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THE WAIVER OF THE TRIPS AGREEMENT FOR COVID-19 AT THE WTO: A RHETORICAL ANALYSIS

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Abstract
This article presents a rhetorical analysis of the discussions and debates at the WTO’s TRIPS Council regarding the request submitted by India and South Africa for a waiver of certain obligations under the TRIPS Agreement in response to the COVID-19 pandemic. Considering the engagement in ‘rhetorical action’ by both sides of the COVID-19 waiver proposal debate, the article explores whether the discussions, debates, and negotiations at the TRIPS Council regarding the proposed waiver is likely to produce any useful solution. The article is structured into three main sections. Section 1 presents a brief overview of the role of the TRIPS Council in international intellectual property law. Section 2 examines both the waiver proposal by India and South Africa on the one hand and the counter-proposal by the EU on the other hand. Section 3 contains a rhetorical analysis of the discussions and debates surrounding the waiver proposal at the TRIPS Council.

Introduction
The COVID-19 pandemic has once again brought the World Trade Organisation (WTO) and other international institutions into the spotlight. Specifically, as it relates to intellectual property rights, the WTO’s Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) is once again at the centre-stage for discussions and debates regarding what should be the precise and appropriate role of intellectual property rights in a public health crisis such as a pandemic.

There is a sense of déjà vu in this regard because, in the early 2000s, just around 6 years after the entry into force of the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the TRIPS Council had to provide a response to the demands of developing and least-developed countries for greater access to antiretroviral medicines due to the HIV/AIDS epidemic.1 The demands made by developing and least-developed countries at the TRIPS Council eventually led to the adoption of the Declaration on the TRIPS Agreement

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and Public Health at the WTO’s Ministerial Conference in Doha (Doha Declaration) in November 2001.²

The Doha Declaration kick-started a process that eventually culminated in the amendment of the TRIPS Agreement via Article 31bis which is aimed at facilitating the use of compulsory licensing to export patented medicines to countries that lack (or possess insufficient) domestic manufacturing capacity.³ Article 31bis of the TRIPS Agreement waives the obligations under Article 31(f) of the TRIPS Agreement.⁴ While the waiver codified in Article 31bis is indeed a solution, it is questionable whether it is in fact a useful solution as it has only been used once, prior to the COVID-19 pandemic, to export drugs from Canada to Rwanda.⁵

In October 2020, almost 20 years after the adoption of the Doha Declaration, in response to the COVID-19 pandemic, India and South Africa tabled a proposal before the TRIPS Council requesting for the waiver of certain obligations under the TRIPS Agreement.⁶ The proposal seeks a waiver of the obligations relating to the implementation and enforcement of the provisions relating to copyright, industrial designs, patent rights, and the protection of undisclosed information under the TRIPS Agreement. However, as will become evident from the analysis below, most of the discussions and debates on the waiver proposal have focused on patent rights and the protection of undisclosed information because a key aim of the waiver proposal is to scale up the global manufacturing capacity for vaccines to combat COVID-19. This proposal has been opposed by some other WTO members, principally developed countries, and it is equally opposed by the European Union (EU) which has submitted its own


³ Paragraph 6 of the Doha Declaration states that: ‘WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.’ As a result of this, the WTO’s General Council, in order to implement paragraph 6 of the Doha Declaration, adopted a decision in August 2003 to temporarily waive the obligations in Articles 31(f) & (h) of the TRIPS Agreement. WTO, ‘Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health’ Decision of 30 August 2003, WT/L/540, (2 September 2003). Thereafter, in December 2005, the General Council adopted a decision to amend the TRIPS Agreement by making the temporary waivers a permanent part of the TRIPS Agreement. WTO, ‘Amendment of the TRIPS Agreement’, Decision of 6 December 2005, WT/L/641, (8 December 2005). This amendment to the TRIPS Agreement, i.e., Article 31bis, entered into force on 23 January 2017.

⁴ Article 31(f) of the TRIPS Agreement provides that the grant of a compulsory licence ‘shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use’.


counter-proposal. As at the time of writing in early 2022, the TRIPS Council has not yet been able to reach any consensus on this issue.

This article critically evaluates the discussions and debates regarding the waiver proposal at the TRIPS Council from a rhetorical perspective. Morin and Gold have contended that ‘when consensus-seeking is elevated to the status of procedural norm’, as is the case with the decision making process at the WTO, ‘it is likely to bring participants into a position of “rhetorical action.”’ They define ‘rhetorical action’ as the ‘strategic deployment of an organized set of claims with the purpose of convincing an audience or depriving opponents of rhetorical materials’. Moreover, as they point out, ‘rhetorical action’ is ‘based on using arguments to persuade others but without a willingness to give up on maximizing one’s own gains.’ This article explores how the key actors involved in the debates surrounding the waiver proposal have engaged in ‘rhetorical action’. Due to constraints of space, the focus here will be on India and South Africa (as proponents of the waiver proposal) on the one hand and the EU (as opponents of the waiver proposal) on the other hand. The analysis here is based on the minutes of the TRIPS Council meetings between October 2020 and June 2021 where the waiver proposal has been debated and discussed.

Specifically, this article critically highlights how the key actors involved in the debates on the waiver proposal have employed the rhetorical device known as ‘narrative’ in presenting their case both for and against the proposal. In other words, this article shows how both the proponents and opponents of the waiver have engaged in a careful selection of key ideas, facts, and issues in making their case to the TRIPS Council. In doing this, the article makes the case that neither side is presenting or attempting to present the complete picture regarding the precise and appropriate role of intellectual property rights in the fight against COVID-19. As Reyman points out:

…narratives, particularly as they appear in discourse about the law, participate in legitimizing and normalizing certain states through their selection of content. Narratives do not relate objective facts and complete pictures of the way the world operates, but rather offer different versions of the truth from various perspectives about the way the world should be. While narratives appear as coherent wholes, no story can include all there is to tell; a narrative is, by nature, a rendering. It is constrained by time, with a set cast of characters, a selection of events, and a resolution point … These selections contribute to the rhetorical work of narratives, creating versions of

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9 Ibid.

10 Ibid.

11 The analysis in this article is based on the minutes of the meetings of the TRIPS Council as recorded in the following documents: WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 15-16 October and 10 December 2020, IP/C/M/96/Add.1, (16 February 2021); WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 23 February 2021, IP/C/M/97/Add.1, (7 April 2021); WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 8, 9, and 29 June 2021, IP/C/M/100/Add.1, (20 October 2021).
experience that define the terms of a conflict and its appropriate resolution while presenting a given version as the natural or complete story. Thus, with regard to the debates on the waiver proposal at the TRIPS Council, it is pertinent to ask what both the proponents and opponents are either including, or excluding, in their narratives before the Council and what are the potential implications of engaging in such ‘rhetorical action’. Therefore, this article is not aimed at supporting or opposing the waiver proposal. Rather, it shows how the negotiations on the waiver proposal may not necessarily produce a solution that will be useful in the long run.

In this regard, it is worth recalling that Article 31bis of the TRIPS Agreement codifies a waiver that was originally adopted by WTO members in 2003. However, as widely acknowledged by a number of scholars, the waiver mechanism in Article 31bis has not really been helpful in terms of facilitating access to medicines in countries with no or insufficient manufacturing capacity. Morin and Gold have attributed this to the fact that the 2003 waiver decision is the result of the procedural norm of consensus-seeking at the WTO which fosters “rhetorical action” on the part of negotiators and which ultimately produces unhelpful outcomes or agreements. This article thus contends that, considering the engagement in ‘rhetorical action’ by both sides of the COVID-19 waiver proposal debate, unless there is a change in this regard, it is highly likely that any outcome or agreement (if there is one) may be an unworkable or unhelpful agreement.

