

The Role of Customary International Law for Intellectual Property Protection beyond Borders

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ABSTRACT

This paper considers the role of customary international law for the protection of intellectual property (IP) beyond borders. As an area where standards of protection are primarily, if not exclusively, governed by treaty law, there seems to be little role left for custom. The analysis shows that this point holds true for principles or rules that commit states to a particular form of protecting the rights of foreign IP owners. However, the interpretation, application and enforcement of these rules are informed by other areas of public international law, including those governed by custom. After reviewing this often neglected role of customary international law for IP protection in general, the paper focuses on the customary right to regulate and its role in neighbouring areas of international economic law, – in particular the protection of foreign investments. Exploring the contours and limits of this right, the main research question then is whether – and if so, how – this right applies to treaty commitments in relation to the protection of IP rights. I conclude that despite a complex web of treaty-based rules, there is usually no specific evidence that the state parties intended to ‘contract out’ of the right to regulate. That aspect is further confined by reference to this right in the Doha Declaration on TRIPS and Public Health. A broader point is to emphasise custom as a necessary contextual factor of the environment within which international IP law operates: it is a relevant element simply because coordinating protection beyond borders often relies on the functionality and tools of international law.

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A. INTRODUCTION: RATIONALISING THE TREATY ORIGINS
OF INTERNATIONAL IP LAW

Based on the principal notion of territoriality, the protection of intellectual property (IP) rights is effected by – and hence in the end remains a matter of – domestic law. Usually, the relevant law is that of the country for whose territory protection is sought. In order to ensure protection for their domestic IP owners abroad, states have essentially relied on an increasingly dense network of international agreements that commit the contracting parties to, for example, treat foreign IP owners no less favourably than domestic parties and to provide defined minimum standards of protection and enforcement of IP rights. In that sense, international IP protection is an area of international law that is primarily governed by treaties, which are agreements between states. Other sources of international law, set out in Article 38 of the Statute of the International Court of Justice¹ – in particular, ‘international custom, as evidence of a general practice accepted as law’ and ‘the general

¹ Statute of the International Court of Justice (ICJ Statute), 26 June 1945, 59 Stat. 1055, 33 *UNTS* 933. In addition to custom and general principles, the ICJ Statute also refers to ‘judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law’. These are hence not ‘primary’ or ‘direct’ sources of international law, but serve as useful and important aides in determining the nature and content of treaties, custom and general principles.

principles of law recognised by civilized nations’ – have received little attention in the context of protecting IP rights beyond borders.

In their treatise, Abbott et al. observe that sources other than treaty law ‘have been of much less importance to the international IPRs system than to the classical domains of international law’ – to an extent that ‘the link between international IP law and the full body of international law has not been fully established’.² Retracing the history of early international agreements on IP protection, Dinwoodie et al. remark that ‘in the milieu of the nineteenth century international system, positive international law gained its readiest expression in the form of treaties between nation states’.³

The focus on treaties as a clear and positive expression of law between states thus seems an obvious one for IP. The principal rationale was to achieve concrete commitments to protect, usually in defined ways by means of exclusive rights operating between private parties for specific types of intangible assets abroad. Arguing for the existence of an unwritten custom that requires such protection, derived from general state practice that had been accepted as law, appears difficult to sustain even today⁴ and would have been much less convincing in the nineteenth century. In light of the significantly diverging national laws on IP protection (with several countries not granting key rights such as patents at all),⁵ one would have been unable to offer evidence for sufficiently general state practice in the protection of different types of IP rights – let alone being able to show that any such practice of protection was undertaken on the basis of a sense of legal obligation, under international law, to do so. Similarly, basing one’s demands for concrete and effective forms of protection (such as the notion of priority rights, a cornerstone of the Paris Convention of 1883)⁶ on general principles of law recognised among states would have equally been a futile exercise.

It was this demand from IP owners for concrete and specific forms of protection for their intangible assets – such as inventions, indicators of origin, industrial designs and literary and artistic works – that required international agreements, which were the only feasible tool for fast and precise law creation on the international plane. And once IP protection beyond borders had been designed as a treaty-based system from inception, its ‘highly specialised and contained’ nature and the lack of interest

² Frederick Abbott, Thomas Cottier and Francis Gurry, *International Intellectual Property in an Integrated World Economy*, 3rd ed. (Kluwer, 2015), at 15.

