WHERE DID THE TRIPS WAIVER END UP - AN ANALYSIS OF THE 2022 WTO MINISTERIAL CONFERENCE AND ITS OUTCOMES

#Fem4PeoplesVaccine
Issue Paper # 6

This short paper provides a summary of the ongoing fight for equitable access to COVID-19 health tools that began in 2020, with a focus on the outcome of the World Trade Organization’s (WTO) 12th Ministerial Conference (MC12) in June 2022. It was at MC12 that important decisions were made to address intellectual property (IP) as a barrier to access to medicines. Unfortunately, the power imbalance in international policy spaces - mostly held by Global North countries - has skewed the outcomes in favor of wealthy developed countries. In this paper, we look at where efforts to harness equitable access were led astray, for what reasons, and who was responsible.

The TRIPS Waiver proposal - a short refresher

The TRIPS Waiver was originally tabled in October 2020 by India and South Africa. It was a comprehensive proposal meant to temporarily waive specific intellectual property obligations, i.e., patents, copyrights, industrial designs, and trade secrets, to ensure timely access to “affordable medical products including diagnostic kits, vaccines, medicines, personal protective equipment and ventilators for a rapid and effective response to the COVID-19 pandemic”.

Such IP measures are required under the Agreement on Trade-Related Aspects of Intellectual Property Rights or TRIPS Agreement administered by the WTO.

The impetus for this TRIPS Waiver proposal was the stock shortages of masks, ventilators, potential treatment medicines and anticipated COVID-19 vaccine distribution disparity. Supply was already constricted as a few vaccines were being rushed out for emergency approvals at the end of 2020. By November 2021, developed countries had obtained 80% of all available vaccines. This left developing and least-developed countries (LDC) with little to no vaccine stocks. In November 2021, they only had about 0.6% of available vaccines.

While the TRIPS Agreement has certain built-in mechanisms called “TRIPS flexibilities” that allow manufacturers to produce patented medicines without the originator manufacturer's consent and to export to countries with insufficient manufacturing capacity, these have proven to be very cumbersome to use. In an
emergency situation where scaling up production is a matter of life and death, a comprehensive blanket waiver would speed up the process.

The TRIPS Waiver proposal gained traction, garnering a total co-sponsorship of 65 WTO Members as well as broader support of about another 40\(^5\). However, developed nations including the United States (US), the United Kingdom (UK), the European Union (EU), and Switzerland were staunch opponents to the Waiver and when global pressure mounted, they sought instead to weaken it. Eventually, however, after the Biden Administration took over from Donald Trump. The US then decided to throw its weight behind the proposal in May 2021 – albeit a narrow waiver only to temporarily suspend IP on vaccines would come out of this support.

Yet, this initial momentum was not enough to take the Waiver proposal further during negotiations. Developed countries purposely stalled progress at TRIPS Council and General Council meetings at the WTO. The General Council is the WTO’s highest-level decision-making body while the TRIPS Council is the body legally responsible for administering and monitoring the operation of the TRIPS Agreement. These negotiations should lead up to the WTO’s 12\(^{th}\) Ministerial Conference (MC12). MC12 was slated to take place in November 2021, therefore raising hope that there would finally be text-based negotiations. So far, developed countries had resisted working on the actual one-pager text of the Waiver proposal. Decision on a final outcome at the Ministerial was of utmost importance. Meanwhile, COVID-19 continued to rage, and more borders were closed with severe disruptions to economies and human lives.

The deadly second wave of COVID-19 resulted in the Ministerial being postponed to June 2022. This further threw a wrench into negotiation processes for the Waiver, as countries around the world struggled to cope with the severe impacts of the pandemic.

