International Economic Law Clinic

Compulsory Licenses and International Investment Treaties

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ABBREVIATIONS

ASEAN	Association of Southeast Asian Nations
BIT	Bilateral Investment Treaty
CPTPP	Comprehensive and Progressive Trans-Pacific Partnership
Doha Declaration	Doha Declaration on TRIPS and Public Health
FET	Fair and Equitable Treatment
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GATS	General Agreement on Trade in Services
IIAs	International Investment Agreements
IP	Intellectual Property
ISDS	Investor-State Dispute Settlement
MFN	Most Favored Nation
NAFTA	North American Free Trade Agreement
NT	National Treatment
Patent Act	Patent Act B.E. 2522 (1979)
PPRs	Prohibitions on Performance Requirements
RCEP	Regional Comprehensive Economic Partnership
R&D	Research and Development
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
VCLT	Vienna Convention on the Law of Treaties
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

This report examines the implications of substantive investor protections set out in international investment agreements ("IIAs") on compulsory licensing regimes against the background of the possible accession of the Kingdom of Thailand ("Thailand") to the Comprehensive and Progressive Trans-Pacific Partnership ("CPTPP").

Compulsory licenses allow governments to override the exclusive monopoly rights granted to a patentee by permitting third parties to use the patented product or process without the patentee's consent. On the international level, compulsory licenses are addressed in Article 31 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), which sets out general safeguards and procedures for issuing compulsory licenses and notes exceptions to these procedures in the case of a "national emergency".

Compulsory licenses are most often issued for patents covering pharmaceuticals. In 2001, in the "Doha Declaration on Public Health and the TRIPS Agreement", WTO members clarified that (a) public health crises can represent a national emergency; (b) each member has the right to determine what constitutes a public health crisis (such as those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics); and (c) each WTO member has the freedom to determine the grounds upon which compulsory licences are granted.

Thai law provides a process for issuing compulsory licenses, and Thailand has issued compulsory licenses with respect to pharmaceutical patents in seven instances. Notably, *in none of these instances has there been an allegation by the patentee's home state that Thailand has violated Article 31 TRIPS, and no complaint has ever been lodged with the WTO.*

Compulsory licenses do not only implicate commitments under the TRIPS Agreement. They also implicate the protections provided to investors and their investments under IIAs, which allow investors to bring claims against the states in which they invest. These protections include the protection against unlawful indirect expropriation, the guarantees of fair and equitable treatment ("FET") and non-discrimination (encompassing "national treatment" and "most-favored-nation treatment"), and the prohibition of the imposition of performance requirements.

Although the protections granted to investors under IIAs are often very broad, thus far, there has been no case in which an investor has claimed that the issuance of a compulsory license infringed the substantive protections set out in IIAs. Nevertheless, because compulsory licenses are an important policy tool for States and because of concerns that investor claims might arise in the future, modern IIAs, like the CPTPP and like the Regional Comprehensive Economic Partnership ("RCEP"), increasingly contain specific provisions curtailing how the treaties' substantive provisions apply to compulsory licenses.

The CPTPP, for example, contains provisions whereby claims of alleged unlawful expropriation and prohibited performance requirements based upon the issuance of a compulsory license are excluded so long as the compulsory license has been issued in compliance with Article 31 TRIPS Agreement and the CPTPP's intellectual property chapter (such provisions are called "TRIPS-plus obligations"). In light of the terms of Article 31 and the WTO's Doha Declaration, the CPTPP provides a strong degree of protection for the State against expropriation and performance requirements claims.

While the CPTPP contains an express exclusion of expropriation and performance requirements claims if the State has adhered to its TRIPS-plus obligations, the CPTPP does not include similarly express exclusions for claims based upon other substantive protections such as violations of the FET standard or the non-discrimination standards. This should not be seen, however, as creating a gap in the State's ability to defend itself in the event of an investor claim based upon a compulsory license. Given the due process requirements already contained in TRIPS Article 31, and the due process requirements found in CPTPP Chapter 18, it seems unlikely that the State's issuance of a TRIPS-plus compulsory license could give rise to a successful FET or discrimination claim. Moreover, it bears noting that beyond the inclusions of specific provisions addressed to compulsory licenses, modern treaties like CPTPP (and RCEP) have generally narrowed the scope of the protection afforded to investors under the FET standard and the non-discrimination standards as well. As a result, the scope of these protections, especially for matters related to public health, is already very narrow. Finally, it bears noting as well that beyond these narrowed limitations in the formulation of the substantive protections themselves, modern treaties also increasingly contain "General Exceptions" provisions which exempt the application of the treaty in situations in which the government is pursuing certain interests and further limits the ability of investors to bring claims.

As a result, this report concludes that the provisions of CPTPP, which are similar to the provisions of RCEP – a treaty to which Thailand is already a party – reflect the state-of-art in treaty drafting with respect to compulsory licensing. Taken together, the provisions of CPTPP provide strong protection from investor claims for States that issue compulsory licenses in accordance with the TRIPS Agreement and its intellectual property chapter.

INTRODUCTION

The Kingdom of Thailand ("Thailand") is seeking to examine the potential implications of its existing investment treaty obligations as well as the Comprehensive and Progressive Trans-Pacific Partnership ("CPTPP") on the issuance of compulsory licenses. Through a compulsory licensing regime, governments override the exclusive monopoly right granted to a patentee by authorizing third parties to use the patented product or process without the patentee's consent. The primary rationale behind a compulsory licensing regime is to allow a State to safeguard the interests of its population by promoting affordability and access to existing medical treatments and drugs, particularly in the context of public health emergencies such as HIV/AIDS and COVID-19. However, patentees, such as global pharmaceutical companies, may bring claims against the host State on the basis that the issuance of compulsory licenses infringes the State's investment treaty obligations, especially concerning the provisions governing indirect expropriation and, to a lesser degree, fair and equitable treatment ("FET"), non-discrimination (encompassing "national treatment" ("NT") and "most-favored-nation treatment" ("MFN")), and prohibitions on performance requirements ("PPRs"). Notwithstanding the risk of claims brought by investors, the number of claims relating to compulsory licenses that have arisen under World Trade Organization ("WTO") law and Investor-State Dispute Settlement ("ISDS") has been scarce – with *no examples of claims brought by investors under investment treaties having been found*.

With the evolution of treaty-making practice, recent Free Trade Agreements ("FTAs"), such as the CPTPP, have begun to specifically address the treatment of compulsory licenses by excluding them from the ambit of certain investment treaty obligations. In light of Thailand's potential accession to the CPTPP,[1] the risk profile posed by the CPTPP is of particular interest in this assessment.

Against this background, this paper organizes the research questions and findings in two parts.

a) **Part A** examines the national and international regimes governing patents that might be implicated by the issuance of compulsory licenses in **Chapter 1**. To this extent, the patent regime under international agreements such as the TRIPS and the 2001 Doha Declaration on TRIPS and Public Health ("the Doha Declaration"), as well as Thailand's domestic law, will be examined in relation to their treatment of compulsory licenses and patent rights.
b) **Part B** examines the implication of Thailand's investment treaty commitments on compulsory licensing regimes by addressing the following questions set out in **Chapter 2**:
    i) First, **Chapter 3** will examine the conditions for a patent to constitute an "investment" under treaties such as the CPTPP and the Regional Comprehensive Economic Partnership ("RCEP).

[1] Chien-Huei Wu, 'ASEAN at the Crossroads: Trap and Track between CPTPP and RCEP' (2020) *23 Journal of International Economic Law* 97, 98. Thailand's exports are expected to increase by 3.47 percent, and investment by 5.14 percent as a result of entering the CPTPP, increasing the country's gross domestic product (GDP) by 0.12 percent, or over 13.3 billion baht (nearly $410 million): Tita Sanglee, 'Will Thailand Ever Join the CPTPP?' (2021) *The Diplomat* <https://thediplomat.com/2021/11/will-thailand-ever-join-the-cptpp/> accessed 18 February 2022.

ii) Second, **Chapter 4** examines the possible application of investment treaty obligations to compulsory licensing regimes, focusing particularly on how such issues would be treated under the investment protection standards of older IIAs, which do not include articles addressing specific flexibilities regarding the State's exercise of its regulatory powers (the "right to regulate") and, specifically, its issuance of compulsory licenses.

iii) Third, **Chapter 5** looks closely at the provisions of modern IIAs, like CPTPP, that explicitly provide the State with flexibilities regarding its right to regulate and particularly its treatment of compulsory licenses. In so doing, Chapter 5 first illustrates the evolution of investment treaty drafting with respect to compulsory licensing and then examines the issues faced by tribunals in applying so-called "TRIPS-compliant" and "TRIPS-plus" provisions, as well as General Exceptions clauses which are present in a number of Thailand's recent IIAs.

iv) Finally, **Chapter 6** provides conclusions with respect to CPTPP.

PART A

Chapter 1: Patent Rights and Compulsory Licensing

This Chapter provides an overview of the international and domestic regimes for patent rights and compulsory licensing. This Chapter serves a foundational purpose, addressing the nature of the rights granted pursuant to a patent and a State's legal authority to limit those rights pursuant to a compulsory license. This background is critical to the analysis contained in Part B regarding the interaction of patent rights, compulsory licenses, and IIAs.

This Chapter begins by describing the international patent regulation regime under TRIPS (Chapter 1.1). It then proceeds to examine the protection of pharmaceutical patents under TRIPS, with particular emphasis on the standards for issuing compulsory licenses contained in Article 31 TRIPS (Chapter 1.2). Finally, this Chapter concludes with an overview of the national patent law of Thailand (Chapter 1.3), the legal framework governing compulsory licensing regimes, and the use of compulsory licensing in Thailand (Chapter 1.4).

1.1 The International Patent Regime under TRIPS

A patent is a "set of legal rights granted to an inventor" by a State.[2] A patent grants the patentee an exclusive right over its invention and prevents others from commercializing, using, marketing, distributing, importing, or selling the innovation without the patentee's permission for a specific period (usually 20 years). After the expiration period, the patent becomes available for public use. Patents are territorial in nature. An invention is therefore only protected in the State(s) in which patent protection has been granted.[3]

At the international level, the TRIPS Agreement, which forms part of the WTO legal order, represents the culmination of multilateral efforts to establish international disciplines for the protection of IP (such as patents).[4] TRIPS was signed alongside the Agreement establishing the WTO in 1994, as part of the "single undertaking" establishing the WTO.[5] All WTO members are, therefore, parties to TRIPS.

TRIPS does not establish uniform rules relating to IP. Rather, TRIPS establishes international minimum standards for the protection of IP which WTO members must ensure are met by their national legal systems.[6] States have discretion, therefore, to determine the means by which they

[2] Frederick M Abbott, 'Intellectual Property, International Protection' (2014) *Max Planck Encyclopedias of International Law*, para 3.
[3] World Intellectual Property Organization, 'Patents' <https://www.wipo.int/patents/en/index.html> accessed 13 February 2022.
[4] Simon Klopschinski, Christopher Gibson and Henning Grosse Ruse-Khan, *The Protection of Intellectual Property Rights Under International Investment Law* (Oxford University Press 2021), para 2.45.
[5] Suma Athreye, Lucia Piscitello and Kenneth C Shadlen, 'Twenty-Five Years since TRIPS: Patent Policy and International Business' (2020) 3 *Journal of International Business Policy* 315, 321.
[6] Article 1(1) TRIPS; Valentina Vadi, *Public Health in International Investment Law and Arbitration* (Routledge 2012), p. 71; Ping Xiong, 'Patents in TRIPS-Plus Provisions and the Approaches to Interpretation of Free Trade Agreements and TRIPS: Do They Affect Public Health?' (2012) 46 *Journal of World Trade* 155.

will comply with the TRIPS standards in their domestic laws.[7] Furthermore, because TRIPS sets "minimum" standards, and not "absolute standards", WTO members are free to set higher (so-called "TRIPS-plus") standards of protection in their national legal systems. IIAs or IP Chapters of FTAs (such as the IP chapters in RCEP and CPTPP) can also include TRIPS-plus standards.

1.2 Pharmaceutical Patents and Compulsory Licensing under TRIPS

TRIPS was the first international treaty to recognise pharmaceuticals as patentable. Article 27(1) TRIPS sets out that "patents shall be available for *any inventions*, whether products or processes, *in all fields of technology*, provided that they are new, involve an inventive step and are capable of industrial application."[8] Article 27(1) TRIPS also includes a non-discrimination requirement which states that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

The recognition of pharmaceuticals as patentable in TRIPS was a significant development. Prior to TRIPS, many (developing) States had not allowed patents for pharmaceuticals under their national laws, taking the view that the absence of patent protection would ensure affordable drug prices.[9] As a trade-off to recognising pharmaceutical patents in TRIPS, therefore, WTO members also gave international recognition to the practice of compulsory licensing in Article 31 TRIPS.[10]

As defined by the WTO, "[c]ompulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself."[11] Compulsory licensing is addressed in Article 31 TRIPS, although, notably, the article does not use the term. Instead, it refers to "[o]ther use without the authorisation of the right holder."[12]

Article 31 TRIPS does not set out uniform grounds upon which a compulsory license may be issued.[13] It is for each State to determine for itself what grounds can justify the issuance of compulsory licenses in national law.[14] Instead, Article 31 TRIPS adopts a flexible approach to compulsory licensing, establishing certain safeguards for the issuance of compulsory licenses, including that:

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[7] Athreye et al. (n. 5), p. 321.
[8] Emphasis added.
[9] See: Hilary Wong, 'The Case for Compulsory Licensing during COVID-19' (2020) 10 *Journal of Global Health* 1.
[10] Compulsory licenses are most often issued for patents covering pharmaceuticals.
[11] World Trade Organization, 'Compulsory Licensing of Pharmaceuticals and TRIPS' <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 24 January 2022.
[12] Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press 2020), p. 304.
[13] Athreye et al. (n. 5), p. 321; Vadi (n. 6), p. 76.
[14] 'WTO | Intellectual Property (TRIPS) - Fact Sheet - Pharmaceuticals - 2' <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm> accessed 16 February 2022).

a) each authorization of a compulsory license must be considered "on its individual merits";
b) a compulsory license may be authorized only if efforts have been made obtain authorization from the right holder on "reasonable commercial terms" (discussed further below);
c) the scope and duration of the compulsory license be limited for the purpose for which it was authorized;[15]
d) the use permitted under the compulsory license must be non-exclusive;
e) the use permitted under the compulsory license must be non-assignable; and
f) the use permitted under the compulsory license must be predominantly for the supply in the domestic market of the State authorizing the compulsory license;[16]
g) the authorisation of a compulsory license shall be subject to termination once the circumstances which gave rise to it have ended;
h) the rights holder shall be paid adequate remuneration "in the circumstances of each case, taking into account the economic valuation of the authorization";
i) the legal validity of the grant of a compulsory license shall be subject to judicial or administration review; and
j) the adequacy of the remuneration provides shall also be subject to judicial or administrative review.

Article 31(b) TRIPS establishes that before the use of a compulsory license, the government must have made efforts to obtain a voluntary license from the patentee on "reasonable commercial terms." However, this requirement is not necessary in cases of "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."

After the implementation of TRIPS, it was ambiguous whether a public health crisis could be seen as '"national emergency or other circumstance of extreme urgency" and would therefore allow a State to issue compulsory licenses without first attempting to obtain authorization from the rights holder on reasonable commercial terms and conditions. Particularly against the

[15] But Article 31 TRIPS Agreement does not provide a maximum duration for the issuance of CL. Instead, member states have the flexibility to determine the scope and longevity of such licenses; See: Ida Madieha bt and Abdul G Azmi, 'Scope and Duration of Compulsory Licensing: Lessons from National Experiences' in Reto M Hilty and Kung-Chung Liu (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer 2015), p. 209.

[16] Article 31(f) limits the amount countries which can manufacture drugs can export when the drug is made under a compulsory license. For countries dependent on imports due to their lack of manufacturing capacity and wanting to import generics it was difficult to find countries which could supply them with drugs produced under compulsory licenses. Article 31(f) posed a legal problem. As described by the WTO:

> "The legal problem for exporting countries was resolved on 30 August 2003 when WTO members agreed on legal changes [in a decision] to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves. The decision contain[ed] three waivers [for Article 31(f)]: Exporting countries' obligations under Article 31(f) are waived — any member country can export generic pharmaceutical products made under compulsory licenses to meet the needs of importing countries. Importing countries' obligations on remuneration to the patentee under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side. Exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement when at least half of the members were categorized as least-developed countries at the time of the decision. That way, developing countries can make use of economies of scale." (WTO Fact Sheet (n. 14)).

background of the HIV/AIDS epidemic, WTO members were struggling to find the right balance between patent protection and public access to essential medicines. Further, among non-governmental organizations and academics, some argued that the balance struck under the TRIPS had been skewed too far in favour of the private interests of the pharmaceutical industry,[17] and that the public interest (and need) for access to affordable medicines was not being sufficiently addressed.[18]

In an attempt to meet these concerns, WTO members agreed in 2001 to the Doha Declaration on the TRIPS Agreement and Public Health, which reaffirmed the wide discretion of WTO members to determine the appropriate grounds for issuing compulsory licenses, especially in the public health context. The Doha Declaration clarifies in paragraph 5(b) that *"[e]ach member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."*[19] Furthermore, paragraph 5(c) clarifies that:

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

The clarification of paragraph 5(c) Doha Declaration is significant in two ways. First, it makes clear that "public health crises" can represent a "national emergency or other circumstance of extreme urgency" under TRIPS Article 31. Second, it makes clear that each WTO member has the right to determine for itself what constitutes a national emergency or other circumstance of extreme urgency, including "public health crises," such as epidemics, for the purposes of issuing a TRIPS-compliant compulsory license under its national law.[20] As a result, a practical effect of paragraph 5(c) is that it allows governments to issue compulsory licenses in cases of national emergency or other circumstance of extreme urgency as those concepts are defined in their national compulsory licensing provisions, thereby exempting governments from the need to seek the prior authorization of the patentee (under Article 31(b) TRIPS).[21]

There seems to be no dispute that the Covid-19 pandemic as it exists today constitutes a public health crisis of the kind capable of justifying the issuance of compulsory licenses without seeking the prior authorization of the patentee under Article 31(b) TRIPS.[22] That said, it bears noting that the exception provided for national emergencies or other circumstances of extreme urgency, such as public health crises, is not unlimited but applies for so long as the situation

[17] The economist Joseph Stiglitz characterized the TRIPS compliant patent regime as "a death warrant for thousands of people in the poorest countries of the world." See: Wong (n. 9), 2 with reference to Joseph Stiglitz, *Making Globalization Work: The Next Steps to Global Justice* (Penguin 2007).
[18] Vadi (n. 6), p. 73; James T Gathii, 'The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties' (2001) 15 *Harvard Journal of Law & Technology* 291, 316.
[19] Content-wise, paragraph 5b has added nothing new to TRIPS. However, in contrast to Article 31 TRIPS, which refers to "[o]ther use without the authorisation of the right holder "it specifically refers to compulsory licenses". Article 31' Correa (n. 12), p. 306.
[20] 'Article 31' Correa (n. 12), p. 306.
[21] 'Article 31' Correa (n. 12), p. 306.
[22] Wong (n. 9), 2.

giving rise to the public health crisis persists.[23] Moreover, even though Article 31(b) TRIPS permits the issuance of a compulsory license in emergency situations without seeking the patentee's prior authorization, Article 31(b) also requires that the patentee be notified of the compulsory license "as soon as reasonably practicable." Further, it bears noting that Article 31(b) does not foresee any formal requirements for determining when a "national emergency or other circumstances of extreme urgency" exist.[24] WTO members can, for instance, declare a state of national emergency as part of the issuance of the compulsory license.[25]

The legal status of the Doha Declaration, however, remains unclear.[26] The language and drafting history of the Doha Declaration suggests that it was intended to be a non-binding statement of intent,[27] lacking the status of a "subsequent agreement" for the purposes of treaty interpretation under Article 31(3)(a) of the Vienna Convention on the Law of Treaties ("VCLT").[28] Nevertheless, in *Australia — Certain Measures Concerning Trademarks*, the WTO Panel stated that the Doha Declaration could be characterized as a "subsequent agreement" and therefore resorted to when interpreting TRIPS.[29] On appeal, the Appellate Body in the same case did not squarely address this issue, stating instead that "regardless of the legal status of the Doha Declaration, we see no error in the Panel's reliance on this general principle of treaty interpretation."[30] The legal status of the Declaration thus remains ambiguous, although it should be noted, as discussed in Chapter 5, that in newer FTAs, like CPTPP, the parties have clarified their intention to treat the Doha Declaration as binding in their relations.

Finally, it warrants noting, especially in light of the analysis in Chapter 5, that a number of the provisions in TRIPS Article 31 address issues of due process with respect to the patentee and the issuance of a compulsory license for its patent. For example, Article 31(a) requires that each authorization of a compulsory license must be considered "on its individual merits", providing protection to the patentee that the compulsory licensing decision will not be based on arbitrary or irrelevant criteria. Further, Article 31(c)-(f) provide substantive criteria for evaluating the legality of the compulsory license under the TRIPS Agreement by ensuring that

[23] 'Article 31' Correa (n. 12), p. 306.
[24] 'Article 31' Correa (n. 12), p. 306.
[25] 'Article 31' Correa (n. 12), p. 306.
[26] SK Verma, 'Chapter 18: The Doha Declaration and Access to Medicines by Countries Without Manufacturing Capacity' in Carlos M Correa (ed.), *Research Handbook on the Protection of Intellectual Property under WTO Rules* (Edward Elgar Publishing 2010), p. 644; Steve Charnovitz, 'The Legal Status of the Doha Declarations Part II: Quick Impressions of the Doha Results' (2002) 5 *Journal of International Economic Law* 207, 211.
[27] Eric M Solovy and Pavan Krishnamurthy, 'TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines' (2017) 50 *George Washington International Law Review* 91, 92.
[28] Eric M Solovy, 'The Doha Declaration at Twenty: Interpretation, Implementation, and Lessons Learned on the Relationship Between the TRIPS Agreement and Global Health' [forthcoming] *Northwestern Journal of International Law & Business* 5.
[29] *Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, Panel Report (28 June 2018) WT/DS435/R, para. 7.2409. Thailand was a third party in the case and considered in its third-party submission that the Doha Declaration should be seen as a "subsequent agreement" within the meaning of Article 31(3)(a) of the VCLTs as well (para. 7.2386) with reference to Thailand's third-party submission, para. 14.
[30] *Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, Appellate Body Report (9 June 2020), WT/DS435/AB/R, para 6.657.

the compulsory license is "proportionate", e.g., by limiting the license's scope and duration to that which is needed for the purpose for which it was authorized[31]; by requiring that the compulsory license be non-exclusive;[32] and by requiring that the authorisation of a compulsory license shall be subject to termination once the circumstances which gave rise to it have ended.[33] Finally, the due process owed to a patentee in the event of a compulsory license is also addressed under TRIPS Article 31(i) and (j). Under these provisions, the legal validity of a compulsory license, as well as the adequacy of the remuneration provided, must be subject to judicial or administrative review in the licensing State.[34]

1.3 Patent Rights under the National Law of Thailand

Thailand has been a member of the WTO since its inception in January 1995. After its WTO accession, Thailand's domestic law was amended to comply with TRIPS[35] and the principal legal instrument governing patent protection is the Patent Act B.E. 2522 (1979) ("Patent Act").[36] The Patent Act is complemented by Ministerial Regulations (of the Ministry of Commerce), which, *inter alia,* prescribe rules and procedures for patent applications. Article 3 Patent Act defines a patent as: "a document issued to grant protection for an invention or a design under the provisions of Chapter 2 (Patent for Inventions) and Chapter 3 (Patents for Designs) of this Act." Under the Patent Act, "invention" means any innovation or invention which creates a new product or process.[37]

As part of the patent application stage, the inventor must disclose a description of the invention in a manner that allows others to retrace the invention process.[38] In Thailand, patent applications must be filed with the Department of Intellectual Property of the Ministry of Commerce. Articles 17-20 Patent Act set out the patent application requirements. Under Article 17, the application shall contain: (1) the title of the invention, (2) a brief statement of its nature

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[31] TRIPS Art. 31(c).
[32] TRIPS Art. 31(d).
[33] TRIPS Art. 31(g).
[34] Notably, with respect to the availability of judicial review under TRIPS Article 31(i) and (j), TRIPS Articles 41-45 set out minimum standards for the review States must provide to patentees to enforce their patent rights against infringement, including unlawful compulsory licensing. For present purposes, it is sufficient to note that these articles require that, in pertinent part:

a) procedures concerning the enforcement of intellectual property rights shall be fair and equitable, and not unnecessarily complicated, costly or entail unreasonable time-limits or unwarranted delay (Article 41(b) and (c));
b) decisions on the merits of the case shall be based only on evidence in respect of which parties were offered the opportunity to be heard (Article 42);
c) parties shall be allowed to be represented by independent legal counsel and procedures shall impose overly burdensome requirements concerning mandatory personal appearances (Article 42);
d) judicial authorities shall have the authority to desist from an infringement (Article 44); and
e) judicial authorities shall have the authority to order the infringer to pay damages (Article 45).

