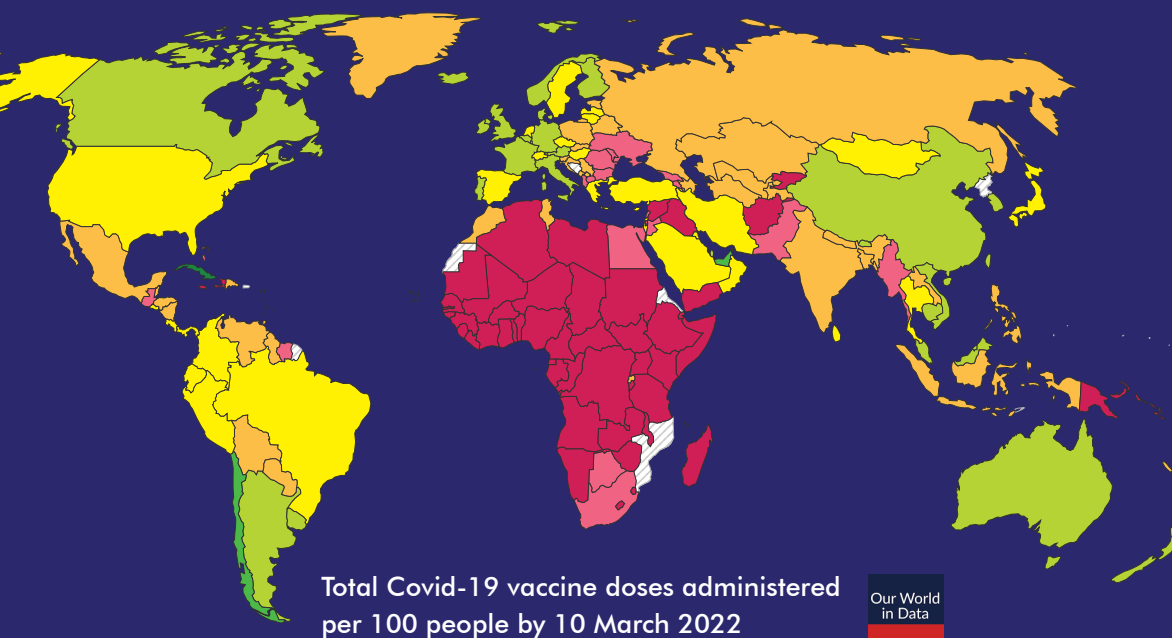


Pandemics and the illumination of “hidden things”

Lessons from South Africa
on the global response to Covid-19

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Decoding the TRIPS decision of June 2022

Sangeeta Shashikant

Arguably the most pressing need facing WTO Member States at the WTO's 12th Ministerial Conference in June 2022 was to reach an agreement on lifting intellectual property-related barriers for the supply of Covid-19 medical products. Blunted by developed countries' intransigence, the eventual decision was a major disappointment that could end up costing lives.

The WTO's decision on the TRIPS Agreement (WTO document WT/MIN(22)/30) gavelled in the final hours of 17 June 2022 may perhaps best be described as a bittersweet outcome for developing countries (Hassan, 2022) (HJI, 2022a) (Vawda et al., 2022).

Bitter for — even after 20 months of intensive discussion and negotiation — the outcome falls severely short of the comprehensive TRIPS waiver proposed by India and SA in October 2020 and discussed widely through this Compendium. That proposal sought to temporarily waive at least 35 articles of the WTO's TRIPS Agreement covering patents, protection of undisclosed information, and copyright and industrial designs in relation to health products and technologies for the prevention, treatment, and containment of Covid-19.

This chapter begins by briefly outlining the motivation for the waiver before discussing its aim. Next, it goes through the key features of the TRIPS Decision, highlighting in particular how the aggressive opposition and rigid positions of developed countries (the EU, US, UK and Switzerland) led to a limited diluted outcome. Finally, it discusses considerations for developing countries in implementing and using the TRIPS Decision.

SA and India's waiver proposal was motivated by the "growing supply-demand gap" early in the Covid-19 pandemic, arguing that "[t]he rapid scaling up of manufacturing globally is an obviously crucial solution to address the timely availability and affordability of medical products to all countries in need." The proposal went on to stress the need for "unhindered global sharing of technology and know-how in order that rapid responses for the handling of Covid-19 can be put in place on a real time basis".