**Sequence of Events**

1. **October 2020**  
   India and South Africa propose a TRIPS Waiver proposal at the WTO

2. **May 2021**  
   US expresses support for TRIPS Waiver when the Biden Administration took over

3. **November 2021**  
   MC12, originally scheduled for this date, is postponed to June 2022

4. **End 2021/Early 2022**  
   ‘Quad’ grouping comprising of India, South Africa, the US and the EU convened by WTO Director-General Ngozi Okonjo-Iweala takes over TRIPS Waiver negotiations

5. **March 15th, 2022**  
   Alleged ‘compromise’ TRIPS Waiver text is leaked; eventually it was clarified it was only endorsed by the EU, NOT by other Quad members

6. **May 3rd 2022**  
   WTO DG Ngozi decides to move forward with this leaked text version for further negotiation
No decision was reached on whether to extend the scope to cover diagnostics and therapeutics, the decision was postponed to the first WTO General Council Meeting in early March 2023.

The US Trade Representative Katherine Tai announced the launch of an investigation by its International Trade Commission (ITC) into the need to extend the TRIPS Decision to diagnostics and therapeutics.

Agreement is reached on the “TRIPS Decision” at MC12, with delegates negotiating to the very last minute. The outcome is a severely diluted version of the original 2020 proposal from India and South Africa – only vaccines are covered for 5 years and the extension of the waiver to diagnostics and therapeutics was to be decided in 6 months.
The lead-up to the 12th WTO Ministerial Conference

In early 2022, after repeated requests from India to move forward with negotiations on the Waiver, the WTO Director-General, Ngozi Okonjo-Iweala, convened informal meetings with India, South Africa, the US, and the EU. This group informally came to be known as the “Quad”. For a while, negotiations among the four members proceeded slowly, excluding other WTO Members. These discussions clearly lacked transparency and had the WTO DG playing a questionable key role.

On March 15th, 2022, a leaked text was posted by media outlet Stat News that purportedly showed a “compromise” on the TRIPS Waiver proposal among the Quad group members. Understandably, this led to much uproar among civil society who immediately noticed how different this version of the waiver was...
from the original. It appeared to be very watered down, a far cry from completely waiving IP on COVID-19 diagnostics, therapeutics, vaccines, and other needed medical products. For instance, only vaccines were mentioned as being covered under the waiver with no reference to diagnostics or therapeutics, let alone other essential products. Overall, the leaked text did little to address equitable access to medicines. It soon emerged that the leaked text only reflected the hardline stances of the EU, with no endorsement whatsoever from India, South Africa, or the US. Civil society was not the only critic; other developing countries were also not supportive.

In a bid to fast-track the process, get the negotiations on the Waiver moving and galvanize support, the WTO DG—despite considerable criticism—decided to move forward anyway with the leaked text and proposed this formally at the WTO “on her own accord” as her own “outcome” text on May 3rd, 2022\(^{10}\). Eventually, this text became the basis for negotiations at MC12.

### Negotiations at MC12

The WTO Ministerial took place from June 12\(^{th}\) to 17\(^{th}\), 2022. Throughout the conference, the WTO DG and developed countries used pressure and divide-and-conquer tactics to push their agenda through\(^ {11}\). For instance, developing countries, LDCs, and members of the Africa Group\(^ {12}\) were excluded from private negotiating meetings\(^ {13}\). Many member states were also notified of decisions or proposals at the last minute, giving them no time to consult their governments. They had little choice and had to make a decision on the spot. Such tactics were used as a way to create bargaining chips – members would be forced to compromise in one area if they wanted a favorable deal in another\(^ {14}\).

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11- See FPV Bulletin #1. Available at [https://mailchi.mp/1b609485f448/bulletin-1-charting-the-course-of-the-mc12](https://mailchi.mp/1b609485f448/bulletin-1-charting-the-course-of-the-mc12)

12- The Africa Group at the United Nations is made up of the 54 African Union Member States at the United Nations.


The WTO DG, when confronted about such unfair moves and manoeuvres to pressure developing countries to give in to what developed countries wanted, claimed that such decisions were made due to the ongoing war in Ukraine. She asserted that countries did not want to be in the same room as Russia out of solidarity with Ukraine, making big group negotiations difficult\(^\text{15}\). As a result, smaller groups were created which would have ‘inadvertently’ left some member states out.