The article is structured into three key sections. Section 1 presents a brief overview of the role of the TRIPS Council in international intellectual property law. Section 2 examines both the waiver proposal by India and South Africa on the one hand and the counter-proposal by the EU on the other hand. Section 3 contains a rhetorical analysis of the discussions and debates surrounding the waiver proposal at the TRIPS Council.

1. The Role of the TRIPS Council in International Intellectual Property Law

The TRIPS Council plays a crucial role in international intellectual property law. Article IV.5 of the Agreement Establishing the WTO (AEWTO) establishes the TRIPS Council as the organ of the WTO responsible for overseeing the functioning of the TRIPS Agreement. Considering the preeminent status of the TRIPS Agreement in international intellectual property law, the

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15 Jean-Frédéric Morin and E Richard Gold (n 8) 581 (noting that, “…a procedural norm can influence both process and outcome. The procedural norm of consensus-seeking brought all interlocutors into a process of rhetorical action that led to an “unworking agreement”. This situation is arguably common in world politics, as the procedural norm of consensus-seeking seems to be spreading in multilateral settings, especially in contexts in which economic, social, and environmental objectives converge.”). They further note at 580 that an “unworking agreement” is made of “sham standards” that allows ‘a claim to the de jure existence of a mechanism and [relieves] pressures for the continuation of the debate as previously framed.’
role that the TRIPS Council plays (and can play) in shaping the direction and content of international intellectual property law cannot be over-emphasised. Article 68 of the TRIPS Agreement provides some elaboration on the functions of the TRIPS Council and it states that:

The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members’ compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights. It shall carry out such other responsibilities as assigned to it by the Members, and it shall, in particular, provide any assistance requested by them in the context of dispute settlement procedures. In carrying out its functions, the Council for TRIPS may consult with and seek information from any source it deems appropriate. In consultation with WIPO, the Council shall seek to establish, within one year of its first meeting, appropriate arrangements for cooperation with bodies of that Organization.16

From the above text, one can discern a number of roles. First, the TRIPS Council is charged with monitoring the operation of and the compliance of WTO members with the TRIPS Agreement. This provides a useful forum for ventilating grievances concerning, for instance, the violation of or non-compliance with the TRIPS Agreement by a WTO member and it can potentially be used as a precursor to the initiation of dispute settlement proceedings. Second, the TRIPS Council is meant to provide a forum for WTO members to consult with each other on topics and issues concerning the trade-related aspects of intellectual property rights. This arguably provides a basis for the TRIPS Council to engage in discussions on issues such as patent rights and access to medicines in developing countries. This equally makes the TRIPS Council an appropriate forum for WTO members to discuss and examine the role of intellectual property rights in the fight against the COVID-19 pandemic. Third, WTO members can assign responsibilities to the Council including requesting for the Council’s assistance in the context of dispute settlement procedures. Fourth, the TRIPS Council has an obligation to make arrangements for cooperation with the World Intellectual Property Organization (WIPO).

Another key function of the TRIPS Council that can be found in the AEWTO is the one relating to the consideration of requests for waivers concerning the TRIPS Agreement. Article IX.3(b) of the AEWTO provides that all waiver requests regarding the TRIPS Agreement must first be submitted to the TRIPS Council for consideration for a period not exceeding 90 days and, after 90 days, the TRIPS Council is meant to submit a report on the waiver request to the Ministerial Conference. If there is no consensus, a decision can be taken by the Ministerial Conference to grant the waiver request by the vote of three-fourths of the WTO members. However, given the usual practice of seeking consensus at the WTO,17 in reality, where no consensus has been reached on a waiver request, further consultations are held in order to arrive at a consensus.18

17 See Article IX.1 of the AEWTO which provides in part that: “The WTO shall continue the practice of decision-making by consensus followed under GATT 1947. Except as otherwise provided, where a decision cannot be arrived at by consensus, the matter at issue shall be decided by voting.”
18 See James Harrison, ‘Legal and Political Oversight of WTO Waivers’ (2008) 11(2) Journal of International Economic Law 411, 412 (noting that, ‘A request for a waiver should first be submitted to the specific Council responsible for administering the agreement from which a waiver is sought. However, a formal decision is made by the Ministerial Conference or General Council. As with all other decisions in the WTO, Member States should attempt to seek consensus on the grant of a waiver. In the case of a waiver, on the other hand, the search for
Importantly, as noted in the introduction, it is this practice of consensus-seeking that encourages states to engage in ‘rhetorical action’ which ultimately leads to the adoption of unhelpful solutions and agreements.

Furthermore, Article X.1 of the AEWTQ empowers the TRIPS Council to submit to the Ministerial Conference proposals to amend the provisions of the TRIPS Agreement. Thus, the 2003 decision that waived the obligation contained in Article 31(f) of the TRIPS Agreement was subsequently submitted for adoption as a permanent amendment to the TRIPS Agreement in 2005. This amendment eventually entered into force as Article 31bis of the TRIPS Agreement in 2017 after it was accepted by two-thirds of WTO members. Therefore, discussions and negotiations (including consideration of waiver requests) at the TRIPS Council can potentially lead to an amendment of the TRIPS Agreement. Thus, as demonstrated by the adoption of Article 31bis of the TRIPS Agreement, the consideration of a waiver request can ultimately result in norm-setting in international intellectual property law via an amendment of the text of the TRIPS Agreement.

2. India and South Africa’s Waiver Proposal and the EU’s Counter-Proposal

Prior to analysing the debates and discussions surrounding the waiver proposal, it is necessary to examine the precise content of the waiver proposal (as well as the EU’s counter-proposal). In October 2020, in response to the COVID-19 pandemic, India and South Africa tabled a proposal before the TRIPS Council requesting for the waiver of the obligations of certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19. In their communication to the TRIPS Council in this regard, India and South Africa stressed the importance of ensuring that intellectual property rights do not become barriers to timely access to affordable medical products needed to combat COVID-19:

…it is important for WTO Members to work together to ensure that intellectual property rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products

consensus is specifically time limited so that after ninety days, a vote may be taken. The consent of three-fourths of the Members is needed for the adoption of a waiver. Although Article IX.3 [of the AEWTQ] provides for voting, the Chair of the General Council has stated that decisions on waivers will ordinarily be sought in accordance with Article IX.1. In other words, consensus is to be preferred to voting.’); WTO, ‘Statement of the President of the General Council, Decision-Making Procedures under Articles IX and XII of the WTO Agreement, as agreed by the General Council on 15 November 1995,’ (24 November 1995) WT/L/93. It should be noted that, in accordance with Article IV.2 of the AEWTQ, the General Council of the WTO is empowered to conduct the functions of the Ministerial Conference in the intervals between the meetings of the Ministerial Conference.

including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19.23

Observing that there are ‘several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients’,24 they therefore requested for the waiver of certain obligations under the TRIPS Agreement. A major component of the waiver request is the contention of the sponsors regarding the difficulties that developing countries face when they use or try to use the existing flexibilities in the TRIPS Agreement. Indeed, the sponsors stressed that Article 31bis of the TRIPS Agreement, which as noted in the introduction codifies a waiver decision originally adopted in 2003, is not particularly helpful to countries with insufficient or no manufacturing capacity. According to the sponsors:

…many countries especially developing countries may face institutional and legal difficulties when using flexibilities available in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). A particular concern for countries with insufficient or no manufacturing capacity are the requirements of Article 31bis and consequently the cumbersome and lengthy process for the import and export of pharmaceutical products.25

The operative paragraphs of the waiver request (annexed to the communication to the TRIPS Council as a draft decision text) are reproduced below:

1. The obligations of Members 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, shall be waived in relation to prevention, containment or treatment of COVID-19, for [X] years from the decision of the General Council.

