

ASSESSING THE TRIPS AGREEMENT'S INFLUENCE ON MEDICINAL ACCESS: NAVIGATING THE COVID-19 PANDEMIC AND INTELLECTUAL PROPERTY WAIVERS

Anila K* and Sheheen Marakkar*

ABSTRACT

The TRIPS agreement significantly shaped access to medicines and vaccines by reinforcing intellectual property rights. Amid the COVID-19 pandemic, this has posed challenges, hindering timely access to affordable treatments and vaccines. The proposed waiver on intellectual property rights for COVID-19 diagnostics and therapeutics aims to address this issue by fostering wider production and distribution. Advocates argue it could enhance global access, especially in low-income countries. However, critics highlight potential drawbacks, such as disincentivizing innovation and jeopardizing future research funding. Balancing intellectual property protection with public health imperatives remains a complex challenge. While the waiver offers potential relief in the current crisis, long-term strategies necessitate broader systemic reforms to ensure equitable access to essential medical innovations.

INTRODUCTION

A new global intellectual property protection (IPP) regime that has a substantial impact on access to medications was established in 1994 when Member States of the World Trade Organization (WTO) adopted the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was a historic moment in WTO history¹. Article 12 of the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR) acknowledges the inherent right of every individual to experience the highest achievable level of both physical and mental health. Similarly, article 15 acknowledges the right of every individual to reap the advantages brought forth by scientific advancements.² When considering these articles collectively, it entails the entitlement of every individual to reach life-saving health technologies, such as vaccines, medications, protective gear, and diagnostic tools. However, disparities persist, with up to two billion individuals in low- and middle-income countries (LMICs) facing challenges in regularly accessing fundamental medicines.³

* Assistant Professor, CHRIST (Deemed to be University), Pune, Maharashtra, India.

* Assistant Professor, CHRIST (Deemed to be University), Pune, Maharashtra, India.

¹World Trade Organization (WTO), Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

²International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI) (1966), arts. 12, 15.

³World Health Organization, *Ten Years in Public Health, 2007–2017*. Geneva: World Health Organization; 2017.

Despite attempts by international organizations, including COVAX, to promote such access, worldwide access to COVID-19 vaccinations has remained remarkably unequal throughout the pandemic.⁴ When compounded with shortages of essential products, inflated prices, limitations on exporting health supplies, constraints on vaccine manufacturing knowledge, and prioritization of national interests by wealthy nations, fair access to COVID-19 diagnostics and health technologies has been significantly hindered.⁵ Throughout the epidemic, vulnerable groups—particularly those in LMICs—have been disproportionately negatively impacted by this unequal access to medications and health technologies.⁶ Just 15.8% of people in low-income countries have received at least one dose of vaccination in the two years after the pandemic began, compared to some high-income countries where 70%–99% of the population has received all recommended vaccinations.⁷ In light of the unequal access to vital medications and health technologies, the connection between intellectual property rights and public health has once again become a matter of worldwide concern. According to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), all members of the World Trade Organization (WTO) are required to uphold patents granted within their own domestic intellectual property (IP) frameworks, regardless of where the patented invention originated initially.⁸ This includes all patents that protect technology essential to the manufacture of COVID-19 vaccines.

Patents grant inventors the exclusive right to control the production, sale, and importation of their technology, which can lead to limited supply and higher prices.⁹ This issue has been a longstanding concern, especially in providing medications for diseases like HIV/AIDS and hepatitis C.¹⁰ With nearly all COVID-19 vaccines being protected by patents, similar concerns have emerged regarding vaccine production and its impact on health equity.