[35] Andrea Morgan, 'Trips to Thailand: The Act for the Establishment of and Procedure for Intellectual Property and International Trade Court' (1999) 23 *Fordham International Law Journal* 795, 799.
[36] The authors have resorted to an English translation of the Patent Act which is accessible on the WIPO Lex Homepage: WIPO Lex, 'Thailand I Patent Act B.E. 2522 (1979)' <https://wipolex.wipo.int/en/legislation/details/3807> accessed 16 February 2022.
[37] Article 3 Patent Act.
[38] Abbott (n. 2), para. 4.

and purposes, (3) a detailed description of the invention,[39] (4) one or more clear and concise claims, and (5) other items prescribed in Ministerial Regulations. Patent applications can either be made on an individual basis exclusively in Thailand or as part of an international application under the Patent Co-operation Treaty,[40] which allows inventors to apply for a patent in several member countries at once.[41] Under Article 5 Patent Act, a patent may only be granted for inventions which are:[42] (1) new;[43] (2) involve an inventive step;[44] and (3) are capable of industrial application.[45] According to Article 35 Patent Act, a patentee's invention is protected for 20 years after the date of filing.

Article 36 Patent Act provides that no other person except for the patentee has the "right to produce, use, sell, have in the possession for sale, offer for sale or import the patented product." Under Article 38 Patent Act, the patentee can license the patent to others on contractually agreed terms, thus allowing third parties to exercise the rights conferred thereunder. For instance, if the patentee lacks manufacturing facilities, the patentee may enter into an agreement to license its patent to a third-party on such terms as the parties may agree.[46] Pursuant to Article 45 Patent Act, in the event that the patentee issues a license for its patent, the patentee must give notice of the license to the Director-General of the Department of Intellectual Property in order for the licensee to be entered onto the patent register.

[39] Article 17(3) Patent Act: "a detailed description of the invention in such full, concise and clear and exact terms as to enable any person ordinarily skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention and setting forth the best mode contemplated by the inventor to carry out his invention."

[40] Patent Co-operation Treaty (adopted 19 June 1970, entered into force 24 January 1978) 1160 UNTS 231; The Patent Co-operation Treaty is administered by the World Intellectual Property Organization and has 155 Contracting States. International patent applications have increased steadily since the Treaty entered into force. In 2020, 275 900 international patent applications were filed (amounting to a 4% increase as opposed to applications in 2019). World Intellectual Property Organization, 'Patent Cooperation Treaty Yearly Review 2021 - The International Patent System' (2021) World Intellectual Property Organization, p. 17 <https://www.wipo.int/publications/en/details.jsp?id=4548> accessed 10 March 2022.

[41] World Intellectual Property Organization, 'Patent Cooperation Treaty – The International Patent System' <https://www.wipo.int/pct/en/index.html> accessed 15 February 2022.

[42] Article 9 Patent Act excludes the following inventions from its protection: (1) naturally occurring microorganisms and their components, animals, plants, or extracts from animal plants; (2) scientific or mathematical rules or theories; (3) computer programs; (4) methods of diagnosis, treatment or cure of human and animal diseases; (5) inventions contrary to public order, morality, health or welfare.

[43] Pursuant to Article 6 Patent Act: "[a]n invention is new if it does not form part of the state of the art." Additionally, Article 6(1)-(5) set out specific situations where an invention is not regarded as new."

[44] Pursuant to Article 7 Patent Act: "[a]n invention shall be taken to involve an inventive step if it is not obvious to a person ordinary skilled in the art."

[45] Pursuant to Article 8 Patent Act: "[a]n invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including handicrafts, agriculture and commerce."

[46] 'Article 31' Correa (n. 12), p. 308.

1.4 Compulsory Licensing under the National Law of Thailand and its Application

In addition to allowing the patentee to exploit its patent rights through the issuance of voluntary licenses, the Patent Act also contains provisions for the grant of compulsory licenses to private parties (Article 46,[47] Article 47,[48] Article 47bis[49] Patent Act) and to the State in order to address public needs (Article 51, Article 52 Patent Act).[50] Of relevance here are the grounds of "public need" set out in Articles 51-52:

Article 51 Patent Act ("public non-commercial use of patented substances for meeting the public needs"):[51]

> "In order to carry out any service for public consumption or which is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of *the Government may*, by themselves or through others, *exercise any right under Section 36*[52] by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of Section 48 and shall notify the

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[47] 'Non-working or inadequate working of patents so as to meet the local demand for the patented products'; Jakkrit Kuanpoth, 'Compulsory Licences: Law and Practice in Thailand' in Reto M Hilty and Kung-Chung Liu (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer 2015), p. 71. Article 46 reads as follows:

> "At any time after the expiration of three years from the grant of a patent or four years from the date of application, whichever is later, any person may apply to the Director-General for a license if it appears, at the time when such application is filed, that the patentee unjustifiably fails to exercise his legitimate rights as follows: (1) that the patented product has not been produced or the patented process has not been applied in the country, without any legitimate reason; or (2) that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices or does not meet the public demand, without any legitimate reason.

[48] '[U]se for working of dependent patents' (Kuanpoth (n. 47)), Article 47 reads as follows:

> "If the working of any claim in a patent is likely to constitute an infringement of a claim in a patent of any other person, the patentee, desiring to exploit his own patent, may apply to the Director-General for a license under the patent of the other person under the following criteria: (1) the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied; (2) the patentee shall be entitled to a cross-license on reasonable terms; (3) the applicant shall not assign his right in the license to other persons except with the assignment of his patent."

[49] '[U]se for working of dependent patents' Kuanpoth (n. 47). Article 47bis reads as follows:

> "If the working of any claim in the patent having obtained a license under Section 46 is likely to constitute an infringement of a claim in a patent of any other person, the applicant for a license under Section 46 may apply to the Director-General for a license under the patent of the other person under the following criteria: (1) the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied; (2) the applicant shall not assign his right in the license to other persons. The applicant for a license must show that he has made an effort to obtain a license from the patentee having purposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period."

[50] Kuanpoth (n. 47), p. 71.

[51] Kuanpoth (n. 47), p. 71.

[52] Section 36 Patents Act includes the right to produce, use, sell, have in the possession for sale, offer for sale or import the patented product.

patentee in writing without delay, notwithstanding the provisions of Sections 46, 46bis and 47."

Article 52 Patent Act ("use for public interest due to war or national emergency"):[53]

> "During a state of war or emergency,[54] *the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any right under any patent* necessary for the defense and security of the country by paying a fair remuneration to the patentee and shall notify the patentee in writing without delay."

As noted above, Thailand's domestic framework for the issuance of compulsory license is subject to the disciplines contained in Article 31 TRIPS. According to the TRIPS Flexibilities Database,[55] there have been seven instances in which Thailand has issued compulsory licenses pursuant to Article 31 TRIPS which complied with Article 51 Patent Act:[56] HIV/AIDS drugs (3 compulsory licenses),[57] cancer drugs (3 compulsory licenses),[58]and one compulsory license for a cardiovascular drug.[59] Notably, in one instance involving a cancer drug, the compulsory license ultimately was not executed as the patentee donated the drug and the issuance of a compulsory license was therefore no longer necessary.[60]

In all of these cases, the issuance of the compulsory licenses was justified to secure access to essential drugs that had been proven effective and crucial for treating the subject diseases.[61] These seven instances were the first time compulsory licenses were ever granted under the Patent Act.[62] According to Kuanpoth, compulsory licenses had not been granted before due to implementation constraints such as a lack of knowledge of how compulsory licenses could be

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[53] Kuanpoth (n. 47), p. 74.

[54] 'Section 52 authorizes the use of patented products in cases of a national emergency, e.g., health-related emergencies due to an insufficient availability of drugs on HIV/AIDS, anthrax, SARS, and bird flu.' See: Kuanpoth (n. 47), p. 72.

[55] The TRIPS Flexibilities Database lists instances where states have "invoked, planned to invoke, or have been asked to invoke a TRIPS flexibility for public health reasons, in particular to assure access to medicines." The database describes itself as being non-exhaustive. See The TRIPS Flexibilities Database, <http://tripsflexibilities.medicineslawandpolicy.org/> accessed 10 March 2022.

[56] Inthira Yamabhai et al., 'Government Use Licenses in Thailand: An Assessment of the Health and Economic Impacts' (2011) 7 *Globalization and Health* 28, 2.

[57] 1. November 2006: Patentee Merck, Invention: Efavirenz drug; 2. January 2007: Patentee Abbot, Invention: Lopinavir/Ritonavir drug; 3. September 2008: Patentee BMS, GSK, Invention: AZT, 3TC, D4T, NVP, 3TC/AZT (TRIPS Flexibilities Database (n. 55)). See generally: Wong (n. 9), 2.

[58] 1. January 2008: Patentee Novartis, Invention: Imatinib drug; 2. January 2008: Patentee Novartis, Invention: Letrozole; 3. January 2008: Patentee Roche, Invention: Tarceva. (TRIPS Flexibilities Database (n. 55)).

[59] February 2007: Patentee Sanofi-Aventis, BMS, Invention: Clopidogrel, (TRIPS Flexibilities Database (n. 55)).

[60] TRIPS Flexibilities Database (n. 55). Wong suggests that this situation illustrates the fact that sometimes the government's announced intention to invoke a compulsory license may lead the patentee to offer a discount or voluntary license rather than become subject to the compulsory license's involuntary terms. Wong (n. 9), 2. However, according to the Program on Information Justice and Intellectual Property, Novartis gave the donation to Thailand only under the condition that it "stops its drive for generic drugs." Timeline for US-Thailand Compulsory License Dispute: Version 3 (2009) Washington College of Law, p. 13, <http://infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf> accessed 6 April 2022

[61] Yamabhai et al. (n. 56), 2.

[62] Jakkrit Kuanpoth, 'Appropriate Patent Rules in Developing Countries-Some Deliberations Based on Thai Legislation' (2008) 13 Journal of Intellectual Property Rights 447, 447.

granted and justified.[63] The following table gives an overview of Thailand's issuance of compulsory licenses.

Table 1: List of Thailand's Issuance of Compulsory Licenses[64]

Date	Patentee	Drug	Disease	Royalty Rate[65]	Additional Information
November 2006	Merck	Efavirenz, EFV	HIV/AIDS	0.5%	-
January 2007	Abbot	Lopinavir and Ritonavir, LPV/r	HIV/AIDS	0.5%	-
February 2007	Sanofi-Aventis, BMS	Clopidogrel	Cardiovascular Disease	0.5%	-
January 2008	Novartis	Imatinib	Cancer	Not Applicable	No execution of compulsory license due to donation
January 2008	Novartis	Letrozole	Cancer	Unknown	-
January 2008	Sanofi-Aventis	Docetaxel	Cancer	Unknown	-
January 2008	Roche	Tarceva	Cancer	Unknown	-

It warrants noting that Thailand has faced retaliation in response to the issuance of compulsory licenses in the past. Following a compulsory license issued for an HIV/AIDS drug in 2007, for example, Abbott, a pharmaceutical conglomerate, stopped the application of new patents in Thailand.[66] Moreover, in connection with this incident, the United States placed Thailand on the watch list of its annual Special 301 report, which evaluates IP practices globally and

[63] ibid.
[64] This table is based on the TRIPS Flexibilities database. See The TRIPS Flexibilities Database (n. 55). More information on the specific issuances of compulsory licenses can be found in the following documents: 1. Ministry of Public Health and The National Health Security Office Thailand, 'Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand' (2007), p. 41, <http://apps.who.int/medicinedocs/documents/s18718en/s18718en.pdf> accessed 6 April 2022; 2. Timeline for US-Thailand Compulsory License Dispute: Version 3 (2009) *Washington College of Law* 4, <http://infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf> accessed 6 April 2022; 3. Health Intervention and Technology Assessment Program, Assessing the implications of Thailand's government use licenses, issued in 2006–2008 (2009), p. 1, 24, available at http://www.hitap.net/en/research/17635 accessed 6 April 2022; 4. Yamabhai et al. (n. 56); 5. Timeline for US-Thailand Compulsory License Dispute (2009) Program on Information Justice and Intellectual Property, p. 4, available at <http://www.infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf> accessed 6 April 2022.
[65] Percentage of sale value in royalty fees. Timeline for US-Thailand Compulsory License Dispute: Version 3 (n. 62), 4.
[66] Donald Harris, 'TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing' (2011) 18 *Journal of Intellectual Property Law* 369, 387.

addresses cases that raise investment and innovation concerns.[67] What is noteworthy, however, is that neither Abbot nor the United States accused Thailand of having breached Article 31 TRIPS.

Thailand has also faced criticism for its issuance of compulsory licenses from the European Commission. Before granting the last three compulsory licenses for cancer drugs in January 2008 (see Table 1),[68] the drugs were initially marked for voluntary licensing.[69] Ultimately, however, Thailand issued compulsory licenses for these drugs.[70] In a 2008 letter, the Commission encouraged Thailand to resort to the issuance of voluntary instead of compulsory licenses and stated the following: "The Commission does not question Thailand's right to issue compulsory licenses [...], but we do have doubts, from a policy point of view, on a systematic recourse to compulsory licenses that could eventually be detrimental to the overall objective of the patent system, i.e., innovation and the development of new medicines."[71] As a final remark, it should be mentioned that the seven compulsory licenses issued by Thailand were neither contested in the Thai courts by the patentees nor sent to the WTO TRIPS Council or submitted to the WTO dispute resolution mechanism by any member State.[72]

[67] Athreye et al. (n. 5), p. 320.
[68] 1. January 2008: Patentee Novartis, Invention: Imatinib drug; 2. January 2008: Patentee Novartis, Invention: Letrozole; 3. January 2008: Patentee Roche, Invention: Tarceva (TRIPS Flexibilities Database (n. 55)).
[69] Timeline for US-Thailand Compulsory License Dispute: Version 3 (n. 62).
[70] Timeline for US-Thailand Compulsory License Dispute: Version 3 (n. 62).
[71] Letter by Peter Mandelson, Member of European Commission, 16 June 2008, <https://tacd.org/wp-content/uploads/2013/09/TACD-IP-2008-Response-from-Comissioner-Mandelson-regarding-compulsory-licensing.pdf > accessed 7 April 2022.
[72] Yamabhai et al. (n. 56), 2.

PART B

Chapter 2: International Investment agreements, Patents, and Compulsory Licensing

Over the past 30 years, international treaties for the promotion and protection of investment have proliferated, with over 3,000 such treaties concluded to date. Thailand has concluded 48 investment IIAs: both BITs and FTAs, with investment chapters.[73]

In broad terms, IIAs provide special protections to foreign investors in host States, such as protections against discrimination and uncompensated expropriation, as well as guarantees of fair and equitable treatment. Generally speaking, the disciplines imposed by these treaties are applicable in relation to any measure attributable to the State in respect of a covered "investment" (or "investor"), regardless of the subject matter of the measure (e.g., environment, public health, energy policy, etc.), regardless of the responsible organ of government, and regardless of the sector of the investment. In addition, investment treaties establish specialized dispute settlement mechanisms. Under IIAs, foreign investors may bring claims for breach of the treaty against the host State before an international arbitration tribunal, generally without having to go first through the host State's domestic courts.

In the context of the present inquiry into the interaction of investment treaty protections, patent rights, and compulsory licensing, questions arise under three broad heads: (1) whether a patent can qualify as a covered "investment" for the purposes of protection under an IIA; (2) whether the issuance of a compulsory license can in principle implicate (and possibly infringe) the substantive protections applicable to an investment under an IIA; and (3) whether specialized provisions within IIAs can serve to eliminate the risk of claims as a result of the issuance of a compulsory license. Part B addresses these questions in the following three chapters.

[73] Can be accessed at <https://investmentpolicy.unctad.org/international-investment-agreements/countries/207/thailand> accessed 8 April 2022

Chapter 3: The Coverage of Patents as "Investments" under International Investment Agreements

This Chapter addresses whether a patent can qualify as an "investment" under an IIA and can thereby benefit from the IIA's substantive protections. This is a threshold question to the issue of whether compulsory licenses can infringe investor rights insofar as IIAs only protect "investments" as defined under the specific, applicable IIA.[74] Accordingly, the broader question of whether the issuance of a compulsory license violates obligations under an IIA necessarily starts with a determination of whether the patent qualifies as an "investment" in the first place.

3.1 Do Patents Qualify as "Investments" under Thailand's International Investment Agreements

Almost all of the 48 IIAs to which Thailand is a party contain a so-called "asset-based" definition of "investment". Under an asset-based definition of investment, an investment is defined solely with reference to a non-exhaustive list of assets which may qualify as protected investments for the purpose of the IIAs. 47 of Thailand's 48 IIAs specifically include IP rights within the list of assets that constitute an investment, with ten specifically mentioning patents.[75]

The definition of investment contained in the Thailand-Myanmar IIA (2008) provides a representative example of the asset-based approach to defining an investment:

> "For the purpose of this Agreement:
>
> 1. The term "investment" shall mean every kind of asset and in particular, though not exclusively, includes:
>
>   a) movable and immovable property and any other property rights such as mortgages, liens and pledges;
>
>   b) shares, stocks and debentures of a company and any other similar forms of participation in a company;
>
>   c) claims to money and any other rights to performance under contract having an economic value;
>
>   d) *intellectual property and industrial property rights as recognised by the law of the Contracting Party in whose territory the investment is made,* know-how, and goodwill;

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[74] See, e.g.,: Article 8.1 of the Canada-Thailand BIT (1997) prohibits the nationalization, expropriation, or subjecting to measures, including taxation measures, having an effect equal to nationalization or expropriation of "investments or investors of either Contracting Party".

[75] The reference to IP rights in the list of investment assets is broad enough to include patents, which are a form of recognized IP right under Thai law. See above: Chapter 2. See also: Carlos M Correa, 'Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses' (2004) 26 *Michigan Journal of International Law* 331, 340.

e) business concession, license, authorisation, and permit, conferred pursuant to laws and regulations or contracts including concessions to search for, cultivate, extract, or exploit natural resources."[76]

Arbitral tribunals, which have interpreted and applied asset-based definitions of investment in cases involving IP rights, e.g., trademarks and patents, have routinely concluded that the IP rights in question qualify as protected investments.[77] Given the breadth of the asset-based approach, this is not surprising.

Asset-based definitions of investment remain the most common approach used in IIAs. Recent treaties, however, like CPTPP and RCEP, have refined the asset-based definition by including language which elaborates that the asset in question must not only be within the class of protected assets listed in the treaty but also that it must possess certain "characteristics of an investment", for example, the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk. The CPTPP provides an example:

> "Investment means every asset that an investor owns or controls, directly or indirectly, that has the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk. Forms that an investment may take include:
> [...]
>
> f) *intellectual property rights. . . .*"[78]

These additional criteria largely derive from the jurisprudence of arbitral tribunals called upon to interpret the meaning of "investment" in Article 25 of the ICSID Convention, e.g., *Salini Costruttori v. Morocco*[79] and its progeny.[80] As is well known, the tribunal in *Salini* interpreted the meaning of "investment" under Article 25 of the ICSID Convention as requiring (a) a substantial contribution of money or assets, (b) a certain duration of performance of contract, (c) an element of risk assumed by the investor, and (d) a contribution to the economic development of the host State.

While the *Salini* decision has been criticized over the years on various grounds, its examination of the characteristics of an investment has been influential, not only in cases interpreting ICSID Article 25 but also in cases interpreting the meaning of investment in non-ICSID cases.[81] Further, the *Salini* criteria have influenced the way in which States draft their treaties, as

[76] Article 1.1 Agreement Between the Government of the Kingdom of Thailand and the Government of the Union of Myanmar for the Promotion and Protection of Investments.
[77] See, e.g.,: *Philip Morris Brands Sàrl, Philip Morris Products SA and Abal Hermanos SA v. Oriental Republic of Uruguay,* ICSID Case No ARB/10/7, where the tribunal held that trademarks and goodwill associated with the use of trademarks are protected investments.
[78] Article 9.1 CPTPP. RCEP is to the same effect: "*investment* means every kind of asset that an investor owns or controls, directly or indirectly, and that has the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gains or profits, or the assumption of risk." RCEP, Article 10.1(c) (emphasis in original).
[79] *Salini Costruttori S.p.A. and Italstrade S.p.A. v. Morocco*, ICSID Case No. ARB/00/4.
[80] See, e.g., *Joy Mining Mach. Ltd. V. Egypt*, ICSID Case No. ARB/03/11.
[81] See, e.g.,: *Romak S.A. (Switzerland) v. The Republic of Uzbekistan*, UNCITRAL, PCA Case No. AA280.

evidenced by the express inclusion of language on the "characteristics of an investment" in the CPTPP and RCEP.

That said, it bears noting that while the *Salini* elements have been broadly influential, the final *Salini* element of "contribution to the economic development of the host State of the investment" has not generally been adopted by other tribunals[82] or by States in their treaty practice. Indeed, it has not been included in either the CPTPP or RCEP.

For present purposes, one question for consideration is whether the inclusion of language elaborating on the "characteristics of investment" in treaties like CPTPP and RCEP is likely to affect whether IP rights and patents specifically will be treated as covered investments.

To date, there has been little case law that has considered whether IP rights, and patents specifically, qualify as investments either under treaties that include language on the "characteristics of investment", such as CPTPP and RCEP or under Article 25 of the ICSID Convention with its elements similar to the *Salini* criteria. That said, the 2017 award in *Bridgestone v. Panama*[83] may offer some insight into at least one of the issues that the "characteristics of investment" analysis may raise.

In *Bridgestone*[84], the tribunal considered the issue of whether a trademark alone could constitute a protected investment under the United States-Panama Trade Promotion Agreement. It also looked at whether a license agreement for the use of that trademark constituted an investment. *Bridgestone*[85] was brought under the ICSID Convention, and thus the tribunal's analysis took account of the *Salini* criteria. Nevertheless, given the general similarity of the elements considered under the *Salini* approach and the characteristics identified in treaties like CPTPP and RCEP, the tribunal's analysis may provide insight into how those treaties may be interpreted in the future.

In conducting its analysis, the tribunal considered that the promotion of trademarks in the host country had involved the commitment of resources over a significant period of time, the expectation of profit, and the assumption of risk that the particular features of the product (automotive tires) might not prove sufficiently attractive to enable it to win or maintain market share in the face of competition. In the tribunal's view, therefore, the trademark satisfied the three generally accepted *Salini* criteria.[86]

However, the *Bridgestone*[87] tribunal went on to find that the mere registration of a trademark in a country *per se* did not amount to, or have the characteristics of, an investment in that country. In the tribunal's view, this conclusion came about by looking at the nature of the rights

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[82] The tribunal in Quiborax S.A., Non-Metallic Minerals S.A. and Allan Fosk Kaplún v. Plurinational State of Bolivia, ICSID Case No. ARB/06/2.

[83] *Bridgestone Licensing v. Panama Services, Inc. and Bridgestone Americas, Inc. and Republic of Panama, ICSID* Case No. ARB/16/34.

[84] *Bridgestone v. Panama* (n. 83).

[85] *Bridgestone v. Panama* (n. 83).

[86] The *Bridgestone* tribunal did not consider a "fourth" *Salini* criterion, namely whether the titular investment contributed to the economic development of the host state.

[87] *Bridgestone v. Panama* (n. 83).

protected under a trademark. As the tribunal observed, a trademark essentially grants the holder a "negative" right – it allows the trademark holder to prevent competitors from using the trademark on their products. In and of itself, therefore, a trademark does create any expectation of profit for the trademark owner. Consequently, according to the tribunal, for a trademark to qualify as an investment, it must, in fact, be exploited in the territory of the host State by the trademark owner. Simple registration of the trademark is not enough. It is through the exploitation of the trademark that it develops the characteristics of an investment, though, for example, the dedication of resources associated with the production of the articles sold bearing the trademark and the dedication of resources to promote and support those sales. Moreover, such exploitation would also likely involve after-sales servicing and guarantees. All of these activities taken together would give a trademark the characteristics of an investment.

Applying the award in *Bridgestone*[88] to the subject matter of the present paper, it seems likely that tribunals would conclude that registered patents satisfy the first two requirements under the *Salini* criteria, namely the contribution of assets and duration. Patents require a substantial commitment of financial and other resources to create, develop, and obtain protection for them and exclude competitors from using the invention. Regarding the second criteria, IP owners normally secure their IP rights with the expectation that those rights will underpin related economic activities for a significant term (as most countries grant patent rights for as long as 20 years[89]). However, to satisfy the criteria of creating an expectation of risk or profit for the patent owner, the investor would need to show exploitation of the patent through sales and other allied activities. This is because a patent, similar to a trademark, merely creates negative rights in allowing the patent holder to prevent competitors and third parties from manufacturing, selling, using, importing, or in any way utilizing the patented invention.[90] For the use of the patent, the patent-holder needs to apply for further regulatory approvals, such as marketing approvals, for which additional information, including the results of clinical and other data needs to be submitted. Thus, similar to trademarks, patent holders would need to show exploitation of the patent to be able to bring it under the definition of investment in the newer treaties, namely CPTPP and RCEP.

