

THE TRIPS WAIVER: TEXTS, CONTEXT AND POLITICS AT THE WTO

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Abstract

On October 2, 2020, India and South Africa circulated the 'TRIPS Waiver' proposal at the World Trade Organization ("WTO"). This proposal, co-sponsored by 64 WTO members, aims to achieve a temporary waiver of certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). However, since WTO practice on waivers requires consensus among members, the proposal has been subject to vigorous debate and opposition from others. This article provides a stock-take of the Waiver debate by mapping the submissions, interventions and proposals made by members in the TRIPS Council during course of the debate. Understanding these discussions is of great significance a time when international intellectual property ("IP") rights are being held up as a barrier for increasing vaccine production and distribution. An overview of these discussions shows that inoperability of the in-built TRIPS flexibilities has been a key motivator for moving the waiver proposal, which presents a 'high-demand ask'. Given this context, this article highlights the negotiating positions and strategies adopted by members before and after tabling of the proposal and how these positions have evolved over time as we approach the WTO's twelfth Ministerial Conference.

I. INTRODUCTION

When Germany's Chancellor Angela Merkel and American President Joe Biden met for a bilateral summit in July 2021, not many expected them to disagree on the task of charting a concerted effort against the COVID-19 pandemic. Rightfully so: were one to read through the transcript of the President's remarks on the summit,¹ it all seemed to be under control. Why then was the summit termed a 'failure'? It would appear that Chancellor Merkel and President Biden had in fact discussed the 'TRIPS Waiver' ("Waiver") – a proposal tabled by India and South Africa at the WTO in October 2021 to temporarily waive away specific obligations related to IP rights standards and enforcement – but the discussion led nowhere due to Germany's opposition to the proposal. Faced with this difficulty, President Biden simply chose not to record this affair in his remarks on the summit.²

If this routine seemed unusual, it also typified in many ways, the approach that the two nations had adopted in addressing the call for a waiver. Currently the European Union ("EU"), the United Kingdom ("UK") and Switzerland are at loggerheads with a growing group of 64 countries – 'co-sponsors' of the Waiver proposal at the WTO – and hundreds of civil society activists and non-governmental organizations. Watching from the side-lines is the influential yet deadpan United States ("US"), which had, until May 2021, strongly opposed the Waiver proposal only to switch sides in a dramatic volte-face episode, agreeing to engage in text-based negotiations on the proposal.

Situated in this politically energized background, this article maps the TRIPS Waiver debate, charting its origin and politics at the WTO. By taking stock of the interventions, submissions and proposals made by WTO members at the TRIPS Council, this article is aligned with the view that the debate not only offers keen insights into the logic and limitations of how the global IP regime is working in the face of a pandemic marking an immediate rise in the global demand for

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¹ Remarks by President Biden and Chancellor Merkel of the Federal Republic of Germany in Press Conference, THE WHITE HOUSE (Jul. 15, 2021), <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/07/15/remarks-by-president-biden-and-chancellor-merkel-of-the-federal-republic-of-germany-in-press-conference/>.

² Jake Johnson, "This Summit Was a Failure": Biden-Merkel Meeting Ends With No Deal on Vaccine Patent Waiver, COMMON DREAMS (Jul. 16, 2021), <https://www.commondreams.org/news/2021/07/16/summit-was-failure-biden-merkel-meeting-ends-no-deal-vaccine-patent-waiver>.

vaccines, it also enables us to understand the role that global intellectual property rules have come to play in members' efforts to contain the spread of the COVID-19 pandemic locally.

Besides promises, it is pertinent to mention the limitations that the reader may face in trying to understand the TRIPS Waiver debate. First, writing *in medias res* is a testing prospect.³ It is well-known that ahead of the long overdue 12th Ministerial Conference ("MC12"), the WTO is undergoing an 'existential crisis'.⁴ WTO members are aware that facilitating consensus on a public-health oriented decision such as the TRIPS Waiver would not only ensure the relevance of the WTO as an international institution but also help tackle the long-held belief that the WTO exists for liberalization *tout court*.⁵ With these prospects in sight, members are engaged in formal and informal consultations on an almost weekly basis and updates on these discussions occur faster than they can be written about.

Second, text-based outcome on the Waiver proposal remains far from sight.⁶ While it is true that Waiver proponents have been engaged in text-based discussions and enjoy support from the US, concerted and consistent opposition to the Waiver from the EU, the UK and Switzerland has ensured that negotiating positions on the Waiver remain unchanged since it was first proposed. The apprehension that the calculated enthusiasm of the US will do little to provide a positive direction in text-based negotiations is proving true. In these troubling circumstances, it is difficult to estimate the final outcome of these negotiations at MC12.

The task of mapping the relatively recent history of these negotiations remains of some importance nevertheless. Not only does this exercise provide an overview of how WTO members understand the role that IP is playing in the containment of the COVID-19 pandemic, but it also helps discern those facets and limitations of the global IP regime to which negotiators may revert to in times of future crises – for example, climate change. Accordingly, the next section sets out the discussions in the TRIPS Council prior to the tabling of the TRIPS Waiver.

³ Adam Tooze, *Chartbook on Shutdown #2: Writing in medias res*, CHARTBOOK (Sept. 4, 2021), <https://adamtooze.substack.com/p/chartbook-on-shutdown-2-writing-in>.

⁴ Banikinkar Pattanayak, *WTO faces deepest existential crisis ahead of its silver jubilee*, THE FINANCIAL EXPRESS (Dec. 9, 2019), <https://www.financialexpress.com/economy/wto-faces-deepest-existential-crisis-ahead-of-its-silver-jubilee/1788127/>.

⁵ This view echoes those presented by Indonesia at the WTO's TRIPS Council on 13 October 2021 on the TRIPS Waiver. *13 October 2021: Indonesia's statement on the TRIPS waiver*, KNOWLEDGE ECOLOGY INTERNATIONAL (October 16, 2021), <https://www.keionline.org/36775>.

