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**Research Report**

## A TRIPS-Covid waiver and overlapping commitments to protect intellectual property rights under international IP and investment agreements

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# A TRIPS-COVID Waiver and Overlapping Commitments to Protect Intellectual Property Rights Under International IP and Investment Agreements

Henning Grosse Ruse-Khan and Federica Paddeu





# **RESEARCH PAPER**

**144**

## **A TRIPS-COVID WAIVER AND OVERLAPPING COMMITMENTS TO PROTECT INTELLECTUAL PROPERTY RIGHTS UNDER INTERNATIONAL IP AND INVESTMENT AGREEMENTS**

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**SOUTH CENTRE**

**27 JANUARY 2022**

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## ABSTRACT

This paper considers legal implications that are likely to emerge from the implementation of a TRIPS Waiver decision. Assuming that a Waiver is adopted in the form presented in the May 2021 proposal by South Africa and India et al, we review the interaction between the Waiver and other commitments to protect IP rights under international IP and investment treaties. Our principal research question is to analyze whether domestic measures implementing the Waiver are compatible with the implementing State's other obligations to protect IP rights established under multilateral IP treaties, IP and Investment Chapters of FTAs as well as BITs. In light of typical examples for such overlapping commitments, we first focus on (1) defences directly affecting compatibility with these treaty commitments (here referred to as 'internal' defences). In a second part, we review (2) potential defences under general international law that may serve to justify (in other words, to preclude the wrongfulness of) such measures. We conclude that often internal and/or general defences will operate to support the implementation of the Waiver despite overlapping commitments in international IP and investment law. This conclusion is reinforced by a purpose-oriented understanding of the TRIPS Waiver as authorizing measures necessary to achieve the goal of "unimpeded, timely and secure access" for all to covered medical technologies "for the prevention, treatment or containment of COVID-19".

*En este documento se examinan las implicaciones jurídicas que probablemente surjan de la aplicación de una decisión de exención del ADPIC. Suponiendo que se adopte una exención en la forma presentada en la propuesta de mayo de 2021 por Sudáfrica e India et al, examinamos la interacción entre la exención y otros compromisos de protección de los derechos de PI en virtud de los tratados internacionales de PI e inversión. Nuestra principal pregunta de investigación es analizar si las medidas nacionales de aplicación de la exención son compatibles con las demás obligaciones de los Estados de proteger los derechos de PI establecidas en los tratados multilaterales de PI, los capítulos de PI e inversión de los TLC y los TBI. A la luz de los ejemplos típicos de este tipo de compromisos superpuestos, nos centramos primero en (1) las defensas que afectan directamente a la compatibilidad con estos compromisos de los tratados (denominadas aquí defensas "internas"). En una segunda parte, revisamos (2) las posibles defensas en virtud del derecho internacional general que pueden servir para justificar (en otras palabras, para excluir la ilicitud de) tales medidas. Llegamos a la conclusión de que, a menudo, las defensas internas y/o generales funcionarán para apoyar la aplicación de la Exención a pesar de los compromisos superpuestos en el derecho internacional de la PI y de la inversión. Esta conclusión se ve reforzada por una interpretación orientada al propósito de la exención del Acuerdo sobre los ADPIC en el sentido de que autoriza las medidas necesarias para lograr el objetivo de un "acceso sin obstáculos, oportuno y seguro" para todos a las tecnologías médicas cubiertas "para la prevención, el tratamiento o la contención de COVID-19".*

*Cet article examine les implications juridiques susceptibles d'émerger de la mise en œuvre d'une décision de dérogation aux ADPIC. En supposant qu'une dérogation soit adoptée sous la forme présentée dans la proposition de mai 2021 par l'Afrique du Sud et l'Inde et al, nous examinons l'interaction entre la dérogation et les autres engagements de protection des droits de PI en vertu des traités internationaux de PI et d'investissement. Notre principale question de recherche est d'analyser si les mesures nationales mettant en œuvre la dérogation sont compatibles avec les autres obligations de l'État d'exécution en matière de protection des droits de PI établies dans le cadre des traités multilatéraux de PI, des chapitres sur la PI et l'investissement des ALE ainsi que des TBI. A la lumière d'exemples typiques de tels chevauchements d'engagements, nous nous concentrons d'abord sur (1) les défenses affectant directement la compatibilité avec ces engagements conventionnels (appelées ici défenses "internes"). Dans une deuxième partie, nous examinons (2) les défenses potentielles en vertu du droit international général qui peuvent servir à justifier (en d'autres termes, à exclure l'illicéité) de telles mesures. Nous concluons que souvent, les défenses internes et/ou générales fonctionneront pour soutenir la mise en œuvre de la dérogation malgré les chevauchements d'engagements dans le droit international de la PI et de l'investissement. Cette conclusion est renforcée par une compréhension axée sur l'objectif de la dérogation ADPIC comme autorisant les mesures nécessaires pour atteindre l'objectif d'un "accès libre, rapide et sûr" pour tous aux technologies médicales visées "pour la prévention, le traitement ou le confinement de la COVID-19".*

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# 1. INTRODUCTION: THE TRIPS WAIVER PROPOSALS IN THE WTO AND OVERLAPPING COMMITMENTS TO PROTECT IP

In October 2020, India and South Africa jointly submitted a proposal under article IX.3 of the Agreement Establishing the World Trade Organization (hereinafter WTO Agreement) to the TRIPS Council requesting a waiver of IP obligations under TRIPS in respect of medical technologies for the prevention, containment and treatment of COVID-19.<sup>1</sup> In May 2021, a group of 64 States, from Africa, Asia and Latin America, submitted a revised proposal for consideration by the TRIPS Council.<sup>2</sup> The text of the revised proposal states, in relevant part, as follows:

The General Council  
(...)

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

(...)

Noting with concern the threat to human health, safety and well-being caused by the COVID-19 pandemic, which has spread all around the globe, as well as the unprecedented and multifaceted effects of the pandemic, including the severe disruption to societies, economies, global trade and travel and the devastating impact on the livelihoods of people;

Noting with great concern the continuous mutations and emergence of new variants of SARS-COV-2, which also highlights the significant uncertainties and complexities of controlling SARS-COV-2;

Recognizing the global need for unimpeded, timely and secure access to quality, safe, efficacious and affordable health products and technologies for all, for a rapid and effective response to the COVID-19 pandemic and consequently the urgent need to diversify and scale-up production to meet global needs and promote economic recovery;

Recognizing also that the COVID-19 global pandemic requires a global response based on unity, solidarity and multilateral cooperation;

Recognizing the importance of preserving incentives for research and innovation, and that these should be balanced with the public health interest;

(...)

Decides as follows:

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<sup>1</sup> 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 (IP/C/W/669, 2 October 2020). The original proposal requested that: “The obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to prevention, containment or treatment of COVID-19, for [X] [sic] years from the decision of the General Council.”

<sup>2</sup> COMMUNICATION FROM THE AFRICAN GROUP, THE PLURINATIONAL STATE OF BOLIVIA, EGYPT, ESWATINI, FIJI, INDIA, INDONESIA, KENYA, THE LDC GROUP, MALDIVES, MOZAMBIQUE, MONGOLIA, NAMIBIA, PAKISTAN, SOUTH AFRICA, VANUATU, THE BOLIVARIAN REPUBLIC OF VENEZUELA AND ZIMBABWE, WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19, World Trade Organization – Council for Trade-Related Aspects of Intellectual Property Rights (IP/C/W/669/Rev.1, 25 May 2021); hereafter referred to as “TRIPS Waiver”.

1. The obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19.
2. This waiver shall be in force for at least 3 years from the date of this decision. (...)
3. The waiver in paragraph 1 shall not apply to the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Article 14 of the TRIPS Agreement.
4. This decision is without prejudice to the right of least developed country Members under paragraph 1 of Article 66 of the TRIPS Agreement.
5. This waiver shall be reviewed by the General Council not later than one year after it is granted (...)
6. Members shall not challenge any measures taken in conformity with the provision of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through the WTO's Dispute Settlement Mechanism.<sup>3</sup>

This proposal will continue being discussed in the World Trade Organization ("WTO"), including at the next meeting of the Ministerial Council of the WTO, currently scheduled to take place early 2022. At the time of writing, the Ministerial Council Meeting is forthcoming, and the analysis in this report is based on the May 2021 revised text for a TRIPS Waiver.

In this paper we consider certain legal implications that are likely to emerge from the potential implementation of a Waiver decision. We take as a starting point that the TRIPS Waiver has been adopted and will not consider the practical or political merits of this decision. Assuming that the Waiver is adopted, we consider the interaction between the Waiver and other international legal rules bearing on the protection of IP rights – both in international IP law and foreign investment law, to the extent that the latter applies to IP rights – which may be affected by a State's domestic implementation of the Waiver decision. In short: when a State adopts measures in its domestic law to implement the Waiver, is this implementation compatible with that State's other obligations to protect and respect IP rights established in other IP, trade and investment treaties? Or will the implementation of the Waiver by a State engage its international responsibility for the breach of these other conventional commitments with respect to IP rights?

Our analysis proceeds in two steps. First, we consider the potential incompatibilities that may arise in the implementation of the TRIPS Waiver. In particular, we consider three broad sets of treaty commitments that are engaged by a State's domestic implementation of the TRIPS Waiver: (i) IP-protection commitments under other multilateral IP treaties, including those incorporated into TRIPS; (ii) so-called "TRIPS-plus" commitments, namely provisions which establish additional protections to those in TRIPS, incorporated into free trade agreements (FTAs);<sup>4</sup> and (iii) the protection of IP rights under international investment

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<sup>3</sup> The May 2021 Communication with the revised text explains that, in addition to adding a paragraph on the proposed duration, 'the operative paragraph (1) has been revised to add specificity to the decision text following concern that the original decision text was too broad'. The revised text addresses this concern "by focusing the text on "health products and technologies" as the prevention, treatment or containment of COVID-19 involves a range of products and technologies and intellectual property issues may arise with respect to the products and technologies, their materials or components, as well as their methods and means of manufacture." See paras 4&5 of the 25 May 2021 Communication, as note 2 above.

<sup>4</sup> We note that commitments in IP Chapters in FTAs at times simply are identical or equivalent to obligations under TRIPS. While much depends on the individual commitment and the measure taken to implement the Waiver, the issues discussed in relation to TRIPS-plus commitments in FTAs in principle equally apply to

agreements, in the form of bilateral investment treaties (BITs) as well as Investment Chapters in FTAs. In each case, we will consider the extent to which these commitments are (potentially) breached by the implementation of the Waiver. As we will argue, in many cases, techniques available in international law, such as the principle of systemic integration in treaty interpretation, can avoid the incompatibility from arising to begin with. Furthermore, in many instances, certain exceptions internal to the treaties (such as “TRIPS-safeguard” clauses) may be applicable to the implementation measures, such that they will not be in breach of the relevant treaty.

Second, in respect of cases in which the above techniques will not avoid incompatibility, and the implementation measures will therefore involve a *prima facie* violation of the relevant treaty commitments, we will review potential defences under general international law that may serve to justify (in other words, to preclude the wrongfulness of) such measures. We will focus on the defences of necessity and consent, codified in the International Law Commission’s (“ILC”) Articles on the Responsibility of States for Internationally Wrongful Acts (“ARS”).<sup>5</sup> We will explain the requirements and conditions of each of these defences, by reference to the work of the ILC, case law and scholarly commentary, and assess how they might apply to the measures implementing the TRIPS Waiver. Both defences are highly context-dependent, so no firm and definitive conclusions can be reached as to their successful invocation to justify the *prima facie* breach of treaty commitments by means of the domestic implementation of the Waiver. The paper will nevertheless provide guidance as to how these defences may be raised.

It may be useful to clarify at the outset that national treatment and most-favoured nation (MFN) commitments under TRIPS (see Art.3, 4 TRIPS – in Section 1 of the Agreement) are not waived. National treatment under TRIPS has been understood to include *de facto* discrimination – that is to say, a situation where a measure affects the “effective equality of opportunities with regard to the protection of intellectual property rights”.<sup>6</sup> A WTO Member might argue that a national measure implementing the Waiver, for example by suspending patent and regulatory test data protection for COVID vaccines, in practice primarily or solely affects foreign IP owners. This, so could be argued, amounts to not providing equal opportunities as to the protection of IP rights, or applies “differentially disadvantageous standards”<sup>7</sup> to foreign IP owners. While our analysis does not consider these arguments further, it should be added that claiming a *de facto* discriminatory effect is unlikely to be sufficient. In *Canada – Patents*, the *de facto* discrimination standard was argued to further require the absence of a justification for the disadvantageous effects<sup>8</sup> – which should generally be easy to establish in relation to measures implementing the TRIPS Waiver. And even without considering such a justification, merely pointing to a foreign nationality of one or more entities owning IP rights in a medical technology affected by a national implementation measure will hardly constitute a sufficient nexus between the measure and nationality-based discrimination.<sup>9</sup>

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commitments that do not go beyond, but are identical or equivalent to those in TRIPS. In addition, it should be noted that TRIPS-plus commitments can also be found in form of additional commitments on IP protection in Protocols of Accession to the WTO.

<sup>5</sup> Articles on the Responsibility of States for Internationally Wrongful Acts (ARS), annexed to UNGA Res 56/83 “Responsibility of States for Internationally Wrongful Acts” (12 December 2001) GAOR 56th Session Supp 49 vol. 1, 499. For the ILC’s Commentary, see: Commentary to the Articles on Responsibility of States for Internationally Wrongful Acts, (2001) Yearbook of the ILC, vol II(2), UN Doc A/CN.4/SER.A/2001/Add.1 (“ILC Commentary” or “Commentary”).

<sup>6</sup> *EC–Geographical Indications (EC–GIs)*, Panel Report (15 March 2005, WT/DS174/R), para 7.176.

<sup>7</sup> A standard set out in the see *Canada–Patents* dispute with regard to the non-discrimination clause in Art 27(1) TRIPS; see *Canada–Patent Protection of Pharmaceutical Products (Canada–Patents)*, Panel Report (17 March 2000, WT/DS114/R), para 7.101.

<sup>8</sup> The Panel suggested that this requires an inquiry whether the “objective characteristics of the measure” show any “discriminatory objectives”; see *Canada–Patents*, para 7.101.

<sup>9</sup> For a detailed discussion, see S. Klopschinski, C. Gibson & H. Grosse Ruse-Khan, *The Protection of Intellectual Property under International Investment Law* (OUP 2020), paras 5.146-151.

## 2. THE FUNCTIONS OF THE TRIPS WAIVER: MEANS AND ENDS

Before turning to our analysis, it is important to set out a key factor that informs our assessment. The TRIPS Waiver, if adopted in line with the proposal of May 2021, performs two different functions: it is both an end in itself, and also a means to an end. The first function of the TRIPS Waiver is to suspend compliance with the respective provisions in Part II and III of TRIPS to protect and enforce IP rights of nationals of other WTO Members. That is, States will not be bound by the obligations stemming from these Parts of TRIPS throughout the period that the Waiver lasts. Insofar as the Waiver suspends IP rights under TRIPS, it is an end in itself. But this is not all.

The TRIPS Waiver also provides a permission to States to adopt measures, in their domestic sphere, to suspend or otherwise alter the IP protection that is otherwise available for COVID-19 medical technologies under TRIPS. This is implicit in the language used in the Preamble of the May 2021 proposal. Thus, WTO Members recognize that:

the global need for unimpeded, timely and secure access to quality, safe, efficacious and affordable health products and technologies for all, for a rapid and effective response to the COVID-19 pandemic and consequently the urgent need to diversify and scale-up production to meet global needs and promote economic recovery[.]

Such unimpeded, timely and secure availability of these technologies could not be obtained if States were not allowed to adopt measures, domestically, which limit IP protections for these technologies. The TRIPS Waiver thus reflects the common intention of WTO Members to authorize measures which can achieve these goals – within the parameters of the medical technologies and types of IP rights covered by the Waiver. Within these parameters, the preambular language of the Waiver hence suggests a common intention of WTO Members to facilitate certain outcomes. This permission or authorization to achieve the stated goals is of fundamental importance. The Waiver is not adopted just as an **end in itself**: it is a means to an end. As such, a purpose- and goal-oriented reading of the agreed Waiver is warranted, least of all by its text.

### **3. OVERLAPPING TREATY COMMITMENTS AND “INTERNAL” DEFENCES**

This section reviews the types of overlapping treaty commitments which may interfere with the ability of a WTO Member bound by such commitments to implement the Waiver within its domestic law. For once, these commitments can originate from international IP treaties – including multilateral treaties such as the Paris Convention or the WIPO Copyright Treaty, or free trade agreements (FTAs) with an IP Chapter. As especially post-TRIPS FTAs often include commitments that go beyond the minimum standards of TRIPS (commonly referred to as “TRIPS-plus”), such additional obligations may be affected by domestic implementation measures undertaken by WTO Members bound by such an FTA. At the same time, most FTAs include clauses that refer to TRIPS, often including the public health related flexibilities of TRIPS. We therefore examine the role of these provisions for determining the relationship between the TRIPS Waiver and overlapping IP commitments in FTAs.

The section then proceeds to analyze the protection available to IP rights under international investment law, to the extent that might impact on measures undertaken to implement the Waiver. As this form of protection can often be directly invoked by investors in front of arbitral tribunals in the context of investor–State dispute settlement (ISDS), it may well serve as the most likely forum where State conduct in reliance on the TRIPS Waiver is challenged. Our analysis begins by considering how IP rights can constitute protected investments under an international investment agreement (IIA). The two most relevant standards of investment protection in the context of the TRIPS Waiver – protection against expropriation and the fair and equitable treatment (FET) standard – are briefly introduced. We focus this section on defences within international investment law, such as the right to regulate and clauses that “safeguard” flexibilities under TRIPS and their role in justifying a claim against domestic measures taken to implement the Waiver.

#### ***a. Treaty Commitments Under Multilateral IP Treaties, Including those Incorporated into TRIPS***

The TRIPS Agreement incorporates a range of provisions from pre-existing international treaties with obligations to protect IP rights. While TRIPS also includes references to other international IP treaties – such as to the Treaty on Intellectual Property in Respect of Integrated Circuits in Art.35 TRIPS (IPIC Treaty)<sup>10</sup> and to the Rome Convention<sup>11</sup> in Art.14 TRIPS – this section focuses on the Berne Convention for the Protection of Literary and Artistic Works<sup>12</sup> and the Paris Convention on the Protection of Industrial Property<sup>13</sup>. To the extent measures taken by a WTO Member under a TRIPS waiver may interfere with obligations to protect, for example, copyright under the Berne Convention, or patent, industrial designs or trademark rights under the Paris Convention, two questions arise: (1) does the waiver incorporate the relevant provisions of the Berne or Paris Convention such that WTO Members are not required, as a matter of WTO law, to comply with these

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<sup>10</sup> While the IPIC Treaty never entered into force and hence does not serve as an autonomous source of commitments to protect IP in the layout design of integrated circuits, the relevant TRIPS provision in Section 6 of Part Two of TRIPS (namely, Art.35) which requires WTO Members to protect integrated circuits in accordance with Art.2-7 of the IPIC Treaty is not covered by the TRIPS Waiver as the latter only refers to IP rights in Sections 1, 4, 5 and 7 of Part Two of the TRIPS Agreement.

<sup>11</sup> Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (RC) (Rome, 26 October 1961) 496 UNTS 43.

<sup>12</sup> Berne Convention on the Protection of Literary and Artistic Works (BC) (Berne, 9 September 1886, last revised at Paris on 24 July 1971 and amended in 1979), 1161 UNTS 30.

<sup>13</sup> Paris Convention on the Protection of Industrial Property (PC) (Paris, 20 March 1883, last revised at Stockholm on 14 July 1967 and amended in 1979), 828 UNTS 306.

provisions? (2) In case the WTO Member in question is – independent of its membership to the WTO – a contracting party of the Berne or Paris Convention, is that Member potentially violating its obligations under these treaties? This second question also arises in relation to IP treaties whose commitments have not been incorporated into TRIPS, to the extent that WTO Members are also contracting parties to such IP treaties, for example the WIPO Copyright Treaty (WCT).<sup>14</sup>

With regard to the first question, the waiver text of 05/2021 (IP/C/W/669/Rev.1) refers to the “obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement”. The TRIPS reference to the Berne Convention can be found in Art.9(1) TRIPS whereby “Members shall comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto”. Since this provision is situated in Section 1 of Part II of TRIPS, it falls within the ambit of the TRIPS waiver, so that – as a matter of WTO law – WTO Members are under no obligation to comply with the Berne Convention provisions incorporated by virtue of Art.9(1) TRIPS. To the extent copyright protection could impede measures to facilitate access to medical treatment and related technologies – such as reliance on text and data mining activities by or to train artificial intelligence for the development of digital solutions to support diagnostics and treatment for COVID-19<sup>15</sup> – the commitments in TRIPS to comply with the Berne Convention are hence covered by the waiver.

The situation is more complex with regard to the incorporation of provisions from the Paris Convention. In this regard, Art.2 TRIPS states:

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).
2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

Art.2(1) TRIPS, which is not within Part II of TRIPS, obliges WTO Members to comply with the substantive commitments of the Paris Convention, inter alia, “in respect of Parts II [and] III” of TRIPS. Since these are the parts of TRIPS establishing obligations on substantive IP rights (Part II) and their enforcement (Part III) which are largely waived under the Waiver text of 05/2021, it could be argued that compliance with Art.1-12 Paris Convention is also captured by the waiver.

On the other hand, in *Australia–Plain Packaging*, the Panel considered that the ordinary meaning of the term “in respect of”, together with the grammatical structure of Art.2(1) TRIPS, suggests that WTO Members shall comply with the incorporated provisions of the Paris Convention to the extent that these provisions relate to Parts II, III and IV of the TRIPS Agreement. It understood this reference to relate to the subject-matter addressed in Parts II, III and IV, namely standards of protection, domestic enforcement, and acquisition and maintenance of intellectual property rights. The Panel agreed with the Appellate Body’s determination in *US–Section 211 Appropriations Act* that the words “in respect of” in Art.2(1) do not have the effect of “conditioning” the scope of Members’ obligations under the Paris Convention rules incorporated into the TRIPS Agreement.<sup>16</sup> For the Panel, this reasoning suggested that the incorporation of the obligations of WTO Members in respect of unfair

<sup>14</sup> WIPO Copyright Treaty (WCT) (Geneva, 20 December 1996), 2186 UNTS 121.

<sup>15</sup> World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the WTO, “Integrated health, trade and IP approach to respond to the COVID-19 pandemic”, Trilateral Study Promoting Access to Medical Technologies and Innovation, p. 9.

<sup>16</sup> United States – Section 211 Omnibus Appropriations Act (US–Section 211), Appellate Body Report (WT/DS176/AB/R), paras 337-341.

competition under Art.10bis of the Paris Convention should likewise not be assumed to be “conditioned” in such a manner as to limit its scope to those subject-matters expressly identified in Parts II, III or IV of the TRIPS Agreement.<sup>17</sup>

On this basis, the terms “in respect of” primarily **characterise the broader modes of IP protection** in relation to which compliance with the Paris Convention rules is owed. Art.2(1) TRIPS hence requires complying with Art.1-12 of the Paris Convention with regard to matters relating to substantive standards of protection under Part II, enforcement standards under Part III, and acquisition and maintenance procedures under Part IV. This said, such a reading does not fully resolve the question whether the Waiver, insofar as it relates to TRIPS commitments in Part II and III, can be extended to cover the obligation to comply with Art.1-12 of the Paris Convention. A clarification in the text of the Waiver to address the issue of incorporation of the Paris Convention provisions would hence be useful.

Furthermore, since the Waiver does not cover TRIPS provisions under Part IV of TRIPS—namely on the “Acquisition and maintenance of intellectual property rights and related inter-partes procedures”, the obligation to comply with Art.1-12 of the Paris Convention “in respect of” Part IV TRIPS is in any case not affected by the Waiver. Depending on how exactly domestic measures implementing the Waiver relate to domestic acquisition and maintenance procedures for IP rights otherwise covered by the Waiver, commitments under Art.63 TRIPS (to allow for e.g., patents to be granted within “reasonable a period of time” and final administrative decisions to be subject to judicial review) may implicate such measures. The scope of the Waiver and its relation to commitments under Part IV – not only with regard to the Paris Convention provision, but also with regard to the substantive obligations under Art.63 TRIPS – therefore also would benefit from specific clarification such that these commitments cannot affect measures taken for the prevention, treatment or containment of COVID-19. The results-oriented understanding of the Waiver outlined in section 1 above would certainly support this.