3.2 Does Clinical Data for Marketing Approval Qualify as Investment?

The development and marketing of a new drug is not only about patent protection. Once a patent on a pharmaceutical product is obtained, the next step is to seek marketing approval from the host State by demonstrating the product's efficacy and safety for its intended use. This requires originators to submit to government regulators undisclosed, proprietary information on the results of testing done on humans and animals in pre-clinical and clinical trials, as well as data on toxicology, manufacturing feasibility, and other scientific studies.[91] For new drugs, the costs of this pre-market process can run anywhere from USD 1.3 billion to USD 1.7

[88] *Bridgestone v. Panama* (n. 83).
[89] See, for e.g., the patent regime in the US.
[90] Richard S. Shear and Thomas E. Kelly, *A Researcher's Guide to Patents*, National Centre for Biotechnology Information, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC526265/> accessed 17 April 2022.
[91] Maximiliano Santa Cruz Scantlebury and Denisse Pérez Fierro, 'IP in the TPP: How Far Beyond the Existing FTAs Does it Go?' in Jorge A Huerta-Goldman and David A Gantz (eds.), *The Comprehensive and Progressive Trans-Pacific Partnership* (Cambridge University Press 2021).

billion.[92] As a result, pharmaceutical manufacturers have long been concerned that unless this proprietary information is protected from disclosure, it might be distributed by the government of the host State to its domestic manufacturers without the need of a compulsory license, and the attendant requirements of due process and compensation.[93]

Proprietary information produced in support of the marketing of a patented drug has only recently come to be addressed in IIAs. CPTPP, however, is an exception and contains provisions that deal specifically with this issue.[94] There are specific provisions not only for new pharmaceutical products, but also for new pharmaceutical products containing biologics, which could cover vector vaccines.[95] Host States cannot permit third persons from marketing the same or similar products based on either this information, or the marketing approval granted. This restriction extends for a period of five years from the date of granting the marketing approval in the territory of the host State for new pharmaceutical products, and eight years for biologics, without the consent of the original person who had submitted the data. The CPTPP provides the flexibility for the period of protection of data concerning pharmaceutical products containing biologics to be reduced to five years, provided that this shorter period is backed up by additional market protection measures. Further, for new clinical information submitted in support of marketing approval for a pharmaceutical product that has already been approved, covering a new indication, formulation, or method of administration, the period of protection stipulated is 3 years.

One issue that can arise in this regard is whether the data submitted for obtaining marketing approval in the context of pharmaceutical products, proprietary in nature, could be argued to be an investment under the definition of investment given under the IIAs. While there is very little literature on the matter, it could be argued that such data satisfies the definition of an "investment" under the head of "other tangible or intangible, movable or immovable property, and related property rights, such as leases, mortgages, liens and pledges."[96] Such data can also be argued to satisfy the other characteristics required for a transaction to qualify as an investment under newer treaties such as the CPTPP and RCEP, namely, a substantial contribution of money or assets, a certain duration of performance of the contract, and an element of risk assumed by the investor.

However, in *Apotex Holdings Inc. and Apotex Inc. v. United States of America,*[97] a North American Free Trade Agreement ("NAFTA") tribunal held that an application submitted by Apotex for marketing approval in the US and the confidential information contained therein did not amount to an investment, notwithstanding the fact that this information might be proprietary in nature. The tribunal held that the process of seeking regulatory approval for marketing of a pharmaceutical product via an application could not change the nature of the

[92] Roger Collier, *Rapidly Rising Clinical Trial Costs Worry Researchers*, National Centre for Biotechnology Information, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2630333/> accessed 17 April 2022.
[93] Scantlebury et al. (n. 91).
[94] See Section F (Patents and Undisclosed Test or Other Data), Sub-Section C (Measures Relating to Pharmaceutical Products) (Articles 18.48-18.54) CPTPP.
[95] Vector vaccines use a modified version of a vector to deliver genetic instruction to the body's cells. The cells then produce harmless pieces of the virus called antigens which trigger an immune response in the body.
[96] See, e.g.,: The definition of "investment" under Article 9.1 CPTPP.
[97] *Apotex Holdings Inc. and Apotex Inc. v. United States of America*, ICSID Case No. ARB(AF)/12/1.

underlying activity or constitute investment in and of itself. This is despite the fact that investment is defined very broadly in NAFTA to include all forms of tangible or intangible property, including intellectual property. Thus, it seems unlikely that the data submitted for marketing approvals can constitute an investment.

At any rate, the link between compulsory licenses and the data submitted for marketing approvals seems tenuous, even though it makes commercial sense for a compulsory license to also include the information submitted for obtaining marketing approvals. This is because of the differential treatment of compulsory licenses and the exception for the disclosure of data submitted for obtaining marketing approval under TRIPS. Article 31 TRIPS provides for compulsory licenses to be granted by states; these are, however, restricted to the "subject matter of the patent". The exception for the disclosure of data submitted for obtaining market approval has been dealt with under Article 39(3) TRIPS. This article allows for disclosure of confidential data submitted for obtaining marketing approval of pharmaceutical or agricultural products which utilize new chemical entities, in the situation where it is necessary to protect the public, as long as steps are taken to ensure that the data is protected against unfair commercial use. This would mean that to ensure the effective use of a patent, the host government would have to not only grant a compulsory license but also allow for the disclosure of the data submitted for obtaining a marketing approval and justify it under the exception in TRIPS.

The intellectual property chapter of CPTPP also provides for an exception for disclosure of the data submitted for obtaining a marketing approval, under Article 18.50(3)(a). This exception provides:

> "Notwithstanding paragraphs 1 and 2 and Article 18.51 (Biologics), a Party may take measures *to protect public health* in accordance with:
>
> (a) The Declaration on TRIPS and Public Health…"

The Doha Declaration, under Article 4 provides that:

> "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitments to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.
>
> In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

These two provisions read together thus seem to re-affirm the exception in favour of public interest, provided under Article 39(3) TRIPS.

Thus, when a state requires a company to make testing data available -- a) it would most likely not qualify as an investment, and b) even if it would, it would most probably fall under the flexibility arrangements of TRIPS and TRIPS-plus. Thereby it can be argued that the disclosure would not be violative of the expropriation or other substantive protection standards under IIAs.

Chapter 4: Compulsory Licenses and Substantive Protections of International Investment Agreements

Having determined in Chapter 3 that it is possible in principle for a patent to qualify as an investment under an IIA, this Chapter considers whether the issuance of a compulsory license for a patent may, in principle give rise to potential claims under the substantive protections of IIAs.[98] While specific provisions governing States' obligations in relation to investment protection vary from treaty to treaty, there are certain general obligations which appear across all of Thailand's IIAs, namely: expropriation protection, FET, and non-discrimination (encompassing NT and MFN).[99] The potential application of these protections in the context of the issuance of a compulsory license is considered in Chapters 4.1, 4.2, and 4.3 below. In addition, this Chapter also considers the impact of IIA provisions that impose PPRs (Chapter 4.4). Although PPRs provisions are relatively uncommon in Thailand's IIAs, they are considered here, in part, because of their inclusion in RCEP as well as in the CPTPP.

At the outset of the analysis contained in this Chapter, two points of clarification should be made. First, this Chapter does not address the application of provisions found in some IIAs which expressly address the State's right to issue a compulsory license – such as are included in RCEP and CPTPP. These provisions are treated separately in Chapter 5. Second, this Chapter does not discuss other provisions found in some IIAs which address the State's right to regulate for the public good more broadly, such as general exceptions provisions, which are also found in RCEP and CPTPP. Again, these provisions are treated separately in Chapter 5. The reason for dividing our analysis in this way is that not all of Thailand's IIAs contain either specialized provisions regarding the treatment of compulsory licenses or provisions addressing the State's right to regulate more generally.[100] Consequently, the relevant analysis under many of Thailand's treaties, with respect to a claim based upon the issuance of a compulsory license, will depend exclusively on the way in which the treaty's 'baseline' protections are interpreted and applied.

[98] Ermias T Biadgleng, 'IP Rights under Investment Agreements: The TRIPS-Plus Implications for Enforcement and Protection of Public Interest' (2006) South Centre Research Paper, p. 7.

[99] Only the ASEAN-Australia-New Zealand FTA and ASEAN-India Investment Agreement do not include an MFN clause; however, the latter, while signed, is not in force, thus this does not have any practical ramifications. The New Zealand-Thailand CEPA does not include FET and Full protection and security ('FPS') clauses, the Investment Agreement among the Governments of Brunei Darussalam, Indonesia, Malaysia, Philippines, Singapore, and Thailand includes neither an NT, nor an FPS clause, and the Australia-Thailand FTA does not include an FPS clause. However, setting a minimum level of investment protection, an expropriation clause is present across all of Thailand's treaties with investment provisions. Further, the RCEP, ASEAN-Australia-New Zealand FTA, and the ASEAN Comprehensive Investment Agreement also include a prohibition against performance requirements which will become relevant for the purposes of the present analysis. FPS obligations are also present across Thailand's investment treaties; however, this standard will not form part of the present analysis.

[100] The sole exception from this is the Canada-Thailand BIT (1997), which expressly exempts the issuance of CLs from the ambit of its expropriation provision (Article 6.1(b)), if the issuance is in accordance with the TRIPS Agreement and provides for a general exception clause under Article 17.3.

4.1 Expropriation

Expropriation concerns the taking of private property, directly or indirectly, by the State for a public purpose. A 'direct' expropriation refers to the situation in which ownership of a protected investment is legally transferred from the investor to the State or to entities for which it is responsible. An 'indirect' expropriation refers to the situation in which, even though legal ownership has not been transferred from the investor to the State, the State has taken a measure (or measures) that have the effect of depriving the investor of the economic use and enjoyment of the investment as though the State had taken the investment directly. Virtually all modern IIAs provide protection with respect to both direct and indirect expropriation.[101]

As a compulsory license does not involve a transfer of legal title to the patent, the investor is not formally deprived of its ownership rights. Accordingly, a claim for a direct expropriation based upon the issuance of a compulsory license would not be possible.[102] Still, insofar as compulsory licenses constitute an interference with the investor's property – i.e., the investor's exclusive patent rights – it must be considered whether the investor might nevertheless be able to bring a claim against the State for an indirect expropriation.

As noted above, a claim for an indirect expropriation rests on a threshold showing the measures taken by the State have been tantamount to a direct expropriation.[103] In other words, the investor must demonstrate at the outset that the State's measure(s) have interfered with its property rights "to such an extent that these rights are rendered so useless that they must be deemed to have been expropriated" even though legal title formally remains with the original owner.[104] Assuming that the investor can satisfy this showing of sufficient interference with its rights, it then may fall to the State to argue that no compensation should in any case be due to the investor in light of the nature and character of the measure and the public purpose for which it was adopted.[105] Lastly, even if the State is able to put forward a compelling reason why it adopted the challenged measure(s), the investor may yet argue that the measures either lacked proportionality, and/or violated the investor's legitimate expectations.[106]

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[101] Rudolf Dolzer and Christoph Schreuer, *Principles of International Investment Law* (Oxford University Press 2012), p. 101.

[102] United Nations Conference on Trade and Development, 'Investor-State Dispute Settlement and Impact on Investment Rulemaking' (2007) UNCTAD/ITE/IIA/2007/3, p. 75-76; Andrew Newcombe, 'The Boundaries of Regulatory Expropriation in International Law' (2005) 20 *ICSID Review* 1, 9-11.

[103] E.g.: *Pope & Talbot Inc. v. The Government of Canada,* UNCITRAL, Interim Award (26 June 2000); *S.D. Myers, Inc. v. Government of Canada*, UNCITRAL, Partial Award (13 November 2000); OECD, '"Indirect Expropriation" and the "Right to Regulate" in International Investment Law' (2004) OECD Working Papers on International Investment 2004/04, p. 9.

[104] *Starrett Housing Corporation v. Islamic Republic of Iran,* Interlocutory Award (19 December 1983) Award No. ITL 32-24-1, para. 66; Louis B Sohn and Richard R Baxter, 'Responsibility of States for Injuries to the Economic Interests of Aliens' (1961) 55 *American Journal of International Law* 545, 553: "A taking of property includes not only an outright taking of property but also any such unreasonable interference with the use, enjoyment, or disposal of property as to justify an inference that the owner thereof will not be able to use, enjoy, or dispose of the property within a reasonable period of time after the inception of such interference."

[105] See, e.g.: *Técnicas Medioambientales Tecmed, S.A. v. The United Mexican States,* ICSID Case No. ARB(AF)/00/2, para. 119; *Compañía del Desarollo de Santa Elena, S.A. v. The Republic of Costa Rica,* ICSID Case No. ARB/96/1; *Ronald S. Lauder v. The Czech Republic,* UNCITRAL, Final Award (3 September 2002): States "are not liable for economic injury that is the consequence of bona fide regulation within the accepted police powers of the State."

[106] *Metalclad Corporation v. The United Mexican States,* ICSID Case No. ARB(AF)/97/1.

We consider these elements of the indirect expropriation analysis below.

4.1.1 The Degree of Interference with the Property Right

A compulsory license has the effect of diminishing a patent holder's rights by depriving the patentee of the exclusive right to use and license its invention. Accordingly, when the State issues a compulsory license requiring the patentee to permit a third party to use its invention at a licensing rate set by the government – rather than through negotiation – the patentee's rights are thereby affected, and its use and enjoyment of the patent as an investment is diminished.[107] As noted in Chapter 1, the grant of a patent gives the patentee the exclusive right in principle to exploit its invention, including granting the use of the invention to others through the issuance of a license. In this respect, the issuance of a compulsory license may be said to have negative effects on the patentee's ability to exploit its invention by removing the element of exclusivity and thereby diminishing the value of the investment. Depending upon the severity of the diminution, the elimination of the patentee's right to freely license its invention might rise to the level of deprivation necessary to constitute a prima facie taking.[108]

It is difficult to generalize as to whether the grant of a compulsory license will affect an investment to the degree of severity required for an expropriation. No investment treaty case has been found in which the issue has been raised or decided. Moreover, while the arbitral case law is replete with various articulations of the degree of interference required to support a finding of indirect expropriation, it is difficult, if not impossible, to predict how such general standards will be applied in a given case.[109] As a practical matter, what can be said is that arbitral tribunals will consider the economic impact of the State's measure(s) on a case-by-case basis to determine whether the impact has risen to a level capable of supporting a finding of expropriation.[110]

It warrants noting that there are *dicta* in the arbitral case law in which tribunals have observed with varying degrees of emphasis that State conduct in the context of an indirect expropriation claim should be assessed "by reference to the effect of relevant acts, rather than the intention

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[107] See, e.g.,: *S.D. Myers v. Canada* (n. 103): Expropriation usually amounts to a lasting removal of the ability of an investor to make use of their economic rights; *CME Czech Republic B.V. (The Netherlands) v. The Czech Republic,* UNCITRAL, Partial Award (13 September 2001), para. 591: The tribunal found that expropriation had occurred because the investor was left "with assets, but without business".
[108] Elena Pantopoulou, 'The Status and Legal Effect of Compulsory License in Investment Law' (2019) *International Journal of Law* 33, 39.
[109] United Nations Conference on Trade and Development (n. 102), p. 75-76; Jan Paulsson and Zachary Douglas, 'Indirect Expropriation in Investment Treaty Arbitrations' in Norbert Horn and Stefan Kröll (eds.), *Arbitrating Foreign Investment Disputes* (Kluwer 2004), p. 145-146 (contending that a flexible measure which takes into account the facts and circumstances of each case is necessary); E.g., *Glamis Gold, Ltd. v. The United States of America,* UNCITRAL, Final Award (8 June 2009), paras. 356-357: If the economic impact on the investment is not sufficiently severe, or the length of deprivation is not sufficient, the state measure will not constitute an expropriation.
[110] *Tokios Tokelės v Ukraine*, ICSID Case No ARB/02/18, Award (26 July 2007), para. 120: The tribunal found that "a diminution of 5% of the investment's value will not be enough for a finding of expropriation, while a diminution of 95% would likely be sufficient" but went on to state that the determination of whether an expropriation has, in fact, occurred, will turn on the particular facts of a case.

behind them."[111] Moreover, in certain earlier cases, it was sometimes suggested that tribunals should focus exclusively on the effects of the measure(s) without regard for other circumstances – the so-called 'sole effects' doctrine.[112] Today, however, the "sole effects" approach is a decidedly minority view. As the investment treaty regime has matured, tribunals, States, and commentators have come to recognize that analysing only the effects of the measure(s) without examining its purpose and other circumstances disregards the right of the host State to strike a balance between the interests of foreign investors and public welfare and, moreover, creates an implicit hierarchy between the protection of investment and other public interests.[113]

4.1.2 The Nature and Purpose of the Measure: "Police Powers"

In the event that the investor can demonstrate that a compulsory license has had such a severe impact on its use and enjoyment of its investment (i.e., the patent) that it rises to the level of a *prima facie* compensable expropriation, the State may seek to rebut this showing by pointing to the nature and character of the measure and the public purpose for which it was adopted.[114]

Under customary international law, and as recognised repeatedly in arbitral case law interpreting and applying IIAs, States are understood to enjoy certain "police powers" by which they are entitled to exercise their sovereign power in pursuit of public interest objectives without being obligated to pay compensation for resultant harms to private property interests.[115]

As described by the tribunal in *Methanex v. United States*:

> "[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 government to the then putative

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[111] *Biwater Gauff (Tanzania) Ltd v. United Republic of Tanzania*, ICSID Case No. ARB/05/22, para. 463.

[112] See, e.g., *Metalclad Corporation v Mexico* (n. 106); See also: *Santa Elena v. Costa Rica* (n. 94); Rudolf Dolzer, 'Indirect Expropriations: New Developments?' (2003) 11 *New York University Environmental Law Journal* 64, 90.

[113] Rodrigo Monardes, Ana Novik and Carlos Portales, 'Addressing the Right to Regulate in the CPTPP Investment Chapter: Identifying New Treaty Practice' in David A Gantz and Jorge A Huerta-Goldman (eds), *The Comprehensive and Progressive Trans-Pacific Partnership: Analysis and Commentary* (Cambridge University Press 2021), p. 370; Dolzer (n. 112) 78: The possible adverse effect of a measure would constitute "a major factor, or even the sole factor in determining whether or not a taking has occurred." See also: Suzy H Niklèma, 'Best Practices: Indirect Expropriation' (2012) International Institute for Sustainable Development, p. 13 (speaking of the effect of the measure as "exclusive criterion").

[114] See, e.g.: *Tecmed v. Mexico* (n. 105), para. 119; *Santa Elena v. Costa Rica* (n. 105); Antony Taubman, 'Rethinking TRIPS: 'Adequate Remuneration' for Non-Voluntary Patent Licensing' (2008) 11 *Journal of International Economic Law* 927, 942-943.

[115] See, e.g., *Lauder v. Czech Republic* (n. 105): States "are not liable for economic injury that is the consequence of bona fide regulation within the accepted police powers of the State."; *S.D. Myers v. Canada* (n. 103), para. 950: "Parties [to the IIA] are not liable for economic injury that is the consequence of bona fide regulation within the accepted police powers of the State"; Catharine Titi, *The Right to Regulate in International Investment Law* (Nomos and Hart Publishing 2014), p. 281.

> foreign investor contemplating investment that the government would refrain from such regulation."[116]

An additional gloss was added by the tribunal in *Philip Morris v. Uruguay*, which noted certain prerequisites to the State's successful invocation of police powers in response to an investor's claim of indirect expropriation:

> "[I]n order for a State's action in exercise of regulatory powers not to constitute indirect expropriation, the action has to comply with certain conditions. Among those most mentioned are that the action must be taken bona fide for the purpose of protecting the public welfare, must be non-discriminatory and proportionate".[117]

Although the concept of police powers is widely accepted, there is no universal consensus as to which governmental measures, pursuing which public interests, come within its scope.[118] That said, there seems to be little argument that measures taken for the protection of public health come within the class of measures subsumed by the police powers doctrine.

For example, in *Philip Morris v Uruguay,* the tribunal applied the police powers doctrine in connection with Uruguay's imposition of cigarette packaging legislation based on public health grounds. The tribunal had no difficulty in concluding that Uruguay's public health measures came within the scope of public interests protected by the police powers doctrine.[119] Moreover, according to the principle of systemic integration, tribunals are given additional flexibility in interpreting treaty provisions.[120] To illustrate, the tribunal found that Article 31(3)(c) of the

[116] *Methanex Corporation v. United States of America,* UNCITRAL, Final Award on Jurisdiction and Merits (8 March 2005), para. 7 (emphasis added).
[117] *Philip Morris v. Uruguay* (n. 77), para. 305.
[118] See *Saluka Investments B.V. v. The Czech Republic,* UNCITRAL, Partial Award (17 March 2006), para. 263: "[I]nternational law has yet to identify in a comprehensive and definitive fashion precisely what regulations are considered 'permissible' and 'commonly accepted' as falling within the police or regulatory power of States and, thus, non-compensable. In other words, it has yet to draw a bright and easily distinguishable line between non-compensable regulations on the one hand and, on the other, measures that have the effect of depriving foreign investors of their investment and are thus unlawful and compensable in international law."
[119] It is possible that arbitral tribunals adopt the police powers test even if the language of the treaty does not specifically provide for this: e.g., *Saluka v. Czech Republic* (n. 118). However, the argument for applying this doctrine will be stronger where the applicable BIT provides a textual basis for a specific category, and newer treaties, such as the CPTPP, have started including this. Article 9.8 of the CPTPP creates specific exceptions for the issuance of compulsory licenses, exempting them from the scope of the article on expropriation under paragraph 5 (see: Chapter 5 for a discussion of the treaty exceptions). Furthermore, the CPTPP provides additional guidance to arbitral tribunals through the Annex on Indirect Expropriation: Annex 9B (Expropriation): The text is based on the language used in the 2004 and 2012 US Model BITs, derived from US Supreme Court jurisprudence (*Penn Central Transportation Co. v. New York City* (1978) 438 U.S. 104). This Annex is central to making a distinction between expropriatory measures and non-compensable regulatory measures which are imposed for achieving a legitimate public policy objective.
[120] Systemic integration refers to the principle that a tribunal shall interpret IIAs against the background of the general body of international law: Daniel Kalderimis, 'Systemic Integration and International Investment Law – Some Practical Reflections' (2012) Society of International Economic Law Working Paper No. 2012/46.

VCLT allowed for the importation of police powers from customary international law[121] and, moreover, that those powers included a right to protect public health.[122]

In view of the public interest involved in the case, the tribunal looked to guidance from the World Health Organization ('WHO') because of its "particular knowledge and expertise".[123] The tribunal found that the Uruguayan measures were in accordance with the WHO Framework Convention on Tobacco Control and, taking into account a WHO submission which concluded that the measures in question were "effective means of protecting public health".[124] The tribunal looked to an independent international legal body and instruments pertaining to it in its decision-making process, reflecting the significance of systemic integration in that international law, and guidance by internationally accredited bodies may be relied upon in the interpretation of IIAs. Thus, the tribunal reiterated the concept that although the governing law will be that of the applicable IIA, this will be supplemented by "relevant" rules of international law, such as TRIPS.[125]

In light of the remaining uncertainty surrounding the scope of the protection against indirect expropriations and, more specifically, the application of the police powers doctrine, States have increasingly drafted their treaties so as to clarify the conditions under which a compensable indirect expropriation will be found.[126] For example, Annex 9-B of the CPTPP, specifies the circumstances which a tribunal must take into account in conducting an indirect expropriation analysis:

> "a) The determination of whether an action or series of actions by a Party, in a specific fact situation, constitutes an indirect expropriation, requires a case-by-case, fact-based inquiry that considers, among other factors:
>
> i. the economic impact of the government action, although the fact that an action or series of actions by a Party has an adverse effect on the economic value of an investment, standing alone, does not establish that an indirect expropriation has occurred;
> ii. the extent to which the government action interferes with distinct, reasonable investment-backed expectations; and
>
> iii. the character of the government action.

[121] *Philip Morris v Uruguay* (n. 77), para. 290. The tribunal read the state's right to regulate into the expropriation provision, para. 287: Uruguay's measures were "a valid exercise of the State's police powers, with the consequence of defeating the claim for expropriation".
[122] *Philip Morris v Uruguay* (n. 77), para. 298.
[123] *Philip Morris v Uruguay* (n. 77), para. 46.
[124] *Philip Morris v Uruguay* (n. 77), para. 38 (referring to the WHO Amicus Curiae Brief).
[125] *Philip Morris v. Uruguay* (n. 77), para. 177. Also, the Doha Declaration (paras. 5(b)-(c)) reiterates the importance of flexibilities such as compulsory licensing available within TRIPS to be used by members to mitigate adverse impacts of the product patent regime on public health.
[126] E.g., Article 9.16 of the CPTPP explicitly states that no provision in the investment chapter shall be considered to prevent the State from adopting measures that are sensitive to environmental, health or other regulatory objectives.