2. The waiver in paragraph 1 shall not apply to the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Article 14 of the TRIPS Agreement.

3. This decision is without prejudice to the right of least developed country Members under paragraph 1 of Article 66 of the TRIPS Agreement.

4. This waiver shall be reviewed by the General Council not later 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.

5. Members shall not challenge any measures taken in conformity with the provision of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through the WTO’s Dispute Settlement Mechanism.

The text of the waiver request reveals a number of things about the objective and scope of the proposed waiver. Firstly, the proposal seeks a waiver of the obligations relating to the implementation and enforcement of the provisions relating to copyright, industrial designs, patent rights, and the protection of undisclosed information under the TRIPS Agreement.

23 Ibid [3].
24 Ibid [9].
25 Ibid [10].
However, with regard to copyright, Article 14 of the TRIPS Agreement is specifically exempted from the scope of the waiver request. Secondly, the waiver is aimed at the prevention, containment, or treatment of COVID-19. Thirdly, the duration of the waiver is not specified. Understandably and unsurprisingly, the waiver proposal was supported by a number of developing countries but it was opposed by developed countries including the United States and the European Union. However, in May 2021, the United States eventually expressed its support for the waiver proposal although this support is strictly limited to the production of vaccines.26

Subsequently, on 25 May 2021, India, South Africa, and other co-sponsors submitted a revised waiver request to the TRIPS Council. According to the co-sponsors of the revised text, the submission of the revised waiver request is aimed at facilitating ‘text-based discussions, taking into account the discussions and feedback received’.27 The revised text does contain some clarifications regarding the scope and duration of the waiver proposal. The operative paragraphs of the revised waiver proposal are reproduced below:

1. The obligations of Members 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, shall be waived in relation 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.

2. This waiver shall be in force for at least 3 years from the date of this decision. The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver.

3. The waiver in paragraph 1 shall not apply to the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Article 14 of the TRIPS Agreement.

4. This decision is without prejudice to the right of least developed country Members under paragraph 1 of Article 66 of the TRIPS Agreement.

5. This waiver shall be reviewed by the General Council not later 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.

6. Members shall not challenge any measures taken in conformity with the provision of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through the WTO's Dispute Settlement Mechanism.


As can be seen from the revised text, some key changes have been made to the original text. First, while the revised waiver proposal still requests for a waiver of the obligations to implement the provisions relating to copyright, industrial designs, patent rights, and the protection of undisclosed information under the TRIPS Agreement, this aspect of the request now specifically includes a request for a waiver of the obligations to enforce these parts of the TRIPS Agreement under Part III of the TRIPS Agreement. In other words, the co-sponsors were now specifically requesting a waiver of the obligations to apply provisions of the TRIPS Agreement dealing with enforcement with regard to copyright, industrial designs, patents, and the protection of undisclosed information.

Second, the co-sponsors equally clarified the aim of the waiver. While the initial proposal was aimed at the ‘prevention, containment or treatment of COVID-19’, the revised text now states that the waiver is ‘in relation 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.’

Third, the duration of the waiver is now clearly stated in the revised text. According to the revised waiver proposal, the waiver ‘shall be in force for at least 3 years from the date of this decision.’ After 3 years, the General Council shall ‘review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver.’ The original waiver did not clearly specify the duration of the proposed waiver.

Between October 2020 when the initial proposal for a waiver was submitted and May 2021 when the revised waiver proposal was submitted to the TRIPS Council, India and South Africa were able to secure the support of more countries. Also, as noted above, the United States equally expressed its support for the waiver albeit strictly limited to vaccines. Nevertheless, a number of other developed countries remained steadfast in their opposition to the revised waiver proposal. In this regard, the EU is worth singling out. The EU did not just oppose the revised waiver proposal, it equally submitted its own counter-proposal.

The EU’s counter-proposal is contained in two documents submitted to the TRIPS Council in June 2021. The first document is titled ‘Urgent Trade Policy Responses to the Covid-19 Crisis: Intellectual Property’ which was submitted to the TRIPS Council on the 4th of June 2021. The second document is a ‘Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic’ which was submitted to the TRIPS Council on the 18th of June 2021.

The main thrust of both documents is that the EU takes the view that a clarification of the provisions relating to compulsory licensing in Articles 31 and 31bis of the TRIPS Agreement is a better response to the COVID-19 pandemic. Specifically, the relevant portion of the operative paragraphs of the text of the EU’s proposed Draft Declaration provides that:

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30 Ibid.
We agree that:

a. A pandemic is ‘a national emergency or other circumstances of extreme urgency’ within the meaning of Article 31(b) of the TRIPS Agreement. For the purposes of issuing a compulsory licence pursuant to Articles 31 and 31bis of the TRIPS Agreement, a Member may waive the requirement of making efforts to obtain authorization from the right holder, provided for in Article 31(b).

b. In the circumstances of a pandemic and to support manufacturers ready to produce vaccines or medicines addressing the pandemic at affordable prices for low- and middle-income countries, a Member may provide, for the purposes of determining the remuneration to be paid to the right holder pursuant to Article 31(h) and paragraph 2 of Article 31bis of the TRIPS Agreement, that the remuneration reflects the price charged by the manufacturer of the vaccine or medicine produced under the compulsory licence.

c. In the circumstances of a pandemic, for the purposes of Article 31bis and paragraph 2.c) of the Annex to the TRIPS Agreement, the exporting Member may provide in one single notification a list of all countries to which vaccines and medicines are to be supplied by the exporting Member directly or through indirect means, including international joint initiatives that aim to ensure equitable access to the vaccines or medicines covered by the compulsory licence. It shall be presumed that such joint initiatives supply those vaccines and medicines to eligible importing Members within the meaning of paragraph 1.b) of the Annex to the TRIPS Agreement.

The EU’s Draft Declaration can be read as a tacit admission that the existing flexibilities in the TRIPS Agreement, especially those contained in Articles 31 and 31bis of the Agreement, are insufficient to address the needs of developing countries with regard to the COVID-19 pandemic. Nevertheless, the counter-proposals contained in the Draft Declaration arguably do not go far enough in terms of rectifying the situation.

The first point of the EU’s counter-proposal, i.e., point (a), is claimed by the EU as a clarification of Article 31(b) of the TRIPS Agreement. Article 31(b) of the TRIPS Agreement provides in part that the requirement to make efforts to obtain a voluntary license from the right holder on reasonable commercial terms within a reasonable period of time prior to the grant of a compulsory license ‘may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.’ It is not really clear how the EU’s counter-proposal offers any further clarity to the already clear text of Article 31(b) of the TRIPS Agreement. Even without the EU’s counter-proposal, it is highly doubtful

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31 WTO (Council for TRIPS) ‘Urgent Trade Policy Responses to the Covid-19 Crisis: Intellectual Property’ (4 June 2021) IP/C/W/680 [10] (noting that: ‘Point (a) refers to Article 31(b) of the TRIPS Agreement, which provides that a compulsory licence may be granted if "the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have been unsuccessful for a reasonable period of time". Article 31(b) further provides that "this requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use". The EU proposes to clarify that the circumstances of a pandemic fulfill the requirement of a national emergency and therefore the requirement to demonstrate the efforts to negotiate for a certain period of time can be waived. Waiving this requirement ensures that any WTO member can proceed quickly to issue a compulsory licence…’).
whether any WTO member can seriously challenge a claim that the COVID-19 pandemic is a circumstance of national emergency or a circumstance of extreme urgency.