At its core, the comprehensive TRIPS waiver proposal sought to create the "freedom to operate" on a temporary basis, to scale up and diversify global manufacturing to address the global inequity in access to Covid-19 health products and technologies for the benefit of the Global South. "Freedom to operate" being a term to describe in this case, the freedom to manufacture, use, sell or distribute a Covid-19 product, without any restrictions.

The TRIPS waiver proposal, which was co-sponsored by 65 WTO members and supported by many others, received tremendous backing from individuals and international organisations such as the WHO, as well as intellectual property experts, parliamentarians, and Nobel laureates (Third World Network, No date) (HJI, 2021) (UNAIDS, 2021).

However, persistent opposition and the uncompromising positions of developed countries, especially the EU, the US, the UK, and Switzerland — amply supported by the WTO Secretariat's manoeuvring — ultimately resulted in a very limited and conditional Ministerial Decision on the TRIPS Agreement at the June 2022 WTO conference.

This outcome was inevitable once negotiations commenced on the basis of a narrowly draft text communicated by the WTO DG to the WTO's TRIPS Council on 3 May 2022. The DG's text — already

public following a leak in March 2022 was globally criticised for its “TRIPS-plus” elements — or intellectual property protections that go beyond TRIPS Agreement requirements — and for its inadequacy in times of a global pandemic (Third World Network, 2022a) (Third World Network, 2022b).

The WTO Ministerial Decision reflects the obstructive positions of the EU, which could agree only to a decision framed in the context of a compulsory licence of patents. Similarly, the outcome reflects the US’s insistence that the Decision should cover only Covid-19 vaccines, excluding therapeutics and diagnostics, and set criteria limiting which WTO members could use the Decision, in particular, excluding China. This exclusion is discussed in detail later in this chapter.

While the Ministerial Decision on the TRIPS Agreement that was eventually adopted does not deliver the desired comprehensive TRIPS waiver, it is nevertheless a marked improvement over the WTO DG’s proposed text (see above). This is worthy to note in view of the vicious hostility of developed countries that had been observed during the course of the negotiations leading to the Decision’s adoption. The UK and Switzerland, in particular, relentlessly sought to narrow the scope and application of the Decision (Third World Network, 2022c) (Third World Network, 2022d).

Making sense of the Ministerial Decision

The Ministerial Decision on the TRIPS Agreement is built on the existing compulsory licensing flexibility under Article 31 of the TRIPS Agreement, and only waives the limit on quantities of vaccines that may be exported when produced under a compulsory licence issued to override patent barriers for the manufacture of Covid-19 vaccines.

Article 31 of the TRIPS Agreement already allows governments to issue a licence to authorise a third party to use and exploit a patented product or process without the consent of the patent holder. This important flexibility is often referred to as a non-voluntary or compulsory licence. Where a compulsory licence is issued for public non-commercial use, it is also commonly known as a “government use” licence.

The use of a compulsory licence is ordinarily subject to various conditions. Among these, Article 31(f) of the TRIPS Agreement states that compulsory licences must be used predominantly for supplying the domestic market, thereby limiting the quantities of the licensed products that may be exported. Now, paragraph 3(b) of the Ministerial Decision on the TRIPS Agreement waives this condition alone, allowing most or all of the production to be exported. This is actually the only “waiver” contained in the Ministerial Decision on the TRIPS Agreement.

Previously, a mechanism to waive the Article 31(f) condition was adopted on 30 August 2003, and in 2005 it was translated into a permanent amendment of the TRIPS Agreement as Article 31bis. But this mechanism has mostly proven to be ineffective and unworkable due to the numerous rigid procedures attached to its use (MSF, 2006) (WTO TRIPS Council, 2021). The Ministerial Decision on the TRIPS Agreement in effect offers a mini-version of that mechanism.

Another interesting element in the Ministerial Decision on the TRIPS Agreement is paragraph 4, which relates to Article 39.3 of the TRIPS Agreement concerning protection of test data. Historically, developed and developing countries have held different interpretations of Article 39.3, which reads as follows:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Developed countries have typically argued that Article 39.3 requires the granting of exclusive rights for a specified timeframe over test data submitted by the originator pharmaceutical companies to regulatory authorities for purposes of obtaining marketing approval, thereby delaying the entry of generic and other follow-on manufacturers.

