

Procedural Dilemmas in the TRIPS Vaccine Waiver Negotiations

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Abstract: This study is grounded in the stark reality of global vaccine inequity during the COVID-19 pandemic, revealing the profound conflict between the intellectual property regime centered on the TRIPS Agreement and urgent public health needs. This tension highlights the structural failure of the WTO's existing decision-making mechanisms in responding to global crises, underscoring the urgency and importance of reform-oriented research. Focusing on the procedural dilemmas exposed in the COVID-19 vaccine TRIPS waiver negotiations, this research employs case analysis to dissect how the WTO's consensus principle and negotiation processes led to a deadlock. The study argues that the WTO's rigid procedural framework was a key cause of the waiver's failure and urgently calls for the establishment of a permanent public health exception and a rapid crisis-response mechanism, alongside reforms to decision-making rules through the introduction of flexible voting methods, to enhance institutional capacity for addressing future global public health emergencies.

Keywords WTO Decision-Making Mechanism; TRIPS Waiver Agreement; COVID-19; Global Intellectual Property System; Waiver

1. Introduction

In October 2020, India and South Africa proposed at the WTO a temporary waiver of certain TRIPS obligations to swiftly remove patent barriers to vaccines. However, the negotiations remained deadlocked for an extended period, and the final agreed text was significantly diluted, failing to effectively address the global demand for vaccine equity. This process exposed the procedural failure of the WTO's decision-making mechanisms in responding to a sudden global public health crisis.

Existing research widely points out that patents and existing licensing mechanisms are

inadequate for achieving rapid, large-scale vaccine dissemination during a pandemic [1]. While voluntary licensing has been promoted, its low transparency and strong geographical restrictions have limited benefits for low- and middle-income countries (LMICs) [2]. The 2022 MC12 TRIPS Decision, though offering limited flexibility, has been criticized as a "TRIPS-plus" arrangement for failing to address core issues like technology transfer and trade secret protection, thus not substantially promoting equitable vaccine access [3]. Furthermore, the WTO's consensus principle has evolved in practice into a de facto veto mechanism, allowing a few members to obstruct progress on urgent matters [4].

Nevertheless, existing studies lack an in-depth analysis of the micro-level procedural mechanisms behind the negotiation deadlock, particularly regarding how major powers utilized procedural rules to delay talks and why the WTO lacks rapid response capacity during crises. Therefore, this study uses the COVID-19 vaccine TRIPS waiver negotiations as a case study. Through process-tracing and institutional analysis, it aims to systematically reveal the procedural flaws within the WTO's decision-making framework and, on this basis, propose actionable institutional reform recommendations, seeking to contribute to building a more resilient global public health governance system.

2. Literature Review: The Origins and Contradictions of the TRIPS Waiver

While the TRIPS Agreement plays a crucial role in incentivizing innovation, it became an institutional barrier to the rapid scaling-up of vaccine access during the pandemic. In October 2020, India and South Africa jointly submitted a proposal to the WTO for a waiver of certain TRIPS provisions, advocating for the temporary suspension of patents and related protections for vaccines, therapeutics, and technologies to facilitate global production and distribution.

This proposal emerged against the backdrop of

severe global vaccine inequity. High-income countries monopolized most of the supply through advance purchase agreements, while LMICs faced multiple challenges including procurement difficulties, limited production capacity, and technological barriers [5]. Although Article 31 of the TRIPS Agreement permits compulsory licensing, its cumbersome procedures and stringent conditions rendered it ineffective in the context of a sudden global crisis [6]. The India-South Africa proposal was thus seen as a vital initiative to promote vaccine equity.

However, the negotiation process was deadlocked from the outset. According to relevant procedural arrangements under Article 31bis of the TRIPS Agreement and the Doha Declaration, the waiver proposal should have been reviewed and reported within 90 days. In reality, the process dragged on for over 14 months, culminating only in a severely limited compromise text at the 12th Ministerial Conference (MC12) in June 2022. This delay not only reflected the North-South divide over IP protection versus the right to public health but, more significantly, highlighted the procedural paralysis of the WTO's decision-making mechanism when confronting a global crisis.

3. Analysis

This study employs a process-tracing method to analyze the procedural deadlock within the WTO. By systematically examining official documents, such as minutes from TRIPS Council meetings and member state proposals, this approach allows for the identification of causal mechanisms linking specific procedural rules (e.g., the consensus principle) to the prolonged negotiation delays. This qualitative analysis reveals how individual member actions, grounded in institutional rules, cumulatively led to the observed outcomes.