In relation to the second point of the EU’s counter-proposal, the EU claims that this is aimed at clarifying the provisions of Article 31(h) of the TRIPS Agreement in the context of a pandemic. Article 31(h) of the TRIPS Agreement provides that, where a compulsory licence has been granted, ‘the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization’. In this regard, the EU is proposing that, in the context of a pandemic, the remuneration paid to the right holder should reflect ‘the price charged by the manufacturer of the vaccine or medicine produced under the compulsory licence.’ While this is not completely unhelpful, one could however argue that the text of Article 31(h) of the TRIPS Agreement is already flexible enough to permit states to do what the EU is now proposing that states should do in the context of a pandemic.

The third point of the EU’s counter-proposal can be regarded as, more or less, an explicit admission of the complexities associated with using the waiver mechanism contained in Article 31bis of the TRIPS Agreement. This indicates that the EU concedes that, as it currently exists, Article 31bis of the TRIPS Agreement is quite unhelpful in the fight against COVID-19. Indeed, as at the time of writing, no WTO member has successfully used Article 31bis of the TRIPS Agreement in response to the COVID-19 pandemic. In its explanation of this particular aspect of its proposal, the EU stated that:

Under point (c), the EU proposes to tackle a procedural aspect of Article 31bis and the Annex to the TRIPS Agreement. Under the procedure established in the Annex, each eligible importing Member makes a notification to the TRIPS Council that specifies in particular the names and quantities of the product needed. At the same time, the exporting Member must also notify the Council for TRIPS of the grant of the licence, including any conditions attached to it. The exporting Member must include the information of the licensee, the product and the quantities, the duration of the licence and the "country(ies) to which the product(s) is (are) to be supplied". The EU proposes that in the circumstances of a pandemic, the WTO Members agree that the exporting Member may provide in one single notification a list of all countries to which vaccines and therapeutics are to be supplied directly ... The objective is to ensure that with a single notification providing the elements required under Article 31bis for transparency purposes, the export can go ahead.\(^{33}\)

While this is a welcome proposal, one wonders whether it would have been more helpful for the EU to propose an amendment of the text that is at the source of this problem, i.e., Article 31(f) of the TRIPS Agreement. Article 31(f) of the TRIPS Agreement provides that the grant

\(^{32}\)Ibid [11] (noting that: ‘Point (b) concerns a clarification of Article 31(h) on the adequate remuneration to be paid to the right holder. Article 31(h) provides "that the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation". Paragraph 2 of Article 31bis specifies this rule for circumstances of export to countries that lack manufacturing capacity. It provides that in a situation of a compulsory licence for export purposes the adequate remuneration is to be determined taking into account the economic value of the licence to the importing member. The EU proposes to clarify that in the circumstances of a pandemic, WTO Members can set the remuneration to the right holder at a level that reflects the price charged by the manufacturer of the vaccine or therapeutic under a compulsory licence. This would support production and supplies of vaccines and therapeutics at affordable prices to low and middle-income countries...’).\(^{33}\)Ibid [12].
of a compulsory licence should be ‘predominantly for the supply of the domestic market of the Member authorizing such use’. Thus, a proposal to, for instance, simply waive the requirements of Article 31(f) of the TRIPS Agreement in the context of a pandemic instead of tweaking the complex provisions of Article 31bis of the TRIPS Agreement would perhaps be a more realistic and beneficial proposal from the perspective of developing countries, especially those developing countries with insufficient or no domestic manufacturing capacity.

Thus, given the tokenistic nature of the EU’s counter-proposal in this regard, it is unsurprising that it has not helped to resolve the current impasse at the TRIPS Council regarding the debates surrounding the waiver proposal. Having considered the texts of the waiver proposal and the EU’s counter-proposal, it is now necessary to critically analyse how both sides of this debate have presented their case before the TRIPS Council.

3. A Rhetorical Analysis of the TRIPS Council’s Discussion of the Waiver Proposal

To start with, it must be acknowledged that both sides of the debate agree that the COVID-19 pandemic is a global problem that requires a global solution. However, beyond this, the parties are not agreed on what this global solution should be. Essentially, while India, South Africa, and the other co-sponsors of the waiver proposal believe that a waiver of some of the obligations under the TRIPS Agreement is the best global solution, opponents of the waiver proposal such as the EU believe that the protection of intellectual property rights is an integral part of any global solution to the pandemic. What follows below is a rhetorical analysis of the discussions and debates on the waiver proposal at the TRIPS Council.

As noted in the introduction, the focus will be on the contributions made by India and South Africa (as proponents of the waiver proposal) on the one hand and the EU (as opponents of the waiver proposal) on the other hand. Specifically, the rhetorical analysis shows how both sides of the debate have carefully selected issues, ideas, and facts in presenting their narratives to the TRIPS Council. Thus, the rhetorical analysis below shows how both sides have not really presented the complete picture regarding the precise and appropriate role of intellectual property rights in the fight against COVID-19 while arguing for or against the waiver proposal at the TRIPS Council.

3.1 Covid-19 is a Global Problem that requires a Global Solution

As noted above, one point on which both sides of the waiver proposal debate seem to be agreed upon is the fact the COVID-19 pandemic is a global problem that requires a global solution. As stressed by India at the October 2020 meeting of the TRIPS Council:

34 Due to space constraints, only some of the key issues debated by the parties will be analysed here.
35 According to South Africa, ‘COVID-19 does not respect national borders; nor does it care about the gross domestic product of a country, no country in the world can insulate itself, even the best plans will be laid to waste. Let us ensure that everyone has access to effective vaccines in the shortest possible time.’ WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 23 February 2021, IP/C/M/97/Add.1, (7 April 2021), para 18. The EU equally acknowledged the fact that covid-19 requires a global solution. It noted that there was a ‘need to find solutions for everyone, whether in the developed or developing countries, because it is a challenge we face together and because no one is safe until everyone is safe.’ WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 15-16 October and 10 December 2020, IP/C/M/96/Add.1, (16 February 2021), para 1026.
At the outset, we would like to emphasize that this is not a proposal only for India but for the global community at large. India may be having the required manufacturing capacity, the national legislations to cater to its needs but we believe that in a global pandemic, where every country is affected, we need a global solution.  

Nevertheless, while the proponents of the waiver proposal take the view that the waiver proposal is the best global solution, the opponents of the waiver proposal disagree with this view.

### 3.2 Are Intellectual Property Rights a Barrier or a Solution?

The proponents of the waiver proposal claim that intellectual property rights are hindering or could potentially hinder access to medical products. In presenting the original waiver to the TRIPS Council in October 2020, South Africa noted that ‘[i]t is evident from an array of lawsuits filed by private companies in different parts of the world for IP infringement on COVID-19 products. In the past few months, we have also seen that IPRs do come in the way of scaling up production of test kit reagents, ventilator valves, N95 respirators, therapeutics, fluorescent proteins and other technologies used in development of vaccines etc.’

