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SOUTH CENTRE

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* Edward Ball Eminent Scholar Prof. of International Law, Florida State University College of Law, Tallahassee, United States of America.

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South Centre
Ch. du Champ d'Anier 17
POB 228, 1211 Geneva 19
Switzerland
Tel. (41) 022 791 80 50
south@southcentre.int
www.southcentre.int

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ABSTRACT

The COVID-19 pandemic has caused Governments to contemplate measures to override patents and other intellectual property rights (IPRs) in order to facilitate production and distribution of vaccines, treatments, diagnostics and medical devices. This paper discusses whether the COVID-19 pandemic may be considered an “emergency in international relations” and how WTO Member States may invoke Article 73 (“Security Exceptions”) of the TRIPS Agreement as the legal basis for overriding IPRs otherwise required to be made available or enforced. It concludes that the pandemic constitutes an emergency in international relations within the meaning of Article 73(b)(iii) and that this provision allows Governments to take actions necessary to protect their essential security interests.

La pandemia de COVID-19 ha hecho que los gobiernos contemplen medidas para privar de efectos a las patentes y otros derechos de propiedad intelectual (DPI) a fin de facilitar la producción y distribución de vacunas, tratamientos, diagnósticos y dispositivos médicos. En el presente documento se examina si la pandemia de COVID-19 puede considerarse una "emergencia en las relaciones internacionales" y la forma en que los Estados Miembros de la OMC pueden invocar el artículo 73 ("Excepciones relativas a la seguridad") del Acuerdo sobre los ADPIC como base jurídica para no aplicar los derechos de propiedad intelectual que, de otro modo, deberían estar disponibles o hacerse efectivos. Concluye que la pandemia constituye una emergencia en las relaciones internacionales en el significado del artículo 73 b) iii) y que esta disposición permite a los gobiernos adoptar las medidas necesarias para proteger sus intereses esenciales en materia de seguridad.

La pandémie COVID-19 a amené les gouvernements à envisager des mesures visant à déroger aux brevets et autres droits de propriété intellectuelle (DPI) afin de faciliter la production et la distribution de vaccins, de traitements, de diagnostics et de dispositifs médicaux. Le présent document examine si la pandémie COVID-19 peut être considérée comme une "urgence dans les relations internationales" et comment les États membres de l'OMC peuvent invoquer l'article 73 ("Exceptions de sécurité") de l'accord sur les ADPIC comme base juridique pour déroger aux DPI dont la mise à disposition ou l'application sont par ailleurs requises. Elle conclut que la pandémie constitue une urgence dans les relations internationales au sens de l'article 73(b)(iii) et que cette disposition permet aux gouvernements de prendre les mesures nécessaires pour protéger leurs intérêts essentiels de sécurité.

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I. INTRODUCTION

The COVID-19 pandemic has caused governments to contemplate measures to override patents and other intellectual property rights (IPRs) in order to facilitate production and distribution of vaccines, treatments, diagnostics and medical devices (hereinafter generally "pharmaceuticals"). Regulatory-based marketing exclusivity rights are included for this purpose within IPRs.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") that entered into force on 1 January 1995 establishes certain minimum standards of IPRs protections that WTO members are expected to maintain, including minimum standards of enforcement procedures available to private IPR owners.[1]

This paper addresses whether, and under what circumstances, WTO Member States may invoke Article 73 ("Security Exceptions") of the TRIPS Agreement as the legal basis for overriding IPRs otherwise required to be made available. In particular, the paper addresses whether the COVID-19 pandemic may be considered an "emergency in international relations", and whether measures taken to override IPRs may be actions "a member … considers necessary for the protection of its essential security interests" within the meaning of Article 73(b).

In undertaking this analysis, the paper also addresses an argument that may foreseeably be raised against such invocation, namely that because the TRIPS Agreement provides certain specific rules with respect to emergency situations, the invocation of the security provision may not be justified.

The paper concludes that the COVID-19 pandemic (1) constitutes an emergency in international relations, (2) that measures taken by WTO members to override IPRs may be considered necessary to protect their essential security interests, and (3) specific provisions in the TRIPS Agreement addressing emergencies do not preclude members from invoking Article 73.

[1] WTO Agreement on Trade-Related Intellectual Property Rights Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Apr. 15, 1994, in WORLD TRADE ORGANIZATION, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 321 (1999), as amended on 23 January 2017 [hereinafter "TRIPS Agreement"]. Available from https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm.

II. ARTICLE 73 AND ITS INTERPRETATION

A. The Legal Text

Article 73 of the TRIPS Agreement provides as follows:

> "Article 73
> Security Exceptions
> Nothing in this Agreement shall be construed:
> (a) to require a member to furnish any information the disclosure of which it considers contrary to its essential security interests; or
> (b) to prevent a member from taking any action which **it considers necessary for the protection of its essential security interests**;
> (i) relating to fissionable materials or the materials from which they are derived;
> (ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;
> (iii) **taken in time** of war or **other emergency in international relations**; or
> (c) to prevent a member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security." [emphasis added]

The Article 73, Security Exceptions, provision in the TRIPS Agreement is identical to the Article XXI, Security Exceptions provision in the General Agreement on Tariffs and Trade (GATT), the latter dating back to the inception of GATT in 1947.[2]

B. Precedent

Throughout GATT and WTO history there were situations in which governments invoked "national security" as grounds for non-compliance with otherwise applicable norms. For example, when the US State of Massachusetts adopted a law prohibiting State agencies from

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[2]The General Agreement on Tariffs and Trade (GATT 1947)[hereinafter "GATT"], https://www.wto.org/english/docs_e/legal_e/gatt47_01_e.htm, provides:

> Article XXI: Security Exceptions
>
> Nothing in this Agreement shall be construed
> (a) to require any contracting party to furnish any information the disclosure of which it considers contrary to its essential security interests; or
>
> (b) to prevent any contracting party from taking any action which it considers necessary for the protection of its essential security interests
>
> (i) relating to fissionable materials or the materials from which they are derived;
>
> (ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;
>
> (iii) taken in time of war or other emergency in international relations; or
>
> (c) to prevent any contracting party from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.

procuring products from companies doing business with Burma (now Myanmar), and the United States of America ("United States") was challenged at WTO by the European Union, the US Federal Government (on behalf of Massachusetts) invoked national security.[3] That case did not result in a WTO Dispute Settlement Body ("DSB") decision because the US Supreme Court overturned the relevant Massachusetts legislation based on conflict with Federal statute.[4]

In recent years, however, the invocation of national security grounds as the basis for WTO inconsistent measures has become commonplace, in particular as the United States has invoked national security as the basis for various WTO-inconsistent measures, including measures imposed on steel imports from China and the European Union,[5] on imports from Canada and Mexico during negotiation of USMCA,[6] and on a wide range of imports from China as part of President Trump's agenda to restrain China's economic ascendance.[7] This relatively recent step up in invocation of national security as grounds for imposing WTO-inconsistent measures has not yet resulted in review of these measures by the DSB.[8]

There are, however, two recent WTO dispute settlement panel decisions that address challenges to WTO-inconsistent measures on national security grounds, one involving a complaint by the Ukraine against Russia with respect to transit of goods,[9] and the other involving a complaint by Qatar against Saudi Arabia for non-application of intellectual property protections otherwise required under the TRIPS Agreement. [10] Recognizing the importance of the first detailed consideration by a WTO panel of the GATT Article XXI exception, the Panel in the *Russia-Transit* case provided an extensive historical review of previous incidents, and a detailed treatment of the issues raised under Article XXI.[11] The Panel in the *Saudi Arabia-IPRs* case substantially relied on the jurisprudence of the Panel in the *Russia-Transit* case, with the important distinction for present purposes that the *Saudi Arabia-IPRs* Panel analyzed the situation under Article 73 of the TRIPS Agreement.