Developing countries maintain that such an interpretation is not supported by Article 39.3 and most developing countries do not implement such a requirement at the national level. However, often due to pressure exerted especially through free trade agreements, some developing countries have implemented data exclusivity at the national level. Evidence suggests that the implementation of data exclusivity delays generic competition, enabling the originator company to charge monopoly prices with significant implications for public sector budgets and access to affordable medicines (Malpani, 2009) (Gamba et al., 2012).

Against this background, paragraph 4 of the Ministerial Decision on the TRIPS Agreement confirms developing countries' interpretation of Article 39.3 that undisclosed test data submitted by originator companies to regulatory authorities may be relied on and used for purposes of granting rapid regulatory approval. Article 39.3 also allows disclosure of data in certain circumstances.

Paragraph 4 of the Ministerial Decision on the TRIPS Agreement reinforces that flexibility in the context of "timely availability of and access to Covid-19 vaccines". Towards that end, paragraph 4 states that Article 39.3 does not prevent a Member State from "enabling the rapid approval for use of a Covid-19 vaccine", which also supports the disclosure of undisclosed test data for the purpose of rapid approval for use of a Covid-19 vaccine produced under this Decision.

Paragraph 3(a) of the Ministerial Decision on the TRIPS Agreement reinforces the existing flexibility in Article 31(b) of the TRIPS Agreement that an eligible WTO Member State may grant a compulsory licence without first having to make attempts to get a voluntary licence from the patent holder.

Paragraph 3(d) of the Ministerial Decision on the TRIPS Agreement adds elements that may be considered when determining payment of adequate remuneration to the patent holder under Article 31(h) of the TRIPS Agreement. Payment of adequate remuneration is in any case subject to national discretion under the TRIPS agreement.

Still, use of the Ministerial Decision on the TRIPS Agreement is subject to several conditions that are not normally applicable when using the compulsory licensing flexibility under the TRIPS Agreement. Hence, these can be said to be TRIPS-plus conditions, for example:

- Paragraph 3(c) of the June 2022 Ministerial Decision on the TRIPS Agreement prevents the re-exportation of products manufactured under the authorisation in accordance with the Decision that have been imported under the Decision, with a footnoted exception for situations of “humanitarian and not-for-profit purposes”. In a public health emergency, there is no logic or basis for such a condition. Still, despite the opposition of most developing countries to the barring of re-exportation, the EU insisted on maintaining this paragraph, only making leeway for the small exception in footnote 3 for humanitarian and non-profit purposes. However, this condition is only applicable when both the manufacturing and importing countries are using the Decision.
- Paragraph 5 and footnote 5 require countries to notify the WTO’s TRIPS Council, which monitors the implementation of the TRIPS Agreement, as soon as possible after the adoption of the measure. Footnote 5 of the Decision states that the council “shall be notified as soon as possible after the information is available”. On several occasions during the negotiations, the UK had insisted on pre-shipment notification, which was not ultimately agreed to by WTO members.
- The eligibility criteria in footnote 1 reflects the US intent that China legally commits to *opting out* of using the Decision. The DG’s text had reflected the US proposal

that, “for the purpose of this Decision, developing country Members who exported more than 10% of world exports of Covid-19 vaccine doses in 2021 are not eligible Members”. China was not agreeable to this formulation, which was clearly targeted at singling it out. A counter-proposal was reflected in the DG’s text: “For the purpose of this Decision, all developing country members are eligible Members. Developing country Member States with capacity to export vaccines are encouraged to opt out from this Decision.”

On 10 May 2022, China formally announced to the WTO General Council that it was opting out of using the Decision. However, the statement was insufficient for the US. Due to US’s domestic anti-China sentiment, the US sought a binding commitment that would exclude China, although China has significant production capacity that could support greater access in developing countries.

The final text of footnote 1 states:

For the purpose of this Decision, all developing country Members are eligible Members. Developing country Members with existing capacity to manufacture Covid-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision. 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, and will be recorded by the Council for TRIPS and will be compiled and published publicly on the WTO website.

