

**Investigation No. 332–596, COVID–19  
Diagnostics and Therapeutics: Supply,  
Demand, and TRIPS Agreement Flexibilities**

*Written submission to the US International Trade Commission*

Ellen 't Hoen LLM, PhD, Director  
Medicines Law & Policy



Amsterdam, 2 May 2023

Submitted to: Secretary, US International Trade Commission, 500 E Street SW,  
Washington, DC 20436. This document contains no confidential business  
information.

## Submission summary

On 17 June 2022, World Trade Organization (WTO) Members adopted a Ministerial Decision outlining flexibilities in the WTO's Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement that countries could use to access Covid-19 vaccines. A decision on whether and how to extend the scope of the decision was tabled for a later date. As part of the decision-making process, the US Trade Representative has commissioned a study to determine the case for extending the Decision.

[Medicines Law & Policy](#) is a research group that brings together experts working at the nexus of international law, intellectual property, medical technology and public health, and is a leading voice on access to countermeasures for Covid-19 and other health emergencies. We recommend that an extension to the Decision:

- **Ensure access to *all* pandemic countermeasures** including vaccines, diagnostics, therapeutics and any other health technologies needed to prevent, address and/or recover from a health crisis.
- **Ensure preparedness for future pandemics** by making the Ministerial Decision applicable to any emerging or declared health emergency in the future.
- **Ensure an easy pathway for countries to opt back into TRIPS Art. 31bis.** In 2003, many countries opted out of using Art. 31bis (compulsory licensing for export). With increasing concentration of pharmaceutical manufacturing, those countries may find themselves in need of this provision, in particular in a crisis situation.
- **Ensure waivers on market and data exclusivity are available** so that effective implementation of a compulsory licence is not delayed by lack of access to information needed for regulatory purposes.

Since 2001, ML&P has been tracking the use of TRIPS flexibilities for public health in our [TRIPS Flexibilities Database \(TFD\)](#). We see that TRIPS Flexibilities are:

- **Widely used.** The TFD currently documents 172 instances, of which 122 concern compulsory licensing, 3 exceptions to patent rights, 46 the least developed country (LDC) extension and 1 parallel import.
- **Effective even when not executed.** The TFD notes 27 instances between 2001 and 2023 where compulsory licences were proposed but not executed. Of those, 16 resulted in an access measure by a company - either a voluntary licence, a price decrease, or a declaration not to enforce rights.
- **Useful in a pandemic.** The TFD shows that since 2020 there have been 10 instances of compulsory licensing that concerned products needed to prevent or treat Covid-19. Five of these instances were in high-income countries and four were executed.

- **Useful in high-income countries.** Of 122 compulsory licence instances in the databases, 23 were for the use in high-income countries.

TRIPS flexibilities have an important role in ensuring access to medicines in general, and access to countermeasures in the case of public health emergencies in particular. The Ministerial Decision has the opportunity to ease their use to ensure a more effective response to Covid-19 and future pandemics. WTO Members should take the recommendations above to extend the Ministerial Decision and work to incorporate TRIPS flexibilities into their national legislation. They should also seek to avoid actions that make it more difficult to use TRIPS flexibilities, including opting out of Art. 31bis, agreeing to or demanding so-called 'TRIPS-plus' provisions, or engaging in political pressure against the use of TRIPS flexibilities.

## Full written submission

### About Medicines Law & Policy

[Medicines Law & Policy \(ML&P\)](#) brings together legal and policy experts in the field of access to medicines, international law, intellectual property and public health. ML&P provides policy and legal analysis, best practice models and other information that can be used by governments, non-governmental organisations, product development initiatives, funding agencies, UN agencies and others working to ensure the availability of effective, safe and affordable medicines and vaccines for all. ML&P maintains a [database of the use or attempts to use TRIPS flexibilities](#), which is regularly updated and publicly available.

### Introduction

Following a proposal by India and South Africa to the World Trade Organization (WTO) in October 2020 for a [waiver](#) from certain provisions of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement for the prevention, containment and treatment of Covid-19, and after lengthy discussions, WTO Members adopted a Ministerial Decision on 17 June 2022. This Decision outlined flexibilities countries can use but limited the Decision to Covid-19 vaccines. The decision whether to extend its scope to include the production and supply of therapeutics and diagnostics was postponed to no later than the end of 2022. This date has since then been extended.

In order to inform the discussions at the WTO, the United States Trade Representative (USTR) has commissioned a study to be carried out by the U.S. International Trade Commission on various aspects of extending the flexibilities contained in the June 17 Decision to include therapeutics and diagnostics.

Our submission intends to provide information on and data about the use of TRIPS flexibilities related to the request for information made by US Trade Representative Ambassador Katherine Tai in [her letter to the U.S. International Trade Commission of 16 December 2022](#). This submission primarily focuses on actions taken by WTO Members to use or attempt to use compulsory licences, including successes and challenges to the effective use of TRIPS flexibilities and recommendations for future health crises.

## Summary recommendations

[Medicines Law & Policy](#) makes this written submission to provide evidence of the effectiveness of TRIPS measures and to describe some of the barriers to their use.