3.1 The Unfolding of Procedural Dilemmas

3.1.1 From 90-day deadline to 14-month delay: procedural stagnation and failure

According to the relevant procedural rules of the TRIPS Agreement, a waiver proposal should be reviewed by the TRIPS Council and a report submitted within 90 days of its submission [7]. However, from the proposal's submission in October 2020 to the emergence of the first concrete negotiation draft in March 2022, the WTO TRIPS Council held dozens of formal and

informal meetings, most of which descended into positional statements and procedural debates, failing to advance substantive text-based negotiations. For instance, despite frequent meetings throughout 2021 and early 2022, core divergences among members remained unresolved, forcing the postponement of the initially scheduled MC12 in November 2021 [8]. This delay was not incidental but a symptom of the systemic failure of the WTO's consensus principle under crisis conditions. The principle grants each member a de facto veto, enabling a few opposing members to obstruct progress through procedural tactics. For example, the European Union and the United States repeatedly opposed setting a clear negotiation timetable during meetings, citing reasons such as "lack of internal consensus [9]. Such procedural strategies kept negotiations stuck in the phase of position articulation, preventing a shift to substantive text-based consultation.

3.1.2 Lack of transparency in text negotiations: closed-door consultations among a few members
During the later stages of negotiations, the drafting and discussion of key texts became concentrated among a handful of major players. The *Quadrilateral Closed-Door Consultations* between the EU, the US, India, and South Africa in March 2022 became a turning point, but the process lacked transparency. Most WTO members and public health organizations were excluded and had limited access to evolving negotiation texts [10]. This closed-door model undermined the inclusiveness and legitimacy of the multilateral process. The final agreement was consequently criticized as lacking a broad consensus base and failing to adequately reflect the collective appeal of developing countries. Historically, similar small-group consultation models in the WTO, such as during the 2008 Doha Round negotiations, have often led to deadlock and agreement failures [11]. In contrast, in other multilateral fora like UN climate change negotiations, enhancing transparency and broadening participation have proven beneficial for building legitimacy and enforceability of agreements.

3.2 Institutional Causes Behind the Procedural Paralysis

3.2.1 The "structural bias" of the consensus principle

The WTO's consensus principle originated from the "club model" of the GATT era, designed to

ensure decision legitimacy through universal agreement. However, as membership expanded to 164 with increasingly diverse interests, this principle has morphed into a “structural veto mechanism,” empowering a minority to block overall progress [12]. In the COVID-19 waiver negotiations, major economies like the EU and the US leveraged this principle, effectively stalling rapid progress through technical objections and procedural delays.

Scholars Fischer et al. (2024) note that the US and EU repeatedly opposed any form of mandatory technology transfer clauses within the TRIPS Council, arguing for the protection of innovation incentives and IP system stability, and refused to compromise in informal consultations [13]. This stance reflected not only domestic industry interests but also the institutionalized power asymmetry within the WTO decision-making framework—weaker members often hesitate to openly oppose dominant members’ positions for fear of trade retaliation or political pressure [14].

3.2.2 The inherent structural problems of the WTO decision-making mechanism

Although Article IX of the WTO Agreement provides for voting procedures, they are almost never used in practice. Members generally view voting as a measure of last resort, potentially undermining the negotiation- and reciprocity-based cooperative culture [15]. This aversion to voting leads to stagnation when consensus is unattainable. In the COVID-19 waiver talks, even with support from a majority of developing countries, the TRIPS Council never referred the issue to the General Council for a vote due to opposition from the EU and US [16].

Furthermore, the WTO’s tradition of “single undertaking” exacerbates decision-making difficulties on specific issues. In the absence of cross-issue trade-offs, a standalone topic like a public health waiver struggles to gain sufficient political momentum, resulting in a “no-trade, no-decision” impasse [17].

3.2.3 Structural FLAWS in the TRIPS agreement and the lack of a crisis response mechanism

The TRIPS Agreement is fundamentally an IP protection framework designed for stable commercial environments, lacking the institutional elasticity to respond to global public health crises. Its compulsory licensing provisions (Article 31) are procedurally complex and restrictive, not designed for the urgency of

rapid authorization and technology transfer during a pandemic [18]. In contrast, the United Nations Security Council (UNSC) possesses mechanisms for rapid voting and resolution enforcement in crises, as seen in its swift adoption of Resolution 2532 in 2020 calling for a global ceasefire and cooperation against COVID-19 [19]. Within the WTO system, even a WHO declaration of a “Public Health Emergency of International Concern” does not automatically trigger a waiver or streamlined procedure under TRIPS, highlighting the institutional disconnect between global health governance and trade governance.

3.3 Building a Proceduralized Public Health Crisis Response Mechanism

3.3.1 Establishing a permanent public health exception and rapid response procedure

To address the lagged and fragmented response of the current WTO system in times of public health crises, a permanent “Public Health Exception Mechanism” should be institutionalized within the TRIPS framework. Unlike temporary or crisis-specific waivers, this mechanism would function as a standing procedural arrangement, activated automatically upon the occurrence of objectively defined public health emergencies. In practical terms, the trigger condition could be formally linked to declarations of Public Health Emergencies of International Concern (PHEIC) issued by the World Health Organization, thereby grounding the WTO’s response in an external, specialized, and scientifically informed assessment.