⁶ Shantanu Singh, *The US support for the TRIPS waiver is only half the battle*, INTERNATIONAL LAW & THE GLOBAL SOUTH (May 6, 2021), <https://internationalawandtheglobalsouth.com/guest-post-covid-19-series-the-us-support-for-the-trips-waiver-is-only-half-the-battle-what-lies-ahead/>.

In the section that follows, the Waiver proposal, the draft text and its overall rationale are analysed. This section is followed by another on the TRIPS Council debates and developments which occurred after the tabling of the Waiver proposal. The concluding section summarizes the key takeaways from the TRIPS Waiver debate.

II. THE TRIPS WAIVER DEBATE

A. Setting the stage

At the very outset of the COVID-19 pandemic, as news media reported the rising number of novel coronavirus cases across the world, it was clear that seamless supply of critical medical products and health equipment, such as diagnostic kits and masks, was going to be essential in containing the spread of the virus. Scientists at the UK's Jenner Institute had also started to design vaccines based on genome sequencing released in January 2020.⁷ However, in the face of an unfathomable rise in demand and the lack of a globally coordinated policy response, all preparedness seemed to be falling short.⁸ If the failure of the global supply chains was becoming apparent in the first few months of the pandemic, IP was being pre-empted as a future barrier in accessing COVID-19 cures.⁹

Given this urgent context, it was not long before that IP's potential role in the response to the COVID-19 became a key discussion item – an 'agenda item' – at the behest of South Africa in the TRIPS Council, the WTO body responsible for monitoring the Agreement's operation. The July 2020 TRIPS Council meeting was to be its first formal plenary since the pandemic started. Accordingly, South Africa opened the discussion in the Council by taking note of the global shortage of medical supplies and the sheer scale of the crisis at hand.¹⁰

⁷ Oliver Franklin-Wallis, *An oral history of Oxford/AstraZeneca: 'Making a vaccine in a year is like landing a human on the moon,'* THE GUARDIAN (Aug. 28, 2021), <https://www.theguardian.com/society/2021/aug/28/oral-history-of-oxfordastrazeneca-making-a-vaccine-in-a-year-is-like-landing-a-human-on-the-moon..>

⁸ *Shortage of personal protective equipment endangering health workers worldwide*, WORLD HEALTH ORGANISATION (Mar. 3, 2020), <https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide.>; Jinshan Hong & Dong Lyu, *World Ventilator Demand Now 10 Times What's Available, Says Maker*, BLOOMBERG (Mar. 25, 2020), <https://www.bloomberg.com/news/articles/2020-03-25/world-ventilator-demand-now-10-fold-what-s-available-says-maker>.

⁹ Press Release, Médecins Sans Frontières, *African Union says urgent need to address patents and technology barriers for access to future COVID-19 vaccines* (Jul. 1, 2020), <https://reliefweb.int/report/world/african-union-says-urgent-need-address-patents-and-technology-barriers-access-future>.

¹⁰ Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting Held in the Centre William Rappard on 30 July 2020*, WTO Doc. IP/C/M/95/Add.1 (Oct. 2, 2020), ¶ 66 [hereinafter Minutes of July 2020].

However, the biggest challenge in relation to IP that South Africa was keen to highlight was that of IP itself. South Africa's strategy would show that it had not brought this item onto the meeting's agenda to merely entertain general remarks on the IP-related measures taken during the pandemic. South Africa was apprehending issues related to the in-built flexibilities of the TRIPS Agreement. For one, in a paper circulated prior to the meeting, South Africa noted that understanding of these flexibilities beyond patents were less understood at a national level, noting that national IP laws in some cases may not even provide for access-related flexibilities concerning other IP rights.¹¹ In South Africa's view, it was time to discuss a more 'integrated approach' towards TRIPS flexibilities. The visible strategy then was to nudge the discussion in the Council under another agenda item – on the 'integrated approach' paper circulated by South Africa – as well.

Consistent with this strategy, South Africa utilized the two agenda items to argue that patents were not the only IP-related hurdle in the context of the pandemic. IP-related barriers, the argument went, were also present in other IP rights, such as industrial designs, copyrights and trade secrets. In addition, it noted that while such flexibilities exist under the TRIPS, there are potential legal, institutional and technical challenges which may arise in the operationalization of these flexibilities by developing countries, especially when they had little to no prior experience in utilizing them.¹² Not only did these flexibilities prove far too complex to operate within the domestic markets, but they were likely to be inadequate for operationalizing the export of vaccines to members who had insufficient or no manufacturing capacities under a mechanism established by Article 31*bis* of the TRIPS. Under this Article 31*bis* system, when exports of pharmaceutical products took place under the grant of a compulsory licence for the purpose of exporting products to members who had insufficient or no manufacturing capacities, then the obligation to use compulsory licenses only for domestic markets, as set out in Article 31(f) of TRIPS, would no longer apply.¹³

While this system appeared comprehensive, operationalizing it was a different matter entirely. To highlight this, South Africa recalled that when *Médecins Sans Frontières* tried to use this procedure

¹¹ Communication from South Africa, *Intellectual Property and Public Interest: Beyond Access to Medicines and Medical Technologies Towards a more holistic approach to TRIPS flexibilities*, WTO Doc. IP/C/W/666 (Jul. 17, 2020).

¹² *Id.* ¶ 69.

¹³ Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 31*bis* 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

in 2006 for the export of crucial HIV medicines from Canada to their operations in Rwanda, it concluded that the Article 31*bis* procedure was “neither expeditious nor workable”.¹⁴ To South Africa, it was becoming apparent that at a time when the inbuilt flexibilities of TRIPS could have played a central role in ensuring equitable distribution of IP-protected products, there was very little in terms of any operating experience which could inspire confidence in the system. In such circumstances, a limited, non-transparent voluntary licencing system and distribution pledges were the only system of vaccine distribution which seemed to be in operation. But such *ad hoc* initiatives, South Africa averred, were inadequate for systematically addressing the IP-related barriers. In other words, ‘business as usual’ i.e., the global IP regime as it exists, was simply not enough.