After many full days of long negotiations, the final outcome reached on the TRIPS Waiver proposal was a heavily watered down “TRIPS Decision”\(^\text{16}\). The outcome is far from what India and South Africa originally proposed in 2020. Developing countries’ resistance to the developed countries’ unfair demands appeared to have crumbled. For one, the outcome text is incredibly narrow and does not address

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equitable access to COVID-19 medical products in the comprehensive manner as was originally proposed. The adopted TRIPS Decision is limited to vaccines and only waives one condition that restricts exports of vaccines manufactured under a compulsory license (i.e. issued by a government to override the patent barrier without the consent of the originator). The Decision is valid only for 5 years\(^\text{17}\). Other elements of the Decision are clarifications of flexibilities already available under the TRIPS Agreement.

Absurdly, the Decision encourages developing country Members “with existing capacity to manufacture COVID-19 vaccines to make a binding commitment not to avail themselves of this Decision”, adding that “Such binding commitments include statements made by eligible Members to the General Council, such as those made at the General Council meeting on 10 May 2022”. This aspect contained in the first footnote of the decision is based on an agreement reached between the US and China, as the US has long insisted that any outcome that emerged should not be available for use by China, even if it could boost the country’s capacity and ability to supply other developing countries.

Finally, a decision to extend the coverage to diagnostics and therapeutics was delayed to 6 months from the date of adoption of the TRIPS Decision. Thus, the overall end result was not a comprehensive waiver of IP that would have led to more equitable access and production of COVID-19 medicines and other needed medical products. Rather, it was an outcome that offered too little too late with a few clarifications of existing flexibilities already available under the TRIPS agreement. The only exception was a temporary waiver of an existing export restriction attached to the use of compulsory licenses. In the end, the outcome decision presented little in the way of new solutions\(^\text{18}\).

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Aftermath of MC 12

The aftermath of the WTO ministerial has left a number of questions that must be answered.

Why did we get such a watered-down TRIPS Decision? There are a number of reasons that have brought us to this point.

First, there was intense opposition throughout from Big Pharma, determining the positions of the EU, the UK, and Switzerland to the original waiver proposal\(^\text{19}\). This was bolstered with unabashed support from the WTO DG and the WTO Secretariat. This alliance between developed member countries and the WTO leadership promoted a highly non-inclusive and opaque process that culminated at the Ministerial Conference and pushed developing countries into a “take-it-or-leave-it” conundrum. As a result, the promise of an extension to cover diagnostics and therapeutics was accepted.

Second, it remains to be seen what becomes of diagnostics and therapeutics. So far, no movement has occurred on extending the TRIPS Decision. At informal and formal meetings, developed countries are once again resorting to stonewalling tactics by asking for “clear evidence” that IP poses barriers to accessing diagnostics and therapeutics\(^\text{20}\). Despite the WHO showing evidence of inequitable access, Switzerland and Mexico proceeded to submit a paper to the TRIPS Council questioning the need for an extension\(^\text{21,22}\). The US has also done its best to delay the process, with its request to the US International Trade Commission to


initiate an investigation on the extension of the TRIPS Decision to diagnostics and therapeutics\(^{23}\). Their investigation will not conclude until October of 2023.

**Who is responsible? IP regimes, Big Pharma, and biased WTO leadership**

With the impasse at TRIPS council meetings, there was no choice but to postpone the decision on extending the TRIPS Decision to the formal General Council meeting in early March 2023. At the time of writing, further progress is subject to the US International Trade Commission’s report to the US Trade Representative.

**Where we are now?**

This requires that we look back at the root of the problem. To keep our fight for equitable access to medicines alive, we must consistently keep in mind who the real culprits are, tightening their hold over IP and its monopolies at the cost of lives every day.

The first root cause of inequitable access is the TRIPS Agreement, which sets global minimum standards of IP protection. The history of the TRIPS Agreement can be traced back to the 1970s. At the time, Edmund Pratt was the CEO of Pfizer and feared the rising competition from pharmaceutical manufacturers in the Global South. Galvanizing support among the biotechnology, pharmaceutical and other proprietary industries (i.e., software and entertainment), Pratt convinced US officials to integrate IP into US trade policy. This snowballed until the Reagan Administration began convincing European and Japanese governments to join the cause and push for IP inclusion in the Uruguay Round of trade negotiations. Pratt also coordinated with industry counterparts in Europe and Japan\(^{24}\).


