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STATEMENT OF THE
NATIONAL FOREIGN TRADE COUNCIL

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

I. Introduction

The National Foreign Trade Council (NFTC) is pleased to provide its perspectives as part of 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*.

Founded in 1914, NFTC advocates on international tax and trade issues on behalf of a diverse membership of U.S.-based businesses. NFTC's broad membership and expertise enable us to contribute to a greater understanding of the critical role of an open, rules-based international economy in the success of American businesses, entrepreneurs, and workers and shared global prosperity.

At the 12th World Trade Organization (WTO) Ministerial Conference (MC12), trade ministers adopted the *Ministerial Decision on the TRIPS Agreement (TRIPS Decision*), which confirmed the right of members to limit patent rights provided under Article 28.1 of the *WTO Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS Agreement) by authorizing the use of patented subject matter without the consent of the right holder for the production and supply of COVID-19 vaccines to the extent necessary to address the COVID-19 pandemic.

In the lead-up to MC12, WTO Members (Members) also discussed whether the TRIPS Decision also should apply to COVID-19-related diagnostics and therapeutics, but there was no consensus on this issue. Consequently, Paragraph 8 of the TRIPS Decision indicated that Members had until December 17 to decide on the possible extension to cover the production and supply of COVID-19 diagnostics and therapeutics. As the December 17 deadline approached, Members had not reached consensus on the extension despite numerous meetings. On December 19, 2022, the General Council, based on a recommendation from the TRIPS Council, agreed to extend the deadline for a decision.

In conjunction with the WTO's extension of time for a decision on expanding the TRIPS Waiver, the United States Trade Representative (USTR) requested the ITC to undertake this investigation into COVID-19 diagnostics and therapeutics and provide information on market dynamics to help inform the discussion around supply and demand, price points, the relationship between testing and treating, and production and access.

NFTC looks forward to providing testimony and responding to questions from the Commissioners.

II. Looking Back – The Creation of the TRIPS Agreement

A. The Need for a TRIPS Agreement

Before considering how the TRIPS Agreement relates to access to COVID-19 diagnostics and therapeutics, it is important to recall how and why the TRIPS Agreement came into being in the first place.

The WTO website describes the TRIPS Agreement as "the most comprehensive multilateral agreement on intellectual property rights (IP) and it plays a central role in facilitating trade in knowledge and creativity, in resolving trade disputes over IP, and in assuring WTO members the latitude to achieve their domestic policy objectives." More specifically, the WTO notes that the TRIPS Agreement, "frames the IP system in terms of innovation, technology transfer, and public welfare. The Agreement legally recognizes the significance of links between IP and trade and the need for a balanced IP system."

Both the Paris and Berne Conventions were negotiated in the 1880s. These conventions have proved to be remarkably resilient throughout all the change and upheaval of the 20th century and today still constitute much of the legal backbone of international relations in IP.

In 1986, when the Uruguay Round negotiations began, innovation and its protection were viewed as beneficial to society. At the same time, there was a sense that the existing legal and institutional framework for IP needed to be updated for a global economy. For example, the Most Favored Nation principle enmeshed in trade law was not part of existing IP conventions Thus, the Punta del Este Declaration directed negotiators to address "trade-related aspects" of IP.

The TRIPS Agreement was consciously built upon the established IP framework and both reaffirmed the existing multilateral law of IP and at the same time incorporated core principles of IP law into the multilateral trading system.

The entry into force of the TRIPS Agreement, along with the creation of the WTO in 1995, marked a turning point for the multilateral system and began the transformation of law, policy, and international relations surrounding intellectual property rights, most notably by emphasizing the "trade-related aspects" of IP rights.

At the heart of this transformation of global trade was the greater recognition of the value added by the intangible knowledge component of globally-traded goods and services and its significance for trade policy and negotiations.

Since the conclusion of the TRIPS Agreement, we have seen the emergence of new consumer markets in digital products such as music, software, books, games, and movies, reflecting the emergence of IP as a tradeable good in itself. Trade in these products has flourished within the standards and framework of IP protection established by TRIPS – just one example of how the TRIPS Agreement has enabled new innovative industries to thrive.

B. Patent Provisions in the TRIPS Agreement

The TRIPS Agreement reflects the patent system's core balance between incentivizing public disclosure of inventions – a key benefit to the public that derives from patent filings – and the expectation of inventors that they will be able to maintain rights to the invention once disclosed (see e.g., TRIPS Articles 28-29). While most governments recognized the substantial public interest in incentivizing the disclosure of inventions to promote additional innovation, considerable debate centered on the extent of private property rights the Agreement would recognize to inventions relating to public health. In recalling his role as the Chief Negotiator for India during the Uruguay Round, A.V. Ganesan clearly stated India's reservations regarding furthering patent protection in the TRIPS Agreement:

> As the industrialized countries were the owners of nearly 99 percent of global patents and other forms of IP, any agreement for their protection would only favour them at the cost of developing countries. In particular, they were concerned that stringent patent protection would emaciate their capacity to provide affordable health care to the poor.[1]

In the TRIPS negotiations, India and other developing countries argued for freedom and flexibility in granting patent protection in the food and pharmaceutical sectors and sought to negotiate a balance between the protection of patents and protection of the public interest.[2]

The final TRIPS text achieves a careful balance by establishing a common basis for providing patent protection, including for pharmaceuticals, while also qualifying these rights with special provisions, such as compulsory licensing.

