the TRIPS waiver for vaccines either refused or destroyed millions of doses due to their inability to distribute and administer excess supply.

Thus, the COVID-19-related evidence that exists points to the conclusion that expansion of the IP waiver is not necessary to address the COVID-19 pandemic.

IV. Expanding the Waiver Will Concentrate Generic Manufacturing Rather Than Expand It

Advocates of expanding the waiver have argued in Geneva that the concentration of manufacturing contributes to the inequitable rollout of COVID-19 diagnostics and therapeutics, threatening to undo public health gains achieved during the pandemic. These members called for a multilateral solution in the form of a trigger-ready mechanism as part of the preparedness for future pandemics.[19]

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[16] See, e.g., Tr., Reid at 29-30, Maybarduk at 40, Wallach at 44, Shashikant at 98, and Baker at XX.
[17] See, Communication from Switzerland and Mexico, *"TRIPS Council discussions on COVID-19 therapeutics and diagnostics: Evidence and questions on intellectual property challenges experienced by Members"* (1 November 2022) (IP/C/W/693).
[18] See Tr., Love at 154.
[19] https://www.wto.org/english/news_e/news23_e/heal_17mar23_e.htm

The Medicines Patent Pool (MPP), referenced frequently throughout the hearing, has made more equitable geographic distribution of pharmaceutical manufacturing capacity a priority. As a result, royalty-free MPP licenses cover more than 127 countries collectively and 191 production sites for COVID-19 therapeutics exist worldwide.[20]

NFTC argued in its testimony and prehearing submission that an expanded TRIPS waiver for diagnostics and therapeutics could jeopardize the progress being made through the MPP's voluntary licensing program by shifting production away from MPP countries to a handful of larger markets with economies of scale.[21] This view appears to be one of the few points on which NFTC and the advocacy groups agree.[22]

As noted at the hearing, the vaccines waiver introduces new exceptions to key IP provisions including regulatory data protection and removes existing guardrails on countries that opt to use compulsory licensing. The removal of anti-diversion measures including labeling, tracking and notification requirements eliminates important protections for rights holders and allow for appropriate reporting and tracking of potential adverse events and they ensure that medicines made for eligible countries are not diverted to others.[23]

NGO witnesses argue that these protections are too complicated and prevent countries like India from obtaining economies of scale and produce unlimited quantities of generic COVID-19 diagnostics and therapeutics. Extending the TRIPS waiver to remove these few remaining guardrails would pave the way for developing countries with sophisticated pharmaceutical sectors to gain scale at the expense of the smaller, developing markets where the MPP and branded pharmaceutical companies are working together to build manufacturing capacity that may not be economically sustainable in the face of competition from large-scale generics manufacturers with unlimited ability to produce these products.

V. Conclusion

NFTC is concerned that expansion of the TRIPS Waiver to therapeutics and diagnostics would put at risk the IP protection of a much broader range of pharmaceutical and non-pharmaceutical innovations. It also furthers the misguided notion that TRIPS Agreement protections must be weakened to address global problems, regardless of whether the facts indicate that doing so would contribute to a solution.

Instead of focusing on ineffective tools like the TRIPS waiver to address the COVID-19 pandemic, WTO members should be looking at more practical solutions to address specific challenges, such as those proposed by the Ottawa Group and in the Draft General Council Declaration proposed by 35 countries (including several developing countries).[24] Any solution

[20] World Trade Organization, *Communication of Mexico and Switzerland*, IP/C/W/693 (1 Nov. 2022) at 2.
[21] Tr., Smith at 303-304.
[22] See, Tr., Shashikant at 48, Love, at 84, 92, and Baker, at 376-77.
[23] Tr., Hanniger at 67.
[24] See NFTC Pre-hearing Statement at 7-8.

that is fit-for-purpose to improve the global distribution of vaccines, diagnostics, and therapeutics must address these challenges, not weaken IP protection.