

THE LEGALITY OF A TRIPS WAIVER FOR COVID-19 VACCINES UNDER INTERNATIONAL INVESTMENT LAW

BRYAN MERCURIO*  AND PRATYUSH NATH UPRETI†

Abstract This article assesses the arguments and challenges that are likely to arise should investors file an investor–State dispute settlement (ISDS) claim over measures taken in response to a waiver of obligations relating to intellectual property rights (IPRs) under the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). After providing an overview of the proposed waiver of IPRs for COVID-19 vaccinations and treatments, it examines the jurisprudence relating to IP and investor–State arbitration and the grounds upon which investors would rely to make a case in ISDS and possible State defences. The analysis, which focuses on fair and equitable treatment and expropriation, concludes that it will be difficult for investors to succeed in claiming that measures taken in response to a TRIPS waiver of IPRs breach any substantive protection provision contained in an international investment agreement. States should, however, seek additional security by revisiting existing treaties and adding additional layers of safeguards to ensure legitimate and non-discriminatory measures taken in response to a TRIPS waiver do not lead to investor claims.

Keywords: international investment law, TRIPS Agreement, COVID-19, investor–State dispute settlement.

I. INTRODUCTION

The outbreak and ongoing nature of the COVID-19 pandemic has severely impacted global investment flows, with 2020 seeing a 35 per cent decline in foreign direct investment (FDI).¹ In response to the pandemic, several

* Simon FS Li Professor of Law, Chinese University of Hong Kong, b.mercurio@cuhk.edu.hk.

† Lecturer in Intellectual Property Law, Queen’s University Belfast, p.upreti@qub.ac.uk.

¹ See Organisation for Economic Co-operation and Development (OECD), ‘Foreign Direct Investment Flows in the Time of COVID-19’ (4 May 2020) <<https://www.oecd.org/coronavirus/policy-responses/foreign-direct-investment-flows-in-the-time-of-covid-19-a2fa20c4/>>; United Nations Conference on Trade and Development (UNCTAD), ‘Global Foreign Direct Investment Set to Partially Recover in 2021 but Uncertainty Remains’ (21 June 2021) <<https://unctad.org/news/global-foreign-direct-investment-set-partially-recover-2021-uncertainty-remains>>. See also World Bank, ‘Supporting Business and Investors: A Phased Approach of Investment Climate Policy Responses to COVID-19’ (2020) <<https://thedocs.worldbank.org/en/doc/>

countries have made legislative and policy changes that negatively affected investors. This raises the possibility of investors seeking redress for losses suffered through the investor–State dispute settlement (ISDS) mechanism included in many international investment agreements (IIAs).² Scholars have already begun examining potential claims and debating the likelihood of success,³ as well as the broader impact COVID-19 will have on transnational business and international investment law.⁴ The possibility of an ISDS case being filed in response to State measures taken to address the COVID-19 crisis is not mere academic curiosity as there are reports of investors threatening such action.⁵ This article avoids discussion of general COVID-19 implications and disputes, instead focusing more narrowly on the potential ISDS claims which could emanate from a waiver of intellectual property rights (IPRs) under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).⁶

Amid concerns over access to COVID-19 vaccines and treatments, India and South Africa proposed a waiver of certain provisions of the TRIPS Agreement to allow for increased manufacture and distribution.⁷ Following initial opposition from leading developed countries and ambivalence from key developing countries, the proposal gained momentum when the United States

[683441596248620234-0130022020/original/COVID19InvestmentClimatePolicyMeasuresPhasedApproach071520.pdf](https://doi.org/10.1017/S0020589322000082)>.

² For the purposes of this article an 'international investment agreement' refers to an agreement between two or more States and includes bilateral investment treaties (BITs) and free trade agreements (FTAs) that contain an investment chapter.

³ See eg J Haynes and AR Hippolyte, 'The Covid-19 Pandemic and the Potential for Investor-State Claims: A Caribbean Perspective' (2021) 21(2) *OUCLJ* 212; V Vadi, 'Crisis, Continuity, and Change in International Law and Arbitration' (2021) 42(2) *MichJIntL* 321.

⁴ See the special issues on 'COVID-19 and International Dispute Settlement' (2020) 13(1) *Contemporary Asia Arbitration Journal*; 'The Impact of the COVID-19 Crisis on Challenges in Int'l Transactions and Int'l Dispute Resolution' (2021) 2 *Transnational Dispute Management*.

⁵ See eg C Sanderson, 'Peru Warned of Potential ICSID Claims over Covid-19 Measures' (*Global Arbitration Review*, 9 April 2020) (Peru suspended the collection of toll fees on some highways to mitigate the economic impact of COVID-19) <<https://globalarbitrationreview.com/coronavirus/peru-warned-of-potential-icsid-claims-over-covid-19-measures>>. More than 600 national and international organisations have written an open letter to governments on potential ISDS claims involving States' measures to tackle the pandemic. See 'Open letter to governments on ISDS and COVID-19' (June 2020) <<http://s2bnetwork.org/sign-the-pen-letter-to-governments-on-ids-and-covid-19/>>.

⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299 (TRIPS Agreement).

⁷ WTO, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa' (2 October 2020) WTO Doc IP/C/W/669. See also the revised version of the proposal dated 25 May 2021: WTO, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: 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' (21 May 2021) WTO Doc IP/C/W/669/Rev.1.

(US) announced it supported waiver negotiations,⁸ a move which China quickly followed.⁹ Several WTO Members remain opposed to a waiver, most notably the European Union (EU), and it remains uncertain whether negotiations will conclude and a waiver will come into effect.

A key issue for the purposes of this article is how the waiver would affect investments by the pharmaceutical industry, whose business model relies heavily on IPRs. The proposal appears based on an assumption that IPRs are an obstacle preventing access to COVID-19 vaccinations and treatment. The assumption is debatable, but more worrying is that the waiver proposal has been advanced without any consideration of the implication on innovation or whether a waiver will disincentivise investment in research and development (R&D) that will be essential in fighting COVID-19 as mutations and emerging variants proliferate and the pandemic becomes endemic.¹⁰ The proposal calls for a waiver for ‘at least three years’ but is drafted in such a way that it is more likely to remain in force for an unforeseeable and perhaps indefinite period of time.¹¹ A waiver for an indeterminate period of time could potentially affect investments made by the pharmaceutical industry. In short, a waiver could hinder the creation of new IPRs and curb revenue streams from IP portfolios.

Assuming that a waiver is agreed and put into effect at the WTO, countries desiring to implement the waiver would have to make it effective at the domestic level either through new laws or amendments to their regulatory control structure and pharmaceutical marketing approval process and by temporarily revoking or creating limitations to affected IPRs. These outcomes will further frustrate investors who may see these changes as a breach of State obligations under IIAs and customary international law practices on foreign investment protection. While the intersection between IPRs and IIAs has been discussed in the literature,¹² the relationship remains unsettled due to

⁸ ‘Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver’ (Office of the United States Trade Representative, Press Release, 5 May 2021) <<https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>>.

⁹ ‘China Supports TRIPS Waiver on COVID-19 Vaccines Proposed by India, South Africa’ (Business & Human Rights Resource Centre, 18 May 2021) <<https://www.business-humanrights.org/en/latest-news/china-supports-trips-waiver-on-covid-19-vaccines-proposed-by-india-south-africa/>>.

¹⁰ See SA Kemp *et al.*, ‘SARS-CoV-2 Evolution during Treatment of Chronic Infection’ (2021) 592 *Nature* 277.

¹¹ WTO, ‘Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text’ (n 7) para 2 (‘waiver shall be in for at least 3 years ... The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver.’).

¹² For background of various positions and arguments on IP and ISDS interactions, see S Klopschinski, C Gibson and H Grosse Ruse-Khan, *The Protection of Intellectual Property Rights Under International Investment Law* (Oxford University Press 2020); C Geiger (ed), *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar 2020); EK Oke,

relatively few relevant ISDS cases.¹³ Scholars have expressed concern over the use of ISDS to expand IP protection¹⁴ but, to date, a wholesale ‘regime shift’ in IP law-making has failed to materialise.¹⁵

While the possibility of an ISDS case being filed in response to State measures taken to address the COVID-19 crisis remains speculative it is nevertheless ripe for discussion, most notably to contribute to the current debate and better prepare for the next pandemic. With this background in mind, the article proceeds as follows: after briefly examining the TRIPS waiver proposal in Part II, Part III provides a general landscape of IP disputes in ISDS, followed by arguments investors are likely to make against the waiver proposal. Part IV then analyses arguments that States could use to defend against investors’ claims, based on investment principles, treaty language and practices. Part V concludes that it will be difficult for investors to succeed in claiming that measures taken in response to a TRIPS waiver of IPRs breach any substantive IIA protection provision, but that States should seek additional security by revisiting existing treaties and adding additional layers of safeguards to ensure legitimate and non-discriminatory measures taken in response to a TRIPS waiver do not lead to investor claims.

II. THE TRIPS AGREEMENT AND A COVID-19 WAIVER

The origins of international IPRs lie in the negotiation and adoption of two important treaties—the Paris Convention for the Protection of Industrial Property (first adopted in 1883) and the Berne Convention for the Protection

The Interface between Intellectual Property and Investment Law: An Intertextual Analysis (Edward Elgar 2021).

¹³ There are three high-profile IP related disputes: *Brands Sarl, Philip Morris Products SA & Abal Hermanos SA v Oriental Republic of Uruguay*, ICSID Case No ARB/10/7, Award (8 July 2016); *Eli Lilly and Company v The Government of Canada*, UNCITRAL ICSID Case No UNCT/14/2, Award (16 March 2017); *Bridgestone Licensing Services, Inc & Bridgestone Americas, Inc v Republic of Panama*, ICSID Case No ARB/16/34, Award (14 August 2020). For detailed discussion, see PN Upreti, ‘Intellectual Property Rights in Investor-State Dispute Settlement: Connecting the Dots through the Philip Morris, Eli Lilly, and Bridgestone Awards’ (2021) 31(4) *American Review of International Arbitration* 337.

¹⁴ See eg B Mercurio, ‘Awakening the Sleeping Giant: Intellectual Property Rights in International Investment Agreements’ (2012) 15(3) *JIEL* 871; R Dreyfuss and S Frankel, ‘From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property’ (2015) 36(4) *MichJIntlL* 557; CM Ho, ‘Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions’ (2015) 30(1) *BerkeleyTechLJ* 213; PN Upreti, ‘Enforcing IPRs Through Investor-State Dispute Settlement: A Paradigm Shift in Global IP Practice’ (2016) 19(1/2) *Journal of World Intellectual Property* 53; PK Yu, ‘The Investment-Related Aspects of Intellectual Property Rights’ (2017) 66(3) *AmULRev* 829; RC Dreyfuss, ‘ISDS and Intellectual Property in 2019: The Case of the Dog that Didn’t Bark’ in LE Sachs *et al.* (eds), *Yearbook on International Investment Law & Policy 2019* (Oxford University Press 2021).