Finally, under Art.2(2) TRIPS, “[n]othing in Parts I to IV of this Agreement shall derogate from existing obligations”, including those that WTO Members may owe to one another under the Paris and Berne Conventions. Of course, this provision is not affected by the Waiver as it is situated in Part I of TRIPS. Rather, this provision relates to the second question raised above: that is, the potential violation of independent obligations to protect IP rights that WTO Members have to one another under the Paris and Berne Conventions. In this regard, the principal purpose of Art.2(2) is to emphasise that TRIPS provisions leave these existing commitments under the IP treaties referred therein intact. This has been confirmed in *EC–Bananas (Article 22.6 – EC)*, where the Arbitrators considered Ecuador’s request under Art.22(2) of the DSU to suspend, inter alia, certain obligations under TRIPS. In relation to the independent and potentially overlapping commitments under other IP treaties which may be affected by domestic measures taken when authorised to suspend TRIPS obligations, the Arbitrators referred to Art.2(2) TRIPS, explaining that:

This provision can be understood to refer to the obligations that the contracting parties of the Paris, Berne and Rome Conventions and the IPIC Treaty, who are also WTO Members, have between themselves under these four treaties. This would mean that, by virtue of the conclusion of the WTO Agreement, e.g., Berne Union members cannot derogate from existing obligations between each other under the Berne Convention. For example, the fact that Article 9.1 of the TRIPS Agreement incorporates into that Agreement Articles 1-21 of the Berne Convention with the exception of Article 6bis does not mean that Berne Union members would henceforth

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<sup>17</sup> Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging (Australia–Plain Packaging) (28 June 2018, WTO/DS435/P), paras 7.2627-7.2628.

be exonerated from this obligation to guarantee moral rights under the Berne Convention.<sup>18</sup>

In the same vein, Art.2(2) should be understood to mean that the TRIPS Waiver, as such, does not automatically also waive commitments under, for example, the Paris and Berne Conventions. First and foremost, the Waiver concerns commitments under TRIPS – and those are of course independent of those in other IP treaties, even if the latter overlap in substance with TRIPS commitments waived.

However, as our discussion in various sections above and below shows, this does not mean that the Waiver could not be construed as (implied) consent by WTO Members to the non-performance of provisions in other IP treaties, including those in the Berne and Paris Conventions. As indicated in section 1 and elaborated in more detail under sections 3(b)&(c) and 4, the text used in the preamble to the waiver suggests an objective – as well as results-oriented interpretation of its scope. Its purpose is enabling WTO Members to address “the global need for unimpeded, timely and secure access to quality, safe, efficacious and affordable health products and technologies for all”. The waiver text adds that this access to health products and technologies is to ensure “a rapid and effective response to the COVID-19 pandemic and consequently the urgent need to diversify and scale-up production to meet global needs and promote economic recovery”. These objectives cannot be achieved in case commitments in other IP treaties, including those under the Paris and Berne Conventions, remain intact to the extent they prevent WTO Members from relying on a TRIPS Waiver. As a means of harmonious interpretation, such overlapping IP and investment treaty commitments hence need not be considered in “clinical isolation”<sup>19</sup> from other international law, including the TRIPS Waiver. In reliance on Art.31(3)c) VCLT and the concept of systemic integration discussed further below, a results-oriented construction of a TRIPS Waiver therefore can affect other, overlapping treaty commitments WTO Members have to another. Furthermore, as section 4 shows, there may also be evidence of (implied) consent by a particular State with regard to the non-performance of these overlapping commitments.

However, before questions of (implied) consent arise, one must carefully determine which, if any, overlapping IP or investment treaty commitments may be implicated by the respective domestic measure implementing the TRIPS waiver. That is not only a question of the scope of these commitments, but also the explicit and inherent exceptions and limitations to such commitments under the relevant treaty. In order to facilitate coherence and mutual consistency within international (IP) law, both these commitments and their limits should be construed – within the accepted parameters of interpretation in public international law – in light of the Waiver and the common intention of WTO Members in terms of that it is meant to achieve.<sup>20</sup>

Individual questions of compliance with overlapping treaty commitments primarily hinge on the nature of the domestic measure implementing the waiver and the specific commitment at issue. However, in the context of the Berne and Paris Convention, not too many treaty commitments are likely to be breached: most domestic measures will not focus on copyright

<sup>18</sup> Decision by the Arbitrators, EC–Bananas (Ecuador) (Article 22.6 – EC), (24 March 2000, WT/DS27/ARB/ECU0, para 149.

<sup>19</sup> United States – Standards for Reformulated and Conventional Gasoline (US–Gasoline), Appellate Body Report (29 April 1996, WT/DS2/AB/R), p. 16.

<sup>20</sup> As discussed further below, this follows from the general international law principle in favour of coherence and against conflict within international law, as specifically embodied in the notions of systemic integration and Art.31.(3)c) VCLT; see International Law Commission, *Fragmentation of International Law: Difficulties Arising From the Diversification and Expansion of International Law* (Report of the Study Group of the International Law Commission – Conclusions, 18 July 2006, UN Doc A/ CN.4/ L.702), p 6 (see generally also the full report of 13 April 2006, UN Doc A/ CN.4/ L.682). For a discussion on the importance of the principle of systemic integration in the international IP context see Henning Grosse Ruse-Khan, *The Protection of Intellectual Property in International Law* (OUP 2016), paras 2.01-10 & 18-28.

protection (hence often excluding the Berne Convention altogether),<sup>21</sup> but rather concern patent, regulatory test data, or trade secret protection. For the same reasons, commitments for the protection of copyright under the WCT (such as concerning the right of communication to the public under Art.8 WCT) are not likely to be implicated by domestic measures relying on the TRIPS waiver – although of course this is always a matter of analyzing the relevant copyright-related commitments related to the specific domestic measure.<sup>22</sup>

From among the IP rights that are likely to be implicated by a waiver, the most important one covered by the Paris Convention relates to the protection of patent rights.<sup>23</sup> The substantive provisions obligating Paris Union countries to protect patents which are most relevant for our analysis mainly concern compulsory licensing in order to address insufficient working of the patented invention. While one might hence suggest that domestic measures implementing the TRIPS Waiver via compulsory licensing could be challenged in relation to Art.5A(4) Paris Convention, the latter only deals with insufficient local working as a specific form of abuse of patent rights. As the commentary by Bodenhausen, a former WIPO Director General, explains:

[Art.5A(2)-(4)] do not deal with measures other than those whose purpose is to prevent the abuses referred to. The member States are therefore free to provide analogous or different measures, for example, compulsory licenses on conditions other than those indicated in paragraph (4), in other cases where the public is deemed to require such measures. This may be the case when patents concern vital interests of the country in the fields of military security or public health or in the case of so-called ‘dependent patents,’ etc. In such cases the rules of paragraphs (3) and (4) of the provision under consideration do not apply, so that the member States have freedom to legislate.

Based on the narrow scope of Art.5A as set out in Bodenhausen’s commentary, it is unlikely that a domestic measure which relies on a compulsory license to enhance affordable access to, and dissemination of health technologies related to COVID-19 would constitute a breach of Art.5A of the Paris Convention.

The discussion in the following section shows that a careful, coherence-oriented construction of the potentially overlapping commitments in question, as well as any applicable exceptions or limitations thereto, may well lead to the conclusion that no instance of inconsistency with the relevant IP or investment treaty exists. This is all the more likely whenever the relevant commitments are set out in broad terms which allow their interpretation in light of the TRIPS Waiver in order to facilitate mutual coherence and avoid conflict.<sup>24</sup> In addition, from a more practical perspective, one also has to consider whether questions of compliance with the

<sup>21</sup> See however fn.15 above, and the further discussion below.

<sup>22</sup> To the extent copyright protected subject matter (e.g., computer programs or databases – simultaneously protected under TRIPS and the WCT) have to be utilized when a WTO Member relies on the waiver to facilitate access to vaccines, again one must carefully consider which limits and exceptions to copyright protection may apply. In addition, the WCT commitments for the (legal) protection of technological protection measures (TPMs) employed by right holders against circumvention may be at issue – but Art 11 WCT only requires protecting these TPMs against uses which are not permitted by (copyright) law, hence again raising questions about exceptions and limitations applicable to the underlying copyright subject matter.

<sup>23</sup> With its broad focus on the “protection of industrial property” (as set out in Art.1 PC), the Paris Convention also covers other IP rights the protection of which can be affected by measures implementing the TRIPS Waiver – in particular commitments to protect industrial designs, utility models and against acts which constitute unfair competition. However, the substantive provisions covering these rights are – in contrast to TRIPS and FTAs – significantly less comprehensive under the Paris Convention, and we hence focus on what we consider the most important commitment that also applies to patents (as well utility models and industrial designs) under Art.5 PC. Additional commitments that could be implicated by measures implementing a TRIPS Waiver can be found in Art.4, 5bis, 5quinquis, and 10bis PC.

<sup>24</sup> See the discussion in fn. 20 and accompanying text above.

relevant treaty are subject to a dispute settlement procedure, and who is entitled to invoke such a procedure. These questions point primarily to investment treaties and investor-State dispute settlement (ISDS) proceedings – which are hence at the forefront of the further analysis in subsection d. and section 4. With regard to the Paris and Berne Conventions, both treaties include provisions that allow contracting parties to bring a dispute to the International Court of Justice (ICJ).<sup>25</sup> However, these provisions are subject to reservations, and have never been invoked since their inclusion into the Conventions in the late 1940s (with regard to the Berne Convention) and the late 1960s (in case of the Paris Convention).

### **b. TRIPS-plus Commitments In Free Trade Agreements (FTAs)**

While international IP law has, post-TRIPS, developed also through multilateral agreements (in particular in the field of copyright, such as the WCT addressed above), the principal driving force for the further strengthening of IP protection has taken place through the proliferation of IP commitments in free trade agreements (FTAs).<sup>26</sup> Several hundreds of these FTAs are in force,<sup>27</sup> and many contain IP chapters and provisions. A general trend in FTAs – especially in those agreements where one of the contracting parties is a typical *demandeur* for stronger IP protection – has been the inclusion of “TRIPS-plus” provisions that go beyond the minimum standards set in TRIPS and the other multilateral treaties it incorporates. In addition, several FTAs reiterate existing commitments or other provisions under TRIPS or other multilateral IP treaties (such as the WIPO Copyright Treaty) and/or require contracting parties to adhere to or comply with existing IP treaties (such as UPOV, a treaty on plant variety protection). At the same time, FTA IP Chapters frequently defer to the TRIPS Agreements, and – especially in the IP and public health context – include provisions that “safeguard” specific TRIPS flexibilities.

This section first considers obligations to providing for additional IP protection which may be implicated in case a WTO Member adopts measures to implement the TRIPS Waiver. It then reviews various TRIPS-reference provisions and TRIPS flexibility “safeguard” clauses in FTA IP Chapters – some of which specifically refer to TRIPS waivers. As will be shown, even where such a specific reference does not exist, these FTA rules generally can be understood as an indication of how the FTA contracting parties view the relation between TRIPS and FTA provisions, including the importance of public health related TRIPS flexibilities and policy space for FTA IP standards.

#### **(1) Additional IP protection under FTAs**

While different IP *demandeurs* have included different types of TRIPS-plus provisions in FTAs that reflect their own trade interests, for the purpose of our analysis, the focus is on additional commitments with regard to patents, trade secrets and test data protection, as well as those on IP enforcement. Since a comprehensive assessment of all types of TRIPS-plus commitments in these areas is well beyond the scope of this paper, this section will consider some examples of commitments which might be implicated by the domestic implementation of the TRIPS waiver by WTO Members.

One illustrative example in terms of patent protection is the US–Australia FTA. This agreement requires that “patents shall be available for any new uses or methods of using a

<sup>25</sup> See for example Art.28 of the Paris Convention.

<sup>26</sup> See Grosse Ruse-Khan, *International IP*, 2016, chapters 5 & 6.

<sup>27</sup> As of June 2021, the WTO counts 349 of what it refers to as “regional trade agreements” (RTAs) in reference to Art. XXIV GATT – see [https://www.wto.org/english/tratop\\_e/region\\_e/region\\_e.htm#facts](https://www.wto.org/english/tratop_e/region_e/region_e.htm#facts). At the same time, WIPO counts 536 bilateral agreements with IP provisions – which however include not only trade, but also investment agreements that are discussed in section d. below; see <https://wipolex.wipo.int/en/treaties/bilateral>.

known product” (Art.17.9:1).<sup>28</sup> New use patents are important in the pharmaceutical sector where they can offer fresh protection for a new use of a known compound (such as using an existing drug for treating a different disease than it had originally be developed for) – but also have been raising concerns over unduly prolonging patent protection (“evergreening”).<sup>29</sup> To the extent that the treatment of COVID-19 may be based on existing drugs which can repurposed, the obligation to offer patent protection for treating COVID-19 (or “long COVID” and other related illnesses) by means of known compounds can affect access to these drugs. The US – Australia FTA also effectively prohibits contracting parties from opting for international exhaustion – that is, the right to allow the distribution of patented products (including pharmaceuticals and other medicinal products) based on a first sale of these products with the patent owner’s consent in another jurisdiction – thereby allowing for “parallel imports”.<sup>30</sup> Parallel imports have for a long time been a policy tool to facilitate affordable access to medicines, and the Doha Declaration on TRIPS and Public Health highlights the flexibilities TRIPS offers in this context.<sup>31</sup> Again, limiting the ability to rely on parallel imports can affect the access to patent-protected medical technologies relevant for treating COVID-19. Finally, the US–Australia FTA also curtails the policy space TRIPS leaves for compulsory licensing. Next to dealing with anti-competitive practices, compulsory licenses can only be issued “in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency” (Art.17.9:7(b)), subject to further conditions. Not only does this commitment undermine TRIPS flexibilities to freely determine the grounds for issuing a compulsory license, but it also prohibits a requirement to submit “undisclosed information or technical know-how related to a patented invention” Art.17.9:7(b)(iii). That prohibition can significantly impede the ability to tie compulsory licensing of vaccines and therapeutics to related trade secrets and know-how.

At the interface of patent protection and marketing approval requirements for pharmaceutical and agrochemical products, many FTAs offer forms of patent term extension, whereby patent owners are granted extra periods of protection as compensation for the time lost after patent grant but prior to obtaining marketing approval.<sup>32</sup> This goes beyond TRIPS, which does not offer any form of patent term extension for regulated products. Furthermore, in relation to these regulated products, many FTAs include protection for the test data submitted to obtain marketing approval, especially for pharmaceutical and biological drugs – often in the form of test data or marketing exclusivity periods of 5 or more years (whereas TRIPS only requires protection against “unfair commercial use”, and against disclosure “except where necessary to protect the public”).<sup>33</sup> Under such exclusivity periods, only the entity having generated and submitted the original data for marketing approval may market the associated drug for the given period, or rely on that data to seek approval for a generic (bio-equivalent) product.<sup>34</sup> As COVID vaccines and related treatments that have received marketing approval will generally be eligible for test data and marketing exclusivity periods, these TRIPS-plus protections of test data potentially set up extra legal hurdles for WTO Members in the implementation of a TRIPS Waiver. Depending on what limits, if any, apply

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<sup>28</sup> See also Art.18.8:1 US–Korea FTA. A similar provision can be found in Art.18.37:2 CPTPP – but this commitment is currently suspended; see the Annex II with a list of suspended provisions here: [https://www.mfat.govt.nz/assets/Trade-agreements/CPTPP/ANNEX-II\\_List-of-suspended-Provisions.pdf](https://www.mfat.govt.nz/assets/Trade-agreements/CPTPP/ANNEX-II_List-of-suspended-Provisions.pdf).

<sup>29</sup> See section 3d) of the Indian Patent Act and the Indian Supreme Court Judgment in *Novartis vs Union of India*, 1 April 2013 (Civil Appeal No. 2706-2716 of 2013).

<sup>30</sup> See Art.17.9:4 US–Australia FTA which states: “Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.”

<sup>31</sup> Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) (Doha, 14 November 2001, WT/MIN(01)/DEC/2), para.5 d).

<sup>32</sup> See Art.20.27 CETA and Art.20.46 USMCA.

<sup>33</sup> See Art.39(3) TRIPS.

<sup>34</sup> See for example Art.20.29 CETA, Art.20.48&50 USMCA, Art.18.50&51 CPTPP (although these provisions are also among the ones currently suspended).

to these test data exclusivity periods under an FTA,<sup>35</sup> the relevant FTA commitments could interfere with a WTO Member's ability to override test data protection in order to allow another entity to obtain marketing approval for a COVID vaccine or other relevant medical treatment, and to rely on test data submitted for this purpose.

Lastly, FTAs also extend the protection of trade secrets (or confidential information), in particular in relation to the remedies the owner of a trade secret can rely on (such as civil and criminal enforcement, as well as provisional measures).<sup>36</sup> These commitments generally go beyond the minimum standards set out in Art.39(1)&(2) TRIPS, and again could serve as a serious legal impediment for relying on the TRIPS waiver – for example when a WTO Member tries to incentivise, mandate or otherwise regulate the sharing of confidential know-how and trade secrets in order to produce vaccines or other medical technology. Similar impediments might also result from TRIPS-plus IP enforcement commitments (in relation to civil remedies, provisional and border measures, and criminal sanctions) more generally: while IP enforcement obligations normally do not determine when IP infringements occur, offering additional remedies to right-holders whose IP rights are also covered by FTAs simply adds to the commitments that could stand in the way of utilising a TRIPS waiver.

As indicated earlier, these are just a few examples of TRIPS-plus provisions in FTAs. In addition, FTAs include provisions that simply reiterate existing commitments or other (optional) provisions under TRIPS (such as exclusions from patentability under Art.27(3) TRIPS, at times with somewhat less flexibility as to what can be excluded from subject matter)<sup>37</sup> or require ratification of, adherence to or compliance with a range of existing IP treaties (hence in one way or another including commitments under those existing IP treaties within the FTA).<sup>38</sup> To the extent these provisions create independent obligations under the FTA to afford protection as required under TRIPS or other international IP treaties, they also establish overlapping commitments which may be implicated when a country bound by such commitments aims to implement the TRIPS Waiver in its domestic IP system. However, in the same way already indicated above with regard to overlapping commitments under multilateral IP treaties and as further discussed below with a focus on TRIPS-plus commitments under FTAs, such overlapping commitments need to be construed in light of the broader international law context in which they operate, including the TRIPS Waiver, other specific clauses in FTAs addressing the TRIPS-FTA relationship, and of course general international law.

## **(2) FTA clauses preserving flexibilities under TRIPS**

The previous section shows that IP chapters in FTAs do not only include commitments to protect IP rights independent of those in TRIPS, but that these generally go beyond the standards of TRIPS in a way that may impede effective reliance on any TRIPS waiver. Implementation of the waiver could, therefore, breach these additional commitments. Before turning to potential defences under general international law that could be relied as justifications for non-compliance with these commitments, it is necessary to consider any relevant provisions **within** FTAs that may allow WTO Members to rely on a TRIPS Waiver. Such provisions can be general rules on the FTA-TRIPS relationship, or in form of specific

<sup>35</sup> See the discussion in section (2) below.

<sup>36</sup> Arts.20.70, 71&73 USMCA, Art.18.78 CPTPP. See also Chapter 1 Section B of the US–China Phase 1 Agreement of 15 January 2020.

<sup>37</sup> See for example Art.20.36 USMCA which mainly reiterates the obligations and flexibilities with regard to patentable subject matter under Art.27 TRIPS – but with regard to excluding plants and animals other than microorganisms, Art.20.36(3) does state that contracting states confirm they offer patent protection at least to inventions “derived from plants”.

<sup>38</sup> See for example Art.10.5 of the EU–Korea FTA, Art.18.7 CPTPP, Art.11.9 RCEP, Art.IP.4 of the UK–EU Trade and Co-operation Agreement (TCA).

provisions that refer to public health flexibilities under TRIPS, or even to a waiver of commitments under TRIPS.

When construing these FTA provisions, insofar as they apply as between WTO members, interpreters should aim for a harmonious and coherent interpretation, aligning as far as possible FTA commitments with a TRIPS Waiver, before considering how to resolve any potential conflicts that may remain.<sup>39</sup> The principle of systemic integration codified in Art.31(3)c) VCLT supports interpreting the FTA commitments in light of the text of the TRIPS Waiver (as a “relevant rule of international law” which is “applicable in the relations between the [FTA] parties”).<sup>40</sup> FTA commitments would therefore be construed, as far as possible, in a way that allowed WTO Members to implement the Waiver.<sup>41</sup> Where the text of the FTA provisions does not allow for harmonious interpretation (in particular if the FTA commitments are too concrete and specific to construe them in a way which gives effect to the objectives of the Waiver), conflict rules in FTAs (if available) or from general international law may be considered. In what follows, we offer an overview of the different type of FTA clauses at issue.

Turning first to general FTA clauses regulating the relation between the FTA and WTO Agreements, relevant clauses include the following:

- The US FTAs offer several examples of provisions whereby contracting parties confirm their “existing rights and obligations with respect to each other under existing bilateral and multilateral agreements to which both Parties are party, including the WTO Agreement”.<sup>42</sup> US FTAs including IP-specific rules also indicate that “parties affirm their rights and obligations with respect to each other under the TRIPS Agreement”.<sup>43</sup>
- EU FTAs include clauses referring to both “rights and obligations between the Parties under the TRIPS Agreement”.<sup>44</sup>
- Several Japanese FTAs also contain such a clause – however, often with the addition that “[i]n the event of any inconsistency between this Agreement and the WTO Agreement, the WTO Agreement shall prevail to the extent of the inconsistency”.<sup>45</sup>

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<sup>39</sup> On the notion of harmonious interpretation in the international IP context, see Grosse Ruse-Khan, *International IP*, 2016, ch.4 & 5, in particular paras 4.67-71, 5.07-15. See generally International Law Commission, Fragmentation of International Law: Difficulties Arising From the Diversification and Expansion of International Law (Report of the Study Group of the International Law Commission – Conclusions, 18 July 2006, UN Doc A/ CN.4/ L.702), pp. 7-10.

<sup>40</sup> Even when we apply the rather narrow construction of relevance by the Appellate Body as rules that “concern the same subject matter as the treaty terms being interpreted” (see *Peru–Additional Duty on Imports of Certain Agricultural Products (Peru–Agricultural Products)*, Appellate Body Report (31 July 2015, WT/ DS457/ AB/ R), para 5.101; see also *EC–Aircraft*, Appellate Body Report, para 846), this condition will usually be fulfilled in TRIPS–FTA relations and would also apply to the TRIPS waiver, to the extent it is understood as an agreement between WTO Members. Since most FTAs are concluded among states that are also WTO Members, the contentious issue of how to define the meaning of “the parties” under Art.31(3)c) VCLT will normally not arise.

<sup>41</sup> On the notion of systemic integration see generally Campbell McLachlan, “The Principle of Systemic Integration and Article 31(1)(c) of the Vienna Convention” (2005) 54(2) ICLQ 279. On its application in the international IP context, as well as concepts of norm conflict and conflict resolution see Grosse Ruse-Khan, *International IP*, 2016, para.3.07-27.

<sup>42</sup> See Art.1.1:2 US–Singapore FTA, Art.1.1:2 US–Australia FTA, Art.1.2:1 US–Bahrain FTA, Art.1.2:1 US–Morocco FTA, Art.1.2:1 US–Oman FTA, Art.1.2 US–Jordan FTA, Art.1.3:1 US–CAFTA-DR, Art.1.3:1 US–Panama TPA, Art.1.3 US–Chile FTA, Art.1.2 US–Colombia FTA, Art.1.2:1 US–Korea FTA, Art.1.2:1 US–Peru TPA. Since TRIPS is annexed to the WTO Agreement, such clauses would generally also include provisions in TRIPS, as well as those from other international IP treaties incorporated into TRIPS by reference.

<sup>43</sup> See Art 17.1:3 of the US–Australia FTA, Art.15.1:7 US–CAFTA-DR, Art.1.3, Ch 17 (IP) preamble, Art.17.1:5 US–Chile FTA (‘nothing shall derogate from’), Art.16.1:6 US–Colombia FTA, Art.18.1:2 US–Korea FTA.

<sup>44</sup> See Art.189:1 EU–Columbia, Peru FTA.

<sup>45</sup> See Art.12 Japan–Indonesia FTA (2007), Art.11 Japan–Thailand FTA, Art.11 Japan–Philippines FTA (2006), Art.11 Japan–Malaysia EPA (2005), Art.9 Japan–Vietnam EPA.

- The EU FTA with Colombia and Peru specifies, in Art.196(2), that its IP provisions “shall complement and specify the rights and obligations of the Parties under the TRIPS Agreement and other multilateral [IP] agreements”, and that therefore, “no provision of this Title will contradict or be detrimental to the provisions of such multilateral agreements”.
- Art.11.3 (“Relation to Other Agreements”) in the IP Chapter of RCEP states that “[i]n relation to intellectual property, in the event of any inconsistency between a provision of this Chapter and a provision of the TRIPS Agreement, the latter shall prevail to the extent of such inconsistency.”<sup>46</sup>

As these examples show, FTA provisions often re-affirm existing rights and obligations under TRIPS, and at times determine FTA IP commitments to be construed so as to not contradict TRIPS, as well as TRIPS provisions to prevail over those in FTAs – if there is indeed a conflict or inconsistency. However, it is difficult to derive much conclusive guidance from these provisions alone as to the relevance of a TRIPS Waiver for overlapping IP commitments in FTAs. TRIPS affirmation clauses could be construed as indicating a common intention of the FTA parties not to undermine TRIPS provisions – but where the FTA then includes specific TRIPS-plus commitments reducing TRIPS flexibilities, one cannot simply disregard such a treaty commitment, especially since the FTA parties agreed to it in light of TRIPS.<sup>47</sup>

On the other hand, given that any TRIPS Waiver will have been agreed after the FTA provisions had been negotiated, TRIPS affirmation clauses could be understood to extend to the TRIPS waiver as the most recent expression of common intention of the WTO Members in relation to their rights and obligations under TRIPS, prevailing over earlier FTA IP rules. This finds support in the general international law rule on successive agreements on the same subject matter under Art.30 VCLT which is commonly understood to embody the *lex posterior* rule.<sup>48</sup> One might consider TRIPS affirmation clauses under Art.30(2) VCLT, so that TRIPS – and therefore also the Waiver – prevails.<sup>49</sup> Alternatively, under Art.30(3) VCLT for FTAs among WTO Members, pre-waiver FTA rules would apply only to the extent they are compatible with the Waiver.<sup>50</sup> For reliance on Art.30(3) VCLT, one needs to either classify the TRIPS waiver as agreement between WTO Members, or as at least updated, post-FTA expression of the common intention of WTO Members vis-à-vis the TRIPS Agreement (which in turn then becomes *lex posterior* to the FTA). The same is not needed for Art.30(2): in this case, the TRIPS affirmation clauses in the FTA give priority to the TRIPS agreement, which includes the possibility of waivers being adopted from time to time. The TRIPS affirmation clauses thus give priority to the TRIPS package, as it were, which includes waivers when they have been adopted in accordance with the rules set out in the WTO Agreement.