South Africa’s sentiments were echoed by developing countries, including India, under both the agenda items. As Indonesia stated, the key concern was that in absence of an effective and global mechanism for ensuring cooperation on IP-rights, scaling up of production and distribution of vaccines depended solely on the industry’s policies.¹⁵ Second, Indonesia suggested that even if IP-related flexibilities were available domestically to members, it was unclear how they would be operationalized since many patented products or technologies could also consist of other IP-rights. Zimbabwe averred that South Africa’s proposal was essential as it was aware of pharma companies protecting their products under IP-rights other than patents, such as through trade secrets and industrial designs, flexibilities for which were unclear.¹⁶ Supporting this call to arms declared by South Africa, India took the opportunity to request members to initiate discussions on TRIPS flexibilities applicable to IPs beyond patents.¹⁷

But to even initiate such a dialogue, members had to get past their conceptual differences in how IP was affecting the fight for public health. In the history of the TRIPS, the road from Punta del Este, where the TRIPS negotiations were launched, to the TRIPS ‘flexibilities’ negotiated in

¹⁴ Minutes of July 2020, *supra* note 10, ¶ 71.

¹⁵ *Id.* ¶ 458.

¹⁶ *Id.* ¶ 489.

¹⁷ *Id.* ¶ 495.

Doha had not been an easy ride.¹⁸ It had been the result of careful alliances and negotiating strategies which were going to be revived as the TRIPS Waiver dialogue took shape.¹⁹

The first signs of such a revival could be sensed when the developed countries began to intervene under the two agenda items brought onboard by South Africa. Speaking under the first of the two agenda items, the US made it clear: IP was not a barrier in addressing the pandemic. Instead, IP had motivated the global efforts to find cures; manufacturing capacities and supply chain issues were of greater ‘concern’.²⁰ Canada, speaking under the second agenda item, called for an ‘appropriate balance’ between the multilateral framework of the TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health, 2001 (“Doha Declaration on TRIPS”).²¹

The EU and the UK joined the US in arguing that the system of IP, especially patents, provided a platform for innovation; there was evidence to show that the lack of access to medicine stemmed from ‘other sources’; and there were no ‘simple solutions’ to the current crisis.²² The EU, based on a report each from the Europol and the EU Intellectual Property Office, argued that global cooperation was most important in this moment of time since counterfeit, fake or substandard goods, medicines and equipment were quickly taking over the market and threatening public health.²³ While Switzerland agreed with South Africa’s observation that, in the context of the pandemic, IP-related issues were also present beyond patents and medical products, it discouraged members from using coercive measures which limit IP rights. Instead, Switzerland thought voluntary measures, such as licensing, to be preferable as they were faster, provided legal certainty and were more promising than limitations on IP rights.²⁴ While Japan agreed with several points raised by others²⁵, the United States went even further to say that

¹⁸ Jayashree Watal, *From Punta Del Este to Doha and Beyond: Lessons from the TRIPS Negotiating Processes* (Dec. 17, 2011), <https://papers.ssrn.com/abstract=1973177>.

¹⁹ Shantanu Singh, *supra* note 6.

²⁰ Minutes of July 2020, *supra* note 10, ¶ 120.

²¹ Minutes of July 2020, *supra* note 10, ¶ 507; World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2 [hereinafter Doha Declaration]. (The origin of the Article 31 *bis* system lies in Paragraph 6 of the Doha Declaration.)

²² Minutes of July 2020, *supra* note 10, ¶ 510-534.

²³ Minutes of July 2020, *supra* note 10, ¶ 536.

²⁴ Minutes of July 2020, *supra* note 10, ¶ 563, 564.

²⁵ Minutes of July 2020, *supra* note 10, ¶ 593

while it recognized the members' right to use compulsory licensing provisions, such mechanisms could have a negative effect on IP-related investments.²⁶

By asking that WTO members turn their attention towards manufacturing capacity and supply chains, the developed countries were deliberately missing the point. Their interventions stated nothing in particular on South Africa's concerns about the lack of confidence among developing countries about the Article 31 *bis* system. Neither did the developed countries address, for example, South Africa's concerns about the voluntary licenses being practiced by Gilead in the production and distribution of remdesivir. South Africa noted that while Gilead had agreed to supply the drug to the US on a one-to-one basis, in utter contrast, supply of the drug for 127 other countries was being managed through 'limited, non-transparent [and] exclusive' licenses to generic manufacturers in three countries.²⁷ To South Africa, that sounded like an oligopolist managing its competition.

Revisiting the foregoing TRIPS Council discussions is essential to understand the genesis of the Waiver proposal. South Africa and the other developing countries attempted to shape a somewhat consistent narrative about the issues with IP and TRIPS flexibilities beyond patents. This narrative was to form the conceptual foundation for the TRIPS Waiver. But, if these concerns enjoyed only hesitant support from fellow developing countries, the Oratorio-like clarity of the message from a set of developed countries was unmistakable: the exclusivity of IP rights needed to be protected during the pandemic; if flexibilities were to be exercised for the supposed IP-related difficulties, then it must be done in the way implicit in the TRIPS or through voluntary licensing. In this sense, as we shall see, the negotiating positions on the TRIPS Waiver have not changed at all till date.

B. In the Limelight: Contours of the TRIPS Waiver

India and South Africa circulated the Waiver proposal on October 2, 2020.²⁸ In line with the views put forth by the developing countries at the TRIPS Council meeting in July, the Waiver proposal was geared to ensure that IP rights do not become a barrier to access to medicines and

²⁶ Minutes of July 2020, *supra* note 10, ¶ 584-585.