C. Justiciability

A key threshold issue in both WTO proceedings was whether the DSB has authority to make a decision regarding the legality of actions taken by a member based on national security grounds. In the *Russia-Transit* case, some members, including Russia,[12] and the United States

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[3] *United States — Measure Affecting Government Procurement*, consultations requested by the European Communities, mutually agreed solution notified (Feb. 11, 2000), WT/DS88/6, WT/DS95/6, Note by Secretariat, 14 February 2000, see, e.g., Ryan Goodman, "Norms and National Security: The WTO as a catalyst for inquiry", *Chicago Journal of International Law* vol. 2, No. 1, (2002). Available from: https://chicagounbound.uchicago.edu/cjil/vol2/iss1/7.

[4] *Crosby v. National Foreign Trade Council*, 530 U.S. 363 (2000).

[5] See *American Institute for Int'l Steel v. United States*, US Ct of Appeals for the Fed. Cir., Feb. 28, 2020, cert. denied June 22, 2020.

[6] Ana Swanson and Jim Tankersley, "Mexico, hitting back, imposes tariffs on $3 billion worth of U.S. goods", *New York Times*, 5 June 2018. Available from https://www.nytimes.com/2018/06/05/us/politics/trump-trade-canada-mexico-nafta.html.

[7] See USTR Section 301 Fact Sheet, Press Release, June 2018, https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2018/june/section-301-investigation-fact-sheet.

[8] But see initiation of dispute settlement consultations by China, *United States – Tariff Measures on Certain Goods from China III*, Request for Consultations by China, WT/DS587/1, G/L/1322, 4 Sept. 2019, "concerning the tariffs measures that the United States accords to certain goods with the estimated trade value of approximately $300 billion originating from China."

[9] *Russia - Measures Concerning Traffic in Transit*, Report of the Panel, WT/DS512/R, 5 April 2019 [hereinafter "*Russia-Transit*"].

[10] *Saudi Arabia – Measures Concerning the Protection of Intellectual Property Rights*, Report of The Panel, WT/DS567/R, 16 June 2020 [hereinafter "*Saudi Arabia-IPRs*"].

[11] The terms of the Security Exceptions of GATT Article XXI and TRIPS Agreement Article 73 are identical.

[12] *Russia-Transit*, at para. 7.27.

as a third-party, argued that assertions of national security are effectively nonjusticiable. The Panel summarized the United States' third-party position:

> 7.51. The United States, in a letter to the Chair of the Panel submitted on the due date for third-party submissions, argues that the Panel "lacks the authority to review the invocation of Article XXI and to make findings on the claims raised in this dispute". The reason advanced is that every WTO member retains the authority to determine for itself those matters that it considers necessary for the protection of its essential security interests, as "reflected" in the text of Article XXI of the GATT 1994. The United States describes this as an "inherent right" that has been repeatedly recognized by GATT contracting parties and WTO members.
>
> 7.52. In its subsequent submissions, the United States clarifies that it considers the Panel to have jurisdiction in the context of this dispute "in the sense that the DSB established it, and placed the matter raised in Ukraine's complaint within the Panel's terms of reference under Article 7.1 of the DSU". However, it considers that the dispute is "non-justiciable" because there are no legal criteria by which the issue of a member's consideration of its essential security interests can be judged. The United States bases its position on its interpretation of the text of Article XXI, specifically, the "self-judging" language of the chapeau in Article XXI(b) "which it considers necessary for the protection of its essential security interests". For the United States, the "self-judging" nature of Article XXI(b)(iii) establishes that its invocation by a member is "non-justiciable", and "is therefore not capable of findings by a panel", obviating the possibility of making recommendations under Article 19.1 of the DSU in this dispute.

That is, once national security grounds are asserted, a panel may not further assess the situation. If panels accepted that rationale, the assertion of national security would automatically act as a shield against a finding of WTO-inconsistency, and against any corollary demand that the claimed-against member withdraw its measures or suffer suspension of concessions.

The Panel in *Saudi Arabia-IPRs* summarized a challenge by Saudi Arabia, and by the United States as third-party, to the scope of authority of the Panel as follows:

> 7.9. While Saudi Arabia did not present the Panel with any arguments formulated in terms of the Panel's "jurisdiction" or the "justiciability" of the dispute, several third parties, including Australia and the European Union, construed Saudi Arabia's arguments as implying that Saudi Arabia regarded the matter as "non-justiciable". Furthermore, the United States argued that Saudi Arabia's invocation of the security exception in Article 73(b)(iii) of the TRIPS Agreement is not reviewable, and therefore, the matter is not "justiciable". There is a degree of overlap between the third parties' arguments presented in terms of "justiciability", on the one hand, and the arguments presented by the parties and third parties in relation to Saudi Arabia's argument that the Panel should decline to make any findings or recommendation based on Articles 3.4, 3.7 and 11 of the DSU, on the other hand.

Neither the Panel in the *Russia-Transit* or *Saudi Arabia-IPRs* cases accepted the argument that national security claims are effectively non-justiciable. After extensive review of the text and the negotiating history of GATT Article XXI, the *Russia-Transit* Panel concluded:

> 7.102. It follows from the Panel's interpretation of Article XXI(b), as vesting in panels the power to review whether the requirements of the enumerated subparagraphs are met, rather than leaving it to the unfettered discretion of the invoking member,

> that Article XXI(b)(iii) of the GATT 1994 is not totally "self-judging" in the manner asserted by Russia.
>
> 7.103. Consequently, Russia's argument that the Panel lacks jurisdiction to review Russia's invocation of Article XXI(b)(iii) must fail. The Panel's interpretation of Article XXI(b)(iii) also means that it rejects the United States' argument that Russia's invocation of Article XXI(b)(iii) is "non-justiciable", to the extent that this argument also relies on the alleged totally "self-judging" nature of the provision.

