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Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements

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SOUTH CENTRE

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IMPLEMENTING A TRIPS WAIVER FOR HEALTH TECHNOLOGIES AND PRODUCTS FOR COVID-19: PREVENTING CLAIMS UNDER FREE TRADE AND INVESTMENT AGREEMENTS

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NOTE

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ABSTRACT

While increasing support from WTO members for a proposed waiver from certain obligations under the TRIPS Agreement with regard to health products required for responding to COVID-19 has made a decision on the TRIPS waiver imminent, the waiver will have to be implemented domestically by WTO members through appropriate legislative, administrative or judicial measures, including through executive orders that have been utilized to implement emergency measures in the context of the COVID-19 pandemic. In this regard, the scope of the TRIPS waiver, as well as the terms of applicable free trade agreements (FTAs) and international investment agreements (IIAs) will also impact the policy space available to countries to implement the waiver. Ensuring a broad scope of the waiver, as well as complementary measures to safeguard the implementation of the waiver from potential challenges under FTAs or IIAs will be critical. This research paper discusses some options that could be explored to enable the implementation of the TRIPS waiver by overcoming possible impediments that could arise under such agreements.

Aunque el creciente apoyo de los miembros de la OMC a una propuesta de exención de determinadas obligaciones en virtud del Acuerdo sobre los ADPIC con respecto a los productos sanitarios necesarios para responder a la COVID-19 ha hecho que sea inminente una decisión sobre la exención de los ADPIC, los miembros de la OMC tendrán que aplicar la exención a nivel nacional a través de medidas legislativas, administrativas o judiciales apropiadas, incluidas las órdenes ejecutivas que se han utilizado para aplicar medidas de emergencia en el contexto de la pandemia de la COVID-19. En este sentido, el alcance de la exención de los ADPIC, así como los términos aplicables en los acuerdos de libre comercio (ALC) y los acuerdos internacionales de inversión (AII) también influirán en el espacio de política disponible para que los países apliquen la exención. Será fundamental garantizar un amplio alcance de la exención, así como medidas complementarias para salvaguardar la aplicación de la exención de posibles impugnaciones en el marco de los ALC o los AII. Este documento de investigación analiza algunas opciones que podrían explorarse para permitir la aplicación de la exención de los ADPIC superando los posibles impedimentos que podrían surgir en el marco de dichos acuerdos.

Bien que le soutien croissant des membres de l'OMC pour une proposition de dérogation à certaines obligations de l'Accord sur les ADPIC concernant les produits de santé nécessaires pour répondre à la pandémie COVID-19 ait rendu imminente une décision sur la dérogation ADPIC, celle-ci devra être mise en œuvre au niveau national par les membres de l'OMC par le biais de mesures législatives, administratives ou judiciaires appropriées, y compris par le biais de décrets qui ont été utilisés pour mettre en œuvre des mesures d'urgence dans le contexte de la pandémie COVID-19. À cet égard, la portée de la dérogation ADPIC, ainsi que les termes des accords de libre-échange (ALE) et des accords internationaux d'investissement (AII) applicables, auront également un impact sur la marge de manœuvre dont disposent les pays pour mettre en œuvre la dérogation. Il sera essentiel de garantir un large champ d'application de la dérogation, ainsi que des mesures complémentaires pour protéger la mise en œuvre de la dérogation contre d'éventuelles contestations dans le cadre des ALE ou des AII. Ce document de recherche examine certaines options qui pourraient être explorées pour permettre la mise en œuvre de la dérogation ADPIC en surmontant les obstacles qui pourraient survenir dans le cadre de tels accords.

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1 INTRODUCTION

In October 2020, India and South Africa jointly submitted a proposal to the TRIPS Council[1] requesting, under article IX.3 of the Agreement Establishing the World Trade Organization (hereinafter WTO Agreement), the grant of a waiver from implementation, application and enforcement of intellectual property (IP) rights and their underlying technologies for prevention, containment and treatment of COVID-19. The proposal has received the support of more than 100 countries as well as over 300 civil society organizations, the World Health Organization, Unitaid, South Centre and other international organizations, lawmakers in various countries, many academics and political leaders.[2] Recently, the proponents submitted a revised proposal[3] co-sponsored by 64 countries from Asia, Africa and Latin America, including the African Group and the least developed countries (LDC) group, for the consideration of the TRIPS Council. This followed the announcement by the United States Trade Representative (USTR) that the United States (US) will engage in text negotiations to adopt a waiver.[4] This has been welcomed as a positive shift from the absolute opposition of the US to the proposed waiver to an "in-principle" recognition of the need for a waiver from TRIPS obligations to overcome the COVID-19 pandemic.[5]

The revised proposal updates the emergency situation currently prevailing as context for the waiver, by reflecting the concern of continuous mutations and emergence of new variants of the COVID-19 virus and the consequent uncertainties and complexities, which make the need for the waiver even more critical. The revised proposal also specifies, in response to concerns raised in past discussions about the broad scope of the waiver, that it would apply only in respect of health products and technologies for the prevention, containment and treatment of COVID-19, including vaccines, diagnostics, therapeutics, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture. The waiver is proposed for a duration of at least three years, subject to annual review of the waiver as mandated under article IX.4 of the WTO Agreement.

In accordance with the procedure under article IX.3 of the WTO Agreement, a proposal for a waiver from obligations under a specific covered agreement (in this case TRIPS) must first be considered by the relevant council (TRIPS Council) for a time period not exceeding 90 days.[6] At the end of this period, the relevant council is required to submit a report to the General Council. Accordingly, following the original waiver request submitted in October 2020, the TRIPS Council had submitted a report to the General Council in December 2020, within the 90-day period, pointing to further consideration of the proposal in the TRIPS Council.[7] It is in this context that a revised proposal has been submitted by the proponents. If a consensus can be reached in the TRIPS Council, the waiver would be formally adopted by the General

[1] WTO document IP/C/W/669, 2 October 2020. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True.
[2] Carlos M. Correa, "Expanding the production of COVID-19 vaccines to reach developing countries: Lift the barriers to fight the pandemic in the Global South", Policy Brief No. 92, South Centre, April 2021, p. 2. Available from https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf.
[3] WTO document IP/C/W/669/Rev.1. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True.
[4] See plants and animals in whole or any part thereof other than micro organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals "Statement from Ambassador Katherine Tai on the Covid-19 TRIPS Waiver", 5 May 2021. Available from https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver.
[5] See, e.g., "MSF applauds US' leadership on waiving IP for COVID-19 vaccines", 5 May 2021. Available from https://msfaccess.org/msf-applauds-us-leadership-waiving-ip-covid-19-vaccines.
[6] Article IX.3 (b), WTO Agreement.
[7] See WTO document WT/GC/M/188, pp. 97–110. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/M188.pdf&Open=True.

Council. However, if a consensus cannot be reached, the waiver can still be adopted by a three-fourth majority if the proponents call for a vote in the General Council.[8] In practice, WTO members prefer to arrive at decisions by consensus.

Despite the growing support for the proposed waiver, some developed countries, particularly the European Union (EU) members, continue to oppose it.[9] Hence, it is uncertain what will be the final scope of the waiver and by when the decision would be adopted. It will be critical that WTO members adopt a waiver that is sufficiently broad in scope and contributes to ramping-up and diversifying production. Speedy conclusion of negotiations will also be of key importance to ensure that the waiver can effectively respond to the ongoing public health emergency.