Ultimately, this final footnote was the outcome of a bilateral negotiation between the US and China. Most WTO members had not even seen the text of footnote 1 even as the Decision was gavelled. Although the stated objective of the Decision is “production and supply of Covid-19 vaccines”, footnote 1 of the text discourages

developing countries with manufacturing capacity from using the Decision, revealing the absurdity, irrational power politics and Big Pharma interests that influenced the textual negotiations.

In implementing the Decision, paragraph 2 may be useful for it presents a simplified approach to implementation and reads:

For greater clarity, an eligible Member may authorize the use of the subject matter of a patent under Article 31 without the right holder's consent through any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place. For the purpose of this Decision, the "law of a Member" referred to in Article 31 is not limited to legislative acts such as those laying down rules on compulsory licensing, but it also includes other acts, such as executive orders, emergency decrees, and judicial or administrative orders.

This paragraph makes clear that the "law of a Member" referred to in Article 31 of the TRIPS Agreement is not limited to legislative acts, such as those laying down rules on compulsory licensing, but also includes other acts, like executive orders, emergency decrees, and judicial or administrative orders.

Paragraph 6 of the Ministerial Decision on the TRIPS Agreement provides that the duration of the Decision is five years. The duration effectively applies to the waiver of Article 31(f) of the TRIPS Agreement contained in paragraph 3(b) of the Decision, as the other elements of the Decision are mere clarifications and reiterations of existing TRIPS Agreement flexibilities.

Importantly, nothing in the Decision prevents any member country from issuing a compulsory licence for a period beyond five years.

Paragraph 7 safeguards against “non-violation and situation” complaints for the duration of the Decision. Until WTO’s 13th Ministerial Conference, there is a moratorium on non-violation complaints with respect to the TRIPS Agreement. The Decision does not, however, stop challenges under the usual WTO dispute settlement mechanism for violating the TRIPS Agreement pursuant to Article XXIII.1(a) of the General Agreement on Tariffs and Trade.

Paragraph 9 clarifies that except for the granted waiver lifting the restriction on export of vaccines, the Decision does not affect the rights and flexibilities of WTO Members provided by the TRIPS Agreement.

Not perfect, but an improvement over leaked texts

As noted above, the final Decision is an improvement over the DG’s text for several reasons, including:

- reference in the DG’s text to “patented subject matter” was changed to “subject matter of a patent”, ensuring consistency with Article 31 of the TRIPS Agreement and that the Decision is applicable not only in situations where the subject matter to be licensed is patented but also to subject matter at the application stage, that is, pending patents;
- deletion of the requirement to list all patents to be covered by the compulsory licences, which if maintained would have been difficult to comply with, given the uncertainty over the patent landscape of a particular product and process;
- addition of a humanitarian and non-profit exception in footnote 3 to the re-export restriction in paragraph 3(c) of the Decision, as discussed above.

What next for developing countries?

Footnote 1: Setting the record straight

Footnote 1 of the Ministerial Decision on the TRIPS Agreement states:

For the purpose of this Decision, all developing country Members are eligible Members. Developing country Members with existing capacity to manufacture Covid-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision. 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, and will be recorded by the Council for TRIPS and will be compiled and published publicly on the WTO website.

On 22 June, the WTO Secretariat issued a WTO document IP/C/W/690 entitled, "Record in accordance with footnote 1 of the Ministerial Decision of 17 June 2022." It states: "This document provides a record of developing country Members that have made a binding commitment not to avail themselves of the Ministerial Decision on the TRIPS Agreement of 17 June 2022. This record will be updated as appropriate." China's opt-out statement at the May General Council meeting is mentioned.

The WTO Secretariat's approach of unilaterally creating such a record is inconsistent with the text in footnote 1, which lists a two-step process whereby commitments will be recorded by the TRIPS Council and published publicly on the WTO website. Footnote 1 requires that any intention to opt out of using the Decision should officially be communicated to the TRIPS Council by the Member State concerned, for only then can it be recorded by the TRIPS Council. The WTO Secretariat's role is to compile and publish it publicly once it has formally been recorded by the TRIPS Council. WTO Members should set the record straight with the secretariat.