In October 2020, India and South Africa proposed a broad waiver of copyright, patent, industrial design, and undisclosed information provisions within the TRIPS Agreement at the WTO. They argued that such a measure was crucial to guaranteeing that intellectual property rights wouldn't hinder the timely access to affordable medical products or impede the expansion of research, development, manufacturing, and supply of essential medical products needed to

⁴ Paremoer L., Nandi S., Serag H., Baum F. “COVID-19 Pandemic and the Social Determinants of Health,” *British Medical Journal*. 2021;372(129); Yamey G., Garcia P., Hassan F. et al. “It Is Not Too Late to Achieve Global COVID-19 Vaccine Equity,” *British Medical Journal*. 2022;376.

⁵ Yamey G. (see note 3); Tagoe E. T., Sheikh N., Morton A. et al. “COVID-19 Vaccination in Lower-Middle Income Countries: National Stakeholder Views on Challenges, Barriers, and Potential Solutions,” *Frontiers in Public Health*. 2021;9

⁶ Devakumar D., Shannon G., Bhopal S. S., Abubakar I. “Racism and Discrimination in COVID-19 Responses,” *Lancet*. 2020;395(10231)

⁷ Hunter D. J., Abdool Karim S. S., Baden L. R. et al. “Addressing Vaccine Inequity: COVID-19 Vaccines as a Global Public Good,” *New England Journal of Medicine*. 2022;386(12); Mathieu E., Ritchie H., Ortiz-Ospina E. et al. “A Global Database of COVID-19 Vaccinations,” *Nature Human Behaviour*. 2021;5.

⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1896 U.N.T.S. 299 (1994), art 27.

⁹ World Intellectual Property Organization, “Frequently Asked Questions: Patents,” Available at: https://www.wipo.int/patents/en/faq_patents.html, last accessed on 12 March 2014.

¹⁰ Hoen E., Berger J., Calmy A., Moon S. “Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All,” *Journal of the International AIDS Society*. 2011;14

combat COVID-19.¹¹ In May 2021, the proposed waiver aimed to cover all COVID-19-related health products and technologies, spanning vaccines, therapeutics, medical devices, and personal protective equipment. However, in March 2022, a compromise suggested by the European Union, India, South Africa, and the United States aimed to limit the waiver's scope to COVID-19 vaccines.¹² Additionally, it proposed restricting the waiver to countries that exported less than 10% of the world's vaccines in 2021. After divided government responses, by June 2022, WTO members agreed to a modified version of the waiver, applicable for five years solely to COVID-19 vaccines.¹³ Notable conditions include limiting the waiver to developing country WTO members, obligations to prevent re-exportation of waiver-made products, and a six-month extension for discussions on expanding the waiver's scope to COVID-19 therapeutics and diagnostics.¹⁴

The analysis of the TRIPS waiver negotiations and the subsequent June 2022 compromise reveals that the positions of WTO members and key stakeholders regarding intellectual property (IP) and access to medicines have remained largely consistent with historical trends. This suggests that despite efforts to address health equity concerns, political and structural barriers persist within the WTO's consensus-based decision-making process. Consequently, policymakers face challenges in leveraging the international trading system to enhance equitable access to health technologies.

TRIPS WAIVER AND ITS IMPORTANCE IN AGE OF PANDEMIC

The integration of Intellectual Property (IP) into the World Trade System occurred through the TRIPS agreement in 1994. Before the development of IP laws, many countries tended to replicate patterns and adopt IP regimes. However, as IP became widely accepted globally and countries advanced in knowledge development, the need for protection became apparent, leading nations to sign the TRIPS agreement. The flexibility within the agreement allowed for the possibility of waivers from IP obligations and also permitted the inclusion of social commitments to member states, which became more evident after the pandemic.

The aim of the waiver proposed by the World Trade Organisation (WTO) was necessary to find an internal solution that could allow for a mechanical modification of the treaty amidst other pressing priorities. The goal of the waiver was to temporarily suspend certain provisions of the TRIPS agreement, particularly crucial in the era of the pandemic. Challenges during the COVID-19 crisis, such as ensuring an adequate supply of vaccines and treatments, were also addressed by the TRIPS waiver. By waiving certain provisions, countries could overcome barriers and facilitate the distribution and production of vaccines on a global scale.