The proponents of the waiver further claim that monopoly rights such as intellectual property rights are unnecessary for inventors to recoup their investments in situations such as the COVID-19 pandemic where governments have expended a lot of public funds on the...
development of medical products such as vaccines.\textsuperscript{41} The EU, however, disagrees with this perspective. While acknowledging that public funding has been provided to support the development of vaccines against COVID-19, it stressed that researchers and the pharmaceutical industry have equally ‘put extraordinary efforts into the development of future treatments and vaccines against COVID-19.’\textsuperscript{42} According to the EU, '[a] well-functioning intellectual property rights system is crucial to ensure that these efforts are adequately incentivised and rewarded.’\textsuperscript{43}

The EU equally questions whether intellectual property rights have been a real barrier with regard to access to COVID-19 related medical products. According to the EU, the problem here may be due to, \textit{inter alia}, an increase in demand and the lack of manufacturing capacity:

There is no indication that IPRs issues have been a genuine barrier in relation to COVID-19-related medicines and technologies. While we agree that maintaining continued supply of such medicines and technologies is a difficult task we all face, non-efficient and underfunded healthcare and procurement systems, spike in demand and lack of manufacturing capacity or materials are much more likely to have an impact on the access to those medicines and technologies.\textsuperscript{44}

Thus, in the EU’s view, rather than serving as a barrier, intellectual property rights can actually play a role in expanding access to COVID-19 vaccines.\textsuperscript{45} One could however argue that the debate regarding whether or not intellectual property rights are a barrier or a solution in this regard is only relevant to countries that already possess domestic manufacturing capacity to produce medicines and vaccines. Thus, for countries such as least-developed countries that are currently exempt from implementing the TRIPS Agreement\textsuperscript{46} but that equally lack domestic

\textsuperscript{41} Ibid [868] (India stating that: ‘…governments across the globe are supporting development of new health technologies, in particular vaccines by pouring billions of USD of public funds into research and development … Therefore, the often-repeated argument that monopoly rights are needed to allow the inventors to recoup their investment does not seem to apply in case of development of health products and technologies required for handling the ongoing COVID-19 crisis.’). In the same vein, South Africa contends that: ‘Never has there been a weaker case for the granting of monopolies. Governments have been funding the development of COVID drugs and vaccines, and no company is able to meet the global demand. In the context of COVID-19, despite the billions of taxpayer dollars invested in R&D, and announcements that COVID-19 vaccines should be considered a public good, no government has openly stated committed to this undertaking.’ Ibid [1164].

\textsuperscript{42} Ibid [1027].

\textsuperscript{43} Ibid. According to the EU at [1031]: ‘…The public funding and support is contributing significantly to the development of the future vaccines, potentially within a timeframe between 12 and 18 months. However, it is the researchers and the industry with their know-how, previous and current investment that will be delivering these new vaccines, including the running of clinical trials in parallel with investing in production capacity to be able to produce millions, or even billions, of doses of a successful vaccine. This work must be incentivised and adequately rewarded and the IPRs system is one the main economic incentives.’).

\textsuperscript{44} Ibid [1028].

\textsuperscript{45} Ibid [1271] - [1272] (According to the EU: ‘The challenges that we face are enormous. The manufacturing at huge scale, the distribution of vaccines, their storage and even their administering will test our financial capacity, our logistical skills and perhaps, most of all, our global collaboration and solidarity in the face of this crisis. We believe that the intellectual property system, with its checks and balances, does not stand in the way of these efforts. Indeed, it is part of the solution to the challenge of universal and equitable access to vaccines and COVID-19 treatments.’).

\textsuperscript{46} Least-developed countries were initially given ten years to implement the TRIPS Agreement (Article 66.1 of the TRIPS Agreement). This has been extended a number of times and the latest extension took place in July 2021 when they were granted a further extension till July 2034 with regard to the implementation of the TRIPS Agreement; see WTO (Council for TRIPS) ‘Extension of the Transition Period under Article 66.1 for Least Developed Country Members’ (29 June 2021) IP/C/88. In a separate decision, in November 2015, least-developed
manufacturing capacity, the debate on this particular issue is largely irrelevant as they will still need to depend on countries with domestic manufacturing capacity for the supply of medicines and vaccines. Whether or not countries that lack domestic manufacturing capacity may nevertheless still benefit from the proposed waiver is an issue that is addressed in section 3.4 below.

3.3 Are the Existing Flexibilities in the TRIPS Agreement Sufficient?

The proponents of the waiver proposal claim that the existing flexibilities contained in the TRIPS Agreement are insufficient to tackle the pandemic. They stress that even the waiver mechanism codified in Article 31bis of the TRIPS Agreement is unhelpful to countries with insufficient or no manufacturing capacity. As stated by South Africa:

…many countries especially developing countries may face institutional and legal difficulties when using flexibilities available in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). A particular concern for countries with insufficient or no manufacturing capacity are the requirements of Article 31bis and consequently the cumbersome and lengthy process for the import and export of pharmaceutical products.

The initial response of the EU to the claim that the existing flexibilities in the TRIPS Agreement are insufficient in the fight against COVID-19 was to disagree and instead claim that the existing flexibilities are indeed enough to respond to COVID-19. At the October 2020 meeting of the TRIPS Council, the EU contended that:

countries were granted a further extension till January 2033 with regard to the provision of patent protection for pharmaceutical products. See WTO (Council for TRIPS) ‘Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products’ (6 November 2015) IP/C/73.

With regard to Articles 31 and 31bis of the TRIPS Agreement, India pointed out that: ‘Article 31 compulsory licences are issued on a case-by-case, country-by-country basis according to national patent law procedures and practices. It is an impractical option if one takes into consideration the need for regional and international collaboration to scale up supply, the need to source materials from various countries, and the need for economies of scale to make manufacturing viable. We have already highlighted the limitations associated with the use of Article 31bis. Countries that have never utilised compulsory license or the Article 31bis mechanism will have to consider what are the national procedures for doing so, what to do if procedures do not exists, who should request this license, who should issue the license, what would be the adequate remuneration to be paid, what are the requirements of Article 31bis, can an importing country that has not implemented Article31bis in its national law utilise the provision, what are the Article 31bis requirements for the exporting country, what are the national law requirements in the exporting country. Many a times, countries also have to deal with pressures from other trading partners and from pharmaceutical companies while dealing with such issues. Given the urgency to save lives and the time it takes to get a compulsory license implemented on ground in most of developing countries, use of this flexibility in context of COVID-19 pandemic does not present a viable solution.’ WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 15-16 October and 10 December 2020, IP/C/M/96/Add.1, (16 February 2021), [1416].

Ibid [860]. This line of argument was also echoed by India at [870] (‘…with regard to existing flexibilities under the TRIPS Agreement, the same are not adequate to address the fast-changing landscape of COVID-19. Of particular concern for countries with insufficient or no manufacturing capacity is Article 31bis, which is limited to pharmaceutical products, and was not designed to address challenges arising from pandemics of this scale and magnitude. Medical devices like ventilators, dialysis machines etc. that are crucial for combating the ongoing pandemic, may not be covered under the scope of Article 31bis. There is a reason why the Special Compulsory Licensing system has been used only once. Requirements under this System that exporters and importers have to comply with, are extremely onerous and time-consuming, thereby rendering it of no practical utility towards handling the ongoing pandemic.’).
The TRIPS Agreement together with the principles endorsed in the Doha Declaration, is fit for purpose and allows for the necessary flexibilities in relation to IPRs protection, including in the case of a health emergency, such as the COVID-19 pandemic.

If all voluntary solutions failed and IP became a barrier to treatments or vaccines against COVID-19, mechanisms to overcome it are already available. The EU has consistently supported the use, where necessary and justified, of the flexibilities provided under the TRIPS Agreement and the Doha Declaration with the objective of ensuring effective access to medicines.