The flexibilities provided for in the TRIPS Agreement were further confirmed and clarified in 2001 in the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration), in which WTO Members affirmed that intellectual property protection is critical for the development of new medicines while confirming that the Agreement contained flexibilities Members could use to promote access to medicines. A subsequent decision adopted by the General Council in 2003 removed limitations on using compulsory licenses for exports to countries that cannot manufacture the needed pharmaceuticals themselves. The Doha Declaration and General Council decision on exportation were made permanent and incorporated into the TRIPS Agreement by formal amendment as Article 31 *bis*, which took effect in January 2017.

In addition, the General Council has adopted decisions ensuring that least-developed WTO Members are exempt from the obligation to provide patents and other protections until at least 2033. WTO Members have also maintained a moratorium on non-violation and situation complaints (NVSCs) under the TRIPS Agreement**.**

[1] A.V. Ganesan, "The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round," Chapter 11, at 213. ("Ganesan")

[2] Ganesan at 221.

III. MC12 TRIPS Waiver Decision

Despite balances between patent rights and public interests that have already been incorporated into the TRIPS Agreement, there is still a fundamental theological debate led by India and certain other WTO Members about the value of IP protection generally, and patents in particular.

Those who would like to see IP protection weakened have seized the opportunity presented by the COVID-19 pandemic to push for the further rollback of IP protection in as broad a manner as possible. Indeed, India and South Africa proposed a broad TRIPS waiver for COVID-19 in October 2020, two months before the first vaccine was granted emergency authorization in the US.

At the same time that certain countries began attacking IP rights as an obstacle to addressing the pandemic, it was already well understood that the rapid development of COVID-19 vaccines, therapeutics, and diagnostics would not have been possible but for the billions of dollars in private investments, over the course of many years, in technologies that were incentivized by strong IP protection.

Pushing for over-reliance on TRIPS waivers drives an "if crisis – then TRIPS wavier" approach that is not justified by the COVID-19 experience and threatens innovation, even beyond the pharmaceutical sector.

A. COVID-19 Vaccine TRIPS Waiver Was Not Necessary

NFTC believes that any measures, such as a TRIPS waiver, that swing the careful balance between rights holders and public health reflected in TRIPS must be fact-based, determined on a case-by-case basis, and should be a tool of last resort. The evidence shows that the TRIPS waiver for COVID-19 vaccines was unnecessary and IP was not a barrier to access to medicines. Rather, other policies (including some trade policies) created significant impediments to the manufacture and distribution in under-resourced settings. More than 14 billion vaccine doses had been produced and there is existing capacity to produce more than enough to vaccinate the world.

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.

John-Arne Røttingen, who chaired the WHO Solidarity Trial of COVID-19 treatments, argued in an article published in The Lancet that a patent waiver is the "wrong approach" because, unlike small molecule drugs, "COVID-19 therapeutics and vaccines are complex biological products in which the main barriers are production facilities, infrastructure, and know-how." He called IP "the least of the barriers."[3] Røttingen instead argued for voluntary partnership agreements like those

[3] Ann Danaiya Usher, "South Africa and India push for COVID-19 patents ban," The Lancet, World Repor, Vol 396, Is. 10265, pp. 1790-1791, (December 5, 2020).

that AstraZeneca and Novavax established with the Serum Institute of India for vaccines as a much faster approach and "to identify where the barriers are and work on those."[4]

B. Expansion Of COVID-19 Waiver To Diagnostics And Therapeutics Is Not Necessary Or Advisable

For similar reasons as vaccines, NFTC opposes the expansion of the TRIPS waiver to diagnostics and therapeutics. Just like with vaccines, there is no supply shortage for COVID-19 treatments. In fact, production exceeds demand for treatments for all variants, disease severity, and patient settings. The Global Fund alone has purchased millions of courses of antivirals to donate to low and middle-income countries. Governments have opted not to procure these products despite having the ability to do so without cost.

As with vaccines, by weakening IP protections for a particular subclass of medicines, WTO members would disincentivize needed investment and voluntary partnerships to support the development of additional therapies and diagnostics and improvements on existing ones. This creates a problematic precedent for addressing the COVID-19 pandemic as well as future pandemics and other non-health crises.