¹⁵ See J Gathii and C Ho, ‘Regime Shift of IP Lawmaking and Enforcement from WTO to the International Investment Regime’ (2017) 18(2) *Minnesota Journal of Law, Science & Technology* 427, 434 (claiming ISDS could result in a regime shift that tilts the balance towards stronger IP protection).

of Literary and Artistic Works (first adopted in 1886).¹⁶ It is the TRIPS Agreement, however, that provides the most meaningful basis for global IP protection through the establishment of minimum substantive and procedural standards. The TRIPS Agreement, however, does not completely harmonise IP standards or prescribe the manner in which Members are to implement the standards.¹⁷ The TRIPS Agreement also incorporates several flexibilities to balance both private and public interests concerning IP protection and promotion.¹⁸ While the TRIPS Agreement is far from perfect it does provide a framework for creative implementation within a Member's legal system.

The importance of IPRs in encouraging innovation is well-known, but some hold the view that IPRs are an obstacle to the availability of COVID-19 vaccinations and treatments.¹⁹ Such commentators further argue that the current IP system is not designed to address a health crisis of this magnitude and the 'incentive-reward' justification of patent protection cannot be applied in times of crisis.²⁰ To this end, India and South Africa proposed a waiver from the implementation, application, and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement—covering copyright, industrial designs, patents, and trade secrets—relating 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'.²¹ The proposal also ensures that any action taken in accordance with the waiver is nonjusticiable at the WTO by providing that Members 'shall not challenge any measures taken in conformity with the provisions of the waivers ... through the WTO's Dispute Settlement Mechanism'.²²

The proposal attracted sponsorship and/or support from most developing countries and least-developed countries (LDCs),²³ but faced opposition from developed countries. Though the US now supports the negotiation of a waiver,²⁴ the announcement of support from the United States Trade Representative was clear that the US does not support the proposal on offer

¹⁶ For a historical background, see G Dutfield and U Suthersanen, *Dutfield and Suthersanen on Global Intellectual Property Law* (2nd edn, Edward Elgar 2020).

¹⁷ See generally B Mercurio, 'Reconceptualising the Debate on Intellectual Property Rights and Economic Development' (2010) 3(1) *The Law and Development Review* 65.

¹⁸ 'Public Policy-related Assistance - Flexibilities' (WIPO) <<https://www.wipo.int/ip-development/en/policy/flexibilities.html>>.

¹⁹ See generally, S Thambisetty *et al.*, 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic' (2021) LSE Legal Studies Working Paper 06/2021 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737&download=yes>.

²⁰ *ibid.*

²¹ See WTO, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text' (n 7).

²² *ibid.*

²³ See, 'TRIPS Council to Continue to Discuss Temporary IP Waiver, Revised Proposal Expected in May' (*WTO News*, 30 April 2021) <https://www.wto.org/english/news_e/news21_e/trip_30apr21_e.htm>.

²⁴ 'Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver' (Office of the United States Trade Representative, Press Release, 5 May 2021) <<https://ustr.gov/about-us/>

but rather that the US would ‘actively participate in text-based negotiations’ over a waiver for ‘vaccines’.²⁵ With the EU and others remaining opposed to a waiver and arguing for revisions to the TRIPS provisions on compulsory licensing and greater use of other flexibilities to address the challenges of COVID-19,²⁶ it may be unrealistic to expect that the waiver will be completed in the short to medium term.

The point of this article is not to advocate for or argue against a waiver, but it is important to understand the points critics make as the same arguments may be raised in future investor claims against States that take measures to implement a waiver. While questions have been raised regarding the effectiveness of a waiver in accelerating the production and distribution of COVID-19 vaccines and treatments,²⁷ the more important assertion for the purposes of this article is that a waiver will likely have a disruptive effect on pharmaceutical R&D and innovation.²⁸ In this regard, the industry would argue that a suspension of IPRs could negatively impact the commercial value of pharmaceutical companies as it is standard for such companies to leverage IP portfolios as collateral for generating revenue and securing funding.²⁹ In short, critics of the waiver view a stable IP environment as an incentive for pharmaceutical companies to invest in R&D and generate new innovations. In this regard, IPRs are seen as essential assets that generate revenue for the industry and a waiver of IPRs could significantly impact the value of IP assets.

policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>.²⁵ *ibid.*

²⁶ European Commission, ‘Opening Statement by Executive Vice-President Valdis Dombrovskis at the European Parliament Plenary Debate on the Global Covid-19 Challenge’ (19 May 2021) <https://ec.europa.eu/commission/commissioners/2019-2024/dombrovskis/announcements/opening-statement-executive-vice-president-valdis-dombrovskis-european-parliament-plenary-debate_en>; European Union, ‘Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property’ (Communication from the European Union to the Council for TRIPS, 4 June 2021) <https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159606.pdf> (EU response to COVID-19).

²⁷ See B Mercurio, ‘WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review’ (2021) 62 *VaIntL Online* 9; P Reddy T and Y Pai, ‘Why Intellectual Property Waiver for Vaccines Is Not So ‘IP ‘IP Hoopay at All’ *The Economic Times* (6 May 2021); J Bacchus, ‘An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines’ (Free Trade Bulletin No 78, CATO Institute, 16 December 2020) <<https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>>; C Ann *et al.*, ‘The Waiving of Intellectual Property: A Poor Response to a Real Problem’ (The Stanislas de Boufflers Institute, 19 May 2021) <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3850550>.

²⁸ RM Hilty *et al.*, ‘Covid-19 and the Role of Intellectual Property’ (Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021) <https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_25_Position_statement_Covid_IP_waiver.pdf>.

²⁹ MA Borsos, ‘Patent Protection Strategy’ in F Giordanetto (ed), *Early Drug Development: Bringing a Preclinical Candidate to the Clinic* (Wiley-VCH Publications 2018).

III. A TRIPS WAIVER AND INVESTOR–STATE DISPUTE SETTLEMENT

A. Intellectual Property and Investor–State Dispute Settlement

To meet the jurisdiction requirements under the International Centre for Settlement of Investment Disputes (ICSID) Convention,³⁰ parties must show that the dispute arises directly out of an investment.³¹ Thus, the starting point of an IP-related claim is to establish that there is an underlying investment. While most IIAs explicitly include IPRs in the definition of investment,³² others rely on vague language to determine the scope of an ‘investment’. To assist in the determination of what would be considered an ‘investment’, arbitral practice has developed the ‘Salini test’ that focuses on contribution, duration, risk and economic development in the host State.³³ To this end, some have argued against viewing IPRs as an investment³⁴ or have discussed the potential for reconceptualising the definition of investment to protect the internal limits of IP.³⁵ This article does not capture those debates, but rather focuses on actual practice. Given the explicit recognition of IPRs as an investment in many treaties and the broad interpretation of the ‘Salini test’ in existing jurisprudence,³⁶ it is extremely likely that pharmaceutical patents and related IPRs will qualify as investments under most IIAs.³⁷

The three most relevant IP-related ISDS cases are *Philip Morris v Uruguay*, *Eli Lilly v Canada*, and *Bridgestone v Panama*.³⁸ In each case, the investor was

³⁰ Convention on the Settlement of Investment Disputes between States and Nationals of Other States (adopted 18 March 1965, entered into force 14 October 1966) 575 UNTS 159 (ICSID Convention). The ICSID Convention has been ratified by 153 Contracting States.

³¹ *ibid* art 25.

³² See B Mercurio, ‘Safeguarding Public Welfare? – Intellectual Property Rights, Health and the Evolution of Treaty Drafting in International Investment Agreements’ (2015) 6(2) *JIDS* 252.

³³ *Salini Costruttori SpA & Italstrade SpA v Kingdom of Morocco*, ICSID Case No ARB/00/4, Decision on Jurisdiction (23 July 2001).

³⁴ RL Okediji, ‘Is Intellectual Property “Investment”?’ *Eli Lilly v. Canada and the International Intellectual Property System* (2014) 35(4) *University of Pennsylvania Journal of International Law* 1121; Dreyfuss and Frankel (n 14).

³⁵ See PN Upreti, ‘The Role of National and International Intellectual Property Law and Policy in Reconceptualising the Definition of Investment’ (2021) 52(2) *International Review of Intellectual Property and Competition Law* 103; C Correa and JE Viñuales, ‘Intellectual Property Rights as Protected Investments: How Open are the Gates?’ 19(1) (2016) *JIEL* 91.

³⁶ See generally, E Gaillard, ‘Identify or Define? Reflections on the Evolution of the Concept of Investment in ICSID Practice’ in C Binder *et al.* (eds), *International Investment Law for the 21st Century: Essays in Honour of Christoph Schreuer* (Oxford University Press 2009); A Grabowski, ‘The Definition of Investment under the ICSID Convention: A Defense of Salini’ (2014) 15(1) *Chicago Journal of International Law* 287; S Pahis, ‘Investment Misconceived: The Investment-Commerce Distinction in International Investment Law’ (2020) 45(1) *YaleJIntlL* 70; M Hwang, ‘Recent Developments in Defining “Investment”’ (2010) 25(1) *ICSIDRev* 21.

³⁷ Mercurio, ‘Safeguarding Public Welfare? – Intellectual Property Rights, Health and the Evolution of Treaty Drafting in International Investment Agreements’ (n 32); L Vanhonnaeker, ‘Intellectual Property Rights in International Investment Agreements’ in J Chaisse *et al.* (eds), *Handbook of International Investment Law and Policy* (Springer 2020) 1994–9.

³⁸ Other cases which indirectly feature IPRs include: *Signa SA de CV v Government of Canada* (Notice of Intent to Submit a Claim to Arbitration under Section B of Chapter 11 of the North American Free Trade Agreement, 4 March 1996) (the dispute was withdrawn later); *F-W Oil*

unsuccessful, and in the first two cases the tribunal gave wide scope and deference to the policy choices made by the host State. In *Philip Morris v Uruguay*, the claimants alleged that tobacco plain packaging measures restricting the use of trademarks were an expropriation of property and destroyed the commercial value of IP and goodwill. Deciding in favour of the host State, the tribunal reaffirmed the State's sovereign right to regulate matters of public interest.³⁹ Likewise, the tribunal in *Eli Lilly v Canada* determined that the court-based invalidation of patents for failing to meet the Canadian patent law requirement of utility was within the scope of public policy, not arbitrary and not a dramatic change in Canadian doctrine.⁴⁰ Finally, in *Bridgestone v Panama* the tribunal found that while the Panamanian Supreme Court erred in assigning undue weight to certain evidence during a trademark opposition proceeding it did not rise to the level of breaching the relevant BIT.⁴¹

B. Mapping a Potential Claim Against a TRIPS Waiver

Investment claims generally rely on two substantive investment principles—expropriation and fair and equitable treatment (FET). These standards aim to protect investors from State action that would result in a substantial deprivation of their investment and the failure of the State to fulfil its obligation to maintain a stable legal framework for the investment.⁴² Our analysis focuses on FET as it presents a more interesting and likely path for investors to challenge measures taken in response to a TRIPS waiver. However, where applicable, and in particular with respect to trade secrets, our analysis will include a discussion of expropriation standards.