³ Graeme Dinwoodie, William Hennessey, Shira Perlmutter and Graeme Austin, *International Intellectual Property Law and Policy*, 2nd ed. (LexisNexis, 2008), p. 31.

⁴ Compare *ibid.*

⁵ See the overview of national laws prior to the 1883 Paris Convention on the Protection of Industrial Property (PC) (Paris, 20 March 1883, last revised at Stockholm on 14 July 1967 and amended in 1979, 828 UNTS 306) in Samuel Ricketson, *The Paris Convention on the Protection of Industrial Property – A Commentary* (Oxford University Press, 2015), at 1.16–1.23.

⁶ See the ‘*droit de priorité*’ as set out in Article 4(1) of the original 1883 ‘*Convention de Paris pour la protection de la propriété industrielle*’ online at <https://wipolex.wipo.int/en/text/287780>.

from general international lawyers were argued to be contributing factors for the widespread disregard for other (usually more generalist) sources of law within the domain of international IP law.⁷ In addition, the private law origins of IP protection on the domestic plane made engagement with broader public international law doctrines and principles much less inevitable than in related fields, such as international investment law.⁸ At the domestic level, distinct from the protection of the property of aliens against state interferences, IP law essentially operates in the form of private rights, applicable primarily between private parties.

While therefore the origins of international IP protection are essentially (if not solely) treaty-based, this growing field over time has coincided with other areas of international law, including those based on custom. In particular, with the integration of IP as one of the three pillars of trade regulation in the World Trade Organization (WTO) and by subjecting IP to WTO dispute settlement, questions of treaty interpretation, dispute settlement and compliance began to receive an increasing amount of attention from experts in IP, trade and public international law.⁹ Based on the invitation in Article 3(2) of the WTO Dispute Settlement Understanding (DSU), WTO adjudicators and commentators have explored how the 'customary rules of treaty interpretation of public international law' operate in relation to the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement and the prior conventions it incorporates by reference.¹⁰ However, this debate has

⁷ Abbott et al., note 2, at 15–16. One might add that IP Conventions prior to TRIPS were not subject to international adjudication, despite the option under Articles 28 PC and 33 of the Berne Convention on the Protection of Literary and Artistic Works (BC) (Berne, 9 September 1886, last revised at Paris on 24 July 1971 and amended in 1979, 1161 UNTS 30) to bring a dispute 'concerning the interpretation or application of this Convention' to the ICJ. It is telling that although international IP law has been a contested field for many decades and despite only a minority of countries having made use of the reservation option under Article 28:2 and 33:2, these provision have never been invoked and have been compared to 'the once new car resting in the garage that has never been driven' (see Ricketson, note 5, 8.66). While the members of the Paris and Berne Unions may have various reasons not to take a dispute to the ICJ, this lack of involvement of the Court as the generalist institution par excellence in international law has certainly contributed to the traditionally self-contained nature of international IP law.

⁸ While this argument would benefit from further systemic substantiation, a telling example is that one of the early textbooks on international industrial property by Ladas does not, in three volumes and over 2000 pages, include any general discussion on public international law other than the impact of World War II and restoration of IP rights under treaties of peace (see Stephen Ladas, *Patents, Trademarks, and Related Rights – National and International Protection*, Harvard University Press, Cambridge (MA), 1975, pp. 1805–1846).

⁹ See for example Rochelle Dreyfuss and Andreas Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 *Virginia Journal of International Law* 275 (1997). For a recent treatment of the IP in the WTO context, see Matthew Kennedy, *WTO Dispute Settlement and the TRIPS Agreement – Applying Intellectual Property Standards in a Trade Law Framework* (Cambridge University Press, 2016).

¹⁰ An in-depth engagement with various aspects of Articles 31–33 VCLT, which the WTO Appellate Body (AB) from its very first decision onward confirmed reflects customary international law (see *United States – Standards for Reformulated and Conventional Gasoline (US – Gasoline)*, Appellate Body Report (29 April 1996, WT/ DS2/ AB/ R), p. 16; *Japan – Taxes on*

not ended with an engagement with custom, as codified in Articles 31–33 of the Vienna Convention on the Law of Treaties (VCLT).¹¹ Due to the WTO rules on dispute settlement, compliance and cross-retaliation, questions of state responsibility and in particular countermeasures¹² – for example, via attempts by several countries to suspend their TRIPS obligations to ‘enforce’ favourable WTO rulings – have become part of international IP law. Of course, in the WTO context, and generally also in relation to free trade agreements (FTAs) if they contain an IP Chapter and subject its obligations to dispute settlement, these questions are primarily addressed via treaty law, namely the DSU (and FTA dispute settlement provisions). However, WTO Panels and the Appellate Body have resorted to the underlying customary international law rules on state responsibility in order to clarify and interpret WTO treaty law where necessary.¹³ And where treaty-based dispute settlement systems are not available, Sam Ricketson has rightly pointed to customary international law on