<sup>46</sup> Here, a footnote further clarifies that “[f]or the purposes of the application of this Article, the Parties agree that the fact that this Chapter provides for more extensive protection of intellectual property than is required by the TRIPS Agreement does not mean there is an inconsistency within the meaning of this Article and paragraph 2 of Article 20.2 (Relation to Other Agreements).”

<sup>47</sup> See the discussion in Grosse Ruse-Khan, *International IP*, 2016, paras 5.15-20, 5.66-68.

<sup>48</sup> Grosse Ruse-Khan, *International IP*, 2016, paras 3.17-27, 5.56-61.

<sup>49</sup> Art.30(2) VCLT states that “[w]hen a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail.” Art.30(3) then sets out the general *lex posterior* principle: “When all the parties to the earlier treaty are parties also to the later treaty but the earlier treaty is not terminated or suspended in operation under article 59, the earlier treaty applies only to the extent that its provisions are compatible with those of the later treaty.” Especially provisions like Art.196(2) of the Colombia, Peru–EU FTA lend themselves to such an understanding.

<sup>50</sup> For FTAs which include non-WTO Members, Art.30(4) VCLT leads to the waiver to prevail in the relations among the FTA parties that are WTO Members, and to the FTA for the relations between WTO and non-WTO Members.

Moving on to specific limits to TRIPS-plus commitments, several FTAs include provisions that can be relevant to the ability of WTO Members bound by these FTAs to effectively rely on the Waiver. The following can again only offer an overview of some of these provisions – ranging from general references to the ability to protect public health, via recognition of the importance of the Doha Declaration for construing FTA IP rules, to specific references to individual TRIPS flexibilities as well as waivers of TRIPS commitments. In terms of the more general FTA clauses, Art.197(1) of the EU–Colombia, Peru FTA, for example, explains that:

[h]aving regard to the provisions of this Title, each Party may, in formulating or amending its laws and regulations, make use of the exceptions and flexibilities permitted by the multilateral intellectual property agreements, particularly when adopting measures necessary to protect public health and nutrition, and to guarantee access to medicines.

Art.8.20 of the Argentina – Chile FTA contains an essentially identical provision.<sup>51</sup>

More common are FTA clauses that “recognise the importance of the Declaration on the TRIPS Agreement and Public Health”, and further emphasise that “[i]n interpreting and implementing the rights and obligations under this Section, each Party shall ensure consistency with the Doha Declaration”.<sup>52</sup> A similar provision is found in Art.11.5(1) of the China–Switzerland FTA whereby “[t]he Parties recognise the principles established in the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by the Ministerial Conference of the WTO and confirm that the provisions of this Chapter are without prejudice to this Declaration”.<sup>53</sup> At times, the meaning of recognising or “reaffirming” the Doha Declaration is further explained – such as in Art.11.8 RCEP – to include the following understandings:

(a) the Parties affirm the right to fully use the flexibilities as duly recognised in the Doha Declaration on the TRIPS Agreement and Public Health;

(b) the Parties agree that this Chapter does not and should not prevent a Party from taking measures to protect public health; and

(c) 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.<sup>54</sup>

Almost identical language on the role and importance of the Doha Declaration can be found in Art.18.6 CPTPP and Art.20.6 USMCA<sup>55</sup> – with the addition of the following text specifically addressing TRIPS waivers:

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<sup>51</sup> That provision states: “No provision of this Chapter shall be construed in the sense of restricting the right of the Receiving party to adopt measures on intellectual property that are in conformity with the TRIPS Agreement or with the multilateral agreements concluded within the framework of the World Intellectual Property Organization”. See Argentina – Chile FTA (2017) Article 8.20 – <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5682/download>.

<sup>52</sup> EU–United Kingdom Trade and Cooperation Agreement (2020), Art.IP.32(1), EU–Japan EPA (2018) Art.14.34, Canada–EU CETA (2016) Art.20.3, EU–Kazakhstan EPCA (2015) Art.92, EU–Ukraine Association Agreement (2014) Art.219, EU–Korea FTA Art.10.34.

<sup>53</sup> China–Switzerland FTA (2013) Art.11.5 “Intellectual Property and Public Health” – online at <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/2751/download>

<sup>54</sup> Art.11.8(1) RCEP, whereas sections (2) and (3) ensure that the Art.31bis mechanism of issuing compulsory licenses for exporting drugs to countries with insufficient domestic manufacturing capacities in the pharmaceutical sector is not undermined by FTA IP commitments.

<sup>55</sup> The relevant provisions can be found in section (1) of Art.18.6 and 20.6 – with the most notable difference to the RCEP text being a specific mention of one of the TRIPS flexibilities highlighted under Doha (namely “the right to determine what constitutes a national emergency or other circumstances of extreme urgency”) – whereas

(c) With respect to the aforementioned [public health] matters, 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.

As the further discussion below and in section c. indicates, several other FTA and IIA clauses make reference to TRIPS waivers.

Before discussing these specific “waiver clauses”, the importance of the more common general provisions in FTAs on IP and public health for the TRIPS Waiver needs to be emphasised. Allowances to rely on exceptions and other flexibilities “permitted by the multilateral intellectual property agreements”<sup>56</sup> arguably point to the common intention of the FTA parties that agreements on IP-related flexibilities, in particular if related to public health, on the multilateral level shall not be undermined by additional commitments undertaken in the FTA. There is no reason to believe that the flexibilities covered here would not also include a TRIPS Waiver agreed in the WTO, even if that technically may not, in itself, constitute a multilateral IP treaty. A waiver certainly would constitute the commonly agreed response by WTO Members to the IP-related access to medicines issues posed by the pandemic, and would be understood as the key, multilaterally agreed TRIPS flexibility in this context (somewhat akin to the recently confirmed further extension of the transition periods for LDCs).<sup>57</sup> Furthermore, contracting States were aware, at the time when they negotiated the FTA, that TRIPS allows waivers to be adopted in accordance with the relevant provisions in the WTO Agreement. If they wished to exclude this mechanism, they should have specifically stated this in their FTAs.

References in FTAs to the Doha Declaration and calls to “ensure consistency” with that Declaration can be understood in a similar way, although the specific wording may well be important here.<sup>58</sup> The principles expressed in the Doha Declaration concern, inter alia, a public health supportive interpretation and implementation of TRIPS.<sup>59</sup> In this connection, WTO members reaffirmed “the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”.<sup>60</sup> Hence, any general reference to the Doha Declaration in FTAs can primarily function as a tool which demands an interpretation and implementation of FTA provisions that does not undermine the flexibilities listed in the Declaration, including the general understanding that IP commitments “should not prevent members from taking measures to protect public health”.<sup>61</sup> Referencing this understanding of WTO Members in an FTA must also apply to the IP commitments in that agreement. Applied to a TRIPS Waiver as the most recent expression of the scope of TRIPS flexibilities in the specific public health context of the COVID pandemic, these clauses again

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Art.11.8(1) RCEP generally refers to the ability to ‘fully use’ all TRIPS flexibilities mentioned in the Doha Declaration.

<sup>56</sup> Art.197(1) of the EU–Colombia, Peru FTA.

<sup>57</sup> “WTO members agree to extend TRIPS transition period for LDCs until 1 July 2034”, 29 June 2021, [https://www.wto.org/english/news\\_e/news21\\_e/trip\\_30jun21\\_e.htm](https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm).

<sup>58</sup> See generally, Grosse Ruse-Khan, *International IP*, 2016, paras 5.69-74.

<sup>59</sup> See para 4 of the Doha Declaration stating that TRIPS “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”.

<sup>60</sup> *Ibid.*

<sup>61</sup> *Ibid.*, para 4 of the Doha Declaration. The same can be followed from the notion of systemic integration, applied to Articles 7 and 8 TRIPS – see Grosse Ruse-Khan, *International IP*, 2016, paras 5.70.

point to the common intention of the FTA parties not to undermine flexibilities under the multilateral system, including the ones expressed through a multilaterally agreed waiver.<sup>62</sup>

Even further go FTA clauses where the FTA parties are under a legal obligation to “ensure consistency” with the Doha Declaration.<sup>63</sup> Such a reference is more concrete and specific in indicating how the Doha Declaration is relevant for the FTA: consistency with Doha requires that the flexibilities referenced in the Declaration need to remain intact, despite additional IP commitments in FTAs. Such a clause should serve as an effective tool to safeguard TRIPS flexibilities: since even a concise and detailed TRIPS-plus provision in an FTA will hardly ever explicitly prohibit reliance on any of the TRIPS flexibilities mentioned in the Doha Declaration, FTA provisions may not undermine those flexibilities. Among those, there is no reason not to include again the general understanding WTO Members set out in Doha that IP commitments “should not prevent members from taking measures to protect public health”.<sup>64</sup> This is not least because the “right to protect public health” also referred to in paragraph 4 of Doha arguably is a reflection of the general right to regulate under customary international law – which applies to IP treaties unless there is specific evidence that contracting parties (here those to the FTA) wanted to exclude or limit this right.<sup>65</sup> With the arguments presented above, this includes ensuring consistency with a TRIPS Waiver as the most recent TRIPS flexibility in the IP – public health context of the COVID pandemic.

Clauses akin to Art.11.8 RCEP, Art.18.6 CPTPP and Art.20.6 USMCA which provide more detail on the role of the Doha Declaration will generally operate in the same way as above – in particular if they include the affirmations of the “right to fully use the flexibilities as duly recognised in the Doha Declaration” and/or set out an agreement among the FTA parties “that this Chapter does not and should not prevent a Party from taking measures to protect public health”.<sup>66</sup> In sum then, most references to the Doha Declaration, whatever their form, will constitute a strong case for ensuring that overlapping FTA commitments leave intact and do not undermine reliance on TRIPS flexibilities – including those that follow from the TRIPS waiver.

Moving lastly to specific references to TRIPS waivers in FTAs, we have already mentioned those in Art.18.6(1)(c) CPTPP and Art.20.6(1)(c) USMCA quoted above (effectively calling for a re-negotiation of any FTA IP commitments that stand in the way of a WTO member relying on a TRIPS waiver). In addition, some specific IP provisions in FTAs relate to waivers. For example, Art.18.41 CPTPP (as well as Art.20.40 USMCA, and similarly Art.11.39 RCEP) ensures that compulsory licensing related flexibilities remain intact by setting out the FTA parties’ understanding “that nothing in this Chapter limits a Party’s rights

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<sup>62</sup> While one might counter that, as with the WTO/ TRIPS consistency clauses discussed above, Doha references in FTAs only work well in cases of open and ambiguous TRIPS-plus obligations in FTAs – while being not particularly helpful in cases where specific and concise TRIPS- plus provisions in FTAs curtail or inhibit the reliance on TRIPS flexibilities. This argument builds on the idea that otherwise, the specific TRIPS commitments loose meaning and become inutile. In the context of the FTA – TRIPS relationship this argument can be backed by the fact that FTAs usually are later in time, and contain the more recent expression of common intention of the parties, including on IP – public health matters. In the context of a TRIPS waiver however, this would not be the case: the latter would form the most recent, multilateral expression of flexibilities applicable in the IP – public health context of the pandemic, so that references to such flexibilities in FTAs which can be construed to include the waiver prevail over earlier IP commitments in the FTAs. As discussed above, the general international law notion of *lex posterior* and its expression in Art.30(2)&(3) VCLT further confirms this.

<sup>63</sup> See the FTAs listed in fn.52, including most of the recent EU FTAs.

<sup>64</sup> Para 4 of the Doha Declaration.

<sup>65</sup> Henning Grosse Ruse-Khan, “The Role of Customary International Law in Intellectual Property Protection Beyond Borders” (4 October 2021). University of Cambridge Faculty of Law Research Paper No. 29/2021, available online from <https://ssrn.com/abstract=3957449>.

<sup>66</sup> The affirmation in the RCEP, USMCA and CPTPP clauses that the IP 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” will also be helpful – but arguably limited to an interpretation of FTA commitments in light of the TRIPS waiver (a result that also follows from Art.31(3)(c) VCLT).

and obligations under Article 31 of the TRIPS Agreement, any waiver or any amendment to that Article that the Parties accept.” Finally, additional IP commitments in FTAs (such as on test data protection) are sometimes limited by reference to, among others, the Doha Declaration or any TRIPS waiver. For example, Art.20.48 USMCA (as well as Art.18.9(3) US–Korea FTA) sets out test data exclusivity period in sections (1) and (2), followed by a section (3) whereby a Party may take measures to protect public health in accordance with:

- (a) the Declaration on TRIPS and Public Health;
- (b) any waiver of a provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration on TRIPS and Public Health and that is in force between the Parties; or
- (c) any amendment of the TRIPS Agreement to implement the Declaration on TRIPS and Public Health that enters into force with respect to the Parties.

While references to waivers in the specific compulsory licensing context arguably can only cover the waivers in place under the so called “paragraph 6 solution”, now implemented via Art.31bis TRIPS (as well as the Annex and Appendix to TRIPS),<sup>67</sup> the USMCA reference to TRIPS waivers quoted above may be construed more broadly to potentially also cover a TRIPS Waiver in the context of the COVID pandemic. Even though the provision clearly had been drafted with the waivers concerning Art.31 (f) and (h) in mind, the language used “any waiver (...) to implement the Declaration of TRIPS and Public Health” should be understood to refer to all flexibilities highlighted in the Doha Declaration – including the agreed understanding that TRIPS “does not and should not prevent members from taking measures to protect public health”. In the current context of the COVID pandemic with the exceptional need for large scale production and distribution of medical technologies (including vaccines) to those with insufficient access, it is exactly this what the TRIPS Waiver aims to ensure.

As a final note, we may add that the call for re-negotiation of FTA commitments which stand in the way of an FTA party’s ability to rely on a TRIPS waiver (see e.g., Art.18.6(1)(c) CPTPP and Art.20.6(1)(c) USMCA) is essentially an indication of the FTA parties’ intention not to undermine multilateral solutions reached, including by means of a Waiver, to protect public health and to facilitate access to medicines. In a nutshell, almost all of the public-health related clauses in FTAs that have been reviewed here show that FTA parties defer to TRIPS and its flexibilities when it comes to “the right to public health” recognised under the Doha Declaration. This right is further underpinned by the broader concept of a right to regulate, firmly established in customary international law.<sup>68</sup> FTA parties usually do not intend to undermine this right, as the various clauses reviewed above show. Overlapping IP commitments in FTAs should therefore not operate to undermine a TRIPS Waiver in the context of the COVID pandemic, as the most recent and context specific expression of this right.

### **c. Commitments to Protect IP Rights Under International Investment Agreements (IIAs)**

International investment law is based on an interpretation of customary international law for the protection of aliens and their property, and increasingly on bilateral or regional investment treaties that update and usually expand investment protections based on custom. International Investment Agreements (IIAs), in the form of bilateral investment treaties (BITs) or investment chapters in FTAs, serve to protect investments made by investors from one

<sup>67</sup> On the Art.31bis mechanism to ensure WTO Members with insufficient manufacturing capacity can make effective use of compulsory licensing flexibilities under TRIPS – primarily by importing drugs produced under a compulsory license abroad – see generally the relevant WTO website here: [https://www.wto.org/english/tratop\\_e/trips\\_e/tripsfacsheet\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm).

<sup>68</sup> See below, subsection c. (3) and generally Grosse Ruse-Khan, *Customary International Law*, 2021.

contracting State (foreign investments) in the territory of another contracting State (host State), and they normally do so by negotiating protections which are equivalent or go beyond those provided by customary international law. Frequently, IIAs also provide a mechanism whereby foreign investors can pursue claims directly against a host State through international arbitration, commonly referred to as investor-State dispute settlement (ISDS). This allows investors to enforce IIA protections directly, so that there is no need to (1) rely on diplomatic protection by their respective home States to espouse their claim; nor to (2) depend on the domestic protections and judicial institutions in the host State. The core function of IIAs hence is to offer substantive and procedural protection to investors for their foreign investments against host State measures that are in violation of obligations set out in the IIA, such as discriminatory measures, unlawful expropriation, or unfair or arbitrary treatment. That protection is directed at host State measures negatively affecting investors' assets in defined ways: in our context of protecting IP assets, it is first and foremost protection against the State interfering with an IP right – to the extent that it constitutes a protected investment.

This section begins with a brief review of how IP rights are protected under IIAs (subsection (1)), and then offers an overview on the two main standards of investment protection potentially at issue in relation to measures implementing a TRIPS Waiver (subsection (2)). It then proceeds to focus on provisions within the international investment regime that might justify such measures (subsections (3) and (4)).

### **(1) IP rights as investments**

IIAs generally include IP rights as a form of asset that may receive protection under the standards available in the relevant IIA. Already in the first BIT, signed between Germany and Pakistan in 1959, the definition of investment under Article 8 included “assets such as ... patents and technical knowledge”. Today, the model BITs of most countries address IP rights.<sup>69</sup> The 2012 US Model BIT, for example, provides in its investment definition in Article 1 that “forms that an investment may take include ... intellectual property rights”. While the approach in BITs differs insofar as some contain merely a general reference to “intellectual property rights” and others include a (generally non-exhaustive) list of types of IP rights, empirical research shows that BITs generally include IP rights as a form of investment.<sup>70</sup> Further, a significant number of FTAs contain an investment chapter. Chapter 11 of the US–Australia FTA, for example, deals with investment which – according to the definition in Article 11.17:4(f) – includes “intellectual property rights”.<sup>71</sup> Since December 2009, Article 207(1) of the Treaty on the Functioning of the European Union (TFEU) extends the competence of the EU for regulating its common commercial policy to “foreign direct investment”. On that basis, more recent FTAs and related Investment Protection Agreements (IPAs) negotiated by the EU (such as CETA, the EU–Vietnam IPA, or the EU–Singapore IPA) include IP rights as investments.<sup>72</sup> Finally, also Japanese FTAs—such as the EPA with Indonesia—do include an investment chapter which again covers IP in a list of rights.

<sup>69</sup> L. Liberti, “Intellectual Property Rights in International Investment Agreements: An Overview” (2009) 6(2) *Transnational Dispute Management* 6, pp. 5-9.

<sup>70</sup> For a comprehensive study on how BITs cover IP rights as protected investment see R 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* 4–7 and Annex 1. And even where the IIA does not explicitly refer to IP rights a potential form of a covered investment, those rights might well still be covered as the definitions of investment tend to be open-ended.

<sup>71</sup> The same definition exists under Art.10.28(f) of CAFTA–DR, Art.10.27(f) of the US–Chile FTA, Art.10.28(f) of the US–Peru Trade Promotion Agreement (TPA), and Art.15.1:17(f) of the US–Singapore FTA, just to name a few. IP rights hence are generally considered as investments under US FTAs.

<sup>72</sup> See for example Art.1.2(g) and accompanying fn.2 of the EU–Singapore Investment Protection Agreement (IPA) which includes all forms of IP rights covered by TRIPS, plus plant variety rights.

However, while most IIAs in one way or the other include IP rights among the types of assets that may constitute a protected investment,<sup>73</sup> actual protection under an IIA comes with further qualifications or conditions. An IP owner must meet the criteria for a protected investor, and normally show that its business activities and assets in the host State qualify as an investment – a hurdle which may demand a more substantial engagement in the host State than simply owning an IP right.<sup>74</sup> Since IIAs do not create the property rights which they then protect as investments, the assets for which an investor claims protection necessarily have to be legally recognised under the domestic law of the host State.<sup>75</sup> For IP rights as legal constructs that cover intangible subject matter with little or no “natural” boundaries, the domestic law that creates property rights around these intangibles serves as the key function of designing all essential aspects of these rights.<sup>76</sup> More generally, without a firm base in the law of the host State, any form of an individual economic right lacks a granting authority that creates and shapes these rights—in other words, they remain “empty concepts”.<sup>77</sup>

In short: international investment law does not create property rights, nor does it define the subject or scope of these rights. In contrast to IP treaties (and in particular expansionist FTAs), IIAs do not even oblige States to design their domestic IP regimes in a particular way. Rather, investment protection is limited to safeguarding investor assets legally recognised under the law of the host State against State interferences that infringe the IIA standards of protection. In principle, IP-owning investors have to live with constraints that follow from the host State’s construction of IP rights under domestic (IP) law. Limits inherent in the IP regime of the host State therefore cannot, without more, amount to for example expropriation or unfair treatment. However, once the investment at issue includes further engagements of the investor in the host State, it is the treatment of that investment as a whole (and not only the specific construction of domestic IP rights) what is protected against State interferences (in defined ways discussed further in the next section).<sup>78</sup> In addition, IP

<sup>73</sup> See C. Correa and J. Viñuales, “Intellectual Property Rights as Protected Investments: How Open are the Gates?”, (2016) 19(1) *Journal of International Economic Law* 91; H. Grosse Ruse-Khan, *International IP*, 2016, paras 7.03-7.16.

<sup>74</sup> See for example the approach taken in *Bridgestone vs Panama* where the tribunal considered the requirements under which an IP right (and by extension, a license to use subject matter protected by such a right) constitutes an investment. After reviewing the requirements set out under the respective clauses for what qualifies as an investment under the IIA, the tribunal concludes that “a registered trademark will constitute a qualifying investment provided that it is exploited by its owner by activities that, together with the trademark itself, have the normal characteristics of an investment”. (para 177); see generally Correa and Viñuales, 2016, and H. Grosse Ruse-Khan, *International IP*, 2016, paras 7.14-16.

<sup>75</sup> For a detailed discussion, see Grosse Ruse-Khan, *International IP*, 2016, para.7.06-09. Further, with a focus on the notion of territoriality, see B. Mercurio, “Awakening the Sleeping Giant: Intellectual Property Rights in International Investment Agreements”, (2012) 15(3) *Journal of International Economic Law* 871-915, at 877. The decision on preliminary objections in *Bridgestone vs Panama* confirms this approach when it discusses the circumstances under which a license to use a trademark may amount to a protected investment. The tribunal explains that “[u]nder the footnote to Article 10.29 (g) of the TPA a license will not have the characteristics of an investment unless it creates rights protected under domestic law, that is under the law of the host State. No similar provision applies to (f) ‘intellectual property rights’, but the Tribunal is in no doubt that they must be rights protected under the law of Panama, otherwise they can neither properly be described as “intellectual property rights”, nor as ‘assets’.” (*Bridgestone vs Panama*, Decision Expedited Objections, ICSID Case No ARB/16/34 (13 December 2017), para 180). See also *PMI vs Uruguay*, Award, ICSID Case No ARB/10/7 (8 July 2016), para 243; *Emmis International Holding, BV Emmis Radio Operation, BV Mem Magyar Electronic Media Kereskedelmi Es Szolgaltato KT v Hungary*, ICSID Case No ARB/12/2, Award, 16 April 2014, paras 161-162 and Z Douglas, *The International Law of Investment Claims* (CUP, 2009), 187.

<sup>76</sup> See generally on the role of the domestic law of the host state Klopschinski, Gibson & Grosse Ruse-Khan, *The Protection of Intellectual Property*, paras 4.97-164; Grosse Ruse-Khan, *International IP*, 2016, paras 7.06-09.

<sup>77</sup> M. Sasson, *Substantive Law in Investment Treaty Arbitration: The Unsettled Relationship between International and Municipal Law*, (Kluwer, 2010), 66.

<sup>78</sup> In its Award in *Philip Morris vs Uruguay* for example, the tribunal on the one hand concluded that “under Uruguayan law or international conventions to which Uruguay is a party the trademark holder does not enjoy an absolute right of use, free of regulation, but only an exclusive right to exclude third parties from the market so that

rights obtained under domestic law seem to enjoy, akin to vested rights, some degree of protection against legislative developments or other changes that affect these rights.<sup>79</sup> And finally of course, the application of domestic (IP) law to the IP-owning investor, i.e., the specific treatment afforded by host State institutions (including courts) to the investor in the individual set of circumstances at issue, can trigger investment claims.<sup>80</sup>

## **(2) Protection against expropriation and “fair and equitable treatment” (FET)**

The standards of protection an IIA offers to IP rights as an investment of course vary. In this paper we can only offer an overview of two of the core protection standards that might be engaged by the implementation of the waiver: the protection against expropriation, and the “fair and equitable treatment” (FET) standard.<sup>81</sup>

Turning first to the protection from expropriation, international investment law regulates, but does not prohibit, the expropriation of foreign investments. In this way, international investment law mediates between the sovereignty of States over their territories and natural resources on the one hand, and the duty of States to respect acquired rights of foreigners on the other. Thus, IIAs generally allow expropriation of foreign-held assets – on the condition that the expropriation is for a public purpose, conducted in a non-discriminatory manner, in accordance with due process, and against compensation. States will rarely adopt measures which amount to a direct expropriation – which in the US Model BIT has been defined as a case of “formal transfer of title or outright seizure”.<sup>82</sup> In most instances, therefore, complaints invoking expropriation protection will concern what is referred to as an “indirect expropriation” or a measure tantamount to an expropriation. Against this background, this section will consider some of the common ways of limiting IP protection that a WTO Member might adopt when implementing and assess whether they amount to an (indirect) expropriation.