²⁷ Minutes of July 2020, *supra* note 10, ¶ 66; South Africa cited a report from The Los Angeles Times. Vidya Krishnan, *How secret deals could keep a COVID-19 drug out of reach for millions*, LOS ANGELES TIMES (July 1, 2020), <https://www.latimes.com/world-nation/story/2020-07-01/gilead-patent-limits-access-to-covid-19-drug-remdesivir>.

²⁸ Communication from India and South Africa, *Waiver from Certain Provisions of The Trips Agreement for The Prevention, Containment and Treatment of Covid-19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020) [hereinafter TRIPS Waiver].

scaling up the research, manufacturing and supply of products necessary for combatting COVID-19.²⁹

Taking note of reports about IP causing such hindrances and the extent of the damage caused by the pandemic, the Waiver proposal presented a draft decision text in the communication's annex. It is this draft text which would be recommended to the General Council, the key decision-making body in the intervals between the WTO's biennial Ministerial Conferences, by the TRIPS Council after due deliberation and discussion. Such a decision by the General Council will have to conform to the consensus-based procedures prescribed in Article IX:3 of the WTO Agreement.³⁰

This draft text presents five paragraphs. While paragraph 2 and 3 ensure that the proposed Waiver decision does not affect the protection of rights of performers and producers of sound recordings and broadcasting organizations under Article 14 and is without prejudice to the exemption from the application of TRIPS provided to least-developed countries under Article 66.1, it is paragraph 1 which sets out the key decision. Paragraph 1 of the draft text exempts WTO members from their 'obligation to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement'.

To understand the effect or operation of this paragraph 1 waiver, it is essential to revisit the purpose of the TRIPS. In stark contrast with the 'patchwork' intellectual property regime which had existed prior to the conclusion of TRIPS i.e., the Paris and Berne Conventions, the TRIPS represents a "legally binding set of substantive, minimum IP standards".³¹ Unlike its predecessors, TRIPS requires WTO members to enact measures within their borders to ensure that they meet the minimum standards set out in the agreement.³² These standards are set out in Part II of the TRIPS agreement, divided into 8 distinct sections, each concerning different intellectual property rights.³³ Part III of the TRIPS provides the minimum standards for the

²⁹ *Id.* ¶ 3.

³⁰ Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154 [hereinafter WTO Agreement]. (Article IX:3 (b), which sets out the procedure for a waiver request for any of the agreements contained in Annex 1A, 1B and 1C of the WTO Agreement and requires that such a waiver request be submitted to the respective Council concerned with that Annex Agreement.)

³¹ CAROLYN DEERE, *THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES* 1 (2008).

³² *Id.*

³³ Part II, TRIPS Agreement, *supra* note 13.

enforcement of intellectual property rights, which include the civil and administrative remedies, criminal remedies, and border or customs measures.³⁴

The function of paragraph 1 of the draft text then is to waive the legal and binding obligations of members with regard to the aforementioned Parts of the TRIPS. Second, the IP rights covered by the draft Waiver text are limited to Copyright and Related Rights', 'Industrial Designs', 'Patents' and 'Protection of Undisclosed Information'. Only these types of IP rights and not others have been included within the scope of the draft text as it is in line with the reasoning that South Africa had first presented in the TRIPS Council meeting in July. The Waiver's scope is also circumscribed by the paragraph 1 clause stating that such obligations shall be waived "in relation to prevention, containment and treatment of COVID-19". While somewhat broad, this linkage certifies the purpose of the Waiver.

Paragraph 1 also includes a placeholder of '[X] years'. Subject to the decision of the TRIPS Council, this placeholder may represent the duration of the Waiver. Making the decision on the duration of the Waiver is key as we are none the wiser on how long the ongoing pandemic may continue.³⁵ Pending a more coherent understanding of how long virus-induced immunity may last, it was understood that the arrival of vaccine in the near future was going to play a key role in determining the future of the pandemic.³⁶ It is perhaps due to such factors that the Waiver text proposes that it remain in force till such time 'widespread vaccination is in place' and 'majority of the world's population has developed immunity'.³⁷ Considering these aspects, the '[X] years' placeholder would permit the TRIPS Council to decide on the Waiver's duration after taking into consideration the latest scientific and technical information related to the pandemic.

In any case, if the Waiver were to be granted, then paragraph 4 of the draft text proposes that the Waiver shall be reviewed by the "General Council not less than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement". The linkage with Article IX:4 is key for this review procedure as Article XI:4 establishes the general procedure regarding any waiver from the

³⁴ Part III, TRIPS Agreement, *supra* note 13.

³⁵ Megan Scudellari, *How the pandemic might play out in 2021 and beyond*, 584 NATURE 22–25 (2020). (This aspect assumes greater importance with the onset of each new variants, the latest among them being reported as the 'Omicron' variant.)

³⁶ *Id.*

³⁷ TRIPS Waiver, *supra* note 28, ¶ 13.

various WTO Agreements. To wit, per Article IX:4, each review of the waiver would require the General Council to examine whether the ‘exceptional circumstances’ which justify the need for the waiver still exist or if the conditions attached to the Waiver have been met. On the basis of this review, the General Council (or the Ministerial Conference) may extend, modify or terminate the waiver.³⁸

Last, and perhaps most importantly, the draft text, in paragraph 5, prohibits any possibility of a member challenging any measure taken in conformity with the Waiver provisions. This provides legal protection to the waiver set out in paragraph 1 by prohibiting members from challenging any conforming measure for nullification or impairment under Article XXIII of the GATT, 1994 or the WTO’s Dispute Settlement Understanding generally.