The *Saudi Arabia-IPRs* panel, in rejecting the non-justiciability argument and a "political question" variant proffered by Saudi Arabia, said:

> 7.13. With these general considerations in mind, the Panel will now turn to the specific arguments presented by Saudi Arabia, beginning with its argument that the current dispute is "not a trade dispute at all", but a "political, geopolitical, and essential security dispute".
>
> ***
>
> 7.16. The Panel is not persuaded that it can decline to make any findings or a recommendation, i.e. "decline to exercise its jurisdiction" on the basis of Saudi Arabia's argument that the "real dispute" between the parties is not a "trade dispute". The Panel considers that it is evident from its terms of reference that it has not been asked by Qatar or the DSB to make any findings or recommendation on any wider dispute between the parties. The matter raised by Qatar in its panel request, which now forms the Panel's terms of reference, concerns alleged violations of the TRIPS Agreement. Accordingly, the matter before the Panel falls within the legal subject-matter jurisdiction of a WTO dispute settlement panel.
>
> 7.17. For similar reasons, the Panel is not persuaded that it can decline to exercise jurisdiction on the basis of Saudi Arabia's argument that it is impossible for any findings or recommendation to secure a positive solution to "the matter" and/or achieve a satisfactory settlement of "the dispute" under the DSU. The Panel considers that this argument, like Saudi Arabia's argument concerning the "real dispute" not being a "trade dispute", is directed at the wider political dispute between the parties that is not at issue before the Panel. …

The dispute concerning whether invocations of GATT Article XXI and/or TRIPS Agreement Article 73 are "justiciable" is important for two reasons, at least. First, the decisions of the Panels make it clear that WTO members are under an obligation to invoke the Security Exceptions provisions with good faith justification, even if the members may have substantial discretion with respect to that justification. Second, the United States was the motivating force behind negotiation of the TRIPS Agreement and has pursued other members for alleged violations of the TRIPS Agreement with vigor. But the United States has argued that invocation of Article 73 (and GATT Article XXI) is entirely at the discretion of the member taking that action, and that there are no grounds for challenging such invocation under WTO law. The United States therefore should be seen to be "equitably estopped" from challenging a measure taken by another member under Article 73 because it is bound to respect its own reiterated position that such action is "non-justiciable".[13] It would indeed be strange for the United States to argue that security-based actions taken against the Ukraine and Qatar are non-justiciable, but that emergency measures affecting US-owned patents are justiciable.

[13] Estoppel may be defined as "a legal bar to alleging or denying a fact because of one's own previous actions or words to the contrary", https://www.merriam-webster.com/dictionary/estoppel.

D. Elements of Article 73(b), TRIPS Agreement

1. Analytic framework

With the issue of justiciability resolved, the Panels in each the *Russia-Transit* dispute and the *Saudi Arabia-IPRs* dispute went on to review the measures taken by the complained-against parties and the justifications under Article XXI (GATT) and Article 73 (TRIPS Agreement), respectively. Because this paper is assessing potential invocation of Article 73, it focuses here on the jurisprudence of the Panel in the *Saudi Arabia-IPRs* dispute, noting that the *Saudi Arabia-IPRs* Panel relied on the jurisprudence of the Panel in *Russia-Transit*. In doing so, the Panel in *Saudi Arabia-IPRs* presented a consolidated overview of the analytical method followed by the *Russia-Transit* Panel. The *Saudi Arabia-IPRs* Panel said:

> 7.230. Article XXI(b)(iii) of the GATT 1994, which is identical to Article 73(b)(iii) of the TRIPS Agreement, was recently addressed by the panel in *Russia – Traffic in Transit.* It held that a panel must determine for itself whether the invoking member's actions were "taken in time of war or other emergency in international relations" in subparagraph (iii) of Article XXI(b) of the GATT 1994. It further found that a panel's review of whether the invoking member's actions are ones "which it considers necessary for the protection of its essential security interests" under the chapeau of Article XXI(b) of the GATT 1994 requires an assessment of whether the invoking member has articulated the "essential security interests" that it considers the measures at issue are necessary to protect, along with a further assessment of whether the measures are so remote from, or unrelated to, the "emergency in international relations" as to make it implausible that the invoking member implemented the measures for the protection of its "essential security interests" arising out of the emergency. According to the panel in *Russia – Traffic in Transit*, the obligation of a member to interpret and apply Article XXI(b)(iii) of the GATT 1994 in "good faith" requires "that the measures at issue meet a minimum requirement of plausibility in relation to the proffered essential security interests, i.e. that they are not implausible as measures protective of these interests".

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> “7.241. As previously stated, the wording of Article 73(b)(iii) of the TRIPS Agreement is identical to that of Article XXI(b)(iii) of the GATT 1994, which was first interpreted by the panel in *Russia – Traffic in Transit*. The panel's interpretation of Article XXI(b)(iii) in that dispute gave rise to an analytical framework that can guide the assessment of whether a respondent has properly invoked Article XXI(b)(iii) of the GATT 1994, or, for the purposes of this dispute, Article 73(b)(iii) of the TRIPS Agreement.
>
> 7.242. Specifically, a panel may proceed by assessing:
> a. whether the existence of a "war or other emergency in international relations" has been established in the sense of subparagraph (iii) to Article 73(b);
> b. whether the relevant actions were "taken in time of" that war or other emergency in international relations;
> c. whether the invoking member has articulated its relevant "essential security interests" sufficiently to enable an assessment of whether there is any link between those actions and the protection of its essential security interests; and
> d. whether the relevant actions are so remote from, or unrelated to, the "emergency in international relations" as to make it implausible that the invoking member considers those actions to be necessary for the protection of its essential security interests arising out of the emergency.

> 7.243. The parties in this dispute and multiple third parties each express agreement with the general interpretation and analytical framework enunciated by the panel in *Russia – Traffic in Transit*. These parties and third parties therefore considered that both can be transposed to Article 73(b)(iii) of the TRIPS Agreement." [footnotes omitted]

2. Emergency in international relations

The first question that a WTO panel would need to assess is whether an "emergency in international relations" exists within the meaning of Article 73(b)(iii). On 30 January 2020, the WHO Director-General declared a Public Health Emergency of International Concern (PHEIC) over the COVID-19 outbreak,[14] stating, *inter alia*, "Our greatest concern is the potential for the virus to spread to countries [outside China] with weaker health systems, and which are ill-prepared to deal with it." The declaration by WHO provides objective evidence of an emergency in international relations.

PHEIC involves interaction between States in the sense that a virus or other pathogen is transmitted across national borders, and it affects individuals across diverse geographies. One of the major issues in addressing the pandemic concerns the allocation of medicines (including vaccines) and medical devices among States. Already as of July 2020 the constrained production capacity of the drug and vaccine suppliers is being allocated to high income countries (HICs) based on their financial capacity to subsidize and/or to pay for these products.[15] Low- and middle-income countries (LMICs) face serious risk that their needs for medicines and medical devices will not be met in a timely way. The issue of allocation of scarce resources is decidedly an issue of "international relations". The international community has yet to establish a viable mechanism to assure equitable access.

Beyond the issue of allocation of scarce resources, there are other aspects relating to the pandemic that create an emergency in international relations, including those created by a sharp slowdown in international trade and travel, which is having a major impact on economies around the world, particularly affecting the most economically vulnerable. Moreover, as the UN Secretary-General has observed to the Security Council, the fact of the pandemic is leading to escalations of hostility and threats of terrorist activities. These circumstances also cross the legal threshold of an emergency in international relations.[16] On 1 July 2020, the UN Security Council adopted a resolution directed to the COVID-19 pandemic:

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[14] WHO Director-General's statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV), 30 Jan. 2020, https://www.who.int/dg/speeches/detail/who-director-general-s-statement-on-ihr-emergency-committee-on-novel-coronavirus-(2019-ncov).

[15] See, e.g., Helen Branswell, As coronavirus pandemic worsens, health officials fear nationalization of drugs and supplies, *STAT HEALTH*, 15 March 2020, https://www.statnews.com/2020/03/15/as-coronavirus-pandemic-worsens-health-officials-fear-nationalization-of-drugs-and-supplies/; Leila Abboud, Michael Peel and Hannah Kuchler, "Macron summons Sanofi chief for claim US has "right to" first Covid-19 jab", Financial Times, 14 May 2020. Available from https://www.ft.com/content/60434224-a70d-4a8d-821f-6ac239b4a349.