¹¹World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/W/669 (2020).

¹²Cullinan K. "WTO Head Welcomes Compromise on IP Waiver for COVID Vaccines—But Activists and Pharma Express Dismay," *Health Policy Watch*. (March 16, 2022), <https://healthpolicy-watch.news/wto-head-welcomes-ip-waiver-compromise/>; World Trade Organization, "Director-General Okonjo-Iweala Hails Breakthrough on TRIPS COVID-19 Solution," *World Trade Organization*. (March 16, 2022), https://www.wto.org/english/news_e/news22_e/dgno_16mar22_e.htm, last accessed on 18 March 2024.

¹³World Trade Organization, Ministerial Conference Twelfth Session, Draft Ministerial Decision on the TRIPS Agreement, WT/MIN (22)/W/15/Rev.2 (2022).

¹⁴Ibid.

These waivers would assist both developing and developed countries that lack resources or capacity to produce medical products independently, enabling access to affordable generic versions of vaccines and treatments. This approach could enhance global health crisis response efficiency. The proposal by India and South Africa emphasized the urgent need to access affordable medical products, including diagnostic kits, vaccines, medicines, and personal protective equipment like ventilators, to actively combat the COVID-19 pandemic.

Among WTO countries, the main supporters of the waiver were Global North states, home to major corporations with monopolies over intellectual property applied to medical technologies. However, some Global North countries, such as the United States, supported limited waivers that might not require the technology transfers necessary to meet the urgent demand for vaccines. In response to the critical healthcare technology access priority, many Global North countries used the situation to push for more liberalization and deregulation of Global South markets, undermining the flexibilities available to Global South countries at the WTO.¹⁵ Section 31bis of the TRIPS agreement, which was introduced from the Doha Declaration, allotted different remedies against the claims for handling public health emergency measures. The TRIPS waiver serves as a mechanism to ensure that intellectual property rights do not hinder the availability of life-saving medical interventions, contributing to the global response to the challenges posed by the COVID-19 pandemic. The World Health Organization (WHO) could have taken steps like establishing the Covid Technology Access Pool (CTPA), enabling multinational drug producers to share their technology with other competent manufacturers. Alternatively, WHO could establish technology transfer mRNA hubs to rapidly increase vaccine manufacturing sites in low and middle-income countries, potentially enhancing access to medications in those regions and shifting control from corporations to the people. The United Nations could provide financial support for COVID-19 technology access mRNA hubs to facilitate technology sharing and compel pharmaceutical companies to contribute their technology to the pool for free. Overall, these initiatives could leverage the TRIPS waiver to address the pandemic's challenges effectively.

INTELLECTUAL PROPERTY GRADUALISM

The 1994 TRIPS agreement, which condensed a decade or more of "Intellectual Property Gradualism," is primarily responsible for the introduction of intellectual property principles into the World Trade system.¹⁶ Intellectual Property Gradualism denotes the historical approach of gradually integrating intellectual property into the global trade framework. During this process, the intellectual property rights of foreign entities have intentionally been disregarded to prioritize the development of indigenous knowledge and foster the expansion of domestic industries.¹⁷

¹⁵ "The Waiver of Certain Intellectual Property Rights Provisions of the TRIPS for the Prevention, Containment and Treatment of COVID-19: A Review of the Proposal under WTO Jurisprudence." *European Journal of Risk Regulation*, January, 1–19. <https://doi.org/10.1017/err.2021.60>.

¹⁶Graham Dutfield (@gmdutfield), Twitter (May 12, 2021, 11:25 PM), Available at <https://mobile.twitter.com/gmdutfield/status/1392539051798978562> - The phrase "IP Gradualism" coined by Prof. Dutfield and reiterated in this tweet.