In the context of a TRIPS Waiver, WTO members might temporarily suspend (for example by means of revocation or annulment) the protection of any IP rights “in relation to health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19”. Depending whether and how the relevant IIA defines the concept of expropriation, such a measure

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only the trademark holder has the possibility to use the trademark in commerce, subject to the State’s regulatory power” (para 271, see also 262, 267). While such a finding could have been used to reject any possible negative impact on the domestic trademark right as constituting investment (as the negative rights character of the trademark rights are not implicated by use restrictions), the tribunal continued that “[t]rademarks being property, their use by the registered owner is protected. As intellectual property assets, trademarks are ‘inherently associated with trade for they imply a situation of intermediation between producers and consumers’. It must be assumed that trademarks have been registered to be put to use, even if a trademark registration may sometime only serve the purpose of excluding third parties from its use.” (para 273, see also 274). The perhaps best way to explain this contradiction is to consider that the tribunal not only looked at the trademark rights, but construed the protected investment more broadly, taking into account the engagement of the investor in the host state as a whole (which then for example further led to the finding that the Uruguayan measures did not amount to an expropriation, *inter alia* because they did not cause a “substantial deprivation” to the claimant’s business as a whole.

<sup>79</sup> See *Eli Lilly vs Canada*, Case No UNCT/14/2, Final Award, 16 March 2017, para 386 – and the respective discussion on the implications of any legislative or judicial development which does not showcase a “solid foundation in prior authority” for the host State’s liability under a range of investment protection standards in section 3 below.

<sup>80</sup> Again, in *Eli Lilly vs Canada*, the tribunal held that investment claims, as a matter of principle, can be based on wrongful decisions by administrative and in particular judicial authorities of the host State, for example relying on the notion of denial of justice and fair and equitable treatment. See the further discussion below.

<sup>81</sup> For a discussion of other standards of investment protection, as applied to IP rights, see Klopschinski, Gibson & Grosse Ruse-Khan, *International Investment and IP*, 2020, Chapters 5 (on national treatment and MFN) and 6 (next to a much more extensive review of FET (including denial of justice, also on full protection and security).

<sup>82</sup> Annex B, No 3 of the US Model BIT, defining direct expropriation.

could even be argued to constitute a direct expropriation because of the complete loss of title on the side of the IP owner (even if temporarily withdrawing IP protection not necessarily transfers the right and/or its protection to the host State). On the other hand, the temporary nature of the suspension would speak against an expropriation – especially if the period of depriving the IP-owning investor from exploitation is not substantial. Alternatively, States could decide not to grant IP rights (if they not arise “automatically” – that is without registration) in relation to relevant medical technologies such as vaccines, or not allow right holders to rely on remedies to enforce their rights. While the latter situation is likely to engage the full protection and security standard, it could also be considered to fall within the notion of indirect expropriation insofar as the IP right (such as a patent) would lose all its value if remedies such as injunctive relief or damage claims against alleged infringers become unavailable for investors. Not granting IP rights (*ab initio*) on the other hand is less likely to be actionable under ISDS: since no IP rights had come into existence, no protected investment exists – unless protection under the IIA encompasses applications for, or expectations of grant.<sup>83</sup>

In respect to access to medicines generally, and in the COVID context specifically, a key question is whether compulsory licensing of patented drugs and other measures to increase affordable access to medicines for domestic populations in need are consistent with the expropriation provisions in IIAs. While the economic impact the issuance of such a license may have on the patent owner may well support arguments of indirect expropriation,<sup>84</sup> the further discussion in section (3) shows how limits to investment protections are likely to apply to compulsory licensing measures.

ISDS cases also show that other host State measures limiting IP rights may lead to expropriation claims by investors, especially if these measures significantly affect the economic value of the IP right. Philip Morris Asia (PMA), for example, alleged that Australia’s plain packaging was tantamount to expropriation as it “substantially deprives PM Asia of ... the intellectual property and the goodwill derived from the use of that intellectual property” and it thereby destroyed the commercial value of its brands without any compensation.<sup>85</sup> In *Eli Lilly vs Canada*, the US pharmaceutical company Eli Lilly argued that the revocation of its Strattera Patent by Canadian courts amounted to a direct expropriation. Alternatively, the company considered this as an indirect expropriation since “the measures in issue have had the effect of destroying the value associated with the Strattera Patent, namely, the exclusive right to make, use and sell the patented product”.<sup>86</sup> Thus, as these examples show, foreign investors are likely to challenge host State measures affecting the commercial exploitation of their IP protected goods or services as indirect expropriations or “regulatory takings”. The indeterminate and multi-faceted interpretation of the term indirect expropriation makes a further analysis of its application to IP rights very context-specific. This said, it is apparent that several types of measures taken by host States to implement the TRIPS waiver will have a significant economic impact on the ability of the affected IP owner to obtain, among others, “monopoly rents”. Such measures therefore may well be challenged as amounting to an (indirect) expropriation.<sup>87</sup> And similar to claims under FET discussed below, such

<sup>83</sup> On this topic, see Grosse Ruse-Khan, *International IP*, 2016, paras 7.10-13.

<sup>84</sup> Bear in mind that under a waiver, no remuneration under Art.31 h TRIPS would be owed.

<sup>85</sup> *PMA v Australia*, Notice of Arbitration, at paras 7.3– 7.4. See also the expropriation claim brought by Philip Morris International (PMI) in its ISDS case against Uruguay: *Philip Morris International vs Uruguay (Philip Morris)*, ICSID Case No ARB/10/7, Award, 8 July 2016, discussed further below.

<sup>86</sup> *Eli Lilly v Canada*, Notice of Intent, at para 91.

<sup>87</sup> This is in particular likely under the so- called “sole effects doctrine” in international investment law which judges expropriation primarily based on its economic effect on the investment. On indirect expropriation and IP rights see generally, Klopschinski, Gibson & Grosse Ruse-Khan, *International Investment and IP*, 2020, chapter 7.

challenges claiming indirect expropriation have been subject to debate for the impact they can have on a State's regulatory space, including in the context of public health.<sup>88</sup>

In respect of the FET standard, almost all BITs and investment chapters in FTAs nowadays contain this standard – either in the preamble, or in the text of the treaty as a self-standing provision or in conjunction with other standards, in particular full protection and security (FPS). FET is the most commonly and most successfully invoked standard of treatment in ISDS practice, frequently relied on as fall-back where an expropriation claim failed.<sup>89</sup> Its apparent practical relevance however has not translated into an equivalent degree of clarity and certainty over the normative content of what treatment exactly a host State owes under FET. Despite well over one hundred awards that found a FET violation, the standard has so far evaded a generally accepted definition or delineation, and – as one commentator observes – remains “maddingly vague, frustratingly general, and treacherously elastic”.<sup>90</sup> The ambiguity inherent in a standard described in the most general of terms (“fair”, “equitable”, and occasionally “just” or “reasonable”) however may well have been instrumental for its appeal amongst investors, and a key factor for invoking it successfully in ISDS.<sup>91</sup> Designed as a *Generalklausel* akin to those found in Private Law Codes of Civil Law jurisdictions and offering a default that may provide protection where more specific standards are not made out,<sup>92</sup> it is not surprising that FET attracts creative lawyering from investors like no other standard of treatment. Since investor-claimants (in particular if they are repeat players in the ISDS game) only stand to gain from an ever-broader reading of the standard, why would they not explore all potential meanings of what might be construed as being “fair” or “equitable”? This system-inherent drive towards expansion has further supported a casuistic approach by tribunals which focuses on the individual circumstances of the case, and – often based on decisions reached by earlier tribunals – frames the contours of the FET standard along specific fields of application or elements, such as (1) stability, predictability and the protection of legitimate expectations; (2) transparency; (3) due process and denial of justice; (3) legality and compliance with contractual obligations; (4) freedom from coercion and harassment; and (5) good faith, as well as protection against discrimination and arbitrariness.<sup>93</sup> While the scope and content of FET protection with regard to several of these categories is contested, the casuistic approach has allowed tribunals to individually develop the categories further and further – to an extent that the combined area of application continues to grow and subjects host state measures to a range of different FET claims.<sup>94</sup>

<sup>88</sup> R. Howse, *International Investment Law and Arbitration: A Conceptual Framework*, IILJ Working Paper 2017/1, and in *INTERNATIONAL LAW AND LITIGATION* (Helene Ruiz-Fabri, ed., 2017) – online at: [https://www.iilj.org/wp-content/uploads/2017/04/Howse\\_IILJ\\_2017\\_1-MegaReg.pdf](https://www.iilj.org/wp-content/uploads/2017/04/Howse_IILJ_2017_1-MegaReg.pdf).

<sup>89</sup> See the UNCTAD Investment Dispute Settlement Navigator at <https://investmentpolicy.unctad.org/investment-dispute-settlement/advanced-search>. By mid-2019 for example, out of 942 cases (including 332 pending ones), 459 involved a FET claim; whereas 121 FET claims had been successful (out of a total of 602 concluded cases – which generally breaks down into 215 wins for the host State, 173 wins for the investor(s), and 137 settlements). In comparison, out of a similarly high number of (direct or indirect) expropriation claims (472 instances – again, out of the total of 942 cases, including the 332 pending ones), the investor(s) only won in 87 cases (again, out of the total of 602 concluded cases).

<sup>90</sup> J. Salacuse, *The Law of Investment Treaties* (OUP, 2012), 221.

<sup>91</sup> See also A. Newcombe & L. Paradell, *Law and Practice of Investment Treaties – Standards of Treatment*, (Kluwer, 2009), 263 who argue that the uncertainty (but positive connotations) inherent in the terms “fair and equitable” has also been instrumental in the widespread adoption of the standard by States in IIAs – which of course was an essential *conditio sine qua non* for its successful invocation in ISDS.

<sup>92</sup> R. Dolzer & C. Schreuer, *Principles of International Investment Law* (2nd ed., OUP 2012), 132.

<sup>93</sup> While commentators and tribunals might divide FET into slightly diverging categories, there seems to be broad agreement about the fact-specific nature of the standard and the need to consider a range of factors, along the lines of those listed above. See for example *Lemire vs Ukraine* (*Lemire*), ICSID Case No ARB/06/18, Decision on Jurisdiction and Liability, 14 January 2010, para 284; as well as Newcombe & Paradell, 278-79. C. McLachlan, L. Shore and M. Weiniger, *International Investment Protection – Substantive Principles* (OUP 2017), 296.

<sup>94</sup> The IP-related ISDS cases *Philip Morris International vs Uruguay* (*Philip Morris*), ICSID Case No ARB/10/7, Award, 8 July 2016, and *Eli Lilly*, Case No UNCT/14/2, Final Award, 16 March 2017, offer ample evidence of this phenomenon as both cases discuss a various FET claims against the same State conduct.

With regard to measures implementing a TRIPS Waiver, many of those listed in reference to expropriation above (from temporary suspensions of protection or enforcement to compulsory licenses without remuneration) may well trigger investor complaints under FET. Relevant categories could involve the protection of legitimate expectations (to the extent this is still accepted), denial of justice (especially if IP enforcement remedies become unavailable), as well as protection against discrimination or arbitrariness (claiming the measure taken is not justified by the public health aims pursued). While a more detailed discussion of the potential application of FET elements to possible TRIPS-waiver based measures cannot be undertaken here, it suffices to say that in particular the concept of protecting legitimate expectations as well as legal stability and consistency are generally problematic in terms of a State's ability to adapt its IP system to a dynamically changing economic, social, and technological environment.<sup>95</sup> Since any form of domestic suspension or additional limitation of IP rights beyond existing TRIPS flexibilities could be perceived by investors as significant change in the domestic IP system, such changes could trigger ISDS claims. The notion of denial of justice can equally be contentious in this context – not least because the Tribunal in *Eli Lilly* gave the impression that any “dramatic change” in how courts apply domestic IP laws might lead to a successful claim.<sup>96</sup> Even a basic concept such as arbitrariness can be misapplied when host States are required to justify their measures under a proportionality test, which allows little or no deference to the balancing and value judgements made by national governments on essential interests like public health.<sup>97</sup>

It is then not surprising that FET has been described as having “the potential to reach further into the traditional *domaine réservé* of the host State than any one of the other rules of the treaties.”<sup>98</sup> Generally speaking, the more FET claims are likely to touch upon areas of regulation, adjudication and administrative decision-making in the public interest, the greater the need to afford tools that weigh and balance the protection of investors' interests against the host State's right to regulate. While the responses to expansive FET claims cannot be discussed in detail here, one needs to mention that there is an overall trend in State (and to some extent also ISDS) practice to “reign in” some of the excessive FET claims. In this context, several ISDS tribunals have emphasised that FET protections are not absolute and must not override the State's eminent domain, its sovereign power to legislate in pursuit of the interests of its people, and its right to adapt its laws and regulations to changing circumstances.<sup>99</sup> With more or less success, tribunals have tried various approaches (such as proportionality or reasonableness) to grapple with the difficult issue of weighing investor protection, for example in the form of legitimate expectations, against the host State's right to regulate.<sup>100</sup>

Alongside the developments detailed so far, it should be added that tribunals have also acknowledged that the host State's right to regulate constrains the protection offered by FET. The award in *Lemire* is illustrative. Immediately after listing the factors potentially triggering FET claims, the tribunal added that:

[t]he evaluation of the State's action cannot be performed in the abstract and only with a view of protecting the investor's rights. The Tribunal must also **balance other**

<sup>95</sup> K. Liddell & M. Waibel, “Fair and Equitable Treatment and Judicial Patent Decisions” (2016) 19(1) *Journal of International Economic Law* 145.

<sup>96</sup> See the discussion in Klopschinski, Gibson & Grosse Ruse-Khan, *International Investment and IP*, Chapter 6, Section B.2.

<sup>97</sup> See the Dissenting Opinion by Gary Born, *Philip Morris*, Award, paras 42-72, 82-88, 125-145.

<sup>98</sup> R. Dolzer, ‘The Impact of International Investment Treaties on Domestic Administrative Law’ (2005) 37 *NYU JILP* 953, 964.

<sup>99</sup> Dolzer & Schreuer, pp. 148-49.

<sup>100</sup> See generally M. Jacobs & S.W. Schill, “Fair and Equitable Treatment” in M. Bungenberg *et al* (eds.), *International Investment Law— A Handbook* (Beck, Hart, Nomos, 2015), 735-743.

**legally relevant interests, and take into consideration a number of countervailing factors**, before it can establish that a violation of the FET standard, which merits compensation, has actually occurred:

1. the State's sovereign right to pass legislation and to adopt decisions for the protection of its public interests, especially if they do not provoke a disproportionate impact on foreign investors;
2. the **legitimate expectations of the investor**, at the time he made his investment;
3. the **investor's duty to perform an investigation** before effecting the investment;
4. the **investor's conduct in the host country**.<sup>101</sup>

Overall, the dominant approach in ISDS practice seems to focus on the development of categories and criteria that can be applied to individual cases to determine what treatment is owed as "fair and equitable". This approach should also take into account the host State's right to regulate – but with open questions in particular on **who decides** on whether the measures at issue can be justified and based on **what standard of review**. In recently negotiated agreements, moreover, States have started to respond to the expansionist tendencies in the FET case law by setting out in much more detail what is and what is not part of the treatment owed under the standard.<sup>102</sup>

### **(3) Common limits to investment protection standards applied to IP rights: the right to regulate to protect public health**<sup>103</sup>

The often expansive investment protections afforded by ISDS tribunals – including under the FET standard as described above – have resulted in a push-back by States, including by means of more concrete and narrow definitions of protection standards, in particular for FET and the minimum standard of treatment (MST).<sup>104</sup> As another expression of the "return of the state",<sup>105</sup> IIAs and ISDS awards have explicitly recognized the State's right to regulate in the public interest, also referred to as the doctrine of "police powers".<sup>106</sup> This right results from the customary international law limits which are commonly accepted to apply to investment protection (including when applied to IP rights), and is based on the notion of State sovereignty.<sup>107</sup> This right may be particularly useful when assessing the implementation of

<sup>101</sup> *Lemire vs Ukraine (Lemire)*, ICSID Case No ARB/06/18, Decision on Jurisdiction and Liability, 14 January 2010, para 285. See also *Saluka Investments BV (The Netherlands) v Czech Republic*, Partial Award, 17 March 2006, para 305; *EDF (Services) Ltd v Romania*, ICSID, Case No ARB/05/13, Award, 2 October 2009, paras 215-216.

<sup>102</sup> See for example Art.8.10:2 CETA and Art.9.6:2-4 CPTPP.

<sup>103</sup> This section is based on Grosse Ruse-Khan, "The Role of Customary International Law for Intellectual Property Protection Beyond Borders" (4 October 2021), University of Cambridge Faculty of Law Research Paper No. 29/2021; to be published in A. Metzger & H Grosse Ruse-Khan, *Intellectual Property Protection Beyond Borders* (CUP, 2022, forthcoming), available online from <https://ssrn.com/abstract=3957449>.

<sup>104</sup> On the scope of the customary protection, see *Ibid.*, pp. 15-22; on the overall historical developments towards treaty standards via IIAs and the remaining role of custom, see P. Dumberry, "Customary International Law in International Economic Law", *Encyclopaedia of International Economic Law* (Edward Elgar, 2017), 44-45. With a specific focus on fair and equitable treatment (FET), the MST, ISDS interpretations and state responses see Klopschinski, Gibson & Grosse Ruse-Khan, *International Investment and IP*, 2020, 6.08-17. An example for state practice aiming to crystalize the contours of MST as part of custom is Art.9.6 of the CPTPP, read together with Annex 9-A to the CPTPP Investment Chapter, defining MST to include FET and full protection and security (FPS) – which in turn are described in various subsections as to include and not include certain elements of protection, with the Annex 9-A confirming the Parties' shared understanding of these protections and their limits reflecting custom.

<sup>105</sup> J. Alvarez, "The Return of the State", (2011) 20(2) *Minnesota Journal of International Law* 223.

<sup>106</sup> See generally Klopschinski, Gibson & Grosse Ruse-Khan, *International Investment and IP*, 2020, paras 6.107-123.

<sup>107</sup> For a discussion on the foundations of the right to regulate in the concept of sovereignty, see J. Viñuales, "Sovereignty in Foreign Investment Law" in Z. Douglas, J. Pauwelyn, and J. Viñuales, *The Foundations of*

the TRIPS Waiver, so this section reviews its customary international law foundations and its relation to treaty-based standards of investment protection.

Not least within its principal operational context of international investment law, the “right to regulate”<sup>108</sup> has been accepted as forming part of custom.<sup>109</sup> This right extends to cover measures adopted for public health.<sup>110</sup> Several ISDS awards have referred to the right to regulate. They have usually grounded this right in customary international law and have applied it even where the relevant IIA does not contain a reference to it. The Tribunal in *Philip Morris vs Uruguay* considered at length the right to regulate, in the context of a dispute involving IP rights protection under IIAs. The Tribunal had to decide whether the host State’s regulations limiting, in various ways, the use of brands on tobacco packaging constituted a breach of expropriation and FET provisions in the Uruguay–Switzerland BIT.<sup>111</sup> Uruguay argued that its measures had been designed to protect the public health of its citizens. As the principal award on IP rights, expropriation and FET, as well as the right to regulate, it may be useful to consider this decision in some detail.

In its award, the Tribunal recognized that while Philip Morris International’s (PMI) trademarks constituted a protected investment, neither under domestic law nor under applicable international (IP) treaties the investor “enjoy[s] an absolute right of use, free of regulation – but only an exclusive right to exclude third parties from the market so that only the trademark holder has the possibility to use the trademark in commerce, **subject to the State’s regulatory power**”.<sup>112</sup> On the expropriation claim, the Tribunal held that PMI failed to show that there was a substantial deprivation of its protected investment (as there was no significant economic loss suffered in consequence of the tobacco packaging measures). Most importantly, it added that “the adoption of the challenged Measures by Uruguay was a valid exercise of the State’s police powers, with the consequence of defeating the claim for expropriation under Article 5(1) of the BIT”.<sup>113</sup> Explaining that “[p]rotecting public health has since long been recognized as an essential manifestation of the State’s police power”,<sup>114</sup> the tribunal then interpreted the provision on expropriation in the BIT in light of the right to regulate under customary international law.<sup>115</sup> For the Tribunal, the right to protect public health was a specific expression of a general right to regulate which allows states to protect public interest so long as the relevant measures are “bona fide actions for the purpose of

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*International Investment Law: Bringing Theory into Practice* (OUP, 2014); K. Ziegler, “Domaine Réservé” in *Max Planck Encyclopaedia of Public International Law* (OUP, 2013); Cook, 257, 261-263 (citing relevant WTO case-law).

<sup>108</sup> See for a general discussion Joel P. Trachtman, *The International Economic Law Revolution and the Right to Regulate*, (Cameron May, 2005); C. Titi, *The Right to Regulate in International Investment Law* (Nomos/Hart, 2014); N. Zamir, “The Police Powers Doctrine in International Investment Law” (2017) 14(3) *Manchester Journal of International Economic Law* 318.

<sup>109</sup> See generally J. Viñuales, “Customary Law in Investment Protection” (2013-14) *Italian Yearbook of International Law* 23, also discussing other expressions of State sovereignty within customary international law (such as necessity and the doctrine of countermeasures) and their role in framing investment protection standards, even if they are treaty-based. See also Dumberry, at 44; OECD, “Indirect Expropriation” and the “Right to Regulate” in *International Investment Law*, OECD Working Papers on International Investment, 2004/4 (Sept. 2004).

<sup>110</sup> *Bischoff v Venezuela* (Germany-Venezuela Mixed Claims Commission) (1903) X RIAA 357.

<sup>111</sup> *Philip Morris Brands Sàrl, Philip Morris Products SA and Abal Hermanos SA v Uruguay* (PMI vs Uruguay), ICSID Case No ARB/10/7, Award, 8 July 2016. For a detailed discussion of this case see Klopschinski, Gibson & Grosse Ruse-Khan, *International Investment and IP*, 2020, paras 3.109-160; P. Ranjan, “Police Powers, Indirect Expropriation in International Investment Law, and Article 31(3)(c) of the VCLT: A Critique of *Philip Morris v. Uruguay*” (2019) 9 *Asian Journal of International Law* 98; Y. Radi, “CASE COMMENT: *Philip Morris v Uruguay*. Regulatory Measures in International Investment Law: To Be or Not to Be Compensated?” (2018) 33(1) ICSID Review 74.

<sup>112</sup> *PMI vs Uruguay*, Award, para 271 (emphasis added).

<sup>113</sup> *Ibid.*, para 287. On the substantial deprivation standard and its application to PM’s investments, see para 274-286 and the discussion by Ranjan, 105-107.

<sup>114</sup> *PMI vs Uruguay*, Award, para 291.

<sup>115</sup> *Ibid.*, para 290.

public welfare” or, differently put, that the measures are not “arbitrary and unnecessary” but “directed to the [public welfare] end” and “capable of contributing to its achievement”.<sup>116</sup> The Tribunal found Uruguay’s tobacco packaging measures to meet these requirements and – as elaborated further in relation to the FET claim – it emphasized the “margin of appreciation” which regulatory authorities of the host state enjoy when making public policy determinations.<sup>117</sup> The Tribunal further held that, as a matter of principle,

[t]he responsibility for public health measures rests with the government and investment tribunals should pay great deference to governmental judgments of national needs in matters such as the protection of public health. In such cases respect is due to the discretionary exercise of sovereign power, not made irrationally and not exercised in bad faith (...) involving many complex factors.<sup>118</sup>

In its analysis, the Tribunal also referred to a range of further ISDS decisions which have, in various ways, recognized the right to regulate.<sup>119</sup> Other tribunals have taken a similar position.<sup>120</sup>

The *Philip Morris v Uruguay* approach is not, however, unanimously followed. Indeed, previous decisions show a wide variety of approaches taken on this question.<sup>121</sup> At one end

<sup>116</sup> Ibid., paras 295, 298-306. For a comprehensive review of the tribunals approach to the police powers doctrine, and a critique of its reliance on potentially different rules resulting from this doctrine, see Ranjan, 107-117.

<sup>117</sup> Ibid., para 398. See also the general discussion, inspired by the *Philip Morris* Award on the applicability of this concept in ISDS by Y Fukunaga, “Margin of Appreciation as an Indicator of Judicial Deference: Is It Applicable to Investment Arbitration?”, (2019) 10 *Journal of International Dispute Settlement* 69.

<sup>118</sup> *PMI vs Uruguay*, Award, para 399 – referring further to *Electrabel SA v Republic of Hungary (Electrabel)*, ICSID Case No. ARB/07/19, Decision on Jurisdiction, Applicability and Liability, 30 November 2012, para 8.35; and *Saluka Investments BV (The Netherlands) v Czech Republic (Saluka)*, UNCITRAL, Partial Award, 17 March 2006, paras 272-3. See however also the Dissenting Opinion of Gary Born on this particular point, *Philip Morris vs Uruguay*, “Concurring and Dissenting Opinion by Mr Gary Born”, paras 87-8.