In the recent TRIPS Council meeting on 8–9 June 2021, the US considered that the revisions in the proposal are "modest" and suggested that "… the most expeditious pathway towards consensus would be to focus…on actions needed to address the supply and distribution of vaccines specifically (emphasis added)." The European Union (EU) has also submitted an alternative proposal to the WTO General Council which, among others, focuses on facilitating the use of the available flexibilities under TRIPS, particularly article 31 bis, without grant of a waiver. Thus, there is likely to be an insistence on the part of developed countries to limit the outcome of the negotiations on the proposed waiver to vaccines and also explore alternative solutions based on good faith collaboration on the part of intellectual property (IP) right holders. Such an outcome would be very modest and inadequate to address the needs of developing and least developed countries.

Indeed, the use of a TRIPS waiver to address a public health need is not unprecedented in the WTO. Pursuant to paragraph 6 of the 2001 WTO Doha Ministerial declaration on the TRIPS Agreement and Public Health (hereinafter the Doha Declaration) which instructed the TRIPS Council to find an expeditious solution to the difficulties faced by countries with insufficient or no manufacturing capacities in the pharmaceutical sector to make effective use of compulsory licensing under the TRIPS Agreement, the General Council adopted a decision on the recommendation of the TRIPS Council, waiving the obligations under articles 31(f) and 3(h) of the Agreement, to allow export of medicines under compulsory licensing to such countries, subject to the conditions contained in that decision. That waiver was made a permanent feature through the adoption of a protocol to introduce a new article 31*bis* which has come into force after receiving the required ratifications of WTO members.[10]

This paper assumes that the requested waiver of TRIPS obligations for COVID-19 will be adopted. It explores how the implementation of a possible waiver of certain TRIPS provisions could be impacted by obligations that States have regarding IP under applicable bilateral or regional free trade agreements (FTAs) and international investment agreements (IIAs), and how the waiver could be implemented by overcoming such obligations. The paper is also

[8] Article IX.3 (a), WTO Agreement.

[9] See Kerry Cullinan, "G20 Leaders Promise to Share More Vaccines While EU Digs In Against TRIPS Waiver", *Health Policy Watch*, 21 May 2021. Available from https://healthpolicy-watch.news/g20-leaders-promise-to-share-more-vaccines-while-eu-digs-in-against-trips-waiver/. See also G20, *The Rome Declaration*, Global Health Summit, 21 May 2021 (Underlining the importance of "… working consistently within the TRIPS Agreement and the 2001 Doha Declaration on the TRIPS agreement and Public Health; and Promoting the use of tools such as voluntary licensing agreements of intellectual property, voluntary technology and knowhow transfers, and patent pooling on mutually agreed terms"). Available from https://www.governo.it/sites/governo.it/files/documenti/documenti/Approfondimenti/GlobalHealthSummit/GlobalHealthSummit_RomeDeclaration.pdf.

[10] However, the system under article 31 bis requires compliance with a number of conditions that have made it unworkable and unsuitable to rapid and scaled up manufacturing and supply of pharmaceutical products to countries with insufficient or no manufacturing capacity. See Carlos M. Correa, "Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?", Policy Brief No. 57, South Centre, January 2019. Available from https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf.

premised on the assumption that the waiver would have a broad scope to cover all health technologies and products for COVID-19. It does not consider issues that may arise regarding implementation of the waiver under constitutional law or applicable national laws, or on the possible need to adopt measures to allow courts to deny preliminary or permanent injunctions if infringement of IP rights covered under a waiver is claimed.

2 EFFECTS OF A WAIVER UNDER WTO LAW

Under WTO law, as interpreted through case law, a waiver is exceptional in nature and is limited to the specific provisions waived. Moreover, the terms and conditions of a waiver are to be interpreted narrowly. In *EC-Bananas III*, the Appellate Body held that a waiver does not constitute a subsequent agreement between the parties to a treaty in terms of the Vienna Convention on the Law of Treaties, and hence, it cannot be construed as modifying or amending the obligations that members have under the covered agreement. Additionally, a waiver must be granted for a limited period time. However, as demonstrated by the waiver granted by the General Council pursuant to paragraph 6 of the Doha Declaration on TRIPS and Public Health (hereinafter the Doha Declaration), a waiver can last for a long period because the specific problem it addresses could materialize at different points in time for different WTO members.

Any measure taken pursuant to a waiver is not exempted from being challenged in a WTO dispute settlement proceeding unless the terms of the waiver state the same. For instance, the General Council waiver decision based on the Doha Declaration specifically included a moratorium against challenging any measures taken in conformity with that waiver. A similar provision has been included in the proposed TRIPS waiver for COVID-19. Nevertheless, this would not exclude a possible dispute settlement complaint against a measure that a complaining party might consider to be outside the scope of the waiver, relying on a narrow interpretation of its terms. This makes the terms of the waiver of critical importance to ensure the accommodation of all possible measures that could be taken to overcome IP barriers in respect of health products and technologies for COVID-19.

This also means that in implementing the waiver, it will be important to ensure that WTO members design their relevant legislative, administrative, policy instruments to utilize the waiver by closely adhering to the terms of the waiver. Otherwise, those measures could be subjected to dispute settlement complaints on the ground that the measures are beyond the terms and conditions of the waiver.

3 IMPLICATIONS ON FTAS OF UTILIZATION OF A WAIVER

It is evident that a waiver from the TRIPS Agreement will only waive the covered provisions of that agreement in relation to COVID-19 related health products and technologies. Hence in implementing the waiver, WTO members will also have to contend with obligations that they have adopted with regard to IP under various FTAs. A narrow reading of the waiver terms, as suggested by existing WTO jurisprudence, will imply that obligations under FTAs will not be implicitly covered.

While a TRIPS waiver would apply to IP rights covered under the Agreement and waive the related obligations thereunder, it will not in itself waive TRIPS-plus obligations that are not arising from TRIPS but assumed under FTAs, such as the obligations on the part of the drug regulatory authorities to deny grant of marketing approval to generic versions of drugs that are under patent protection, or to grant data exclusivity for a specified period over clinical trial data submitted by an originator. Hence, it may be necessary to execute complementary waivers under FTAs, including for TRIPS-plus provisions.

It is interesting to note in this regard that article 18.6 (1) (c) of the IP chapter of the Comprehensive Trans-Pacific Partnership Agreement (CPTPP) anticipates waivers under the TRIPS Agreement in relation to public health. This provision states

> if any waiver of any provision of the TRIPS Agreement, or any amendment of the TRIPS Agreement, enters into force with respect to the Parties, and a Party's application of a measure in conformity with that waiver or amendment is contrary to the obligations of this Chapter, **the Parties shall immediately consult in order to adapt this Chapter as appropriate in the light of the waiver** or amendment (emphasis added).

This provision in CPTPP is similar to article 20.6 (c) of the Agreement between the United States of America, the United Mexican States and Canada (USMCA). This means that insofar as parties to CPTPP and USMCA are concerned, a TRIPS waiver should not be impeded by any obligation under those agreements, as the parties have the obligation to immediately undertake consultations and align the provisions in the FTA with the TRIPS waiver.

Many other FTAs also contain provisions that refer to the relationship with TRIPS. For example, article 11.8 (1) (b) and (c) of the Regional Comprehensive Economic Partnership Agreement (RCEP) states that "the Parties agree that this Chapter does not and should not prevent a Party from taking measures to protect public health" , and that "… the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all." Some FTAs, e.g., the US-Dominican Republic-Central America (US-CAFTA-DR) FTA clarifies through side letters that the obligations under the FTA "do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all…."[11] Such side letters have been held out by the US as waivers for public health purposes, though the legal weight of such side letters may be very low.[12] Hence, it is unclear to what extent such general provisions or side letters would allow a party to ignore its obligations under the FTA in the context of implementation of a TRIPS waiver.