We recommend that any extension of the WTO TRIPS Ministerial Decision at least deals with the following issues:

- Ensure any WTO Decision aimed to increase access to pandemic countermeasures covers preventative, therapeutics, diagnostics and other health technologies needed to prevent and or treat the disease as well as recover from the health crisis.
- To increase preparedness for future pandemics, any extension to the Ministerial Decision needs to go beyond Covid-19 and should be applicable to any emerging or declared health emergency in order to be relevant for future outbreaks.
- The extension of the Ministerial Decision should provide for an easy pathway for countries that in 2003 opted out of the TRIPS Art. 31bis (compulsory licensing for export) mechanism [to opt back in](#).
- The extension of the Ministerial Decision should clarify that data and market exclusivity waivers shall be available, so the use of TRIPS flexibilities can be employed effectively and without delays.

These recommendations are made with the understanding that compulsory measures may not be necessary where voluntary licensing and technology transfer is provided for under reasonable terms and conditions. However, considering the reluctance and/or delays by rights and technology holders to enter into such voluntary agreements during the Covid-19 pandemic, including with the [WHO Covid-19 Technology Access Pool](#), it seems prudent to ensure effective non-voluntary mechanisms are in place.

To be better prepared for future health crises, governments and other public funding bodies should attach conditions to their funding of research and development and to pre-market commitments of pandemic products and processes. Such conditions should ensure that government funded innovations are available for licensing and technology transfer. For example, in the case of the Covid-19 pandemic the WHO Covid-19 Technology Access Pool (C-TAP) could have licenced technologies needed to scale up production needed to respond to the pandemic if such conditions had existed.

## Use of TRIPS flexibilities from 2001 until 2023

Since 2001, ML&P has been tracking the use of TRIPS flexibilities for public health purposes, specifically compulsory licensing and government use (TRIPS Art. 31), exceptions (TRIPS Art. 30) and transition period for least developed country (LDC) Members of the WTO (TRIPS Art. 66). The data is published in the regularly updated [TRIPS Flexibilities Database \(TFD\)](#) which is publicly available. The TFD currently documents 172 instances, of which 122 concern compulsory licensing, 3 exceptions to patent rights, 46 the LDC extension and 1 parallel import<sup>1</sup>.

The cases collected concern executed instances of the use of a TRIPS flexibility, planned or requested instances, and non-executed instances. The reason for the latter is that the anticipation by a company of being confronted with a TRIPS flexibility may prompt the offer of a lower price, a donation or a voluntary licence and thus have a positive effect on access.

Between 2001 and 2023 there were 27 non-executed instances of compulsory licensing. Of these, 16 resulted in an access measure by the company. For example, following Israel's decision to issue a compulsory licence for lopinavir/ritonavir (brand name: Kaletra) to be used to treat Covid-19, AbbVie [informed the Medicines Patent Pool \(MPP\)](#) that in light of the pandemic, the company waives any restriction on the MPP licensees that would prevent generic companies from supplying lopinavir/ritonavir anywhere in the world for any purpose, effective immediately. AbbVie further indicated that it would no longer be enforcing patents relating to adult or paediatric lopinavir/ritonavir anywhere in the world. This also meant that the restrictions on the generic supply of the treatment for HIV were lifted worldwide.

In the first ten years after the adoption of the Doha Declaration on TRIPS and Public Health TRIPS flexibilities were predominantly used in the field of HIV. This tapered off after the establishment of the Medicines Patent Pool in 2010. In recent years the TFD has shown a greater diversity in diseases for which TRIPS flexibilities are proposed or invoked.

---

<sup>1</sup> This parallel import case was included because it concerned the importation of a generic. In general, parallel import refers to the practice of procuring in another jurisdiction the branded product against a lower price. This procurement practice is likely taking place more frequently than the TFD shows.

## TRIPS flexibilities and Covid-19

The TFD shows that since 2020 there have been 10 cases of compulsory licensing that concerned products needed to prevent or treat Covid-19. Five of these instances were in high-income countries and four were executed.

The Covid-19 pandemic also prompted countries to be better prepared for the use of TRIPS flexibilities by amending patent legislation to allow for the rapid execution of a compulsory licence. This has for example happened in [Germany](#), [Canada](#), [Chile](#) and [Ecuador](#). On 27 April 2023, the [European Commission published draft legislation](#) that would establish a European Union compulsory licensing mechanism for crisis management.

## TRIPS flexibilities and high-income countries

The TFD shows that TRIPS flexibilities are not only useful for developing countries or LDCs. Of the 122 Art. 31 related instances, 23 were in high-income countries.

Covid-19 has further demonstrated that the need for high-income countries to invoke a TRIPS flexibility is not hypothetical. For example, the US company Eli Lilly refused to make its monoclonal antibody, bebtelovimab, available in the European Union as a treatment for Covid-19. Bebtelovimab had received FDA emergency use authorisation in the US but the company did not want to apply for marketing authorisation in the EU, thereby leaving patients that could not use Pfizer's Covid-19 treatment, Nirmatrelvir/ritonavir (Paxlovid) without options. This is particularly detrimental for immunosuppressed patients.