[16] "The UN Secretary General, on April 9, 2020, addressed the Security Council, saying:

While the COVID-19 pandemic is first and foremost a health crisis, its implications are much more far-reaching. We are already seeing its ruinous social and economic impacts, as governments around the world struggle to find the most effective responses to rising unemployment and the economic downturn.

But the pandemic also poses a significant threat to the maintenance of international peace and security – potentially leading to an increase in social unrest and violence that would greatly undermine our ability to fight the disease.

My concerns are many and widespread, but let me identify eight risks that are particularly pressing: …

Resolution 2532 (2020)
Adopted by the Security Council on 1 July 2020

The Security Council,

Recalling its primary responsibility for the maintenance of international peace and security,

Reaffirming the principles and purposes of the Charter of the United Nations,

Expressing grave concern about the devastating impact of the COVID-19 pandemic across the world, especially in countries ravaged by armed conflicts, or in post-conflict situations, or affected by humanitarian crises,

Recognizing that conditions of violence and instability in conflict situations can exacerbate the pandemic, and that inversely the pandemic can exacerbate the adverse humanitarian impact of conflict situations,

Recognizing that the peacebuilding and development gains made by countries in transition and post-conflict countries could be reversed in light of the COVID-19 pandemic outbreak,

Underscoring that combating this pandemic requires greater national, regional and international cooperation and solidarity, and a coordinated, inclusive, comprehensive and global international response with the United Nations playing a key coordinating role,

Commending the continued contribution and commitment of national and international health and humanitarian relief personnel to respond urgently to the COVID-19 pandemic,

Recognizing efforts and measures proposed by the Secretary-General concerning the response to the potential impact of the COVID-19 pandemic to conflict-affected countries, in particular his appeal for an immediate global ceasefire,

Having considered the resolution 74/270 “Global solidarity to fight the coronavirus disease 2019 (COVID-19)” adopted by the UN General Assembly on 2 April 2020,

Acknowledging the launch of the Global Humanitarian Response Plan for COVID-19 by the United Nations, which puts the people at the center of the response,

Considering that the unprecedented extent of the COVID-19 pandemic is likely to endanger the maintenance of international peace and security,

1. Demands a general and immediate cessation of hostilities in all situations on its agenda and supports the efforts undertaken by the Secretary-General and his Special Representatives and Special Envoys in that respect;
2. Calls upon all parties to armed conflicts to engage immediately in a durable humanitarian pause for at least 90 consecutive days, in order to enable the safe, unhindered and sustained delivery of humanitarian assistance, provisions of related services by impartial humanitarian actors, in accordance with the humanitarian principles of humanity, neutrality, impartiality and independence, and medical evacuations, in accordance with international law, including international humanitarian law and refugee law as applicable;
3. Affirms that this general and immediate cessation of hostilities and this humanitarian pause do not apply to military operations against the Islamic State in Iraq and the Levant (ISIL, also known as Da’esh), Al Qaeda and Al Nusra Front (ANF), and all other individuals, groups, undertakings and entities associated with Al Qaeda or ISIL, and other terrorist groups, which have been designated by the Security Council;

4. Requests the Secretary-General to help ensure that all relevant parts of the United Nations system, including UN Country Teams, in accordance with their respective mandates, accelerate their response to the COVID-19 pandemic with a particular emphasis on countries in need, including those in situations of armed conflict or affected by humanitarian crises;
5. Requests the Secretary-General to provide updates to the Security Council on the UN efforts to address the COVID-19 pandemic in countries in situations of armed conflict or affected by humanitarian crises, as well as on the impact of COVID-19 on the ability of peace-keeping operations and Special Political Missions to deliver their mandated priority tasks;
6. Requests the Secretary-General to instruct peace-keeping operations to provide support, within their mandates and capacities, to host country authorities in their efforts to contain the pandemic, in particular to facilitate humanitarian access, including to internally displaced persons and refugee camps and allow for medical evacuations, and further requests the Secretary-General and Member States to take all appropriate steps to protect the safety, security and health of all UN personnel in UN peace operations, while maintaining the continuity of operations, and to take further steps towards the provision of training for peacekeeping personnel on issues related to preventing the spread of COVID-19;
7. Acknowledges the critical role that women are playing in COVID-19 response efforts, as well as the disproportionate negative impact of the pandemic, notably the socio-economic impact, on women and girls, children, refugees, internally displaced persons, older persons and persons with disabilities, and calls for concrete actions to minimize this impact and ensure the full, equal and meaningful participation of women and youth in the development and implementation of an adequate and sustainable response to the pandemic;
8. Decides to remain seized of the matter.

The Panels in both the *Russia-Transit* and *Saudi Arabia-IPRs* disputes recognized that a presumption of deference should be accorded to members that determine an emergency in international relations exists. There should be objective facts supporting the determination. The COVID-19 pandemic appears to satisfy the requirement of objectively verifiable circumstances of emergency in international relations.[17]

The first element necessary to justify invocation of Article 73 – the existence of an emergency in international relations – is satisfied by the COVID-19 pandemic.

The second element is that the relevant measures be “taken in time of” war or international emergency. Not much discussion is required here. Whatever measures a WTO Member Government takes to address the pandemic are almost certainly to be taken during the course of the pandemic, including what could be an extended period of continuing requirement for medicines and vaccines to prevent re-emergence once the virus has been brought under control. At some point in the future COVID-19 will no longer represent a threat to public health, and at some point further action by members might not be justified as “taken in time of” international emergency, but when that end-point might arise does not need to be addressed at this stage.

[17] In the *Russia-Transit* and the *Saudi Arabia-IPRs* cases, the conflicts related to disputes over threats to territorial boundaries and political independence to which the complained-against parties had reacted with transit restrictions and non-enforcement of intellectual property rights, respectively. But "international relations" is capable of broader definition than political or territorial conflict. International relations also involve movement of persons, trade, finance and other aspects of human interaction.

The third element is that the country taking the measures articulated its "essential security interests". This element, as with the second, should not require detailed elaboration in the context of the COVID-19 pandemic. The *Russia-Transit* Panel referred to this element in the context, *inter alia*, of the "maintenance of law and public order internally", as well as in the context of external threats.[18] While the Panel went on to say that members have an obligation to make a determination regarding essential security interests "in good faith", and may not simply relabel trade interests as essential security interests, the obligation on the invoking member is to "articulate the essential security interests said to arise from the emergency in international relations sufficiently enough to demonstrate their veracity".[19] The protection of the public health of the nation is one of the core obligations of a government, and the threat of a pandemic to public health directly affects the internal order of the state. Even if member interests are looked at from the narrow perspective of military/defense vulnerability, the health of the national population is manifestly related to "essential security interests". It is difficult to foresee the WTO Dispute Settlement Body deciding that protecting the national population from a pandemic is not within the essential security interests of the state.

The fourth and final element is whether "the relevant actions are so remote from, or unrelated to, the 'emergency in international relations' as to make it implausible that the invoking member considers those actions to be necessary."[20] This fourth element derives from the language of Article 73(b) referring to actions that the member "considers necessary", and the limits on what a member might consider necessary within the parameters of a good faith determination.