The generally accepted elements of the FET standard are (i) the host State failed to protect the investor's legitimate expectations; (ii) the host State failed to act transparently; (iii) the host State exhibited arbitrary or discriminatory conduct; (iv) the host State denied the investor access to justice or procedural due process; and (v) the host State acted in bad

Interests, Inc v The Republic of Trinidad and Tobago, ICSID Case No ARB/01/14, Award (3 March 2006); *Shell Brands International AG and Shell Nicaragua SA v Republic of Nicaragua*, ICSID Case No ARB/06/14, Proceeding discontinued (12 March 2007); *Apotex Holdings Inc and Apotex Inc v United States of America*, ICSID Case No ARB (AF)/12/1, Award (25 August 2014); *Erbil Serter v French Republic*, ICSID Case No ARB/13/22, Proceeding discontinued (2 March 2018). For more details and general discussion, see Upreti, 'Intellectual Property Rights in Investor-State Dispute Settlement: Connecting the Dots through the Philip Morris, Eli Lilly, and Bridgestone Awards' (n 13) 345–350. See also the ongoing dispute of *beIN Corporation v Kingdom of Saudi Arabia*, UNCITRAL, Notice of Arbitration (1 October 2018) para 26 (claiming Saudi Arabia's arbitrary measures disrupted the ability to operate in Saudi Arabia and destroyed the investment's value by depriving the Claimant of its contractual rights (including IPRs) to exclusively broadcast sports and entertainment content in the Saudi market).

³⁹ *Philip Morris v Uruguay* (n 13) paras 295–305.

⁴⁰ *Eli Lilly v Canada* (n 13) para 351.

⁴¹ *Bridgestone v Panama* (n 13) Decision on Expedited Objections, paras 68–79, 505–530.

⁴² See *Bayindir Insaat Turizm Ticaret Ve Sanayi AS v Islamic Republic of Pakistan*, ICSID Case No. ARB/03/29, Decision on Jurisdiction (14 November 2005) paras 239–40.

faith.⁴³ Despite these standards, FET is a flexible and elastic standard that can be expanded to include new elements,⁴⁴ making it a promising avenue for investor claims.⁴⁵

1. Would domestic implementation of a TRIPS waiver impede investors' legitimate expectations?

Investor expectations are one of the quintessential elements of the FET standard. Indeed, 'investor expectations are fundamental to the investment process [and the] fundamental goal of virtually all investment treaties is to create an expectation of profit in the minds of potential investors ... [so that they] commit their capital and technology to the country in question'.⁴⁶ The expectations, backed by laws and regulations, guarantee investors the opportunity of a return and it is 'generally considered unfair for the states to take subsequent actions that fundamentally deny or frustrate those expectations'.⁴⁷

The question for our purposes is whether a State acting in accordance with a waiver of international trade law obligations could nevertheless violate the legitimate expectation of a return on investment if the action undermines investors' exclusive rights to reap the fruits of their investments. Here, it is important to differentiate between a waiver from obligations under the TRIPS Agreement and State action to waive/temporarily eliminate the IPRs of inventors and investors. While the latter would not violate trade obligations, it does not necessarily follow that a TRIPS waiver would alleviate a State from obligations it has taken under international investment law. For this reason, the State action must be analysed in accordance with existing international investment law principles and jurisprudence.

a) Change in law arguments

The question before the arbitral tribunal in *Eli Lilly v Canada* was whether the judicially created 'promise doctrine' resulted in a 'dramatic change' in the Canadian approach to the issue of utility.⁴⁸ Eli Lilly argued that the inconsistent application of the promise doctrine created uncertainty:

⁴³ JW Salacuse, *The Three Laws of International Investment: National, Contractual, and International Frameworks for Foreign Capital* (Oxford University Press 2013).

⁴⁴ K Yannaca-Small, 'Fair and Equitable Treatment Standard: Recent Developments' in A Reinisch (ed), *Standards of Investment Protection* (Oxford University Press 2008).

⁴⁵ UNCTAD, 'Fair and Equitable Treatment: UNCTAD Series on Issues in International Investment Law Agreement II' (2012) UN Doc UNCTAD/DIAE/IA/2011/5.

⁴⁶ Salacuse (n 43) 231.

⁴⁷ *ibid.*

⁴⁸ *Eli Lilly v Canada* (n 13) para 307. For an overview of the Canadian Promise Doctrine, see E Richard Gold and M Shortt, 'The Promise of the Patent in Canada and Around the World' (2014) 30 (1) Canadian Intellectual Property Review 35.

[Investors] could not reasonably have expected that Canada would promulgate the unique promise utility doctrine, which has no basis in Canada's statutory patent law and adds a second utility hurdle distinct from the mere scintilla test embodied in the Patent Act ... This dramatic and internationally wrongful departure in Canada's patent law was plainly outside the 'acceptable margin of change' that investors must reasonably anticipate.⁴⁹

Eli Lilly distinguished a 'change in law' from 'clarification of previously unsettled law', viewing only the latter as acceptable.⁵⁰ In response, Canada argued the promise doctrine was not a change in law but rather had evolved over the years and is simply a part of normal legal development. Furthermore, Canada argued that:

Even if such a change had occurred, it is trite to say that the common law evolves over time. Any sophisticated investor expects developments in the law, particularly in the area of patent law. It simply cannot be that every time a court overrules a precedent, it violates customary international law.⁵¹

The tribunal agreed with Canada, concluding that the change in doctrine was more 'incremental and evolutionary than dramatic'.⁵² The tribunal found that as Eli Lilly was not able to 'predict the precise trajectory of the law on utility, it should have, and could have, anticipated that the law would change over time as a function of judicial decision-making ... and the law did in fact undergo a reasonable measure of change and development'.⁵³ For these reasons, Eli Lilly failed to demonstrate a fundamental or dramatic change in Canadian patent law.⁵⁴

The tribunal did not elaborate on what changes are 'dramatic' or on what grounds the change in the law is treated as a minor or radical change. To this end, what is striking is that the tribunal assessed the change in domestic patent law as fact—since there was no dramatic change in domestic patent law, the tribunal did not further discuss or determine whether a 'dramatic change in law' is a criterion or threshold to examine legitimate expectations of investors. While acknowledging that the tribunal's reasoning 'creates a real possibility that the dramatic change criterion will be used as the Award's principle standard for determining whether a change in the [IP] law of the host state is acceptable',⁵⁵ some commenters have observed that the tribunal's reliance on the failure to prove a 'dramatic change in law' cannot be regarded as the new threshold for legitimate expectations:

[T]he tribunal relied on the existence of a 'dramatic change' as a matter of judicial economy—with no indication that the criterion was to serve as the relevant legal threshold for establishing a breach of FET, including its 'legitimate expectations' elements.⁵⁶

⁴⁹ *Eli Lilly v Canada* (n 13) para 263. See also Claimant Memorial, para 279.

⁵⁰ *ibid* para 269. ⁵¹ *ibid* para 306. ⁵² *ibid* paras 350–351. ⁵³ *ibid* para 384.

⁵⁴ *ibid* (n 13) para 389. ⁵⁵ Klopschinski *et al.* (n 12) 339. ⁵⁶ *ibid*.

Similarly in *Philip Morris v Uruguay* the claimants alleged the policy objective of tobacco plain packaging legislation that restricted the use of trademarks was inconsistent with the reasonable expectation of investors in exploiting IP, capitalising on assets and enjoying property rights.⁵⁷ More specifically, the claimants alleged that requiring tobacco packaging to contain health pictograms and meet other requirements created an unstable legal framework that eviscerated investor expectations. The tribunal dismissed these arguments and relied on the State police power doctrine to conclude that States are within their rights to adopt measures necessary to protect public health:

[R]equirements of legitimate expectations and legal stability as manifestations of the FET standard do not affect the State's rights to exercise its sovereign authority to legislate and to adapt its legal system to changing circumstances ... if they do not exceed the exercise of the host State's normal regulatory power in the pursuance of a public interest and do not modify the regulatory framework relied upon by the investor at the time of its investment 'outside of the acceptable margin of change'.⁵⁸

Taken together, the tribunals in *Eli Lilly* and *Philip Morris* make clear that a change in the law will be deemed acceptable if it does not result in a dramatic change or is within an acceptable margin of change. In *Philip Morris* and *Eli Lilly*, the change in domestic law was deemed to be narrow and with clear and specific objectives, outcomes and rationale. In *Philip Morris*, the tobacco plain packaging legislation did not revoke the trademark holder's use of its mark, but only restricted the manner in which it could be used.⁵⁹ Whereas in *Eli Lilly*, the promise utility doctrine was found to have evolved through judicial practice and not as the result of a sudden change. In essence, the tribunals in *Philip Morris* and *Eli Lilly* both agree:

IP owners/investors should not have any great expectation that the status of a granted patent, trademark, or other IP rights will not change and that interpretations of the law will remain static or entirely stable. Interpretations have always been and will continue to be relatively fluid and flexible, narrowed or widened so as to keep up with technological progress and needs and priorities of the government.⁶⁰

Of course, it must be remembered that 'legitimate expectations' for the purposes of FET must be assessed on a case-by-case basis that balances interests and rights.⁶¹

⁵⁷ *Philip Morris v Uruguay* (n 13) para 341. See also para 197 (arguing the measure lacked 'serious, objective and scientific assessment').

⁵⁸ *ibid* paras 422–423. ⁵⁹ Uruguay's legislation required 80 per cent of tobacco packaging to be covered by health warnings, see *Philip Morris v Uruguay* (n 13) Uruguay's Memorial on Jurisdiction, paras 31–32.

⁶⁰ B Mercurio, 'Keep Calm and Carry On: Lessons from the Jurisprudence on Fair and Equitable Treatment and Intellectual Property Rights' in C Geiger (ed), *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar 2020) 177.

⁶¹ *El Paso Energy International Company v The Argentine Republic*, ICSID Case No ARB/03/15, Award (31 October 2011) para 356.

In this respect, the tribunal in *El Paso v Argentina* offered the following objective criteria: (i) the violation of legitimate expectations does not require subjective bad faith on the part of the State; (ii) legitimate expectations cannot solely be the subjective expectations of the investor but are rather the objective expectations that must be deduced from the surrounding circumstances and with due regard to the rights of the State; and (iii) legitimate expectations might differ based on the status of a country (ie a country that is either developing or whose economy is in transition).⁶²

b) What is an acceptable change in the law?

In relation to domestic legislation and measures implementing a TRIPS waiver, the question goes beyond a change in law argument. The waiver intends to allow governments to override and take away existing rights in what would be a total deprivation of investor protection.

In this regard, it is debatable whether the exercise of regulatory power can change the law in totality. The jurisprudence indicates that, while the State can change the legal framework without running afoul of an IIA, there is a legitimate expectation that there will not be a total alteration of the legal framework. For example, the tribunal in *El Paso v Argentina* stated:

There can be no legitimate expectation for anyone that the legal framework will remain unchanged in the face of an extremely severe economic crisis. No reasonable investor can have such an expectation unless very specific commitments have been made towards it or unless the alteration of the legal framework is total.⁶³

Similarly, the tribunal in *Toto v Lebanon* acknowledged the regulatory freedom of the State to make changes but also confirmed that:

[C]hanges in the regulatory framework would be considered as breaches of the duty to grant full protection and fair and equitable treatment only in case of a drastic or discriminatory change in the essential features of the transaction.⁶⁴

Other tribunals likewise recognise the ability to modify the legal framework but caution against unreasonable modifications. For example, the tribunal in *Impregilo v Argentina* states:

The legitimate expectations of foreign investors cannot be that the State will never modify the legal framework, especially in times of crisis, but certainly investors must be protected from unreasonable modifications of that legal framework.⁶⁵

⁶² *ibid* paras 357–364.

