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Reigniting the Spirit of the Doha Declaration

WHY A TRIPS WAIVER EXTENSION IS KEY TO THE LEGITIMACY OF THE WORLD TRADE ORGANIZATION

RACHEL THRASHER

EXECUTIVE SUMMARY

Members of the World Trade Organization (WTO) have an opportunity at the 13th Ministerial Conference (MC13) in February 2024 to grant an extension to the much-embattled Waiver to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The Waiver, proposed more than three years ago, was intended to allow countries and their pharmaceutical firms to manufacture and distribute generic versions of COVID-19 products to their populations more freely.

Recently, the international community quietly passed by the 22nd anniversary of the conclusion of the Doha Declaration on TRIPS and Public Health in November 2023. The Doha Declaration, originally adopted at the insistence of the Africa Group, was a landmark moment in international cooperation in which the members of the WTO agreed (in principle) that public health should not be undermined by a narrow reading of global rules governing intellectual property (IP).

This policy brief explores the origins of the Doha Declaration as a reflection on the history of the WTO and its TRIPS Agreement, and makes the case that there is still room for the WTO to contribute to increased access to medicines by extending the TRIPS Waiver to diagnostics and therapeutics.

MC13 presents the WTO with an opportunity to strengthen the priority for public health at the institutional level. Moreover, despite some arguments to the contrary, research makes a strong case for the benefit and importance of the TRIPS Waiver extension:

1. **The TRIPS Agreeent is not universally linked to increased innovation**. While patent protection has been found to increase innovation in high-income countries, the same cannot be said for low- and middle-income countries.
2. **The TRIPS Agreement may have a negative impact on access to medicines.** A strong thread through access to medicines research has shown that strong IP protection is linked to various measures of decreased access to medicines, such as higher prices and decreased quantities.
3. **Both political pressure and the legal complexity of newer medicines has made the TRIPS flexibilities difficult, if not impossible, to use**. This history of the experience of WTO developing country members demonstrates that the underutilization of TRIPS flexibilities does not mean those measures themselves are not useful or unnecessary.

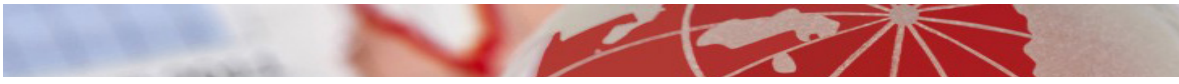
Twenty-two years after the Doha Declaration, and in the wake of a global pandemic, MC13 represents yet another historic moment and renewed urgency to explore amending global trade rules to better protect public health. WTO member states should be willing to grant an extension of the TRIPS Waiver to diagnostics and therapeutics because it is consistent with the spirit of the Doha Declaration and because it increases the legitimacy of the WTO as an institution by demonstrating an on-going commitment to a "fairer and more open multilateral trading system for the benefit and welfare of [all] peoples."

INTRODUCTION

Members of the World Trade Organization (WTO) have an opportunity at the 13th Ministerial Conference (MC13) in February 2024 to grant an extension to the much-embattled Waiver to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The Waiver, proposed more than three years ago, was intended to allow countries and their pharmaceutical firms to manufacture and distribute generic versions of COVID-19 products to their populations more freely (Communication from India and South Africa 2020). Early supply chain shortages and stockpiling by rich countries that left many other countries without diagnostics and personal protective equipment provided the underlying rationale for the proposal – as treatments and vaccines were developed, many countries feared that such materials would not become widely available or at an affordable cost until later in the pandemic.

Despite an earlier signal of support by the United States, when the Waiver text arrived in June 2022, it waived very little of the TRIPS Agreement and covered only COVID-19 vaccines (WTO 2022a). Nevertheless, there was a small window of hope suggesting that, within six months of the original agreement, an extension could be made to cover COVID-19 diagnostics and therapeutics as well. The six-month deadline passed, as WTO members could not agree on whether a TRIPS Waiver would be harmful or helpful for global health. Instead, the US, at the 12th hour, proposed that the United States International Trade Commission (USITC) study the requested extension; a protracted process that took 10 months to complete (USITC 2023).

Meanwhile, the world quietly passed by the 22nd anniversary of the conclusion of the Doha Declaration on TRIPS and Public Health in November 2023 (WTO 2001b). The Doha Declaration, originally adopted at the insistence of the Africa Group, was a landmark moment in international cooperation



in which the members of the WTO agreed (in principle) that public health should not be undermined by a narrow reading of global rules governing intellectual property (IP) (Solovy 2022).