<sup>119</sup> Among others, it referred to the award in *Saluka vs Czech Republic*, where the Tribunal stated that: “It is now established in international law that States are not liable to pay compensation to a foreign investor when, in the normal exercise of their regulatory powers, they adopt in a non-discriminatory manner bona fide regulations that are aimed to the general welfare. (...) [T]he principle that the State adopts general regulations that are ‘commonly accepted as within the police power of States’ forms part of customary international law today” (at paras 255, 260, 262); to *Técnicas Medioambientales Tecmed SA v United Mexican States (Tecmed)*, ICSID Case No ARB (AF)/00/2, Award, 29 May 2003, para 119, stating that “[t]he principle that the State’s exercise of its sovereign power within the framework of its police power may cause economic damage to those subject to its powers as administrator without entitling them to any compensation whatsoever is undisputable” (although note that the tribunal however went on to also state that regulatory measures are not per se exempted from expropriation claims (para 121), and therefore adopted a proportionality test which – as discussed further below – balances the impact of the State action against its aims, and the extent to which the action achieves those (para 122)); and *Methanex Corp v United States of America (Methanex)*, UNCITRAL, Award, 3 August 2005, Part IV, Ch D, para 7, confirming that: “as a matter of general international law, a non-discriminatory regulation for a public purpose, which is enacted in accordance with due process and, which affects, inter alios, a foreign investor or investment is not deemed expropriatory”.

<sup>120</sup> See for example *Chemtura Corp (formerly Crompton Corp) v Canada*, ICGJ 464 (PCA 2010), Final Award, para 266; *Renée Rose Levy de Levi v Peru*, ICSID Case No ARB/10/17, Award, 26 February 2014, para 476; *Pope & Talbot Inc v Canada*, Interim Award, 26 June 2000, para 96; for an extensive review of the early case-law and State practice (among NAFTA States in particular) confirming custom, see *Marvin Feldman v Mexico*, ICSID Case No. ARB(AF)/99/1, Award, 16 December 2002, paras 98-150.

<sup>121</sup> For an overview and classification of these approaches, see: U. Kriebaum, “Expropriation” in M. Bungenberg et al (eds) *International Investment Law* (Beck, Hart, Nomos 2015) 1001-1006, 1005. The author identifies cases that (1) primarily focus on the economic impact on the investor, or (2) the nature of the regulatory measure, or (3) adopt some sort of a proportionality or reasonableness test to balance the investor- and the public interests. See also Ranjan, at 107. For a similar, but conceptually broader differentiation between the Hull formula (about the extent and criteria for compensation), the sole effect doctrine (with the principal focus on the effect on the relevant assets) and proportionality tests (which can also be seen as additional requirements, applying next to the police powers doctrine), see Titi, “Police Powers Doctrine and International Investment Law” in *General Principles of Law and International Investment Arbitration*, A. Gattini, A. Tanzi and F. Fontanelli (eds.) (Brill, 2018), section II.

of the spectrum, and closer to the *Philip Morris v Uruguay* approach, are those tribunals which have had recourse to proportionality tests, at times informed by the approach of the ECHR, in balancing the state's right to regulate with its commitments under investment treaties.<sup>122</sup> These tribunals have demanded some reasonable relationship of proportionality between the means employed and the aim to be realized.<sup>123</sup> By way of example, in *El Paso vs Argentina*, the Tribunal's balancing exercise considered whether "the interference with private rights of the investors is *disproportionate* to the public interest".<sup>124</sup> This approach is more closely aligned with the deferential test adopted in *PMI vs Uruguay*, which leaves room for a "discretionary exercise of sovereign power" and only reviews whether a decision taken in the public interest is "not made irrationally and not exercised in bad faith".<sup>125</sup> Similar deferential approaches, at times specifically linked again to the notion of margin of appreciation adopted by the ECtHR, have been adopted in relation to FET claims or other aspects of balancing international investment protection and the sovereign power of the state to regulate.<sup>126</sup>

At the other end, are tribunals that have found that despite the public welfare purpose, a measure amounted to an expropriation since it had a detrimental effect on the investors' assets.<sup>127</sup> Similarly, other tribunals have emphasized the limits of the right to regulate, in particular those which follow from specific obligations states agreed to in an investment treaty.<sup>128</sup>

While there seems to be some convergence on the basic proposition that "[i]t is an accepted principle of customary international law that where economic injury results from a bona fide non-discriminatory regulation within the police power of the State, compensation is not required",<sup>129</sup> various differences on the exact (and potentially additional) conditions as well as on scope of the right to regulate remain.<sup>130</sup> Different views also exist on the interpretative methods used to import the right to regulate as a customary principle (in whatever exact form) into the specific treaty context – in particular whether references to public welfare and non-discrimination as requirements for the legality of (compensatory) expropriation in the

<sup>122</sup> See for example *James vs United Kingdom* (1986), ECtHR Judgment of 21 February 1986, paras 50, 63.

<sup>123</sup> *Azurix vs Argentina*, para 311-12 (agreeing with the ECtHR that proportionality is lacking when the measure leads to an "excessive burden" for the individual investor); *LG&E Energy v Argentina*, 46 ILM 40 (2007), paras 189, 195 (balancing the "degree of the measure's interference with the right of ownership and the power of the state to adopt its policies" – para 189); see also *Continental Casualty Company v The Argentine Republic (Continental Casualty)*, ICSID Case No. ARB/03/9, Award, 5 September 2008, para 276; *Les Laboratoires Servier, SAS Bioforma, SAS, Arts et Techniques du Progrès SAS v Poland (Servier)*, PCA (UNCITRAL), Final Award, 14 February 2012, para 569; *Fireman's Fund Insurance Company v Mexico*, ICSID Case No. ARB(AF)/02/01, Award, 17 July 2006, para 176.

<sup>124</sup> *El Paso Energy International Company v The Argentine Republic (El Paso)*, ICSID Case No. ARB/03/15, Award, 31 October 2011, para 233 (emphasis added). Similarly, the tribunal in *Servier vs Poland* (at para 570) re-phrased the (positively formulated) proportionality test into one where it needed to determine whether the State had exercised its regulatory powers "in bad faith, for some non-public purpose, or in a fashion that was either discriminatory or lacking in proportionality between the public purpose and the actions taken".

<sup>125</sup> *PMI vs Uruguay*, Award, para 399; see also the further discussion by the tribunal in paras 409-10, 418-20.

<sup>126</sup> *Glamis Gold, Ltd v The United States of America (Glamis Gold)*, UNCITRAL (NAFTA), Award, 8 June 2009, para 805; *Continental Casualty vs Argentina*, para 199; *RWE Innogy GMBH & RWE Innogy AERSA SAU v Kingdom of Spain (RWE)*, ICSID Case No. ARB/14/34, Decision on Jurisdiction, Liability and Certain Issues of Quantum, 30 December 2019, para 553. See generally the discussion in Klopschinski, Gibson & Grosse Ruse-Khan, *International Investment and IP*, 2020, at paras 6.114-123.

<sup>127</sup> *Compañía del Desarrollo de Santa Elena, SA v Costa Rica*, ICSID Case No. ARB/96/1, Final Award, 17 February 2000, paras 71-72; *Metalclad Corporation v Mexico*, ICSID Case No. ARB(AF)/97/1, Award, 30 August 2000, para 103; *Vivendi Universal SA v Argentina*, ICSID Case No. ARB/97/3, Award, 20 August 2007, para 7.5.20; on this issue see generally the discussion in *Azurix Corp v Argentina (Azurix)*, ICSID Case No. ARB/01/12, Award, 14 July 2006, paras 306-323.

<sup>128</sup> *ADC Affiliate Ltd and ADC and ADMC Management Ltd v The Republic of Hungary (ADC)*, ICSID Case No. ARB/03/16, Award 2 October 2006, paras 423-424.

<sup>130</sup> See in particular the critique by Radi, 75-77, 78-80) and Ranjan, 107-117) concerning the reasoning in *PMI vs Uruguay*, Award, in particular, and of the ambiguities in the police powers doctrine more generally.

treaty bar an interpretative integration of police powers in order to exclude certain public welfare oriented and non-discriminatory measures from the notion of (indirect) expropriation altogether.<sup>131</sup> And while authors have generally recognized an increased tendency to resort to the concept of police powers, Titi for example cautions – in the words of Tribunal in *Saluka vs Czech Republic* – that “international law has yet to identify in a comprehensive and definitive fashion precisely what regulations are considered “permissible” and “commonly accepted” as falling within the police or regulatory power of States and, thus, non-compensable”.<sup>132</sup>

The overall picture that emerges from this necessarily brief review is a somewhat blurry image of a right to regulate whose exact contours remain ambiguous. Its basic idea seems to receive increasing support from all sides, ambiguities remain in respect of its scope (what type of public interests are covered, and against which type of claims does it apply?) and requirements (subject to meeting which conditions exactly can it be invoked? If the latter include some sort of a proportionality test, who decides on the balancing, and with what degree of deference to policy choices made by the host state?). Scope and requirements are, furthermore, likely to differ depending on the specific (treaty) context.

With this rather open assessment, this section can only offer some basic parameters on the question of how the right to regulate might support a WTO Member implementing the TRIPS Waiver by reducing IP protection below minimum standards otherwise owed under TRIPS. To begin with, the most decisive parameter is likely to be the specific terms in the relevant IIA: how and in what degree of detail does the treaty set out the standards of protection? And are there any specific, treaty-based limits to the relevant standards which allow to conclude on the common intention of the parties to either limit or expand the customary right to regulate? ICJ case law suggests that unless there is clear evidence (usually in form of an express treaty rule) that the State Parties wished to contract out of custom, customary international law principles and rules apply – at least as a source of guiding treaty interpretation.<sup>133</sup> The ILC explains the continued role of custom in a world dominated by treaties in similar terms in its Fragmentation report:

It is in the nature of “general law to apply generally” – namely inasmuch as it has not been specifically excluded. It cannot plausibly be claimed that these parts of the law - “important principles” as the [ICJ] put it – have validity only as they have been “incorporated” into the relevant regime.<sup>134</sup>

The basic starting point therefore is that the right to regulate as a rule of custom applies – unless there is clear evidence that States, for example by including specific terms in a treaty, wished to contract out of it. In other words: one needs to positively identify State intent to exclude a rule of custom – rather than an intention to retain that rule as soon as related treaty rules exists.

Against this background, the default position is for a right to regulate to apply even in case of an IIA with commitments protecting foreign investments. The onus hence is on the investor bringing an ISDS claim to show that specific treaty terms indicate the common intention of the parties to (partially or fully) opt out of custom – for example by setting specific treaty

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<sup>131</sup> On this, see Radi, 78-80, and Ranjan, 121-124.

<sup>132</sup> Titi, *Police Powers*, 2018, at III, citing *Saluka vs Czech Republic*, para 263. See also her discussion of various specific open questions at IV.

<sup>133</sup> For example, on the applicability of the local remedies rule, the ICJ expressed that it “finds itself unable to accept that an important principle of customary international law could be held to have been tacitly dispensed with, in the absence of any words making clear the intention to do so”: *Elettronica Sicula SpA (ELSI) (United States of America v Italy)*, ICJ Reports 1989 p. 42, para 50.

<sup>134</sup> International Law Commission, *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law*, para 185.

standards and/or limits on how far public health measures are justified. Unless there is such evidence of contracting out, WTO Members will therefore be able to rely on the right to regulate when implementing the TRIPS Waiver. Since the customary right covers as its core, “the right to protect public health,”<sup>135</sup> there is no question that measures taken to implement the TRIPS waiver in order to facilitate access to health technologies for dealing with the COVID-19 pandemic fall within the scope of State’s police powers.

Given that the right to regulate is often understood as involving conditions of reasonableness or proportionality of the measure to achieve its (public health) purpose, the lesser the interference with IP protection resulting from the measure or the stronger the public health case for adopting it, the more likely a justification based on the right to regulate will be accepted. To exemplify, a full (albeit temporary) termination of all protection available for a patent covering a COVID vaccine will set a relatively higher bar than issuing a compulsory license without any remuneration for the patent owner: the former may well still fall within the right to regulate – if less interfering alternatives are not reasonably available.

The right to regulate to protect health hence should always be considered in ISDS claims made against a measure implementing the TRIPS waiver. It can be relied on as a customary rule that informs the interpretation of the relevant investment protection standards (such as expropriation and FET), or in those cases where the relevant IIA incorporates a right to regulate, as informing the interpretation of this right.<sup>136</sup> The role this right can play hence depends very much on the particular factual and legal context.<sup>137</sup>

#### **(4) IP-specific defences in IIAs**

A broad range of clauses in Investment chapters in FTAs as well as in BITs address the relation of investment protection standards under the respective IIA and IP protection under TRIPS and/or international IP treaties more generally. As the examples and further analysis below shows, the principal idea is to (1) give precedence to TRIPS and other IP treaties as the more specific set of norms governing IP rights (an expression of the *lex specialis* principle); and, relatedly, (2) ensure that TRIPS flexibilities – in particular those related to the public health and access to medicines context – are not undermined when investment protection standards are applied to IP rights as investments. Since some of these clauses specifically include TRIPS waivers, it is useful to begin the discussion with these, followed by clauses focused on compulsory licensing and other (public health) related limits to IP rights, concluding with general provisions on the relation between IIAs and TRIPS (at times including other international IP treaties).

IIA provisions that specifically refer to TRIPS waivers include Art.8.15:4 CETA, whereby the general prohibition to impose performance requirements on foreign investors under Art.8.5:1(f) CETA to “transfer technology, a production process or other proprietary knowledge to a natural person or enterprise in its territory” can be derogated from “if permitted by the TRIPS Agreement, including any amendments to the TRIPS Agreement in force for both Parties, and waivers to the TRIPS Agreement adopted pursuant to Article IX of the WTO Agreement”.<sup>138</sup> In addition, Art.10.7(5) of the Panama – US FTA sets out that

<sup>135</sup> Para 4 of the Doha Declaration. As one of the authors has discussed in detail elsewhere (see Grosse Ruse-Khan, Customary International Law, 2021), the Doha Declaration reinforces the right to regulate and its application in the international IP treaty context, in particular the TRIPS Agreement.

<sup>136</sup> See for example Art.8.9:1, 2 CETA, as well as Art.28.3(1) CETA (although this “general exception” type clause does not seem to apply to expropriation and FET claims) and Art.16.1 of the Brazilian Model BIT. For a general discussion, see Klopschinski, Gibson & Grosse Ruse-Khan, *International Investment and IP*, 2020, at paras 5.152-156, 6.108-113, and 7.50-59.

<sup>137</sup> For a discussion of the different approaches to the police powers doctrine by investment tribunals see: Viñuales, “Sovereignty in Foreign Investment Law”, 317ff.

<sup>138</sup> Art.8.5:1 CETA states: “A Party shall not impose, or enforce the following requirements, or enforce a commitment or undertaking, in connection with the establishment, acquisition, expansion, conduct, operation, and

expropriation protection under Art.10.7 does not, *inter alia*, apply to TRIPS-consistent compulsory licenses. A footnote 3 then adds that “[f]or greater certainty, the reference to ‘the TRIPS Agreement’ in paragraph 5 includes any waiver in force between the Parties of any provision of that Agreement granted by WTO Members in accordance with the WTO Agreement.”<sup>139</sup> An essentially identical provision can be found in Art.14.11:6 of the Australia–Japan EPA.<sup>140</sup> While these clauses had not been drafted with the TRIPS COVID Waiver in mind, they show that the IIA Contracting States explicitly include waivers of TRIPS commitments under what they understand as flexibilities permitted by TRIPS, or more generally as forming part of the TRIPS Agreement. This in turn indicates that for domestic measures requiring to “transfer technology, a production process or other proprietary knowledge” as well as issuing compulsory licenses, the IIA State Parties wanted to ensure that TRIPS flexibilities, including those resulting from a TRIPS waiver, are not undermined by investment protection when applied to IP rights and related tacit knowledge. As the further discussion below indicates, these are expressions of a broader principle whereby investment protection standards are generally understood to be subject to TRIPS flexibilities.<sup>141</sup>

Many IIAs include TRIPS flexibility “safeguard clauses” along the lines of Art.10.7(5) of the US–Panama FTA, albeit without specific reference to TRIPS waivers. A typical formulation of such a clause can be found in Art.14.8(6) USMCA, whereby the protection against expropriation under Art.14.8:

does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or creation of intellectual property rights, to the extent that the issuance, revocation, limitation, or creation is consistent with [the USMCA IP Chapter] and the TRIPS Agreement.<sup>142</sup>

Essentially the same provision can be found in Article 9.8(5) CPTPP,<sup>143</sup> Art.10.13(4) RCEP,<sup>144</sup> Article 11.6(5) of the Korea–US FTA (2007), Art.10.7(5) of the Colombia–US TPA (2006) Art.10.6(5) Oman–US FTA, Art.2.6(3) of the EU–Singapore Investment Protection Agreement (2018), Art.8.12(5) CETA (2016), and Article 2.7(4) of the EU–Viet Nam Investment Protection Agreement (2019). These FTA clauses refer to consistency with TRIPS regarding its flexibilities on compulsory licensing and hence effectively exempt from

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management of any investments in its territory to (f) transfer technology, a production process or other proprietary knowledge to a natural person or enterprise in its territory.” Article 8.15:4 CETA then continues that “[i]n respect of intellectual property rights, a Party may derogate from Articles 8.5.1(f), 8.6, and 8.7 [the latter two of which concern national treatment and MFN] if permitted by the TRIPS Agreement, including any amendments to the TRIPS Agreement in force for both Parties, and waivers to the TRIPS Agreement adopted pursuant to Article IX of the WTO Agreement.” Canada–EU CETA (2016) – <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/3593/download>.

<sup>139</sup> See Art.10.7(5) of the Panama–United States FTA (2007): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/2535/download>. Panama–United States FTA (2007), Art.10.7(5): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/2535/download>.

<sup>140</sup> Art.14.11:6 Australia–Japan EPA (2014): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/3058/download>.

<sup>141</sup> See also Grosse Ruse-Khan, *International IP*, 2016, paras 7.73-74, 7.91-105, discussing further implications of these “safeguard clauses” as an invitation to litigate compliance with TRIPS within ISDS. This issue, however, should pose less of a problem in case of a TRIPS waiver since the latter offers a much more straightforward “flexibility” that should not pose too many options for diverging interpretations on its scope.

<sup>142</sup> USMCA (2018) – Art.14.8, paragraph 6 – where a further fn. 9 explains: “For greater certainty, the Parties recognize that, for the purposes of this Article, the term ‘revocation’ of an intellectual property right includes the cancellation or nullification of that right, and the term ‘limitation’ of an intellectual property right includes exceptions to that right.” Online available at <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/6008/download>.

<sup>143</sup> See also fn. 19 to that Article – which is equivalent to fn.9 in the USMCA.

<sup>144</sup> See also fn. 31 which again includes the same clarification as the USMCA and CPTPP.

expropriation claims any measures compliant with those TRIPS flexibilities. However, when it comes to other IP limits (such as revocations or exceptions) the clauses referred to above require not only consistency with TRIPS, but also the relevant IP Chapter of the FTA. On the other hand, since these FTA IP chapter themselves frequently refer back to TRIPS, and – especially for public health-related measures – protect policy space under TRIPS,<sup>145</sup> asking for consistency with IP commitments under the FTA does not necessarily undermine reliance on the TRIPS Waiver. Instead, such clauses arguably reflect the common intention of the FTA Parties to safeguard TRIPS flexibilities – at least to the extent that they are not specifically modified by the additional IP commitments in the FTA – and ensure investment standards do not stand in the way of adopting measures in reliance on such flexibilities. Along the lines of the arguments made in section b)(2) above, there is no reason to believe that a TRIPS waiver – even if not explicitly included in such a “safeguard clause” – does not form part of the TRIPS-based policy space that the Parties intend to protect.

One should add that a limited number of FTAs further include a clarification that “[m]oreover, determination that the measure is inconsistent with the TRIPS Agreement and [the IP Chapter] does not establish that there has been an expropriation.”<sup>146</sup> In the context of the TRIPS waiver, such an additional clarification is likely to be relevant only where a domestic measure exceeds the scope of the TRIPS waiver (and hence is inconsistent with TRIPS): in such situations, this inconsistency as such does not lead to a positive finding of expropriation – but merely allows the expropriation analysis to proceed, including on the question about a right to regulate.<sup>147</sup> Arguably, these additional clauses quoted above have primarily a clarificatory character: even without them, a finding of inconsistency with TRIPS does not automatically lead to a finding of expropriation.<sup>148</sup> That primarily results from the consequences these clauses foresee in case a measures complained about is consistent with TRIPS. In such a case, the expropriation clause of the IIA simply does not apply to the measure that falls within TRIPS policy space. If, on the other hand, a measure is not found to be TRIPS consistent, the expropriation clause can apply – but that alone of course does not allow to conclude an expropriation has occurred. With or without the specific clarification, safeguard clauses aim to ensure that flexibilities under the TRIPS Agreement are the first and foremost reference point for determining the international legality of measures affecting IP rights – even if these rights are protected under IIAs. Any TRIPS Waiver should be seen as forming part of this IP-specific reference point which forms relevant *lex specialis vis-à-vis* investment protection for IP rights.

Finally, the FTA provisions safeguarding IP-related flexibilities discussed here are also commonly included in many equivalent BIT clauses, reaffirming the general idea that TRIPS-consistent compulsory licenses and other IP limits as such do not constitute expropriation.<sup>149</sup>

<sup>145</sup> See the discussion in section c. (2) above.

<sup>146</sup> EU–Singapore Investment Protection Agreement (2018) – ANNEX 3 (EXPROPRIATION AND INTELLECTUAL PROPERTY RIGHTS) – online available at <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5714/download>; and Art.8.12(6) of the Canada–EU CETA (2016) – online available at <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/3593/download>.

<sup>147</sup> See the discussion in subsection c. (3) above.

<sup>148</sup> See generally the analysis in H Grosse Ruse-Khan, “Litigating Intellectual Property Rights in Investor-State Arbitration: From Plain Packaging to Patent Revocation” (8 July 2014) *Fourth Biennial Global Conference of the Society of International Economic Law (SIEL) Working Paper No. 2014-21*, <http://ssrn.com/abstract=2463711>, as well as Klopschinski, Gibson & Grosse Ruse-Khan, *International Investment and IP*, 2020, paras 7.14-158, explaining that the main reason for introducing this additional clarification had been Canada’s experience in the *Eli Lilly* case.

<sup>149</sup> See e.g., Georgia–Japan BIT (2021), Art.11(5): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/6078/download>; Côte d’Ivoire–Japan BIT (2020), Art.11(6): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/6099/download>; Argentina–Japan BIT (2018), Art.11(8): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5799/download>; Japan–Jordan BIT (2018), Art.11(6): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5808/download>; Armenia–Japan BIT (2018), Art.12(6): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5778/download>; Brazil–

A few of these BIT clauses then do not refer specifically to TRIPS as benchmark, but rather exempt “measures [that] are consistent with international agreements regarding intellectual property rights to which both Contracting Parties are parties”.<sup>150</sup> In case of measure implementing a TRIPS Waiver, this would raise the question about the relation between the latter and overlapping IP commitments in other treaties binding the BIT Contracting Parties. Sections a) and b) have shown that these other IP treaties need, as a minimum, to be construed in light of the TRIPS waiver, and – if that is not possible in order to ensure mutual coherence – are likely subject to the waiver as *lex posterior*. A broader IP treaty consistency clause in a BIT hence is unlikely to change the outcomes for measures undertaken by a WTO Member in implementing a TRIPS Waiver.

In addition to the expropriation clauses safeguarding TRIPS flexibilities discussed above, some IIAs include similar provisions with regard to performance requirements that concern the transfer of (often IP protected) technology. For example, Art.10.6(1) RCEP sets out that

[n]o Party shall impose or enforce, as a condition for establishment, acquisition, expansion, management, conduct, operation, or sale or other disposition of an investment in its territory of an investor of any other Party, any of the following requirements: (...) (f) to transfer a particular technology, a production process, or other proprietary knowledge to a person in its territory.

Art.10.6(3)(b) RCEP then adds that subparagraph 1(f):

shall not apply: (i) if a Party authorises use of an intellectual property right in accordance with Article 31 or Article 31bis of the TRIPS Agreement, or to measures requiring the disclosure of proprietary information that fall within the scope of, and are consistent with, Article 39 of the TRIPS Agreement.<sup>151</sup>

Footnote 23 then clarifies that:

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United Arab Emirates BIT (2019), Art.2(5): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5855/download>; Brazil–Guyana BIT (2018), Art.2(5): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5763/download>; Brazil–Suriname BIT (2018), Art.2(5): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5715/download>; Argentina–Japan BIT (2018), Art.11(8): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5799/download>; Argentina–United Arab Emirates BIT (2018), Art.6(7): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5761/download>; Brazil–Morocco BIT (2019), Art.6(2): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5890/download>; Brazil–Ecuador BIT (2019), Art.7(7): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5887/download>; Brazil–Chile BIT (2015), Art.7(4): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/4712/download>; Brazil–Colombia BIT (2015), Art.6(7): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5765/download>.

<sup>150</sup> Canada–China BIT (2012), Art.10(2) <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/3476/download>; Japan–Morocco BIT (2020), Art.9(5) <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5908/download>; Japan–Kenya BIT (2016), Art.10(6): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5374/download>; Brazil–India BIT (2020), Art.3, 3.6 (c): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5912/download>.