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[11] Bryan Mercurio, "TRIPS-Plus Provisions in FTAs: Recent Trends", in Lorand Bartels and Federico Ortino (eds.), *Regional-Trade Agreements and the WTO Legal System* (Oxford University Press, 2006), p. 234. Available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=947767.

[12] Ibid.

Even though similar provisions to give effect to a TRIPS waiver may not be present in a number of other FTAs, if a waiver is adopted by consensus among WTO members, it should be possible for them to give effect to the waiver in the context of FTAs. In particular, major trading partners in FTAs, like the US and EU, can give effect to the waiver by abstaining from invoking rights under the FTAs they are parties to with developing countries.

Another possible option could be to include in the waiver decision itself specific wording indicating the commitment by WTO members not to invoke any provisions of FTAs that would frustrate the utilization of the waiver should one party to an FTA choose to do so. It is worth recalling that the waiver granted by the General Council pursuant to paragraph 6 of the Doha Declaration allowed developing country or LDC members who are parties to regional trade agreements at least half of whose membership comprised LDCs, to export pharmaceuticals imported under the system to all other developing country or LDC parties to such regional trade agreements.[13] Thus, giving effect to a TRIPS waiver for parties under FTAs is not unprecedented in the WTO.

However, in the absence of specific wording in the FTA or in the TRIPS waiver, and in the event a measure taken by a State pursuant to such waiver is challenged under the applicable dispute settlement mechanism under an FTA, the general principle of estoppel in international law may be invoked to deny consideration of claims challenging measures implementing the waiver, as discussed below.

[13] WTO document, WT/L/540 and Corr.1, 30 August 2003, paragraph 6. Available from https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

4 ESTOPPEL DOCTRINE

The estoppel doctrine is a general principle of international law that could be relevant in this context. The doctrine is based on the notion that a State must be consistent in its attitude to a given factual or legal situation.[14] In other words, if a State agrees to a waiver in relation to IP protection and enforcement in the WTO, it will be legitimate for other States to expect a similar attitude in relation to IP issues in other applicable agreements between them. The essence of this doctrine is the legitimate expectation of reasonable predictability to how a State will react to an issue. As remarked by the renowned jurist Lord McNair, "… international jurisprudence has a place for some recognition of the principle that a State cannot blow hot and cold - *allegans contraria non audiendus est."*

Article 45 of the International Law Commission's 2001 Draft Articles on the Responsibility of States for Internationally Wrongful Acts states that the responsibility of a State may not be invoked if a) the injured State has validly **waived** the claim; or b) if the injured State can be deemed to have, by its conduct, validly acquiesced to the lapse of the claim. This expresses the general principle of international law that a waiver can be express or it can be implied from the conduct of the claiming State. Since the TRIPS waiver will be an express waiver over the same subject matter over which some of the WTO members may have legal obligations under FTAs, it would be logical to deduce that through the conduct of negotiating an express waiver under TRIPS, the WTO members have waived corresponding obligations relating to health technologies and products for COVID-19 under FTAs.

[14] I.C. MacGibbon, "Estoppel in International Law", *The International and Comparative Law Quarterly,* vol. 7, No.3, 1958, p. 468.

5 POSSIBLE DEFENSES UNDER INTERNATIONAL INVESTMENT AGREEMENTS

Currently, there are about 2,622 IIAs in force.[15] Of these, almost 90 per cent contain a broad definition of "investment". Such definitions, better known as "asset-based" definitions, usually extend the scope of protection of IIAs beyond foreign direct investment to cover "every kind of asset" or "any kind of asset,"[16] which might include intangibles, comprising IPRs. Almost 1,200 IIAs explicitly mention IPRs, intangible property, or patents and other IPRs as protected investments.[17] Provisions included in IIAs could allow investor-State dispute settlement (ISDS) tribunals to consider claims relating to "investment" based on IP rights, and consequently have a chilling effect on the implementation of the proposed TRIPS waiver.

WTO law and IIAs have been traditionally conceived as self-contained regimes of international law,[18] which basically means that the implementation and interpretation of WTO agreements and IIAs are independent from the principles or provisions included in other international legal regimes. Although there are some cases where ISDS tribunals have been deferential to WTO jurisprudence, they have done so through comparative analysis because States have raised WTO jurisprudence as defense. In those cases, tribunals have considered the "unique institutional features of investor-state dispute settlement"[19] above certain interpretations by WTO panels, and in the majority of cases ISDS tribunals have declined States' defenses relying on other branches of international law.[20] It should also be noted in this context, as discussed above, that WTO jurisprudence concerning waiver decisions are limited.

ISDS could reduce the scope of States to review their decisions at the domestic level to either improve their measures or modify them for the attainment of public welfare,[21] and could be used to undermine the judicial systems of States by circumventing domestic courts' decisions. ISDS tribunals can determine the applicable law in each case, as well as the methods and principles of interpretation, which can lead to a series of restrictive interpretations in the application of other disciplines and principles of international law. For instance, States' defenses based on obligations deriving from other international legally binding instruments have been rejected by ISDS tribunals, arguing that positive obligations, or obligations of performance, can only be assumed by private investors under specific instruments deriving from domestic law (civil or commercial contracts) or through the inclusion of obligations to perform in IIAs.[22]

Even in times of crises, ISDS claims have been filed against States. Almost 25 per cent of the total number of cases initiated since the 2000s were against States dealing with severe

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[15] UNCTAD, Investment Policy Hub in https://investmentpolicy.unctad.org/international-investment-agreements. Accessed 31 May 2021.

[16] See: Kinda Mohamadieh and Daniel Uribe, *Approaches to International Investment Protection: Divergent approaches between the TPPA and Developing Countries' Model Investment Treaties,* Research Paper No. 68, (Geneva, South Centre, June, 2016). Available from https://www.southcentre.int/wp-content/uploads/2016/06/RP68_Approaches-to-International-Investment-Protection_EN.pdf. Accessed 31 May 2021.

[17] See: Ben van der Merwe, *Opinion: A TRIPS waiver won't stop pharma lawsuits*, Investment Monitor (June 2021) in https://investmentmonitor.ai/business-activities/covid-19/trips-waiver-pharma-lawsuits-covid Accessed 2 June 2021.

[18] Anja Lindroos and Michael Mehling, "Dispelling the Chimera of 'Self-Contained Regimes' International Law and the WTO". *The European Journal of International Law*, vol. 16, No. 5 (2006), pp. 861–866.

[19] Jurgen Kurtz, "The Use and Abuse of WTO Law in Investor-State Arbitration: Competition and its Discontents," The European Journal of International Law Vol. 20 No. 3 (2009), p. 763.

[20] See: International Centre for Settlement of Investment Disputes, *Urbaser S.A. and Consorcio de Aguas Bilbao Bizkaia Ur Partzuergoa v. The Argentine Republic*, ICSID Case No. ARB/07/26.

[21] See: The Court of Justice of the European Union, *Opinion 1/17 (ECLI:EU:C:2019:341)*, 30 April 2019, para. 150.