It is important to distinguish the concept of "considers necessary" in the context of Article 73(b) as compared with the concept of "necessary" in the context of Article XX of GATT, such as in Article XX(b) with respect to measures "necessary to protect human, animal or plant life or health" and XX(d) with respect to measures "necessary to secure compliance with laws or regulations which are not inconsistent …". There is a rich WTO jurisprudence concerning the circumstances in which members may invoke Article XX(b) and (d), and other subparagraphs of GATT Article XX, to justify measures otherwise inconsistent with GATT.[21] These decisions include as part of the analysis of whether a measure is "necessary" the consideration of potential reasonably available alternative measures that might be less trade restrictive. Under Article XX(b) and (d) jurisprudence, a measure inconsistent with GATT should not be "more trade restrictive than necessary". (There is consistent jurisprudence that each member may determine the level of protection it considers appropriate.[22]) Whatever the precise boundaries of the "necessity test" under GATT Article XX, the Panel in the *Russia-Transit* case made clear that a different approach is proper under GATT Article XXI, and by extension TRIPS Agreement Article 73.

The Panel in the *Russia-Transit* dispute, reflecting also the views of all third-party participants, said that members have substantial discretion to decide what measures they "consider necessary" to protect their essential security interests, and that a WTO Panel would not analyze whether the same objectives could be accomplished using alternative measures.[23] This flows from the underlying concept underlying Article XXI that recognizes

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[18] See *Russia-Transit*, paras. 7.130-7.131.
[19] See *Russia-Transit*, paras. 7.132-7.133
[20] See *Saudi Arabia-IPRs*, para. 7.242.
[21] See, e.g., discussion in *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, AB-2000-11, Report of the Appellate Body, WT/DS135/AB/R, 12 March 2001, at paras. 169-72.
[22] *EC-Asbestos, Ibid*., at para. 168.
[23] See *Russia-Transit*, paras. 7.146-7.147:

> 7.146. … [I]t is for Russia to determine the "necessity" of the measures for the protection of its essential security interests. This conclusion follows by logical necessity if the adjectival clause "which it considers" is to be given legal effect.222

the inherent sovereign right of Governments to protect essential security interests, and that GATT (and WTO) will not try to dictate the measures that governments may take to do that.

The Panel in the *Russia-Transit* readily found that Russia's action in blocking the transit of Ukrainian goods across its territory was within Russia's necessity discretion once it had established that it acted in times of emergency in international relations.[24] Russia was not required to demonstrate that it could accomplish its objectives with alternative or less trade restrictive measures.

And yet, while members have wide discretion to decide on measures necessary to protect their essential security interests, the discretion is not "unlimited". A measure does not need to be "reasonable", nor does it need to be the "least trade restrictive", but it does need to be "plausibly related" to the emergency that the member is addressing.[25]

The requirement of a plausible relationship was important in the outcome of the *Saudi Arabia-IPRs* dispute. There was in Saudi Arabia a "pirate" satellite broadcast network ("beoutQ") that was showing content produced by nationals of various countries and regions, including by nationals of Qatar, but also prominently including by producers in the European Union, Brazil and elsewhere. This included popular European football matches. When Saudi Arabia announced a series of measures against Qatar based on protecting its essential security interests, it included non-application of criminal proceedings against the Saudi pirate network. The availability of such criminal procedures is a requirement of Article 61 of the TRIPS Agreement.[26]

Qatar and its nationals owned and operated a satellite TV broadcast station ("beIN") that broadcast works own by foreign copyright owners under license, such as broadcasts of European football league games. Saudi Arabia was claiming that by failing to protect content broadcast by Qatar, it was pursuing a broad regime of sanctions against Qatar and its nationals. But third-party members whose nationals owned copyrights in the work broadcast by the pirate station in Saudi Arabia demanded an explanation regarding how failure by Saudi Arabia to enforce third-country member copyrights could plausibly protect Saudi Arabia's essential security interests.

> 7.147. The Panel has been referred to EC – Bananas III (Ecuador) (Article 22.6 – EC) in which the arbitrators interpreted the phrase "if that party considers" in Articles 22.3(b) and 22.3(c) of the DSU as providing a margin of appreciation to the party which was nevertheless subject to review by the arbitrators. The arbitrator's decision regarding the scope of review under Article 22.3 of the DSU was based on the fact that the discretion accorded to the complaining party under the relevant subparagraphs of that provision was subject to the obligation in the introductory words to Article 22.3 of the DSU, which provides that "[i]n considering what concessions or other obligations to suspend, the complaining party shall apply the following principles and procedures". There is no equivalent obligation anywhere in the text of Article XXI that expressly conditions the discretion accorded to an invoking Member under the chapeau of Article XXI(b).

[24] See *Russia-Transit*, para. 7.144.

[25] See *Russia-Transit*, para 7.138:

> The obligation of good faith, referred to in paragraphs 7.132 and 7.133 above, applies not only to the Member's definition of the essential security interests said to arise from the particular emergency in international relations, but also, and most importantly, to their connection with the measures at issue. Thus, as concerns the application of Article XXI(b)(iii), this obligation is crystallized in demanding that the measures at issue meet a minimum requirement of plausibility in relation to the proffered essential security interests, i.e. that they are not implausible as measures protective of these interests.

[26] TRIPS Agreement, Article 61, provides: "Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale…."

The Panel found that there was no plausible relationship between Saudi Arabia's non-application of criminal enforcement actions against pirate broadcasts of works of non-Qatari nationals and whatever essential security interest Saudi Arabia might have vis-à-vis Qatar, saying:

> 7.289. In the Panel's view, however, the same conclusion cannot be reached regarding the connection between Saudi Arabia's stated essential security interests and its authorities' non-application of criminal procedures and penalties to beoutQ. In contrast to the anti-sympathy measures, which might be viewed as an aspect of Saudi Arabia's umbrella policy of ending or preventing any form of interaction with Qatari nationals, the Panel is unable to discern any basis for concluding that the application of criminal procedures or penalties to beoutQ would require any entity in Saudi Arabia to engage in any form of interaction with beIN or any other Qatari national.
>
> 7.290. Multiple third-party right holders submitted evidence directly to the Saudi authorities and have made such evidence available to these authorities in the course of this dispute….[27]
>
> 7.291. The Panel recalls that the non-application of criminal procedures and penalties to beoutQ, a commercial-scale broadcast pirate, affects not only Qatar or Qatari nationals, but also a range of third-party right holders. **The Panel recalls that several third parties commented on the question of whether—and, if so, how—the non-application of criminal procedures and penalties to beoutQ could plausibly be connected to Saudi Arabia's essential security interests.** Brazil stated that it "fails to see how the respondent's proffered essential security interests, or any country's essential security interests for that matter, could be protected by allowing the operation of a copyright pirate whose broadcasts have spread beyond the respondent's borders and encompass not only the copyrights held by the claimant's nationals but by other countries' nationals as well, including Brazil's". Similarly, the European Union stated that, without taking a position on the facts of this case, it would "welcome a detailed explanation clarifying why, in order to protect its essential security interests, Saudi Arabia considers it necessary to breach the rights of third party right-holders". **In its third-party oral statement, the European Union reiterated that it "would appreciate it if Saudi Arabia could provide a plausible explanation of the reasons why 'it considers necessary' to allow the**

[27] Excerpted evidence materials quoted in decision, para. 7.290:

> This third-party corroborating evidence includes, for example:
> a. letters issued by UEFA and BBC Studios to the Ministry and GCAM containing evidence concerning beoutQ's operations and efforts to target the Saudi market, its use of Arabsat satellites and its sale of STBs and subscriptions in Saudi Arabia and elsewhere in the MENA region;
> b. letters from UEFA, La Liga and the Premier League to Arabsat reporting beoutQ's use of particular Arabsat satellite frequencies to transmit its pirated content, which Arabsat's legal representative stated in letters to third-party right holders that Arabsat would take into account in its ongoing investigation;
> c. FIFA's letter to Arabsat concerning the scope of its satellite coverage and its transmission of beoutQ's pirated content;
> d. submissions made to the USTR concerning beoutQ's piracy, which were summarized in the USTR's 2019 Special 301 Report and have been submitted to the Panel and Saudi Arabia in this dispute;
> e. a public joint statement made by seven major football right holders condemning beoutQ and requesting enforcement action by Saudi Arabia against beoutQ; and
> f. a technical report produced by the anti-piracy and cybersecurity firm MarkMonitor, at the request of the seven football right holders, making specific findings concerning beoutQ's unauthorized re-streaming of copyrighted content, the transmission of beoutQ's pirated content on specific Arabsat satellites and frequencies, the design and operation of the hardware and software of beoutQ STBs to target Saudi Arabia, and the technically sophisticated and organized nature of beoutQ's operation.

> **systematic infringement of the intellectual property rights of EU right holders in order to protect its essential security interests".**
>
> 7.292. The Panel observes that, in further contrast to the anti-sympathy measures, **neither party has suggested that there is any direct link between the non-application of criminal procedures and penalties, on the one hand, and any action taken on, or consequential to, the 5 June 2017 "comprehensive measures" severing relations with Qatar, on the other hand**. Whereas the anti-sympathy measures were announced on 6 June 2017, there is no such temporal connection between the non-application of criminal procedures and penalties and the 5 June 2017 "comprehensive measures". **For the reasons given above, there is also no rational or logical connection between the comprehensive measures aimed at ending interaction with Qatar and Qatari nationals, and the non-application of Saudi criminal procedures and penalties to beoutQ.**
>
> **7.293. The Panel concludes that the non-application of criminal procedures and penalties to beoutQ does not have any relationship to Saudi Arabia's policy of ending or preventing any form of interaction with Qatari nationals. Therefore, the Saudi authorities' non-application of criminal procedures and penalties to beoutQ is so remote from, or unrelated to, the "emergency in international relations" as to make it implausible that Saudi Arabia implemented these measures for the protection of its "essential security interests". As a consequence, the Panel concludes that the non-application of criminal procedures and penalties to beoutQ does not "meet a minimum requirement of plausibility in relation to the proffered essential security interests, i.e. that they are not implausible as measures protective of these interests".** [emphasis added]

This is the first time that a WTO panel has disallowed a national security exception claim, whether under GATT XXI, Article 73 of the TRIPS Agreement, or Article XIV*bis* of the General Agreement on Trade in Services (GATS).

The Panel in *Saudi Arabia-IPRs*, and the third-party submissions, framed the issue of the necessary-ness of the Saudi measures that affected foreign (non-Qatari) IP owners as one of “plausible relationship” to protecting Saudi Arabia’s essential security interests. It might equally well have framed the issue as one of acceptable levels of “collateral damage” to third-party member interests. Saudi Arabia’s decision to allow the operation of the pirate broadcast network that affected the commercial interests of Qatar and its nationals presumably had an adverse financial impact on Qatar. It might affect Qatari policy in a way deemed desirable by Saudi Arabia. Saudi Arabia’s “bad act” was not that it put a Saudi pirate broadcast station into competition with a Qatar broadcast station, but that it failed or refused to license its content from European and/or other content originators. This created unacceptable damage to third-member content owners – an injury “collateral” to the intended target of its action – which could have been avoided, and presumably without undermining its objective of adversely affecting Qatari commercial interests.

Whether the issue is framed in terms of “plausible relationship” or “acceptable collateral damage”, it is difficult to foresee a situation where this issue could prove problematic in relation to use of Article 73 to override patent or market exclusivity interests in medicines or medical devices used to address COVID-19. If a WTO member seeking to produce or supply medicines overrides patents held by foreign nationals, that is directly related to addressing the problem it is seeking to address. These measures would be “plausibly related” to protecting essential security interests. If to secure a vaccine a WTO member suspended patent rights in vaccine technology to allow its domestic industry, or importers,

to use a foreign-IP owner's technology, that would manifestly be reasonably related to addressing the national security interest.

For present purposes it does not appear important to speculate as to what the "outer boundaries" of a security exception claim might be with respect to a WTO member that chooses to suspend patent, regulatory marketing exclusivity or other IP addressed by the TRIPS Agreement in order to address the COVID-19 pandemic.[28]

The fourth element of a "not implausible" relationship between suspending IPRs and the objective of protecting essential security interests is met in the context of invoking TRIPS Agreement Article 73 to address the COVID-19 pandemic.

[28] As example of a nuanced case, a Member might suspend broadcast copyright on the theory that individuals in self-quarantine need access to video content and might not be able to afford it. Is Netflix streaming plausibly related to addressing the COVID-19 pandemic? Some would think so.

III. TRIPS AGREEMENT OBLIGATIONS AND FLEXIBILITIES

A. Flexibilities

As is well-known, the TRIPS Agreement embodies various "flexibilities" that authorize governments to take measures allowing use by third parties of otherwise protected rights. Though often framed as "exceptions", the flexibilities are a customary part of the international IP framework that seeks a balance between exclusive private interests, on one side, and broader public interests, on the other. In this regard, rather than "exceptions", the flexibilities might better be thought of as the flip side of the exclusive characteristic of various IP subject matters covered by the TRIPS Agreement.

The main flexibilities relevant to addressing the COVID-19 pandemic are the compulsory patent licensing (Articles 31 and 31*bis*, TRIPS Agreement) provisions, and the patent-related limited exception (Article 30) provision. The compulsory licensing provisions authorize governments to permit parties other than the owners/grantees (i.e. third parties) to make use of patents without the consent of the patent owners. (The third-party user may be the government itself under a "government use" license.) With respect to Articles 31 and 31*bis* certain procedural steps are laid out. National law generally should incorporate these procedural steps in accordance with the relevant member's customary practices.

Copyright, design right, trademark and trade secret (as well as regulatory data protection), each incorporate TRIPS Agreement flexibilities, some more relevant than others to addressing the pandemic.

In reaction to political and legal hostility faced by developing countries attempting to make use of TRIPS Agreement flexibilities, WTO members in November 2001 adopted the Doha Declaration on the TRIPS Agreement and Public Health that affirmed the right of WTO members to use the flexibilities, and to promote access to medicines "for all".[29]

As discussed earlier, the COVID-19 pandemic is a public health emergency affecting all WTO members, even those without significant numbers of infected individuals.[30] The fact of an emergency triggers certain specific accommodations under Article 31 of the TRIPS Agreement, in particular that a compulsory license may be issued without prior negotiation with the patent owner for a license on reasonable terms and conditions.[31]

Other procedural rules under Article 31 include that a license be considered on its individual merits, and that a mechanism for contesting the grant of a license before an administrative or judicial body is available.