Alcoholic Beverages, Appellate Body Report (4 October 1996, WT/DS8/AB/R), pp 96–106) can be found in the Panel Report in *United States – Section 110 (5) of the US Copyright Act (US – Copyright)* (WTO/DS160/R, 15 June 2000), at para. 6.43–55. However, as lamented by several commentators referred to below, WTO adjudication has not consistently engaged with all aspects of the customary international law treaty interpretation framework and has, until recently, not given much weight to the object and purpose of TRIPS. As explained further below, this has somewhat changed with the Panel and AB decision in *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging (Australia – Plain Packaging)* (WTO/DS435), Panel report circulated 28 June 2018, AB report circulated 9 June 2020. In addition to all major IP treatise and TRIPS commentaries, which now routinely consider the meaning of IP treaty provisions in light of the interpretative framework codified in Articles 31–33 VCLT, see for example Susy Frankel, *The WTO’s Application of ‘the Customary Rules of Interpretation of Public International Law’ to Intellectual Property* (2005) 46 *Virginia Journal of International Law*; Robert Howse, *The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times* (2000) 3(4) *Journal of World Intellectual Property* 493–507; Bryan Mercurio and Mitali Tyagi, *Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements* (2010) 19(2) *Minnesota Journal of International Law* 275; Henning Grosse Ruse-Khan, *Proportionality and Balancing within the Objectives of Intellectual Property Protection*, in *Intellectual Property and Human Rights*, Paul Torremans, ed. (Kluwer, 2008), pp. 161, 184.

¹¹ Vienna Convention on the Law of Treaties (VCLT) (Vienna, 23 May 1969, 1155 UNTS 331).

¹² See *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, Recourse to Arbitration by the European Communities under Article 22.6 of the DSU (WT/DS27/ARB/ECU), 24 March 2000; A Subramanian and J Watal, *Can TRIPS Serve as an Enforcement Device for Developing Countries in the WTO?* (2000) *Journal of International Economic Law* 403–416; *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, Recourse by Antigua and Barbuda to Article 22.2 DSU (WT/DS285/22, 22 June 2007); Henning Grosse Ruse-Khan, *A Pirate of the Caribbean? The Attractions of Suspending TRIPS Obligations* (2008) 11(2) *Journal of International Economic Law* 313.

¹³ See *United States – Subsidies on Upland Cotton* (Recourse to Arbitration by the United States under Article 22.6 of the DSU and Article 4.11 of the SCM Agreement – Decision by the Arbitrator (WT/DS267/ARB/1, 31 August 2009), fn. 129; and *United States – Definitive Anti-Dumping and Countervailing Duties on Certain Products from China* (WT/DS379/AB/R, 11 March 2011), para. 316. On the role of customary law on countermeasures in relation to

countermeasures against a material breach as the potential basis for member states of the Paris or Berne Union to react to instances of non-compliance with commitments under the conventions.¹⁴

An initial analysis therefore suggests that while the international law – which contains the principal commitments to protect the inventions, indicators of origins, industrial designs or literary and artistic works – is treaty law, the interpretation, application and enforcement of that law has been informed by other areas of public international law. Such areas include those governed by custom (whether predominantly or to a lesser extent). Many of these interfaces remain to be explored more fully,¹⁵ but this chapter does not offer the space for a comprehensive review of all aspects of customary international law relevant for IP protection beyond borders.

The following sections focus on the customary right to regulate and its interface with treaty commitments to protect IP rights. However, first, an additional example of a well-known customary rule and its reception in the IP context shall suffice to show the complex interplay of treaty and customary rules that is likely at play in the context of international IP law. Even though set out in Article 26 VCLT, the principle of *pacta sunt servanda* emanates from custom.¹⁶ In the TRIPS Agreement, it has found general expression in the very first sentence of its first Article: ‘Members shall give effect to the provisions of this Agreement.’ Article 1(1) 3rd sentence qualifies this by

cross-retaliation by means of suspending treaty commitments to protect IP rights, see Grosse Ruse-Khan, note 12.