[22] See: *Urbaser S.A. and Consorcio de Aguas Bilbao Bizkaia Ur Partzuergoa v. The Argentine Republic*, para. 1210.

economic crises or States facing a political transition that required social and political measures to overcome it.[23] Therefore, there is a reasonable concern about the possibility of investors challenging States' course of action in dealing with public health-related measures to stop the spread of the coronavirus, including the procurement of personal protective equipment, diagnostic tests and securing medicine and equipment required as treatment for the COVID-19.[24] Similarly, even under a WTO waiver, pharmaceutical companies may bring claims "against the host country alleging that the suspension or the non-enforcement of IPRs"[25] amounts to a breach of the IIAs provisions, thereby detrimentally impacting the policy space that is necessary for developing countries to overcome the challenges arising from the COVID-19 pandemic. This scenario has become plausible as international law firms are preparing to launch several cases against governments over actions taken during the coronavirus crisis. Lawyers say investors can lodge claims for lost expected profits resulting from government measures to protect public health and provide economic relief.[26]

As noted, most BITs and IIAs include IPRs as protected investments, which are generally defined as any "assets" held by a foreign legal or natural person. While claims relating to IPRs may not be subject to ISDS under the IP Chapter of an FTA, they can be submitted for resolution under the respective investment chapter of the agreement.[27]

Unlike in the case of legal provisions directly concerned with the protection of IPRs (such as national patent laws and provisions in international agreements if directly applicable),[28] the exercise of investors' rights might not lead to court injunctions preventing the alleged infringer from continuing manufacturing or selling an IPRs protected product, but to demands for the host State to pay a compensation for the alleged breach of its obligations regarding the IPR holder as "investor".

Despite that the inclusion of IPRs in bilateral investment treaties (BITs) and other IIAs is not new,[29] there is little case law regarding the scope and extent of the protection conferred to the right-holders as "investors". Only in three cases have arbitration tribunals dealt with situations in which IPRs were involved.[30] In addition, international investment law is very fragmented,

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[23] See: Federico Lavopa, "Crisis, Emergency Measures and the Failure of the ISDS System: The Case of Argentina", Investment Policy Brief No. 2, South Centre (2015).

[24] See OECD's Health System Response Tracker here: https://www.oecd.org/health/COVID19-OECD-Health-System-Response-Tracker.xlsx.

[25] Prabhash Ranjan, "TRIPS Waiver: A BIT of a Challenge for India", The Wire (May 2021) in https://thewire.in/trade/trips-waiver-a-bit-of-a-challenge-for-india (Accessed 4 June 2021)

[26] Pia Eberhardt, "Cashing in on the pandemic: how lawyers are preparing to sue states over COVID-19 response measures" (Corporate Europe Observatory, 18 May 2020). Available from https://corporateeurope.org/en/2020/05/cashing-pandemic-how-lawyers-are-preparing-sue-states-over-covid-19-response-measures.

[27] 'Will the Intellectual Property Chapter of the CPTPP be subject to Investor-State Dispute Settlement (ISDS)? No. The Intellectual Property Chapter of the CPTPP cannot be directly enforced via ISDS. An ISDS dispute under the CPTPP could only be brought in relation to intellectual property where there has been an alleged violation of a commitment in the Investment Chapter' from the Australia's Q&A on the CPTPP, see https://www.dfat.gov.au/trade/agreements/in-force/cptpp/outcomes-documents/Pages/cptpp-intellectual-property#:~:text=Will%20the%20Intellectual%20Property%20Chapter,be%20directly%20enforced%20via%20ISDS.

[28] In many countries, sufficiently detailed provisions in international agreements are deemed self-executing and may be directly invoked by private parties and applied by the courts. This is notably the case in Latin American countries.

[29] See, e.g., Carlos Correa, "Bilateral Investment Agreements: Agents of New Global Standards for the Protection of Intellectual Property Rights?" GRAIN, 2004. Available from https://grain.org/article/entries/125-bilateral-investment-agreements-agents-of-new-global-standards-for-the-protection-of-intellectual-property-rights; Rachel A. Lavery, "Coverage of Intellectual Property Rights in International Investment Agreements: An Empirical Analysis of Definitions in a Sample of Bilateral Investment Treaties and Free Trade Agreements" (2009) 6(2) Transnational Dispute Management 1.

[30] Philip Morris Brands Sarl, Philip Morris Products S.A and Abal Hermanos S.A v. Oriental Republic of Uruguay, ICSID Case No: ARB/10/7, Award (8 July 2016) [hereinafter Philip Morris v. Uruguay]; Eli Lilly and Company v. The Government of Canada, UNCITRAL, ICSID Case No. UNCT/14/2, Award (16 March 2017) [hereinafter Eli Lilly v. Canada]; Bridgestone Licensing Services, Inc. And Bridgestone Americas, Inc. v. Republic of Panama (ICSID Case No. ARB/16/34) Decision on Expedited Objections (13 December 2017) [hereinafter *Bridgestone v. Panama*].

and the interpretations given in a particular case have no precedential value for other cases; moreover, the same concepts are often applied in different, and even contradictory ways by arbitration tribunals leading to a great deal of unpredictability in the outcomes of investment litigation.[31]

Different defenses may be articulated to prevent an investment claim from succeeding. Some of them are briefly discussed below. [32]

5.1 Definition of a Protected Investment

BITs and other IIAs include IPRs either by reference to any "assets", "property" (including intangible), or by specific references to such rights either in general or—as it is the trend in the most recent agreements—by listing the **categories** of covered IP, such as patents, copyright, designs, trade secrets, etc.[33]

While the coverage, in principle, of IPRs may be out of any controversy in most BITs and IIAs, a further and more complex question is **when** a particular IPR qualifies as a "protected investment", i.e., when the requirements set out to consider it as such are met. In fact, many agreements do not define what a "protected investment" is (this is notably the case of the ICSID) or define it in imprecise terms and, therefore, whether a particular IPR is protected or not depends on the particular treaty wording and the (variable) interpretations of the arbitration tribunals in cases where litigation arise.

There are various examples of BITs and IIAs that provide certain elements for characterizing an investment as protected. For instance, Article 14.1 of USMCA defines "investment" as:

> every asset that an investor owns or controls, directly or indirectly, that has the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk.

Other recent agreements (for example, the 2005 BIT between Uruguay and the USA, and the 2019 BIT between the EU–and Vietnam) add "a certain duration" to the elements mentioned in the USMCA.

In *Salini v. Morocco* the arbitration tribunal identified five elements that would characterize a protected investment. They include the elements referred to above but, importantly, the tribunal added the "contribution to economic development of host state". [34] This is a significant

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[31] See, e.g., August Reinisch, "The Proliferation of International Dispute Settlement Mechanisms: The Threat of Fragmentation vs. the Promise of a More Effective System? Some Reflections from the Perspective of Investment Arbitration", in I. Buffard, J. Crawford, A. Pellet and S. Wittich (eds), *International Law between Universalism and Fragmentation. Festschrift in Honour of Gerhard Hafner* (BRILL 2008) 107–126; Giovanni Zarra, 'The Issue of Incoherence in Investment Arbitration: Is There Need for a Systemic Reform?', *Chinese Journal of International Law*, Volume 17, Issue 1, March 2018, Pages 137–185, https://doi.org/10.1093/chinesejil/jmy005.

[32] This paper does not intend to provide an exhaustive analysis of such defenses, but only to highlight some of them.

[33] See, e.g., Carlos Correa, "Intellectual Property as Protected Investment: Redefining the Reach of Investors' Rights" in Geiger C. (ed), *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar 2020) 120–136; Pratyush Nath Upreti, "The Role of National and International Intellectual Property Law and Policy in Reconceptualising the Definition of Investment" (2021) 52 IIC 103–136. Available from https://doi.org/10.1007/s40319-020-01009-7.

