Submission by: Initiative for Medicines, Access & Knowledge (I-MAK)

For U.S International Trade Commission Investigation No. 332-596 on COVID-19 Diagnostics and Therapeutics Supply, Demand and TRIPS Agreement Flexibilities.

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My name is Tahir Amin. I am a Founder and an Executive Director of the Initiative for Medicines, Access & Knowledge, also known as I-MAK, a non-profit organisation working to address structural inequities in how medicines are developed and distributed. I-MAK would like to make the following comments regarding the U.S ITC Investigation 332-596, on COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities.

Background

In October 2020, India and South Africa submitted a proposal to the World Trade Organization (WTO) requesting a waiver of member states' obligations with respect to all intellectual property (IP) rights—patents, copyrights, industrial designs, and trade secrets (undisclosed information)—as required under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The proposed TRIPS waiver was in response to the hoarding of essential medical equipment by the global North countries at the beginning of the pandemic and specifically sought to suspend IP on all COVID-19 vaccines, therapeutics, and diagnostics until widespread vaccination could help achieve immunity among people in low- and middle-income countries.

Since the original TRIPS waiver was proposed, officially more than 6 million people globally have lost their lives, although the figure could be over 3 times that based on alternative modelling estimates. Out of the nearly 12 billion doses that have been administered globally, only 16.2% of people in low-income countries received at least one dose by June 2022.

The original TRIPS waiver proposal was co-sponsored by more than 60 developing countries and supported by more than 170 former heads of government and Nobel laureates. But any movement on the proposal was stalled as a result of the US, EU, and other wealthy countries that have ample access to vaccines, treatments and diagnostics, and pharmaceutical companies that control supplies and the knowledge to make them, not pushing hard enough to make the waiver happen or blocking the suggestion outright.

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After over 18 months, on 17 June 2022, a final text was agreed by member states of the WTO, known as the known as the Ministerial Decision on the TRIPS Agreement (WTO Decision). The announcement of the agreement was lauded by the WTO, member states, and many in the media that an IP waiver had been agreed and proof that multilateralism still works. However, the final WTO Decision significantly watered down the original proposal by India and South Africa, limiting it only to patents on vaccines and the use of protected clinical trial data for regulatory approval. The end result was not a broad IP waiver of the kind imagined and needed, but a clarification of existing flexibilities already available under the TRIPS Agreement.

A History of TRIPS and Broken Promises

To better understand the case for a global IP waiver in the case of COVID-19 products, it is necessary to revisit the history around the creation of the WTO in 1995 and how it has functioned. This important context is often left out of the discussions around IP and its impact on the global South—especially when it comes to global public health and matters of trade policy.

The issue of IP and technology transfer between the global North and South is not a new one. As many new nation-states started gaining independence in the 1950s from disintegrating European empires, the need to catch up technologically with the industrialized global North as a means of economic transformation and to develop self-sufficiency was a priority. However, agreements for the transfer of technology from multinational corporations to countries in the global South were one-sided. Ultimately, very little technology was transferred or indigenous capacity developed, resulting in these countries falling victim to a form of “technological colonialism”.

As these emerging economies came to terms with the technological gap and insufficient technology transfer, some sought to repeal patent laws remaining from their times as part of the empires. For example, after a 20-year investigation of its patent laws between 1948 and 1970, India realized it had among the highest drug prices in the world and was overdependent on multinational pharmaceutical companies. As a result, it removed patent protection on medicine products and food in 1970, only allowing process patents. This decision helped India develop its modern pharmaceutical industry.

It was also around this time that a group of countries from the South, also known as the G77, turned to the UN General Assembly for help in their quest to close the technological gap and challenge the IP systems that stood in the way of their development. In 1974, the UN General Assembly adopted the resolution known as the Declaration on the Establishment of a New International Economic Order (NIEO), in which the North would help formerly colonized countries become more self-reliant through the transfer of technology. But the global North rejected the call for a NIEO, with the U.S in particular unwilling to abandon enforcement of patent laws and taking up the policy that “the best thing northern governments could do for the third world is to establish stable, continuous growth in their own, northern economies.”

And focus on the growth of the northern economies is what the global North did. Edmund Pratt, then-CEO of Pfizer, feared that manufacturers from the global South would compete with companies like his for these new markets. Along with other business leaders from the copyright industries (software and entertainment), he encouraged US officials in the 1970s and early 1980s

to integrate the defense of IP into US trade policy. Pushed by the pharmaceutical and copyright industries, the Reagan administration persuaded the European and Japanese governments to join the cause, helping place IP at the heart of the General Agreement on Tariffs and Trade. Thus was born the WTO and the TRIPS Agreement.