¹⁴ Ricketson, note 5, para. 8.67–68. While the principal customary rule here has been codified in Article 60 VCLT, the latter is generally understood to reflect customary international law (Malcolm Shaw, *International Law*, 8th ed [Cambridge University Press, 2018] pp. 685 and 717–719).

¹⁵ This is important not only as an academic exercise but also has a central normative dimension. As the analysis below shows, the interplay between treaty and custom does not generally preempt the application (or more general interpretative relevance) of the latter in favour of the former. While treaty law may often be considered as *lex specialis*, custom retains relevance – for example in informing the proper construction of treaty norms in light of the underlying principles expressed in customary rules, or by means of gap-filling where treaty norms do not exist. Disregarding custom therefore means not fully accounting for the broader contextual framework within which international IP treaties operate, which can lead to further self-isolation and containment of the international IP system. Since that system was primarily put in place to protect the interests of right holders, an isolated focus on its treaty rules alone will likely prevent a full appreciation of its normative context.

¹⁶ Article 26 VCLT states that ‘[e]very treaty in force is binding upon the parties to it and must be performed by them in good faith.’ It is generally understood to reflect customary international law (see e.g. the ICJ in *Gabcikovo Nagymaros*, ICJ reports 1997, pp. 7, 78–79; *United States – Continued Dumping and Subsidy Offset Act of 2000* (WT/DS217/AB/R, 16 January 2003) Report of the Appellate Body, fn. 247; Shaw, note 14, p. 685), and its ‘codification’ in the VCLT shows how custom can be clarified and crystallised via treaty rules, in particular those originating from the work of the International Law Commission (ILC), including the codification conventions it has drafted.

leaving members 'free to determine the appropriate method of implementing [TRIPS] within their own legal system and practice.' This interplay of custom and its reception – as well as qualification – in IP treaties can also be found in Part III of TRIPS on IP enforcement. Here, Article 41(5) TRIPS adds further clarification on what is not owed by members (including in terms of specific IP courts, law enforcement in general and the distribution of resources for IP enforcement). Article 41(1) otherwise reiterates the *pacta sunt servanda* rule by demanding that 'Members shall ensure that enforcement procedures . . . are available under their law so as to permit effective action against any act of infringement' of IP rights covered by TRIPS.¹⁷

Altogether, this example reveals a complex interplay between general and specific treaty rules, underpinned by general principles emanating from customary international law – a scenario where the latter is not necessarily completely superseded by treaty law, but where custom may well serve an important role in informing the proper interpretation of the individual treaty provisions. As the following discussion on the right to regulate shows, one can derive important conceptual, systemic and normative insights from contextualising IP treaty law within its relevant broader international law environment, including customary law.

With these initial considerations on the role of custom and its relation to treaties in the context of international IP law in mind, this chapter proceeds as follows. Section B looks at the difficulties in identifying customary international law, in particular in relation to (primary) commitments on the protection of IP rights beyond borders – while pointing to the sometimes neglected but important role of custom in relation to the (secondary) principles and rules about the interpretation and enforcement of, as well as general public interest defences relating to, IP protection commitments.

Using the customary 'right to regulate' as an example, Section C then explores the contours and limits of this right in the context of international investment law. Section D considers whether – and if so, how – this right applies to treaty commitments in relation to the protection of IP rights. It does so by reviewing the potential operational scope of such a customary right the context of international IP law (subsection I); by then asking the question as to whether states have contracted out of this customary right when entering into IP treaties (subsection II); and by identifying the contours of this right in the specific context of the WTO–TRIPS Agreement (subsection III). Section E concludes with some broader observations on the role of customary international law for IP protection beyond borders and the politics and consequences of not properly accounting for custom.

¹⁷ For an analysis of the IP enforcement obligations that reflect the *pacta sunt servanda* rule and the related flexibilities in this context, see *China – Measures affecting the Protection and Enforcement of Intellectual Property Rights (China – IPRs)*, Panel Report (26 January 2009, WT/DS362/R), paras. 7.323, 7.511–515 and 7.591–599.