[34] *Salini Costruttori S.p.A. and Italstrade S.p.A. v. Kingdom of Morocco* (*ICSID* Case No. ARB/00/4), available at https://www.italaw.com/cases/958.

improvement as it ultimately may help to balance the rights of investors with a duty to contribute to the development of the host country.[35]

Moreover, in *MHS v. Malaysia* the tribunal opined, in relation to the meaning of Article 25.1 of the ICSID Convention, that even if the five conditions in the Salini test were found, this would not automatically mean that a protected investment exists. The tribunal held that:

> The classical *Salini* hallmarks are not a punch list of items which, if completely checked off, will automatically lead to a conclusion that there is an 'investment.' If any of these hall- marks are absent, the tribunal will hesitate (and probably decline) to make a finding of 'investment.' However, even if they are all present, a tribunal will still examine the nature and degree of their presence in order to determine whether, on a holistic assessment, it is satisfied that there is an ICSID 'investment'.[36]

In spite of the above-mentioned heterogeneity in investment law interpretations, however, not all tribunals have followed these approaches. It has been noted in this regard that while:

> Four of the *Salini* criteria are gaining acceptance, the fifth—contribution to the economic development of the host country—has received less attention. Moreover, accepting the *Salini* criteria is a matter for tribunals' discretion; also, the criteria have been elaborated in relation to the ICSID Convention, and do not necessarily come into play in arbitrations conducted under other procedural rules. Still, they offer an entry point for tribunals that recognize the need for investment to contribute to sustainable development.[37]

The fifth criterion in the *Salini* tests—the contribution to the host country economic development—has been the most problematic for some tribunals. In *LESI SpA v Algeria,* for instance, the tribunal suggested that the requirement of whether an investment has contributed to the development of the host state was implicit in those relating to a commitment, duration and risk of an investment.[38] In contrast, such a criterion was fully incorporated into the Model BIT developed by India, which represents a significant breakthrough in the determination of the scope and extent of investment protection.[39]

If a TRIPS waiver were adopted, could the extent and type of exploitation of IPRs (including its contribution to the host country's development) influence their consideration as "protected investment"?[40] The response to this question may certainly differ depending on the terms of the relevant IIA, and on the interpretation that the arbitration tribunal may give to its provisions. Given that tribunals are conformed *ad hoc* and that, as noted, the tribunal awards have no precedential value, governments face a huge legal uncertainty on this matter.

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[35] See, e.g., L. Ngobeni, "Do the SALINI Criteria apply to the Definition of an Investment provided in Annex 1 of the 2006 and 2016 SADC Protocol on Finance and Investment? An Assessment" (2020), 23 PER / PELJ. Available from http://www.scielo.org.za/scielo.php?script=sci_arttext&pid=S1727-37812020000100025.

[36] *Malaysian Historical Salvors SDN, BHD v. the Government of Malaysia* (ICSID Case No. ARB/05/10), para 106(e). Available from https://www.italaw.com/sites/default/files/case-documents/ita0496.pdf.

[37] Karl Sauvant, "Promoting Sustainable FDI through International Investment Agreements" (2019), Columbia FDI Perspectives, Perspectives on topical foreign direct investment issues No. 251. Available from https://academiccommons.columbia.edu/doi/10.7916/d8-zgc5-x057.See also Alex Grabowski, "The Definition of Investment under the ICSID Convention: A Defense of Salini" (2014) 15(1) *Chicago Journal of International Law.* Available from https://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=1058&context=cjil.

[38] *LESI SpA et Astaldi SpA v Algeria* (ICSID Case No. ARB/05/3), Decision on Jurisdiction [12 July 2006], para 72(iv). Available from https://www.italaw.com/sites/default/files/case-documents/ita0456_0.pdf

[39] Model Text for the Indian Bilateral Investment Treaty. Available from https://dea.gov.in/sites/default/files/ModelBIT_Annex_0.pdf.

[40] A patent may be i) not exploited neither by importation nor by local production; ii) merely exploited through importation, or (iii) exploited through local production undertaken by the patent owner or a licensee.

In the expedited decision on jurisdiction in *Bridgestone License v. Panama*—one of the few cases in which the issue of IPRs as an investment was considered[41]—the tribunal asserted that the **exploitation** of a trademark conferred it the characteristic of a protected investment.[42] While this opinion would exclude IPRs that are merely registered but not exploited, could the simple exploitation be deemed sufficient for investors' rights to be asserted if other conditions are not met?

In summary, investment case law provides a basis for the complainant government to articulate, as a first defense, the absence of a protected investment if the elements characterizing such an investment—as defined, for instance, in accordance with the Salini test—are not present in the particular case, without prejudice to other defenses as discussed below.

5.2 Exemptions under IIAs

Old generation IIAs include vague language on the standards of protection of investments under its provisions. These standards add a layer of protection for investors when operating abroad by providing horizontal obligations that require States to provide protection for investors and investments, particularly non-discrimination, fair and equal treatment, protection against unlawful expropriation and denial of justice. In parallel, some IIAs may exclude certain sectors or policy measures from the protection of investment agreements, particularly through the inclusion of exceptions.

These provisions in IIAs are characterized as non-precluded measures (NPM) and serve as primary legal rules that limit or exempt certain State policy measures from the application of the treaty.[43] In general terms, these provisions are based on a "prohibition or restriction"[44] model, which implies that the agreement in question will not restrict or prohibit the adoption of measures that pursue the fulfilment of certain covered interests of States, for instance essential security considerations and general public policy concerns,[45] including human rights and health. For Example, article 9.8 in the Australia-China FTA stipulates:

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[41] In *Eli Lilly v. Canada*, the defendant did not object to the tribunal's jurisdiction based on arguments about the existence of a protected investment despite that Eli Lilly had no other assets in Canada than the revoked patents (on ' Strattera' and 'Zyprexa') patents and that the patents were null and void *ex tunc*. See, e.g., Carlos Correa, "Modelling Patent Law Through Investment Agreements", in *Investment Treaties: Views and Experiences from Developing Countries* (South Centre 2015). Available from https://www.southcentre.int/wp-content/uploads/2016/05/Bk_2015_Investment-Treaties_EN.pdf. While the use of trademarks was a key issue in *Philips Morris v. Uruguay*, the companies' interests in Uruguay were "*taken as a whole*—including shares in the company, facilities, operations in Uruguay, *and* Philip Morris' trademarks—constituted a protected investment"; (See, Simon Klopschinski, Christopher Gibson, and Henning Grosse Ruse-Khan, *The Protection of Intellectual Property Rights Under International Investment Law* (OUP 2021) 137). See also Alebe Linhares Mesquita and Vivian Daniele Rocha Gabriel, "Countries' Policy Space to Implement Tobacco Packaging Measures in the Light of Their International Investment Obligations: Revisiting the Philip Morris v. Uruguay Case", (2021) South Centre Investment Policy Brief No. 20. Available from https://www.southcentre.int/wp-content/uploads/2021/01/Investment-PB-20.pdf.

[42] Pratyush Nath Upreti, "IP Licence, Trademarks and ISDS: Bridgestone v. Panama" (2018), South Centre Investment Policy Brief No. 13. Available from https://www.southcentre.int/wp-content/uploads/2018/12/IPB13_IP-Licence-Trademarks-and-ISDS-Bridgestone-v.-Panama_EN.pdf.