> b) Non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety and the environment, do not constitute indirect expropriations, except in rare circumstances."[127]

Notably, while Annex 9-B does not use the phrase "police powers," the analysis described is virtually the same. Annex 9-B, para 3 (b) specifically clarifies the state's power to issue non-discriminatory regulations in the public interest, includes public health measures:

> "Non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as *public health,* safety and the environment, do not constitute indirect expropriations, *except in rare circumstances*".

Footnote 37 in Annex 9-B, which is associated with the phrase "public health", goes on to clarify that:

> "For greater certainty and without limiting the scope of this subparagraph, regulatory actions to protect public health include, among others, such measures with respect to the regulation, pricing and supply of, and reimbursement for, pharmaceuticals (including biological products), diagnostics, vaccines, medical devices, gene therapies and technologies, health-related aids and appliances and blood and blood-related products."

In light of the language of CPTPP Annex 9-B and specific reference to public health in newly concluded BITs and FTAs,[128] it seems that non-discriminatory measures taken to address

[127] CPTPP, Annex 9-B, Art. 3(a)-(b).

[128] The Norwegian Model BIT (2015) states that "it is inappropriate to encourage investment by relaxing domestic health, human rights, safety or environmental measures or labour standards" (Article 11.1) and virtually all modern Model BITs contain some form of reference to public health (e.g., Indian Model BIT (2016); Dutch Model BIT (2018)). However, neither the Norwegian model BIT nor the Indian model BIT have resulted in any actual treaties Freya Baetens, 'Protecting Foreign Investment and Public Health Through Arbitral Balancing and Treaty Design' (2022) 71 (1) International and Comparative Law Quarterly 139, 159 (and specifically speaking of the "urgency of investing in a sustainable framework for global public health" (p. 179).;

Examples for references of FTAs to public health are the EU-Vietnam FTA (Article 2.2. Investment and Regulatory Measures and Objectives, Article 3.52 Expert Reports, Article 4.6 General Exceptions), and the EU-Singapore FTA (Article 2.2. Investment and Regulatory Measures, Article 2.3 National Treatment, Article 4.6 Taxation);

It is also interesting to look into WTO Appellate Body decisions related to the public health exception under Article XX(b) GATT (which can serve as a reference point here due to the dearth of investor-state arbitrations) See, e.g.: *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products,* Appellate Body Report (12 March 2001) WT/DS135/AB/R: The WTO Appellate Body upheld the public health exception under Article XX(b) GATT in relation to an import ban on asbestos or asbestos-containing products (a product known for its carcinogenic properties). The Appellate Body also considered WHO guidance (see the above discussion of *Philip Morris v. Uruguay* (n. 77));. Also at the WTO level, the notion of public health has prominently surrounded the discussion about the health risks posed by tobacco; *United States – Measures Affecting the Production and Sale of Clove Cigarettes,* Appellate Body Report (4 April 2012) WT/DS406/AB/R, para. 236: States can adopt measures "to pursue legitimate health objectives such as curbing and preventing youth smoking" so long as this is done in consistency with treaty obligations; See also: *Thailand – Customs and Fiscal Measures on Cigarettes from the Philippines,* Appellate Body Report (15 July 2011) WT/DS371/AB/R; *Philip Morris v. Uruguay* (n. 77); The CPTPP carve-out, in this respect, presents an example of how states have addressed one specific issue of public health which has caused a significant number of claims to be brought (possibly 'preempting' floodgates of litigation in this area). Chapter 29 (Exceptions and General Provisions) CPTPP, Article 29.5 (Tobacco Control Measures), footnote 11 allows states to choose to deny benefits of investment protection under the relevant investment chapter with respect to claims challenging tobacco control public health concerns, including "with respect to the regulation, pricing and supply of, and reimbursement for, pharmaceuticals (including biological products), diagnostics, vaccines […]", come within the recognised scope of the State's police powers. That said, simply because the state takes measures within the recognised scope of its police powers, it does not mean that its actions are beyond review. As Annex 9-B notes, there may be "rare circumstances" in which the State may nevertheless obligated to pay compensation for its actions.

4.1.3 Proportionality of the Measure

Although Annex 9-B does not elaborate on the "rare circumstances" in which a tribunal will find that non-discriminatory regulatory actions taken in view of protecting legitimate public welfare objectives might still constitute an instance of compensable expropriation, one circumstance identified by tribunals concerns the proportionality of the actions.[129]

As explained by the tribunal in *Philip Morris v Uruguay*,[130] the police powers doctrine requires not only that the State's measures be taken in pursuit of a legitimate public aim, such as the protection of public health, but that there be "a reasonable relationship of proportionality between the means employed and the aim sought to be realized."[131] In other words, the measure must be appropriate for achieving the legitimate public policy objective in question.[132]

A proportionality assessment aims to balance the protections provided under IIAs and the State's right to regulate. However, the interpretation of what is "proportionate" is left to the individual tribunal.[133] For example, in *PL Holdings v. Poland,* the tribunal found that the

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measures; Andrew D Mitchell, Tania Voon, and Devon Whittle, 'Public Health and The Trans-Pacific Partnership Agreement' (2015) 5 *Asian Journal of International Law* 279, 291.

[129] *OAO Neftyanaya Kompaniya Yukos* v. *Russia,* ECtHR Judgment (20 September 2011), Application no. 14902/04, para. 647-648: "State measures must be "proportionate to the legitimate aim pursued" and, in this respect, the "task is to determine whether a fair balance was struck between the demands of the general interest of the public and the requirements of the protection of the individual's fundamental rights"; See, e.g.: *Les Laboratoires Servier, SAS, Biofarma, SAS and Arts et Techniques du Progres SAS v. Republic of Poland*, UNCITRAL, Final Award (14 February 2012), para. 575: The tribunal held that the revocation of marketing authorization of medicines was disproportionate, discriminatory and "not a matter of public necessity" (finding that it constituted indirect expropriation).

[130] *Philip Morris v. Uruguay* (n. 77).

[131] *James and Others v. the United Kingdom*, ECtHR 8793/79, Sentence of 21 February 1986, paras. 50 and 63; *Tecmed v. Mexico* (n. 105), paras. 121-122; *SAUR International SA v. Republic of Argentina*, ICSID Case No ARB/04/4, para. 394: Argentina argued that it acted in accordance with its police powers to protect public health and was therefore not obliged to pay compensation to the investor – although the tribunal rejected Argentina's argumentation.

[132] *Tecmed v. Mexico* (n. 105), para. 122: "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." Absent an explicit inclusion of a proportionality test in treaty provisions, such an assessment does not occur automatically, see, e.g., the discussion in *Philip Morris* v. *Uruguay* (n. 77) about whether it would be possible to import the concept of "margin of appreciation" from the European Court of Human Rights to investment arbitration proceedings (Concurring and Dissenting Opinion by Gary Born), paras. 85-87; Eric De Brabandere and Paula Baldini Miranda da Cruz, 'The Role of Proportionality in International Investment Law and Arbitration: A System-Specific Perspective' (2020) *Nordic Journal of International Law* 471, 482: The formulations of the police powers doctrine do not explicitly include any reference to a proportionality test, but the general principle of proportionality is read into the provisions. Also, the effect of provisions specifically addressing the right to regulate (such as in Annex 9-B of the CPTPP) have not yet been fully tested in practice.

[133] When tribunals determine that there is a need to consider the proportionality of the State's action, they often do not explain how that assessment should be made. See for example: Nicolas Jansen Calamita, 'The Principle of

measures adopted by the State were disproportionate because there were less restrictive alternative measures available to the State.[134] That said, tribunals have emphasized that in considering the proportionality of a challenged measure, it is not the role of the tribunal to "second-guess" the policy choices of the host State, especially with respect to public health. As was put forcefully by the tribunal in *Philip Morris v. Uruguay*: "The responsibility for public health measures rests with the government and investment tribunals should pay great deference to governmental judgments of national needs in matters such as the protection of public health. In such cases respect is due to the 'discretionary exercise of sovereign power, not made irrationally and not exercised in bad faith … involving many complex factors.'"[135] Thus, while a proportionality analysis will require the tribunal to consider whether there were other policies by which the State might have achieved its policy aims with less impact of affected parties (like protected investors), properly conceived that analysis should be undertaken by affording the State a significant margin of appreciation, especially in cases involving public health.

4.1.4 Specific Representations Made by the State

A second "rare circumstance" that might be raised in opposition to a State's invocation of the police powers defence can arise when the State has made a prior specific representation to the investor that it would not take the measures it is now taking.[136] In such cases, especially where the investor has reasonably relied upon the State's representations, principles of fairness and equity will prevent the State from relying on the police powers doctrine. This was the point noted by the tribunal in *Methanex* when it observed:

> "[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

Proportionality and Problem of Indeterminacy in Investment Treaties' (2014) *Yearbook of International Investment Law and Policy* 157, 200; De Brabandere and Baldini Miranda da Cruz (n. 132), 491. See, e.g., *Watkins Holdings Sàrl, Watkins (Ned) BV, Watkins Spain SL, Redpier SL, Northsea Spain Sl, Parque Eólico Marmellar SL, and Parque Eólico La Boga, SL v. The Kingdom of Spain,* ICSID Case No ARB/14/55, para. 601: The tribunal found that there was "a requirement of proportionality" without explaining how such an assessment should be made.

[134] *PL Holdings S.à.r.l. v. Republic of Poland*, SCC Case No V2014/163, Partial Award (28 June 2017), paras. 355 and 375. See also: *S.D. Myers v. Canada* (n. 103), para. 221; *Continental Casualty Company v. Argentine Republic,* ICSID Case No. ARB/03/9, paras. 208–235.

[135] *Philip Morris v. Uruguay* (n. 77), para. 399. Note that although the tribunal was speaking in the context of Philip Morrris's FET claim, the principle enunciated is equally applicable with respect to a proportionality inquiry in an indirect expropriation claim. See generally *Methanex v. United States* (n. 116), para. 101: The government report under review was subject to public hearings, testimony and peer-review and thus emerged "as a serious scientific work from such an open and informed debate" which presented "the best evidence that it was not the product of a political sham". See also, e.g.: *Valeri Belokon v. Kyrgyz Republic*, PCA, Award (24 October 2014), paras. 232, 243.

[136] See, e.g.: *Parkerings-Compagniet AS v Republic of Lithuania*, ICSID Case No. ARB/05/8, para. 331: "The expectation is legitimate if the investor received an explicit promise or guarantee from the host-State, or if implicitly, the host-State made assurances or representation that the investor took into account in making the investment." Furthermore, in the context of foreign investment, there also often exists an investment contract between the investor and the state. This might be the most obvious example of specific representations made to the investor, see, e.g.: *MTD Equity Sdn. Bhd. and MTD Chile S.A. v. Chile*, ICSID Case. No. ARB/01/7, paras. 160-167: The tribunal found that by entering into the investment contract Chile had given rise to legitimate expectations that the project would be carried out, and by denying the investor the relevant permits, the state had frustrated these expectations.

> affects, inter alios, a foreign investor or investment is not deemed expropriatory and compensable unless specific commitments had been given by the regulating government to the then putative foreign investor contemplating investment that the government would refrain from such regulation."[137]

In the context of a State's treatment of a patent as an investment, one can imagine different situations which might give rise to the exception noted in *Methanex*. For example, one can imagine the situation where, at the time of the investment, the granting of the patent, the host government makes a promise to the investor that it will not use its power to issue a compulsory license except after 10 years or only under certain circumstances. In such a case, if the State were later to rely on that promise, a question would likely be raised with respect to the State's prior representation and whether it should be estopped from now relying upon police powers as a defence.

The law protects the investor in situations in which it has been induced to act in reliance upon the State's specific representations as a matter of equity.[138] In such circumstances, the investor is said to have 'legitimate expectations' which the law will protect from contrary action by the State. In *Methanex*, the tribunal's reference was with respect to 'specific commitments' given by the State to the specific investor with the implication being that the commitments in question were somehow personal or particular to the investor.[139] But what of the situation in which the State has not made a specific or individualized representation to the investor, but rather the investor seeks to rely upon more general commitments by the State, such as the provisions of the law as it stood at the time of the investor's investment? Can the mere legal framework of the host State give rise to a 'legitimate expectation' in the investor such that the State will later be prohibited from invoking its police powers when it enacts new (and different) regulations?

In the context of a compulsory licensing decision, the question would be whether the State's decision to issue a compulsory license can somehow be seen to implicate the investor's legitimate expectations. Under normal circumstances this seems very unlikely.[140] As noted above in Chapter 1, the State's grant of patent rights creates specific legal rights under the law of the host State. While those rights are powerful, they are not absolute or without limit. In

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[137] *Methanex v. United States* (n. 116), Part IV, Chapter D, para. 7.

[138] For legitimate expectations to arise, there must have been a representation or conduct by the State, possibly in "quasi-contractual" form, on which the investor relied in making the investment, see, e.g.: *Glamis Gold* (n. 109), para.766; See, also: *Sempra Energy International v. The Argentine Republic*, ICSID Case No. ARB/02/16, para. 298: The requirement to protect legitimate expectations "becomes particularly meaningful when the investment has been attracted and induced by means of assurances and representations." Also, footnote 36 to CPTPP Annex 9-B emphasizes that the importance of *specific* representations to the protection of the investor's expectations: "For greater certainty, whether an investor's investment-backed expectations are reasonable depends, to the extent relevant, on factors such as whether the government provided the investor with binding written assurances and the nature and extent of governmental regulation or the potential for government regulation in the relevant sector."

[139] Note, however, that "the existence of legitimate expectations and the existence of contractual rights are two separate issues" (*Gustav F W Hamester GmbH & Co KG v. Ghana*, ICSID Case No. ARB/07/24, para. 335).

[140] Tsai-Yu Lin, 'Compulsory Licenses for Access to Medicines, Expropriation and Investor-State Arbitration Under Bilateral Investment Agreements – Are There Issues Beyond the TRIPS Agreement?' (2009) 40 *IIC International Review of Intellectual Property and Competition Law* 152, 157: The investor should "foresee that the compulsory license law is applicable and will have associated effects," such that investors "should have reasonably expected that the existence of a compulsory license law will create associated effects, and should take this into consideration before making any investment decision".

most countries, like Thailand, the grant of a patent is made within a legal framework that allows for the possibility that the State may at some point and under certain conditions issue a compulsory license for the patent. Further, compulsory licenses are an internationally accepted limitation under Article 31 TRIPS.[141] In other words, when the patent is granted, it is already subject to the possibility that it may be compulsorily licensed in the future. Accordingly, as noted by Gibson, when the State grants a compulsory license it is "essentially reacquiring rights that it can use or grant to another party in the future."[142]

The situation might be different, however, if, after the issuance of the patent, the State were to change its patent law so as to modify the terms and/or conditions under which a compulsory license could be granted. Although not addressing compulsory licensing, the claim in *Eli Lilly v. Canada* suggests the kind of argument that might be made and the difficulties that would still be faced by the investor.

In *Eli Lilly*, the investor argued that Canada had violated its rights under the North American Free Trade Agreement when, following the grant of two patents for different pharmaceuticals, the Canadian courts adopted a "dramatic" change in the interpretation of Canada's patent law which resulted in the invalidation of the patents. The investor argued that it had a legitimate expectation in the general stability of Canada's patent law[143] and a more specific legitimate expectation that the law would not be subject to dramatic, "arbitrary and unpredictable" changes.[144] The tribunal rejected the investor's claim. First, it noted that a patent does not come with a guarantee of stability in relation to possible changes in the applicable law. In other words, an investor is not automatically entitled to have a legitimate expectation of an unchanging *status quo* legal regime; the State is entitled to a wide margin of appreciation when changing or evolving its law.[145] Consequently, the mere fact that the law changes, and the change affects the investor's rights, is not in itself a violation of the investor's legitimate expectations.[146] Moreover, the tribunal noted, on the facts of the case, that the changed interpretation of the patent law by the Canadian courts was not unpredictable or dramatic.[147] Indeed, the tribunal found, a long series of cases in Canada had suggested that the courts' interpretation of the law was evolving in the way it in fact did.[148]

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[141] World Intellectual Property Organization, 'Draft Reference Document on the Exception Regarding Compulsory Licensing' (2019) Standing Committee on the Law of Patents SCP/30/3: 156 countries and territories provide for compulsory and government-use licenses under their respective legal frameworks.
[142] Christopher Gibson, 'A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation' (2010) 25 *American University International Law Review* 357, 386-387.
[143] *Eli Lilly and Company v. The Government of Canada,* ICSID Case No. UNCT/14/2, para. 302.
[144] *Eli Lilly v. Canada* (n. 143), para. 392.
[145] *Eli Lilly v. Canada* (n. 143), para. 269.
[146] See, e.g.: *Marvin Roy Feldman Karpa v. United Mexican States*, ICSID Case No. ARB(AF)/99/1: The tribunal held that the Mexican government's change in tax policy did not constitute indirect expropriation because tax laws and regulations are subject to change and the investor could have had no legitimate expectation that the Mexican tax rules would continue without change.
[147] *Eli Lilly v. Canada* (n. 143), para. 442.
[148] *Eli Lilly v. Canada* (n. 143), para. 421.

4.2 Fair and Equitable Treatment

While claims for indirect expropriation have received the most attention from States in their treaty-making, the issuance of a compulsory license may not only be challenged for being expropriatory, but in principle, it may also be challenged for violating other substantive protections, such as the FET obligation that is typically contained in most IIAs. This section considers the possible application of the FET to compulsory licensing. It should be emphasized here that in providing this analysis, the authors are not considering the situation in which the IIA expressly addresses the State's right to issue a compulsory license – such as is the case with RCEP and CPTPP. These provisions and their impact on the application of substantive protections are treated separately in Chapter 5. Moreover, the authors note further that this analysis of FET does not take into account other provisions found in some IIAs which address the State's right to regulate for the public good more broadly, such as general exceptions provisions, which are also found in RCEP and CPTPP. Again, these provisions are treated separately in Chapter 5. To recall, the reason for dividing the analysis in this way is that not all of Thailand's IIAs contain either specialized provisions regarding the treatment of compulsory licenses or provisions addressing the State's right to regulate more generally. Consequently, the relevant analysis under many of Thailand's older treaties, with respect to a claim based upon the issuance of a compulsory license, will depend exclusively on the way in which the treaty's 'baseline' protections are interpreted and applied.[149]

The FET standard establishes a minimum baseline of protection for foreign investments. Violations of the fair and equitable treatment standard are the most common type of treaty violation committed by governments. What constitutes 'fair and equitable treatment' is determined by analysing all the circumstances of a particular case. However, not all treaties are the same, so the way in which fair and equitable treatment is interpreted and applied may depend upon the exact wording of a treaty.[150] That said, it is possible to identify a number of circumstances that have been considered by tribunals in determining whether there has been fair and equitable treatment. These include:

a) whether there has been a fundamental change in the host country's law that is contrary to the investor's legitimate expectations;[151]
b) whether the host country has gone back on specific representations made to the investor that the investor relied upon in making the investment decision;[152]
c) whether "due process" has been denied to the investor;

[149] The sole exception from this being the Canada-Thailand BIT (1997), which expressly exempts the issuance of CLs from the ambit of its expropriation provision (Article 6.1(b)), if issuance is in accordance with the TRIPS Agreement, and provides for a general exception clause under Article 17.3.
[150] The language of the specific treaty will also be relevant in formulating a claim on this basis, whether the FET provision is (i) open-textured, (ii) synonymous with the customary international law international minimum standards, or (iii) whether international law is used as a baseline. For example, CPTPP Article 9.6 specifically provides a minimum standard of treatment (footnote 15 explicitly referring to customary international law (under Annex 9A) and Article 9.6(2)(a) provides guidance on what conduct might constitute an FET violation.
[151] *Tecmed v. Mexico* (n. 105), para. 154; *Saluka v. Czech Republic* (n. 118), paras. 301-302: Legitimate expectations are the "dominant element" of FET.
[152] E.g., *Crystallex International Corporation v. Bolivarian Republic of Venezuela*, ICSID Case No. ARB(AF)/11/2.

d) whether the actions of the host country have been ambiguous or whether there has been an absence of transparency in the legal procedures or actions of the host country;[153]

e) whether there has been harassment, coercion, abuse of power or bad faith conduct by the host country;[154] and

f) whether the actions of the host country have been arbitrary or lacked "proportionality".[155]

As noted from the above list, the FET standard addresses both substantive and procedural concerns. In terms of substance, the FET is concerned with the actual fairness of the State's decisions, such as whether the State has created legitimate expectations that it would act one way and then acted in another or whether the State's action has been disproportionate or arbitrary. In terms of procedural concerns, the FET standard is concerned with the process by which government decisions are reached.

The consideration of "legitimate expectations" in the context of FET is similar to the way in which it arises in an indirect expropriation analysis. As in the indirect expropriation context, legitimate expectations in the FET analysis seek to address the investor's desire for stability in the laws and regulations on which it has relied when making its investment and its concern that those laws and regulations may undergo fundamental change (to the investor's detriment) after its investment has been made.

At the same time, as also addressed in the indirect expropriation context, the FET standard is not a guarantee that laws and regulations will never change, but rather it is a guarantee that the government will act according to an international standard in making such changes, for example, that it will not induce the investor to rely on specific representations in making the investment decision and then later resile upon those commitments.

In the context of a State's compulsory licensing decision, issues might conceivably be raised by an investment with respect to the legitimate expectations component of the FET standard.

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[153] E.g., *Tecmed v. Mexico* (n. 105), para. 154:

> "The foreign investor expects the host State to act in a consistent manner, free from ambiguity and totally transparently in its relations with the foreign investor, so that it may know beforehand any and all rules and regulations that will govern its investments, as well as the goals of the relevant policies and administrative practices or directives, to be able to plan its investment and comply with such regulations."

In this respect, providing clear rules, for example, in relation to remuneration for compulsory licenses, may support the idea of the state acting 'transparently' and at the same time ensure more predictability for investors, see: James Love, 'Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies' (2005) World Health Organization WHO/TCM/2005.1, p. 45.

[154] E.g., *Lauder v. Czech Republic* (n. 105), paras. 212-213: The State's hostile conduct towards the investor undermined the rights initially granted to the investor, thus the tribunal found the State measures to be arbitrary and discriminatory; See also: *Deutsche Bank AG v. Democratic Socialist Republic of Sri Lanka*, ICSID Case No. ARB/09/2, paras. 483-484; *Occidental Petroleum Corporation and Occidental Exploration and Production Company v. The Republic of Ecuador,* ICSID Case No. ARB/06/11.

[155] Nicolas Jansen Calamita, *Handbook on Handbook on Obligations in International Investment Treaties* (2020), Asia Pacific Economic Cooperation (APEC) Committee on Trade and Investment, p. 30.

For example, similar to the concerns discussed above in connection with indirect expropriation, if a State promises to an investor that it will not issue a compulsory license for a term of three years, this representation is sufficiently individualized and specific. Therefore, if the State subsequently reneges on its promise, the investor may bring a claim for a violation of its legitimate expectations under the FET standard.[156]

Alternatively, it is conceivable that an investor's legitimate expectations may arise out of the State's regulatory framework even absent specific representations made by the State.[157] This approach relies on notions of predictability and stability of the law, often based on the language found in a treaty.[158] As aforementioned, investors cannot reasonably expect that the law of the host State remains unchanged for the entire duration of their investments. However, if domestic legislation was designed specifically to attract foreign investment by creating incentives for investment for a fixed period, such as in *Micula v. Romania,*[159] an investor may have grounds to argue that a subsequent change in the law would violate its legitimate expectations in this regard.

In this respect, the CPTPP seeks to clarify the scope of the FET provision, albeit without defining the concept of FET, aiming to balance the right to regulate with investment protection.[160] Article 9.6.4 states that "[f]or greater certainty, the mere fact that a Party takes or fails to take an action that may be inconsistent with an investor's expectations does not constitute a breach of this Article, even if there is loss or damage to the covered investment as a result." Moreover, paragraph 4 goes on to state that the protection of legitimate expectations of an investor does not form part of a State's obligation in respect of FET under the CPTPP. That said, it remains the case that most investment treaties – including those to which Thailand is a party – do not contain this kind of clarifying language about legitimate expectations. As a result, in cases arising under those treaties, once legitimate expectations are found to exist,

[156] E.g., *Crystallex v. Venezuela* (n. 154): A letter by the Venezuelan Ministry of Environment had assured the investor of the authorization to commence operations, thereby instilling legitimate expectations on which the investor relied and acted; acting contrary to the representations made, Venezuela frustrated these legitimate expectations and thus violated the IIA. Ivan Stepanov, *Eli Lilly and Beyond: The Role of International Intellectual Property Treaties in Establishing Legitimate Expectations in Investor-State Dispute Settlement* (Nomos 2018), p. 60: "The promise must accordingly be addressed directly at the investor and not the general public."