¹⁷ Ha-Joon Chang, *Bad Samaritans: The myth of free trade and the secret history of capitalism* (Bloomsbury Press 2007) 119-122; See also Christopher May and Susan Hell, *Intellectual Property Rights: A Critical History* (Lynne Rienne 2006) 205-207

Intellectual Property Gradualism underscores the disparity between developed countries and the rest of the world in establishing and enforcing IP rights. Developed nations took over 100 years to develop industries without strict IP protection, while developing countries had to adopt and enforce IP regulations within 5 to 50 years. This concept has significant implications for IP politics, particularly in the pharmaceutical industry, affecting innovation and technological learning. TRIPS agreements enforce IP rights, benefitting developed countries' dominance in the global knowledge market, while hindering developing countries' access to essential technologies and medicines. The pandemic has heightened these disparities, prompting discussions about the need for IP rights waivers for equitable access to vaccines and therapeutics. IP gradualism calls for a re-evaluation of global IP politics to address the knowledge divide, decolonize IP, and achieve distributive justice.

HISTORICAL SIGNIFICANCE OF TRIPS WAIVER

TRIPS waiver existed under the article XXV¹⁸ of GATT and had a similar requirement for waiving in global trade obligations. Ensuring that the escapes specified in the rules "cover cases which were exceptional and caused particular hardship to any of the particular members" was the drafters' primary goal. No country should escape the obligations it has undertaken, according to the French delegate, who also suggested that in more extraordinary circumstances, temporary exemptions might be granted when certain countries would experience temporary economic hardships as a result of the specific obligations of the charter. The absence of a clear definition of "Exceptional Circumstances" in the GATT agreement has been a key reason for excluding waiver use during emergencies. Between 1947 and 1995, there were 115 original waivers, with the most contentious being the United States' waiver to restrict agricultural imports, aimed at safeguarding its domestic agricultural economy and ensuring the effectiveness of US Department of Agriculture initiatives. During the Uruguay Round of negotiations in global trade treaties, waiver powers were extensively reviewed, particularly concerning Article XXV, paragraph V of the GATT, which aimed to revise and limit waiver powers to prevent permanently privileged situations. The European Economic Community proposed reforms to address the negative impact of waiver duties on the balance of rights and obligations among contracting parties. Waivers granted did not have expiry dates but were subject to certain conditions. For example, a TRIPS waiver granted to France and the Federal Republic of Germany in 1957 regarding trade with SAAR became duty-free for intra-trade after 13 years, fulfilling the condition for expiry in 1970.

The European Economic Community proposed specific guidelines for waivers, including specifying a non-uniform time limit deemed appropriate at the time of granting, providing a clear economic justification for the waiver, explaining why internal provisions or exceptions of the agreement are not utilized for the policy goal, conducting annual reviews to assess continued justification for the waiver, phasing out waivers during the enactment of new

¹⁸ Article XXV of GATT

In exceptional circumstances not elsewhere provided for in this agreement, the CONTRACTING PARTIES may waive an obligation imposed upon a contracting party by this agreement; provided that any such decision shall be approved by a two-thirds majority of the votes and that such majority shall comprise more than half of the contracting parties.

agreements, and clarifying that waivers do not pertain to dispute settlement but may unjustly nullify or affect benefits granted by the agreement.

The impact of the European Economic Community's communications led to the development of a draft decision for future waivers with clear conditions and guidelines, published on July 23rd, 1990, and forwarded to the negotiation committee. The draft required specific policy declarations for extension or fresh waivers, including justification and termination dates. Approved waivers had to be renewed annually, with termination if no expiry date was specified. Negotiations took place in the Trade Negotiations Committee at the Ministerial Level, and on December 15th, 1993, the final draft was published at the Multilateral Trade Organization, later replaced by the World Trade Organization. This draft eliminated Article XXV of GATT and included the waiver provision within the statute twice. In the WTO agreement at article IX.3¹⁹ and IX.4 13 and once within the GATT 1994, phrase the “understanding in respect of waiver of obligations under the GATT. In the early stages, the waiver method relied on consensus, with voting as a last resort in the absence of agreement. A proposal was made to raise the voting threshold from two-thirds to three-fourths, but guidelines for interpreting the term "exceptional circumstances" were not provided. The proposal also introduced a 90-day time limit for Ministerial Conference consideration of waiver proposals. Waiver requests would be initially submitted to TRIPS, which would then refer them to Ministerial consideration, as outlined in Article IX.4. The terms and conditions of the waiver, as put forward by the European Economic Communities, would be clearly specified. Additionally, an annual review of the waiver would determine if the exceptional circumstances mentioned had been met.