<sup>151</sup> RCEP (2020), Art.10.6: <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/6032/download>. See also Korea–US FTA (2007), Art.11.8(3): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/2542/download>; Panama–United States FTA (2007), Art.10.9(3): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/2535/download>; Colombia–United States TPA (2006), Art.10.9(3): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/2737/download>; Oman–US FTA (2006), Art.10.8(3): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/2718/download>.

[t]his includes any amendment to the TRIPS Agreement implementing paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) adopted at Doha on 14 November 2001.

An overall similar approach can be found in Article 14.9:2(f)(ii) of the Australia–Japan EPA which subjects the prohibition of performance requirements relating to technology transfer when those concern “the disclosure of proprietary information or the use of intellectual property rights which is undertaken in a manner not inconsistent with the TRIPS Agreement”.<sup>152</sup>

The outcome of clauses like Art.10.6(3)(b)(i) RCEP is to disapply the prohibition of performance requirements related to the transfer of proprietary technology and/or know-how if such requirements are consistent with TRIPS’ flexibilities related to compulsory licensing and/or trade secret protection. These clauses hence again reinforce the broader idea of ensuring that specific TRIPS flexibilities are not undermined by the operation of the more general rules in IIAs, here with regard to the prohibition of performance requirements. As the RCEP example as well as the equivalent IIA provisions cited in fn. 151 show, these clauses carefully include updates and amendments to the relevant TRIPS policy space, such as the Art.31bis TRIPS amendment for granting compulsory licenses to export pharmaceuticals to countries with insufficient domestic manufacturing capacities. They reaffirm the general proposition that can be derived from other safeguard clauses discussed above – namely that TRIPS flexibilities in their most current expression are the first and foremost benchmark against which standards of investment protection for IP-related investments are to be judged. This in turn confirms the position here adopted in relation to a TRIPS waiver: as the most recent expression of the policy space under TRIPS agreed by WTO Members with regard to measures adopted to facilitate access to and widespread use of medical technologies for tackling the COVID-19 pandemic, there is no reason to believe that a TRIPS Waiver should not also form part of the consistency benchmark alluded to above, and hence part of the TRIPS flexibilities the IIA State Parties intended to safeguard. As the example of Art.10.9:3 of the US–Panama FTA referred to at the very beginning of this section shows, IIA State Parties have at times specifically included TRIPS waivers. And even where they have not, the general approach adopted in these safeguard clauses strongly suggests that IIA parties wish to judge IP-related measures primarily against the multilateral consensus under TRIPS – and only in a secondary step consider these measures against the more general IIA standards.

Finally, the principal argument above in favour of TRIPS and its flexibilities, including the waiver, is also supported by general clauses in IIAs addressing the TRIPS (as well as other IP treaties) – investment protection relationship. For example, Art.15 of the Argentina–UAE BIT states that

[n]othing in this Agreement shall be construed to restrict the right of the Parties to adopt measures related to intellectual property in conformity with the TRIPS Agreement, or with other treaties on intellectual property rights to which both Parties are party.<sup>153</sup>

More generally still, the China–Japan–Korea Trilateral Investment Agreement (2012) sets out in its Art.9(2) that “[n]othing in this Agreement shall be construed so as to derogate from the rights and obligations under international agreements in respect of protection of

<sup>152</sup> See also India–Japan EPA (2011), Art.89(1)(h)(ii): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/2627/download>;

<sup>153</sup> Argentina–United Arab Emirates BIT (2018), Art.15: <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5761/download>.

intellectual property rights to which two or more Contracting Parties are parties.”<sup>154</sup> Almost identical clauses ensuring that not only obligations, but also rights under TRIPS and other IP treaties are not undermined by investment protection standards applied to IP rights can for example be found in Japanese and Spanish BITs.<sup>155</sup> The notion of “rights” of contracting parties here has to be construed to cover provisions in these agreements which leave flexibility for implementing minimum standards of IP protection, in particular those relevant to give effect to the “right to protect public health” as referenced in the Doha Declaration.<sup>156</sup> And for the reasons explained in this and earlier sections above, a TRIPS Waiver is best understood as forming part of the consensus among WTO Members about the policy space available to adopt measures in the exceptional circumstances of the COVID pandemic.

<sup>154</sup> China–Japan–Korea, Republic of Trilateral Investment Agreement (2012), Art.9(2): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/2633/download>.

<sup>155</sup> Georgia–Japan BIT (2021), Art.18(2): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/6078/download>; Côte d’Ivoire–Japan BIT (2020), Art.18: <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/6099/download>; Japan–Jordan BIT (2018), Art.18: <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5808/download>; Japan–United Arab Emirates BIT (2018), Art.21: <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5741/download>; Armenia–Japan BIT (2018), Art.19: <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5778/download>; Israel–Japan BIT (2017), Art.18: <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5849/download>; Japan–Kenya BIT (2016), Art.19: <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5374/download>; Islamic Republic of Iran–Japan BIT (2016), Art.14: <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/3578/download>; Ethiopia–Spain BIT (2009), Art.8(3): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/1174/download>; Bahrain–Spain BIT (2008), Art.8(3): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/4846/download>; Libya–Spain BIT (2007), Art.8(3): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/3234/download>; Spain–Yemen BIT (2008), Art.8(3): <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/5515/download>.

<sup>156</sup> As discussed in section (3) and in more detail in Grosse Ruse-Khan, *Customary International Law*, 2021, this “right to protect public health” can best be understood as reference to the customary right to regulate.

#### 4. DEFENCES UNDER GENERAL INTERNATIONAL LAW

Section 3 has shown that despite good arguments for a range of “internal” defences from within international IP and investment treaties to be applied to measures taken in implementing the Waiver, it is possible that TRIPS-plus commitments in IP Chapters of FTAs, or investment protections applicable to IP rights under IIAs may nevertheless be infringed by TRIPS Waiver implementing measures. In respect of the latter, as a last alternative, respondent States might be able to rely on the defences in the law of State responsibility to justify their *prima facie* breach of the obligations discussed in section 3 above. These defences are listed in Articles 20-25 of the International Law Commission’s (“ILC”) Articles on the Responsibility of States for Internationally Wrongful Acts (“ARS”), and include, respectively, consent, self-defence, countermeasures, *force majeure*, distress and state of necessity.<sup>157</sup>

Two of these defences may be particularly relevant to respondent States in these circumstances: state of necessity and consent. Each of these will be considered in the next two sections.

##### a. State of Necessity

Article 25 of the ILC Articles on State responsibility provides that:

1. Necessity may not be invoked by a State as a ground for precluding the wrongfulness of an act not in conformity with an international obligation of that State unless the act:

- (a) is the only way for the State to safeguard an essential interest against a grave and imminent peril; and
- (b) does not seriously impair an essential interest of the State or States towards which the obligation exists, or of the international community as a whole.

2. In any case, necessity may not be invoked by a State as a ground for precluding wrongfulness if:

- (a) the international obligation in question excludes the possibility of invoking necessity; or
- (b) the State has contributed to the situation of necessity.<sup>158</sup>

The situation envisaged in Article 25 involves a conflict between two interests: an essential interest of the State, threatened by a grave and imminent peril, and a lesser interest of another subject, the infringement of which is the only way to protect the State’s essential interest. In this situation of conflict, where harm to one of the two interests appears probable, the defence of necessity exonerates a State who acts for the protection of the superior

<sup>157</sup> ARS, Arts.20-25.

<sup>158</sup> This section draws on previous work co-authored with Prof Michael Waibel: “Necessity 20 Years On: The Limits of Article 25 ARSIWA”, (2021) 36 *ICSID Review* (forthcoming), available from [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3858530](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3858530); and with Dr. Freya Jephcott: “COVID-19 and Defences in the Law of State Responsibility: Parts I and II”, *EJIL:Talk!* (17 March 2020), available from <https://www.ejiltalk.org/covid-19-and-defences-in-the-law-of-state-responsibility-part-i/> and <https://www.ejiltalk.org/covid-19-and-defences-in-the-law-of-state-responsibility-part-ii/>.

interest, as this reduces overall net harm. State of necessity is, to put it in analogous domestic law terms, a defence premised on a lesser-evil logic.

This is a strict defence as evidenced by the use of the double negative in the chapeau (“necessity *may not* be invoked *unless*...”), and has been interpreted as such by tribunals. Indeed, despite several invocations in recent (but also earlier) times,<sup>159</sup> particularly in investment treaty arbitration, it has almost never been successful.<sup>160</sup> The defence can be invoked against private parties, such as IP owners: all of Part One of the ILC Articles, including Article 25, are applicable with respect to all obligations of the State, regardless of their source or content.<sup>161</sup> Further, there is nothing in the language of Article 25 or its Commentary to suggest that it may not apply against private parties, and investment tribunals have routinely accepted that the defence can be invoked against investors.

States allegedly violating their obligations under international IP and/or investment treaty commitments, as a result of the implementation of the TRIPS Waiver, may consider raising an argument on the basis of necessity to justify their conduct.<sup>162</sup> To successfully plead the defence of necessity, a State must fulfil the following three requirements: (i) there must be a grave and imminent peril; (ii) the State must protect an essential interest, to the detriment of a lesser one; (iii) the State’s act was the “only way” to safeguard the interest from that peril. In addition, the plea is excluded if: (iv) the obligation in question excludes reliance on necessity; and (v) the State contributed to the situation of necessity. These will be addressed in turn, with the exception of (iv) as this will depend on an interpretation of the specific obligation impaired.

### **(1) Grave and imminent peril**

First, there must be a grave and imminent peril. This requirement is best understood by separating the elements of risk and harm. What is required is that there is an imminent **risk** that an essential interest will be gravely **harm**ed.

The harm refers to a setback to the interest in question: in the sense that the interest will be worse off than it would otherwise have been.<sup>163</sup> The harm must be “imminent” in the sense that it has not yet materialized.<sup>164</sup> Further, imminence does not mean immediacy (as in the peril is **about** to happen), but as explained by the ICJ in *Gabčíkovo-Nagymaros* it refers to the “certainty” of the peril: namely, whether it can be established, with a (sufficient) degree of certainty that the peril will occur at some point in the future.<sup>165</sup> In all cases, since the harm

<sup>159</sup> For a historical overview, see: F Paddeu, *Justification and Excuse in International Law: Concept and Theory of General Defences* (CUP, 2018), ch. 8.

<sup>160</sup> For a rare example of success, see: *LG&E Energy Corp, LG&E Capital Corp, LG&E International Inc v Argentine Republic*, ICSID Case ARB/02/1, Award, 25 July 2007. On which see: G Falkof, “‘State of Necessity’ Defence Accepted in *LG&E v Argentina* ICSID Tribunal” (2006) 3(5) *TDM*; C Foster, “Necessity Knows No Law! *LG&E v Argentina*” (2006) 9 *Int’l Arb LR* 149; J Fourret, “*CMS c/ LG&E* ou l’état de nécessité en question” (2007) 2 *Rev de l’Arbitrage* 249; M Waibel, “Two Worlds of Necessity in ICSID Arbitration: *CMS* and *LG&E*” (2007) 20 *LJIL* 637.

<sup>161</sup> See ARS Art.12.

<sup>162</sup> Article 25 also allows a State to act in the protection of an essential interest of the international community of States as a whole, in this case the protection of the wellbeing of the world’s population from the virus. However, despite its desirability, the legality of this kind of “public necessity” has no grounding in the practice and *opinio juris* of States. Indeed, this possibility was included in the last stages of the drafting of Article 25 without much commentary and passed almost unnoticed by States in the Sixth Committee of the UN General Assembly. See G. Gaja, « La possibilité d’invoquer l’état de nécessité pour protéger les intérêts de la communauté internationale » in *Droit du pouvoir, pouvoir du droit: Mélanges offerts à Jean Salmon*, Corten et al (eds.), (Bruylant, 2007), 417-424.

<sup>163</sup> For the understanding of “harm” as a setback to an interest, see: J Feinberg, *The Moral Limits of the Criminal Law: Harm to Others* (OUP, 1987) vol. 1, 31-35.

<sup>164</sup> ARS Art.25, Commentary para 16.

<sup>165</sup> *Gabčíkovo-Nagymaros Project* (Hungary/Slovakia) (1997) ICJ Rep 7.

need not have materialized, the State will be required to estimate the *risk* of its occurrence. Risk is “measurable uncertainty” or quantifiable uncertainty.<sup>166</sup> With risk, it is possible to know the probability of an event occurring, and the expected harm can be predicted.<sup>167</sup> Nevertheless, no “certainty” is possible here: only probabilities can ever be established.<sup>168</sup> It is likely for this reason that in its Commentary to Article 25, the ILC preferred to speak in the opposite terms: a degree of uncertainty about the harm occurring cannot exclude the plea.<sup>169</sup> The ILC Commentary to Article 25 does not clarify this, but it seems reasonable that the defence should also be available to prevent an unfolding harm from becoming graver or more extensive: after all, the purpose of the plea is to minimize overall harm.

The source of the harm (that is, the event that will cause harm to the essential interest) can be a past event, an ongoing event, or an event in the future. And the risk can refer to the occurrence of the event itself (so the State can act to prevent its occurrence) or to the materialization of the harm as a result of the event (so the State can adopt measures to safeguard interests from the event). In the *Torrey Canyon* incident, for example, damage to the leaking ship (a past event) threatened the UK coasts with environmental harm (future harm); the UK thus took measures to prevent the harm from materializing.<sup>170</sup> In respect of the Argentine financial crisis, some tribunals held that the financial crisis, alone or in combination with the attendant political and social instability (an ongoing event), generated the threat of grave harm to, among others, the wellbeing of the State’s population and the continuity of its public services (future harm);<sup>171</sup> Argentina’s economic package was intended to address the event and, in that way, prevent the harm from materializing or worsening. In *Gabčíkovo–Nagymaros* the completion and operation of works in the Nagymaros sector (a future event) threatened to harm the people and environment of Hungary (a future harm);<sup>172</sup> Hungary’s suspension and later termination of work was intended to prevent the event which would trigger the harm.

For present purposes, the outbreak and spread of COVID-19 would appear to meet this requirement. It is an unfolding event which continues to pose an imminent threat of a grave harm to each State’s population, and to the world’s population more generally, as it can lead to death or (plausibly) long term health consequences. The threat of harm is differentiated from country to country and will depend on the degree of susceptibility of a population (as determined by reference to the prevalence of immunity in that population, resulting from both vaccination programs and prior infection). Nevertheless, the emergence of more serious variants, capable of evading immunity and/or cause more serious illness, as the virus spreads through susceptible populations remains high. The fast spread of the infection, coupled with the mortality rate, and the risk of new and more serious variants, pose a risk of grave harm to the population.

<sup>166</sup> J. Peel, *Science and risk regulation in international law* (CUP, 2010), 85.

<sup>167</sup> Expected harm refers to “the average harm that would occur were the act repeated many times”, see e.g., S. Shavell, “The optimal structure of law enforcement”, (1993) 36 *The Journal of Law and Economics* 256; O. Bar-Gill and G. Blum, “Defenses” (2019) 97 *Texas Law Review* 881 (expected harm in the law of armed conflict).

<sup>168</sup> The further the harm is into the future, the harder it will be to know the probability of its occurrence. Crucially, however, the defence of necessity does not cover situations of uncertainty: namely where the probability of the harm occurring is unknown/unknowable: Peel, *Science and risk regulation in international law*, 86; D. Färber, “Uncertainty” (2011) 99 *Geo LJ* 901.

<sup>169</sup> ARS Art.25, Commentary para 15. Note, however, that the ILC and the case law do not clarify the *degree* of probability of the harm occurring that is required to meet this condition.

<sup>170</sup> The *Torrey Canyon* incident is often used to illustrate the operation of this defence, and is included in the Commentary to Article 25: para 9. Note, though, that the UK did not invoke necessity in relation to this measure: Comments by Governments on all the Draft Articles, UN Doc A/CN.4/488 and Add.1-3, ILC Yearbook 1998, vol. II(1), 134-135.

<sup>171</sup> See e.g., *Metalpar SA and Buen Aire SA v Argentine Republic* ICSID Case ARB/03/5, Award, 6 June 2008, para 208; *Impregilo Spa v Argentine Republic*, ICSID Case No ARB/07/17, Award, 21 June 2011, paras 347-50.

<sup>172</sup> *Gabčíkovo–Nagymaros*, para 55. The plea failed because Hungary could not prove with the required degree of certainty that harm to the environment would occur, see *Gabčíkovo–Nagymaros* at para 42ff.

## **(2) Weighing essential interests**

As noted earlier, the lesser-evil logic of necessity requires weighing two conflicting interests: one of the two must be sacrificed. Either an interest is harmed by the grave and imminent peril, or the other interest is infringed by the State in its bid to protect the other interest. The plea of necessity permits the State to act to protect the interest, which is deemed superior in the circumstances, for doing so avoids a greater harm. Indeed, necessity is only available to protect an essential interest, so long as no other essential interest is harmed.

The ILC does not define, or list, interests which are essential.<sup>173</sup> It states that whether an interest is essential for the purposes of the plea “depends on all the circumstances, and cannot be prejudged”.<sup>174</sup> James Crawford has explained that the etymology of the word “essential” “suggests a connection to the ‘life’ of the State.”<sup>175</sup> And indeed, the interests that have been considered as essential by international courts and tribunals, and therefore as meeting this requirement of the plea, respond to this explanation: the existence and independence of the State,<sup>176</sup> the maintenance of public order,<sup>177</sup> the wellbeing of the State’s population, access to public services, and the functioning of public institutions,<sup>178</sup> and ecological interests.<sup>179</sup> For the most part, tribunals have not reviewed the invoking State’s qualification of its own interests as essential; but there is no suggestion in the case law or in the drafting history of Article 25 to support the self-judging, or unreviewable, character of this determination.<sup>180</sup>

For the plea to succeed the interest protected “must outweigh all other considerations ... on a reasonable assessment of the competing interests, whether these are individual or collective”.<sup>181</sup> Moreover, Article 25 requires that the act in necessity does not “seriously impair an essential interest of the State towards which the obligation is owed or of the international community of States as a whole.”<sup>182</sup> That is, the interest protected must be deemed superior to the interest impaired in the circumstances. In the context of investment disputes, tribunals have had some difficulty determining whose interests matter in this analysis. Article 25, like all of Part One of the ILC Articles on State Responsibility, is applicable to **all** international obligations, regardless of content. That is, it is applicable to obligations owed as between States, or between States and individuals. However, Article 25 indicates that the measure in necessity must not impair essential interests of “other States” or of the “international community as a whole”. It does not mention individuals. Tribunals have accepted that the defence can be invoked against investors and, for the most part,

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<sup>173</sup> The examples referred to in the Commentary are intended to illustrate the generality of the defence and not to provide a list of which interest may count as essential: ARS Article 25, Commentary para 14.

<sup>174</sup> ARS Art.25, Commentary para 16.

<sup>175</sup> Crawford, *State Responsibility: The General Part* (CUP, 2013), 307.

<sup>176</sup> E.g., *Enron Corporation and Ponderosa Assets LP v Argentine Republic*, ICSID Case ARB/01/3, Award, 22 May 2007, para 289; *von Pezold et al v Republic of Zimbabwe*, ICSID Case No ARB/10/15, Award, 28 July 2015, para 628.

<sup>177</sup> See e.g., *von Pezold*, para 620.

<sup>178</sup> E.g., *Sempra Energy International v Argentine Republic*, ICSID Case ARB/02/16, Award, 29 September 2007, para 326; *BG Group Plc v Argentina*, UNCITRAL Award, 24 December 2007, para 393; *National Grid Plc v Argentine Republic*, UNCITRAL Award, 3 November 2008, para 245.

<sup>179</sup> *Gabčíkovo-Nagymaros*, para 53. For an overview, see: M. Fitzmaurice, “Necessity in International Environmental Law” (2010) 41 NYIL 159.

<sup>180</sup> This may have been entirely contingent: many of these are investment treaty cases, where the comparative weight of the interests of the invoking State may have appeared intuitively more important than those of investors, or of their home States (namely, the home State’s interest in compliance with BIT commitments). See: Paddeu and Waibel, “Necessity 20 Years On: The Limits of Article 25 ARSIWA”, (2021) 36 *ICSID Rev*, section 2.2(iii).

<sup>181</sup> ARS Art.25, Commentary para 17.

<sup>182</sup> ARS Art.25(1)(b). It is reasonable to assume that the method for determining whether the interests impaired are “essential” is the same as for the interest safeguarded.

have either not taken into account the interests of investors in the weighing exercise or considered them not to be essential in the circumstances.<sup>183</sup>

As evidenced by the decision of the WHO Director-General to classify the outbreak as a Public Health Emergency of International Concern,<sup>184</sup> and the ample evidence from various States to date, the outbreak of COVID-19 poses a serious threat to the health and lives of individuals within a State and also to the lives and health of individuals worldwide. As has been recognized by international tribunals, both the protection of their citizens' health and lives and the protection of a State's healthcare system from being overwhelmed by COVID-19 patients are essential interests of a State. In light of the existing case law, it seems accepted that these interests are superior, in the circumstances, to the interests of, for example, IP right holders protected under an FTA with TRIPS-plus commitments, or foreign investors in respect of their IP rights in COVID-related medical technologies. Furthermore, these interests in live and health of a State's population are also likely to be held to outweigh the interests of other States in compliance with their rights under investment and free trade agreements, as well as under IP agreements.

### (3) The “only way”

Necessity justifies the conduct of a State so long as the conduct in question is the “only way” to protect the essential interest from the impending harm at the time the State adopts the relevant measures. As explained in the Commentary to Article 25, necessity is excluded if “there are other (otherwise lawful) means available, even if they may be more costly or less convenient.”<sup>185</sup> “Costly” refers to financial cost,<sup>186</sup> and “less convenient” probably refers to measures with increased administrative or organizational burdens. In other words, it is not enough to meet this requirement to say that there were alternative lawful measures, but these were too expensive or difficult to adopt. The “only way” is a strict requirement. To quote the late Judge James Crawford, the ILC Special Rapporteur on State Responsibility who oversaw the second reading of the ARS, “Here ‘only’ means ‘only’.”<sup>187</sup>

This element has caused the most problems in the investment case law and is usually the element on which the defence fails.

One of the difficulties concerns the focus of assessment. Investors often challenge a specific measure because the State has adopted only one measure and because that measure impairs investor rights under investment treaties.<sup>188</sup> Other times, however, the State may address a crisis with a package of measures, and investors might consider that only one measure or subset of all the measures impaired their entitlements under investment treaties. The Argentine financial crisis cases are illustrative. Argentina adopted a package of measures from mid-2000 to mid-2002 to address the crisis. Among others, it abandoned the 1:1 currency peg between the peso and the US dollar in 2001 and forced conversion of dollar-denominated assets and liabilities into pesos, it tightened public spending, increased

<sup>183</sup> Considering only the other State's interests: *Impregilo*, para 354. Considering both interest of the other co-contracting party and the investor: *Enron*, para 342; *Sempra*, para 392. Subsuming the investor's interests as part of the other co-contracting party's interests (i.e., the other BIT party has an interest in the protection of investments of its nationals): *CMS Gas Transmission Company v Argentine Republic*, ICSID Case ARB/01/8, Award, 12 May 2005, paras 357-358.

<sup>184</sup> WHO, Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV), 30 January 2020, available from [https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)).

<sup>185</sup> ARS Art.25, Commentary para 15.

<sup>186</sup> Crawford, *General Part*, 311.

<sup>187</sup> Crawford, *General Part*, 311.

<sup>188</sup> *von Pezold* (n 8).

taxes, limited withdrawals from deposit taking institutions, introduced capital controls, and restructured its sovereign debt.<sup>189</sup>

When faced with claims against Argentina, the approach of investment tribunals on this point varied considerably. For the most part, tribunals have focused on the discrete measure challenged.<sup>190</sup> In other instances, the tribunal took a broader outlook and considered the package of measures.<sup>191</sup> The former approach is too narrow, and the latter, at least as interpreted in *LG&E* (i.e., the State had to do something, and it did something) is too broad. The approach of the *Urbaser* Tribunal charts an appropriate middle way:

The emergency measures and the state of necessity associated with them were events of nation-wide importance. Therefore, the question whether ‘other means’ were available has to be captured in both perspectives: the wide one, taking into account the needs of Argentina and its population nation-wide, and the narrower one of the situation of investors engaged in performing contracts protected by the international obligations arising out of one of the many BITs.<sup>192</sup>

This approach underscores that the specific measure challenged must be understood in the context (and as an integral part of) the State’s response to the crisis. Each measure individually is unlikely to be the “only way” – indeed, the very fact that the State’s response is composed of a package of measures suggests that **multiple** measures are available (and perhaps necessary or reasonable). Such a narrow focus misses the point: macro crises require multipronged responses.<sup>193</sup> To assess a single measure of this package alone is artificial. Framing the question as focused on a **single measure** already presupposes the answer. As the Argentine investment tribunals have shown, when the question is posed in this way the answer, invariably, is “no, it is not the only way”.<sup>194</sup>

Another, perhaps more complex, difficulty involves a counterfactual question: did the State have any alternatives to the measure it adopted to protect the essential interest? On the whole, investment tribunals have been quick to find that alternatives were available and so dismiss that the State’s measure was the “only way”.<sup>195</sup> With the benefit of hindsight, one can always find alternatives. But this should not be enough to dismiss the plea. Indeed, as Matthew Parish has observed: a “general principle to the effect that any theoretical alternative means to the course pursued negates a defence of necessity, no matter how expensive, cannot be right. It would allow the defence to be defeated by wild, theoretical or whimsical suppositions.”<sup>196</sup>

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<sup>189</sup> For an excellent overview see Federico Sturzenegger and Jeromin Zettelmeyer, *Debt defaults and lessons from a decade of crises* (MIT Press, 2006), 165-186; Paul Blustein, *And the money kept rolling in (and out): Wall Street, the IMF, and the bankrupting of Argentina* (PublicAffairs 2005), ch. 9.