[157] See, e.g.: *Murphy Exploration & Production Company International v. Republic of Ecuador,* UNCITRAL, Final Award (10 February 2017): The tribunal held that a 50% levy on profits in the oil sector was not in violation of FET because the investor could not have reasonably expected the government not to react in response to a steep increase in oil prices; however, raising the rate to 99% triggered a violation of FET based on a violation of the investor's legitimate expectations; Moreover, the question could arise, for instance, whether accession to the CPTPP would change the compulsory licensing regime in Thailand in a way that investors could not foresee or have foreseen at the time the investment was made. However, this will likely be a moot point because accession to the CPTPP is not expected to alter the compulsory licensing framework in Thailand.

[158] For example, in the Preamble of RCEP, the signatory States recognize the importance of "good governance and a predictable, transparent, and consistent business environment". However, a general reference to stability in the treaty language is not in and of itself enough to give rise to legitimate expectations.

[159] *Ioan Micula, Viorel Micula, S.C. European Food S.A, S.C. Starmill S.R.L. and S.C. Multipack S.R.L. v. Romania*, ICSID Case No. ARB/05/20: Romania provided investors with preferential subsidies and exemptions from customs duties, as well as from value-added taxes and taxes on profits, and in prematurely terminating these benefits it caused economic damage to the investors who had made investments under the development scheme.

[160] Article 9.6 CPTPP (Minimum Standard of Treatment).

State action contrary to those expectations may be sufficient by itself to constitute a breach of FET.[161]

A further aspect of the FET standard's concern with the substantive fairness of decisions is with respect to arbitrariness and a lack of proportionality. Arbitrariness raises questions about whether there is a reasonable connection between the objectives pursued by the government and the effectiveness of the means that the government has chosen to achieve those objectives. Proportionality is similar. In assessing whether a government measure is proportionate, questions may arise as to whether the means employed by the government to achieve its objective correspond to the importance of the objective and whether the chosen means are necessary (the least intrusive of private rights) for its achievement.

Looking at these issues in the context of the issuance of a compulsory license, one sees evident similarities with the issues addressed in the indirect expropriation analysis, particularly in connection with the police powers doctrine.[162]

Recalling the above discussion of predictability and stability of the law, it is worth noting that the proportionality requirement also applies to the manner in which States change their laws. This means that if a State decides to change its law, it must have regard for the interests of parties who had committed resources in reliance on the framework which was in place at the time the investment was made.[163]

As noted at the outset, the FET standard also addresses questions about the procedural fairness of the host State's regulatory processes. In terms of procedure, the FET standard addresses issues of due process, requiring that the government make decisions according to established rules and procedures. Due process in this context also requires that decision-making be impartial and treat the investor equally and fairly. Examples of due process include the requirement that an investor receives notice of decisions which may affect its rights and be given an opportunity to be heard; that the decision maker have the legal authority to act and

[161] For example, in *Gold Reserve Inc. v. Bolivarian Republic of Venezuela*, ICSID Case No. ARB(AF)/09/1, the tribunal found that state conduct could violate FET if it eviscerated the arrangements in reliance upon the investor was induced to invest.
[162] See the above discussion of *Philip Morris v. Uruguay* (n. 77) and the tribunal's analysis of 'arbitrariness' of State measures, in particular the reliance it placed on the WHO Framework Convention on Tobacco Control in informing its analysis. Note though that FET does not require a threshold showing of a substantial impact of the State measure on the investment. This is a major difference between FET and indirect expropriation: An investor could succeed in a claim for indirect expropriation if a State acts disproportionately and the investment is substantially impacted, but if the claim is based on FET, there is no requirement for such a threshold showing and disproportionate actions in themselves may constitute a breach of FET.
[163] See: *Blusun S.A., Jean-Pierre Lecorcier and Michael Stein v. Italian Republic,* ICSID Case No. ARB/14/3: Italy established a framework to subsidize the production of solar power. Part of that framework was a guaranteed level of 'feed-in-tariffs' that would be paid to solar energy producers. The Italian government subsequently decided to reduce the level of feed-in-tariffs made available in the future. The investor, Blusun, alleged that it had relied on the existing subsidy framework in making its investment in a solar energy project and that the reduction in tariffs would cause damage to it. However, absent a specific commitment, the State was under no obligation to grant subsidies or incentives to any investor or to maintain them at a specific level once granted. Nevertheless, if the State does decide to modify or withdraw subsidies or incentives provided to investors, it should do so in a manner that is proportionate, "and should have due regard to the reasonable reliance interests of recipients who may have committed substantial resources on the basis of the earlier regime" (para. 372).

that it uses its authority only for the purpose it was given; that decisions are made on the basis of all relevant information, disregarding irrelevant considerations, and so forth.[164]

Finally, it bears noting that the FET standard can be violated where the State exercises in sovereign power in "bad faith" or in an abusive way.[165] Put simply, to adhere to the standard States should act in good faith in their conduct with the investor. This includes that States should not use compulsory licensing as a threat to patent holders in view of making them lower their prices of, for example, patented drugs.[166] States should be transparent about the reasons for issuing a compulsory license and must not do so for 'illegitimate' reasons, such as for political motivations or protectionism.[167]

[164] E.g.: *Metaclad v. Mexico* (n. 104), para. 76: the tribunal emphasized that FET encompassed the obligation on part of the state to act transparently and according to due process. This entailed that all relevant requirements for the purpose of initiating, and successfully completing an investment "should be capable of being readily known to all affected investors." This decision places a heavy burden on the state to ensure legal certainty pertaining to foreign investment, in that it is the state's responsibility to ensure a transparent and predictable investment framework; Due process further includes non-denial of justice and lack of arbitrariness on part of the state. See: Calamita (n. 157), p. 33.

[165] See, e.g.: *Nuclear Tests case (Australia v. France),* ICJ Judgment (20 December 1974), para. 46: The principle of good faith is "[o]ne of the basic principles governing the creation and performance of legal obligations"; See also: *Russia – Measures Concerning Traffic in Transit,* Panel Report (5 April 2019) WT/DS512/R, para. 7.133: The obligation of good faith requires that States do not take measures to circumvent treaty obligations.

[166] For example, the US threatened Bayer AG Corporation during the Anthrax scare to issue a compulsory license unless the corporation lowered the price of its ciprofloxacin: Divya Murthy, 'The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health' (2002) 17 *American University International Law Review* 1299, 1314-1315. For example, Brazil was criticized for its actions in response to the HIV/AIDS crisis for violating the duty of good faith because the State was using compulsory licensing to exert pressure on patent holders: Muhammad Ardiansyah Arifin, 'Good Faith in TRIPS Compulsory Licensing of Pharmaceutical Patents: Lessons from Previous Pandemic Cases' (2021) *Lampung Journal of International Law* 85, 97.

[167] This means that a compulsory license must be issued in accordance with the Thai Patent Act and TRIPS, for example, for the protection of public health. See: *Tecmed v. Mexico* (n. 105), para. 154: The state failed to act consistently by arbitrarily revoking preexisting decisions regarding permits issued by the state which the investor relied upon commencing business activities in the host state (and the state must comply with its "pattern of conduct"). Good faith entails the host State acting consistently, unambiguously, and transparently so the investor knows *inter alia* what "the goals of the relevant policies and administrative practices or directives" are which may affect its investment. For example, State action must not be motivated by protectionism, see, e.g., *S.D. Myers v. Canada* (n. 103), para. 298: The tribunal found that an export ban was motivated by protectionism under the guise of promoting public interest. Also, it must not be politically motivated, see, e.g.: *Bear Creek Mining v. Republic of Peru*, ICSID Case No ARB/14/21, para. 451: The revocation of the investor's license was found to have been politically motivated and targeted directly at the investor in question.

4.3 Non-discrimination

In this section the authors consider whether in principle the issuance of a compulsory license may be challenged as discriminatory. Under the rubric of discrimination the authors place both NT and MFN. As with our analyses of other substantive protections above, the authors emphasise that in considering the application in principle of the NT and MFN standards to the issuance of a compulsory license, the authors are not considering the situation in which the IIA expressly addresses the State's right to issue a compulsory license – such as is the case with RCEP and CPTPP. IIAs which include such specialised provisions and their impact on the application of substantive protections are treated separately in Chapter 5. Instead, the authors here address the possible application of NT and MFN standards in situations in which the IIA does not contain specialised provisions on compulsory licensing. As noted, the authors do so on the ground that not all of Thailand's IIAs contain such specialized provisions and, consequently, the relevant analysis under many of Thailand's older treaties, with respect to a claim based upon the issuance of a compulsory license, will depend exclusively on the way in which the treaty's 'baseline' protections are interpreted and applied.

The standard of NT requires that the host State grant "protected investment and investors treatment that is no less favorable than the treatment it accords to national investors/investments in like circumstances."[168] The MFN standard is similar in that it entails that the host State grants "protected investment and investors treatment that is no less favorable than the treatment that it accords to the investments and investors of any third State in like circumstances".[169] Beyond these general statements as to the content of the two standards, however, it bears emphasizing that the scope of NT and MFN obligations can vary considerably between IIAs depending upon the treaty text.[170]

NT and MFN are relative standards of treatment in that their content is dependent upon a comparison of the treatment given to the protected investor and a national or third-state investor in like circumstances. As a result, in applying both standards, the treatment of the protected investor must be assessed against an appropriate comparator to see whether, relatively speaking, the protected investor is being treated less favourably.[171]

In applying the NT and MNF standards, arbitral tribunals generally assess three questions when considering a potential breach: (1) Are there "like circumstances" between the protected

[168] Calamita (n. 157), p. 26.
[169] Calamita (n. 157), p. 28.
[170] For example, in the *MTD Equity v. Chile* (n. 136), the tribunal held that the specific applicable MFN clause can "attract any more favourable treatment extended to third state investments and does so unconditionally" (para. 46).
[171] Klopschinski et al. (n. 4), para. 5.17: "This requires an assessment of "like circumstances" between investors (whether national and foreign investor or between different foreign investors), involving inter alia whether investors are active in the same business sector or whether their products or services are in a competitive relationship. Under general international law, the need for identifying an appropriate comparator follows also from the *ejusdem generis* principle, which is a doctrine of presumption, that general words when following and sometimes when preceding special words are limited to the genus, if any, indicated by the special words. (see also: Articles 9 and 10 of the ILC *Draft Articles on Most-Favoured-Nation Clauses*, Yearbook of the International Law Commission, 1978)."

investor and a national or third-state investor? (2) Is the treatment of the protected investor "less favourable"? and (3) If so, is there a justification for the difference in treatment?[172]

While most treaties expressly note that the NT and MFN standard rests upon an inquiry into the treatment between investors in "like circumstances",[173] some treaties expressly indicate that differential treatment may be justified – and therefore excused – where it is reasonable and based on legitimate policy grounds. CPTPP is one such treaty. Footnote 14 of Article 9.4 CPTPP clarifies that:

> "For greater certainty, whether treatment is accorded in "like circumstances" under Article 9.4 (NT) or Article 9.5 (MFN Treatment) depends on the totality of the circumstances, including whether the relevant treatment distinguishes between investors or investments on the basis of legitimate public welfare objectives."[174]

With respect to the CPTPP framework for NT and MFN clauses, it can be stated that footnote 14 ensures a broad approach to be taken when assessing the existence of "like circumstances" as it includes whether the relevant treatment distinguishes between investors or their investments on the basis of "legitimate public welfare objectives".[175] Arguably, the use of the phrase "legitimate public welfare objectives" can be seen as giving adjudicators space to scrutinize the purpose of a specific regulatory measure; however, it also indicates that the State's regulatory authority is a central feature of the analysis, returning to the idea that new generation treaties seek to safeguard the State's right to regulate and therefore give prominence to the nature and purpose of a government measure in the assessment of whether a treaty violation has occurred. The footnote, therefore, helps to rebalance the right to regulate and the right to investment protection.[176]

In thinking about the application of these non-discrimination standards in the context of compulsory licensing, it bears noting that historically arbitral tribunals have been more likely to find a breach of an IIA based on the substantive obligations of FET and indirect expropriation than on one of the non-discrimination standards.[177] That said, one can imagine situations in which the administration of a compulsory licensing scheme could give rise to questions with regards to discrimination.

For example, an investor could bring a claim for a breach of NT if the issuance of a compulsory license was, in fact, motivated by an industrial policy objective in order to boost the domestic industry by taking away a foreign investor's monopoly rights and allowing domestic licensees

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[172] Chin Leng Lim, Jean Ho, and Martins Paparinskis. *International Investment Law and Arbitration: Commentary, Awards and other Materials* (Cambridge University Press 2021), p. 321.
[173] In some treaties the phrase used is "like situations".
[174] See also, e.g., the tribunal in *S.D. Myers v. Canada* (n. 103) which recognized that the assessment of like circumstances must take into account circumstances "that would justify governmental regulations that treat [investors] differently in order to protect the public interest" (para. 250).
[175] Lim et al. (n. 181), p. 296.
[176] Monardes et al. (n. 113), p. 298-299.
[177] Lim et al. (n. 181), p. 293 with reference to Investor-State Dispute Settlement: Review of Developments in 2016 (May 2017) IIA Issues Note No. 1, p. 4.

to produce and sell the patented product in the host State.[178] Alternatively, questions might be raised by an investor if a compulsory license was granted for one vaccine patent, but not for a vaccine patent owned by an investor from a different State. In such a case, questions would likely arise as to whether the patentees of the two different vaccines were, in fact, in "like circumstances", especially in a situation in which, for example, the efficacy data for one vaccine was different from the other. In these circumstances, the provision in footnote 14 to Article 9.4 of CPTPP would be of particular benefit to the State.

4.4 Prohibitions on Performance Requirements

A final area of consideration with respect to the application of substantive protections to compulsory licenses concerns PPRs found in the CPTPP and some of Thailand's treaties (e.g., RCEP). PPRs prohibit the government from imposing certain conditions ("performance requirements") on the investor that must be fulfilled either in order for an investment either to be established in the country or in order for an investor to qualify for an incentive or other benefit.

Different performance requirements may be prohibited depending upon whether they are imposed in connection with the investor's establishment, operation, or sale, or other disposition of an investment or whether they are imposed as a condition for the investor to receive an incentive or other benefit (e.g., a subsidy, preferential tax treatment, land allocation, etc.). Article 9.10(1) of CPTPP lists prohibited performance requirements *imposed in connection with the investor's establishment, operation, sale, or other disposition of an investment:*

a) to export a certain amount of the goods or services;
b) to achieve a certain level of domestic content;
c) to purchase, use or give a preference to goods, services or technology produced in the host State's territory, or to purchase goods from persons its territory;
d) to relate the volume or value of imports to the volume or value of exports by the investment or to the amount of foreign exchange inflows associated with the investment;
e) to restrict sales of goods or services in the host State that the investment produces or supplies by relating those sales in any way to the volume or value of the investment's exports or foreign exchange earnings.
f) to transfer a particular technology or other proprietary knowledge to a particular person in the host State's territory;
g) to adopt a given rate of royalty under a licence contract; or
h) to adopt a given duration of the term of a licence contract.

[178] For example, when Ecuador considered the use of CL as a broader policy tool, see: Catherine Saez, 'Ecuador Grants First Compulsory Licence, For HIV/AIDS Drug' (22 April 2010) *Intellectual Property Watch* <https://www.ip-watch.org/2010/04/22/ecuador-grants-first-compulsory-licence-for-hivaids-drug/> accessed 18 February 2022; Under such a claim the public health objective would arguably have been used as a guise for protectionist and/or trade-restrictive measures.

Article 9.10(2) of CPTPP lists prohibited performance requirements *imposed as a condition for the investor to receive an incentive or other benefit:*

a) to achieve a certain level of domestic content;
b) to purchase, use or give a preference to goods produced in the host State, or to purchase goods from persons in the host State;
c) to relate the volume or value of imports to the volume or value of exports or to the amount of foreign exchange inflows associated with the investment; or
d) to restrict sales of goods or services in the host State that the investment produces or supplies by relating those sales in any way to the volume or value of the investment's exports or foreign exchange earnings.

The rationale for PPRs is the concern that performance requirements are "market distorting" and hinder the free flow of investment.[179] Developing states, on the other hand, have generally opposed PPRs, viewing them as potentially effective tools to maximize the development impact of foreign investments. In any case, the inclusion of PPRs in IIAs has grown more prevalent over the past decade,[180] and PPRs are now routinely contained in treaties involving the European Union and regional treaties like CPTPP (as noted above) and RCEP.[181]

PPRs can have potential application to the grant of compulsory licenses. CPTPP Article 9.10(2), for example, prohibits States from imposing requirements in connection with the investor's establishment, operation, sale, or other disposition of an investment that the investor (a) transfer a particular technology or other proprietary knowledge to a particular person in the host State's territory; (b) adopt a given rate of royalty under a license contract; or (c) adopt a given duration of the term of a license contract.[182]

In order to address the possibility that the CPTPP's PPRs might prevent States from issuing compulsory licenses, CPTPP, like some other IIAs, includes special rules with regard to compulsory licenses. Thus, CPTPP Article 9.10.3(b)(i), expressly allows States to authorize the use of an IP right in accordance with Article 31 TRIPS, thereby exempting compulsory licenses from the ambit of the PPRs provision[183] so long as the compulsory license complies

[179] Alexandre Genest, *Performance Requirement Prohibitions in International Investment Law* (Brill Nijhoff 2019), p. 25. The PPR regime in IIAs is heavily influenced by the US BIT regime. Article 8 of the 2012 US Model BIT addresses performance requirement prohibitions and offers a broad regulatory scope as it goes beyond the protection granted in the WTO Agreement on Trade-Related Investment Measures ("TRIMs Agreement"). Article 8 of the 2012 US Model BIT, for instance, covers mandatory technology transfer requirements, whereas the TRIMS agreement does not cover such requirements. The TRIMS Agreement, for example, does not cover mandatory technology transfer requirements. Furthermore, Article 8 covers both trade in goods and services, whereas the TRIMS agreement only covers trade in goods (see: Lee M Kaplan and Jeremy K Sharpe, 'United States' in Chester Brown, *Commentaries on Selected Model Investment Treaties* (Oxford University Press 2013), p. 799).
[180] States have started resorting to PPRs much later than to somewhat traditional substantive protections such as expropriation provisions or FET: Barton Legum, 'Understanding Performance Requirement Prohibitions in Investment Treaties' in Arthur W Rovine (ed.), *Contemporary Issues in International Arbitration and Mediation: The Fordham Papers 2007* (Martinus Nijhoff 2008) p. 53, 55-56.
[181] Article 10.6 RCEP.
[182] By way of example, PPRs could bar states from adopting "a given rate or amount of royalty" in a compulsory license, Article 9.10.1(h)(i) CPTPP, which directly contradicts the idea of compulsory licensing. Further, PPRs could undermine the State's ability to set "a given duration of the term" of a compulsory license should be imposed. Article 9.10.1(h)(ii) CPTPP.
[183] A similar provision is contained in RCEP, Article 10.6(3)(b)(i).

with TRIPS. (Compliance with TRIPS Article 31 and its more general interaction with substantive investment protections is addressed in detail in Chapter 5 below). Article 9.10.3(b)(i) CPTPP thus ensures that States retain the ability to issue compulsory licenses without contravening their obligations under Article 9.10 CPTPP, so that States remain able to "transfer a particular technology, a production process or other proprietary knowledge" to a third party.[184]

[184] Article 9.10.1(f) CPTPP.

Chapter 5: Treaty Flexibilities Applicable to Compulsory Licenses: TRIPS Exemptions and General Exceptions Clauses

Having analysed how the substantive provisions in IIAs might apply in principle to compulsory licensing decisions, this Chapter considers how the provisions contained in certain treaties, like CPTPP and RCEP, enshrine the State's regulatory freedom to issue compulsory licenses and insulate the State from investor claims.

The analysis begins with a brief recitation of the evolution of investment treaty drafting with respect to compulsory licensing (**Chapter 5.1**). Thereafter, treaties that explicitly address the treatment of compulsory licenses through "TRIPS-compliant" provisions (**Chapter 5.2**) and "TRIPS-plus" provisions (**Chapter 5.3**) are discussed. In so doing, the authors note that such provisions address compulsory licensing specifically with respect to the protection against unlawful expropriation and, in more recent treaties, the prohibition on performance requirements (as noted above at **Chapter 4.4**).[185] That said, while treaties like CPTPP contains express exclusions for expropriation and performance requirements when the State has adhered to its TRIPS-plus obligations, the authors also observe in **Chapter 5.3** that this focus on expropriation and performance requirements should not be seen as creating a significant gap in the State's ability to defend itself from other claims in connection with a compulsory license. As discussed, given the due process requirements for a compulsory license contained in TRIPS Article 31, as well as the due process requirements found in CPTPP Chapter 18, it seems remote that the State's issuance of a TRIPS-plus compliant compulsory license could give rise to a successful FET or discrimination claim. Moreover, as noted above at **Chapter 4,** it bears noting that beyond the inclusions of specific provisions addressed to compulsory licenses, modern treaties like CPTPP (and RCEP) have generally narrowed the scope of the protection afforded to investors under the FET standard and the non-discrimination standards as well. As a result, the scope of these protections especially with respect to matters related to public health is already very narrow.

Finally, **Chapter 5.4** takes notice of the increasing use of "General Exceptions" provisions in modern treaties which serve to exempt the application of the treaty in situations in which the government is pursuing certain interests and further limits the ability of investors to bring claims. Depending upon the text of the treaty, such provisions may help to insulate the State's issuance of compulsory licenses, especially with respect to pharmaceutical patents.

5.1 Evolution of Investment Treaty Drafting with Respect to Compulsory Licensing

Compulsory licensing is a recognized and important tool for States to respond to public health emergencies, allowing States to increase access to essential medicines while controlling price fluctuations.[186] Although it is ultimately up to each WTO member to decide whether to make

[185] See, for example, Article 9.10.3(b)(i) CPTPP.

[186] Correa (n. 75), 313. When South Africa issued a compulsory license for antiretroviral medicines in response to the HIV/AIDS outbreak, the important public health objective underpinning new national legislation was sufficient to justify the issuance of a CL in this instance, irrespective of the negative reaction that pharmaceutical companies had to this; See: Pantopoulou (n. 108), 37.

use of the flexibility of issuing compulsory licenses, it is a flexibility that on the evidence most states have embraced. Indeed, according to WIPO, 156 countries and territories either have domestic laws or are part of a regional agreement containing provisions on compulsory licensing.[187]

Although patents, as discussed in Chapter 2, can constitute "investments" for the purposes of IIAs, *to date, there appear to have been no cases brought by investors under an investment treaty challenging the issuance of a compulsory license***.** Nevertheless, as the total number of claims brought by investors over the past two decades has continued to rise, States have become increasingly concerned about the potential applicability of treaty protections to their issuance of compulsory licenses.[188] As a result, countries around the world have been paying more attention to the treatment of compulsory licenses in their IIAs with the result that contemporary treaties have started to provide guidance on how, and if, the treaty should apply to a State's issuance of compulsory licenses.

Although most of Thailand's IIAs in force are silent with respect to the treatment of compulsory licenses,[189] a review of Thailand's treaties reveals an emerging shift in its treaty-making, which is reflective of the global trend described above. Treaties that expressly address the applicability of substantive standards of protection to compulsory licensing decisions generally do so in one of two ways: (1) TRIPS-compliant provisions and (2) TRIPS-plus provisions. Thailand's investment treaty portfolio contains examples of both types of provisions[190] which are discussed below.

5.2 TRIPS-compliant exemptions

Article 12.5 of the ASEAN-Korea Investment Agreement (2009) provides a representative example of a TRIPS-compliant provision that can be found in eight of Thailand's investment treaties. In all these examples, the "TRIPS-compliant" language is contained in the expropriation article of the relevant IIA and is specifically applicable to the expropriation protection:

[187] See Danielle Navarro and Marcela Vieira, 'Compulsory Licensing' (2021) Graduate Institute of Geneva, Global Health Centre, p. 3 <https://www.knowledgeportalia.org/compulsory-licensing> accessed 30 January 2022 with reference to: World Intellectual Property Organization Draft Reference Document (n. 141).

[188] Gibson (n. 142), 367 ("one concern is that frequent or overbroad compulsory licensing of patents can seriously undermine the incentive to invest") and 420; Monardes et al. (n. 113), p. 290: The regulatory chill could deter states from imposing detrimental regulations, such as rules discriminating based on nationality, but it could also restrain government capacity to regulate; For example, when Brazil issued a compulsory license for Efavirenz, Merck claimed that this constituted expropriation, stating that it would send a "chilling signal to research-based companies about the attractiveness of undertaking risky research on diseases that affect the developing world" and that this would have a "negative impact on Brazil's reputation as an industrialized country seeking to attract inward investment" (Press Release, Merck & Co., Statement on Brazilian Government's Decision To Issue Compulsory License for Stocrin (2007) <http://www.drugs.com/news/merck-amp-co-inc-statement-brazilian-government-s-decision-issue-compulsory-license-stocrin-6088.html> accessed 7 March 2022.

[189] At present, out of Thailand's 48 investment treaties, only eight contain provisions explicitly addressing the treatment of compulsory licenses. See, for example, the Canada-Thailand BIT (1997), the RCEP and the ASEAN-India Investment Agreement (2014). Refer to the Annex for the remaining examples.

[190] See the Annex for the way in which compulsory licensing is treated in all of Thailand's treaties.