[43] William W. Burke-White and Andreas von Staden, "Investment protection in Extraordinary Times: The Interpretation and Application of Non-Precluded Measures Provisions in Bilateral Investment Treaties", Virginia Journal of International Law, Vol. 48 (2007), pp. 321–322.

[44] See: Pathirana D and McLaughlin M, "Non-Precluded Measures Clauses: Regime, Trends, and Practice", in Julien Chaisse, Leïla Choukroune and Sufian Jusoh (eds), *Handbook of International Investment Law and Policy* (Springer Singapore 2019). Available from http://link.springer.com/10.1007/978-981-13-5744-2_6-1. Accessed 8 June 2021.

45 See: United Nations Conference on Trade and Development, Mapping of IIA Content, Investment Policy Hub in https://investmentpolicy.unctad.org/international-investment-agreements/iia-mapping.

> "For the purposes of this Chapter and subject to the requirement that such measures are not applied in a manner which would constitute arbitrary or unjustifiable discrimination between investments or between investors, or a disguised restriction on international trade or investment, **nothing in this Agreement shall be construed to prevent a Party from adopting or enforcing measures:**
>
> *(a)* **necessary to protect human, animal or plant life or health** (…) (emphasis added*)."*[46]

The Morocco-Nigeria IIA uses a broader language to refer to measures that may put limits to investment activities:

> **"Nothing in this Agreement shall be constructed to prevent a Party from adopting maintaining, or enforcing, in a non-discriminatory manner, any measure otherwise consistent with this Agreement that it considers appropriate to ensure that investment activity in its territory is undertaken in a manner sensitive to environmental and social concerns"** (emphasis added).

In principle, the inclusion of exceptions in IIAs should avoid triggering international liability for the adoption of measures by the State, that are related to the objectives described as NPM in the agreement. Nevertheless, the ambiguous language which is used from time to time in these provisions, and the inclusion of "arbitrary or unjustifiable discrimination" standards, have allowed ISDS tribunals to increasingly scrutinize the scope and effects of NPM provisions,[47] transforming the "exception" into an affirmative defense of States for a breach of obligations under the international investment agreement,[48] bearing the risk of making NPMs non-effective.

Given that the effects of a potential WTO waiver on IPRs related to the COVID-19 pandemic can give way to ISDS claims raised by IPRs holders, States should carefully consider the requirements needed for these IPR-related measures to be considered under the "exceptions" of their IIAs to preserve their regulatory autonomy and justify them before ISDS tribunals: otherwise, the WTO waiver's objectives could be undermined by ISDS arbitration.

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[46] See: Free Trade Agreement between the Government of Australia and the People's Republic of China, Article 9.8 (a) in https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/3454/download. Accessed 4 June 2021.

[47] See: Lorenza Mola, "International Investment Arbitration and Serious Economic Crises: Lessons Learned in the Argentinean Crisis of 2000–200", in *International Investment Law in Latin America*, Leiden, The Netherlands: Brill, Nijhoff. doi: https://doi.org/10.1163/9789004311473_014.

[48] Prabhash Ranjan and Pushkar Anand, "Covid-19, India, and Investor-State Dispute Settlement (ISDS): Will India Be Able to Defend Its Public Health Measures?" *Asia Pacific Law Review*, vol. 28, No. 1 (2020), p. 229.

6 NON-PRECLUDED MEASURES, PERMISSIBLE POLICY OBJECTIVES, NEXUS REQUIREMENTS AND PROPORTIONALITY ANALYSIS

Non-precluded measures (NPMs), general or otherwise referred to a standard of protection, are comprised of two different elements, permissible objectives, and nexus requirements. Permissible objectives refer to the sectors or measures which remain permissible even if they result in the breach of investment protection standards.[49] In the case of the COVID-19 pandemic, "health", "essential security interest", and "circumstances of extreme emergency" could be possible permissible objectives used as defenses in ISDS cases.[50]

With regard to the WTO waiver proposal, the public health objectives included in NPM clauses could be the most clearly permissible one with respect to ISDS threats. Measures required to protect public health are the most susceptible to objective scientific proof.[51] In *Philip Morris v. Oriental Republic of Uruguay*,[52] the tribunal considered the "legislative policy decision taken against the background of a strong scientific consensus as to the lethal effects of tobacco"[53] as developed in the World Health Organization guidelines and studies related to the Framework Convention on Tobacco Control (FCTC).[54] For the tribunal, such evidentiary weight on scientific studies made measures adopted by the State reasonable in the context of the obligations of the State under FCTC. Similarly, in *Methanex Corporation v United States*,[55] the tribunal heavily relied on scientific and technical studies carried out by the State of California on the "widespread and potentially serious MTBE contamination of its water resources" that led to the prohibition of the use of methanol in California.[56]

Similarly, the nexus requirement is the causal link between the adopted measures and the permissible objectives to be achieved through those measures. The severity of the standard of proof required to determine each nexus will be dependent on the language of the NPM. For example, while the Morocco-Nigeria BIT requires the measure to be "appropriate" to attain the permissible objective included in the NPM, the US-Argentina BIT requires the measure to be "necessary" for achieving such objectives.[57]

The "necessity" test is the most stringent nexus between the regulatory measure and the objective pursued.[58] The Argentina cases in the early 2000s[59] have tested the rigor of the "necessity" standard to identify the nexus requirement, concluding that a tribunal should consider whether a measure is apt to and did make a "material or a decisive contribution"[60] for the attainment of a public objective, and if alternative and available measures could have been put in place that were not in breach of the IIA.[61] In such cases, the necessity test would also assess the proportionality of the measures adopted and "the pertinence of the

[49] William W. Burke-White and Andreas von Staden, p. 332.
[50] Ibid.
[51] Ibid., p. 361.
[52] *Philip Morris v. Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7 (2010)
[53] Ibid. para. 418.
[54] Ibid. para. 393.
[55] *Methanex Corporation v United States*, Final Award on Jurisdiction and Merits, (2005)
[56] *Methanex Corporation v United States*, para. 20.
[57] Treaty between the United States of America and Argentine Republic concerning the Reciprocal Encouragement and Protection of Investment, Article XI, entered into force in 1994. https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/127/download.
[58] Prabhash Ranjan and Pushkar Anand (2020), p. 235.
[59] UNCTAD Investment Policy Hub, Investment Dispute Settlement Navigator. Available from https://investmentpolicy.unctad.org/investment-dispute-settlement/country/8/argentina.
[60] Continental Contingency, Para. 196.
[61] Ibid. para 198.

hypothetical economic measures that could have achieved the same result as those adopted by Argentina, without affecting the interests of foreign investors."[62]

Therefore, to safeguard against possible claims under IIAs, any measure adopted by States under the proposed WTO waiver should also state the scientific standards and evidence developed by WHO to qualify COVID-19 as a threat to public health and the effect of the pandemic, to trigger the NPMs. Similarly, although the waiver on IPRs will be based on a decision taken by WTO for combating the pandemic, it will be convenient to include a preambular paragraph indicating that other measures (for example, facilitating compulsory licensing under the current TRIPS Agreement flexibilities) are not alternatives to attain the "need for unimpeded and timely access to affordable medical products including diagnostic kits, vaccines, medicines, personal protective equipment and ventilators for a rapid and effective response to the COVID-19 pandemic"[63]. The inclusion of such language could provide the basis and motivation underpinning national measures implementing the waiver on IPRs, which could be valuable in case of ISDS claims.