Intellectual property gradualism provides a balanced approach, extending rights to new areas to avoid negative consequences of strict IP protection. The TRIPS waiver mechanism, existing before the pandemic, serves as a dispute resolution tool, preventing challenges associated with extending intellectual property rights.

TRIPS WAIVER UNDER MARRAKESH AGREEMENT

Article IX.3²⁰ of the Marrakesh agreement of the WTO held to define “exceptional circumstances”. The rejection of the Motta Draft by the United States highlighted concerns regarding AIDS/HIV, malaria, and other epidemics in developing and least developed countries (LDCs), particularly their lack of pharmaceutical manufacturing capacity. The draft aimed to address compulsory licensing for drug development but was rejected due to objections from

¹⁹Article IX.3 of WTO Agreement

In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements, provided that any such decision shall be taken by three fourths of the Members unless otherwise provided.

A request for a waiver concerning this Agreement shall be submitted to the Ministerial Conference for consideration pursuant to the practice of decision-making by consensus. The Ministerial Conference shall establish a time-period, which shall not exceed 90 days, to consider the request. If consensus is not reached during the time-period, any decision to grant a waiver shall be taken by three fourths of the Members.

A request for a waiver concerning the Multilateral Trade Agreements (in Annexes 1A or 1B or 1C and their annexes) shall be submitted initially to the Council for Trade in Goods, the Council for Trade in Services or the Council for TRIPS, respectively, for consideration during a time-period which shall not exceed 90 days. At the end of the time-period, the relevant Council shall submit a report to the Ministerial Conference.

²⁰ Article IX.3 - In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a member by this agreement or any of the Multilateral Trade Agreements, provided that any such decision shall be taken by three fourths of the Members unless otherwise provided.

the US, which sought to limit exemptions to specific diseases. However, the General Council of the World Trade Organization (WTO) adopted the waiver on August 30, 2003, encompassing obligations for both product and process patents in the pharmaceutical sector to address public health problems outlined in the Doha Declaration. The waiver did not include a termination date but provided for termination upon the existence of an amendment replacing the decision in the TRIPS agreement. This decision reflected a shift in focus from economic policy to socioeconomic well-being and health-related concerns, acknowledging the humanitarian needs of developing and least developed countries. The waiver mechanism under the Marrakesh Agreement allows for flexibility in addressing exceptional circumstances, balancing the integrity of the multilateral trading system with the legitimate needs of member countries.

CONCLUSION

Access to critical health technologies, like COVID-19 vaccines, remains severely unequal across countries. Stakeholders, including WTO members, civil society groups, and pharmaceutical industry players, acknowledge this disparity in response to the proposed TRIPS waiver. While supporters see the waiver as vital for removing IP barriers during the pandemic, opponents argue it's unnecessary and won't rapidly increase supply.

The TRIPS waiver proposal sought to temporarily suspend certain intellectual property rights associated with COVID-19 vaccines, aiming to enhance global access to these vital medicines. Its outcome hinged on developments and agreements among WTO member countries. The proposal sparked extensive debate, with supporters believing it could facilitate widespread vaccine distribution, particularly in low- and middle-income countries, and help mitigate the global impact of the COVID-19 pandemic. Opponents raised concerns about potential drawbacks on innovation, advocating for voluntary measures, technology transfer, and collaborative efforts as alternatives to suspending intellectual property rights.