Article 31 also requires that the patent owner receive adequate remuneration in the circumstances of the case, and that a compulsory licensee should not export a predominant part of its production (Article 31(f)). The latter limitation of Article 31 is modified by Article 31*bis* that establishes procedures pursuant to which compulsory licenses may be issued predominantly for export, and that establishes criteria for "eligible importing countries". Eligibility is automatically open to least developed countries (LDCs), and to other countries that do not have adequate capacity to manufacture the pharmaceutical products they are seeking.

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[29] Declaration on the TRIPS Agreement and Public Health (14 November 2001), Doc. WT /MIN(O1)/DEC/2 (20 November 2001) [hereinafter "Doha Declaration"].

[30] There is ample evidence that a small outbreak may rapidly evolve into a wide-scale outbreak.

[31] This same flexibility to avoid prior negotiation applies with respect to "government use" licenses in the absence of an emergency.

A number of high income countries (HICs) have “opted out” of eligibility as importing countries, and in principle may not import the products exported under Article 31*bis,* although there is possibility that at least some of the opted out WTO members may choose to opt back in as eligible importing members. Rather than opting back in, HICs that have opted out may invoke Article 73.

B. TRIPS and Emergencies

Existing jurisprudence regarding the TRIPS Agreement might affect analysis under the Security Exceptions. The most relevant jurisprudence is in the decision by the Panel in the *Canada-Patent Protection of Pharmaceutical Products* case that addressed the EU claim that Canadian legislation embodying a regulatory review exception (and stockpiling exception) was inconsistent with Article 30 of the TRIPS Agreement.[32] In assessing Canada’s argument in favor of a broad exception reflecting public health interests, the Panel (chaired by Prof. Robert Hudec) observed that the countries negotiating the TRIPS Agreement deliberately designed mechanisms to take account of public health interests, including certain limitations, and that this balancing during the negotiating process should not be reassessed by a Panel:

> 7.25 The EC did not dispute the stated goal of achieving a balance within the intellectual property rights system between important national policies. But, in the view of the EC, Articles 7 and 8 are statements that describe the balancing of goals that had already taken place in negotiating the final texts of the TRIPS Agreement. According to the EC, to view Article 30 as an authorization for governments to "renegotiate" the overall balance of the Agreement would involve a double counting of such socio-economic policies. In particular, the EC pointed to the last phrase of Article 8.1 requiring that government measures to protect important socio-economic policies be consistent with the obligations of the TRIPS Agreement. The EC also referred to the provisions of first consideration of the Preamble and Article 1.1 as demonstrating that the basic purpose of the TRIPS Agreement was to lay down minimum requirements for the protection and enforcement of intellectual property rights.
>
> 7.26 In the Panel's view, Article 30's very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments. On the other hand, *the three limiting conditions attached to Article 30 testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement*. Obviously, the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.

Assume for the sake of argument that a national government invokes Article 73, TRIPS Agreement, to justify a failure to follow certain steps or substantive requirements with respect to the grant of a compulsory license under Article 31, or to act inconsistently with the Article 31*bis* provisions applicable to compulsory licensing predominantly for export. Article 31 makes express provision regarding the compulsory patent licensing rules that may be avoided in a situation of national emergency or other circumstances of extreme urgency.[33] It can be argued

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[32] *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, 17 March 2000.

[33] TRIPS Agreement, Article 31(b):

> “such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. ***This requirement may be waived***

that Article 31 expressly contemplates the situation of a pandemic outbreak (i.e. a national emergency) and prescribes the rules to be followed in such event. If the negotiating members expressly addressed that situation – and confirmed that in the Doha Declaration on the TRIPS Agreement and Public Health[34] – might this affect a determination that an emergency measure under Article 73 is "necessary"?

Simply put, the argument against invocation of Article 73 as grounds for avoiding otherwise applicable obligations under Article 31 or 31*bis* would be that these provisions were negotiated with the possibility of an international emergency and/or pandemic in mind, and that the rules for addressing those situations were spelled out in advance. Therefore, WTO members have no basis to assert that the COVID-19 pandemic represents some new or un-contemplated circumstance justifying extraordinary measures.

There are several potential responses to this line of argument.

First, the *Russia-Transit* Panel and the *Saudi Arabia-IPRs* Panel have recognized that a member taking measures to protect its essential security interests can take those measures which it "considers necessary" and does not need to analyze whether there are alternative or less trade-restrictive measures available. The measures need only be plausibly related to the objectives of the measures. This alone is enough to rebut the suggestion that the existence of alternative mechanisms in the TRIPS Agreement precludes invocation of Article 73.

Second, notwithstanding that Article 31 and 31*bis* contemplate the possibility of a national emergency involving public health, the negotiators may not have foreseen the extent to which a particular event would impact national and global public health, and so did not have all the information relevant to negotiating the proper framework. Even six months into the COVID-19 outbreak there remain major gaps in scientific understanding of the nature of the disease and the means to bring the pandemic under control. Therefore, to say that the negotiators of the TRIPS Agreement in 1986-1993, or of the 2017 amendment, contemplated the COVID-19 pandemic is not correct.

Third, Article 31 and Article 31*bis* are only part of the TRIPS Agreement rule set that are applicable to members with respect to intellectual property in relation to the pandemic. There are various other provisions that affect matters such as the ability of pharmaceutical manufacturers to place vaccines, treatments, diagnostics and medical devices on the market.[35] For example, Article 39.3 governs the treatment of regulatory data submitted to drug regulatory authorities, providing protection in specific circumstances against "unfair commercial use" of

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> ***by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.*** In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;" [emphasis added].

[34] Doha Declaration, Para. 5(c):

> "Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."

[35] Under ordinary circumstances, a significant part of the world's legal profession is devoted to asserting protections on behalf of the pharmaceutical industry enterprises and associations, and a more modest part of the world's legal profession is devoted to challenging those assertions of protection. What this means is that "everything is complicated". Virtually every effort by a generic producer to bring a product to market confronts IP-owner legal representatives seeking to block that effort through threats of legal action, and/or legal action before courts or administrative bodies. Governments "as such" ordinarily do not step in to mediate these activities, except to provide the courts, administrative bodies, and police enforcement agents required to carry out orders.

that data. Article 39.3 is the basis for the adoption by various members of regulatory marketing exclusivity rules (although Article 39.3 does not require such rules). If members choose to authorize manufacturing and distribution, and/or importation, of pharmaceutical products to address COVID-19, they may need to suspend prior grants of marketing exclusivity rights. Article 73 would provide the flexibility to overcome exclusive marketing rights, regardless of proffered interpretation of Article 39.3. Articles 31 and 31*bis* of the TRIPS Agreement operate in tandem with provisions addressing other IPRs, and invocation of Article 73 would facilitate an efficient approach to overcoming IP-related obstacles.

Beyond rules regarding patents and regulatory market exclusivity, trademark claimants may attempt to block distribution of pharmaceutical products that have the same color and shape of products they have previously marketed; copyright claimants may seek to block reproduction of information pamphlets, online materials, etc., used by physicians and patients; design right claimants might assert exclusive rights with respect to delivery devices (e.g., syringes, vials, etc.);[36] trade secret holders may attempt to prevent use of production processes or other commercially valuable information used to make relevant products. These additional forms of IP and related subject matter are covered by a significant group of TRIPS Agreement rules.