In particular, the TRIPS Agreement provides for the possibility, under certain conditions, of issuing a compulsory licence for local consumption of medicines and provides for fast-track procedures in health emergencies. The TRIPS Council Secretariat has, regularly and consistently, offered its services to any WTO Member that sees itself in the need of getting help to manage the process of Article 31bis. This was confirmed in the presentation we saw the previous day.

This system is accompanied by other inbuilt TRIPS flexibilities, applying to the various IP rights. In addition, we note that the least developed countries are exempt from the application of the TRIPS Agreement and, in particular, its pharmaceutical-related provisions.49

In response to this, South Africa countered by restating its previous position that the existing flexibilities are not enough and that the waiver proposal offers the best global solution in the circumstances:

We heard the refrain from the EU and others that the TRIPS Agreement is fit for purpose and its flexibilities are usable without limitation or any problem? We once again contest this notion. Delegations that have taken the floor to condemn this waiver proposal claim that that TRIPS flexibilities already include the option to issue compulsory licences where necessary.

The proposal for a waiver on certain IP provisions offers an expedited, open and automatic global solution that allows for uninterrupted collaboration in development and scale up of production and supply and that collectively addresses the global challenge facing all countries. Countries should continue to use TRIPS flexibilities to safeguard public health, including issuing compulsory licences and placing limitations on or making exceptions to exclusive rights.

However, the “case by case” or “product by product” approach required when using flexibilities to address IP barriers at the national level could be limiting during the pandemic. Some countries also face limitations with respect to their national laws, pressures from their trading partners, or lack the practical and institutional capacity required to exercise TRIPS flexibilities during the pandemic quickly and effectively. The existing mechanisms for compulsory licences under Article31 and Article 31bis of the TRIPS Agreement contain territorial and procedural restrictions that make the practice of issuing product-by-product compulsory licences a complex process, making it difficult for countries to collaborate. Article 31 requires that compulsory licences are

49 Ibid [1038] – [1041].
issued on a case-by-case basis and used predominantly to supply domestic markets, thereby limiting the ability of manufacturing countries to export to countries in need.

Article 31bis requires that any product produced and exported under a compulsory license be identified with specific packaging and quantities, which can lead to unnecessary delays in the context of COVID-19 where countries need urgent access to medical tools. There is even less experience in areas such as industrial designs, trade secrets, algorithms and copyright, applying compulsory licences to such areas may be legally complicated and novel.\(^\text{50}\)

The EU however eventually changed its tone regarding the difficulties experienced by developing countries with the use of the existing flexibilities under the TRIPS Agreement. At the meeting of the TRIPS Council in June 2021, the EU presented its own counter-proposal to the waiver proposal which centres on clarifying the rules regarding compulsory licensing in Articles 31 and 31bis of the TRIPS Agreement.\(^\text{51}\) As pointed out in section 2 above, one can construe the counter-proposal contained in the EU’s Draft Declaration as a tacit admission that the existing flexibilities in the TRIPS Agreement are insufficient to address the needs of developing countries with regard to the COVID-19 pandemic. The tokenistic nature of this counter-proposal has already been examined in section 2 above and will, therefore, not be repeated here.

The proponents of the waiver proposal are, therefore, correct in highlighting the fact that developing countries have experienced difficulties with using the flexibilities contained in the TRIPS Agreement. Indeed, the waiver mechanism codified in Article 31bis of the TRIPS Agreement has only been used once prior to the COVID-19 pandemic and (as at the time of writing) it has in fact not yet been successfully employed by any country in the context of the COVID-19 pandemic.

Nevertheless, one could also argue that without domestic manufacturing capacity, a number of the flexibilities in the TRIPS Agreement may not be particularly helpful. In this regard, it should be recalled that least-developed countries are currently exempt from implementing the TRIPS Agreement but this does not mean that they have the capacity to produce medicines and vaccines. Thus, even if the proposed waiver is adopted, the fact still remains that several least-developed countries would still be dependent on other countries that possess domestic manufacturing capacity for the supply of medicines and vaccines.

### 3.4 Will the Proposed Waiver Help Countries that Lack Manufacturing Capacity?

A key claim of the proponents of the waiver proposal is that the waiver would be helpful to countries that possess insufficient or no manufacturing capacity. As India contended at the

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50 Ibid [1153] – [1156].
51 WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 8, 9, and 29 June 2021, IP/C/M/100/Add.1, (20 October 2021), [279] (According to the EU: ‘The discussions in the Council for TRIPS since the start of the COVID-19 pandemic have identified aspects related to the use of compulsory licensing that, in the view of a number of WTO Members, limit the use of this tool. In order to address these aspects, provide more legal certainty and enhance the effectiveness of the system, the EU considers that all WTO Members should be ready to agree on the following: first, the pandemic is a circumstance of national emergency and therefore the requirement to negotiate with the right holder may be waived; second, to support manufacturers ready to produce vaccines or therapeutics at affordable prices, especially for low- and middle-income countries, on the basis of a compulsory licence, the remuneration for patent holders should reflect such affordable prices; and third, the compulsory licence could cover any exports destined to countries that lack manufacturing capacity... ’).
TRIPS Council meeting in October 2020 when the initial waiver request was presented to the Council: ‘we would like to emphasize that this proposal is, particularly important to cater for those who have insufficient or no manufacturing capacities in the health products required to combat the COVID crisis.’ At the meeting of the TRIPS Council in February 2021, South Africa also argued that the waiver proposal would help countries to tap into unused production capacity:

The Waiver Proposal constitutes a very real compromise that will immediately enable countries to tap into unused production capacity by accessing spare capacity in the developing world which will satisfy the ongoing demand for COVID-19 vaccines (including therapeutics and diagnostics) and will also negate the need for any donations from rich countries. Take the African continent for example: as a whole, Africa currently imports more than 80% of its pharmaceutical and medical consumables. This is unsustainable and puts the continental population of 1.3 billion people at the mercy of a few monopolistic companies. This is a recipe for disaster as we have witnessed not only with the COVID-19 pandemic but with all other diseases and pandemics that continue to affect the continent.

At the same meeting, India equally stated that, ‘[i]f the existing global manufacturing capacity can be used for mass manufacturing by providing legal certainty to manufacturers over [the] use of COVID-related IP, which is the chief objective of the Waiver, then humanity can accelerate the fight to win over the virus.’ However, India seems to have tacitly admitted that implementing the waiver alone may not necessarily be enough to increase global manufacturing capacity for the production of vaccines as the scaling up of production capacity may require further investments to either enhance existing capacity or to create new capacity:

…Once the Waiver is in place, the existing manufacturing capacity worldwide can be put to immediate use for production of COVID products. Our past experience suggests that if supported with adequate regulatory framework, vaccines are relatively quick and inexpensive to make. The other option is to scale up the existing capacity through brown-field investments which can be done in a few months. Yet another option is to invest in creating new capacity through green-field investments, a matter of a few quarters.

The proponents of the waiver proposal further contend in this regard that voluntary licences are not the best way to expand manufacturing capacity in response to COVID-19 due to the unwillingness of pharmaceutical companies to offer non-exclusive licenses with worldwide coverage. Thus, in the view of the proponents of the waiver proposal, only the proposed waiver can help to scale up manufacturing capacity across the globe.