⁶³ *ibid* para 374 (emphasis added).

⁶⁴ *Toto Construzioni Generali SpA v The Republic of Lebanon*, ICSID Case No ARB/07/12, Award (7 June 2012) para 244.

⁶⁵ *Impregilo SpA v Argentine Republic*, ICSID Case No ARB/07/17, Final Award (21 June 2011) para 291.

Based on these decisions, investors would argue that domestic measures waiving IPRs amount to an unreasonable modification of the legal framework. Bolstering this argument is the fact that the waiver bypasses less restrictive flexibilities contained in the TRIPS Agreement and incorporated into domestic legislation, namely the possibility to issue a compulsory licence. To illustrate this point, consider how India (one of the sponsors of the waiver proposal at the WTO) has shown little interest in using compulsory licensing to increase vaccine production. This can be seen from the Indian government's response to a writ petition for use of compulsory licensing.⁶⁶

When there is a surge in cases and in demand of patented medicines/drugs/vaccines from all over the world the solution needs to be found out essentially at an executive level engaging at diplomatic levels. Any exercise of statutory powers either under the Patents Act 1970 read with TRIPS agreement and Doha declaration or in any other way can only prove to be counter-productive at this stage, the central government is very actively engaging itself with global organizations at a diplomatic level to find out a solution in the best possible interest of India. It is earnestly urged that any discussion or a mention of exercise of statutory powers either for essential drugs or vaccines having patent issues would have serious, severe and unintended adverse consequences in the countries [sic] efforts being made on global platform using all its resources, good-will and good-offices though diplomatic and other channels.⁶⁷

For ISDS purposes, the question becomes whether wilfully ignoring existing flexibilities designed to ensure equitable distribution of pharmaceuticals and endorsing a waiver of IPRs would amount to an 'unreasonable modification' or a 'total alteration' running counter to the legitimate expectations of investors.

This is in contrast to the situation where a State modifies the framework to clarify existing IP mechanisms to address the health crisis. For example, the EU has proposed changes to Article 31 and Article 31*bis* of the TRIPS Agreement to clarify that the 'pandemic' fulfils the requirement of a 'national emergency' under Article 31⁶⁸ so that a compulsory licence can be issued without prior efforts to obtain authorisation from the right holder.⁶⁹ Similarly, as Article 31(h) and paragraph 5 of Article 31*bis* require payment of adequate remuneration to the right holder, the EU proposes that 'WTO Members can set the remuneration to the right holder at a level that reflects the price charged by the manufacturer of the vaccines and therapeutics at affordable prices to low and

⁶⁶ See *Re: Distribution of Essential Supplies and Services During Pandemic v Unknown* (Suo Moto Writ Petition No 3 of 2021) Affidavit dated 9 May 2021, filed on behalf of the Union of India, paras 36–48. ⁶⁷ *ibid* para 47.

⁶⁸ TRIPS Agreement (n 6) art 31 requires 'the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time'. However, this requirement is waived in the case 'of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'. ⁶⁹ EU response to COVID-19 (n 26) 10.

middle-income countries'.⁷⁰ Likewise, the EU proposes a single notification system where an exporting Member under Article 31*bis* could list all 'countries to which vaccine and therapeutics are to be supplied directly or through the COVAX Facility'.⁷¹ Designed to facilitate the issuance of compulsory licences related to COVID-19 vaccines and treatments, changes in line with this proposal would fall under reasonable modifications and not violate legitimate expectations.

Likewise, the previous TRIPS waiver (turned amendment) allowing for countries with insufficient or no pharmaceutical manufacturing capabilities to make use of the compulsory licensing provisions contained in Article 31 cannot be said to have totally changed or unreasonably modified the legal framework. More specifically, the waiver/amendment still required the issuance of a compulsory licence and along with it the payment of a reasonable royalty and procedural safeguards against abuse. It would be hard to see how the modification of Article 31 in the form of the waiver/amendment would violate legitimate investor expectations. In contrast, the current waiver proposal goes far beyond the earlier waiver in that if applied at the domestic level it would render certain IPRs entirely null and void for an undetermined and potentially indefinite period of time, with no compensation or payment of royalties.

What is clear is that an investor's legitimate expectations are fundamental to the investment process. Here, Potestà observed that the legitimate expectations argument has become an inherent element of FET: 'there is in fact no single tribunal on record that has steadfastly refused to find that—at least in principle—such a standard encompasses legitimate expectations'.⁷² However, it is important to remember that not all expectations are legitimate. In assessing legitimate expectations, one should keep State regulatory rights in mind. Concerning this matter, the tribunal in *Electrabel SA v Republic of Hungary* noted:

While the investor is promised protection against unfair changes, it is well established that the host State is entitled to maintain a reasonable degree of regulatory flexibility to respond to changing circumstances in the public interest. Consequently, the requirement of fairness must not be understood as the immutability of the legal framework, but as implying that subsequent changes should be made fairly, consistently and predictably, taking into account the circumstances of the investment.⁷³

Similarly, the tribunal in *Parkerings v Lithuania* emphasised that a State's regulatory rights are 'undeniable right[s] and privilege[s] to exercise its

⁷⁰ *ibid* 11.

⁷¹ *ibid*.

⁷² M Potestà, 'Legitimate Expectations in Investment Treaty Law: Understanding the Roots and the Limits of a Controversial Concept' (2013) 28(1) ICSIDRev 100.

⁷³ *Electrabel SA v Republic of Hungary*, ICSID Case No ARB/07/09, Decision on Jurisdiction and Liability (30 November 2012) Part VII, para 7.77.

sovereign legislative power. A State has the right to enact, modify or cancel a law at its own discretion.⁷⁴ In *Eiser Infrastructure and others v Spain*, the tribunal acknowledged that the FET standard ‘does not give a right to regulatory stability *per se*. The State has a right to regulate, and investors must expect that the legislation will change.’⁷⁵ On this line of thought, if one is to accept that the State can change laws then it is equally entitled to rescind IPRs in accordance with a waiver of obligations under the TRIPS Agreement.

That said, tribunals have also acknowledged that changes made in times of crisis can be problematic. For instance, the dispute in *Enron Corporation v Argentina* related to the elimination of fixed exchange rates (from USD to peso) and the abolition of the US Producer Price Index used to calculate import tariffs in order to forestall an impending economic crisis.⁷⁶ The tribunal found that Argentina’s complete dismantling of the legal framework exceeded its obligations with regard to investment,⁷⁷ but adopted a high threshold for what is to be considered arbitrary conduct:

The measures adopted might have been good or bad, a matter which is not for the Tribunal to judge, and as concluded they were not consistent with the domestic and the Treaty legal framework, but they were not arbitrary in that they were what the Government believed and understood was the best response to the unfolding crisis.⁷⁸

To this end, a State could argue that since COVID-19 is a health crisis there is a greater responsibility on the State to take measures to control the virus through vaccination. Quite clearly, any specific measure adopted to address the pandemic would fall within the scope of public interest. However, whether suspending the minimum standard of IP protection is within the scope of the exercise of regulatory authority is something that the tribunal would need to consider in assessing FET requirements. Since there is little direct jurisprudence pertaining to public health and no jurisprudence on a health crisis such as the COVID-19 pandemic, investors would look to emphasise

⁷⁴ *Parkerings-Compagniet AS v Republic of Lithuania*, ICSID Case No ARB/05/8, Award (11 September 2007) para 332. See also *Continental Casualty Company v The Argentine Republic*, ICSID Case No ARB/03/9, Award (5 September 2008) para 258; *EDF(Services) Limited v Romania*, ICSID Case No ARB/05/13, Award (8 October 2009) paras 217–219; *Marvin Roy Feldman Karpa v United Mexican States*, ICISD Case No ARB (AF)/99/1, Award (16 December 2002).

⁷⁵ *Eiser Infrastructure Ltd & Energía Solar Luxembourg Sàrl v Kingdom of Spain*, ICSID Case No ARB/13/36, Award (4 May 2017) para 362.

⁷⁶ *Enron Corporation and Ponderosa Assets, LP v Argentine Republic*, ICSID Case No ARB/01/3, Award (22 May 2007) paras 41–46. For a general discussion on the economic crisis and ISDS, see C Bellak and M Leibrecht, ‘Do Economic Crises Trigger Treaty-Based Investor–State Arbitration Disputes?’ (2021) 24 (1) JIEL 127.

⁷⁷ *Enron Corporation v Argentina* (n 76) para 275.

⁷⁸ *ibid* para 281.

the existence of alternative measures such as the TRIPS flexibilities to question the urgency of State measures.⁷⁹

c) Do measures intended to address the crisis also contribute to the crisis?

Even if a State establishes the need to waive IPRs, investors will question whether a waiver contributes to the crisis by discouraging innovation in vaccine development, refinement and distribution. Scientific studies predict that the COVID-19 virus is likely to continue mutating and become endemic;⁸⁰ for these reasons, extensive R&D will be required to develop and modify vaccines and treatments to effectively combat emerging virus variants.⁸¹ Accordingly, the Max Planck Institute for Innovation and Competition is concerned that waiving IPRs would make society vulnerable:

It is important to consider potential effects of a comprehensive waiver of IP protection on innovation incentives in vaccine development (including emerging variants of Covid-19), as well as in *other* areas of medical research ... A waiver of IP protection could leave the society vulnerable to such emerging variants of Covid-19 if the current IP holders/vaccine developers abandoned research efforts as a result of such a waiver. In this regard, a waiver ... appears to be highly disproportionate in its scope.⁸²

Similarly, the International Association for the Protection of Intellectual Property (AIPPI) stated:

[W]aiving TRIPS provisions would negatively impact the framework established to reach the objectives mentioned above on both a medium and a long-term basis ... [and] urges WTO members to recognize how intellectual property rights have contributed to the advancement of science and to innovations in medicine and public health. The recently developed COVID-19 vaccines and therapeutics were discovered based on years of research supported by intellectual property rights.⁸³

Given such concerns, tribunals might assess whether a waiver was the only way to achieve equitable vaccination distribution and whether alternatives were available. Of course, a tribunal does not *per se* have the authority to question the policy choice of the State, but tribunals have confirmed that their assessment could be based on whether the decision made by the State was the only available choice.⁸⁴ For instance, the tribunal in *CMS v Argentina*

⁷⁹ See B Mercurio and PN Upreti, 'The Challenge and Effectiveness of a TRIPS Waiver for COVID-19 Vaccination and Treatment' (2022) (on file with authors) (discussing how TRIPS provides in-built flexibilities designed to deal with global crises such as COVID-19).

⁸⁰ Kemp *et al.* (n 10). ⁸¹ Hilty *et al.* (n 28). ⁸² *ibid* 5 (emphasis in original text).

⁸³ The International Association for the Protection of Intellectual Property, 'AIPPI's Position Paper on the Waiver for Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 Proposed by Some Countries within the WTO' (12 May 2021) para 6, <https://aippi.org/wp-content/uploads/2021/05/AIPPI-Position-Paper-on-WTO-Waiver_12May2021.pdf>.