In addition to the substantive obligations established by the TRIPS Agreement, there are the enforcement-related obligations, which in certain cases prescribe procedural steps that should be followed by judicial and administrative authorities, as well as conferring procedural rights on holders of IP.

Article 73 addresses a broader set of TRIPS Agreement rules than those applicable to compulsory patent licensing (including the Article 61 criminal enforcement provision addressed by *Saudi Arabia-IPRs* Panel). Article 73 may be invoked to address the panoply of rules provided that the measures taken by the invoking government plausibly related to the objective of addressing its essential security interests.

[36] The term "claimants" is used in this paragraph because certain of the potentially asserted "rights" may not be within the legitimate scope of the relevant IP.

IV. ARTICLES 73 AND OTHER OBLIGATIONS

A. National Laws and Measures

A government suspending IP rights may face challenges under its national Constitution, or under a domestic legislative enactment protecting the interest of IP owners. This paper does not address the potential domestic legal complexities that may be involved in suspending IPRs. It is important not to confuse the national and international legal issues. The reason for invoking Article 73 is that one WTO member may claim against another member in WTO for having violated an international obligation (i.e., the TRIPS Agreement), which raises a different set of issues than whether the claimed-against WTO member acted improperly under its domestic Constitution and/or legislation. Solving a TRIPS Agreement problem by invoking Article 73 does not "cure" a potential domestic law problem. At the same time, the fact that a government has acted improperly (or properly) under its domestic law does not in itself create a TRIPS Agreement violation or problem. The international and legal issues are generally distinct.[37]

This point is worth emphasizing. The questions that may be raised by invocation of Article 73 of the TRIPS Agreement (or Article XXI of GATT) are questions of international law and principally affect inter-governmental relations.

B. Trade and Investment Agreements

It is also important to recognize that the TRIPS Agreement is not the only set of international rules that may affect government decisions to suspend IPRs. Many WTO members are also parties to preferential trade and investment agreements (TIAs) that incorporate obligations similar to those arising under the TRIPS Agreement and may include more restrictive rules (such as in the area of investment and related disputes). These TIAs also include security exceptions that may be equivalent to those found in the WTO agreements, though there might be differences. A WTO member should be careful to study the range of its international commitments before it acts.

With that said, with the life and health of the national population under threat by COVID-19, the grounds for invoking protection of essential security interests appears to be compelling. Article 73 is a flexibility provided by the TRIPS Agreement, and the Doha Declaration "affirm[s] that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all".[38]

[37] In countries that follow a monist approach to the incorporation of treaty rules in domestic law, violation of a national rule may be the equivalent of a violation of the TRIPS Agreement.
[38] Doha Declaration, at para. 4.

V. THE CONTEXT OF INVOCATION

A. Article 73 as the Basis for Domestic Action

As discussed in the previous section, the obligations established by the TRIPS Agreement are generally among WTO Member Governments at the international level. For some countries, the TRIPS Agreement nevertheless is directly effective as a part of national law as a consequence of the constitutionally defined relationship between treaties and domestic law. In countries where treaties are directly effective an individual may rely on the treaty as a source of rights, and the Government may act based on the treaty rules, provided that the treaty rules have not otherwise been modified for domestic purposes. In other countries, the rules of treaties they have joined must be "transformed" into domestic law by an act of the parliament or legislature.[39]

With respect to the TRIPS Agreement it would be unusual – even in cases where the agreement is directly effective – for IP rules such as those defining the terms and conditions under which patents are granted to be implemented solely based on the TRIPS Agreement patent provisions. Most likely there will be a patent act prescribing terms and conditions, as well as patent office regulations further refining those rules. A government act to override patent rights must not only address TRIPS Agreement obligations, but also rights provided for under national patent rules.

Article 73 says that the TRIPS Agreement does not prevent a member from taking action to protect its essential security interests. From an internal domestic legislative standpoint, Article 73 standing alone might not sufficiently empower the Government to override the various rights that patent owners may have under national law.

In most cases it is likely preferable that existing national legislation relating to emergencies, and/or newly adopted legislation (or executive action), is used to implement emergency measures relating to IP.

B. Article 73 as a WTO Defense

On the other hand, while Article 73 may not be designed to serve as the basis for domestic action to override patents and other IP, it is precisely designed to serve as the basis for a defense against an action brought by a WTO member challenging that domestic action.

To solidify a defense in WTO, it may be useful for a WTO member overriding IP to expressly take cognizance of an international emergency, such as by referring to the WHO declaration of a Public Health Emergency of International Concern, and stating that its actions are taken to address essential interests. Although it may be preferable to frame the national declaration of emergency in a way that tracks the language of Article 73 (e.g., referring to an "emergency in international relations" and "essential security interests") this is not required as a condition of defending the action under WTO law.

[39] There is no uniform rule that prescribes the way that national or regional governments incorporate treaties into their domestic legislative systems, and there is considerable nuance in the way this relationship is addressed. See, e.g., S. Riesenfeld and F. Abbott, eds., *Parliamentary Participation in the Making and Operation of Treaties: A Comparative Study*, (Dordrecht, Martinus Nijhoff, 1994).

A national declaration might take form along the following lines:

> Taking cognizance of an emergency in international relations as evidenced by the declaration of a Public Health Emergency of International Concern in relation to the COVID-19 Pandemic by the WHO Director-General;
>
> Recognizing the necessity and urgency of taking appropriate measures to protect the essential security interests of the nation, and especially to protect public health and social order;
>
> The State hereby suspends any and all intellectual property rights, including rights in and deriving from patents, trademarks, copyrights, design rights, trade secrets and regulatory data (including regulatory market exclusivity), that pertain to health products used to address COVID-19, including vaccines, pharmaceuticals (including biologics), diagnostics and medical equipment (including personal protective equipment (PPE)). The aforesaid suspension is effective immediately and remains in effect until terminated by a subsequent act of the State.

The suspension of intellectual property rights by a national Government does not presuppose that the Government will not establish some mechanism for compensating owners for the IP that may be used during the period of suspension. Whether and how much compensation might be paid will likely be a function of the capacity to pay of the country suspending the rights. By way of illustration, least developed countries would not be expected to pay compensation. Article 73 of the TRIPS Agreement makes no provision for compensating those economically affected by emergency measures. Compensation is not a legal requirement under Article 73.

VI. Conclusion

This paper has reviewed the legal rules and jurisprudence applicable to the potential use of Article 73 of the TRIPS Agreement by WTO members in addressing the COVID-19 pandemic. It concludes that Article 73 may justifiably be invoked to override protections of intellectual property otherwise mandated by the TRIPS Agreement because the pandemic constitutes an emergency in international relations within the meaning of Article 73(b)(iii), and because a WTO member acting to override IP rights will be taking action necessary to protect its essential security interests within the meaning of the introductory clause of Article 73(b). The presence in the TRIPS Agreement of some provisions that address public health emergencies does not constitute an obstacle to the justifiable invocation of Article 73.

It is a fundamental responsibility of sovereign governments to protect the health and safety of their citizens. Article 73 acknowledges that reality and concedes that the TRIPS Agreement cannot stand in the way.

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Chemin du Champ-d'Anier 17
PO Box 228, 1211 Geneva 19
Switzerland

Telephone: (41) 022 791 8050
E-mail: south@southcentre.int

Website:
http://www.southcentre.int

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