B. DIFFICULTIES IN IDENTIFYING CUSTOM
IN INTERNATIONAL IP LAW

Custom derives its status as law from a common practice among states, backed by their volition – or at least cognition – regarding the legal (rather than ethical, moral, political or courteous) nature of that practice.¹⁸ The essence of custom brings with it inherent difficulties. Any serious analysis on customary international law needs to begin with a careful scrutiny as to whether a particular rule, set of rules or principle of custom actually exists and what exactly its content is. Discussing a possible role for custom in international IP law therefore faces the foremost challenge of identifying custom – which essentially involves an empirical exercise of establishing a general practice of states, undertaken with a sense of legal right or obligation.¹⁹ This methodological ‘two element approach’ – which applies uniformly to all areas of international law – requires one to assess (1) whether there is general practice between states and (2) whether that practice is accepted as law.²⁰

The 2018 Draft conclusions of the International Law Commission (ILC) offer instructive guidance on this assessment: for example, that state practice can take many forms, involving all types of state organs; and it must be general, in the sense of being ‘sufficiently widespread and representative, as well as consistent’.²¹ If that is the case, no specific duration is required, and the assessment is relative – that is to say, the required spread and consistency depend on the specific context.²² Under the second constituting element, the state practice so identified must be accepted as law (*opinio juris*), meaning that ‘the practice in question must be undertaken with a sense of legal right or obligation’.²³ Therefore, general practice must be accompanied by a conviction among states ‘that it is permitted, required or prohibited by customary international law’ – which must be shown in relation to states engaging in the relevant practice as well as those in a position to react to it.²⁴

¹⁸ For a more comprehensive discussion on the theoretical and jurisprudential basis of custom, as well as its legal nature, see Tullio Treves, *Customary International Law*, Oxford Public International Law (Oxford University Press, 2015), para. 4–9 (<http://opil.oupplaw.com>).

¹⁹ Treves, note 18, para. 17–18; see generally International Law Commission (ILC), Draft conclusions on identification of customary international law, with commentaries, ILC Report (A/73/10), 2018, para. 66 (2)–(3). The draft conclusions were adopted by the ILC at its seventieth session in 2018 and submitted to the General Assembly as a part of the Commission’s report covering the work of that session (A/73/10). The report also contains commentaries to the draft articles (para. 66) and appears in *Yearbook of the International Law Commission, 2018*, vol. II, Part Two.

²⁰ See the ILC’s Draft conclusions, note 19, para. 66 (2)–(3) and Conclusion 2 (1)–(2), (6).

²¹ *Ibid*, Conclusions 6–8 and accompanying commentary.

²² *Ibid*, Conclusion 8 (2), (9).

²³ *Ibid*, Conclusion 9.

²⁴ *Ibid*, at (2)–(5). Conclusion 10 then summarises the forms of evidence for *opinio juris* and highlights that under certain circumstances the mere tolerance of practice can be relevant; see (8).

Finally, the ILC Conclusions 11 and 12 offer important guidance on the role of treaties and resolutions of international organisations or intergovernmental conferences in providing evidence for determining the existence and content of custom. As the discussion in this chapter will come back to this topic in greater detail, it suffices to say here that a rule set out in a treaty can serve as evidence for its customary international law status (in terms of codifying, crystallising or giving rise to custom), in particular when that rule is reflected in various agreements between states.²⁵ In order to distinguish appropriately between custom and treaty law, it is essential to show that states not only act in accordance with the rule because of the *pacta sunt servanda* principle but also because they feel that it represents a rule of custom.²⁶ (Here, of course, ‘states’ crucially includes those non-parties to the treaty.) Similarly, a provision in a resolution can reflect customary international law, but it cannot, in itself, create custom without being backed by general state practice and *opinio juris*.²⁷

Considering the ILC guidance for our question of custom and IP protection beyond borders, one might usefully pick up the distinction made above between (1) the (primary) norms concerning the protection of IP rights, and (2) the (secondary) principles and rules related to the interpretation and enforcement of IP protection commitments. On (1), the question is then whether it is possible to identify customary rules that oblige countries to protect an IP right in a particular way. In other words, have certain minimum standards of IP protection gained the status of customary rules in international law? On the one hand, one might think of some of the core principles of the international IP system, such as the obligation to offer foreign right holders national treatment. While this question is not examined in full detail here, several arguments speak against a customary national treatment rule: first of all, state practice in relation to newly evolving IP rights that are not covered by an IP treaty (such as a right for database makers or press publishers) shows no widespread, let alone consistent, approach to granting such rights to foreigners.²⁸ And

²⁵ Ibid, Conclusion 11 and accompanying commentary, in particular (1)–(7).

²⁶ Ibid, at (4) and (7). The ILC Conclusions highlight the importance of the text and terminology used here: treaty language whereby the Parties ‘confirm’ the customary status of a rule or express their intention to ‘codify’ custom might carry key evidentiary value, but is not the sole determinant, see *ibid*, at (5).