An assessment of the contours of the Waiver proposal shows that it presented a particularly high-standard ‘ask’ in terms of the demands that it made of WTO members. Wholesale waivers of entire substantive and procedural portions of a WTO Agreement are rare, to say the least.³⁹ But as India and South Africa have argued in the TRIPS Council and through the Waiver proposal, so were the circumstances. The TRIPS Council was well aware that IP was playing a key role in the pandemic, be it in the manufacturing and supply of medical products or in the research and development of novel vaccines. If it is indeed obvious that IP rights are impeding the efforts of countries in tackling the pandemic, the pressure on the TRIPS Council would surely be immense. And this means that regardless of whether the Waiver proposal will help relieve this pressure or whether the proposal’s high-demand asks will create more of it, a suffering world is looking to the TRIPS Council – and the WTO – for answers, including an international policy response for addressing current vaccine shortages and those which may arise in the future.

C. No curtain fall after all?

India and South Africa’s Waiver proposal was first discussed in the Council’s meeting held in mid-October and in December.⁴⁰ In the interval, members circulated two submissions related to

³⁸ WTO Agreement, *supra* note 30.

³⁹ See, e.g., the latest compilation of all waivers granted at the WTO. Note from the Secretariat, *Waivers 1995- 2020*, WTO Doc. WT/GC/W/718/Rev.1 (Jan. 25, 2021).

⁴⁰ Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting Held on 15-16 October and 10 December 2020*, WTO Doc. IP/C/M/96/Add.1 (Feb. 16, 2021) [hereinafter *Minutes of October and December 2020*].

the Waiver. While South Africa shared a paper titled ‘Examples of IP Issues and Barriers in COVID-19 Pandemic’⁴¹, Australia, Canada, Chile and Mexico shared a set of questions for the Waiver’s proponents on various aspects of the proposed Waiver.⁴² In contrast with the previous TRIPS Council meeting, support from developing countries at the mid-October meeting for the Waiver proposal was clear, with a host of members supporting discussions on the Waiver. For example, by the time the December meeting took place, Kenya, Mozambique, Eswatini, Pakistan and Bolivia had joined the Waiver proposal as co-sponsors. The litmus test for the Waiver proposal, however, was always going to be a measure of how well it sat with the set of developed countries who had intervened in the previous TRIPS Council meeting.

Consistent with its previous submissions, for the EU, there was “no indication that IPR issues have been a genuine barrier in relation to COVID-19 related medicines and technologies”.⁴³ In any case, even if IP became a barrier, the EU, Switzerland and Norway pointed out that the TRIPS contained in-built flexibilities which can be employed. For their part, the US and Japan were deft in rejecting the Waiver proposal⁴⁴, as was Australia.⁴⁵ Besides rejecting the Waiver, the US also posted a flurry of questions on the proposal and expressed concerns regarding the broad scope of the Waiver’s language, in particular objecting to the clause that members’ obligations would be waived “in relation to prevention, containment and treatment of COVID-19”.⁴⁶ Curiously enough, the Waiver proposal was also rejected by Brazil⁴⁷, which had been one of the developing countries batting for access to medicines during the Doha negotiations.⁴⁸

Confronted by this consolidating group of members opposed to the proposal, South Africa took to the floor to reply to their specific queries.⁴⁹ Taking note of the ‘case by case’ nature of the TRIPS flexibilities, South Africa noted that, in contrast, the Waiver proposal represented an ‘expedited, open and automatic’ solution.⁵⁰ Besides recalling the lack of experience with TRIPS

⁴¹ Communication from South Africa, *Examples of IP Issues and Barriers in Covid-19 Pandemic*, WTO Doc. IP/C/W/670 (Nov. 23, 2020).

⁴² Communication From Australia, Canada, Chile and Mexico, *Questions on Intellectual-Property Challenges Experienced by members in relation to COVID-19*, WTO Doc. IP/C/W/671 (Nov. 27, 2020).

⁴³ Minutes of October and December 2020, *supra* note 40, ¶ 1028.

⁴⁴ Minutes of October and December 2020, *supra* note 40, ¶ 1049, 1070.

⁴⁵ Minutes of October and December 2020, *supra* note 40, ¶ 1121.

⁴⁶ Minutes of October and December 2020, *supra* note 40, ¶ 1333.

⁴⁷ Minutes of October and December 2020, *supra* note 40, ¶ 1099.

⁴⁸ Watal, *supra* note 18.

⁴⁹ Minutes of October and December 2020, *supra* note 40, ¶1147-1171.

⁵⁰ Minutes of October and December 2020, *supra* note 40, ¶ 1155.

flexibilities for IP rights beyond patents and the Article 31 *bis* system, South Africa also took note of the EU's IP enforcement Report of 2020 and the US Trade Representative's ("USTR") Special 301 report of 2020, both of which, it argued, acted as deterrents to the issuing of compulsory licenses.⁵¹ Nevertheless, it was key to continue these discussions and South Africa requested that this proposal be kept on the agenda of the TRIPS Council for future meetings.⁵²

Even as subsequent TRIPS Council meetings took place, there was little change in the negotiating positions on the Waiver. In January 2021, Waiver proponents released two comprehensive answer sheets on the queries raised by members.⁵³ In retort perhaps, the Waiver proponents also circulated a paper of their own; this time setting out a list of questions addressed to the Waiver 'opponents'.⁵⁴

By March 2021, the co-sponsorship of the Waiver had swelled up to 57 members with many others supporting discussions on the proposal. However, progress on the text seemed distant. In fact, even though COVID-19 vaccines had been invented globally, members had made no progress on text-based negotiations on the Waiver. At the TRIPS Council meeting held in February 2021, the Waiver proponents called upon other members to begin these negotiations,⁵⁵ but to no avail. While Switzerland, the EU, Japan, Norway and Australia remained opposed to the waiver, a key change was afoot.

With a change of guard in the US Administration and increased pressure from civil society⁵⁶, the US had become less vociferous in its opposition to the Waiver discussions. Reports noted that the initial signs of this volte-face were present in the Biden administration's run up to the Oval

⁵¹ Minutes of October and December 2020, *supra* note 40, ¶ 1155-1157.