Pushed through despite objections from key negotiators from some developing countries (the majority were not fully aware of the implications of including IP in the global trade rules), this movement led to the birth of the TRIPS Agreement in 1995. This international legally binding agreement inherently protects the interests and investments of the Global North while simultaneously blocking the Global South from partaking in the growing knowledge economy\textsuperscript{25}.

In the current COVID-19 context, the TRIPS Agreement is a proven barrier to timely and equitable access to medical products. However, while enshrining minimum protection standards for IP, the Agreement also has in-built flexibilities that would circumvent IP protection on pharmaceutical products in certain circumstances, including for public health needs. One such mechanism is that of compulsory license, which the TRIPS Decision at the MC12 in June reaffirms.

A compulsory license is a tool that allows a government to license the use of a patented product or technology to a third party without the consent of the patent holder. However, the patent holder continues to have a right over the patent, including the right to be paid adequate remuneration for the generic version of the products made under compulsory licenses. In the case of health needs, these licenses can be used to manufacture, import and/or export medicines, vaccines, diagnostics and other medical products.

A compulsory license ensures that essential medicines are available at affordable prices in a timely manner, especially in developing countries. Countries, however, are free to determine the grounds for granting it. It is one of the vital flexibilities provided for in the TRIPS Agreement that can be invoked to protect and realize the right to health. It balances public rights and private privileges. It is a win-win for both - countries that issue them and the pharma companies who are entitled to adequate remuneration.

\textsuperscript{25} Amin, T., & Kesselheim, A. S. (2022, October). A global intellectual property waiver is still needed to address the...Third World Network. Retrieved May 6, 2023, from https://www.twn.my/title2/briefing_papers/twn/IP%20waiver%20TWNBP%20Oct%202022%20Amin.pdf
However, the use of compulsory licenses is often a time-consuming process, usually done on a product-by-product basis. In addition, though compulsory licensing is a legal right of WTO Members, its use by developing countries has often been subjected to intense pressures from industry and developed countries that are home to Big Pharma. In situations of health emergencies such as COVID-19, this tool is not enough, as explained by the TRIPS Waiver proposal proponents in several lengthy submissions to the TRIPS Council.

Furthermore, countries that do not have the requisite manufacturing capacities will not immediately benefit from such licenses. Therefore, it is imperative that countries with manufacturing capacity can export without restrictions to those countries in need. The TRIPS Agreement has complicated and cumbersome rules for the export of the majority of pharmaceutical products manufactured under compulsory licenses. Thus, a comprehensive TRIPS waiver across the whole supply chain was needed for COVID-19. This is also legally allowed by the WTO rules but developed countries blocked it.

The second root cause of inequitable access can be pinpointed to the role of Big Pharma and philanthrocapitalists. As we have already seen above, the influence that pharmaceutical companies have on national and international policy is unchecked. In the current context of COVID-19 and the TRIPS Waiver, the influence of Big Pharma was apparent through the actions of developed countries such as the US, Germany (a major force for the EU position), the UK, Switzerland, and Japan. Each of these countries did their best in stalling and diluting the TRIPS Waiver to protect their domestic pharmaceutical industries. This comes at the cost of Global South countries being able to build up their own domestic industries, with COVID-19 exposing the deep vulnerabilities of dependence on a handful of manufacturers based in the Global North. All this is to show that Big Pharma uses developed countries as mouthpieces to fulfil their profit-driven agendas and did not hold back their punches when COVID-19 ravaged the world.

This was most aptly demonstrated when private text messages were reported between current Pfizer CEO Albert Bourla and EU Commission President Ursula von der Leyen. It was found that these messages pertained to a COVID-19 vaccine deal. Bourla and von der Leyen had been corresponding for about a month negotiating a deal that was “the biggest contract ever sealed” for 900 million COVID-19 vaccine doses\(^2\). Clearly, such communication between senior members of government and Big Pharma leadership demonstrates the close alliance between the two. If a wealthy Global North country wishes to buy vaccines, all they have to do is send a few text messages over the phone. Meanwhile, Global South countries struggled to secure enough doses to even provide one round of vaccination for their populations. Any attempt to ease their burden of access was severely lobbied against in international policy spaces.