> "This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights *under the TRIPS Agreement* (emphasis added)."

As the phrase in italics indicates, such provisions import the TRIPS Agreement, which is part of WTO legal order, directly into the investment dispute. As a result, in order to apply this provision, an ISDS tribunal must make a substantive determination as to whether Thailand's issuance of compulsory licenses is consistent with TRIPS and, particularly, Article 31.

As noted in Chapter 1, Article 31 TRIPS sets out a list of obligations which the State must meet in order to come within its scope. Viewed in terms of an exemption to IIA protections, these obligations become critical points of analysis for an arbitral tribunal when considering whether the State's issuance of a compulsory license is exempted from an investor's expropriation claim under a TRIPS-compliant provision. In principle, as discussed further below, they should also be relevant with respect to non-expropriation claims that investors might bring as well.

To recap from Chapter 1, Article 31 TRIPS establishes a set of criteria for the issuance of compulsory licenses, including that:

a) each authorization of a compulsory license must be considered "on its individual merits";
b) a compulsory license may be authorized only if efforts have been made obtain authorization from the right holder on "reasonable commercial terms";[191]
c) the scope and duration of the compulsory license be limited for the purpose for which it was authorized;
d) the use permitted under the compulsory license must be non-exclusive;
e) the use permitted under the compulsory license must be non-assignable; and
f) the use permitted under the compulsory license must be predominantly for the supply in the domestic market of the State authorizing the compulsory license;
g) the authorisation of a compulsory license shall be subject to termination once the circumstances which gave rise to it have ended;
h) the rights holder shall be paid adequate remuneration "in the circumstances of each case, taking into account the economic valuation of the authorization";
i) the legal validity of the grant of a compulsory license shall be subject to judicial or administration review; and
j) the adequacy of the remuneration provides shall also be subject to judicial or administrative review.

The inclusion of a TRIPS-compliant provision in the expropriation provision of an IIA is an important way for States to limit the risk of expropriation claims based upon grants of compulsory licenses. That said, as recognized in a study conducted by Thailand's Parliamentary Select Committee,[192] TRIPS-compliant provisions also raise a number of legal

[191] Recall that Article 31(b) TRIPS notes that this requirement is not necessary in cases of "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."
[192] Kraijakr Thiratayakinant, 'Thailand's International Investment Agreements: Moving Towards A More Balanced Investment Protection Regime?' (2021) Trade and Development Regional Forum

issues – not yet addressed by any arbitral tribunal or judicial body – with respect to the way in which they incorporate the Article 31 TRIPS obligations into the text of the IIA. Ultimately, the authors are of the view that these are significant issues with respect to the incorporation of TRIPS disciplines into the text of an IIA. The authors note them, however, for the sake of completeness.

First, by applying the TRIPS Agreement in an investment dispute, an ISDS tribunal may risk contravening the exclusive jurisdiction of the WTO dispute settlement mechanism.[193] This is because a TRIPS-compliant provision incorporates the above-mentioned safeguards set out under Article 31 TRIPS into the IIA, effectively rendering the satisfaction of those requirements a 'defence' for the State subject to a claim of purported expropriation. However, this is unlikely to hinder the ability of ISDS tribunals to interpret TRIPS-compliant provisions because (1) they have been granted jurisdiction under investor-State consent to address the disputed issues,[194] and (2) their substantive determination with regards to "TRIPS-compliance" would be as a matter of *fact*, rather than *law*.[195] This means that the eventual ISDS ruling would not constitute an adjudication of the purported compulsory license's legality under the TRIPS Agreement (which is part of the WTO legal order). Further, investment arbitrations should be seen as a complementary, rather than competing mode of adjudication to the WTO Dispute Settlement Body.[196]

Second, in assessing the applicability of a TRIPS-compliant provision, an ISDS tribunal will face the question of how to reconcile the different standards of compensation that are required under the TRIPS Agreement and under the relevant IIAs. Under Article 31(h) TRIPS, the State is obliged to pay "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization" to the patent owner after issuing a compulsory license. This is generally understood as providing the State with flexibility to set the level of compensation at a level it finds reasonable under the circumstances, and certainly at a level which is lower than the traditional "market value" standard of compensation under most IIAs.[197] Further, the textual formulation of Article 31(h) does not provide a precise formula for

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<https://www.itd.or.th/en/itd-data-center/thailands-international-investment-agreements-moving-towards-a-more-balanced-investment-protection-regime/> accessed 3 March 2022,

193 Article 23 of the DSU states: "When Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this Understanding." See: Simon Klopschinski, 'The WTOs DSU Article 23 as Guiding Principle for the Systemic Interpretation of International Investment Agreements in the Light of TRIPS' (2016) 19(1) *Journal of International Economic Law* 229. Yamashita Tomoko, 'Procedural and Normative Competition between the WTO's Dispute Settlement and the Investor-State Arbitration: Focusing on the National Treatment Principle' (2020) 16 *Public Policy Review* 1, 2.

194 Stanley Nweke-Eze, 'Jurisdiction: Main Elements' (2022) Global Arbitration Review <https://globalarbitrationreview.com/guide/the-guide-investment-treaty-protection-and-enforcement/first-edition/article/jurisdiction-main-elements> accessed 15 April 2022.

195 Henning Grosse Ruse-Khan, *The Protection of Intellectual Property in International Law* (Oxford University Press 2016) para. 7.105.

196 Brooks Allen and Tommaso Soave, 'Jurisdictional Overlap in WTO Dispute Settlement and Investment Arbitration' (2014) 30 *Arbitration International* 1 <https://papers.ssrn.com/abstract=2446806> accessed 15 April 2022.

197 Taubman (n. 114), 963. The "market value standard of compensation" is sometimes spelled out directly in the treaty text. In other cases, however, the treaty will simply provide that in the event of an expropriation the investor is entitled to "prompt, adequate and effective" compensation, aka the "Hull formula" in reference to statement by

the assessment of “adequacy”, “circumstances of each case”, and the “economic value of the authorization”. Consequently, it is entirely possible for the State issuing a compulsory license to provide less than the *higher* (“market value”) standard of compensation required under the expropriation provision of the applicable IIA. Again, however, as noted above, because the IIA incorporates the standards set out under Article 31 TRIPS, it effectively renders the satisfaction of those requirements a ‘defence’ for the State and supplants the other requirements of the expropriation protection, including standards of compensation.

5.3 TRIPS-plus provisions

“TRIPS-plus” provisions similarly provide an exemption to expropriation claims based upon compulsory licenses, and the abovementioned legal issues regarding the application of TRIPS-compliant provisions continue to apply. But in addition to satisfying the conditions under Article 31 TRIPS, TRIPS-plus provisions also require the State to satisfy the terms set out in the IP chapter found in many FTAs, which may create additional obligations with respect to IP rights above those contained in the TRIPS Agreement or, indeed, may provide important clarifications and increased flexibilities with respect to the parties’ TRIPS obligations.[198]

Article 10.13.4 of the RCEP, which addresses the protection against unlawful expropriation, provides a representative example of a TRIPS-plus provision that can also be found in the CPTPP:

> “This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is *consistent with Chapter 11 (Intellectual Property) and the TRIPS Agreement*. (emphasis added)”

Accordingly, in order to benefit from a compulsory license exemption under the RCEP (and CPTPP), the State will need to demonstrate that its actions have complied not only with the TRIPS Agreement but also with requirements under the separate IP chapter contained in the relevant IIA. For example, Article 11.41.2 RCEP sets out elements that patent procedures should provide for, including a communication in writing in case of patent application’s refusal, as well as the opportunity to at least file an opposition or provide information that could influence patentability criteria. As for the CPTPP, Articles 18.48.2 and 18.48.3 sets out the

Secretary of State Cordell Hull, see: Foreign Relations of the United States Diplomatic Papers (1938) <https://history.state.gov/historicaldocuments/frus1938v05/d665> accessed 15 March 2022. In interpreting the phrase “prompt, adequate and effective” compensation, arbitral tribunals have consistently found it to mean “market value” compensation. See also: Nicolas Jansen Calamita, ‘The British Bank Nationalizations: An International Law Perspective’ (2009) 58 *Int’l & Comparative Law Quarterly* 119, 149.

[198] David Vivas-Eugui, ‘Regional & Bilateral Agreements and a TRIPS-plus World: The Free Trade Area of the Americas’ (2003) Quaker United Nations Office <https://quno.org/resource/2003/8/regional-bilateral-agreements-and-trips-plus-world-free-trade-area-americas-ftaa> accessed 12 March 2022: The author noted that TRIPS-plus agreements may imply the inclusion of a new IP right, implementation of a more extensive standard for the period of protection, and elimination of an option for members under the TRIPS Agreement to protect plant varieties only with reference to the International Union for the Protection of New Varieties of Plants (UPOV) system.

operative elements for patent adjustment in relation to the granting of marketing authorization, providing for an extended protection period for "unreasonable curtailment of the effective patent term".

It is important to note, however, that although the literal wording of TRIPS-plus provisions may appear to impose more demanding conditions for the issuance of compulsory licenses on the State than a simple TRIPS-compliant provision, this may not be the case in practice, as the IP Chapters of FTAs, like RCEP and CPTPP, generally provide extended flexibilities for the State's right to regulate. As an illustration, the IP Chapter of the RCEP refers to the Doha Declaration in Article 11.8, where it explicitly sets out the State parties' understanding concerning: (a) the right to fully exploit the *public health* flexibility contained in the Doha Declaration; (b) the fact that measures necessary to protect *public health* are not and should not be limited by the IP Chapter of the RCEP; and (c) the interpretation and implementation of the RCEP in a "pro-*public health* perspective". Therefore, RCEP's IP Chapter does not prevent States from adopting measures for protecting public health, including determining what constitutes situations of "national emergency" or other circumstances of "extreme urgency".[199]

The same exception is explicitly recognized in Article 18.6 of the CPTPP, which affirms the State parties' commitment to the Doha Declaration, and clarifies that the CPTPP obligations do not prevent a party from taking measures to protect public health.[200] While Article 18.50 CPTPP offers protection for undisclosed test or other data concerning the safety and efficacy of a new pharmaceutical product, State parties are still allowed to take measures to protect public health as long as they are in accordance with the Doha Declaration.[201]

TRIPS-plus provisions thus use "public health" as a shield that preventatively safeguard parties from undue claims for alleged violations of IIA obligations. For example, if Thailand issues a compulsory license and the affected investor alleges this to be in contravention of the CPTPP or RCEP, Thailand will be entitled to refer to the Doha Declaration and the principles of the TRIPS Agreement to dismiss the claim.[202] Scholars have argued that the more specific and demanding such a clause is in its reference to the Doha Declaration, the more effective it is in safeguarding TRIPS flexibilities.[203]

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[199] Vitor Ido, 'TRIPS Flexibilities and TRIPS-plus Provisions in the RCEP Chapter on Intellectual Property: How Much Policy Space Is Retained?' (2021) South Centre Research Paper 131, p. 10.

[200] Article 18.6(a) CPTPP:

> "The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all. Each Party has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."

[201] Article 18.50.3 CPTPP.

[202] Ido (n. 218).

[203] See for example: Henning Grosse Ruse-Khan and Teemu Alexander Puutio, 'A Handbook on Negotiating Development Oriented Intellectual Property Provisions in Trade and Investment Agreements' (2017) United Nations Economic and Social Commission for Asia and the Pacific.

5.4 The Implication of TRIPS & TRIPS-plus Flexibilities for Other Investment Treaty Obligations

As noted above, in modern IIAs such as CPTPP and RCEP, TRIPS flexibilities are addressed expressly in connection with the protection against illegal expropriation and the prohibition on performance requirements. Where the State satisfies the criteria of TRIPS Article 31, these modern IIAs expressly exempt investor claims claiming an expropriation or prohibited performance requirement.

With respect to other substantive protections, however, the authors have also noted that the TRIPS Agreement is not directly referenced in IIAs. In other words, modern IIAs like CPTPP and RCEP do not treat compliance with TRIPS as an express exemption to claims based on, for example, FET or non-discrimination. This is not to say, however, that the absence of language directly referring to TRIPS with respect to FET or non-discrimination represents a gap in the State's protection. Rather, as discussed below, under the wording of modern IIAs like RCEP and CPTPP, TRIPS- and TRIPS-plus compliant compulsory licensing decisions seem well protected from FET and non-discrimination claims. This conclusion stems from the fact that (a) these treaties have been drafted specifically to narrow the scope of protections like FET and non-discrimination and expand the scope of the State's right to regulate and (b) with respect to the compulsory licensing of patents in particular, when the State acts in compliance with TRIPS, especially Article 31, the State is not only insulating itself from expropriation and PPR claims as per the IIA's specialised exemptions, but it is also further insulating itself from FET and discrimination claims as well by following basic rule of law requirements.

The structure of modern FET and non-discrimination provisions in treaties like RCEP and CPTPP has already been addressed in Chapter 4 (especially 4.2 & 4.3) above and will not be repeated here. Instead, the authors focus on how compliance with the TRIPS Agreement's provisions on compulsory licensing serves indirectly to insulate the State from FET and non-discrimination claims, in addition, to directly insulating it from expropriation and PPR claims.

As noted above in Chapter 1.2, it warrants noting that although references to TRIPS Article 31 are contained in the expropriation articles of modern IIAs, the provisions of Article 31 arguably also address issues of due process with respect to the patentee and the State's issuance of a compulsory license for its patent. Article 31(a), for example, requires that each authorization of a compulsory license must be considered "on its individual merits", which provides the patentee with protection that the compulsory licensing decision will not be based on arbitrary or irrelevant criteria such as discriminatory or abusive grounds. Further, Article 31(c)-(f) provide substantive criteria for evaluating the legality of the compulsory license under the TRIPS Agreement by ensuring that the compulsory license is "proportionate", e.g., by limiting the license's scope and duration to that which is needed for the purpose for which it was authorized[204]; by requiring that the compulsory license be non-exclusive;[205] and by requiring that the authorisation of a compulsory license shall be subject to termination once the

[204] TRIPS Art. 31(c).
[205] TRIPS Art. 31(d).

circumstances which gave rise to it have ended.[206] Finally, the due process owed to a patentee in the event of a compulsory license is also addressed under TRIPS Article 31(i) and (j). Under these provisions, the legal validity of a compulsory license, as well as the adequacy of the remuneration provided, must be subject to judicial or administrative review in the licensing State, thereby insulating the State from claims alleging a denial of justice.[207] As a result, even though the reference to Article 31 TRIPS may appear expressly in the expropriation article (and with respect to the prohibition against performance requirements), in the event that the State complies with its obligations for issuing a lawful compulsory license pursuant to TRIPS, the likelihood of an investor bringing a successful claim for a violation of FET or non-discrimination seems very remote.

5.5 General Exceptions

Finally, an additional avenue of potential protection for States issuing compulsory licenses should be discussed, namely General Exceptions clauses. General Exceptions clauses serve as broad-based exemptions that provide the State with latitude to regulate foreign investments, including IP rights, under certain conditions in pursuit of the public interest. In general, their formulation follows that of Article XX of the General Agreement on Tariffs and Trade (1994)[208] ("GATT"), and in a number of Thailand's treaties,[209] such as RCEP, "Article XX of GATT 1994 is incorporated into and made part of this Agreement, *mutatis mutandis*" with respect to *inter alia* the provisions of the investment chapter.[210] Notably, although CPTPP contains a General Exceptions clause based on Article XX GATT, it has not been made applicable to the investment chapter.[211] Nevertheless, given its presence in RCEP and a number of Thailand's other treaties, the authors address it here for the sake of thoroughness.

For present purposes, specific aspects of Article XX GATT are especially relevant, namely the chapeau and subparagraph (b):

> "Subject to the requirement that such measures are not applied in a manner which would constitute a means of *arbitrary or unjustifiable discrimination* between

[206] TRIPS Art. 31(g).

[207] To recall, TRIPS Articles 41-45 set out minimum standards for the review States must provide to patentees to enforce their patent rights against infringement, including unlawful compulsory licensing. For present purposes it is sufficient to note that these articles require that, in pertinent part:

f) procedures concerning the enforcement of intellectual property rights shall be fair and equitable, and not unnecessarily complicated, costly or entail unreasonable time-limits or unwarranted delay (Article 41(b) and (c));
g) decisions on the merits of the case shall be based only on evidence in respect of which parties were offered the opportunity to be heard (Article 42);
h) parties shall be allowed to be represented by independent legal counsel and procedures shall impose overly burdensome requirements concerning mandatory personal appearances (Article 42);
i) judicial authorities shall have the authority to desist from an infringement (Article 44); and
j) judicial authorities shall have the authority to order the infringer to pay damages (Article 45).

[208] General Agreement on Tariffs and Trade 1994, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994).

[209] See, e.g.: the Canada-Thailand BIT (1997) and the ASEAN-HKSAR Investment Agreement (2017). See also the examples listed in Part II of the Annex which includes a detailed analysis of Thailand's investment treaties.

[210] Article 17.12 RCEP.

[211] Article 29.1.2 CPTPP.

countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures…(b) *necessary* to *protect human, animal or plant life or health* (emphasis added)."

In considering the possible application of a General Exceptions clause in a case in which the treaty contains no TRIPS-compliant or TRIPS-plus provision, it bears noting the State's burden of proof under Article XX GATT. Thus, if a State intends to rely on a General Exceptions clause to provide a "safe harbor" for its decision to issue compulsory licenses over pharmaceutical patents, it bears the evidential burden of proving three criteria before an ISDS tribunal: (a) the measure must protect public health; (b) the measure must satisfy the test of necessity; and (c) the measure must not be arbitrary or unjustifiable.[212] If a relationship between the compulsory licensing measure in question and the protection of public health can be established, criterion (a) should generally be satisfied. This is because tribunals have traditionally recognised the extensive regulatory autonomy of States to enact measures to uphold the physical wellbeing of their citizens.[213] The greater challenge, however, may lie in establishing criteria (b) and (c) under the existing formulation of General Exceptions clauses in Thailand's IIAs.

First, it may be challenging for the State to show that the issuance of a compulsory license is "necessary" for protecting public health. The assessment of "necessity" under Article XX(b) GATT involves a "weighing and balancing process" that depends on various factors, including (a) the relative importance of the alleged policy objective (i.e., public health); (b) the contribution of the measure (e.g., compulsory licensing) to the realization of the policy objective; and (c) the restrictive impact of the measure on international commerce.[214] In addition, the Tribunal must consider whether there are reasonably available alternatives to compulsory licensing that would have similar effectiveness in achieving the stated public health objective.[215] Therefore, the State bears the burden to show that other alternatives were either not reasonably available or would not have achieved the stated policy objective to the same degree as its issuance of compulsory license.[216]

Even if the State succeeds in displaying "necessity" under Article XX(b) GATT, it is still required to satisfy the requirement contained in the chapeau of Article XX i.e., to show that its issuance of compulsory license does not constitute "arbitrary or unjustifiable discrimination". While some degree of discrimination may be inevitable when compulsory licenses are issued

212 Sabanogullari Levent, 'The Merits and Limitations of General Exception Clauses in Contemporary Investment Treaty Practice' (Investment Treaty News, 22 May 2015) <https://www.iisd.org/itn/es/2015/05/21/the-merits-and-limitations-of-general-exception-clauses-in-contemporary-investment-treaty-practice/> accessed 14 March 2022.

213 See, e.g.: *Philip Morris v. Uruguay* (n. 77), para. 291.

214 Joseph Weiler and Cho Sungjoon, 'The Law of Regional Economic Integration in the American Hemisphere - Unit VIII, General Exceptions' <https://jeanmonnetprogram.org/resources/the-law-of-the-world-trade-organization-through-the-cases/teaching-materials/> accessed 16 April 2022.

215 *Brazil – Measures Affecting Imports of Retreaded Tyres*, WT/DS332/AB/R, adopted 17 December 2007 ("*Brazil – Retreaded Tyres*"), [156] and [178]; *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, adopted 10 January 2001, [164]; *European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/R, adopted 5 April 2001 ("*EC – Asbestos*"), [170]–[172].

216 *Brazil – Retreaded Tyres* (n. 234), [170]; *EC – Asbestos* (n. 234), [8.204].

by the State, it would be considered "arbitrary or unjustifiable" where no rational connection exists between the reasons for the discrimination and the stated policy objective.[217] This difficulty arose in *Bear Creek Mining v. Republic of Peru*,[218] which concerned the revocation of an investor's concession to operate a mining project. The Peruvian government justified its actions on, *inter alia*, grounds of protecting public safety.[219] The tribunal found that the public purpose justification, despite falling within the scope of "General Exceptions", could not be considered an appropriate exercise of the State's police powers due to the absence of notice given to the investor (which violated the investor's right of defence) and the lack of compensation.[220] This decision should serve as a caution for States when issuing compulsory license, as solely possessing a legitimate policy justification (e.g. protection of public health) may not shield them from investor claims if they behave in a manner which lacks due process or is arbitrary or unjustifiable.[221] That said, if a measure, such as a compulsory licenses, is found to fall within one of the enumerated objectives listed in a General Exceptions clause (or is broadly understood by the tribunal to constitute a legitimate public interest objective), and it is applied in a manner that does not constitute arbitrary or unjustifiable discrimination, nor does it constitute a disguised restriction on trade (as per the 'chapeau' requirements of Article XX GATT and Article XIV GATS), then there is likely to be a strong case for the State to argue that it is not in breach of its investment treaty obligations.[222]

Having analysed the application of TRIPS-compliant, TRIPS-plus, and General Exceptions provisions in the context of possible claims brought by investors, it is apparent that these treaty mechanisms provide States with a "safe harbor" for compulsory licensing decisions. However, these exemptions do not automatically insulate the State from investor claims, as they are subject to the satisfaction of various conditions (e.g., fulfilling the requirements of TRIPS Article 31; fulfilling the commitments contained in FTA IP chapters, like CPTPP Chapter 18; or fulfilling the "necessity" test under Article XX(b) GATT when invoking a General Exceptions clause). Further, in the absence of cases brought by investors under an IIA that challenge the issuance of a compulsory license, there remain unresolved legal issues with respect to how these provisions would apply in practice. Nevertheless, these provisions and these approaches represent the state-of-the-art in current investment treaty-making and reflect the balance of investor rights and State flexibilities to which a broad range of States have been willing to agree. Moreover, as summarised in the following chapter, these provisions serve to provide States with strong degrees of protection for their compulsory licensing decisions, rendering the prospect of successful investor claims remote in cases in which the State has complied with its TRIPS or TRIPS-plus obligations.

[217] *China – Measures Related to the Exportation of Rare Earths, Tungsten and Molybdenum*, WT/DS431/R, adopted 29 August 2014, [7.352]; *Brazil – Retreaded Tyres* (n. 234), [227].
[218] *Bear Creek Mining v. Peru* (n. 173).
[219] *Bear Creek Mining v. Republic of Peru* (n. 173).
[220] *Bear Creek Mining v. Republic of Peru* (n. 173), para. 451. The revocation of the investor's license was found to have been politically motivated and targeted directly at the investor in question.
[221] *Bear Creek Mining v. Republic of Peru* (n. 173), paras. 476-477.
[222] See: Newcombe (n. 102), p. 11 – in relation to FET and expropriation.

Chapter 6: Conclusion

One of the highly debated issues relating to Thailand's potential accession to the CPTPP has been the impact that the CPTPP might have on the State's discretion to regulate in the interest of public health, especially with regard to the right to issue compulsory licenses.[223]

As noted, compulsory licenses implicate commitments under the TRIPS Agreement while also implicating the protections provided to investors and their investments under IIAs, including the protection against unlawful expropriation, the guarantees of FET and non-discrimination, and the prohibition of the imposition of performance requirements.

Although the protections granted to investors under IIAs are often very broad, *research has revealed no case in which an investor has claimed that the issuance of a compulsory license infringed the substantive protections set out in IIAs*. Nevertheless, because compulsory licenses are an important policy tool for States and due to concerns that investor claims might arise in the future, modern IIAs like the CPTPP contain specific provisions curtailing the way in which the treaties' substantive provisions apply to compulsory licenses.

Thus, for example, CPTPP contains provisions whereby claims of alleged unlawful expropriation and prohibited performance requirements based upon the issuance of a compulsory license are excluded so long as the compulsory license has been issued in compliance with Article 31 TRIPS Agreement and the CPTPP's intellectual property chapter. In light of the terms of Article 31, the WTO's Doha Declaration, and the CPTPP's intellectual property chapter, these provisions provide a strong degree of protection for the State against expropriation and performance requirements claims.

Even though the CPTPP's express exclusion of claims arising from compulsory licenses only applies to the expropriation and performance requirements protections, this does not mean there is a significant gap with respect to the possibility of claims based on FET or non-discrimination. Given the due process requirements that the State must meet in order to issue a compulsory license in compliance with TRIPS Article 31 and CPTPP Chapter 18, the likelihood that a State could issue a "TRIPS-plus-compliant" compulsory license which would nevertheless give rise to a successful FET or discrimination claim seems highly remote. Moreover, it bears noting that beyond the inclusion of specific provisions addressed to compulsory licenses, the CPTPP has significantly narrowed the scope of the protection afforded to investors under the FET standard and the non-discrimination standards as a general matter. As a result, the scope of these protections, especially concerning matters related to public health is already very narrow.