This policy brief explores the origins of the Doha Declaration as a reflection on the history of the WTO and its TRIPS Agreement and makes the case that there is room for the WTO to contribute to increased access to medicines through an extension of the TRIPS Waiver. Twenty-two years later, and in the wake of a global pandemic, MC13 represents yet another historical moment and renewed urgency to explore amending global trade rules to better protect public health.

The WTO member states should be willing to grant an extension of the TRIPS Waiver to diagnostics and therapeutics because it is consistent with the spirit of the Doha Declaration. More importantly, extending the Waiver increases the legitimacy of the WTO as an institution because it demonstrates an on-going commitment to a "fairer and more open multilateral trading system for the benefit and welfare of [all] peoples" (WTO 1994).

HAPPY BEGINNINGS FOR DOHA

In 2001, during the fourth Ministerial Conference (MC4) of the WTO, member states kicked off the Doha "Development" Round of trade negotiations, committing to put the needs of developing countries at the center of WTO priorities (WTO 2001a). At the time, developing countries were growing increasingly dissatisfied with the impact of global trade rules on their economies, and this new negotiating round was born out of the hope that global cooperation could deliver on its promise of improving global welfare through a fairer trading system (WTO 1994). Between the WTO's entry into force and the initiation of the Doha Round, there had, undoubtedly, been some growing pains (Moore 1999; Moberg 2020). Amid battling an AIDS epidemic, South Africa faced a lawsuit brought by 42 pharmaceutical companies for exercising the policy flexibilities available to them in the TRIPS Agreement (Musungu, Villanueva and Blasetti 2004; In re Pharma of South Africa et al. v. President Nelson Mandela et al. 1998). Public backlash from that lawsuit, along with a moment of global unity in the wake of the terrorist attacks on September 11, 2001, set the stage for what seemed a successful negotiation (Love 2011).

As the major success of the first ministerial of the Doha Round, the Doha Declaration on TRIPS and Public Health sought to clarify the scope of the TRIPS Agreement. It empowered states to determine what constitutes a public health "emergency" and reiterated that the agreement should be interpreted in a way that does not undermine public health priorities (WTO 2001b). In addition, it clarified key "flexibilities" granted to WTO member countries, including developing country members, especially with respect to granting non-voluntary or compulsory licenses.

What is more, the Declaration required states to quickly come up with a solution for states with insufficient pharmaceutical manufacturing capacity to use compulsory licensing mechanisms to gain access to affordable medicines manufactured in other countries – a challenge that had not been addressed in the TRIPS Agreement. That solution was negotiated relatively quickly in the form of a "waiver," allowing countries with pharmaceutical manufacturing capacity to export generic versions of medicines to countries without, even if the original medicines were still patent-protected (WTO General Council 2003).[1] At the time, prominent global health advocates expressed hope that this was a step in the right direction ('t Hoen 2002; Love 2011).

[1] This waiver become a permanent feature of the Agreement in 2017 (WTO 2017).

CHALLENGES TO IMPLEMENTATION

Despite these happy beginnings, benefitting from the TRIPS policy "flexibilities" proved elusive. While countries were theoretically free to deploy policies that would increase access to medicines by allowing generic producers to produce, export and import equivalent medicines, the obstacles to deploying those policies were substantial.

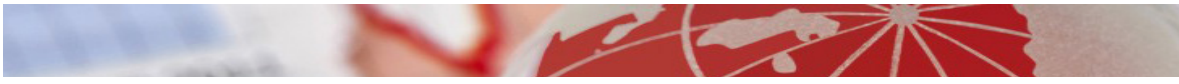
The TRIPS Agreement and its Doha Declaration were only the first step toward helping countries prioritize public health. Access to medicines depended heavily on national law and practice in implementing the treaty commitments. In the early years, many countries did not have the technical expertise to undertake such legal reform (Musungu, Villanueva and Blasetti 2004). For example, the Doha Declaration helped to establish a process whereby countries could issue compulsory licenses to their firms for importing or exporting generic versions of patented medicines (WTO 2001b). Unfortunately, incorporating those processes into law and successfully issuing such licenses turned out to be institutionally complex (Baker and Thrasher 2023). Even traditional compulsory licenses presented a high institutional burden due to the increasingly complex landscape of pharmaceutical patents and global supply chains (Bowonder et al. 2003; Amin and Kesselheim 2012). These procedurally intensive compulsory licensing laws make individual product and country-by-country initiatives incredibly difficult to implement (Baker and Thrasher 2023).