6.1 Defenses Under Customary International Law: Policy Power Doctrine, Necessity and Force Majeure

Under customary international law, States are responsible for the consequences of any wrongful action or omission that constitute a breach of its international obligations.[64] Nevertheless, customary international law also includes circumstances that preclude the wrongfulness of conducts that would otherwise conflict with their primary obligations under international law. According to the International Law Commission, these circumstances "provide a justification or excuse for non-performance while the circumstance in question subsists,"[65] but does not annul or terminate the obligation. The Draft Articles on Responsibility of States for Internationally Wrongful Acts[66] mentions six circumstances leading to the exclusion of liability by States: consent (art. 20), self-defense (art. 21), countermeasures (art. 22), *force majeure* (art. 23), distress (art. 24) and necessity (art. 25).

In the case of ISDS, the most common circumstances raised as defenses have dealt with necessity and *force majeure*. In the case of defenses under "necessity" these circumstances would require proving the existence of an exceptional circumstance that presents an "irreconcilable conflict between an essential interest on the one hand and an obligation of the State" on the other.[67] As such, the International Court of Justice has recognized that "necessity" can only be raised as defense on exceptional basis and under "strictly defined conditions which must be cumulatively satisfied,"[68] particularly that an essential interest of the State is in **grave and imminent peril** and that the act being challenged is the **only means** to safeguard such interest, which in other way will **seriously impair** the essential interest of the

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[62] Federico Lavopa, "Crisis, Emergency Measures and the Failure of the ISDS System: The Case of Argentina", South Centre Investment Policy Brief No. 2, July 2015 p. 6.

[63]Communication from India and South Africa, "WAIVER from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19", World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights Doc. IP/C/W/669 (2020).

[64] See : International Law Commission, *Draft Articles on Responsibility of States for Internationally Wrongful Acts with Commentaries*, Yearbook of the International Law Commission, 2001, vol. II, Part Two (2001), p. 71 in Draft articles on Responsibility of States for Internationally Wrongful Acts, with commentaries - 2001 (un.org). Accessed 7 June 2021.

[65] International Law Commission, Draft Articles on Responsibility of States for Internationally Wrongful Acts, Article 25.

[66] See: International Law Commission, Draft Articles on Responsibility of States for Internationally Wrongful Acts with Commentaries, Commentary on Chapter V, p. 71.

[67] International Law Commission, Draft Articles on Responsibility of States for Internationally Wrongful Acts with Commentaries, Commentary on Article 25, p. 80.

[68] See: GabCikovo-Nagymaros Project (Hungary v. Slovakia), Judgment, International Court of Justice, Reports 1997, para. 51.

State, and that the State **has not contributed to the occurrence of the state of necessity**.[69] In the case of ISDS, as mentioned above, tribunals have considered that the "necessity" test does not require the extent under customary law, but will require to prove that the measure is targeted to protect an essential interest of the State (nexus) and that such measures should have objectively considered other "reasonable alternatives less in conflict or more compliant with international legal obligations."[70] The defenses based on "necessity" under ISDS have been rarely successful, as tribunals have been very restrictive in their interpretation, in particular by requiring evidence that such measures were "the only possible measures" to be adopted in the circumstances of the case.[71]

The defense under *force majeure* is also quite narrow as it requires that: (a) the act in question must be brought about by an irresistible force or an unforeseen event; (b) which is beyond the control of the State concerned; and (c) which makes it materially impossible in the circumstances to perform the obligation.[72] According to the International Law Commission (ILC) commentaries, deference to *force majeure* will also require a degree of due diligence by the State, as the criteria of "irresistible force" will require the existence of "a constraint which the State was unable to avoid or oppose by its own means."[73] Given that the *force majeure* standard will imply the non-performance of the obligation for as long as the circumstance exists, tribunals have considered that defense will require to prove that the implementation of a given obligation is "absolute or materially impossible"[74] by the State. Tribunals have considered that rendering performance more difficult or burdensome, or impossible as the result of a unilateral decision of a State, does not constitute a case of *force majeure.*[75]

Under the doctrine of Police Powers, States have the right to adopt lawful measures that may "affect foreign interests considerably without amounting to expropriation."[76] Although certain ISDS tribunals have considered "a consistent trend in favor of differentiating the exercise of police powers from indirect expropriation"[77] when such exercise is exerted following reasonable and *bona fide* manner,[78] other tribunals[79] have considered that relying on the police powers doctrine is automatically inapplicable when 'specific exceptions' have been included in the Agreement.[80]

For the purposes of the WTO waiver, States should consider that policy powers, necessity and *force majeure* doctrines are not an absolute guarantee concerning expropriation, as tribunals have also applied the Sole Effects Doctrine, by which tribunals should consider solely the effects of the measures on the investment (i.e., indirect expropriation), rather than the

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[69] See: *GabCikovo-Nagymaros Project (Hungary v. Slovakia,* para. 50–51.
[70] Deutsche Telekom AG v India, PCA Case No. 2014–10, Interim Award, 13 December 2017 (hereafter 'Deutsche Telekom'), para 239 cited by Prabhash Ranjan and Pushkar Anand (2020), p. 236.
[71] Federica Paddeu and Freya Jephcott, "COVID-19 and Defences in the Law of State Responsibility: Part II", EJIL:Talk!, 17 March 2020. Available from https://www.ejiltalk.org/covid-19-and-defences-in-the-law-of-state-responsibility-part-ii/.
[72] *Draft Articles on Responsibility of States for Internationally Wrongful Acts with Commentaries,* p. 76 art. 23.
[73] Ibid.
[74] Ibid.
[75] Libyan Arab Foreign Investment Company (LAFICO) v. Republic of Burundi (Dispute concerning the Libyan Arab-Burundi Holding Company), 96 I.L.R. 279 (1991), par. 55.
[76] Prabhash Ranjan and Pushkar Anand, "Covid-19, India, and Investor-State Dispute Settlement (ISDS): Will India Be Able to Defend Its Public Health Measures?" (2020) 28 *Asia Pacific Law Review* 225, p. 240. Available from https://www.tandfonline.com/doi/full/10.1080/10192557.2020.1812255. Accessed 7 July 2020.
[77] *Philip Morris v. Oriental Republic of Uruguay*, Award, para 295, in Prabhash Ranjan and Pushkar Anand, "Covid-19, India, and Investor-State Dispute Settlement (ISDS): Will India Be Able to Defend Its Public Health Measures?" (2020).
[78] Ibid.
[79] Bear Creek Mining Corporation v. Republic of Peru, ICSID Case No. ARB/14/21, Award, 30 November 2017.
[80] Dilini Pathirana and Mark McLaughlin, "Non-Precluded Measures Clauses: Regime, Trends, and Practice", in Julien Chaisse, Leïla Choukroune and Sufian Jusoh (eds.), *Handbook of International Investment Law and Policy* (Springer Singapore 2019). Available from http://link.springer.com/10.1007/978-981-13-5744-2_6-1. Accessed 8 June 2021.

intended purpose of the State's measures.[81] Nevertheless, the inclusion of clear language in the WTO waiver, and its linkages with WHO scientific evidence, could allow States to identify the reasonable nexus and proportionality of the measures with its intended purpose, therefore limiting the sole effects doctrine.[82] In addition, States could also decide to make a declaration explicitly rejecting this doctrine, or excluding health measures from the expropriation chapter, including IPRs. An example of this language can be identified in the Agreement between Japan and the Republic of Colombia for the liberalization, promotion, and protection of investments, which states:

> Art. 11.5.- The provisions of this Article do not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with the TRIPS Agreement.