Privatization of global public goods has been another objective of Big Pharma, one that severely inhibits the fight for equitable access to medicines. At the start of the pandemic, there were glimpses of hope that COVID-19 treatments and essential medical products would be slated as public goods, i.e., they would be available to everyone, and one’s consumption of them would not affect the ability of another to partake in their share of treatment. For example, back in 2020, Moderna pledged not to enforce patents on its mRNA vaccine\(^2\). Similarly, Oxford University was in the throes of developing their jab at the time—a promising endeavor because a vaccine developed by public funding signalled the intention of the vaccine being made a public good as well.

However, promising prospects of a widely available and affordable vaccine proved to be nothing more than a pipe dream. The Bill and Melinda Gates Foundation effectively hijacked Oxford’s vaccine by convincing them to partner with the private pharmaceutical company AstraZeneca. The Gates Foundation


convinced Oxford that partnering with AstraZeneca would enable them to scale up production and market the vaccine better\textsuperscript{29}. While this may appear to be a benign reason to do so, it would inadvertently turn the Oxford vaccine into a private good protected by IP. This effectively kept the vaccine out of reach for developing country manufacturers to produce domestically.

The third root cause of inequitable access to medicines can be found in the WTO’s power dynamics and its Secretariat’s staunch allegiance to global North interests.

To start with, there are severe asymmetries in the governance structure of the WTO. The US, UK, EU, and other developed nations have almost unchecked influence, and through them, enormous influence from the private sector as stated above. This is also clear from the manner in which the WTO Secretariat's leadership conducted themselves before and during MC12.

The WTO Director-General herself was seen to be lobbying for the watered-down leaked text at the LDC retreat and to the Africa Group in the run-up to the Ministerial Conference. She proposed the leaked text as a “take it or leave it” deal and reportedly admonished any Global South opposition to it, warning member states that it would not be beneficial to block progress. The negotiations process at MC12 in June 2022 was extremely opaque, such that developing countries were consistently shut out of small group negotiations. The DG was desperate to deliver a deal and therefore pushed for more compromise among countries\textsuperscript{30}. Unfortunately, this translated to more compromises on the part of developing countries. Furthermore, the TRIPS Council chair often marginalized suggestions from developing countries during the negotiation process, while prioritizing those from the key developed countries.

Therefore, the resulting limited and diluted text adopted on June 17\textsuperscript{th}, 2022 was apparent in its favouring of the negotiation position of the EU (led by Germany), US, Switzerland, and the UK.


\textsuperscript{30} See FPV Bulletin #2. Available at https://mailchi.mp/49a1075c5b7a/bulletin-1-charting-the-course-of-the-mc12-8898825
How do we move forward?

It is imperative for Global South nations to re-orient themselves behind the original Waiver proposal and continue the fight for equitable access to medicines.

For one, developing nations should take full advantage of TRIPS flexibilities. The outcome text adopted at MC12 reaffirms compulsory license flexibilities enshrined in the TRIPS Agreement. Now that there has been a clear endorsement from developed nations of the existing flexibilities as a solution to equitable access, member states should take full advantage of these rights that were otherwise marginalized by developing countries due to political pressure and intimidation. The one actual waiver of export restriction in the TRIPS Decision should be used in cases where patents are a barrier in developing countries with manufacturing capacity. COVID-19 is not over. Millions remain unvaccinated and new vaccines may be needed for new variants.

Second, the fight for diagnostics and therapeutics is not over. Surges in new cases and hospitalization are reported in several countries so testing and treatment remain urgently needed.

Additionally, South-South cooperation in the context of knowledge and technology sharing should be built up. In this way, dependence on Global North countries can be reduced. Civil society’s knowledge on the issue of IP as a barrier to access also must be strengthened. Coordination between national governments and local civil society organisations should be fostered to create a stronger voice in WTO and other global processes. Finally, there must be a strong call for full WTO reform, starting with the overhaul of the TRIPS Agreement and related IP regimes.