As a result, this report concludes that the provisions of CPTPP, which are similar to the provisions of RCEP – a treaty to which Thailand is already a party – reflect the state-of-art in treaty drafting with respect to compulsory licensing. Taken together, the provisions of CPTPP

[223] See, e.g.: The Nation, 'Joining Trans-Pacific Group "Will Have No Impact on Compulsory Licensing of Drugs"' The Nation Thailand (22 June 2020) <https://www.nationthailand.com/in-focus/30389980> accessed 13 March 2022.

provide strong protection from investor claims for States which issue compulsory licenses in accordance with the TRIPS Agreement and its intellectual property chapter.

BIBLIOGRAPHY

Primary Sources

Case Law

Alpha Projektholding GmbH v. Ukraine, ICSID Case No. ARB/07/16

Ambiente Ufficio S.P.A & Ors. v. The Argentine Republic, ICSID Case No. ARB/08/9

Asian Express International (S) Pte Ltd. v. Greater Colombo Economic Commission (1985) ICSID Annual Report 6

Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, Appellate Body Report (9 June 2020), WT/DS435/AB/R

Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, Panel Report (28 June 2018) WT/DS435/R

Azurix Corp. v The Argentine Republic, ICSID Case No. ARB/01/12

Bayindir Insaat Turizm Ticaret Ve Sanayi A. (Scedil) v. Pakistan, ICSID Case No. ARB/03/29

Bear Creek Mining Corporation v. Republic of Peru, ICSID Case No. ARB/14/21

Biwater Gauff (Tanzania) Ltd v. United Republic of Tanzania, ICSID Case No. ARB/05/22

Blusun S.A., Jean-Pierre Lecorcier and Michael Stein v. Italian Republic, ICSID Case No. ARB/14/3

Brazil – Measures Affecting Patent Protection, Notification of Mutually Agreed Solution (19 July 2001) WT/DS199/4

Brazil – Measures Affecting Imports of Retreaded Tyres, WT/DS332/AB/R, adopted 17 December 2007

Bridgestone Licensing v. Panama Services, Inc. and Bridgestone Americas, Inc. and Republic of Panama, ICSID Case No. ARB/16/34

Bureau Veritas, Inspection, Valuation, Assessment and Control, BIVAC B.V. v. The Republic of Paraguay, ICSID Case No. ARB/07/9

Canfor Corporation v. United States of America; Terminal Forest Products Ltd. v. United States of America, UNCITRAL, Decision on Preliminary Question (6 June 2006)

CME Czech Republic B.V. (The Netherlands) v. The Czech Republic, UNCITRAL, Partial Award (13 September 2001)

CMS Gas Transmission Company v. Argentina, ICSID Case No. ARB/01/8

China – Measures Related to the Exportation of Rare Earths, Tungsten and Molybdenum, WT/DS431/R, adopted 29 August 2014

Compañía del Desarollo de Santa Elena, S.A. v The Republic of Costa Rica, ICSID Case No. ARB/96/1, Final Award (17 February 2000)

Consortium R.F.C.CC v. Morocco, ICSID Case No. ARB/00/6

Consorzio Groupement LESI-Dipenta (Italy) v. Algeria, ICSID Case No. ARB/03/08

Continental Casualty Company v. Argentine Republic, ICSID Case No. ARB/03/9

Corn Products International, Inc. v. United Mexican States, ICSID Case No. ARB (AF)/04/01

Crystallex International Corporation v. Bolivarian Republic of Venezuela, ICSID Case No. ARB(AF)/11/2

Deutsche Bank AG v. Democratic Socialist Republic of Sri Lanka, ICSID Case No. ARB/09/2

Elettronica Sicula S.p.A. (ELSI) (United States of America v. Italy), International Court of Justice, Judgment of 20 July 1989

Eli Lilly and Company v. The Government of Canada, ICSID Case No. UNCT/14/2

Enron Corporation and Ponderosa Assets, L.P. v. Argentina, ICSID Case No. ARB/01/3

European Communities – Measures Affecting Asbestos and Asbestos-Containing Products, Appellate Body Report (12 March 2001) WT/DS135/AB/R

GAMI Investments, Inc. v. Mexico, UNCITRAL, Final Award (15 November 2004)

Glamis Gold, Ltd. v. The United States of America, UNCITRAL, Final Award (8 June 2009)

Gold Reserve Inc. v. Bolivarian Republic of Venezuela, ICSID Case No. ARB(AF)/09/1

Gustav F W Hamester GmbH & Co KG v. Ghana, ICSID Case No. ARB/07/24

Inmaris Perestroika Sailing Maritime Services GmbH & Ors. v. Ukraine, ICSID Case No. ARB/08/8

International Thunderbird Gaming Corporation v. Mexico, UNCITRAL, Award (26 January 2006), Separate Opinion Thomas Wälde

Invesmart, B.V. v. Czech Republic, UNCITRAL, Award (26 June 2009)

Ioan Micula, Viorel Micula, S.C. European Food S.A, S.C. Starmill S.R.L. and Multipack S.R.L. v. Romania, ICSID Case No. ARB/05/20

James and Others v. the United Kingdom, ECtHR 8793/79, Sentence of 21 February 1986

Joy Mining Machinery v. Egypt, ICSID Case No. ARB/03/11

Les Laboratoires Servier, SAS, Biofarma, SAS and Arts et Techniques du Progres SAS v. Republic of Poland, UNCITRAL, Final Award (14 February 2012)

The Loewen Group, Inc and Raymond L. Loewen v. United States of America, ICSID Case No. ARB(AF)/98/3

Malaysian Historical Salvors SDN, BHD v. The Government of Malaysia, ICSID Case No. ARB/05/10

Marvin Roy Feldman Karpa v. United Mexican States, ICSID Case No. ARB(AF)/99/1

Metalclad Corporation v. The United Mexican States, ICSID Case No. ARB(AF)/97/1

Methanex Corporation v. United States of America, UNCITRAL, Final Award on Jurisdiction and Merits (8 March 2005)

MTD Equity Sdn. Bhd. and MTD Chile S.A. v. Chile, ICSID Case No. ARB/01/7

Murphy Exploration & Production Company International v. Republic of Ecuador, UNCITRAL, Final Award (10 February 2017)

Nuclear Tests case (Australia v. France), ICJ Judgment (20 December 1974)

OAO Neftyanaya Kompaniya Yukos v. *Russia,* ECtHR Judgment (20 September 2011), Application no. 14902/04

Occidental Petroleum Corporation and Occidental Exploration and Production Company v. The Republic of Ecuador, ICSID Case No. ARB/06/11

Parkerings-Compagniet AS v Republic of Lithuania, ICSID Case No. ARB/05/8

Penn Central Transportation Co. v. New York City (1978) 438 U.S. 104

Philip Morris Brands Sàrl, Philip Morris Products SA and Abal Hermanos SA v Oriental Republic of Uruguay, ICSID Case No ARB/10/7

PL Holdings S.à.r.l. v. Republic of Poland, SCC Case No V2014/163, Partial Award (28 June 2017)

Pope & Talbot Inc. v. The Government of Canada, UNCITRAL, Interim Award (26 June 2000)

Romak S.A. (Switzerland) v. The Republic of Uzbekistan, UNCITRAL, PCA Case No. AA280

Ronald S. Lauder v. The Czech Republic, UNCITRAL, Final Award (3 September 2002)

Russia – Measures Concerning Traffic in Transit, Panel Report (5 April 2019) WT/DS512/R

S.D. Myers, Inc. v Government of Canada, UNCITRAL, Partial Award (13 November 2000)

Saipem S.p.A. v. Bangladesh, ICSID Case No. ARB/05/07

Salini Costruttori S.p.A. and Italstrade S.p.A. v. Morocco, ICSID Case No. ARB/00/4

Saluka Investments B.V. v. The Czech Republic, UNCITRAL, Partial Award (17 March 2006)

SAUR International SA v. Republic of Argentina, ICSID Case No ARB/04/4

Sempra Energy International v. The Argentine Republic, ICSID Case No. ARB/02/16

Société Civile Immobilière de Gaëta v. Republic of Guinea, ICSID Case No. ARB/12/36

Starrett Housing Corporation v Islamic Republic of Iran, Interlocutory Award (19 December 1983) Award No. ITL 32-24-1

Suez, Sociedad General de Aguas de Barcelona S.A. and InterAguas Servicios Integrales del Agua S.A. v. The Argentine Republic, ICSID Case No. ARB/03/17

Técnicas Medioambientales Tecmed, S.A. v. The United Mexican States, ICSID Case No. ARB(AF)/00/2

Thailand – Customs and Fiscal Measures on Cigarettes from the Philippines, Appellate Body Report (15 July 2011) WT/DS371/AB/R

Tokios Tokelės v Ukraine, ICSID Case No ARB/02/18, Award (26 July 2007)

United States – Measures Affecting the Production and Sale of Clove Cigarettes, Appellate Body Report (4 April 2012) WT/DS406/AB/R

Valeri Belokon v. Kyrgyz Republic, PCA, Award (24 October 2014)

Watkins Holdings Sàrl, Watkins (Ned) BV, Watkins Spain SL, Redpier SL, Northsea Spain Sl, Parque Eólico Marmellar SL, and Parque Eólico La Boga, SL v. The Kingdom of Spain, ICSID Case No ARB/14/55

Secondary Sources

Abbott FM, 'Intellectual Property, International Protection' (2014) *Max Planck Encyclopedias of International Law*

Aldrich GH, 'What Constitutes a Compensable Taking of Property? The Decisions of the Iran-United States Claims Tribunal' (1994) 88 *American Journal of International Law* 585

Allen B and Soave T, 'Jurisdictional Overlap in WTO Dispute Settlement and Investment Arbitration' (2014) 30 *Arbitration International* 1 <https://papers.ssrn.com/abstract=2446806> accessed 15 April 2022.

Arifin MA, 'Good Faith in TRIPS Compulsory Licensing of Pharmaceutical Patents: Lessons from Previous Pandemic Cases' (2021) *Lampung Journal of International Law* 85

Athreye S, Piscitello L and Shadlen KC, 'Twenty-Five Years since TRIPS: Patent Policy and International Business' (2020) 3 *Journal of International Business Policy* 315

Baetens F, 'Protecting Foreign Investment and Public Health Through Arbitral Balancing and Treaty Design' (2022) 71 (1) *International and Comparative Law Quarterly* 139

Bernieri R, 'Compulsory Licensing and Public Health: TRIPS-Plus Standards in Investment Agreements' (2009) *Transnational Dispute Management* 2

Biadgleng ET, 'IP Rights under Investment Agreements: The TRIPS-Plus Implications for Enforcement and Protection of Public Interest' (2006) South Centre Research Paper

Bondy E and Saggi K, 'Compulsory Licensing, Price Controls, and Access to Patented Foreign Products' (2014) 109 *Journal of Development Economics* 217

Borgen C, 'Resolving Treaty Conflicts' (2005) *George Washington International Law Review* 573

Calamita NJ, 'The British Bank Nationalizations: An International Law Perspective' (2009) 58 *Int'l & Comparative Law Quarterly* 119

Calamita NJ, *Handbook on Handbook on Obligations in International Investment Treaties* (2020), Asia Pacific Economic Cooperation (APEC) Committee on Trade and Investment

Calamita NJ, 'The Principle of Proportionality and Problem of Indeterminacy in Investment Treaties' (2014) *Yearbook of International Investment Law and Policy*, 157

Charnovitz S, 'The Legal Status of the Doha Declarations Part II: Quick Impressions of the Doha Results' (2002) 5 *Journal of International Economic Law* 207

Correa CM, 'Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses' (2004) 26 *Michigan Journal of International Law* 331

Correa CM, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press 2020)

De Brabandere E and Baldini M, 'The Role of Proportionality in International Investment Law and Arbitration: A System-Specific Perspective' (2020) *Nordic Journal of International Law* 471

De Nanteuil A, 'General Exceptions to Investment Protection' in *International Investment Law* (Edward Elgar Publishing 2020)

Dolzer R and Schreuer C, *Principles of International Investment Law* (Oxford University Press 2012)

Dolzer R, 'Indirect Expropriations: New Developments?' (2003) 11 *New York University Environmental Law Journal* 64

Ewing-Chow M, 'Thesis, Antithesis and Synthesis: Investor Protection in BITs, WTO and FTAs' (2007) 30 *University of New South Wales Law Journal* 548

Foreign Relations of the United States Diplomatic Papers (1938) <https://history.state.gov/historicaldocuments/frus1938v05/d665> accessed 15 March 2022

Gathii JT, 'The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties' (2001) 15 *Harvard Journal of Law & Technology* 291

Genest A, *Performance Requirement Prohibitions in International Investment Law* (Brill Nijhoff 2019)

Gibson C, 'A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation' (2010) 25 *American University International Law Review* 357

Grando MT, *Evidence, Proof, and Fact-Finding in WTO Dispute Settlement* (Oxford University Press 2009)

Grosse Ruse-Khan H and Puutio TA, 'A Handbook on Negotiating Development Oriented Intellectual Property Provisions in Trade and Investment Agreements' (2017) United Nations Economic and Social Commission for Asia and the Pacific

Grosse Ruse-Khan H, *The Protection of Intellectual Property in International Law* (Oxford University Press 2016)

Halajian D, 'Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem' (2013) 38 *Brooklyn Journal of International Law* 1191

Harris D, 'TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing' (2011) 18 *Journal of Intellectual Property Law* 369

Hoelck Thjoernelund MC, 'State of Necessity as an Exemption from State Responsibility for Investments' (2009) 13 *Max Planck Yearbook of United Nations Law* 421

Ido V, 'TRIPS Flexibilities and TRIPS-plus Provisions in the RCEP Chapter on Intellectual Property: How Much Policy Space Is Retained?' (2021) South Centre Research Paper 131

International Law Commission, *Draft Articles on Most-Favoured-Nation Clauses*, Yearbook of the International Law Commission, 1978, vol. II, Part Two

International Law Commission, *Draft Articles on Responsibility of States for Internationally Wrongful Acts with Commentaries*, November 2001, Supplement No. 10 UNGA A/56/10

International Federation of Pharmaceutical Manufacturers Association, 'Encouragement of New Clinical Drug Development: The Role of Data Exclusivity' <https://www.who.int/intellectualproperty/topics/ip/en/DataExclusivity_2000.pdf> accessed 12 March 2022

Kalderimis D, 'Systemic Integration and International Investment Law – Some Practical Reflections' (2012) Society of International Economic Law Working Paper No. 2012/46

Kaplan LM and Sharpe JK, 'United States' in Brown C (ed.), *Commentaries on Selected Model Investment Treaties* (Oxford University Press 2013)

Klopschinski S, 'The WTOs DSU Article 23 as Guiding Principle for the Systemic Interpretation of International Investment Agreements in the Light of TRIPS' (2016) 19(1) *Journal of International Economic Law* 229

Klopschinski S, Gibson C and Ruse-Khan HG, *The Protection of Intellectual Property Rights Under International Investment Law* (Oxford University Press 2021)

Kohpaiboon A, 'Should Thailand Join the CPTPP?' in Lee C and Bhattacharya P (eds.), *The Comprehensive and Progressive Agreement for Trans-Pacific Partnership* (ISEAS–Yusof Ishak Institute 2021)

Kuanpoth J, 'Compulsory Licences: Law and Practice in Thailand' in Reto M Hilty and Kung-Chung Liu (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer 2015)

Kuanpoth J, 'Intellectual Property in the CTPP and Access to Medicines A Thai Perspective' in Lee C and Bhattacharya P (eds.), *The Comprehensive and Progressive Agreement for Trans-Pacific Partnership: Implications for Southeast Asia* (ISEAS–Yusof Ishak Institute 2021)

Lim CL, Ho J, and Paparinskis M, *International Investment Law and Arbitration: Commentary, Awards and other Materials* (Cambridge University Press 2021)

Legum B, 'Understanding Performance Requirement Prohibitions in Investment Treaties' in Rovine AW (ed.), *Contemporary Issues in International Arbitration and Mediation: The Fordham Papers 2007* (Martinus Nijhoff 2008)

Levent S, 'The Merits and Limitations of General Exception Clauses in Contemporary Investment Treaty Practice' (Investment Treaty News, 22 May 2015) <https://www.iisd.org/itn/es/2015/05/21/the-merits-and-limitations-of-general-exception-clauses-in-contemporary-investment-treaty-practice/> accessed 14 March 2022.

Lin TY, 'Compulsory Licenses for Access to Medicines, Expropriation and Investor-State Arbitration Under Bilateral Investment Agreements – Are There Issues Beyond the TRIPS Agreement?' (2009) 40 *IIC International Review of Intellectual Property and Competition Law* 152

Love J, 'Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies' (2005) World Health Organization WHO/TCM/2005.1

Madieha I and Azmi AG, 'Scope and Duration of Compulsory Licensing: Lessons from National Experiences' in Hilty RM and Liu KC (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer 2015)

Letter by Mandelson P, Member of European Commission, 16 June 2008, <https://tacd.org/wp-content/uploads/2013/09/TACD-IP-2008-Response-from-Comissioner-Mandelson-regarding-compulsory-licensing.pdf > accessed 7 April 2022

Mitchell AD, Voon T, and Whittle D, ‘Public Health and The Trans-Pacific Partnership Agreement’ (2015) 5 *Asian Journal of International Law* 279

Monardes R, Novik A and Portales C, ‘Addressing the Right to Regulate in the CPTPP Investment Chapter: Identifying New Treaty Practice’ in Gantz DA and Huerta-Goldman JA (eds.), *The Comprehensive and Progressive Trans-Pacific Partnership: Analysis and Commentary* (Cambridge University Press 2021)

Morgan A, ‘Trips to Thailand: The Act for the Establishment of and Procedure for Intellectual Property and International Trade Court’ (1999) 23 *Fordham International Law Journal* 55

Murthy D, ‘The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health’ (2002) 17 *American University International Law Review* 1299

Nakamura T, ‘Foreign Investment, Technology Transfer and the Technology Gap: A Note’ (2002) 6:1 *Review of Development Economics* 39

The Nation, ‘Joining Trans-Pacific Group “Will Have No Impact on Compulsory Licensing of Drugs”’ (2020) *The Nation Thailand* <https://www.nationthailand.com/in-focus/30389980> accessed 13 March 2022

Navarro D and Vieira M, ‘Compulsory Licensing’ (2021) Graduate Institute of Geneva, Global Health Centre <https://www.knowledgeportalia.org/compulsory-licensing> accessed 30 January 2022

Newcombe A, ‘The Boundaries of Regulatory Expropriation in International Law’ (2005) 20 *ICSID Review* 1

Nweke-Eze S, ‘Jurisdiction: Main Elements’ (2022) Global Arbitration Review <https://globalarbitrationreview.com/guide/the-guide-investment-treaty-protection-and-enforcement/first-edition/article/jurisdiction-main-elements> accessed 15 April 2022.

Niklèma SH, ‘Best Practices: Indirect Expropriation’ (2012) International Institute for Sustainable Development

OECD, ‘“Indirect Expropriation” and the “Right to Regulate” in International Investment Law’ (2004) OECD Working Papers on International Investment 2004/04

Pantopoulou E, ‘The Status and Legal Effect of Compulsory License in Investment Law’ (2019) *International Journal of Law* 33

Paulsson J and Douglas Z, ‘Indirect Expropriation in Investment Treaty Arbitrations’ in Horn N and Kröll S (eds.), *Arbitrating Foreign Investment Disputes* (Kluwer 2004)

Pires de Carvalho N, *The TRIPS Regime of Patent Rights* (Wolters Kluwer 2010)

Press Release, Merck & Co., Statement on Brazilian Government's Decision To Issue Compulsory License for Stocrin (2007) <http://www.drugs.com/news/merck-amp-co-inc-statement-brazilian-government-s-decision-issue-compulsory-license-stocrin-6088.html> accessed 7 March 2022

Pusceddu P, ‘Assessing Access to Medicines in Preferential Trade Agreements: From the Trans-Pacific Partnership to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership’ (2018) 49 *International Review of Intellectual Property and Competition Law* 1048

Ranjan P, ‘Medical Patents and Expropriation in International Investment Law – with Special Reference to India’ (2008) *Manchester Journal of International Economic Law* 72

Reuters, ‘Thailand Orders Additional 30 Mln Doses of Pfizer-BioNTech Vaccine’ (2021) <https://www.reuters.com/business/healthcare-pharmaceuticals/thailand-orders-additional-30-mln-doses-pfizer-biontech-vaccine-2021-11-23/> accessed on 16 February 2022

Sabanogullari L, 'The Merits and Limitations of General Exception Clauses in Contemporary Investment Treaty Practice' (Investment Treaty News, 22 May 2015) <https://www.iisd.org/itn/es/2015/05/21/the-merits-and-limitations-of-general-exception-clauses-in-contemporary-investment-treaty-practice/> accessed 14 March 2022

Saez C, 'Ecuador Grants First Compulsory Licence, For HIV/AIDS Drug' (22 April 2010) *Intellectual Property Watch* <https://www.ip-watch.org/2010/04/22/ecuador-grants-first-compulsory-licence-for-hivaids-drug/> accessed 18 February 2022

Sanglee T, 'Will Thailand Ever Join the CPTPP?' (2021) *The Diplomat* <https://thediplomat.com/2021/11/will-thailand-ever-join-the-cptpp/> accessed 18 February 2022.

Santa Cruz Scantlebury M and Pérez Fierro D, 'IP in the TPP: How Far Beyond the Existing FTAs Does it Go?' in Huerta-Goldman JA and Gantz DA (eds.), *The Comprehensive and Progressive Trans-Pacific Partnership* (Cambridge University Press 2021)

Sohn LB and Baxter RR, 'Responsibility of States for Injuries to the Economic Interests of Aliens' (1961) 55 *American Journal of International Law* 545

Solovy EM and Krishnamurthy P, 'TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High Level Panel Report on Access to Medicines' (2017) 50 *George Washington International Law Review* 91

Solovy EM, 'The Doha Declaration at Twenty: Interpretation, Implementation, and Lessons Learned on the Relationship Between the TRIPS Agreement and Global Health' [forthcoming] *Northwestern Journal of International Law & Business* 5

Stepanov I, *Eli Lilly and Beyond: The Role of International Intellectual Property Treaties in Establishing Legitimate Expectations in Investor-State Dispute Settlement* (Nomos 2018)

Stiglitz J, *Making Globalization Work: The Next Steps to Global Justice* (Penguin 2007)

Taubman A, 'Rethinking TRIPS: 'Adequate Remuneration' for Non-Voluntary Patent Licensing' (2008) 11 *Journal of International Economic Law* 927

Thiratayakinant K, 'Thailand's International Investment Agreements: Moving Towards A More Balanced Investment Protection Regime?' (2021) Trade and Development Regional Forum <https://www.itd.or.th/en/itd-data-center/thailands-international-investment-agreements-moving-towards-a-more-balanced-investment-protection-regime/> accessed 3 March 2022

Titi C, *The Right to Regulate in International Investment Law* (Nomos and Hart Publishing 2014)

Tomoko Y, 'Procedural and Normative Competition between the WTO's Dispute Settlement and the Investor-State Arbitration: Focusing on the National Treatment Principle' (2020) 16 *Public Policy Review* 1

Vadi V, *Public Health in International Investment Law and Arbitration* (Routledge 2012)

Vanhonnaeker L, 'Performance Requirements and the Issue of Technology Transfer' in *Intellectual Property Rights as Foreign Direct Investment: From Collision to Collaboration* (Elgar 2015)

Verhoosel G, 'The Use of Investor-State Arbitration Under Bilateral Investment Treaties to Seek Relief for Breaches of WTO Law' (2003) 6 *Journal of International Economic Law* 493

Verma SK, ‘Chapter 18: The Doha Declaration and Access to Medicines by Countries Without Manufacturing Capacity’ in Correa CM (ed*), Research Handbook on the Protection of Intellectual Property under WTO Rules* (Edward Elgar Publishing 2010)

Vivas-Eugui D, ‘Regional & Bilateral Agreements and a TRIPS-plus World: The Free Trade Area of the Americas’ (2003) Quaker United Nations Office <https://quno.org/resource/2003/8/regional-bilateral-agreements-and-trips-plus-world-free-trade-area-americas-ftaa> accessed 12 March 2022

Volman L, ‘The TRIPS Article 31 Tug of War: Developing Country Compulsory Licensing of Pharmaceutical Patents and Developed Country Retaliation’ (LL.M. Thesis, The University of Dublin, Trinity College 2018)

Weiler J and Cho S, ‘The Law of Regional Economic Integration in the American Hemisphere - Unit VIII, General Exceptions’ <https://jeanmonnetprogram.org/resources/the-law-of-the-world-trade-organization-through-the-cases/teaching-materials/> accessed 16 April 2022

WIPO Lex, ‘Thailand I Patent Act B.E. 2522 (1979)’ <https://wipolex.wipo.int/en/legislation/details/3807> accessed 16 February 2022

Wong H, ‘The Case for Compulsory Licensing during COVID-19’ 10 *Journal of Global Health*

World Intellectual Property Organization, ‘Draft Reference Document on the Exception Regarding Compulsory Licensing’ (2019) Standing Committee on the Law of Patents SCP/30/3

World Intellectual Property Organization, ‘Patent Cooperation Treaty Yearly Review 2021 - The International Patent System’ (2021) World Intellectual Property Organization

World Intellectual Property Organization, ‘Patent Cooperation Treaty – The International Patent System’ <https://www.wipo.int/pct/en/index.html> accessed 15 February 2022

World Intellectual Property Organization, ‘Patents’ <https://www.wipo.int/patents/en/index.html> accessed 13 February 2022

World Intellectual Property Organization, Survey on Compulsory Licenses Granted by WIPO Member States to Address Anti-Competitive Uses of Intellectual Property Rights’ (2011) CDIP/4/4 REV./STUDY/INF/5

World Trade Organization, ‘Compulsory Licensing of Pharmaceuticals and TRIPS’ <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 24 January 2022

World Trade Organization, World Intellectual Property Organization, World Health Organization, ‘Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade’ (2020)

Wu CH, ‘ASEAN at the Crossroads: Trap and Track between CPTPP and RCEP’ (2020) 23 *Journal of International Economic Law* 97

Xiong P, ‘Patents in TRIPS-Plus Provisions and the Approaches to Interpretation of Free Trade Agreements and TRIPS: Do They Affect Public Health?’ (2012) 46 *Journal of World Trade* 155

Yu P, ‘Crossfertilizing ISDS with TRIPS’ (2017) 49 *Loyola University Chicago Law Journal* 321

‘Investor-State Dispute Settlement and Impact on Investment Rulemaking’ (2007) UNCTAD/ITE/IIA/2007/3

‘WTO | Intellectual Property (TRIPS) - Fact Sheet - Pharmaceuticals - 2’ <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm> accessed 16 February 2022

ANNEX

I. Detailed Analysis of CPTPP provisions Related to Compulsory Licensing

<table>
<thead>
<tr><th rowspan="2">Principal Legal Obligations</th><th colspan="2">Specific Reference to Compulsory Licenses</th><th rowspan="2">General Exceptions</th><th rowspan="2">“investment” includes IP rights?</th><th rowspan="2">Miscellaneous</th></tr>
<tr><th>Silence</th><th>Exceptions</th></tr>
</thead>
<tbody>
<tr>
<td>Article 9.4 (NT)

Article 9.5 (MFN)

Article 9.6 (Minimum Standard of Treatment): “Each Party shall accord to covered investments treatment in accordance with applicable customary international law principles…[this] prescribes the customary international law minimum standard of treatment of aliens as the standard of treatment to be afforded to covered investments.”