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52 WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 15-16 October and 10 December 2020, IP/C/M/96/Add.1, (16 February 2021), [865].
53 WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 23 February 2021, IP/C/M/97/Add.1, (7 April 2021), [17].
54 Ibid [69].
55 Ibid [75].
56 WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 15-16 October and 10 December 2020, IP/C/M/96/Add.1, (16 February 2021), [869] (India stating that: ‘…we have heard from some Members in the previous meetings that voluntary licenses are the most appropriate solution to scale up manufacturing in response to COVID-19. However, the fact remains that not a single IP holder has shown willingness to commit to the
The EU however takes the view that voluntary licensing, and not the waiver proposal, can help to expand the manufacturing of COVID-19 vaccines. According to the EU:

What is most needed now, beyond developing vaccines, is the ramping up of manufacturing of vaccines and the best way of achieving that is by disseminating the technology and know-how of those who developed the vaccines through licensing arrangements. Manufacturing cannot take place without the required technology and know-how. In addition, we need these vaccines to be produced in a manner that ensures their efficacy and safety. Intellectual property is a key factor in providing a framework that enables these arrangements. Developers of vaccines can enter into manufacturing agreements, transfer technology and expand production with their licensees. Our main concern is that suspending the relevant IP rights will not enhance such collaboration and manufacturing but, to the contrary, will slow it down or even block it, to the detriment of all.57

In addition, the EU contended that, even if there is underused capacity anywhere in the world, the best way to utilise this capacity is through the transfer of technology and know-how and this can only be facilitated by intellectual property rights which provide a basis for collaboration.58 In this regard, the EU pointed out the examples of some pharmaceutical companies that had already entered into partnerships with companies in developing countries to facilitate the manufacturing and distribution of vaccines:

Many pharmaceutical companies have committed publicly and are already working closely with governments to ensure that the vaccines will be available and affordable to all who need them. We also see agreements on expanding manufacturing capacity, we understand that e.g. AstraZeneca entered into agreements with companies in various countries to support the manufacturing, procurement and distribution of vaccines. It also entered into a technology transfer agreement with Serum Institute of India to supply doses for low and middle-income countries. We also understand that Johnson &

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57 Ibid [1159].
58 The EU notes in this regard that: ‘Where such capacity exists and can be deployed quickly, the best way of using it to the fullest is by disseminating the technology and know-how of those who developed the vaccines through a collaboration with other companies that can contribute to the developers’ manufacturing capacity. Intellectual property is a key factor in providing a framework that enables this collaboration. This is because the IP system is crucial in providing a legal framework for the collaboration and dissemination of any new technology. The objective of an IP system is not merely to create exclusivity for the owner of intellectual property, but also to ensure the publication and dissemination of research results when otherwise they would remain secret. And this dissemination is precisely what we need now. The IP system enables commercialisation of the research results and their transfer through licensing agreements. Developers of vaccines can enter into manufacturing agreements, transfer technology and expand production with their licensees.’ WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 23 February 2021, IP/C/M/97/Add.1, (7 April 2021), [152] – [153].
Johnson entered into manufacturing service agreements for large-scale manufacturing for its vaccines. And there are other examples, also as regards collaboration to increase manufacturing of promising COVID-19 therapeutics.\(^{59}\)

It is not really clear how the proposed waiver would help countries with no or insufficient domestic manufacturing capacity. Crucially, even if the waiver can help to increase manufacturing capacity in other countries that possess such capacity, it is not entirely clear how private pharmaceutical companies can be compelled to disclose the necessary know-how and trade secrets that may be required to produce medical products such as vaccines.

Indeed, the EU had requested the proponents of the waiver proposal to ‘explain in more detail how concretely the waiver could operate with regard to the vaccine production, including the transfer of the required technology and know-how’.\(^{60}\) In response to this, India contended that:

…The EU has sought an explanation as to how the waiver could operate with regard to the vaccine production, including the transfer of the required technology and know-how…

…In the area of vaccines, there are two primary barriers, patents and protection of undisclosed information. Patents are used to protect various aspects of the underlying technology as well as the product itself.

In addition, manufacturing know-how, test data, and cell lines are needed to facilitate diversification of vaccine production. Hence the importance of addressing protection of undisclosed information under Article 39 of the TRIPS Agreement.

The wide range of patents and patent applications as well as exclusivity related to undisclosed information creates a complex and uncertain legal environment for scaling up vaccine development, production and supply. The waiver, if granted, would provide potential manufacturers the freedom to operate and achieve economies of scale, thereby incentivizing production and supply of therapeutics and vaccines.\(^{61}\)

While it is true that a waiver may make things easier for other potential manufacturers, besides the owners of patent rights, to engage in vaccine production, India’s response does not actually provide a concrete answer to the question of how private pharmaceutical companies with know-how and trade secrets regarding the production of vaccines can be compelled to transfer such to other manufacturers. This may not be a problem when it comes to the production of patented medicines. But it may arise with regard to the production of vaccines.\(^{62}\) If a key objective of the waiver proposal is to ramp up the production of vaccines, then this is a problem that requires a viable solution.

\(^{59}\) WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 15-16 October and 10 December 2020, IP/C/M/96/Add.1, (16 February 2021), [1275].

\(^{60}\) Ibid [1283].

\(^{61}\) Ibid [1419] – [1422]; South Africa also did not provide a satisfactory answer to this question. It simply stated in this regard that: ‘It is also worth recalling that Article 31 and 31bis only address patent barriers while there are also challenges with respect to protection of undisclosed information, a barrier which remains unaddressed. Our colleagues have addressed problems surrounding Article 39.3 so I will not go into the matter further.’ Ibid [1494].

\(^{62}\) As the EU pointed out: ‘Contrary to simple chemical medicines that are relatively easy to replicate, COVID-19 vaccines involve a complex biological process which requires the relevant know-how.’ WTO, Council for TRIPS, ‘Minutes of Meeting’, held on 8, 9, and 29 June 2021, IP/C/M/100/Add.1, (20 October 2021), [275].
Thus, it is unclear how a waiver would be useful with regard to the production of vaccines as patent rights are quite distinct from trade secrets and know-how. It is true that there could be some potential shortcomings in relation to relying on voluntary licences such as the inclusion of restrictive terms in licensing agreements or the inclusion of restrictions with regard to the territories where the licensed products can be supplied to. It is however far from certain that simply waiving intellectual property rights (in particular, the protection of undisclosed information) would encourage or compel private pharmaceutical companies to disclose their technical know-how or trade secrets to other potential manufacturers.63

Conclusion

In sum, a rhetorical analysis of the debates and discussions of the proposed waiver at the TRIPS Council between October 2020 and June 2021 reveals a number of things. First, both the proponents and the opponents of the waiver proposal agree that the COVID-19 pandemic is a global problem that requires a global solution. However, they differ with regard to what the appropriate global solution should be. Proponents of the waiver proposal believe that the waiver proposal is the best solution but opponents of the waiver proposal disagree with this.

Second, whether or not intellectual property rights are a barrier or a solution with regard to tackling the COVID-19 pandemic is only relevant to countries that possess domestic manufacturing capacity. Third, despite the difficulties with using the existing flexibilities in the TRIPS Agreement, only countries that possess domestic manufacturing capacity can even meaningfully consider utilising the existing flexibilities in the TRIPS Agreement to produce medicines and vaccines to combat COVID-19.

Fourth, a key claim of the proponents of the waiver proposal is that the proposed waiver would be helpful to countries that possess insufficient or no manufacturing capacity because it would help to scale up manufacturing capacity across the globe. However, even if it is true that there is unused production capacity waiting to be unlocked after the proposed waiver is adopted at the WTO, it is unclear how the proposed waiver can compel or encourage pharmaceutical companies to disclose and share the technical know-how and trade secrets that may be required to produce vaccines. In this regard, the proponents seem to be conflating patent rights with the protection of undisclosed information. Fifth, the counter-proposal of the EU is merely tokenistic in nature and it would not make any significant difference to the situation of countries that lack domestic manufacturing capacity to produce medicines and vaccines.