Even when countries were able to tackle the institutional and legal barriers to implementing TRIPS flexibilities into their IP laws, they often faced pushback from the very countries that had initially supported the Doha Declaration. The United States Trade Representative (USTR) published an annual trade "watch-list," its Special 301 Report, wherein it criticized countries for exercising their rights under international law (USTR, n.d.). The US put regular pressure on India for its compulsory license on an expensive cancer drug, claiming that India is "diluting" IP rights and violating the TRIPS Agreement (Medecins Sans Frontieres Access Campaign 2015). Colombia and Malaysia faced similar backlash when they took the first steps toward issuing a compulsory license for a leukemia treatment and a Hepatitis C medication, respectively (Baker 2018). In addition to the US, Switzerland joined with Novartis to complain that compulsory licenses are "tantamount to expropriation" – code for exercising a sort of eminent domain through regulation (Goldman and Balasubramaniam 2015). These unilateral measures resulted in a chilling effect so that many countries were reluctant to take advantage of the flexibilities they were granted under the TRIPS Agreement (Baker and Thrasher 2023).

THE PROPOSED TRIPS WAIVER: A DOHA DECLARATION 2.0?

When the COVID-19 pandemic hit, there was a new opportunity, and an urgency, to further expand on the progress of the Doha Declaration. Although there were myriad initiatives that sought to expand access to diagnostics, treatments and (eventually) vaccines for COVID-19, only one was directed at the language of the TRIPS Agreement: negotiations for a temporary TRIPS Waiver (WTO 2022b). The original proposal included a broad waiver of IP rights identified in the TRIPS Agreement and called on member states to allow each other to abrogate these rights in order to increase access to COVID-19 countermeasures – diagnostics, therapeutics and vaccines (Communication from India and South Africa 2020). In May 2021, the USTR unexpectedly came out in support of text-based negotiations towards a temporary waiver for COVID-19 vaccines, the exact scope and breadth to be determined (USTR 2021).

One could not but be reminded of the positively surprising Doha Declaration outcome just 20 years earlier. Once more the world seemed like it might be able to unite under a common goal of global



public health and the US was taking the lead. The outcome of that negotiation in June 2022, which narrowly covered patents only for vaccines, did little more than clarify existing flexibilities, though it did reduce bureaucratic red tape for exporting unlimited quantities of vaccines to developing countries – except China (WTO 2022b). In this way, the TRIPS Waiver was also reminiscent of the Doha Declaration in many respects, falling far short of the hopes of TRIPS Waiver advocates for a more substantial suspension of IP rights (IPR) enforcement (TWN 2022; Thrasher 2021; Patnaik 2022). Although it was narrow, WTO members agreed to at least consider the possibility of extending the waiver beyond vaccines to diagnostics and treatments within six months (WTO 2022a).

By December 2022, it became clear that WTO members were not nearing a consensus. Opponents of the TRIPS Waiver extension pointed to the underutilization of the original TRIPS flexibilities to argue that either they were not useful (and therefore additional flexibilities would not help), or that they were sufficient, and countries were simply not using them well. There is some evidence in recent research that demonstrates that at least some of the flexibilities, like compulsory licensing legislation, have been widely implemented in national laws (McGivern 2023). Concomitantly, it is clear that such measures are not consistently or frequently deployed (Tenni et al. 2022). Indeed, there is only one historic example of a country taking full advantage of one of the flexibilities, compulsory licensing for export, when Canada licensed an anti-viral AIDS drug for export to Rwanda (Hestermeyer 2007). Throughout the COVID-19 pandemic, only three compulsory licenses appear to have been issued (Medecins Sans Frontieres Access Campaign 2021).

Opponents argue that research has not shown IP to be a barrier to access to medicines, and thus, a TRIPS Waiver extension would do more harm than good – undermining stressed supply chains and innovation at a crucial time without any corresponding benefit (Copan 2023). As stated, the US requested a study of the TRIPS Waiver extension proposal by the USITC, which brought WTO deliberations to a standstill.