<sup>190</sup> E.g., *Suez Sociedad General de Aguas de Barcelona SA and InterAgua Servicios Integrales del Agua SA v Argentine Republic*, ICSID Case ARB/03/17, Decision on Liability (30 July 2010) para 238; *Suez Sociedad General de Aguas de Barcelona SA and Vivendi Universal SA v Argentine Republic*, ICSID Case ARB/03/19, Decision on Liability (30 July 2010) para 260.

<sup>191</sup> E.g., *LG&E* (n 60) para 257.

<sup>192</sup> *Urbaser SA and Consorcio de Aguas Bilbao Bizkaia, Bilbao Biskaia Ur Partzuergoa v The Republic of Argentina*, ICSID Case ARB/07/26, Award (8 December 2016) para 716.

<sup>193</sup> Cf. The Appellate Body has accepted that a WTO member may need to adopt a “suite” of measures to address a policy problem. Regarding the necessity criterion under the general exceptions of Art. XX GATT, see Appellate Body Report, *Brazil-Measures Affecting Imports of Retreaded Tyres* 172 (“these measures already figure as elements of a comprehensive strategy designed by Brazil to deal with waste tyres. Substituting one element of this comprehensive policy for another would weaken the policy by reducing the synergies between its components, as well as its total effect”); subsequently referred to in Panel Report, *Australia–Certain Measures Concerning Trademarks, Geographical Indications and Other Plainpackaging Requirements Applicable To Tobacco Products And Packaging* 7.1384.

<sup>194</sup> E.g., *Enron* (n 12) paras. 308-9; *Sempra* (n 12) para. 350.

<sup>195</sup> Though note that more recent awards have paid more attention to this question: *Unión Fenosa Gas SA v Arab Republic of Egypt*, ICSID Case No ARB/14/4, Award, 31 August 2018, paras 8.41-8.46; *von Pezold*, 638-46.

<sup>196</sup> M. Parish, “On Necessity” (2010) 11 *J World Investment & Trade* 169, 183.

Elaborating on this requirement, scholars have argued that in order for a measure to be an alternative capable of excluding the defence of necessity, it must meet three characteristics.<sup>197</sup> First, as clarified in the ILC Commentary, an alternative measure must be a lawful measure, in the sense that it does not infringe on any of the other obligations of the invoking State.<sup>198</sup> Second, the measure must be feasible for the State at the relevant time.<sup>199</sup> Third, the alternative measure must be effective, in the sense that it is capable of safeguarding the essential interest in question. This last characteristic involves a complex assessment, requiring a comparative analysis of the predicted effectiveness of the measures in question.<sup>200</sup>

It is undeniable that vaccinations and medical treatments are crucial to protect individuals' lives from the SARS-Cov-2 virus, and to protect healthcare systems from being overwhelmed by COVID-19 patients suffering severe symptoms. Likewise, access to vaccinations plays a significant role in reducing the risk that new variants of concern will develop.<sup>201</sup> This notwithstanding, States may face some difficulty raising a necessity defence against claims of breach relating to the TRIPS Waiver. The impugned measure in these circumstances is not the administration of vaccines or other medical treatment, but rather the domestic measure implementing the TRIPS Waiver. States will thus be required to show that the suspension of IP protections in domestic law in whatever form these take place, by application of the TRIPS Waiver, is the "only way" to protect the essential interest(s) under threat (i.e., the lives of their citizens, and the protection of their healthcare services). To this end, States will need to show that there were no other lawful alternatives to the TRIPS Waiver that were feasible at the relevant time for that State, and that were projected to be more effective at protecting the interest in question. This in turn, is likely to depend on the specific measure undertaken to implement the TRIPS Waiver (how exactly does it facilitate access to medical technologies, to what extent and when), the importance of this specific measure for protecting health and lives, and whether alternatives (such as vaccines and other health technologies provided by the IP owner or with its consent, as well as reliance on compulsory licenses – including under the existing Art.31bis TRIPS mechanism if there are insufficient domestic manufacturing facilities – or other flexibilities that do not involve a breach of the FTA or investment treaty) are available. In this context, States should consider their own domestic manufacturing and other relevant capabilities necessary for the production of the relevant medical technologies at issue, as well as whether they may be able to source them from generic competitors from abroad.

#### (4) Non-contribution

Finally, the plea may not be relied upon if the State has "contributed" to the situation of necessity. The Commentary explains that a State's contribution must be "sufficiently

<sup>197</sup> See R. Manton, *Necessity in International Law*, (unpublished PhD thesis, University of Oxford, 2016), 164-177; Paddeu and Waibel, "Necessity 20 Years On", section 2.3 (forthcoming).

<sup>198</sup> It is not enough for there to be an alternative unlawful measure available, even if this is less harmful, as suggested by the Enron Annulment Committee: *Enron Corporation and Ponderosa Assets LP v Argentine Republic*, ICSID Case ARB/01/3, Annulment, 30 July 2010, paras 347-50. While this would be desirable, it is not required by the plea. The defence of necessity permits causing the lesser harm, but it does not require causing the least harm.

<sup>199</sup> Manton, *Necessity in International Law*, 175.

<sup>200</sup> *Enron (Annulment)*, para 371. See also Paddeu and Waibel, "Necessity 20 Years On", section 2.3(iii). Cf Manton, *Necessity in International Law*, 170-171 (arguing that the analysis is too complex, and therefore should not be attempted. He proposes a threshold test: so long as another feasible and lawful measure is capable of protecting the threatened interest, that is enough to displace the plea).

<sup>201</sup> On the impact of vaccination on variant development, see: J. Gog, et al, "Vaccine escape in a heterogeneous population: Insights for SARS-CoV-2 from a simple model" (2021) 8(7) *Royal Society Open Science*, available at: <https://doi.org/10.1098/rsos.210530>. See also: Thompson, Hill & Gog, "SARS-CoV-2 incidence and vaccine escape" (2021) 21(7) *Lancet Infectious Diseases* 913-914, available from [https://doi.org/10.1016/S1473-3099\(21\)00202-4](https://doi.org/10.1016/S1473-3099(21)00202-4).

substantial and not merely incidental or peripheral” in order to exclude the plea.<sup>202</sup> The Commentary does not elaborate any further on what “substantial” means, other than to say that it is more “categorical” than the equivalent standard in the ARS provisions on *force majeure* (Articles 23) and distress (Article 24). These two defences may not be invoked if the situation of *force majeure* or distress, as the case may be, is “due” to the conduct of the State invoking it: a contribution to the situation is not enough to exclude these two defences. Moreover, explains the Commentary, both defences are available where “a State may have unwittingly contributed” to the situation “by something which, in hindsight, might have been done differently but which was done in good faith and did not itself make the event any less unforeseen”.<sup>203</sup> *A contrario*, then, in the case of necessity any substantial contribution to the situation of necessity, even if it flows from measures adopted in good faith by the State, excludes the plea.

There is, nevertheless, disagreement in the case law on the interpretation of this requirement. Some tribunals have approached the requirement as a purely causal one such that “well-intended but ill-conceived policies” that substantially contribute to the situation of necessity are sufficient to exclude reliance on the plea.<sup>204</sup> Their understanding of this requirement seems in line with the Commentary to Article 25. But such an approach is too strict: for it is likely to make the plea unarguable. As stated by the *Unión Fenosa* Tribunal: “To an extent, a situation of necessity can always be traced back, as a matter of history, to political and economic mistakes made by a State years, if not decades, earlier”.<sup>205</sup> In line with the ILC position on first reading,<sup>206</sup> instead, other tribunals have interpreted this standard more narrowly, as requiring some degree of fault.<sup>207</sup> In all cases, there is a further difficulty: at what point in time do policies and other State behaviour become too remote to be a relevant contribution to the situation?<sup>208</sup>

This requirement will be met when States can show that they did not substantially contribute to the SARS-Cov-2 pandemic, which is the peril that threatens the State’s essential interests.

<sup>202</sup> ARS Art.25, Commentary para 20.

<sup>203</sup> ARS Art.23, Commentary para 9; Art.24, Commentary para 9.

<sup>204</sup> Endorsing this understanding explicitly: *Impregilo*, para 356. For implicit support of this understanding, see: *CMS*, paras 328-329; *Enron*, paras 311-312; *Suez Sociedad General de Aguas de Barcelona SA and InterAgua Servicios Integrales del Agua SA v Argentine Republic [Suez-InterAgua]*, ICSID Case ARB/03/17, Liability, 30 July 2010, paras 241-242; *Suez Sociedad General de Aguas de Barcelona SA and Vivendi Universal SA v Argentine Republic [Suez-Vivendi]*, ICSID Case ARB/03/19, Liability, 30 July 2010, paras 263-264; *El Paso Energy International Company v Argentine Republic*, ICSID Case ARB/03/15, Award, 31 October 2011, para 618. Note, however, that tribunals rarely explain what it means for a contribution to be substantial.

<sup>205</sup> *Unión Fenosa*, para 8.60. Similarly: M Waibel, “Two Worlds”, 643; Sloane, “On the Use and Abuse of Necessity in the Law of State Responsibility” (2012) 106 *AJIL* 447, 481, 488; J Viñuales, “Defence Arguments in Investment Arbitration”, (2020) 18 *ICSID Rev* 9, 86.

<sup>206</sup> The Commentary to draft Art 33, para 41, stated that: “the Commission intended to refer to the case in which the State invoking the state of necessity has, in one way or another, intentionally or by negligence, contributed” to the situation. In support of a fault-based standard of contribution, see: Requiring intent, see e.g., R. Ago, “Eighth Report on State Responsibility – Add.5-7”, *ILC Yearbook* 1980, vol II(1), 20 (para 13); P. Pillitu, *Lo stato di necessità nel diritto internazionale* (Università di Perugia, 1981), 315; S. Cassella, *La nécessité en droit international* (Martinus Nijhoff, 2011), 168-169; requiring foresight of consequences: Manton, *Necessity in International Law*, 201. Requiring some degree of negligence: T. Gazzini, “Foreign Investment and Measures Adopted on Grounds of Necessity: Toward a Common Understanding” (2010) 7(1) *TDM*, 19-22; J. Viñuales, “Las medioambientales y el concepto de estado de necesidad” (2009) 119 *Universitas* 223, 235; A Alvarez-Jiménez, “Foreign Investment Protection and Regulatory Failures as States’ Contribution to the State of Necessity under Customary International Law - A New Approach” (2010) 27 *J Int’l Arb* 144, 159. Willem Riphagen in the ILC’s debates on the predecessor to Art 25 also seemingly took this view, see: 1614th meeting, *ILC Yearbook* 1980, vol. I, 161 (paras 6, 8).

<sup>207</sup> Requiring at least negligence: *LG&E Energy Corp, LG&E Capital Corp, LG&E International Inc v Argentine Republic*, ICSID Case ARB/02/1, Liability, 3 October 2006, para 256; *Enron*, para 311; *Sempra*, para 353. Requiring intent or recklessness: *Urbaser SA and Consorcio de Aguas Bilbao Bizkaia, Bilbao Biskaia Ur Partzuergoa v Argentina*, ICSID Case ARB/07/26, Award, 8 December 2016, para 711.

<sup>208</sup> *Unión Fenosa*, para 8.60.

In sum, the defence of necessity is strict, and is usually interpreted narrowly by tribunals. Many of its requirements are also to some degree uncertain, making it difficult for respondent States to successfully rely on it. States are most likely to have difficulty showing that a waiver of protection of IP-rights was the “only way” to protect the essential interests under threat.

## **b. Consent**

States could also rely on consent, a defence which has so far not been raised in investment treaty arbitration.<sup>209</sup> Pursuant to Article 20 of the ILC Articles on State Responsibility:

Valid consent by a State to the commission of a given act by another State precludes the wrongfulness of that act in relation to the former State to the extent that the act remains within the limits of that consent.

When implementing the TRIPS Waiver and disregarding TRIPS commitments in respect of vaccines, a WTO Member that is also a contracting party to an IP treaty with commitments that coincide and overlap with those covered by the TRIPS Waiver, could – in response to a claim by that contracting party that such overlapping commitments have been breached – invoke consent, as long as at least the complaining party is also a WTO Member. Similarly, in the context of investment treaty arbitration, a respondent State could argue that the home State of the investor claimant has consented to the non-performance of the obligations arising under international investment agreements, to the extent that these interfere with a measure implementing the TRIPS Waiver. For this reason, its failure to accord the investor the treatment to which it would be otherwise entitled under the investment agreement is not an internationally wrongful act.

In the next few sections, we explain the concept of consent as a defence, and address its requirements and conditions. We conclude our analysis by explaining that consent can be invoked against investors and other private parties holding IP rights for which protection is mandated under the types of overlapping commitments identified in section 3.

### **(1) Consent as a defence**

States can, and regularly do consent to the non-performance of obligations owed to them; or, similarly, they temporarily renounce the performance of one of their rights by another State.<sup>210</sup> For example, States consent to the overflight of foreign military aircraft: the territorial State thereby dispenses the flag State from complying with its obligation to respect

<sup>209</sup> States could also make an argument based on estoppel, see: Correa, Syam and Uribe, *Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims under Free Trade and Investment Agreements*, Research Paper 135 (Geneva, South Centre, September 2021), 7, available from <https://www.southcentre.int/research-paper-135-september-2021/>. Note that there are important differences between the two concepts. Consent, as explained in more detail in section 4.b(1), affects the legal relation existing between the two States in question: it consists in the displacement of the relevant obligation, with respect to a specific act or a class of acts, in the relations between the two States. As such, conduct that would have been prohibited for one State, is now permitted as a result of the other State's consent. Estoppel in contrast, “does not change a legal status but, rather, precludes assertion of a specific fact that would provide the basis for a certain legal claim”: A. Kulick, “About the Order of Cart and Horse, Among Other Things: Estoppel in the Jurisprudence of International Investment Arbitration Tribunals”, (2016) 27 *EJIL* 107, 109. The requirements of consent as a defence and estoppel are also different: in the case of consent, there is no need to provide evidence of detrimental reliance by a State. For the classic formulation of the law of estoppel in international law, see: D. Bowett, “Estoppel Before International Tribunals and its Relation to Acquiescence” (1957) 33 *BYIL* 176, 202.

<sup>210</sup> On the possibility of temporary renunciations, see Biscottini, *Contributo alla teoria degli atti unilaterali nel diritto internazionale* (1951), 169-170; U. Villani, “Rinuncia (diritto internazionale)” *Enciclopedia del Diritto* (Giuffrè editore, 1989) vol. XL, 953-954.

its right to territorial sovereignty. The flag State will then be **permitted** to fly over the territory of the territorial State.<sup>211</sup> This might be done by way of treaty; in which case the defence of consent will not be necessary: an overflying State will be able to rely on the treaty to ground the legality of its overflight. However, this can also be done by means of a unilateral act or in an informal way. In this last case, consent can provide a justification to a State who engages in conduct that, while incompatible with an obligation it owes to the consenting State, falls within the scope of the latter State's consent. By implication, to the extent that a State's conduct falls within the scope of the consent of another State, it will be permitted and, therefore, not wrongful. This principle is reflected in Article 20 of the ARS, and the accompanying ILC Commentary elaborates on the requirements and conditions for the invocation of this defence.

At the outset, it is important to clarify that the defence of consent does not affect the relevant substantive obligation: it does not suspend or set aside that obligation **as such**.<sup>212</sup> Rather, by way of consent, a State dispenses with the performance of an obligation owed to it either for a specific case, or for a class of cases.<sup>213</sup> In other words, the State can permit conduct to occur which, without such permission, would be unlawful in its respect. In the words of the ILC Commentary:

In such cases, the primary obligation continues to govern the relations between the two States, but it is displaced on the particular occasion or for the purposes of the particular conduct by reason of the consent given.<sup>214</sup>

In the overflight example given above, the consenting State dispenses with the performance of its right to territorial sovereignty (or with the other State's obligation to respect its territorial sovereignty) for a particular instance (overflight by a particular aircraft at a particular time) or, generally, for a category of activity (overflight by a certain class of aircraft for a period of time). That State is not, however, suspending or in any other way waiving its right to territorial sovereignty **as such** – this rule continues to govern the relations between the two States in question, but it is disapplied in respect of the specific act or the class of acts as a result of the State's consent.

## **(2) Timing and scope of consent**

Consent must be given in advance or at the time of the conduct in question.<sup>215</sup> This is an important requirement, as it distinguishes the defence of consent from a waiver of claims. In the case of consent, the consented-to conduct is not wrongful. In the case of waiver, there is a wrongful act, but the injured State waives its rights to invoke the responsibility of the wrongdoing State (and thereby, it waives its right to reparation).<sup>216</sup>

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<sup>211</sup> In Hohfeldian terms, when State A consents to the non-performance of a right it holds against State B, it places itself in a position of no-rights vis-à-vis State B. This results, for B, in a position of liberty or privilege. To illustrate, if State A has a right that State B does not fly over its territory, through consent it places itself in a position where it no longer has a right that State B does not fly over its territory (at least temporarily). Correlatively (that is, looking at the same legal relation from the point of view of State B), where B initially had a duty to A to fly over its territory, A's position of no-rights (which results from its consent) means that now B no longer has duty to fly over A's territory, and thus has a privilege or liberty of overflight in A. See Hohfeld, "Some Fundamental Legal Conceptions as Applied in Judicial Reasoning", (1913) 23 *Yale LJ* 16.

<sup>212</sup> A Ben Mansour, "Consent" in *The Law of International Responsibility*, J Crawford *et al* (eds.) (OUP, 2010), 445; Crawford, *General Part*, 283.

<sup>213</sup> Or, correlatively, with the exercise of one of its rights.

<sup>214</sup> ARS Art.20, Commentary para 2.

<sup>215</sup> Even if given "at the time", consent will probably take place before the acting State engages in the relevant conduct – if only by a second.

<sup>216</sup> While these two situations are conceptually distinct, it is not clear whether it gives rise to significant differences in practice.

In the context of the TRIPS Waiver, a respondent States facing a claim challenging its measures of implementation of the waiver will need to establish that by the time they implemented those measure (the suspension of IP protections for COVID-related medical technologies), the consent of the home State of a claimant investor, or of a claimant State, with respect to these obligations already existed. Invoking States should be warned that, depending on the source of consent, it may not be possible to establish the existence of consent with respect to all States and that not all States may have given their consent at the same time. In many cases, as we will explain below, it could be possible to infer a State's consent from the text of the TRIPS Waiver and from that State's behaviour in relation to the TRIPS Waiver: namely, from its statements in the discussions leading to the adoption of the text of the waiver; the manner in which they vote for the waiver; and the language of the waiver decision itself. If that is the case, then these States' consent will exist prior to the implementation of the TRIPS Waiver decision domestically. But this may not be true of all States: some could, for example, express their consent to non-performance of IIA/FTA obligations in relation to COVID-related IP rights subsequent to the Waiver. In these cases, the conduct of the respondent State will be justified from the moment when the consent of the home or claimant State can be established.

As to scope, consent only justifies so long as the relevant act remains "within the limits" of the State's consent. A consenting State could, for example, say that it will dispense with the performance of a right altogether for a certain period. For example, State A may dispense State B from payment of fees for the lease of land for a period of, say, 12 months. In this case, the consent overlaps with the extent of the obligation. However, a State can dispense with the performance of a right **for a specific** case only, or for a specific class of cases only. Thus, in the overflight example, consent to overflight by military aircraft does not overlap with the extent of the territorial State's right to territorial sovereignty: while State B will be permitted to fly over A's territory with military aircraft, it will still need to respect A's territorial sovereignty in every other respect. Namely, it will be prohibited from encroaching on State A's land with its armed forces, or to exercise extraterritorial jurisdiction on its territory, and so on. In short, consent need not be coextensive with the obligation that the State wishes to dispense; it can be more limited and refer only to the application of the obligation in question in respect of a particular act or class of acts.

Depending on the different basis for consent, respondent States will thus need to be careful about the extent of the consent given by the specific home or claimant State. For example, a State's consent (expressed or implied) may only refer to the non-performance of obligations in international IP and investment commitments in respect of COVID vaccines, but it may exclude other therapeutic technologies. Furthermore, a State could also limit its consent to the non-performance of some aspects of FET, such as legitimate expectations, but not others such as discrimination.

### (3) **Validity of consent**

Consent must also be **validly** given – namely, it must not be vitiated by defects and be given by a competent person.<sup>217</sup>

As to defects, the ILC Commentary to Article 20 refers to the "principles concerning the validity of consent to treaties" for guidance on these issues.<sup>218</sup> Under the Vienna Convention on the Law of Treaties, consent can be vitiated by the violation of certain provisions of internal law,<sup>219</sup> error,<sup>220</sup> fraud,<sup>221</sup> corruption,<sup>222</sup> coercion of a representative of a State,<sup>223</sup> or

<sup>217</sup> ARS Art. 20, Commentary para 4.

<sup>218</sup> ARS Article 20, Commentary para 6.

<sup>219</sup> VCLT Art.46.

<sup>220</sup> VCLT Art.48.

<sup>221</sup> VCLT Art.49.

coercion of the State by the threat or use of force.<sup>224</sup> These provisions or the parallel customary rules are not (always) applicable themselves to consent given under Article 20,<sup>225</sup> or even by analogy to situations involving consent as a defence. The ILC simply suggests that they provide “guidance” on the matter. This is certainly an obscure indication, but one that is unlikely to pose difficulties for present purposes so no more will be said on these issues.

As to the competence to give consent, the ILC Commentary notes that **who** is authorized to give consent on behalf of the State is a question addressed by rules of international law outside the framework of State responsibility. Indeed, authorization to consent on behalf of the State is a different question from that of attribution of conduct under the law of State responsibility.<sup>226</sup> That is, not every entity whose conduct is attributable to the State can consent to the non-performance of obligations owed to that State.<sup>227</sup> For example, a border official, whose conduct is attributable to the State, does not have the competence to consent to the use of force in his or her State’s territory. Who is authorized to give consent will, therefore, change depending on the substantive rule in question. This must be a person who is both authorized to speak on behalf of the State internationally, and have the competence to do so in respect of the specific rule.<sup>228</sup> For example, practice shows that it is only the highest officials, and principally, the Head of State or Head of Government who can consent to the use of force in the State’s territory.<sup>229</sup> Other times, treaties themselves indicate who is authorized to give consent: thus, only the head of a diplomatic mission can consent to the entry of officials of the receiving State into embassy premises.<sup>230</sup>

To the extent we are aware, international IP or investment treaties do not contain specific provisions as to who can consent to their non-performance.<sup>231</sup> Insofar as consent involves the non-performance of a treaty commitment, and absent specific guidance in the relevant treaty, it seems reasonable to assume that any of the offices who can bind the State as a matter of the law of treaties (the “troika” of Head of State, Head of Government and Foreign Minister)<sup>232</sup> can also consent to their non-performance. It is also possible that given the subject matter of the treaty, other Ministers are authorized to give consent,<sup>233</sup> and this can vary from State to State. Thus, for the purposes of investment law, ministers entrusted with the power to negotiate and represent the State internationally on matters regarding the law of foreign investment can also consent to the non-performance of investment treaty obligations. This could be, for example, a Minister for Trade and Development, or a Foreign Minister. The same holds true for trade and IP related obligations. Note, in this regard, that the Ministers present in the Ministerial Conference at the time of adoption of the Waiver decision may not be competent in all these fields: for example, these ministers might be competent only on matters relating to trade, but not of investment. So, in each case it will be

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<sup>222</sup> VCLT Art.50.

<sup>223</sup> VCLT Art.51.

<sup>224</sup> VCLT Art.52.

<sup>225</sup> Consent under Art.20 can be given by written agreement. In these cases, consent is subject to the provisions in the law of treaties and, more particularly, the VCLT if the relevant States are parties to the latter. It is not clear that a defence of consent under Art.20 would always be necessary in these instances: a State could rely on the relevant agreement as a *lex specialis* or as a *lex posterior* to justify the permissibility of its conduct.

<sup>226</sup> Crawford, *General Part*, 285.

<sup>227</sup> ARS Art.20, Commentary para 5.

<sup>228</sup> Ben Mansour, “Consent”, 443.

<sup>229</sup> E de Wet, *Military Assistance on Request and the Use of Force* (OUP, 2020), 154-155; for practice in support, see ch 3.

<sup>230</sup> Art.22(1), Vienna Convention on Diplomatic Relations (signed 18 April 1961, in force 24 April 1964), (1961) 500 UNTS 95.

<sup>231</sup> Where this specification exists, then those entities will be authorized to consent to non-performance.

<sup>232</sup> Art.7(2)(a), Vienna Convention on the Law of Treaties (VCLT) (adopted 23 May 1969, in force 27 January 1980), (1969) 1155 UNTS 331.

<sup>233</sup> Crawford, *General Part*, 286.

important to establish that the Minister or ministers whose statements form the source of consent are authorised and competent to do so in respect of each obligation.