Thus, it appears that the members of the TRIPS Council are once again engaged in ‘rhetorical action’ which is unlikely to produce any meaningful solution. As can be seen from the above, both the proponents and the opponents of the proposed waiver are not really attempting to present a full and complete picture of the precise and appropriate role of intellectual property rights in the fight against COVID-19. Both sides seem content in presenting their carefully crafted narratives to the TRIPS Council.

63 Of course, it may be possible to produce vaccines without the transfer of know-how or trade secrets through the process of reverse-engineering. This would however only require the waiver of the obligations relating to patent rights but not the waiver of the obligations regarding the protection of undisclosed information. The key point being made here is that it is not entirely clear from the narratives of the proponents of the waiver how the waiver of the obligations regarding the protection of undisclosed information would necessarily compel or encourage pharmaceutical companies to transfer the required know-how and trade secrets that may be needed for the production of vaccines to other potential manufacturers.
Importantly, a more viable solution that may be useful both to countries that possess manufacturing capacity and those that do not is, perhaps, an amendment of Article 31(f) of the TRIPS Agreement to permanently remove the requirement that compulsory licences should ‘predominantly’ be used ‘for the supply of the domestic market of the Member authorizing such use’. The removal of this requirement can be specifically limited to situations such as when there is a pandemic like the COVID-19 pandemic. This would enable states with domestic manufacturing capacity to grant compulsory licenses that can be used to export products like medicines and vaccines to other countries that lack domestic manufacturing capacity. Crucially, under this proposal, states with domestic manufacturing capacity can use the threat of compulsory licensing as a leverage to obtain better terms for voluntary licences from pharmaceutical companies.

It is further suggested here that developing and least-developed countries should equally intensify their efforts with regard to improving their national and regional capacities to produce medicines and vaccines. Ultimately, enhancing a country’s domestic manufacturing capacity is one crucial way to unlock that country’s ability to make use of the existing flexibilities under the TRIPS Agreement. In this regard, the initiative being spearheaded by the World Health Organization (WHO) to boost the manufacturing capacity of countries in Africa and in other developing countries outside Africa in order to help them produce vaccines is a welcome development.\(^\text{64}\) It is worth pointing out that one of the reasons why India has been able to make use of the flexibilities in the TRIPS Agreement\(^\text{65}\) is because it does possess domestic manufacturing capacity.

**Postscript**

After this article was written, but prior to its publication, WTO members adopted a TRIPS waiver decision at the Twelfth Ministerial Conference in June 2022.\(^\text{66}\) As highlighted below, a critical assessment of the text of the TRIPS waiver decision confirms the thesis of the article that, considering the engagement in ‘rhetorical action’ by both sides of the COVID-19 waiver proposal debate, it is highly likely that any outcome or agreement may be an unworkable or unhelpful agreement.

The provisions of the TRIPS waiver decision are far from the demands contained in the revised waiver proposal submitted by India and South Africa. Indeed, one could plausibly argue that the waiver decision is closer to the positions of both the EU and the US in this regard. In other words, the waiver decision merely provides some concessions regarding the rules governing


compulsory licensing contained in Article 31 of the TRIPS Agreement and its scope is limited to the production and supply of COVID-19 vaccines. Specifically, paragraph 1 of the waiver decision provides that:

Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter "the Agreement") by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic, in accordance with the provisions of Article 31 of the Agreement, as clarified and waived in paragraphs 2 to 6 below.

Nevertheless, when compared with the permanent waiver codified in Article 31bis of the TRIPS Agreement, one could say that the provisions of the waiver decision are not as cumbersome and complex as the provisions contained in Article 31bis of the TRIPS Agreement.

In terms of aspects of the TRIPS waiver decision that may be considered as positive or gains for proponents of the waiver request, a few points are worth pointing out. Paragraph 2 of the waiver decision allows an ‘eligible Member’ to ‘authorize the use of the subject matter of a patent under Article 31 without the right holder's consent through any instrument’. So, this could be done via executive orders, emergency decrees, government use authorisations, and judicial or administrative orders. In this regard, the ‘law of a Member’ pursuant to Article 31 of the TRIPS Agreement is deemed as not limited to legislative acts for the purposes of the waiver decision.

Perhaps, the most significant concession in the waiver decision can be found in paragraph 3(b) which permits an eligible member to ‘waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market’. Paragraph 3(b) goes on to provide that an eligible member ‘may allow any proportion of the products manufactured under the authorization in accordance with this Decision to be exported to eligible Members, including through international or regional joint initiatives that aim to ensure the equitable access of eligible Members to the COVID-19 vaccine covered by the authorization.’ This is a crucial departure from the strictures codified in Article 31bis of the TRIPS Agreement which was ironically originally intended to address the problems associated with Article 31(f) of the TRIPS Agreement especially for countries with no or insufficient domestic manufacturing capacity. Although the scope of the waiver decision is currently limited to the production of vaccines, paragraph 3(b) of the waiver decision is an implied admission of the practical difficulties associated with the use of Article 31bis of the TRIPS Agreement.

According to paragraph 6 of the waiver decision, eligible members can apply the provisions of the waiver decision ‘until 5 years from the date of this Decision.’ The second sentence of paragraph 6 states that the duration of the waiver decision may be extended by the WTO’s General Council. Another positive aspect of the waiver decision can be found in paragraph 4 which provides that: ‘Recognizing the importance of the timely availability of and access to COVID-19 vaccines, it is understood that Article 39.3 of the Agreement does not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine produced under this Decision.’ One could however contend that this merely confirms the existing
flexibilities in Article 39.3 of the TRIPS Agreement, although it is certainly helpful to clarify this in the text of the waiver decision.

An examination of what could be perceived as the negative aspects of the TRIPS waiver decision provides an insight as to why it may be considered to be a compromise that may not necessarily be helpful in the fight against COVID-19. First, whereas the waiver proposal requests for the waiver of obligations relating to copyright, patents, industrial designs and the protection of undisclosed information, the waiver decision only covers the compulsory licensing of patents.

Second, as noted previously, the scope of the TRIPS waiver decision is limited in paragraph 1 to the production and supply of COVID-19 vaccines. Furthermore, paragraph 8 of the waiver decision provides that: ‘No later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics.’ It is unclear why it was deemed necessary to postpone the decision on diagnostics and therapeutics to a later date.

Third, the definition of an ‘eligible Member’ in footnote 1 of the waiver decision is quite restrictive to say the least. While the first sentence of footnote 1 states that all developing country members are eligible members, the second sentence of footnote 1 goes on to state that: ‘Developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision.’ So, on the one hand, only developing countries are eligible members; on the other hand, those developing countries with manufacturing capacity are not supposed to use this waiver decision. This, in a sense, undermines the waiver of Article 31(f) of the TRIPS Agreement in paragraph 3(b) of the TRIPS waiver decision.

Fourth, while the waiver proposal requests for the waiver of all obligations relating to the protection of undisclosed data, the TRIPS waiver decision only addresses Article 39.3 of the TRIPS Agreement in its paragraph 4. Fifth, there are equally obligations regarding taking reasonable efforts to prevent the re-exportation of vaccines imported via this waiver decision (paragraph 3(c)) and to notify the TRIPS Council of any measures adopted pursuant to this waiver decision (paragraph 5). Although it should also be noted that footnote 3 of the waiver decision provides that: ‘In exceptional circumstances, an eligible Member may re-export COVID-19 vaccines to another eligible Member for humanitarian and not-for-profit purposes, as long as the eligible Member communicates in accordance with paragraph 5.’