In addition, unlike vaccines, which were developed and targeted specifically to COVID-19, most COVID-19 therapeutics are based on existing drugs that treat a wide variety of conditions. If a TRIPS waiver were granted to these products, there is no way to limit the use of the drugs only for COVID-19. Thus, any waiver would, as a practical matter, be much broader than envisioned in the conditions of the TRIPS Waiver, which provides the waiver only "to the extent necessary to address the COVID-19 pandemic."

Granting an expansive waiver of patent protection for all applications of COVID-19 therapeutics could have unintended consequences that disrupt the market for drugs to treat all of these other conditions and could put patient health at risk.

USTR and the WTO must break the cycle of assuming that compulsory licensing, and weaker IP protections, must be the default solution for any global crisis. The mere fact that a global pandemic exists should not be a sufficient basis for weakening WTO IP rules, especially without any factual basis. Indeed some WTO members are seeking expansion of the TRIPS waiver even as their own manufacturers benefit from voluntary IP sharing incentivized by the very protections they seek to undermine.

Patentholders have used numerous mechanisms to ensure an available supply of diagnostics and therapeutics worldwide, such as hundreds of voluntary partnerships, including with manufacturers in developing countries. Without the predictability provided by patent protection, innovators will not be willing to make the significant investment required to test hundreds of candidates to find the handful that show promise in treating future health concerns.

C. Repeated Reliance On TRIPS Waivers Threatens Innovation Beyond Medical Goods

In addition to not being necessary and harming the development and manufacture of pharmaceuticals and diagnostics, NFTC is concerned that expansion of the TRIPS Waiver,

[4] *Id.*

which currently includes "ingredients and processes necessary to manufacture vaccines", to therapeutics and diagnostics would put at risk the IP protection of a much broader range of pharmaceutical and non-pharmaceutical innovations.

Several activists, including the South Centre, have argued that the language of the footnote can be interpreted broadly. For example, a South Centre paper on implementing the MC12 TRIPS waiver notes:

> The long discussions and the divergencies regarding this footnote essentially reflected the concern of developed countries that the Decision may apply beyond the components that were strictly necessary to produce COVID-19 vaccines, such as equipment or vials. There was also the concern, as noted above, that the technologies eventually subject to compulsory licenses could be used for non-COVID-19 products. . . .Notably, the use of the term "includes" makes it clear that the coverage of "subject matter" as indicated in the footnote is not exhaustive. While it refers to "ingredients and processes necessary for the manufacture of the COVID-19 vaccine", it does not exclude equipment nor any products needed, for example, to stock or administer the vaccines.[5]

Such a broad expansion of the scope of the vaccine waiver beyond ingredients and processes necessary for the manufacture of the vaccine would put at risk the IP protection of a much broader range of innovations well beyond pharmaceutical products.

Moreover, NFTC continues to be concerned by advocacy against intellectual property in a range of international fora and the expansion of its advocacy into areas beyond public health. India has played a leading role in driving an IP-weakening agenda at the UN Framework Convention on Climate Change (UNFCCC) and World Intellectual Property Organization (WIPO) in the context of addressing the climate crisis, representing IPR as a barrier to economic advancement and leveraging access to technology for developing countries as a justification to advance work programs that would undo IP protections.

For example, in the discussions in advance of the 2016 UNFCCC COP22 in Marrakech, India was a key proponent of weakening intellectual property rights through various negotiating texts. India has also led efforts within the UN Post-2015 Sustainable Development Goals process to achieve a "balancing" of IPRs that would weaken the framework in the development context.

The South Center, long an opponent of IP protection, has already focused on IP as a barrier to technology transfer and development and has championed the cause proposed at the WTO that countries be allowed not to patent environmentally-sound technologies to facilitate their transfer and use. The relaxation of the TRIPS rules in the case of climate-related technologies has also been proposed by developing countries in the UNFCCC; however, this was opposed by major developed countries.

Seeking the TRIPS waiver for vaccines and its expansion to diagnostics and therapeutics is just another step forward by countries that have never wanted to see strong IP protection and

[5] 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 at 5.

leaves unaddressed those problems that actually affected manufacturing and distribution of essential medical products during the pandemic.

NFTC strongly believes that TRIPS waivers and other steps to weaken IP protection should be used only when there is clear factual support for doing so – i.e., where no other options exist to address an urgent public crisis, such as where patients cannot obtain access to medicines, and that such a waiver would likely improve access. Such circumstances do not exist for COVID 19 and the TRIPS waiver should not be expanded.

IV. More Effective Alternatives to a TRIPS Waiver

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.