In addition, Annex III of the Colombia–Japan Agreement, excludes the possible use of the Sole Effects Doctrine by recognizing that the "fact that such measure or series of such measures has an adverse effect on the economic value of investments, standing alone, does not establish that an indirect expropriation has occurred."[83]

[81] Ben Mostafa, *The Sole Effects Doctrine, Police Powers and Indirect Expropriation under International Law*, Australian International Law Journal, vol. 15 (2008), pp. 279–280.
[82] Satyajit Bose, "Police Powers as a Defence to COVID-19 Liability: Does it Protect Host States?" (2020). Available from http://blogs2.law.columbia.edu/aria/police-powers-as-a-defence-to-covid-19-liability-does-it-protect-host-states/. Accessed 24 June 2020.
[83] See: Agreement between Japan and the Republic of Colombia for the liberalization, promotion, and protection of investments, Annex III, para 2 (a). Available from http://www.sice.oas.org/Investment/BITSbyCountry/BITs/COL_JPN_AN3_e.pdf.

7 A MORATORIUM ON ISDS CLAIMS RELATED TO IPRS

Different calls for an ISDS moratorium have been made by civil society organizations (CSOs) and experts.[84] These calls have considered establishing a complete moratorium or temporary suspension of ISDS claims related to the COVID-19 pandemic and requested States to clarify international law defenses during these extraordinary times.

These calls have been echoed during the Thirteenth Extraordinary Session of the Assembly of the Heads of State and Government on the African Continental Free Trade Agreement (AfCFTA), when the African Union endorsed the "Declaration on the Risk of Investor-State Dispute Settlement (ISDS) with respect to COVID-19 pandemic related measures", inviting their "Member States to explore all possibilities for mitigating the risks of ISDS, including a mutual temporary suspension of ISDS provisions in investment treaties in relation to COVID-19 pandemic government measures."[85]

The possibility of establishing bilateral or multilateral suspension of ISDS has precedents. New Zealand has signed agreements in the form of side letters with five countries to exclude compulsory ISDS between them under the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). The terms of the side letters vary as some exclude the use of ISDS between New Zealand and other countries entirely, while other side letters allow for arbitration to proceed only if the relevant Government agrees[86]. These "side letters" have the same treaty-level status as the Agreement. The US and Canada have also agreed on excluding ISDS bilaterally under USMCA.[87]

The adoption of a WTO waiver on IPRs related to combating the COVID-19 pandemic could build momentum to explore the possibility of establishing an ISDS suspension related to IPRs and linked to the temporary nature of the WTO waiver.[88] Following the example of New Zealand experiences, such suspension could be achieved through the exchange of side letters among the Heads of States, which could have the same effect of subsequent agreement under Article 31(3)(a) of the Vienna Convention on the Law of Treaties.[89]A BIT-specific IPR waiver agreement could either take the form of a separate multilateral or a bilateral treaty stating that it would override all the existing BITs in regard to COVID-19 products for as long as the pandemic lasts. In the first case, several world leaders have considered the need to work towards a "new international treaty for pandemic preparedness and response,"[90] including a commitment to ensure "universal and equitable access to safe, efficacious and affordable

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[84] IISD, Protecting Against Investor–State Claims Amidst COVID-19: A call to action for governments, 14 April 2020. https://www.iisd.org/library/investor-state-claims-amidst-covid-19 and Columbia Centre for Sustainable Investment, Call for ISDS Moratorium During COVID-19 Crisis and Response, 6 May 2020. http://ccsi.columbia.edu/2020/05/05/isds-moratorium-during-covid-19/.

[85] See: Thirteenth extraordinary session on the AfCFTA: The Assembly of the Union adopts decision on the start of trading, African Union, 5 December 2020. Available from https://au.int/en/pressreleases/20201205/thirteenth-extraordinary-session-afcfta-assembly-union-adopts-decision-start cited by Daniel Uribe and Danish, "Investment Policy options for facing COVID-19 related ISDS Claims", forthcoming.

[86] *New Zealand signs side letters curbing investor-state dispute settlement*, 9 March 2018. https://www.beehive.govt.nz/release/new-zealand-signs-side-letters-curbing-investor-state-dispute-settlement.

[87] See: Agreement between the United States of America, the United Mexican States, and Canada, Annex 14-C and Annex 14-D available in https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/14-Investment.pdf. Accessed 7 July 2021.

[88] Prabhash Ranjan, 2021.

[89] See: Prabhash Ranjan (2021) and Daniel Uribe and Danish, "Investment Policy options for facing COVID-19 related ISDS Claims", forthcoming.

[90] World Health Organization, "COVID-19 shows why united action is needed for more robust international health architecture". Available from https://www.who.int/news-room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture. Accessed 7 July 2021.

vaccines, medicines and diagnostics for this and future pandemics."[91] Therefore, the World Health Organization could have an opportunity to include such a waiver as a response for future pandemics. In the second case, it will be possible for treaty partners to sign a BIT-specific IPR waiver bilaterally as a subsequent agreement under Article 31(3)(a) of the Vienna Convention on the Law of Treaties.

[91] Ibid.

8 CONCLUSIONS

The TRIPS waiver in itself will not suspend or remove the application of the domestic IP law provisions to health technologies for responding to COVID-19. WTO members will have to give effect to the waiver by adopting implementation laws, regulations, or administrative measures, as appropriate. In adopting such measures, the scope of the waiver as well as obligations that may be applicable to a country under an FTA or an IIA will also be of critical importance. Therefore, it will be important for developing countries to ensure that the waiver is sufficiently broad in scope and not limited for example to patents on vaccines.

To ensure that provisions in FTAs do not impede the implementation of the waiver, the text of the waiver decision could include a provision restraining WTO members from invoking any FTA provision that could frustrate the utilization of the waiver. Parties to FTAs could also negotiate complementary waivers from FTA provisions where there may be conflict with the implementation of the waiver. As described in this paper, some FTAs like CPTPP and USMCA contain specific provisions that require parties to undertake consultations to adapt the provisions under those agreements in the light of a TRIPS waiver. Moreover, if a State agrees to a waiver in relation to IP protection and enforcement in WTO, under the general principle of estoppel in international law it can be argued that it will be legitimate for other States to expect a similar attitude in relation to IP issues in other applicable agreements between them. Hence, it will be legitimate and reasonable to expect that a country agreeing to the waiver in the WTO under TRIPS, has by implication waived corresponding obligations relating to health technologies and products for COVID-19 under FTAs.

Similarly, measures pursuant to the implementation of the TRIPS waiver may hypothetically be challenged under bilateral investment treaties (BITs) and other investment agreements (IIAs). A first defense in such situations could be based on the requirements needed to characterize IPRs as protected investments. States could also use provisions on exceptions in IIAs as primary means of defense against such claims, but ambiguous language in traditional IIAs as well as ISDS arbitration tribunals practice might bear risks of making these exceptions non-effective. Nevertheless, customary international law also includes circumstances that preclude the wrongfulness of conducts that would otherwise conflict with the primary obligations of States under international law providing a justification and defenses for non-compliance with obligations under IIAs.

Although virtually all States could make use of these defenses in face of possible ISDS claims, it would be necessary for States to carefully design the measures intended for the implementation of the TRIPS waiver with a view of preventing these claims. This will require considering all conditions needed for making these defenses effective, including by justifying such measures (based on WHO scientific evidence), and decisions taken by other international organizations. States would then be able to identify the reasonable nexus and proportionality of the measures with the intended purpose of combating the COVID-19 emergency. In addition, the adoption of a WTO waiver could build momentum for an ISDS moratorium related to IPRs and linked to the temporary nature of the WTO waiver.

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