In June 2022, the World Trade Organization (WTO) issued a decision on the TRIPS waiver proposed by India and South Africa. However, the final ruling was limited to vaccine patents and the use of protected clinical trial data for regulatory purposes. The decision largely reiterated or clarified existing options for IP rights, overlooked crucial elements for improving access to medical devices, had a limited duration of five years, and exclusively impacted vaccines without addressing other significant medical devices.

REFERENCE

- World Trade Organization (WTO), Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).
- International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI) (1966), arts. 12, 15.
- World Health Organization, Ten Years in Public Health, 2007–2017. Geneva: World Health Organization; 2017.

- Paremoer L., Nandi S., Serag H., Baum F. “COVID-19 Pandemic and the Social Determinants of Health,” *British Medical Journal*. 2021;372(129); Yamey G., Garcia P., Hassan F. et al. “It Is Not Too Late to Achieve Global COVID-19 Vaccine Equity,” *British Medical Journal*. 2022;376.
- Yamey G. (see note 3); Tagoe E. T., Sheikh N., Morton A. et al. “COVID-19 Vaccination in Lower-Middle Income Countries: National Stakeholder Views on Challenges, Barriers, and Potential Solutions,” *Frontiers in Public Health*. 2021;9
- Devakumar D., Shannon G., Bhopal S. S., Abubakar I. “Racism and Discrimination in COVID-19 Responses,” *Lancet*. 2020;395(10231)
- Hunter D. J., Abdool Karim S. S., Baden L. R. et al. “Addressing Vaccine Inequity: COVID-19 Vaccines as a Global Public Good,” *New England Journal of Medicine*. 2022;386(12); Mathieu E., Ritchie H., Ortiz-Ospina E. et al. “A Global Database of COVID-19 Vaccinations,” *Nature Human Behaviour*. 2021;5.
- Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1896 U.N.T.S. 299 (1994), art 27.
- World Intellectual Property Organization, “Frequently Asked Questions: Patents,” Available at: https://www.wipo.int/patents/en/faq_patents.html, last accessed on 12 March 2014.
- ‘t Hoen E., Berger J., Calmy A., Moon S. “Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All,” *Journal of the International AIDS Society*. 2011;14
- World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/W/669 (2020).
- Cullinan K. “WTO Head Welcomes Compromise on IP Waiver for COVID Vaccines—But Activists and Pharma Express Dismay,” *Health Policy Watch*. (March 16, 2022), <https://healthpolicy-watch.news/wto-head-welcomes-ip-waiver-compromise/>; World Trade Organization, “Director-General Okonjo-Iweala Hails Breakthrough on TRIPS COVID-19 Solution,” World Trade Organization. (March 16, 2022), https://www.wto.org/english/news_e/news22_e/dgno_16mar22_e.htm, last accessed on 18 March 2024.
- World Trade Organization, Ministerial Conference Twelfth Session, Draft Ministerial Decision on the TRIPS Agreement, WT/MIN (22)/W/15/Rev.2 (2022).
- Graham Dutfield (@gmdutfield), Twitter (May 12, 2021, 11:25 PM), Available at <https://mobile.twitter.com/gmdutfield/status/1392539051798978562> - The phrase “IP Gradualism” coined by Prof. Dutfield and reiterated in this tweet.
- Ha-Joon Chang, *Bad Samaritans: The myth of free trade and the secret history of capitalism* (Bloomsbury Press 2007) 119-122; See also Christopher May and Susan Hell, *Intellectual Property Rights: A Critical History* (Lynne Rienne 2006) 205-207
- Article XXV of GATT
- In exceptional circumstances not elsewhere provided for in this agreement, the CONTRACTING PARTIES may waive an obligation imposed upon a contracting party by this agreement; provided that any such decision shall be approved by a two-thirds majority of the votes and that such majority shall comprise more than half of the contracting parties.