⁸⁴ See eg *Enron Corporation v Argentina* (n 76) para 309.

observed that Argentina had alternative options and that the chosen measures contributed to the crisis:

The issue, however, is whether the contribution to the crisis by Argentina has or has not been sufficiently substantial. The Tribunal, when reviewing the circumstances of the present dispute, must conclude that this was the case. The crisis was not of the making of one particular administration and found its roots in the earlier crisis of the 1980s and evolving governmental policies of the 1990s that reached a zenith in 2002 and thereafter. Therefore, the Tribunal observes that government policies and their shortcomings significantly contributed to the crisis and the emergency and while exogenous factors did fuel additional difficulties they do not exempt the Respondent from its responsibility in the matter.⁸⁵

Depending on the precise action taken by a State to effectuate the TRIPS waiver, a claimant could attempt to follow the same path as CMS Gas Transmission Company and argue that the policy choice worsened the crisis. This claim could be plausible given the tribunal in *CMS v Argentina* confirmed that State actions with no evidence of effectiveness are at risk of contributing to the crisis. Waiving IPRs during a pandemic without any evidence of effectiveness is unprecedented, and a foreseeable outcome could be a negative effect on R&D and innovation.⁸⁶ Moreover, and again depending on how the scenario plays out, a measure taken in accordance with a waiver may contribute to other public health difficulties, such as those resulting from untested and unregulated copycat medical products and supply chain disruption as unqualified manufacturers divert scarce inputs. Such arguments are, of course, fact-dependent and difficult to prove but are likely to be claimed in any ISDS proceedings.

2. IP treaties as a source of legitimate expectations

a) The TRIPS Agreement

As mentioned above, the TRIPS Agreement establishes minimum standards of IP protection but also provides Members with the freedom to determine the method of implementing the obligations within their legal system and practice.⁸⁷ To this end, the TRIPS Agreement provides clusters of flexibilities relating to health, public interest and other issues to safeguard and ensure policy

⁸⁵ *CMS Gas Transmission Company v The Republic of Argentina*, ICSID Case No ARB/01/8, Award (12 May 2005) para 329.

⁸⁶ See generally, E Mansfield, 'Patents and Innovation: An Empirical Study' (1986) 32(2) *Management Science* 173, 174–5; CT Taylor, A Silberston and ZA Silberston, *The Economic Impact of the Patent System: A Study of the British Experience* (Cambridge University Press 1973) 197–9; A Arora *et al.*, 'R&D and the Patent Premium' (2008) 26(5) *International Journal of Industrial Organization* 1153, 1172–3.

⁸⁷ See Panel Report, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS 362/R, adopted 20 March 2009, para 7.513.

space.⁸⁸ Members may, but are not obliged, to provide more extensive protection than the minimum standards but cannot derogate from the basic obligations of the TRIPS Agreement.

The relevant question for ISDS purposes is whether the minimum IP protection set out in the TRIPS Agreement (or another international IP treaty) could become the basis for a State commitment to provide a stable legal environment. The issue has been raised in several recent disputes. For example, the claimant in *Philip Morris Asia v Australia* claimed that Australia's tobacco plain packaging legislation ran counter to investors' 'legitimate expectation that Australia would comply with its international treaty obligations' under the TRIPS Agreement and the Paris Convention.⁸⁹ Similar claims were presented in *Philip Morris v Uruguay*,⁹⁰ where the tribunal did not address whether international IP treaties are a source of legitimate expectations but did refer to international treaties as an interpretive tool regarding whether there is a right to use a trademark:

[N]owhere does the TRIPS Agreement, assuming its applicability, provide for a right to use ... [the relevant TRIPS provision] provides only for the exclusive right of the owner of a registered trademark to prevent third parties from using the same mark in the course of trade.⁹¹

After referring to the relevant international IP treaties, the tribunal concluded that:

[U]nder Uruguayan law or international conventions to which Uruguay is a party the trademark holder does not enjoy an absolute right to use, free of regulation, but only an exclusive right to exclude 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.⁹²

Two meanings could be drawn from the preceding paragraphs. First, since the tribunal refers to the TRIPS Agreement to clarify the scope of the right to use, it considers international IP treaties as a source of legitimate expectations. Investors are likely to point to the tribunal's reference to the TRIPS Agreement in clarifying a point of law central to the dispute as an indication that international IP treaties can be a source of legitimate expectations. The second possible interpretation is that since TRIPS is not directly enforceable,⁹³ reference to the relevant TRIPS provision is simply a way to

⁸⁸ See WTO, 'Doha Ministerial Declaration' (14 November 2001) WTO Doc WT/MIN (010)/DEC/1, para 19; WTO, 'Doha Declaration on the TRIPS Agreement and Public Health' (20 November 2001) WTO Doc WT/MIN(01)/DEC/2, para 4.

⁸⁹ *Philip Morris Asia Limited v The Commonwealth of Australia*, UNCITRAL PCA Case No 2012-12, Notice of Arbitration (21 November 2011) paras 6.5–6.6 (the case was dismissed on jurisdiction).

⁹⁰ *Philip Morris v Uruguay* (n 13) Request for Arbitration (19 February 2010) paras 85–86.

⁹¹ *Philip Morris v Uruguay* (n 13) para 262. ⁹² *ibid* para 271.

⁹³ On this point, see C Heath, 'The Direct Application of International IP Agreements before National Courts' in C Heath and AK Sanders (eds), *Intellectual Property and International Dispute Resolution* (Wolter Kluwer International 2019).

understand Uruguay's domestic legal framework.⁹⁴ Both views have merit, and the tribunal does not clarify whether *Philip Morris*'s legitimate expectations are derived from Uruguay's commitment to the international treaty obligations.

In *Eli Lilly v Canada* the legitimate expectations' claims relied on the argument that Canada was under an obligation to ensure that Canadian law complied with the State's treaty obligations.⁹⁵ Eli Lilly's argument was made with reference to the Patent Cooperation Treaty (PCT) application as the basis of legitimate expectations. Since the PCT does not require evidence of the utility to be disclosed in forms or other requirements, Eli Lilly argued that the PCT application met Canada's substantive disclosure requirement. Therefore, in imposing additional requirements Canada breached its obligation and claim that it would 'adhere to the PCT in its entirety'.⁹⁶ Canada countered that compliance with the PCT application did not give rise to legitimate expectations as the PCT is a procedural treaty that does not deal with patentability requirements.⁹⁷ The tribunal, however, did not engage with the question as there was not enough evidence to establish a dramatic change in the Canadian promise doctrine.

The tribunals in *Philip Morris* and *Eli Lilly* did not determine whether international IP treaties are a source of legitimate expectations. The *Philip Morris* tribunal, however, did acknowledge that legitimate expectations can come in conflict with the State's regulatory rights. In the context of a TRIPS waiver that suspends copyright, industrial designs, patents and trade secrets, the scenario becomes rather different. As the international treaty obligation is no longer in force (at least temporarily), it would be more challenging to find that legislation in accordance with a suspension of TRIPS could nevertheless violate the minimum expectations found in the FET provisions of IIAs. While investors would maintain that a waiver under TRIPS cannot override the balance between legitimate expectations and State regulatory rights, investors may find it difficult to rely on international IP treaties as a source of legitimate expectations when the obligation contained in that particular IP treaty has been waived.

b) The Paris and Berne obligations

The preceding section showed how investors have relied upon the TRIPS Agreement as a source of legitimate expectations under FET, but also that a waiver of TRIPS obligations at the WTO would mean any expectations in the original form of the treaty are unlikely to be sustained. What is often forgotten,

⁹⁴ Klopschinski *et al.* (n 12) 345 ('The better reading is that the tribunal considers the relevant provisions of TRIPS and the Paris Convention to understand Uruguay's domestic trademark law in light of its international legal context and whether that domestic law—as the decisive legal framework that determines the scope and limits of the investor's IP rights—provides for a positive right to use').

⁹⁵ *Eli Lilly v Canada* (n 13) Notice of Intent, paras 95–96.

⁹⁶ *ibid* Claimant Memorial, para 280.

⁹⁷ *ibid* para 304.

however, is that while the TRIPS Agreement essentially incorporates the Paris and Berne Conventions,⁹⁸ these treaties remain in force as stand-alone legal obligations. In this regard, Article 2 of the TRIPS Agreement states:

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).

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.

Negotiated in the late 1880s and revised throughout the 20th century, the Paris Convention was adopted to address patents, trademarks and unfair competition while the Berne Convention focuses on copyright. The Paris Convention establishes common rules for patents, trademarks and unfair competition. Both treaties multilateralised key principles of IP protection to all signatory States. In addition, the treaties introduced minimum standards and other regulations which increased certainty and predictability to the IP community. Both treaties, however, merely serve as a framework for developing IP policy and signatories retain wide scope to implement their own laws.

When parties to an IIA are signatories to the Paris and/or Berne Convention—and both agreements have near-universal membership⁹⁹—an argument can be made that covered investors would expect the minimum IP protections from these conventions to be maintained. This raises the question of whether suspension of TRIPS through a waiver would automatically suspend a State's obligation under the Paris and Berne Conventions. While those agreements are incorporated into the TRIPS Agreement, they remain independent agreements that create their own set of obligations. Moreover, and unlike obligations arising from the WTO, national courts in some jurisdictions have even applied the conventions directly, despite the absence of a self-executing provision.¹⁰⁰ This further supports an argument that the inclusion of the Paris and Berne provisions into the TRIPS Agreement does not exclusively suspend States'

⁹⁸ See TRIPS Agreement (n 6) arts 1–2. Paris Convention for the Protection of Industrial Property (adopted 14 July 1967, entered into force 26 April 1970) 828 UNTS 305; Berne Convention for the Protection of Literary and Artistic Works (adopted 14 July 1967, entered into force 29 January 1970) 828 UNTS 221.

⁹⁹ As of 1 October 2020, the Paris Convention has 177 Contracting States, whereas the Berne Convention has 179 Contracting States. See <<https://www.wipo.int/treaties/en/>>.

¹⁰⁰ In the US, the Paris Convention has been directly applied in some cases. See *Cumo v Pall*, 729 F Supp 234 (EDNY 1989) (applying Article 4bis of the Paris Convention); However, the US Supreme Court denied direct applicability of the Paris Convention in *Cameron Septic v City of Knoxville* (1913) 227 US 39, 48–9; *Grupo Gigante SA v Dalo & Co*, 391 F 3d 1088 (2004) (denying direct application of Articles 6bis and 10bis of the Paris Convention). For more detail, see C Heath (n 93) 107–15. In the context of the Berne Convention, see *SUISA v Rediffusion AG, Bundesgericht* (Switzerland) (1982) ECC 481, 20 January 1981 (referring to the Berne Convention as applicable law).

obligations under those Conventions even if an obligation has been waived under the TRIPS Agreement.

