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NATIONAL FOREIGN TRADE COUNCIL

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

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The National Foreign Trade Council (NFTC) is pleased to provide its perspectives as part of the ITC's Investigation on *COVID-19 Diagnostics and Therapeutics.*

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.

In 1986, when the Uruguay Round negotiations began, there was a sense that the existing legal and institutional framework for IP, which dated back to the 1880s, needed to be updated for a global economy.

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

At the heart of this transformation was the greater recognition of the value added by intangible knowledge in globally-traded goods and services.

The TRIPS Agreement reflects the patent system's core balance between incentivizing public disclosure of inventions – a public benefit - and the expectation of inventors that they will be able to maintain rights to disclosed inventions.

Considerable debate in Geneva centered on the extent of patent protection that would be given to inventions in the food and pharmaceutical sectors.

The final TRIPS text achieves a careful balance by establishing a common basis for providing patent protection, including 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 the Doha Declaration on TRIPS and Public Health.

A 2003 General Council decision later removed the export limitation to address countries that cannot manufacture.

The Doha Declaration and General Council decision were incorporated into the TRIPS Agreement by amendment as Article 31 *bis*, which took effect in January 2017.

In addition, least-developed WTO Members have no patent obligations until at least 2033.

Despite these flexibilities already incorporated into the TRIPS Agreement, there remains a fundamental theological debate 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.

Notably, 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.

Pushing the TRIPS waiver feeds an "if crisis – then TRIPS wavier" approach that is not justified by the COVID-19 experience and threatens innovation.

Any measures 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 IP was not a barrier to access during COVID-19 – rather, other policies (including some trade policies) created significant impediments to distribution in under-resourced settings.

Indeed, 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. It is now well-documented that supply exceeds demand.

We 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.

NFTC is concerned that further expansion of the TRIPS Waiver for COVID-19, 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.

Moreover, NFTC continues to be concerned that this is simply part of a pattern to undermine patent protections by certain actors who are theologically opposed to IP rights.

For example, 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.

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 leaves the real problems that affected the manufacturing and distribution of COVID-19 products unaddressed.

Like-minded WTO Members known as the Ottawa Group unanimously endorsed a Trade and Health Initiative, calling for further cooperation to strengthen global supply chains and facilitate the flow of essential medical goods, amid the pandemic.

Many of the challenges identified by the Ottawa Group also are reflected in an indicative list developed by the WTO Secretariat of trade-related bottlenecks.

The list identifies a range of issues relating to manufacturing, regulatory approval, and distribution.

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

One common theme that emerged is that essential goods and inputs need to flow efficiently and expeditiously to support the rapid scaling up of production capacity worldwide.

In response, 35 developed and developing countries proposed a draft WTO General Council Declaration including commitments on such things as export restrictions, best practices in customs and trade facilitation, tariff reduction or elimination, transparency and notifications, and collaboration with the private sector to support the innovation, production, and distribution of essential medical goods.

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.

Ironically, an expanded TRIPS waiver could jeopardize the Medicine's Patent Pool's goal of more equitable geographic distribution of manufacturing by shifting production away from MPP partner 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 also contributes 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.

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

Thank you.