Art 9.8 (Expropriation)

Annex 9-B (3(b)): “Non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health,</td>
<td>N.A.</td>
<td>Article 9.8.5: “This Article shall not apply to the issuance of compulsory licences granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation or creation of intellectual property rights, to the extent that the issuance, revocation, limitation or creation is consistent with Chapter 18 (Intellectual Property) and the TRIPS Agreement.”

Article 18.6.1: “The Parties affirm their commitment to the Declaration on TRIPS and Public Health. In particular, the Parties have reached the following understandings regarding this Chapter: (a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party’s right to protect public health and, in particular, to promote access to medicines for all. Each Party has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. (b) In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the WTO</td>
<td>N.A.</td>
<td>✓</td>
<td>Article 9.10: Performance Requirements

Article 9.10.3(b)(i) Paragraphs 1(f), 1(h) and 1(i) shall not apply: “if a Party authorises use of an intellectual property right in accordance with Article 31 of the TRIPS Agreement, or to measures requiring the disclosure of proprietary information that fall within the scope of, and are consistent with, Article 39 of the TRIPS Agreement.”</td>
</tr>
</tbody>
</table>

Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	“investment” includes IP rights?	Miscellaneous
	Silence	Exceptions			
safety and the environment, do not constitute indirect expropriations, except in rare circumstances.” Footnote 37 to “public health” in the Annex above, says “for greater certainty and without limiting the scope of this subparagraph, regulatory actions to protect public health include, among others, such measures with respect to the regulation, pricing and supply of, and reimbursement for, pharmaceuticals (including biological products), diagnostics, **vaccines**, medical devices, gene therapies and technologies, health-related aids and appliances and blood and blood-related products.		General Council of August 30, 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) and the WTO General Council Chairman’s Statement Accompanying the Decision (JOB(03)/177, WT/GC/M/82), as well as the Decision of the WTO General Council of December 6, 2005 on the Amendment of the TRIPS Agreement, (WT/L/641) and the WTO General Council Chairperson’s Statement Accompanying the Decision (JOB(05)/319 and Corr. 1,WT/GC/M/100) (collectively, the “TRIPS/health solution”), this Chapter does not and should not prevent the effective utilisation of the TRIPS/health solution. (c) With respect to the aforementioned matters, if any waiver of any provision of the TRIPS Agreement, or any amendment of the TRIPS Agreement, enters into force with respect to the Parties, and a Party’s application of a measure in conformity with that waiver or amendment is contrary to the obligations of this Chapter, the Parties shall immediately consult in order to adapt this Chapter as appropriate in the light of the waiver or amendment.” Article 18.50.3: “Notwithstanding [the protection of undisclosed test or other data], a Party may take measures to protect public health in accordance with: (a) the Declaration on TRIPS and Public Health; (b) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration on TRIPS and Public Health and that is in force between the Parties; or (c) any amendment of the TRIPS Agreement to implement the Declaration on TRIPS and Public Health that enters into force with respect to the Parties.”			

II. Detailed Analysis of Thailand's Investment Treaties

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
Thailand - United Arab Emirates BIT (2015)	Article 4.1 (FET) Article 5.1 (MFN) Article 5.1 (NT) Article 7 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Myanmar - Thailand BIT (2008)	Article 3.2 (FET) Article 4.1 (MFN) Article 4.1 (NT) Article 6 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Thailand - Turkey BIT (2005)	Article 3 (FET) Article 4 (MFN) Article 4 (NT) Article 5 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Jordan - Thailand BIT (2005)	Article 3.2 (FET) Article 4.1 (MFN) Article 4.1 (NT) Article 6 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Hong Kong, China SAR - Thailand BIT (2005)	Articles 2.2 and 3.1 (FET) Article 3.1 (MFN)	✓	N.A.	N.A.	✓	N.A.

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
	Article 3.1 (NT) Article 5 (Expropriation)					
Bulgaria - Thailand BIT (2003)	Article 2 (FET) Article 3 (MFN) Article 3 (NT) Article 5 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Germany - Thailand BIT (2002)	Article 2.3 (FET) Article 3.1 (MFN) Article 3.1 (NT)	✓	N.A.	N.A.	✓	N.A.
Bangladesh - Thailand BIT (2002)	Article 2 (FET) Article 3 (MFN) Article 3 (NT) Article 4 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Bahrain - Thailand BIT (2002)	Articles 3 and 4 (FET) Article 4 (MFN) Article 4 (NT) Article 6 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Korea, Dem. People's Rep. of - Thailand BIT (2002)	Articles 3 and 4 (FET) Article 4 (MFN) Article 4 (NT) Article 6 (Expropriation)	✓	N.A.	N.A.	✓	N.A.

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
BLEU (Belgium-Luxembourg Economic Union) - Thailand BIT (2002)	Article 4 (FET) Articles 4 and 9 (MFN) Article 4 (NT) Article 5 (Expropriation) (Articles 4.1(c) (MFN/NT)	✓	N.A.	N.A.	✓	N.A.
Croatia - Thailand BIT (2000)	Article 3 (FET) Article 4 (MFN) Article 4 (NT) Article 5 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Israel - Thailand BIT (2000)	Article 2 (FET) Article 3 (MFN) Article 3 (NT) Article 5 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Slovenia - Thailand BIT (2000)	Article 2 (FET) Article 3 (MFN) Article 3 (NT) Article 4 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Argentina - Thailand BIT (2000)	Art 4 (FET) Article 4 (MFN) Article 4 (NT)	✓	N.A.	N.A.	✓	Article 11: "*If the provisions of law of either Contracting*

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	**Exceptions**			
	Article 6 (Expropriation)					*Party or obligations under international law existing at present or established thereafter between the Contracting Party and the other Contracting Party contain more favourable rules for the investors, such rules shall be applicable*."
Egypt - Thailand BIT (2000)	Articles 3 and 4 (MFN) Articles 3 and 4 (NT) Article 4 (FET) Article 5 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Sweden - Thailand BIT (2000)	Article 3 (FET) Article 3 (MFN) Article 3 (NT)	✓	N.A.	N.A.	✓	N.A.

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
	Article 5 (Expropriation)					
Indonesia - Thailand BIT (1998)	Articles 3.2 and 4.1 (FET) Article 3.2 (Full Protection and Security) Article 4.1, 4.2 and 5.2 (MFN) Article 6 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Switzerland - Thailand BIT (1997)	Article 4 (FET) Article 4 (MFN) Article 4 (NT) Article 5 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Canada - Thailand BIT (1997)	Article 2.2(a) (FET) Article 2.2(b) (Full Protection and Security) Articles 2.3(a) and 4 (NT) Articles 2.3(b) and 3 (MFN) Article 8 (Expropriation)	N.A.	Article 6.1(b): "*The provisions of Article VIII do not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights contained in the Final Act embodying the results of the Uruguay Round of Multilateral Trade Negotiations, done at Marrakesh on 15th April, 1994*."	Article 17.3(b): "*Provided that such measures are not applied in an arbitrary or unjustifiable manner, or do not constitute a disguised restriction on international trade or investment, nothing in this Agreement shall be construed to prevent a Contracting Party from*	✓ Includes patent rights specifically	N.A.

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
				adopting or maintaining measures, including environmental measures: *…* *(b) necessary to protect human, animal, or plant life or health; or* *…"*		
Sri Lanka - Thailand BIT (1996)	Articles 3.2 and 4.2 (FET) Article 3.2 (Full Protection and Security) Articles 4.1 and 4.2 (NT) Articles 4.1 and 4.2 (MFN) Article 6 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Taiwan Province of China - Thailand BIT (1996)	Article 3.2 (Most Constant Protection and Security) Article 4.1 (FET) Article 4.1 (MFN) Article 6 (Expropriation)	✓	N.A.	N.A.	✓	N.A.

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	**Exceptions**			
Cambodia - Thailand BIT (1995)	Articles 3.2(b), 4.1(a) and 4.1(b) (FET) Article 3.2(b) (Full Protection and Security) Articles 4.1(a) and (b) (MFN) Articles 4.1(a) and (b) (NT) Article 6 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Philippines - Thailand BIT (1995)	Articles 3.2 and 4.2 (FET) Article 3.2 (Full Protection and Security) Articles 4.1 and 4.2 (NT) Articles 4.1 and 4.2 (MFN) Article 7 (Expropriation)	✓	N.A.	N.A.	✓ Includes patent rights specifically	N.A.
Finland - Thailand BIT (1994)	Articles 3.2 and 4.2 (FET) Article 3.2 (Full Protection and Security) Articles 4.1 and 4.2 (NT)	✓	N.A.	N.A.	✓	N.A.

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
	Articles 4.1 and 4.2 (MFN) Article 6 (Expropriation)					
Czech Republic - Thailand BIT (1994)	Article 3.2 (Most Constant Protection and Security) Articles 4.1 and 4.2 (FET) Articles 4.1 and 4.2 (MFN) Articles 4.1 and 4.2 (NT) Article 6 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Romania - Thailand BIT (1993)	Articles 3.1(a) and (b) (FET) Articles 3.1(a) and (b) (MFN) Articles 3.1(a) and (b) (NT) Article 4 (Expropriation)	✓	N.A.	N.A.	✓ Includes patents specifically	N.A.
Poland - Thailand BIT (1992)	Article 2.5 (Most Constant Protection and Security)	✓	N.A.	N.A.	✓	N.A.

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
	Articles 3.1 and 3.2 (FET) Articles 3.1 and 3.2 (MFN) Articles 3.1 and 3.2 (NT) Article 6 (Expropriation)				Includes patents specifically	
Thailand - Viet Nam BIT (1991)	Article 3.2 (Most Constant Protection and Security) Articles 4.1(a) and (b) (FET) Articles 4.1(a) and (b) (MFN) Article 6 (Expropriation)	✓	N.A.	N.A.	✓ Includes patents specifically	N.A.
Peru - Thailand BIT (1991)	Article 3.2 (Most Constant Protection and Security) Articles 4.1(a) and (b) (FET) Articles 4.1(a) and (b) (NT) Articles 4.1(a) and (b) (MFN) Article 6 (Expropriation)	✓	N.A.	N.A.	✓	N.A.

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
Hungary - Thailand BIT (1991)	Article 3.2 (Most Constant Protection and Security) Article 4.1 and 4.2 (FET) Articles 4.1 and 4.2 (MFN) Articles 4.1 and 4.2 (NT) Article 6 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Lao People's Democratic Republic - Thailand BIT (1990)	Article 3.2 (Most Constant Protection and Security) Articles 4.1(a) and (b) (FET) Articles 4.1(a) and (b) (MFN) Articles 4.1(a) and (b) (NT) Article 6 (Expropriation)	✓	N.A.	N.A.	✓ Includes patents specifically	N.A.
Korea, Republic of - Thailand BIT (1989)	Article 3.2 (Most Constant Protection and Security) Articles 4.1(a) and (b) (FET) Articles 4.1(a) and (b) (MFN)	✓	N.A.	N.A.	✓ Includes patents specifically	N.A.

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
	Articles 4.1(a) and (b) (NT) Article 5 (Expropriation)					
China - Thailand BIT (1985)	Article 3.2 (Most Constant Protection and Security) Articles 4.1(a) and (b) (Equitable Treatment) Articles 4.1(a) and (b) (MFN) Article 5 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Thailand - United Kingdom BIT (1978)	Article 4.2 (Most Constant Protection and Security) Articles 5.1(a) and (b) (FET) Articles 5.1(a) and (b) (MFN) Articles 5.1(a) and (b) (NT) Article 6 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Netherlands - Thailand BIT (1972)	Article 5.1 (MFN, but only with respect to payment of taxes, fees or charges and to the	✓	N.A.	N.A.	X	N.A.

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	**Exceptions**			
	enjoyment of fiscal deductions and exemptions) Article 6.1 (NT, but only with respect to protection of industrial property) Article 7.1 (FET) Article 7.2 (Same Protection and Security as that accorded to nationals of third states) Article 9 (Expropriation)					
RCEP (2020) (Regional Comprehensive Economic Partnership)	Articles 10.3 and 11.7 (NT) Article 10.4 (MFN) Article 10.5 (FET) Article 10.5 (Full Protection and Security) Article 10.6 (PPR) Article 10.13 and Annex 10B (Expropriation)	N.A.	Article 10.6.3(b)(i): "*Subparagraphs 1(f) and (h) shall not apply:* *(i) if a Party authorises use of an intellectual property right in accordance with Article 31 or Article 31bis of the TRIPS Agreement,23 or to measures requiring the disclosure of proprietary information that fall within the scope of, and are consistent with, Article 39 of the TRIPS Agreement*." (*No Party shall impose or enforce, as a condition for establishment, acquisition, expansion, management, conduct, operation, or sale or other disposition of an investment in its territory of an investor of any other Party, any of the following requirements:*	Article 11.4: "*A Party may, in formulating or amending its laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to its socio-economic and technological development, provided that such measures are*	✓ Includes patents specifically	Article 10.8: Non-Confirming Measures Article 11.5: TRIPS Plus

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
			(f) to transfer a particular technology, a production process, or other proprietary knowledge to a person in its territory; *(h) to adopt a given rate or amount of royalty under a licence contract, in regard to any licence contract in existence at the time the requirement is imposed or enforced, or any future licence contract freely entered into between the investor and a person in its territory, provided that the requirement is imposed or enforced in a manner that constitutes direct interference with that licence contract by an exercise of non-judicial governmental authority of a Party. For greater certainty, this subparagraph does not apply when the licence contract is concluded between the investor and a Party.*" Article 10.13.4: "*This Article does not apply to the issuance of compulsory licences granted in relation to intellectual property rights, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter 11 (Intellectual Property) and the TRIPS Agreement.*" Article 11.8: "*The Parties reaffirm the Doha Declaration on the TRIPS Agreement and*	*consistent with this Chapter.*" Article 17.12: "*For the purposes of Chapter 2 (Trade in Goods), Chapter 3 (Rules of Origin), Chapter 4 (Customs Procedures and Trade Facilitation), Chapter 5 (Sanitary and Phytosanitary Measures), Chapter 6 (Standards, Technical Regulations, and Conformity Assessment Procedures), Chapter 10 (Investment), and Chapter 12 (Electronic Commerce), Article XX of GATT 1994 is incorporated into and made part of this Agreement, mutatis mutandis.* *For the purposes of Chapter 8 (Trade in Services), Chapter 9 (Temporary Movement*		

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
			Public Health adopted on 14 November 2001. In particular, the Parties have reached the following understandings regarding this Chapter: *(a) the Parties affirm the right to fully use the flexibilities as duly recognised in the Doha Declaration on the TRIPS Agreement and Public Health;* *(b) the Parties agree that this Chapter does not and should not prevent a Party from taking measures to protect public health; and* *(c) the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all.* *In recognition of the Parties' commitment to access to medicines and public health, this Chapter does not and should not prevent the effective utilisation of Article 31bis of the TRIPS Agreement, and the Annex and Appendix to the Annex to the TRIPS Agreement.* *The Parties recognise the importance of contributing to the international efforts to implement Article 31bis of the TRIPS*	*of Natural Persons), Chapter 10 (Investment), and Chapter 12 (Electronic Commerce), Article XIV of GATS including its footnotes is incorporated into and made part of this Agreement, mutatis mutandis.*" (Article XX of GATT: "*Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement*		

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
			Agreement, and the Annex and Appendix to the Annex to the TRIPS Agreement" Article 11.39: "*For greater certainty, nothing in this Agreement shall limit a Party's rights and obligations under Article 31 and Article 31bis of the TRIPS Agreement, and the Annex and Appendix to the Annex to the TRIPS Agreement.*"	*by any contracting party of measures:* *(b) necessary to protect human, animal or plant life or health*." (Article XIV of GATS: "*Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where like conditions prevail, or a disguised restriction on trade in services, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measures:* *(b) necessary to protect human, animal or plant life or health*.")		

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
ASEAN - Hong Kong, China SAR Investment Agreement (2017)	Article 3 (NT) Article 4 (MFN) Article 5 (FET) Article 5 (Full Protection and Security) Article 10 and Annex 2 (Expropriation)	N.A.	Article 10.5: "*For greater certainty, this Article does not apply to the issuance of compulsory licences granted in relation to intellectual property rights, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with TRIPS Agreement*."	Article 9: "*Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between the Parties or their investors where like conditions prevail, or a disguised restriction on investors of another Party or their investments, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Party of measures:* *(b) necessary to protect human, animal or plant life or health.*"	✓	Article 6 (Non-Conforming Measures)

Bilateral Investment Treaties	Principal Legal Obligations	Specific Reference to Compulsory Licenses		General Exceptions	"Investment" includes IP rights	Miscellaneous
		Silence	Exceptions			
<u>ASEAN - India Investment Agreement (2014)</u> (signed, but not in force)	Article 3 (NT) Article 7 (FET) Article 7 (Full Protection and Security) Article 8 (Expropriation)	N.A.	Article 8.7: "*This Article does not apply to the issuance of compulsory licences granted in relation to intellectual property rights, in accordance with the TRIPS Agreement.*"	Article 4.5: "*Nothing in this Agreement shall be construed so as to derogate from rights and obligations under international agreements in respect of protection of intellectual property rights to which the Parties are party, including the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and other treaties concluded under the auspices of the World Intellectual Property Organization.*" Article 8.9: "*Non-discriminatory regulatory measures by a Party or measures and awards by judicial bodies of a Party that are designed and applied in pursuit of public policy to achieve*	✓	N.A.

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				legitimate public interest or public welfare objectives, such as the protection of public health, safety, and the environment, do not constitute expropriation of the type referred to in subparagraph 2(b) of this Article." Article 21: "*Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination against or amongst the Parties, their investors, or their investments where like conditions prevail, or a disguised restriction on investors of any Party or their investments, nothing in this Agreement shall be construed to prevent the*		

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				adoption or enforcement by any Party of measures: *(b) necessary to protect human, animal or plant life or health*."		
ASEAN - China Investment Agreement (2009)	Article 4 (NT) Article 5 (MFN) Article 7 (FET) Article 7 (Full Protection and Security) Article 8 (Expropriation)	N.A.	Article 8.6: "*This Article shall not apply to the issuance of compulsory licences granted to intellectual property rights in accordance with the Agreement on Trade- Related Aspects of Intellectual Property Rights in Annex 1C to the WTO Agreement*."	Article 16: "*Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between the Parties, their investors or their investments where like conditions prevail, or a disguised restriction on investors of any Party or their investments made by investors of any Party, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Party of measures:*	✓ Includes patents specifically	Article 6: Non-Conforming Measures

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				(b) necessary to protect human, animal or plant life or health."		
ASEAN-Korea Investment Agreement	Article 3 (NT) Article 4 (MFN) Article 5 (FET) Article 5 (Full Protection and Security) Article 12 (Expropriation)	N.A.	Article 12.5: "*This Article does not apply to the issuance of compulsory licences granted in relation to intellectual property rights under the T R IPS Agreement.*"	Article 9.5: "*Nothing in this Agreement shall be construed so as to derogate from rights and obligations under international agreements in respect of protection of intellectual property rights to which the Parties are party, including the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and other treaties concluded under the auspices of the World Intellectual Property Organization.*" Article 20: "*Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable*	✓	Article 6: Performance Requirements

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				discrimination between the Parties or their investors where like conditions prevail, or a disguised restriction on investors or investments made by investors of any other Party, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Party of measures: *(b) necessary to protect human, animal or plant life or health*.”		
AANZFTA (ASEAN-Australia-New Zealand FTA)	Article 4 of Chapter 11 and Article 4 of Chapter 13 (NT) Article 5 (PPR) Article 6 (FET) Article 6 (Full Protection and Security) Article 9 and Annex on Expropriation and Compensation (Expropriation)	N.A.	Article 9.5: “*This Article does not apply to the issuance of compulsory licences granted in relation to intellectual property rights in accordance with the TRIPS Agreement*.”	Article 3 of Chapter 13: “*Each Party affirms its rights and obligations with respect to each other Party under the TRIPS Agreement*.”	✓	N.A.

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ASEAN Comprehensive Investment Agreement (2009)	Article 5 (NT) Article 6 (MFN) Article 7 (PPR) Article 11 (FET) Article 11 (Full Protection and Security) Article 14 and Annex 2 (Expropriation)	N.A.	Article 14.5: "*This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement.*"	Article 17: "*Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Member States or their investors where like conditions prevail, or a disguised restriction on investors of any other Member State and their investments, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member State of measures:* *(b) necessary to protect human, animal or plant life or health.*"	✓	N.A.
Japan-Thailand EPA	Articles 93 and 124 (NT) Article 95 (FET) Article 95 (Full Protection and Security)	N.A.	Article 122.4(a): "*The Parties re-affirm their commitment to comply with the obligations set out in the following international agreements and the cited provisions thereof:* *(a) The TRIPS Agreement;*	N.A.	✓	N.A.

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	Articles 96 and 125 (MFN) Article 102 (Expropriation) Article 149 (Non-Discrimination)		*(b) The Berne Convention; and* *(c) Articles 1 through 12, and Article 19 of the Paris Convention.*" (not a direct reference to CL)			
New Zealand-Thailand CEPA (2005)	Articles 9.6 and 9.7 (NT) Article 9.8 (MFN) Article 9.11 (Expropriation)	✓	N.A.	N.A.	✓	N.A.
Australia-Thailand FTA (2004)	Articles 904 and 907 (NT) Articles 908 and 910 (MFN) Article 909 (FET) Article 912 (Expropriation)	✓	N.A.	N.A.	✓	Article 901: "*Covered investment means, with respect to a Party, an investment in its territory of an investor of the other Party in existence as of the date of entry into force of this Agreement or established, acquired or expanded*

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						thereafter and which has been admitted by the latter Party in accordance with its laws, regulations and policies." "*Direct investment means a direct investment as defined by the International Monetary Fund under its Balance of Payments manual, fifth edition (BMP 5), as amended by Article 905 and 911 (Denial of benefits)*."
Investment Agreement among the Governments of Brunei Darussalam,	Article 3 (FET) Article 4 (MFN) Article 6 (Expropriation)	✓	N.A.	Article 5: "*The provisions of this Agreement shall not apply to matters of*	✓	N.A.

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Indonesia, Malaysia, Philippines, Singapore and Thailand				*taxation in the territory of the Contracting Parties. Such matters shall be governed by Avoidance of Double Taxation Treaties between Contracting Parties and the domestic laws of each Contracting Party*."		