Relying on the Berne Convention in ISDS is not without precedent. In the ongoing dispute of *Einarsson v Canada*, the claimant is relying upon the Berne Convention to argue a breach of State obligations to protect minimum standards under the Convention.¹⁰¹ The dispute revolves around the Canadian government's disclosure of seismic data to third parties, over which Einarsson claims copyright protection. Einarsson argues that domestic legislation cannot unilaterally abrogate rights and obligations created under the Berne Convention,¹⁰² that is, Canada's unilateral disclosure of the data violates its obligation to provide certain minimum protections of copyright works under the Berne Convention,¹⁰³ as implemented through the Canadian Copyright Act.¹⁰⁴ Einarsson further argues that Canada should have granted copyright to seismic data by virtue of the Canadian Copyright Act, but the Queen's Bench of Alberta emphasised the *lex specialis* nature of the Canadian Petroleum Resources Act (CPRA) and concluded that the seismic data should only receive five years of protection as per the CPRA.¹⁰⁵ Whether *lex specialis* domestic law can be used to override States' international IP treaty obligations is debatable, and as *Einarsson v Canada* remains ongoing it is unclear whether and to what extent the tribunal will consider the obligations of States under the Berne Convention.

While the *Philip Morris* and *Eli Lilly* tribunals did not answer the issue of whether investors can rely on international IP treaties as a source of legitimate expectations, *Einarsson v Canada* takes the debate further to inquire whether local courts can declare that domestic law overrides a State's international IP obligations. If we contextualise this with a TRIPS waiver and assume that domestic legislation or a court declares that laws made in pursuance to a waiver override the State's obligations under the Paris and Berne Conventions, investors may be keen to explore a FET claim in ISDS. Given the limited jurisprudence on international IP treaties as a source of legitimate expectations, the chance of success is uncertain. With no clarity on this issue arising from current jurisprudence, investors have 'a window for the application' of using the Paris and Berne Conventions in investment disputes.¹⁰⁶

¹⁰¹ Theodore David Einarsson, Harold Paul Einarsson and Russell John Einarsson, *Geophysical Service Incorporated v Government of Canada*, UNCITRAL, Notice of Arbitration (18 April 2019) para 17. ¹⁰² *ibid* para 19. ¹⁰³ See Berne Convention (n 98) arts 9, 8, 12.

¹⁰⁴ *Einarsson v Canada* (n 101) Notice of Intent, para 51.

¹⁰⁵ *ibid* para 14. *Geophysical Service Incorporated v 612469 Alberta Limited (CalWest Printing & Reproduction)* 2016 ABQB 356. *Geophysical Service Incorporated v Encana Corporation*, 2016 ABQB; Canada Petroleum Resources Act, RSC 1985, c 36 (2nd Supp).

¹⁰⁶ This phrase was used in the context of investors using TRIPS-based claims in ISDS by L Vanhonnaecker, *Intellectual Property Rights as Foreign Direct Investments: From Collision to Collaboration* (Edward Elgar 2015) 110.

3. *Would compelling pharmaceutical firms to disclose trade secrets amount to a breach of investment obligations?*

Perhaps the most controversial aspect of the proposed TRIPS waiver is the suspension of trade secrets protection purportedly for the ‘rapid and effective response to the COVID-19 pandemic and to diversify and scale-up production to meet global needs and promote economic recovery’.¹⁰⁷ Trade secrets are an inherent part of the pharmaceutical manufacturing life cycle,¹⁰⁸ and several aspects of mRNA manufacturing technologies are protected as trade secrets.¹⁰⁹ Trade secrets are essential for the industry as they provide an incentive to invest in R&D and develop valuable information to use without risk of knowledge spillovers.¹¹⁰

Given the importance of trade secrets, drug companies are unlikely to willingly disclose secrets and it is uncertain whether governments would or even could compel companies to do so. Reddy T and Pai bluntly State: ‘no Western government will force their companies to share their vaccine technology with foreign companies’.¹¹¹ Thus, while some Western countries such as the US may support a TRIPS waiver, it appears unlikely they will put in place the necessary legislation to force the transfer of trade secrets.

If a State does compel a pharmaceutical company to disclose its trade secrets, the company would likely seek redress through the FET and expropriation clause contained in IIAs.¹¹²

In regard to FET, investors would first argue that the forceful transfer of trade secrets results in a violation of their legitimate expectations. As discussed in Section B of this article, investors expect legal stability and predictability in regulatory changes. The commercial value of trade secrets is its secrecy, and once the asset loses its secrecy the asset will be rendered valueless. Therefore, if a trade secret relating to a pharmaceutical is forcibly disclosed and provided to generic pharmaceutical companies, the investments of the

¹⁰⁷ WTO, ‘Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text’ (n 7).

¹⁰⁸ See N Pardi *et al.*, ‘mRNA Vaccine – A New Era in Vaccinology’ (2018) 17 *Nature Reviews Drug Discovery* 261.

¹⁰⁹ For example, BioNtech have protected mRNA manufacturing technologies through trade secret protection <<https://www.sec.gov/Archives/edgar/data/1776985/000119312520195911/d939702dfl.htm>>.

¹¹⁰ See OECD, ‘Approaches to the Protection of Trade Secrets’ in OECD, *Enquires into Intellectual Property’s Economic Impact* (2015) 134 <<https://www.oecd.org/sti/ieconomy/KBC2-IP.Final.pdf>>.

¹¹¹ P Reddy T and Y Pai, ‘What’s the Point of Contributing a Discussion on the Unworkable TRIPs COVID-19 Waiver Proposal?’ (IPKAT, 13 July 2021) <<https://ipkitten.blogspot.com/2021/07/whats-point-of-continuing-discussion-on.html>>.

¹¹² Most IIAs explicitly include trade secrets under the definition of investment. For example, see Indonesia–Denmark BIT (2007) art 1(1)(e) (‘intellectual property rights including not limited to patents, copyrights, trademarks, geographical indications, industrial designs, layout design of integrated circuits, trade secrets, and rights in plants varieties, as well as business names, technical processes, know-how and good will’).

pharmaceutical company will be negatively affected. Since trade secrets do not require any legal formalities, pharmaceutical companies often protect and improve their secrets with R&D investments. Similarly, trade secrets in pharmaceutical innovations are potentially linked to other trade secrets. This means that if a particular trade secret (for example, related to mRNA technology) is forcibly disclosed, it could potentially result in the disclosure of other trade secrets. Moreover, competitors would use the disclosure of the trade secret to reverse engineer and access other secrets. The innovator companies will argue that this will hinder both present and future investments made under the expectation of legal stability.¹¹³

It is also a mistake to equate compulsory licensing of patents to the forced disclosure of trade secrets. Importantly, international IP treaties contemplate the issuance of compulsory licensing for patents but do not do so for trade secrets. In addition, unlike a patent, trade secrets do not prevent competitors from using information and developing an invention. Moreover, in the case of patents State control over exclusive rights through compulsory licensing is time-bound but ownership remains with the patent holder. However, in the case of trade secrets, once a secret is disclosed forcefully, it is currently not possible to subsequently undo the disclosure and reinstate the trade secret. Therefore, the innovator companies may question the reasonableness of the State interference as there is currently no clear evidence that the trade secrets are a hindrance to equitable distribution of vaccines. On the contrary, innovators have been generous in licensing technology transfer and production and one would be hard-pressed to find credible reports of qualified generic producers being refused a licence. To this end, many trade-related bottlenecks in vaccine manufacturing and distribution have been identified.¹¹⁴ Therefore, it is plausible to claim that the forced transfer of trade secrets amounts to the violation of legitimate expectations of predictability and consistency of legal framework.

Turning to the issue of whether the forced transfer of trade secrets would amount to an expropriation of investor property, international investment law allows the host State to expropriate foreign property—intangible assets (including IPRs) qualify as property rights that are capable of being expropriated¹¹⁵—so long as the expropriation is conducted with a public purpose, in a non-discriminatory manner, in accordance with due process

¹¹³ See generally, UK Intellectual Property Office, 'The Economic and Innovation Impacts of Trade Secrets' (19 April 2021) (discussing trade secrets as a preferred and flexible innovation tool and strategy for companies) <<https://www.gov.uk/government/publications/economic-and-innovation-impacts-of-trade-secrets/the-economic-and-innovation-impacts-of-trade-secrets>>.

¹¹⁴ World Trade Organization, 'Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measure on Critical Products to Combat COVID-19' (20 July 2021) <https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_report_e.pdf>.

¹¹⁵ *Case Concerning Certain German Interests in Polish Upper Silesia (Germany v Poland)* (Merits) [1926] PCIJ Rep Series A No 7, para 136 ('[i]t is clear that the rights ... to the exploitation of the factory and to the remuneration fixed by the contract for the management of

of the law and with payment of compensation. Direct expropriation occurs with the ‘taking’ of an asset whereas indirect expropriation occurs when a State’s action renders property rights useless despite the investor retaining title. The grounds for an indirect expropriation are assessed on a case-by-case basis, but in practice claims for indirect expropriation rarely succeed in ISDS.¹¹⁶

Investors have included trade secrets or undisclosed information in expropriatory claims. For example, in *Garanti Koza v Turkmenistan*, the investor claimed a breach of contract resulted in the loss of IP and know-how used to construct highway bridges through the investor’s parent company.¹¹⁷ The tribunal, however, found no credible basis for assigning any value to the know-how, thus dismissing the expropriation claims.¹¹⁸ Likewise, in *Cortec Mining v Kenya*, investors unsuccessfully claimed that the revocation of a mining licence was against the claimants’ assets and interest, such as shares, IP rights, and know-how, resulting in injuries that amounted to an expropriation of investment.¹¹⁹ A slightly different claim has been made in *Einarsson v Canada*, where seismic data collected by the mining company—disclosed to the Canadian government as a requirement for safety and environmental purposes—were subsequently divulged to third parties by the State without the consent of the claimant.¹²⁰ The seismic data generated by the mining company was essential to the claimant’s business model. The Notice of Arbitration captures this:

Creating marine seismic data is a capital-intensive and time-consuming process. It requires significant investment in order to produce final works, which are, in turn, extremely valuable. Seismic surveys cost millions of dollars to create and are closely guarded trade secrets governed by strict licensing agreements relating to the confidentiality and reproduction of the data. In this instance, the estimated costs expended to create the Seismic Data are approximately USD\$ 781,000,000, with estimated outstanding returns from existing license agreements with third parties for the Seismic Data worth approximately USD\$ 2,529,000,000.¹²¹

In the case, the claimant argues that State action expropriated their copyright and trade secrets protection over the data. The case remains ongoing but given that seismic data was generated through large investments and its exclusivity was essential to their whole business operation,¹²² one can draw a

the exploitation and for the use of its patents, licences, experiments, etc., have been directly prejudiced by the taking over ...).

¹¹⁶ Y Zhu, ‘Do Clarified Indirect Expropriation Clauses in International Investment Treaties Preserve Environmental Regulatory Space?’ (2019) 60(2) *HarvIntLLJ* 377 (discussing the rich jurisprudence on indirect expropriation).

¹¹⁷ *Garanti Koza LLP v Turkmenistan*, ICSID Case No ARB/11/20, Award (19 December 2016).

¹¹⁸ *ibid* para 417.

¹¹⁹ *Cortec Mining Kenya Limited, Cortec (Pty) Limited and Stirling Capital Limited v Republic of Kenya*, ICSID Case No ARB/15/29, Award (22 October 2018) para 323.

¹²⁰ *Einarsson v Canada* (n 101) Notice of Arbitration, para 17

¹²¹ *ibid* para 11.