Once activated, the mechanism would temporarily suspend or relax the application of specific TRIPS obligations directly related to the production, supply, and distribution of essential medical products, including vaccines, diagnostics, and therapeutics. At the same time, an expedited review and notification procedure would be initiated within the WTO, allowing members to clarify the scope, duration, and modalities of the exception without reopening substantive negotiations. This approach would preserve the integrity of the TRIPS Agreement while introducing procedural flexibility necessary for emergency situations [20].

3.3.2 Designing a proceduralized technology transfer and production licensing mechanism

To ensure the practical implementation of a public health exception, this study proposes the establishment of a “Public Health Emergency

Technology Transfer Working Group” under the TRIPS Council as a temporary procedural body activated upon the triggering of the public health exception. The Working Group would provide an institutionalized channel for coordinating licensing arrangements between patent holders and qualified manufacturers, while maintaining consistency with existing TRIPS flexibilities. Procedurally, the mechanism would prioritize voluntary licensing as the initial step, subject to a predefined and time-bound negotiation window. If no substantive progress is achieved within a specified period, the process would shift automatically to a compulsory licensing phase conducted under standardized procedural guidelines and administrative supervision. This sequential design aims to reduce uncertainty and delay without altering the underlying substantive standards of intellectual property protection. In addition, the mechanism incorporates a limited transparency component, requiring the disclosure of essential technical information necessary for manufacturing during the emergency period. Such disclosure would be procedurally circumscribed in scope and duration, functioning as an operational complement to licensing rather than as an independent policy instrument. By formalizing these procedural steps *ex ante*, the mechanism seeks to enhance the predictability and operational coherence of technology transfer arrangements in public health crises.

4. Conclusion

This study, using the COVID-19 vaccine TRIPS waiver negotiations as a case, reveals the procedural dilemmas of the WTO’s decision-making mechanism in responding to global public health crises. The prolonged delay and limited outcome of the negotiations are rooted in the consensus principle being exploited as a veto tool by a few members and the WTO’s lack of a rapid crisis-response mechanism. The structural rigidity of the TRIPS Agreement itself and its institutional disconnect from the global health governance system further compounded the failure of emergency response.

While this study primarily focuses on institutional-level analysis, future research could further integrate political economy perspectives to explore the impact of great power politics on WTO decision-making. Comparative studies of crisis-response mechanisms across different international organizations could also provide

more comprehensive insights for reforming the global governance architecture.

References

- [1] Kohler, J., Wong, A., Taylor, L. (2022). Improving Access to COVID-19 Vaccines: An Analysis of TRIPS Waiver Discourse among WTO Members. *Health and Human Rights Journal*, 24(2), 159–175.
- [2] Mercurio, B., & Upreti, P. N. (2022). From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for Covid-19 Vaccines and Treatments. *World Trade Review*, 21(5), 633–649.
- [3] ICTSD. (2022). The TRIPS Waiver Negotiations: A Timeline. Retrieved from <https://www.ictsd.org>
- [4] Yeo, M., et al. (2021). Tensions Between Consensus and Voting in WTO Decision-Making. *Steptoe International Compliance Blog*.
- [5] WTO. (2021). Minutes of the TRIPS Council Meeting, IP/C/M/101.
- [6] Abbott, F. M. (2021). The TRIPS Waiver and the International Intellectual Property System. *WIPO Journal*, 12(1), 45–67.
- [7] TRIPS Agreement, Article 31bis.
- [8] WTO. (2022). Ministerial Conference-Twelfth Session-Geneva, 12–17 June 2022, WT/MIN(22)/W/15.
- [9] European Union. (2021). Statement at the TRIPS Council, October 2021.
- [10] South Centre. (2022). The TRIPS Waiver Process: A Developing Country Perspective. Policy Brief No. 108.
- [11] Narlikar, A. (2020). *International Negotiation in a Complex World*. Routledge.
- [12] Steger, D. P. (2021). The Consensus Rule in the WTO: Is It Fit for Purpose? *Journal of International Economic Law*, 24(3), 545–562.
- [13] Fischer, S. E., et al. (2024). Intellectual Property and the Politics of Public Good during COVID-19. *Journal of Health Politics, Policy and Law*, 49(1), 9–42.
- [14] Ho, C. M. (2022). *The TRIPS Waiver: A Missed Opportunity for Global Solidarity*. Cambridge University Press.
- [15] WTO Agreement, Article IX.
- [16] WTO General Council. (2021). Minutes of Meeting, WT/GC/M/192.
- [17] Elsig, M. (2021). The WTO in an Era of Preferential Trade Agreements. *Global Policy*, 12(2), 45–58.

- [18] Correa, C. M. (2020). The TRIPS Agreement and Public Health. South Centre.
[19] United Nations Security Council. (2020). Resolution 2532 (2020).

- [20] Gleeson, D., & Legge, D. (2023). WTO Decision-Making in Times of Crisis: Lessons from COVID-19. *Global Health Governance*, 17(1), 22–40.