<https://www.ft.com/content/36b1d91d-6b0c-453e-b4a0-37f3d21912e4>

In early 2020 there was a severe shortage of the lysis buffer used in the testing machines sold by Roche, the predominant testing method for Covid-19 in the Netherlands. While hospital pharmacists were able to produce the buffer themselves, they needed the technical specification from Roche to ensure effective use in Roche's machines. However, the company refused to share those. The minister of health intervened to persuade Roche to disclose the technical specifications of the lysis buffer and the [Dutch competition authority \(Authority for Consumers and Market\) announced an investigation](#) into Roche in connection with the limitations of testing capacity. While this instance concerned the refusal to share a trade secret rather than a patent, members of parliament called for a compulsory licence to be issued. After the [European Commission announced an investigation](#) into Roche's market position, Roche decided to share the formula. This case shows that market monopolies may be rooted in trade secrets for which the TRIPS flexibilities do not

offer relief. It was, however, interesting that the political action and the swift response of competition authorities helped to unblock the situation.

## **Challenges to the effective use of TRIPS flexibilities**

One can identify the following challenges to the effective use of TRIPS flexibilities:

### Lack of effective national or regional legislation

Enable effective use of TRIPS flexibilities requires implementation of the mechanisms at the national or regional level. Often national and regional laws and regulations are needlessly complex and not suitable to swift response in a crisis situation. It would be helpful if the WTO and WIPO would provide model legislation for easy-to-use legislation of TRIPS flexibilities at national and regional level.

### Opting out of TRIPS Art. 31bis

35 high-income countries have opted out of TRIPS Art. 31 as importers, including in crisis situations. TRIPS Art. 31bis is the WTO mechanism for compulsory licensing for export, which waives the requirement of Art. 31(f) that products produced under a compulsory licence are predominantly for the supply of the domestic market. By ruling out the use of the Art. 31bis system for importation in all circumstances, even in 'situations of national emergency or other circumstances of extreme urgency', the opt-out countries have left themselves exposed to the Art. 31(f) problem which limits the amount of product that can be exported when produced under a compulsory licence. For details see [our briefing paper on the subject](#).

### TRIPS-plus provisions

Limitations to the use of TRIPS flexibilities, such as the introduction of data exclusivity, are often proposed in trade negotiations. These are known as TRIPS-plus provisions. The negotiations on the extension of the WTO Decision should aim at addressing TRIPS-plus issues and clarify that any TRIPS-plus provision in regional trade agreements in crisis situations will remain without effect.

### Political pressure

Countries that have used TRIPS flexibilities have often been confronted with [political pressures from the USA and the EU, often prompted by the patent-holding pharmaceutical companies](#). Such pressures have a chilling effect on the willingness of governments to make use of TRIPS flexibilities including in crisis situations. Countries



should commit to refrain from such pressures which would be inconsistent with TRIPS Art. 1.1 which states:

*Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.*

## Recommendations for future approach

Preparedness for future pandemics will require additional measures to the Ministerial Decision. In particular, it will be important to ensure public financing for innovations needed to prevent and counter a pandemic as well as conditions that ensure access to publicly financed innovations and access to the intellectual property and know-how needed to produce products are available globally. Member States negotiating [the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response](#) at the World Health Organization are expected to address the issue of access to government-funded innovations. See also additional resources, below.

## Additional Resources

WTO Covid-19 TRIPS Decision: Some observations

By [Medicines Law & Policy](#), June 17, 2022. <https://medicineslawandpolicy.org/2022/06/wto-covid-19-trips-decision-some-observations/>

The Medicines Law & Policy TRIPS Flexibilities Database: <http://tripsflexibilities.medicineslawandpolicy.org>

Perehudoff, K., Hoen, E. T., Mara, K., Balasubramaniam, T., Abbott, F., Baker, B., ... & Love, J. (2022). A pandemic treaty for equitable global access to medical countermeasures: seven recommendations for sharing intellectual property, know-how and technology. *BMJ global health*, 7(7), e009709. <http://dx.doi.org/10.1136/bmjgh-2022-009709>

Perehudoff, K., Hoen, E. T., & Boulet, P. (2021). Overriding drug and medical technology patents for pandemic recovery: a legitimate move for high-income countries, too. *BMJ Global Health*, 6(4), e005518. <http://dx.doi.org/10.1136/bmjgh-2021-005518>

t Hoen, E. F., Boulet, P., & Baker, B. K. (2017). Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation. *Journal of Pharmaceutical Policy and practice*, 10(1), 1-9. <https://joppp.biomedcentral.com/articles/10.1186/s40545-017-0107-9>

t Hoen, E. F.M., Veraldi, J., Toebes, B., & Hogerzeil, H. V. (2018). Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016. *Bulletin of the World Health Organization*, 96(3), 185. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5840629/>

Improving access to novel Covid-19 treatments. A briefing to Member States on how to navigate interfaces between public health and intellectual property. *World Health Organization*. 11 April 2023 <https://www.who.int/publications/m/item/improving-accessto-novel-covid-19treatments>