In November 2020, Canada and 14 other like-minded WTO Members[6] known as the Ottawa Group unanimously endorsed a Trade and Health Initiative, calling for further cooperation among all WTO Members to strengthen global supply chains and facilitate the flow of essential medical goods, including vaccines, amid the pandemic. The Initiative identifies a range of actions that Members are encouraged to adopt, including:

- implementing trade-facilitating measures in the areas of customs, services, and technical regulations,
- exercising restraint in the imposition of export restrictions,
- temporarily removing or reducing tariffs on essential medical goods, and
- improving transparency.

These approaches provided solutions targeted to the real-world experiences that occurred during the pandemic.

Many of the challenges identified by the Ottawa Group are reflected in an indicative list developed by the WTO Secretariat of trade-related bottlenecks and trade-facilitating measures on critical products to combat COVID-19. The indicative list is based on issues identified and suggestions made by speakers at a WTO webinar on Regulatory Cooperation during the COVID-19 Pandemic and the WTO symposium on COVID-19 Vaccine Supply Chain and Regulatory Transparency both held in June 2021.

On trade-related bottlenecks, the list identifies a range of issues relating to manufacturing, and regulatory approval, and distribution. With respect to vaccine manufacturing, the Secretariat identified such issues as:

- an absence of expedited procedures for exporting/importing vaccine inputs, which remain subject to rigorous documentation requirements and frequent renewal of licenses and certificates;

[6] Australia, Brazil, Canada, Chile, European Union, Japan, Kenya, South Korea, Mexico, New Zealand, Norway, Singapore, Switzerland, and the United Kingdom.

- difficulty in sending non-commercial samples for testing and quality control purposes to specialized laboratories located abroad;
- a lack of predictability in the administration of import and export restrictions, which makes it difficult for vaccine manufacturers to plan and execute the sourcing of critical inputs;
- export restrictions on exports of vaccines to foreign fill and finish sites;
- lockdowns and closures of some embassies and consulates, making it impossible to complete consular transactions;
- high applied tariffs for certain inputs in some manufacturing countries, which can have a cumulative effect on manufacturing cost; and
- complicated visa entry requirements that made it difficult for qualified personnel to move across borders to support vaccine manufacturing in other countries.

Notably absent from this list of bottlenecks was any reference to patent or other IP protection.

One common theme that emerged from the Secretariat's list is that essential goods and inputs need to flow efficiently and expeditiously to support the rapid scaling up of COVID-19 vaccine production capacity worldwide. The delay of a single component may significantly slow down, or even halt, vaccine production given the globally integrated supply chains that underpin COVID-19 vaccine manufacturing.

A group of 35 developed and developing countries proposed a draft WTO General Council Declaration outlining a trade policy response to the COVID-19 pandemic and to enhance resilience against future pandemics. The draft declaration included commitments regarding such things as export controls, best practices in customs and trade facilitation, tariff reduction or elimination, transparency and notifications, and collaboration with other international organizations and the private sector to support the innovation, production, and distribution of essential medical goods.

While not adopted by the General Council, the draft Declaration correctly identifies and targets the range of challenges that arose during the COVID-19 pandemic and provides practical approaches to remedy these issues.

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

It is also the case that biopharmaceutical manufacturers are already sharing their IP voluntarily and demonstrates their commitment to providing timely, equitable global access to safe and effective COVID-19 vaccines and treatments.

One successful program, in particular, is the Medicines Patent Pool (MPP). The MPP is a United Nations-backed public health organization working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. MPP partners with civil society, governments, international organizations, industry, patient groups, and other stakeholders, to prioritize and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations.

Royalty-free MPP licenses cover more than 127 countries collectively. As a result of these agreements, 191 production sites for COVID-19 therapeutics exist worldwide.

Ironically, an expanded TRIPS waiver could jeopardize the MPP's goal of more equitable geographic distribution of manufacturing by shifting production away from MPP countries to a handful of larger markets with economies of scale.

One final factor to consider is that limited demand for COVID-19 diagnostics and therapeutics is also contributing to the lack of global uptake. In these markets, it would be much more useful to try to understand why demand is so low and address those root causes, rather than weaken IP protection.

V. Conclusion

The speed with which COVID-19 vaccines, tests, and therapeutics were developed, brought to market, and distributed worldwide was nothing short of miraculous. It took an intense commitment by the innovative pharmaceutical industry working in concert with governments, logistics companies, and the global health community to achieve this outcome.

Expanding the COVID-19 TRIPS waiver to diagnostics and therapeutics would undermine the ability to achieve this kind of outcome in the future and is not supported by the facts.

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.

NFTC and its members would look forward to working with the Biden Administration and our trade partners to find practical solutions to any lingering challenges to the global uptake of diagnostics and therapeutics, but we continue to believe that further expansion of the COVID-19 TRIPS Waiver is not necessary and could, in fact, be harmful to addressing this and future pandemics.

Thank you.