⁵² Minutes of October and December 2020, *supra* note 40, ¶ 1171.

⁵³ Communication from the Plurinational State Of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe, *Waiver from Certain Provisions of The TRIPS Agreement for The Prevention, Containment and Treatment of Covid-19 - Responses to Questions*, WTO Doc. IP/C/W/672 (Jan. 15, 2021); Communication from the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe, *Response to questions on Intellectual-property challenges experienced by members in relation to COVID-19 in document IP/C/W/671*, WTO Doc. IP/C/W/673 (Jan. 15, 2021).

⁵⁴ Communication from India, Mozambique, Pakistan and South Africa, *Waiver from Certain Provisions of The TRIPS Agreement for The Prevention, Containment and Treatment of Covid-19 – Questions by Proponents*, WTO Doc. IP/C/W/674 (Jan. 15, 2021).

⁵⁵ Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting Held in the Centre William Rappard on 23 February 2021*, WTO Doc. IP/C/M/97/Add.1, ¶ 19 (Apr. 7, 2021) [hereinafter Minutes of February 2021].

⁵⁶ *TRIPS waiver: Pressure mounts on WTO as supporting voices grow*, MINT (Feb. 21, 2021), <https://www.livemint.com/news/india/trips-waiver-pressure-mounts-on-wto-as-supporting-voices-grow-11614221180404.html>.

Office.⁵⁷ Elsewhere, the newly appointed USTR Katherine Tai admitted that the ‘business as usual’ mindset could continue no longer.⁵⁸ Then, instead of its old tactic of drowning the discussions in a barrage of questions and clarifications, the US proposed that it was open to discussions for a multilateral solution.⁵⁹ This meant that while the US was not yet onboard with the Waiver itself, its opponents had lost a significant voice in their cause. Increasingly isolated in the TRIPS Council discussions, the Waiver opponents, especially the EU, began to reiterate their support for the in-built TRIPS flexibilities for countering IP-related difficulties.⁶⁰ Meanwhile, the Waiver proponents, emboldened by the wind in their sails, informed the TRIPS Council that they had been working on a revised proposal, focusing on “a pragmatic approach” towards the scope of the Waiver and the introduction of “a specific duration of years based on scientific and epidemiological data”.⁶¹

A strong blow to the opposition came in early May 2021, when, despite having courted strong lobbying from the domestic pharmaceutical industry⁶², the USTR announced its support for text-based negotiations at the WTO.⁶³ A work of mindful drafting, the USTR’s statement only spoke of supporting text-based negotiations on COVID-19 vaccines alone. It was interesting to see how the US, a hawkish promotor and enforcer of IP protections globally, had gone from opposing the Waiver to becoming a key backer of it. Reports on this episode stated that key figures in the Biden administration considered supporting the Waiver to be “a low-risk way to secure a diplomatic victory”.⁶⁴ Seen from this realist viewpoint, the ‘symbolism’ of the USTR’s announcement worked seamlessly,⁶⁵ even as it was aware of how text-based negotiations at the WTO could take months - if not more than a year, considering the opposition from the EU and

⁵⁷ Kiran Stacey & Aime Williams, *Vaccine diplomacy: inside Biden’s decision on Covid patents*, FINANCIAL TIMES (May 8, 2021), <https://www.ft.com/content/7046b35a-7c6a-4ad4-8b9c-cc9a367da865>.

⁵⁸ *Id.*

⁵⁹ Minutes of February 2021, *supra* note 55, ¶ 242.

⁶⁰ Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting held in the Centre William Rappard on 10-11 March 2021*, WTO Doc. IP/C/M/98/Add.1, ¶ 381-382 (July 30, 2021).

⁶¹ Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting held in the Centre William Rappard on 30 April 2021*, WTO Doc. IP/C/M/99/Add.1, ¶ 36 (July 30, 2021).

⁶² Hannah Kuchler & Aime Williams, *Vaccine makers say IP waiver could hand technology to China and Russia*, FINANCIAL TIMES (Apr. 25, 2021), <https://www.ft.com/content/fa1e0d22-71f2-401f-9971-fa27313570ab>.

⁶³ *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver*, OFFICE OF UNITED STATES TRADE REPRESENTATIVES (May 5, 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>.

⁶⁴ Stacey & Williams, *supra* note 57.

⁶⁵ Alan Beattie, *Katherine Tai springs a surprise on Covid vaccine patents*, FINANCIAL TIMES (May 6, 2021), <https://www.ft.com/content/0930fe14-5187-45dc-b573-4f4098211bf4>.

others. Aware of these concerns, the 62-members strong set of Waiver co-sponsors circulated a joint statement, calling upon WTO members to “prioritise and expedite text-based negotiations”.⁶⁶ While the USTR’s support itself could do little immediately, it did have an immediate effect in breaking the opposition as Australia and New Zealand, erstwhile Waiver opponents, along with fence-sitters such as Russia, China and Ukraine, announced their support for the TRIPS Waiver.⁶⁷

Seeing this renewed impetus in the Waiver debate, the co-sponsors circulated the revised proposal in May 2021.⁶⁸ This revised decision text, considering the members’ concerns on the scope of the Waiver, limited it to “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19”. While this improved on the rather broad language of the previous draft text, it did little to actually shift the scope of the Waiver in terms of its coverage. Second, in the revised decision text, instead of the placeholder indicating the duration of the Waiver, a term of “at least 3 years” was proposed through a new paragraph. Furthermore, this duration was made subject to a review process, not unlike the one set out in Article IX:4 of the WTO Agreement. On the whole, the revision exercise had altered precious little in substance. But, if the text had to be amended towards a ‘convergence’, it required the participation of the WTO membership outside of the Waiver co-sponsors and supporters.

⁶⁶ Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe, *Waiver from Certain Provisions of The TRIPS Agreement for The Prevention, Containment and Treatment of Covid-19 – Joint Statement of Co-sponsors*, WTO Doc. IP/C/W/677 (May 18, 2021).