¹²² *ibid* paras 10, 27. See Upreti, ‘Intellectual Property Rights in Investor-State Dispute Settlement: Connecting the Dots through the Philip Morris, Eli Lilly, and Bridgestone Awards’ (n 13) 401–3.

comparison with drug companies' use of confidential information and know-how and of a business model that relies heavily on trade secrets protection to accelerate innovations in the pharmaceutical sector.

As stated above, there has not been any discussion at the TRIPS Council on a mechanism to operationalise the transfer of trade secrets, and it is unlikely that companies will voluntarily disclose their secrets and in the process lose all potential future financial benefits stemming from that information (as the legality of trade secrets remains only for so long as the secrets are not publicly disclosed).¹²³ The forced disclosure, or even seizure, of trade secrets would become the basis for an expropriation claim. The impact of forced disclosure/seizure will be severe, undoubtedly affecting future drug innovations and offering a competitive advantage to competitors not only in COVID-related vaccines.¹²⁴ Here, it is important to remember that the investment in R&D that resulted in the development of mRNA started more than 25 years ago and did not originally target coronaviruses.¹²⁵ Therefore, the claim will be that the State's interference will deter existing and future IPRs (trade secrets) and further disincentivise investors.¹²⁶ The more specific claim will be that forced disclosure of trade secrets, even if done in response to a waiver of obligations under the TRIPS Agreement, will 'substantially deprive the investor of the use or enjoyment of its investment, even if the legal and beneficial title of the asset remains with the investment'¹²⁷ and violate basic expectations that State conduct in pursuance of policy objectives is sound, effective and rational.

IV. CARVE-OUTS AND EXCEPTIONS FROM TREATY OBLIGATIONS

Arbitral tribunals rely on both treaty language and established customary international law principles.¹²⁸ The State will depend on both these sources to defend its action against investors' claims. Generally, deference is accorded to State conduct but the level varies depending on the degree and

¹²³ Article 39 of the TRIPS Agreement explains the requirements for protection: (i) *Secrecy* – the information must be secret and not available in the public domain; (ii) *Commercial Value* – the secrets must have an economic value; and (iii) *Reasonable Efforts to Maintain Secrecy* – the rights holder must take necessary efforts to ensure that the information is kept secret. See OECD, 'Approaches to the Protection of Trade Secrets' (n 110) 127–72.

¹²⁴ See D Kim, 'Protecting Trade Secrets Under International Investment Law: What Secrets Investors Should Not Tell States' (2016) 15(2) *John Marshall Review of Intellectual Property Law* 229.

¹²⁵ T Cueni, 'The Risk in Suspending Vaccine Patent Rules' *The New York Times* (10 December 2020) <<https://www.nytimes.com/2020/12/10/opinion/coronavirus-vaccine-patents.html>>.

¹²⁶ *Saluka Investments BV v The Czech Republic*, UNCITRAL, Partial Award (17 March 2006) para 301.

¹²⁷ See *Técnicas Medioambientales Tecmed, SA v The United Mexican States*, ICSID Case No ARB (AF)/00/2, Award (29 May 2003) para 115.

¹²⁸ States could also rely on defences recognised under international law, such as the doctrine of necessity. See further, L Bartels and F Paddeu (eds), *Exceptions in International Law* (Oxford University Press 2020).

effect of those measures.¹²⁹ This section provides an overview of possible defences States may raise in support of domestic measures taken in response to a TRIPS waiver.

Most IIAs contain specific carve-outs and general exclusions that may be essential in defending a TRIPS waiver claim. Several contemporary IIAs also have explicit IP-related regulatory carve-outs that could be relied upon as a defence against a claim. For instance, many IIAs exclude compulsory licences as well as the invalidation and revocation of IPRs from the scope of the provision on expropriation. A typical provision resembles that of the Argentina–Japan BIT (2018), which states that the ‘issuance of compulsory licenses granted concerning intellectual property right in accordance with the TRIPS Agreement, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with the TRIPS’.¹³⁰ Similar language can be found in most IIAs with different variables referring to ‘consistent with applicable domestic law and regulations of either Contracting Party and international agreements on intellectual property’.¹³¹

Another clause, which appears in the Japan–Papua New Guinea BIT (2011) and applies more widely than the above provision as it extends not only to expropriation but also other substantive obligations, broadly preserves regulatory rights in emphasising that the BIT ‘shall not be construed so as to derogate from the rights and obligations under multilateral agreements in respect of [the] protection of intellectual property rights to which the contracting Parties are parties’.¹³² The essential outcome of these treaties is that such wording allows States to defend regulatory change made in pursuance of a TRIPS waiver, but of course, the outcome is less certain in regard to obligations arising under the Paris Convention and other international IP treaties.

In defending a claim, a State could also rely on general regulatory carve-outs. Recent IIAs often include a provision on the ‘right to regulation’ that safeguards State regulatory rights to protect the public interest. For example, Article 8.9 of the CETA reads:

[T]he parties reaffirm their right to regulate within their territories to achieve legitimate policy objectives, such as the protection of public health, safety, the environment or public morals, social or consumer protection or the promotion and protection of cultural diversity.

¹²⁹ See SW Schill, ‘Deference in Investment Treaty Arbitration: Re-conceptualizing the Standard of Review’ (2012) 3(3) *JIDS* 577; P Ranjan and P Anand, ‘Covid-19, India, and Investor-State Dispute Settlement (ISDS): Will India Be Able to Defend Its Public Health Measures?’ (2020) 28(1) *Asia Pacific Law Review* 225 (discussing general health-related defences).

¹³⁰ Argentina–Japan BIT (2018) art 11.8. Some IIAs have even defined the meanings of the terms ‘revocation’ and ‘limitation’ to ensure clarity, see Comprehensive and Progressive Agreement for Trans-Pacific Partnership (2018) art 9.8(5).

¹³¹ Columbia–UAE BIT (2017) art 7.7.

¹³² Japan–Papua New Guinea BIT (2011) art 19(2).

[T]he modification to its laws, in a manner which negatively affects an investment or interferes with an investor's expectations, including its expectations of profits, does not amount to a breach of an obligation under this Section.¹³³

This provision ensures a State's sovereign right to regulate matters related to the general public interest and clarifies that a change in the law cannot be the basis for investor expectations. In this context, any domestic regulatory changes which purport to implement a TRIPS waiver are likely to be justified. Many IIAs also contain provisions that refer to public interests and public health-related regulatory space that allow the host State to take measures protecting public interests.

That being said, the majority of IIAs do not explicitly address health-related exceptions. Some agreements allow States to take measures in 'circumstances of an extreme emergency posing a threat to the life or health of human beings'.¹³⁴ This reference to 'extreme emergency' would likely be construed as encompassing the circumstances COVID-19—a grave threat to human lives. Therefore, an argument can be made that regulatory measures related to the implementation of a TRIPS waiver are directly related to efforts to curtail the spread of the virus and equitable vaccination as the virus poses an extreme threat. The challenge lies in the older generation IIAs which contain limited safeguards for State regulatory measures. This is a genuine issue, as less than 7 per cent of IIAs concluded before 2012 contain general public policy exceptions, with approximately 4 per cent containing an explicit reference to the right to regulate and less than 2 per cent providing carve-outs for regulatory measures.¹³⁵ In contrast, 92 per cent of IIAs concluded since 2018 contain an explicit reference to public health and accompanying exceptions and carve-outs.¹³⁶

Another route for a State to defend its measures is through the general exception provisions contained in an increasing number of IIAs. Provisions on general exceptions often closely follow or reproduce the language of Article XX of the General Agreement on Tariffs and Trade (GATT).¹³⁷ The rationale for the inclusion of exceptions in the WTO framework is to provide insurance to the government that its domestic regulatory space or policy space will be protected in the process of trade liberalisation; that is, that trade concerns do not trump legitimate non-trade concerns.¹³⁸ Likewise, GATT-style general exceptions in IIAs empower the State to enjoy regulatory autonomy in

¹³³ Comprehensive Economic and Trade Agreement (CETA) Chapter Eight, Section D, art 8.9.

¹³⁴ India–Spain BIT (1998); India–Kuwait BIT (2003) art 14.

¹³⁵ UNCTAD, 'International Investment Policies and Public Health' (IIA Issues Note, issue 2, July 2021).

¹³⁶ *ibid* 2–3, see Fig I titled 'Public health provisions in IIAs concluded between 2018–2020' (highlighting that most IIAs concluded between 2018–20 contain public health provisions, including expropriation (64 per cent), general public policy exceptions (58 per cent), preambular language (44 per cent) and a right to regulate clause (42 per cent).

¹³⁷ See eg Turkey–Burkina Faso BIT (2019) art 5; Japan–Iran BIT (2016) art 13.

¹³⁸ BM Hoekman and MM Kostecki, *The Political Economy of the World Trading System: The WTO and Beyond* (Oxford University Press 2009) 416.

matters related to public health and other public interests.¹³⁹ The assumption is that the general exception provisions will offer a host State greater regulatory flexibility in pursuance of a specific objective,¹⁴⁰ but this assumption is somewhat ‘unclear’ and scholarship is divided on the question of whether GATT-styled general exceptions offer more regulatory freedom than the arbitral tribunal practice of balancing rights and obligations through the margin of appreciation or proportionality principle.¹⁴¹

General exception clauses have rarely been interpreted in ISDS, but when they have tribunals have not viewed them as an escape from liability. For example, in September 2021 the tribunal in *Eco Oro v Columbia*¹⁴² acknowledged that regulatory measures taken by Columbia fall within the scope of the general exceptions clause contained in the Canada–Columbia FTA (art 2201(3)) but concluded that the clause is not intended to exclude the liability of States for their actions.¹⁴³ Other tribunals have reached similar conclusions.¹⁴⁴

Another possible defence for a State is the police powers doctrine established under customary international law which provides an inherent power to regulate in the protection of public interest. The tribunal in *Methanex Corporation v United States* stated:

[A]s 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 and compensable unless specific commitments had been given by the regulating

¹³⁹ See generally, C Glöckle, ‘Exempting and Justifying Covid-19 Related Export Restrictions under WTO’ (2021) 48(2) *Legal Issues of Economic Integration* 201, 207–14 (discussing the use of Article XX of GATT).

¹⁴⁰ Although there are risks if the treaty adopts the ‘necessary’ language of GATT Article XX. For discussion on this point, see Mercurio, ‘Safeguarding Public Welfare? – Intellectual Property Rights, Health and the Evolution of Treaty Drafting in International Investment Agreements’ (n 32) 268–75.

¹⁴¹ *ibid.* For differing views on the inclusion of GATT-styled general exceptions in IIAs, see A Mitchell, J Munro and T Voon, ‘Importing WTO General Exceptions into International Investment Agreements: Proportionality, Myths, and Risks’ in L Sachs *et al.*, (eds), *Yearbook on International Investment Law & Policy 2017* (Oxford University Press 2019); B Mercurio, ‘Smoke Them Out: Why Excluding Tobacco from the Scope of International Investment Agreements Is Unwise and Unnecessary’ (2018) 37(1) *Medicine & Law* 125; A Newcombe and L Paradell, *Law and Practice of Investment Treaties: Standard of Treatment* (Wolter Kluwer International 2009) 505.

¹⁴² *Eco Oro Minerals Corp. v Republic of Columbia*, ICSID Case No ARB/16/41, Decision on Jurisdiction, Liability and Directions on Quantum (9 September 2021).