Therapeutics and diagnostics

WHO has said that “it is simply not acceptable that in the worst pandemic in a century, treatments that can save lives are not reaching those that need them”, calling the inequitable access a “moral failing” and adding that the world was “playing with a fire that continues to burn us” (WHO, 2022a).

By 29 June 2022, WHO DG, Tedros Adhanom Ghebreyesus, noted that Covid-19 cases were on the rise in 110 countries, causing overall global cases to increase by 20% and leading to rising deaths in three WHO regions. He stressed that countries should be integrating testing and antivirals into clinical care to ensure people receive prompt treatment (WHO, 2022b).

The crucial role of therapeutics and diagnostics in controlling Covid-19 is undisputed. They are recommended by WHO as well as by national strategies, increasingly as part of test-and-treat strategies.

Yet timely, affordable access remains a challenge in most developing countries.

Most of the limited supply of Covid-19 therapeutics has been procured by wealthy countries, which represent a mere 16% of the global population. Even when available, they are unaffordable to most developing countries. Voluntary licences are often put forward as the solution to the challenge of access in developing countries. However, as the licences are “voluntary”, there is no guarantee that a patent holder will make available such a licence for supply to developing countries. And where voluntary licences exist, they exclude supply to many developing countries and contain other unjustified terms and conditions that delay or hinder generic production (MSF, 2022) (MSF, 2020).

Expanding supply options requires lifting the intellectual property barriers to the entry of generic manufacturers, especially as patent filings related to therapeutics considerably outnumber those on vaccines by some four-fold. Extending the scope of the TRIPS Decision beyond vaccines to cover therapeutics and diagnostics could have secured the availability of compulsory licences to override the patent barrier to production and export. It is a no-

brainer from a public health perspective and yet it was one of the most contentious aspects of the negotiations on the Decision.

Paragraph 8 of the Decision states: “No later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of Covid-19 diagnostics and therapeutics.”

This two-track approach of “vaccines first, therapeutics and diagnostics later” reflects the US’s obstinate position during the negotiations. Even when US concerns were addressed with the two-track approach, paragraph 8 was bitterly disputed until the end of the negotiations as the UK and Switzerland unsuccessfully attempted to dilute the definitive commitment to address therapeutics and diagnostics, proposing that the text regarding an extension give States six months to decide “whether to extend this Decision” instead to decide “on its extension”.

At the time of writing, the six-month time period for extension of the Decision to Covid-19 therapeutics and diagnostics had been postponed indefinitely (Patnaik, 2022).

Implementing and using the Decision

Compulsory licensing is one of the most important tools that developing countries have to address patent barriers to production and access. The Decision could motivate the greater use of compulsory licences for Covid-19 vaccines in the Global South. The main beneficiaries of the Decision are developing countries manufacturing or planning to manufacture Covid-19 vaccines with the intent to export the majority or all of the vaccines but who are facing existing or potential patent barriers. Countries that are importing vaccines or exporting a non-predominant portion under a compulsory licence need not use the Decision. These countries may continue to import or export under Article 31 of the TRIPS Agreement.

Least developed countries enjoy full exemption from TRIPS Agreement obligations at least until 1 July 2034 and should utilise this exemption to import, export or use any patented products (Shashikant, 2022). They do not need to use compulsory licensing,

including under the decision, to address potential/existing patents or other intellectual property barriers.

For other products beyond Covid-19 vaccines, developing countries that wish to import and export may continue to use compulsory licences under Article 31 of the TRIPS Agreement to override any patent barriers. Article 31 limits neither the products that may be compulsorily licensed nor the duration of the licence, which may be for the duration of the patent term. Apart from compulsory licensing under Article 31, developing countries may also use other TRIPS Agreement flexibilities to address patent or other intellectual property barriers to access.

At the global level, the process that began in October 2020 with SA and India's proposal for a TRIPS waiver provided a platform for developing countries and the international community to highlight the challenge of timely and affordable access, exposing the hypocrisy of developed countries and their failure to deliver on promises of global solidarity and equitable access. Most notably, it has brought immense global visibility and awareness to the intellectual property monopolies that underpin and enable highly concentrated supply chains that are unsuitable for addressing public health needs in developing countries especially during a public health emergency, and consequently the need for greater freedom to operate for local manufacturers to diversify production and expand supply options.

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