⁶⁷ Kirtika Suneja, *China, Ukraine and New Zealand back India and South Africa’s IPR waiver joint proposal on Covid medical products*, THE ECONOMIC TIMES (June 1, 2021), <https://economictimes.indiatimes.com/news/india/china-ukraine-and-new-zealand-back-india-and-south-africas-ip-waiver-plan-on-covid-medical-products/articleshow/83134286.cms?from=mdr>; Paul Karp & Elias Visontay, *Australia to support vaccine waiver after months of pressure from human rights groups*, THE GUARDIAN (Sept. 8, 2021), <https://www.theguardian.com/society/2021/sep/08/australia-to-support-vaccine-waiver-after-months-of-pressure-from-human-rights-groups>.

⁶⁸ Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe, *Waiver from Certain Provisions of The TRIPS Agreement for The Prevention, Containment and Treatment of Covid-19 – Revised Decision Text*, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021).

Instead of engaging in that way, in June 2021, the EU drove the divergence further by circulating a paper and a draft decision text of its own.⁶⁹ The crux of the argument presented in these two documents was that the in-built TRIPS flexibilities were enough to tackle the pandemic. All that this system of flexibilities contained in Article 31 and 31*bis* required was clarifications which could simplify its use by members in granting compulsory licenses. Accordingly, the EU's draft decision text proposed that a pandemic was covered within the meaning of 'a national emergency or other circumstances of extreme urgency' in Article 31(b) of the TRIPS, which exempts prospective users of compulsory licences to make efforts towards gaining a voluntary license from the right holder under specific circumstances.⁷⁰ Next, the draft text proposed that the 'adequate remuneration' paid to the right holder within the meaning of Article 31(h) be equal to the "price charged by the manufacturer of the vaccine or medicine produced under the compulsory licence". Last, the EU proposed that in using the Article 31*bis* system, members may issue a single notification for the list of countries to which vaccines and medicines are being supplied by the exporting member.

It is highly doubtful that the EU's draft decision provided any novel clarification or interpretation. For one, the Doha Declaration on TRIPS recognizes the right of each member to determine what constitutes a 'national emergency'.⁷¹ Moreover, the Declaration expressly states that "...epidemics, can represent a national emergency".⁷² At a time when WTO members had adopted unprecedented measures to contain the spread of the pandemic, who would admit that it did not constitute a 'national emergency' within the scope of Article 31(b)? In advancing such a redundant proposal, the EU not only further isolated itself and weakened the stance of fellow opponents, it deliberately misrepresented the efforts of the proposed Waiver.

Second, the issue of waiving IP rights was not limited to patents. In the TRIPS Council meetings, Waiver proponents had repeatedly argued that the flexibilities available for use in the case of patents, must also be made workable for other IP rights. The other clarifications presented in EU's draft text added nothing new to the working mechanism of the Article 31 or

⁶⁹ Communication from the European Union, *Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property*, WTO Doc. IP/C/W/680 (June 4, 2021); Communication from the European Union, *Draft General Council Declaration on the TRIPS Agreement and Public Health in the circumstances of a Pandemic*, WTO Doc. IP/C/W/681 (June 18, 2021).

⁷⁰ TRIPS Agreement art. 31(b), *supra* note 13.

⁷¹ Doha Declaration, *supra* note 21, ¶ 5 (c).

⁷² Doha Declaration, *supra* note 21.

Article 31 *bis* beyond elaborating upon what was already present in the text of the TRIPS provisions. It was increasingly apparent that the EU's draft text neither offered any serious clarification nor did it address the outstanding concerns raised by the Waiver proponents.

Split between the divergences of the two proposals, the TRIPS waiver debate entered into another phase at the TRIPS Council meeting held in June 2021. The number of members supporting the Waiver had reached above 100, of which 63 were its co-sponsors. Growing support meant that the Waiver proponents were successful in initiating text-based negotiations at the June meeting.⁷³ While talks on the text would start immediately after the meeting, India proposed that, considering the severity of the rising COVID-19 infections, members must aim to finish the negotiations by the end of July.⁷⁴

The current circumstances reveal that that timeline was not only ambitious, it had resulted in little to no headway. As of September 2021, while the waiver was being co-sponsored by 64 members, opposition from the UK, the EU and Switzerland remained the key roadblock. While the EU wished for convergence at the TRIPS Council meetings held in September and October 2021, leaks from the EU's Directorate-General for Trade showed that it had explicitly dismissed the Waiver.⁷⁵ Another leak made it apparent that the EU's understanding of 'convergence' was based on expanding its proposal for easing the operation of TRIPS flexibilities contained in Article 31 and 31 *bis*.⁷⁶ As before, this would do nothing to address the issues in relation to trade secrets or undisclosed information, which were brought up by the Waiver proposal. At the opposite end, the Waiver co-sponsors circulated another text in the TRIPS Council, summarizing the context and rationale behind the Waiver.⁷⁷ In sum, as the TRIPS Council

⁷³ D. Ravi Kanth, *WTO Members agree to text-based negotiations on revised TRIPS waiver*, THIRD WORLD NETWORK (June 11, 2021), <https://www.twm.my/title2/wto.info/2021/ti210606.htm>.

⁷⁴ Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting held in the Centre William Rappard on 8, 9 and 29 June 2021*, WTO Doc. IP/C/M/100/Add.1, ¶ 409 (Oct. 20, 2021).

⁷⁵ Ashleigh Furlong (@ashleighfurlong), TWITTER (Oct. 14, 2021, 6:53 PM), <https://twitter.com/ashleighfurlong/status/1448640647263571969>.

⁷⁶ Daniel Marans, *New European Vaccine Proposal Offers Limited Help to Developing Countries*, HUFFPOST UK (Oct. 13, 2021), https://www.huffpost.com/entry/european-union-covid-vaccine-intellectual-property-proposal_n_61664498e4b0f26084edbbff.