¹⁴³ *ibid.* paras 822–837. See also JB Heath, ‘Eco Oro and the Twilight of Policy Exceptionalism’ (International Institute for Sustainable Development, 20 December 2021) <<https://www.iisd.org/itm/en/2021/12/20/eco-oro-and-the-twilight-of-policy-exceptionalism/>> (stating ‘the tribunal’s failure to consider the environmental exception allowed it to gloss over several defects that, once revealed, suggest that these provisions are not much of a safety net and may even be dangerous’).

¹⁴⁴ For example, see *Ber Creek Mining Corporation v Republic of Peru*, ICSID Case No ARB/14/21, Award (30 November 2017) paras 472–478.

government to the then putative foreign investor contemplating investment that the government would refrain from such regulation.¹⁴⁵

The application of the State powers doctrine has evolved, and the effect of the measure on investors is not the critical factor in assessing expropriating claims.¹⁴⁶ Instead, a tribunal either employs a reasonable nexus standard or proportionality test in applying the police powers doctrine.¹⁴⁷ Compared to the proportionality test,¹⁴⁸ the reasonable nexus standard is more suitable as a justification related to the implementation of a TRIPS waiver for two reasons. First, the tribunal in *Philip Morris v Uruguay* emphasised that the reasonable nexus between the measure in question and the public policy objective is enough to satisfy the police powers doctrine. Second, the tribunal acknowledged the sources of investment law to endorse the police power doctrine and noted that a 'state's reasonable *bona fide* exercise of police powers in such matters as the maintenance of public order, health or morality, excludes compensation even when it causes economic damage to an investor and that the measure taken for that purpose should not be considered as expropriatory did not find immediate recognition in investment treaty decisions'.¹⁴⁹

Two points can be drawn from the *Philip Morris* award that a State could use in justifying COVID-19 related measures. First, if the State could prove that measures are taken *bona fide* to protect the public interest, then such actions would fall under a valid exercise of police power for the protection of public health. Second, the tribunal acknowledged that States are better placed to assess the public health emergency to exercise their police power:

The responsibility for public health measures rests with the government and investment tribunals should pay great deference to governmental judgements of

¹⁴⁵ See *Methanex Corporation v United States of America*, UNCITRAL, Final Award of the Tribunal on Jurisdiction and Merits (3 August 2005) para 7, and Part IV-Chapter D at 4. See also *Saluka Investments v Czech Republic* (n 126) para 262 ('the principle that a State does not commit an expropriation and is thus not liable to pay compensation to a dispossessed alien investor when it adopts general regulations that are "commonly accepted as within the police power of States" forms part of customary international law today').

¹⁴⁶ *Compañía de Aguas del Aconquija SA and Vivendi Universal SA v Argentine Republic*, ICSID Case No ARB/97/3, Award (20 August 2007) para 7.5.20.

¹⁴⁷ See generally, C Henckels, *Proportionality and Deference in Investor-State Arbitration: Balancing Investment Protection and Regulatory Autonomy* (Cambridge University Press 2015); V Vadi, *Proportionality, Reasonableness and Standards of Review in International Investment Law and Arbitration* (Edward Elgar 2018).

¹⁴⁸ *Técnicas v Mexico* (n 127) para 122 ('The Arbitral Tribunal will consider ... whether such actions or measures are proportional to the public interest presumably protected thereby and to the protection legally granted to investments, taking into account that the significance of such impact has a key role upon deciding the proportionality. Although the analysis starts at the due deference owing to the State when defining the issues that affect its public policy or the interests of society as a whole, as well as the actions that will be implemented to protect such values ... There must be a reasonable relationship of proportionality between the charge or weight imposed to the foreign investor and the aim sought to be realized by any expropriatory measure.').

¹⁴⁹ *Philip Morris v Uruguay* (n 13) para 295.

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.”¹⁵⁰

Therefore, if the State could establish that their actions were bona fide and aimed at equitable vaccination of COVID-19, the State is likely to receive some leeway considering the highly mutative nature of the virus. Thus, the reliance on the police powers doctrine will likely justify measures taken at the domestic level to give effect to the TRIPS waiver proposal.

As discussed in the preceding sections, investors will rely on the lack of scientific evidence that IPRs are an obstacle to the equitable distribution of vaccines. States will employ the reasoning of the *Philip Morris v Uruguay* tribunal to rebut such claims. In *Philip Morris v Uruguay*, the claimants challenged the scientific evidence of the tobacco plain packaging legislation since Uruguay did not perform any studies to support the effectiveness of plain packaging measures in reducing tobacco consumption.¹⁵¹ The *Philip Morris* tribunal, however, held that there was no obligation on States to perform additional studies on the effectiveness of the plain packaging measures because the measures were based on the World Health Organization (WHO) Framework Convention on Tobacco Control.¹⁵² Furthermore, the tribunal confirmed that the ‘responsibility for public health measures rests with the government’.¹⁵³ This indirectly confirms that if an international institution like the WTO acknowledges and endorses the TRIPS waiver (with the support of the WHO), that may be enough to establish the rationale of domestic measures even if it would otherwise violate IIA obligations.

V. CONCLUSION

The TRIPS Agreement is designed to ensure the stability of the IP regime through minimum standards of protection. The security offered by the TRIPS Agreement encourages investment in R&D, with inventors provided the possibility of a return on investment only if minimum standards of IP protection and enforcement are effective. The expectation of a return on

¹⁵⁰ *ibid* para 399.

¹⁵¹ *ibid* paras 328–333. By contrast, in *Philip Morris Asia v Australia*, Australia provided evidence justifying its policy initiative, including the establishment of a National Preventive Health Taskforce (NPHT) which conducted ‘extensive research and reviews of available evidence and undertook widespread consultation with stakeholders’ that become the basis for endorsing tobacco plain packaging legislation in Australia. *Philip Morris Asia v Australia* (n 89), Australia’s Response to the Notice of Arbitration (21 December 2011) paras 9–28, quoting para 19. See also Australian Government Department of Health, ‘Post Implementation Review: Tobacco Plain Packaging 2016’ (2016) 4 (acknowledging that the measure ‘is achieving its aim of improving public health in Australia and is expected to have substantial public health outcomes in the future’).

¹⁵³ *ibid* para 399.

¹⁵² *Philip Morris v Uruguay* (n 13) para 394.

investment is further backed through a network of IIAs. The obligations imposed on States do not change the basic tenets of the regulatory framework in place for the benefit of public interest, but merely provide a certain layer of protection for investors.

This article provided an analysis of potential claims arising from domestic measures taken to implement a TRIPS waiver. While such measures will undoubtedly affect foreign investment and innovation and undermine the basic expectation of minimum IP standards enforced through international treaties, this does not automatically mean that such measures are inconsistent with IIAs. Through extensive reference to the handful of IP-related ISDS cases, this article has highlighted a potential gap in those disputes which could potentially allow investors to leverage a change in laws to make a plausible claim of expropriation and legitimate expectations.

Whilst the grant of an IPR cannot be construed as the basis of legitimate expectations because the nature of IP protection includes limitations and exceptions to the rights, the TRIPS waiver is different from a limitation or exception to rights. Domestic measures implementing a TRIPS waiver could potentially make the existing rules futile and remove all the rights of inventors to IP protection and enforcement. Investors will claim that the measures would go beyond a mere change in law and are a substantial alteration of the legal framework resulting in a complete deprivation of rights and thus inconsistent with their legitimate expectations and a violation of FET. Here, investors will point to the drastic change in the essential features of the law and, as the host State ignored available flexibilities (such as compulsory licences), will claim the law has been unreasonably modified.

The FET claim will be difficult to sustain as not all expectations are legitimate and States have a right to regulate. Moreover, arbitral tribunals have provided States considerable leeway to regulate in times of crisis for the public interest. While measures to change the legal framework taken in times of crisis can be problematic and even contribute to or worsen the crisis, the jurisprudence indicates that such measures will withstand an attack so long as they are not arbitrary. Investors will also find it difficult to claim that IP treaties are a source of legitimate expectations as the TRIPS obligations would be waived at the WTO and therefore the multilateral trade treaty could no longer be a source of an expectation. The TRIPS Agreement, however, does not exclusively suspend States' obligations under other treaties—including the Paris and Berne Conventions—and thus investors will argue these treaties remain a source of legitimate expectations.

It may be more difficult for a State to defend a claim of expropriation for measures forcing disclosure or seizure of trade secrets. While such actions are unlikely, should they occur, they would substantially deprive investors of use, title and enjoyment of both present and future property rights. The impact of a forced disclosure/seizure would be severe, undoubtedly affecting future drug innovations and offering a competitive advantage to competitors

not only in COVID-related vaccines. Even if a State would claim the existence of public policy exceptions (detailed below), the challenge would lie in whether a State is also exempted from the obligation to pay compensation for an expropriation.

Should an investor be able to sustain a claim for FET or expropriation, States can rely on a host of provisions to defend the measures. First, most IIAs exclude compulsory licences and the invalidation and revocation from the scope of the provision on expropriation, with some agreements going further to include TRIPS-specific exceptions. Second, IIAs contain provisions relating to general regulatory carve-outs, police powers taken to protect the public interest and, increasingly, the right to regulate. Such provisions provide for the sovereign right to regulate matters related to the public interest and clarify that a change in the law cannot be the basis for investor expectations, with some going further to include even more policy space in situations of extreme emergency. Finally, some modern IIAs contain a general exception clause which could provide an additional safeguard to ensure a legitimate measure is not deemed to violate a substantive treaty provision.

Given tribunals' deference to State regulatory powers, evolving textual interpretations and (in some treaties) the existence of a specific exception clause and other safeguards, claims made in relation to measures taken in response to a TRIPS waiver of IPRs are unlikely to be sustained. That said, older generation treaties contain imprecise, vague language and provide for fewer safeguards than more modern agreements. To reduce uncertainty in the post-pandemic world, States should revisit treaties to better reflect State intent and delineate the extent to which legitimate and non-discriminatory health-related measures would be consistent with treaties. To this end, the recently released Canadian Model BIT of 2021 has adopted treaty language that considers a waiver of IPRs.¹⁵⁴ More specifically, the expropriation clause states that a 'measure [does not constitute expropriation] if it is consistent with the TRIPS Agreement and any waiver or amendment of that Agreement accepted by that Party'.¹⁵⁵ Further, the general exceptions clause contains a direct reference to a WTO waiver:

If a right or obligation in this Agreement duplicates one under the WTO Agreement, the Parties agree that a measure adopted or maintained by a Party in conformity with a waiver decision granted by the WTO pursuant to Article IX of the WTO Agreement is deemed to be also in conformity with the present Agreement. Such conforming measure of either Party may not give rise to a claim by an investor of one Party against the other under Section E (Investor-State Dispute Settlement).¹⁵⁶

¹⁵⁴ See Canada's 2021 Foreign Investment Promotion and Protection Agreement (FIPA) Model <<https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/fipa-apie/index.aspx?lang=eng>>.

¹⁵⁵ *ibid* art 9(6).

¹⁵⁶ *ibid* art 22(7).

The Canadian Model BIT can serve as a model for others, and the adoption of similar provisions to exempt any liabilities related to the existence of a WTO waiver would better safeguard regulatory rights and the promotion of health-related measures.