#### (4) Form of consent

Consent is not subject to any requirements of form. It can thus be given orally or in writing, and no formalities are needed in either case. Furthermore, consent can be express, or it can be tacit or implied.<sup>234</sup> In all cases, it must be “clearly established”,<sup>235</sup> and it can never be presumed. The Commentary does not indicate the type of act through which a State can give consent: consent could thus be given unilaterally, and plausibly also by way of agreement.<sup>236</sup> As noted earlier, there may be questions as to the utility of the defence of consent when it is given by way of agreement, especially written agreement: in this case, there will be a question of priority of rules, rather than a question of justification of an otherwise unlawful act. But such situations should not be excluded altogether: as in *DRC v Uganda*, discussed in more detail below, it may be that the source of consent is an informal or implicit act of the consenting State and a treaty is merely the formalization, but not the source, of that consent.<sup>237</sup>

The ILC seems to take an expansive view on these matters, such that consent to non-performance can be found in, and can thus be inferred from, any manifestation of a State’s will: namely, from its words or acts, including its silences and omissions;<sup>238</sup> and from unilateral or conventional acts. Likewise, there are no limitations as to the settings in which these acts must take place, and there is no requirement of publicity. Alexandre Kiss, writing in the context of renunciation of rights, thus noted that State may renounce one of its rights through acts performed in domestic settings (for example, a speech in Parliament),<sup>239</sup> as well as international settings. Where consent is implicit or tacit, the statements or conduct from which it is inferred must be interpreted in light of the context in which they occurred.

The absence of any requirements of form is justified, insofar as States can (and do) express their consent to legal relations and acts in many different ways. The key is that a State’s intention to consent to the non-performance of one of its rights (or what is the same, the dispensation with the performance of an obligation owed to it) is clearly established, and that its consent is never presumed.<sup>240</sup> It may be worth to illustrate this point with some examples from practice, as respondent States will likely need to establish that the home or claimant State had implicitly or tacitly consented to the non-performance of IP protections for COVID-related medical technologies arising under international IP and investment commitments. That is, they will need to establish the consent of the home or claimant State by inference from its statements in the context of, and from its conduct in connection with, the negotiation and adoption of the TRIPS Waiver. The following ICJ cases are illustrative of the variety of State conducts from which their consent to a certain act can be inferred.

<sup>234</sup> Crawford, *General Part*, 284. See e.g., *Russian Indemnity Case (Russia/Turkey)* (1912) Scott Hague Court Rep 297, 322-323.

<sup>235</sup> ARS Art.20, Commentary para 6.

<sup>236</sup> See R. Kolb, *The International Law of State Responsibility: An Introduction* (Edward Elgar, 2018), 114. When consent is given by way of agreement, its legal regulation will be subject to the law of treaties and, in particular, to the VCLT if the agreement is in writing and its parties are also parties to the VCLT.

<sup>237</sup> *Armed Activities on the Territory of the Congo (DRC v Uganda)* (2005) ICJ Rep 168, para 46.

<sup>238</sup> See e.g., A Kiss, « Les actes unilatéraux dans la pratique française de droit international » (1961) *RGDIP* 317, 330.

<sup>239</sup> Kiss, “Les actes unilatéraux”, 331.

<sup>240</sup> Presumed consent, says Affef Ben Mansour, “is supposed, not established”: Ben Mansour, “Consent”, 442. Roberto Ago illustrated this situation with the following example: “A small State is suddenly attacked by a great Power, another Power, having learned of this, invades the neutral State to save it from this attack and alleges that it is acting exclusively in the urgent interest of that State, the consent of which it presumes; the circumstances do not permit it to wait until the consent is given expressly”: R. Ago, “Le délit international”, (1939) 68 *Recueil* 415, 535.

In *DRC v Uganda* the Court accepted that consent could be given informally. The case concerned the use of force by Ugandan troops in the territory of the DRC, which Uganda claimed had taken place with the consent of the DRC. In 1998, the parties had signed a Protocol which referred to the parties' desire "to put an end to the existence of rebel groups operating on either side of the common border", and in which they agreed that their respective armies would "co-operate in order to insure security and peace along the common border".<sup>241</sup> The parties disputed whether this Protocol constituted consent to the presence and operation of Uganda's troops in DRC territory.<sup>242</sup> The Court considered the text of the Protocol, as well as the conduct of the parties before and after its adoption. It concluded that consent antedated the Protocol and could be evidenced from the lack of objection to Uganda's military presence in DRC territory, from references in the DRC written pleadings to authorized Ugandan operations, and from the "practice subsequent to the signing of the Protocol".<sup>243</sup> The Protocol was, according to the Court, a formalization of that consent and not its source. The Court does not state this much, but it can be inferred from the Court's reasoning that DRC expression of consent to the presence of Uganda's troops had been given informally and through conduct.

In *Certain Phosphate Lands in Nauru*, the Court accepted in principle (if not in fact) that a waiver (namely, consent to renunciation of a claim) could be inferred from a treaty and from statements made in the UNGA.<sup>244</sup> The case concerned a claim by Nauru that Australia was responsible for the rehabilitation of phosphate lands that had been exploited by the Administering Authority, of which Australia was a member. Australia sought to have the case dismissed on the basis that Nauru had waived its claim against the Administering Authority. First, Australia argued that Nauru's waiver could be inferred from the silence of the Agreement of 14 November 1967 in respect to the rehabilitation of phosphate lands. The Agreement, in its view, was intended as a comprehensive settlement of all claims by Nauru in relation to the phosphate industry, and consequently the silence on the matter of rehabilitation must be understood as a waiver of that claim. The Court considered the context of, and the discussions leading to, the conclusion of the Agreement, as well as the treaty text as a whole. It noted that the record showed that the Nauruans wished to maintain their claim, and that the treaty text contained no express waiver provision. On the basis of this evidence, it rejected Australia's claim.<sup>245</sup> Second, Australia relied on a statement made by Nauru in 1967 at the UNGA which, in its view, amounted to undertakings by Nauru to finance themselves the rehabilitation of the lands. For Australia, this constituted a waiver of the claim against the Administering Authority.<sup>246</sup> The Court explicitly held that "to ascertain the significance of this statement, it needs to be placed in context".<sup>247</sup> The Court considered a number of statements by Nauruan representatives before UN organs, both predating and post-dating the 1967 statement, and found that Nauru had consistently maintained its claim that the responsibility to rehabilitate the island fell to the Administering Authority. For the Court, the statement relied upon by Australia, while somewhat ambiguous in its wording, did not depart from the clear and repeated position stated by Nauru. Australia's second argument was thus found to be also without merit.

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<sup>241</sup> *DRC v Uganda*, para 46.

<sup>242</sup> *Ibid.*, para 46.

<sup>243</sup> *Ibid.*, para 46.

<sup>244</sup> This case concerned the waiver or renunciation of a claim. Both a waiver of claims and consent as a defence involve the renunciation of a right (permanently in the former case, temporarily in the latter), and both require an expression of will of the State, which can be given implicitly or tacitly. As such, the Court's reasoning and, in particular, the evidence it relied upon to determine the existence (or non-existence) of Nauru's waiver are a good example of the types of State conducts that can be relied upon to infer consent, and how to assess them.

<sup>245</sup> *Certain Phosphate Lands in Nauru (Nauru v Australia)*, Preliminary Objections, Judgment (1992) ICJ Rep 240, para 16.

<sup>246</sup> *Ibid.*, para 17.

<sup>247</sup> *Ibid.*, para 18.

To argue that the home State of a private investor claimant, or a claimant State, had consented to the non-performance of obligations under international IP and investment treaties to protect COVID-related IP, a respondent State could, first of all, rely on an express statement by the home or claimant State to this effect. These statements could be made in press conferences or other media appearances,<sup>248</sup> in the discussions leading to the adoption of the TRIPS Waiver in the Ministerial Conference,<sup>249</sup> or in the context of introducing legislation or other administrative processes for the domestic implementation of the Waiver in the claimant State or the home State of the investor claimant. The language of these statements should be as clear as possible; indeed, the more specific the reference to the obligations that the State wishes to dispense with, the better. Such clear expressions of consent, while ideal as they would leave no doubt, are unlikely to occur, or at the very least unlikely to be widespread among States.

Absent an express statement, respondent States could rely on the implicit consent of the home or claimant State. In all cases, it will be crucial to understand the intention of the State in question. Evidence of the State's consent can be found in its statements during the negotiations of, or in connection with, the TRIPS Waiver, interpreted by reference to the relevant context. On the one hand, one might argue that a statement that a State wishes to remove "all legal obstacles" may appear to be too vague to clearly establish that State's consent. However, one must bear in mind that such a statement is made against the backdrop of the pandemic, and in the context of discussions of a waiver of IP protections in which the goal is to ensure "unimpeded, timely and secure access to quality, safe, efficacious and affordable health products and technologies for all"<sup>250</sup> across the globe, and that States wish to do so without having to compensate patent-holders (as would be required in case States rely on compulsory licensing – see Art.31 h) TRIPS). Against this background, it seems plausible to infer that the reference to "all legal obstacles" includes all potential legal provisions that may hinder the stated goal. Indeed, this goal could not be achieved insofar as other international IP and investment commitments remain applicable, as these would constitute significant legal obstacles to any implementation of the TRIPS Waiver, as explained in section 3 above. For example, States may be deterred from domestic implementation of the TRIPS Waiver due to fears of claims, for considerable sums, from foreign investors claiming that the domestic implementation of the Waiver was a violation of their BIT protections.

It is also possible to infer consent from the text of the TRIPS Waiver itself, and from States' support for this text.<sup>251</sup> Indeed, as noted by the ILC in its work on identification of customary law, the resolutions of international organizations can reflect "the collective expression of the views" of States:

Although resolutions of organs of international organizations (unlike resolutions of intergovernmental conferences) emanate, strictly speaking, not from the States members but from the organization, ... they may reflect the collective expression of the views of such States: when they purport (explicitly or implicitly) to touch upon legal matters, the resolutions may afford an insight into the attitudes of the member States towards such matters.<sup>252</sup>

<sup>248</sup> See, e.g., *Nuclear Tests (Australia v France)*, Judgment (1974) ICJ Rep 253, paras 37-41, 49.

<sup>249</sup> Certain Phosphate Lands in Nauru, para 15.

<sup>250</sup> See the Waiver proposal quoted at length in Section 1 above.

<sup>251</sup> The ILC work on Identification of Customary Law indicates that States' *opinio juris*, defined as their acceptance that a rule is part of customary law (Conclusion 9), can be evidenced in the resolutions of international organizations.

<sup>252</sup> Conclusion 12, Commentary para 3.

While the TRIPS Waiver decision may be perceived as an act of the WTO (and not an intergovernmental agreement),<sup>253</sup> it may nevertheless reflect the view of WTO Member States. A key consideration in this context will be the language of the Waiver decision, as well as the manner of its adoption.

The operative part of the TRIPS Waiver is likely to focus on TRIPS obligations: after all, the waiver is a mechanism provided for in the TRIPS Agreement with respect to TRIPS obligations. However, the Preamble of the Waiver could express the States' intention to remove all barriers preventing accessibility to COVID vaccines, in particular that they intended to do so by dispensing with the performance of all IP protections (or, more generally, all IP-based barriers) hindering the production and distribution of COVID medical technologies. In its present wording, the proposed Waiver thus states in its preamble that it seeks to ensure "unimpeded, timely and secure access to quality, safe, efficacious and affordable health products and technologies for all". As noted earlier, in light of this stated goal, it would be contradictory for WTO Members to, at one and the same time, remove one specific set of legal impediments (IP protection) under the TRIPS Agreement, in an effort to speed and ensure the cheap and wide production and distribution of vaccines, while maintaining other legal impediments in place (say, FET protection under IIAs, or TRIPS-plus commitments under FTAs).

The manner of adopting the TRIPS Waiver may also be relevant. The inference as to States' consent will be stronger for those States voting in favour of the Waiver decision, or if the Waiver is adopted by unanimity. But this does not exclude that such inferences may be made in relation to decisions adopted by consensus (that is, in the absence of dissent – even if a specific WTO Member had not explicitly voted in favour). Indeed, in the *Nicaragua* case the ICJ drew significant inferences as to States' consent from their attitude to the text of Resolution 2625 of the UN General Assembly (the "Friendly Relations Declaration"),<sup>254</sup> despite it having been adopted without a vote.<sup>255</sup>

The consent of the home State of private claimants, or of the claimant State, to the non-performance of obligations under international IP and investment treaties, to the extent that their commitments interfere with the goals of the TRIPS Waiver, can therefore be express. But it can also be implicit. In this case, it will need to be clearly established from the statements of the relevant State made in the context of, or in connection with, the Waiver decision, or from the text of the Waiver itself and the State's attitude towards it.

## **(5) Invoking home State consent against investors**

Consent, as explained in the Commentary to Article 20, is an inter-State defence: it "is concerned with the relations between the two States in question".<sup>256</sup> The Commentary adds that Article 20 "states a general principle so far as enjoyment of the rights and performance of the obligations of States are concerned."<sup>257</sup> So can the consent of the home State to the non-performance of obligations owed to it under investment treaties be invoked against its investors? The matter has not arisen in the case law, and has rarely been addressed in the literature.<sup>258</sup>

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<sup>253</sup> Though see that this is not always clear-cut: I Feichtner, *The Law and Politics of WTO Waivers: Stability and Flexibility in Public International Law* (CUP, 2011), 163-169.

<sup>254</sup> UNGA A/RES/2625 (XXV), Declaration on Principles of International Law concerning Friendly Relations and Co-operation among States in accordance with the Charter of the United Nations, 24 October 1970.

<sup>255</sup> *Military and Paramilitary Activities in and Against Nicaragua (Nicaragua v United States of America)* (1986) ICJ Rep 14, para 188.

<sup>256</sup> ARS Art.20, Commentary para 9.

<sup>257</sup> ARS Art.20, Commentary para 10.

<sup>258</sup> For an exception, see M Paparinskis, "Circumstances Precluding Wrongfulness in International Investment Law" (2016) 31 *ICSID Review* 484, 488-491. Paparinskis analyzes this situation as a suspension of treaty provisions, and therefore under the law of treaties rather than under the law of responsibility. While this can of

A similar question has arisen in respect of the invocation of countermeasures as a defence to investor claims. After all, in these cases, a countermeasure is adopted by the host State against the home State, in response to a violation of the host State's rights by the home State. If the countermeasure concerns investment protection obligations, can the host State rely on this countermeasure to deflect claims made by investors under that same obligation? In three cases under NAFTA, Mexico invoked countermeasures it had taken against the US, and in response to an alleged breach of NAFTA by the US, to justify the imposition of a tax on sweetened-drinks which affected US importers of high-fructose corn syrup (HFCS). The measure was in contravention with provisions of NAFTA. The three tribunals hearing the claims all dismissed Mexico's defensive argument, although on different grounds. In *CPI* the Tribunal held that Mexico owed substantive obligations under NAFTA directly to investors, which were autonomous and distinct from those of their home State.<sup>259</sup> Therefore, their rights could not be affected by a countermeasure directed against the home State.<sup>260</sup> Likewise, the Tribunal in *Cargill* asserted that countermeasures could not justify the infringement of obligations owed to third parties, including "specific obligations owed to nationals of the offending State".<sup>261</sup> In contrast to the Tribunal in *CPI*, however, the *Cargill* Tribunal maintained that the substantive or procedural character of investor rights was irrelevant. So long as investors possessed direct rights against the host State which were affected by the countermeasures, then the latter would be impermissible.<sup>262</sup> The third tribunal, in the *ADM* case, reached the opposite conclusion: countermeasures affecting investors were permissible, since investor rights under NAFTA were procedural in character.<sup>263</sup> The tribunal nevertheless dismissed the defence because the Mexican measure did not meet the conditions and requirements of countermeasures.<sup>264</sup>

Despite the different reasoning, the three tribunals have one thing in common: they treated investors as "third parties" in the relation between the US and Mexico, and queried whether the rights of those third parties could be affected by a countermeasure taken in the inter-State relation. Such an approach has received mixed reviews in the literature. It has been championed by some, like Martins Paparinskis, who considers that all private parties who derive rights from treaty regimes should be treated as third parties for the purposes of the law of State responsibility.<sup>265</sup> On his view, then, countermeasures adopted against the home State cannot validly be invoked against investors: these are third parties, whose rights cannot be affected by the countermeasure. Paparinskis then extends the same reasoning to consent – insofar as consent cannot affect the rights of third parties, consent as between the contracting parties to an investment agreement cannot validly be invoked against an investor.<sup>266</sup> Even for countermeasures, others have questioned this approach. Junianto James Losari and Michael Ewing-Chow have challenged the idea that investor rights are

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course occur as between treaty-parties, it is an unduly narrow understanding of the operation of consent as a defence to responsibility in respect of treaty obligations. Paparinskis's approach would subject the consent to non-performance of a treaty obligation to the formal and strict requirements, both substantive and procedural, for the suspension of treaty provisions which is established in the VCLT (and potentially, under the customary law of treaties). Furthermore, the law-of-treaties approach would require consideration of whether the specific treaty provision in question was separable for the purposes of suspension, in accordance with Article 43 of the VCLT. Otherwise, suspension is only possible with respect to the treaty as a whole. As discussed in the text of the report, consent under ILC Article 20 is a much more flexible circumstance, which need not meet any particular formalities.

<sup>259</sup> *Corn Products International, Inc v Mexico*, ICSID AF Case No ARB/(AF)/04/1, Decision on Responsibility, 15 January 2008, paras 168-169.

<sup>260</sup> *Ibid.*, para 176.

<sup>261</sup> *Cargill, Inc v Mexico*, ICSID Case No ARB/(AF)/05/2, Award, 18 September 2009, para 422.

<sup>262</sup> *Ibid.*, para 426.

<sup>263</sup> *Archer Daniels Midland Company and Tate & Lyle Ingredients Americas, Inc v Mexico*, ICSID Case No ARB/(AF)/04/5, Award, 21 November 2007, para 180.

<sup>264</sup> *Ibid.*, para 180.

<sup>265</sup> See, generally, M. Paparinskis, "Investment Arbitration and the Law of Countermeasures" (2008) 79 *BYIL* 264.

<sup>266</sup> Paparinskis, "Circumstances Precluding Wrongfulness", 488-491.

**independent** from those of their home State.<sup>267</sup> They note that even if investors possess rights under investment treaties, and regardless of their substantive or procedural character, these rights are to some extent dependent on the rights of their home States, as evidenced by the fact that they are subject to modification, suspension or termination by their home State, as well as subject to the interpretations agreed upon by the States parties. On this basis, then, they would allow the invocation of countermeasures between the host State and the home State as against investors.

At any rate, there is a crucial difference between countermeasures and consent, which can justify a (potentially) different answer to the question of the effect of these two defences on investors. The taking of countermeasures is an act of the host State; whereas the giving of consent is an act of an investor's **own** home State. Investment treaties are usually adopted for the purpose of protecting investors from the actions of host States. However, one chooses to classify the entitlements bestowed upon investors in investment treaties (whether they are direct or indirect rights; whether they are substantive or procedural), these entitlements are in some respects dependent on their home State. Perhaps most importantly, their initial coming into being and hence the very **existence** of investor "rights" is dependent on the home State: it is the home State that enters into investment agreements establishing protections for investors. The home State, as a party to the investment agreement, also retains the power to modify, suspend or terminate such treaty commitments.<sup>268</sup> If the home State can modify, suspend and even terminate the investment treaty, with the consequent modification, suspension or termination of the protections afforded to investors, *a fortiori* the home State can agree to the temporary non-performance of one of the obligations in that same treaty.<sup>269</sup>

Therefore, when the home State consents to the non-performance of an obligation owed to it under a treaty, the relevant obligation is, in the ILC terms,<sup>270</sup> temporarily displaced (in full or in part, depending on the scope of the consent) and the State bound by it is under no obligation to perform it while the consent lasts. The implication, for the investor, is that whatever entitlements it might derive from the obligation in question will **also** be temporarily displaced. Simply put, as long as the consent of the home State lasts and as far as it reaches, the investor will have no entitlements derived from the obligations in question for the simple reason that those obligations have been "displaced". Indeed, it would be difficult to maintain that the host State did not owe, say, an obligation to treat investors fair and equitably towards the home State but at the same time **did** owe that obligation towards the home State's investors. Any action of the host State which falls within the scope of the consent of the home State will be permissible and will not amount to a violation of the investor's entitlements.

The host State can, therefore, rely on the consent of the home State to justify the non-performance of protections under investment treaties against investors of that State, as long as the State parties in question have agreed to the WTO TRIPS Waiver. Under the same condition can a contracting State party to a multilateral agreement on IP protection and/or to an FTA with TRIPS-plus protection rely on consent of other contracting States for the non-performance of overlapping protections in IP treaties.

<sup>267</sup> J.J. Losari and M. Ewing-Chow, "A Clash of Treaties: The Lawfulness of Countermeasures in International Trade Law and International Investment Law", (2015) 16 JWIT 274, 299-300. See also: F González de Cossío, "Investment Protection Rights: Substantive or Procedural?" (2011) 26 *ICSID Rev* 107, 114.

<sup>268</sup> We are not aware of any investment treaty that excludes the State parties' power to modify, suspend, or terminate the agreement.

<sup>269</sup> On the termination of investment treaties, and refuting arguments that investor consent is necessary, see: F. Bordin, "Reasserting Control through Withdrawal from Investment Agreements: What Role for the Law of Treaties?" in A. Kulick (ed.), *Reassertion of Control over the Investment Treaty Regime* (CUP, 2015), 214-217. See further: T. Voon *et al*, "Parting Ways: The Impact of Mutual Termination of Investment Treaties on Investor Rights", (2014) 29 *ICSID Rev* 451.

<sup>270</sup> ARS Ar.20, Commentary para 2.

## 5. CONCLUSIONS

This paper considered legal implications that are likely to emerge from the implementation of a TRIPS Waiver decision. Assuming that a Waiver is adopted in the form presented in the May 2021 proposal by South Africa and India et al, we have considered the interaction between the Waiver and other commitments to protect IP rights under international IP and investment treaties. Our principal research question has been to consider when a State adopts measures in its domestic law to implement the Waiver, whether this implementation is compatible with that State's other obligations to protect IP rights established under multilateral IP treaties, IP and Investment Chapters of FTAs as well as BITs?

We have approached this question in two steps. First, we reviewed potential incompatibilities with overlapping commitments that could arise from different measures implementing the TRIPS Waiver – such as temporarily suspending all protection for the medical technologies covered or various forms of reducing protection, including issuing compulsory licenses without any compensation and/or other restrictions set out under TRIPS. With a focus on TRIPS-plus commitments in FTAs and international investment protection for IP rights, we discussed relevant standards of protection and enforcement of IP rights potentially affected by such measures. However, the focus of our analysis in this first part has been on clauses preserving flexibilities under TRIPS, the right to regulate, and general international law techniques in favour of aligning TRIPS with other international IP and investment treaties. While these questions are highly dependent on the individual measure adopted and the specific and general international law rules applicable, we conclude that often, no overlapping treaty commitment will have been breached.

Two arguments are of general importance for this conclusion: For once, the TRIPS Waiver, understood in light of the common intention of WTO Members expressed in its preamble, aims to ensure “unimpeded, timely and secure access” for all to medical technologies “for the prevention, treatment or containment of COVID-19”. As we argue in section 2, the TRIPS Waiver thus reflects the common intention of WTO Members to authorize measures which can achieve these goals – within the parameters of the medical technologies and types of IP rights covered by the Waiver. Within these parameters, the preambular language of the waiver hence suggests a common intention WTO Members to facilitate certain outcomes. As a means to this end of facilitating access for medical technologies, the Waiver needs to be construed and implemented in a purpose and goal-oriented way – within the specific parameters set out in the Waiver text. Second, many of the FTAs and IIAs with overlapping commitments include various forms of clauses that generally refer to TRIPS or specifically to its public health related flexibilities. Such clauses offer ample evidence that FTA and IIA contracting parties generally do not wish to undermine policy space available under TRIPS to protect public health. This finding based on the review of a broad range of specific clauses is further supported by the customary right to regulate – including a “right to protect public health” that WTO Members expressively referred to in the Doha Declaration. There is no reason to suggest that the public health-related TRIPS policy space WTO Member intend to preserve vis-à-vis additional IP protections under FTAs and IIAs does not also include a TRIPS Waiver.

Second, in the event that means of interpretation or internal defences cannot avoid the incompatibility between domestic measures of implementation and other international IP and investment commitments, we considered the possible application of general defences in the customary law of State responsibility: these defences could be relied upon by States to justify, or in other words to preclude the wrongfulness of, their domestic measures of implementation of the Waiver vis-à-vis their international IP and investment commitments. In

particular, we considered how the defences of state of necessity and consent could apply in these circumstances. For the defence of necessity, the crucial consideration will be demonstrating that the specific measure adopted by a State in the domestic implementation of the Waiver was the “only way” to preserve an essential interest of that State – that is, to preserve the life and health of its inhabitants, and the continued functioning of healthcare services (both interests that have been accepted in the case law as constituting “essential” interests for the purposes of this defence). For the defence of consent, States will need to show that through clear individual statements, or through the Waiver, including the circumstances of its adoption, the claimant State or the home State of the claimant investor had expressly or implicitly consented to the non-performance of its rights under international IP and investment commitments. In other words, that they had consented to dispense the invoking State from performing its obligations under such commitments.

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