⁷⁷ Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Jordan, Kenya, The LDC Group, Malaysia, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe, *Waiver from Certain Provisions of The TRIPS Agreement for The Prevention, Containment and Treatment of Covid-19*, WTO Doc. IP/C/W/684 (Sept. 30, 2021).

Chairperson, Ambassador Dagfinn Sørli, observed, there had been very little change in the overall positions of the members.⁷⁸

Where was the US in all this? In the TRIPS Council meeting held in October, the US reiterated its support for the waiver proposal while stressing the need for consensus in decision-making.⁷⁹ On the same day, when USTR Tai was quizzed about the Waiver at an event in Geneva, she assured the audience that work was being undertaken behind the scenes, alluding to the imagery of a duck which appeared to be sitting still in the waters but vigorously paddling its leg underneath.⁸⁰ Public reports, however, told a different story: that of two flocks of ducks in Lake Léman, each paddling in the opposite direction as the US watched on.⁸¹

Even in the weeks prior to MC12, there were no public reports of a change in stance. At a stocktake exercise conducted in October 2021, Ambassador Sørli reported to the General Council that in the TRIPS Waiver debate, each camp had more or less stuck to their guns.⁸² The writing on the wall was becoming apparent: despite the numerous multilateral, bilateral and small-group meetings being held each week,⁸³ there were little signs of any convergence regarding what the TRIPS Waiver debate will achieve at the upcoming Ministerial Conference.⁸⁴

III. CONCLUSION

In chronicling the rather recent history of the TRIPS waiver debate, this article shares the fate of the Italian chronicler Giovanni Villani. Villani, who chronicled life in Florence, remains famous for never finishing a sentence telling of the end of the Black Death, on account of his own demise from the plague.⁸⁵ Much the same, we remain too ill-equipped – and too out of time – to

⁷⁸ D. Ravi Kanth, *EU, Switzerland, UK continue opposition, amid support for TRIPS waiver*, THIRD WORLD NETWORK (Sept. 16, 2021), <https://www.twn.my/title2/wto.info/2021/ti210913.htm>.

⁷⁹ Priti Patnaik, *Examining the “subtle shift” in the TRIPS Waiver talks*, GENEVA HEALTH FILES (Oct. 15, 2021), <https://genevahealthfiles.substack.com/p/examining-the-subtle-shift-in-the>.

⁸⁰ Jamey Keaten, *US reaffirms support for easing WTO rules on COVID vaccines*, AP NEWS (Oct. 14, 2021), <https://apnews.com/article/coronavirus-pandemic-technology-business-geneva-global-trade-ad794a94ff05a179dd5ddf329b6ce4f7>.

⁸¹ Alan Beattie, *Talks to waive patents on Covid vaccines are ‘stuck’, WTO head warns*, FINANCIAL TIMES, (Nov. 25, 2021), <https://www.ft.com/content/b9a66140-f031-4ed6-9048-f6029832c511>.

⁸² General Council, *Informal Heads of Delegation – Monday, 25 October 2021 – MC12 October stocktake*, WTO Doc. JOB/GC/279, ¶ 2.2-2.8 (Oct. 26, 2021).

⁸³ D. Ravi Kanth, *EU & allies adopt “diversionary” tactics on TRIPS waiver at WTO*, THIRD WORLD NETWORK (Nov. 8, 2021), <https://twn.my/title2/wto.info/2021/ti211112.htm>.

⁸⁴ Priti Patnaik, *The Emerging Path to the TRIPS Waiver*, GENEVA HEALTH FILES (Nov. 12, 2021), <https://genevahealthfiles.substack.com/p/the-emerging-path-to-the-trips-waiver>.

⁸⁵ OLE JØRGEN BENEDICTOW, *THE BLACK DEATH, 1346-1353: THE COMPLETE HISTORY* 69 (2006).

estimate the outcome of the TRIPS Waiver debate as we approach MC12. However, an overview of these discussions does allow us to frame some key takeaways at this stage.

First, the Waiver proposal did not appear out of the blue. While the pandemic presented the precise circumstances for it, the Waiver co-sponsors had crafted a clear strategy by voicing their concerns on the limitations of the TRIPS flexibilities in the face of a pandemic-like crisis. Second, the Waiver proposal presented a ‘high-demand ask’ by calling for the waiver of obligations under entire Parts of the TRIPS, notwithstanding its duration. This was possible only because the proponents drew heart from the swelling support among civil society actors and the volte-face of the US. And because the initial proposal presented a high-standard ask in the first go, it enabled the co-sponsors to table a ‘revised’ proposal which offered little in the way of a substantial revision. Third, while the USTR’s change in stance was a key milestone in the TRIPS waiver debate, the US has done precious little to argue anyone’s cause in it – giving increased impetus to the idea that the volte-face was nothing but a symbolic act.⁸⁶

Fourth: at the other end of the debate, the opponents, led by the EU, find themselves increasingly isolated. Under immense pressure to make their opposition understandable, the camp has chosen to present interventions and proposals in this debate which drag it back to the original question: are the in-built flexibilities of TRIPS enough to deal with a crisis of this proportion? The nature of the debate embodies an anxiety that these flexibilities cannot meet the challenge. Any point of ‘convergence’ or resolution in the foregoing waiver debate then must reflect an effort to rework the global IP regime to be an adept facilitator times of crisis like the COVID-19 pandemic.

⁸⁶ Gabriele Steinhauser et. al., *Prospects of Intellectual-Property Waiver on Covid-19 Vaccines Fade*, THE WALL STREET JOURNAL (Nov. 18, 2021), [wsj.com/articles/prospects-of-intellectual-property-waiver-on-covid-19-vaccines-fade-11637251190](https://www.wsj.com/articles/prospects-of-intellectual-property-waiver-on-covid-19-vaccines-fade-11637251190).