EVIDENCE SUPPORTING A WAIVER EXTENSION

The weight of the empirical evidence gathered in the USITC process, together with the history of the TRIPS Agreement, however, tells a different story. Research has conclusively shown that strong IP protection does not consistently contribute to increased innovation, especially in developing countries (USITC 2023). Moreover, additional research has shown that strong IP protection has been linked to various measures of decreased access to medicines in those same countries, both historically and during the COVID-19 pandemic. Finally, the history of the experiences of WTO developing country members demonstrates that the under-utilization of flexibilities does not mean that the flexibilities themselves are not useful or unnecessary.

Trips is Not Universally Linked to Innovation

Although incentivizing innovation is the primary public policy rationale for IP laws and for the TRIPS Agreement specifically, research about the extent to which it reaches that aim is mixed (World Trade Organization 1994). While some studies show an increase in innovation resulting from stronger IP rights, many others have identified a non-linear relationship, suggesting that the right amount of IP protection should vary depending on the development level of a particular country (Papageorgiadis and Sharma 2016; Williams 2016; Allred and Park 2007; Stiglitz 2014). A recent report released by the USITC noted that "patent protection is generally found to be more beneficial to innovation in the health sector for more developed countries and less for developing countries" (USITC 2023).

Trips May Decrease Access to Medicines

Not only is the TRIPS Agreement not correlated with increased innovation in developing countries, the Agreement has been linked to various measures of decreased access to medicines, such as increased prices and lower volumes of trade (Tenni et al. 2022; Gleeson et al. 2019). Moreover, strong IP protection at the domestic level, encouraged and governed by the TRIPS Agreement, has kept some countries from accessing COVID-19 treatments at affordable prices during critical moments of the pandemic (MSF 2022; Rees, Mihigo and Gray 2022). Conceptually, this is not surprising, given that the purpose of these agreements is to create a monopoly incentive for initial innovators. Rights to exclude competition, by definition, raise the price and constrain supply of a new product. The TRIPS Agreement, even with its flexibilities and the clarifications in the Doha Declaration, sets a global IP standard which thereby limits access to medicines.

Political Pressure and Legal Complexity Make the Flexibilities Hard to Use

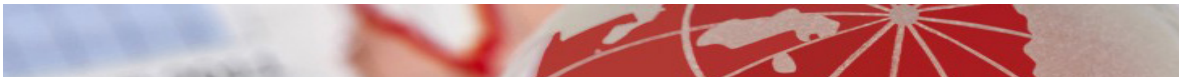
Finally, given the well-known history of the TRIPS Agreement and the Doha Declaration, there are good reasons to believe that the under-utilization of the flexibilities is not due to poor country practice or their inherent ineffectiveness. Rather, countries do not invoke these exceptions in their laws because the legal requirements and patent landscapes are overly complex (Baker and Thrasher 2023), and because of the political pressure they experience when they do use them (Baker 2018; Goldman and Balasubramaniam 2015). Many of these experiences have been described in previous sections, but as another example, note that India has not issued any compulsory licenses since its first in 2012, which resulted in inordinate backlash from the US government (Medecins Sans Frontieres Access Campaign 2015; 2021).

WHY THE WAIVER EXTENSION SUPPORTS PUBLIC HEALTH AND INSTITUTIONAL LEGITIMACY

Recently, two prominent WTO members have taken steps that suggest a slight shift in the narrative when it comes to IP and public health. The USTR has noted in a public statement that it "respects the rights of its trading partners to exercise the full range of the existing flexibilities in the TRIPS Agreement and the Doha Declaration" (USTR 2022). The US agency has also changed its Special 301 Report policy to explicitly acknowledge the legality of compulsory licensing (USTR 2023). In parallel, it seems that the European Commission has proposed a new compulsory licensing legislation to the European Parliament and the Council to facilitate such licenses and harmonize legal approaches across the Union (European Commission 2023).

As these policy developments represent a narrative shift, they could lay the groundwork for countries to agree to the need for greater legal flexibility during a pandemic. If WTO members agree to extend the TRIPS Waiver to diagnostics and therapeutics, it would join the Doha Declaration as a multilateral step forward in global public health. Such a move would be consistent with the spirit of the earlier declaration and would advance global goals towards access to medicines.

More importantly, the WTO faces a decision that will set the precedent for how the institution responds in a crisis. If member states are committed to the legitimacy of the WTO and especially to its role as a negotiating body that truly prioritizes "the welfare of all peoples," they should vote in favor of an extension of the TRIPS Waiver.



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