TRIPS was formalized in 1995, when the global North countries pushed it through over the objections of many Southern countries. While the deal protected the investments of the global North countries and their corporations, it also prevented countries from the global South competing on an even footing in the growing knowledge economy. The Agreement required WTO member states to provide a minimum level of protection and enforcement for all types of IP, even when they may not have previously. Indeed, when many countries in the global North were developing their economies and technological capabilities, they did not always allow patents on pharmaceutical products. For example, Germany and Switzerland, home to some of leading pharmaceutical companies today, only introduced protection for pharmaceutical product patents in 1968 and 1977, respectively. Since TRIPS was signed into existence, the global North and the companies based in it have shifted forums to pursue bilateral free trade deals with Southern countries to further strengthen IP protections.

Those advocating against the IP waiver consistently point to the flexibilities within the agreement, claiming the existing framework offers enough space for countries to manage any IP issues, such as through issuing compulsory licenses for patents, when faced with a public health emergency. Indeed, this has been the negotiating position of the EU, Germany, Switzerland and the UK throughout the TRIPS waiver discussions and largely reflects the final text of the WTO Decision. Despite these flexibilities and the objectives and principles of the TRIPS Agreement (Articles 7 and 8) that were supposed to provide policy space for countries to meet their national interests and public health needs, the 27-year history of the TRIPS Agreement is a story of continual broken promises related to technology transfer to the global South.

Whenever countries in the South have attempted to use these flexibilities during epidemics or other urgent public health needs, whether it be HIV, hepatitis C, tuberculosis, or non-communicable diseases, the U.S and E.U, with lobbying from their pharmaceutical industries, have responded with opposing political pressure. The consequence of such pressure over time has resulted in countries in the global South becoming more and more reluctant to use the TRIPS flexibilities to their fullest to address access to medicines. Even in this pandemic—although the US supported a waiver of IP on vaccines only—the 2022 Special 301 Report of the US Trade Representative still admonishes a number of countries for using the flexibilities permitted by TRIPS in their domestic IP laws. The global North's pharmaceutical companies have followed suit. Pfizer is currently attempting to thwart the Dominican Republic from issuing a compulsory license on patents covering its COVID-19 drug nirmatrelvir/ritonavir (Paxlovid), arguing that its IP is a human right.

These constant trade threats and pressures have squeezed the policy space within which Southern countries can serve their national needs, something that the global North countries never had as they developed technologically. As a result, the only way for local manufacturers in these countries to survive is to enter into heavily restricted voluntary licensing agreements with multinational pharmaceutical companies. These licenses not only undermine any flexibilities a country may have used, they also manage the competition by restricting the territories where products can be sold. For example, the Paxlovid licenses that Pfizer recently established have excluded many middle and upper-middle income countries in need of affordable access to the drug.

Relying solely on flexibilities such as compulsory licenses on patents—which the current WTO Decision re-confirms—and not a broad IP waiver is not enough. Compulsory licenses have to be applied for on a product-by-product basis, which is too slow and cumbersome for addressing a pandemic. Paradoxically, the current WTO Decision could be most useful in relation to COVID-19 therapeutics, especially given the existing ability of manufacturers in the global South to make such products without the need for trade secrets and transfer of technologic know-how.

De-centralizing Production for COVID-19 and Pandemic Preparedness

Throughout the pandemic, opponents of a broad IP waiver have made a variety of arguments while simultaneously moving the goalposts to further delay dissemination of lifesaving medical products. Having successfully delayed a broad TRIPS waiver, a more recent argument from those against suspending IP for therapeutics and diagnostics is that it is now an outdated proposal as the demand is no longer there.

This argument misrepresents the current situation in many global South countries. With only 20% of people in these 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 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.

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.

Demand is very much linked to availability and affordability of treatments and diagnostics. 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.

Given the existing ability of many manufacturers in the global South to make therapeutic products for COVID-19 without the need for the transfer of know-how, extending the IP waiver could help other countries and manufacturers invest in developing their own manufacturing capabilities and capacity, which would not only serve this pandemic but also future ones. Indeed, local manufacturing of COVID-19 rapid tests in Africa and Latin America have been expanded through collaborations with producers in China and Brazil as a result of the World Health Organization's Access to COVID-19 Tools (ACT) Accelerator and financial support from Unitaid and the Foundation for Innovative New Diagnostics (FIND).

Conclusion

The current WTO Decision will do little to increase manufacturing capability for vaccines, while excluding therapeutics and other COVID-19 health related technologies. Based on the history of TRIPS to date, perhaps that is what the global North wanted to achieve—to provide the illusion of giving something, knowing that that it will not work in practice. As it stands, the global South can expect the same treatment it has been receiving over the past 27 years of TRIPS and we will be back scrambling for solutions either during this pandemic, the next one, or as the climate crisis gets worse, while untold lives are lost. Leaders in the global North need to look past their own historical biases and economic self-interest and think of how we can build a system that promotes the collective good. Extending the current WTO Decision to therapeutics and diagnostics would at least alleviate some of its current inadequacies. It would help meet not only the current moment, but also would prepare us for future equitable pandemic preparedness.

It is still not too late to take this course.

Sincerely,

Tahir Amin

Executive Director