²⁷ Ibid, Conclusion 12, in particular accompanying commentary (3)–(8).

²⁸ The EU (and by extension all its twenty-seven members) in particular has a reputation for not making ‘new’ IP rights available to foreign right holders (see e.g. Article 15 DIRECTIVE (EU) 2019/790 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC and corresponding recital 55 on a ‘copyright-style’ right for press publishers – but only those established in an EU Member State); or for allowing foreigners only to benefit from such rights when their own home state offers equivalent protection (see Article 11 of the DIRECTIVE 96/9/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 March 1996 on the legal protection of databases and corresponding recital 56). In addition, the USA in the 1980s made the protection of the layout of semiconductor chips available only

while of course almost all countries offer national treatment in relation to copyright, trademarks, patents, industrial designs and other IP rights that are internationally common, there is no evidence that this protection against discrimination is not solely because of the respective treaty commitments in the Paris and Berne Conventions as well as TRIPS. In fact, recent FTAs which add to the national treatment clauses in those IP treaties by clarifying that, for example, legal protection for technological protection measures (TPMs) and digital rights management (DRM) systems falls within the notion of ‘protection’ of copyright, and hence within the scope of the national treatment principle, show that states still consider treaty rules in this area to be necessary.²⁹ A further argument against considering national treatment as part of custom follows from the fact that protection of foreign investors and their proprietary assets against discrimination is commonly seen as a treaty standard and not part of custom in international investment law.³⁰

In light of the arguments above, identifying a rule of custom to protect IP rights will face a steep uphill battle of showing evidence of general practice that is accepted as law. For the time being, the flurry of new treaties’ rules on IP protection (primarily set out in IP Chapters of FTAs) is not likely to change this situation. While one might see some degree of convergence of IP protection standards in FTAs (for example in relation to test date exclusivity rules, the protection of TPMs and DRMs, or TRIPS-plus border measures or criminal sanctions in IP enforcement), such convergence at best indicates the future prospect for consolidation of these standards on the multilateral treaty level. There is no evidence that those states who are willing to commit to these IP protections in FTAs are doing so because they deem providing such protection to foreign IP owners to be something owed in the absence of the treaty rule.

An example from the *China – IPRs* dispute shows that a WTO Panel was not even willing to consider various FTA provisions concerning criminal sanctions for IP infringements on a ‘commercial scale’ as subsequent interpretative practice under Article 31(3)(b) VCLT, which would – akin to custom – establish an agreement of the parties, here regarding the interpretation of Article 61 TRIPS.³¹ If common provisions in an FTA do not, in the view of the Panel, meet the standard of a

to US manufacturers, subject to reciprocity clauses in Sec. 902 and 914 of the US Semiconductor Protection Act 1984, for a detailed discussion, see Kim Feuerstein, *Chips Off the Trade Bloc: International Harmonization of the Laws on Semiconductor Chips* (1992) 2 *Fordham Intellectual Property, Media and Entertainment Law Journal* 137.

²⁹ See Article 20.8(1) and fn. 2 USMCA, Article 18.8(1) and fn. 4 CPTPP.

³⁰ Stephan Hobe, *The Law relating to Aliens, the International Minimum Standard and State Responsibility*, in *International Investment Law*, Marc Bungenberg, Jörn Griebel, Stephan Hobe and August Reinisch eds. (Hart, Beck & Nomos, 2015), pp. 14–15; Andrea K Bjorklund, *National Treatment in Investment Law in Elgar Encyclopaedia of International Economic Law*, Thomas Cottier and Krista Nadakavukaren Schefer, eds. (Elgar 2017), 203; Simon Klopschinski, Christopher Gibson and Henning Grosse Ruse-Khan, *The Protection of Intellectual Property Rights under International Investment Law* (Oxford University Press, 2020), para. 5.08.

³¹ *China – IPRs*, Panel Report, para. 7.580–581.

‘common, consistent, discernible pattern of acts or pronouncements’ among WTO members,³² they certainly cannot be considered custom among all states.

In sum, showing the emergence – let alone existence – of a customary international law rule with regard to an obligation to protect IP rights of foreigners in a particular way is not likely to be a very successful undertaking. The following analysis thus focuses on point (2) of the distinction made above, namely to identify custom in relation to the (secondary) principles and rules related to the interpretation and enforcement of IP protection commitments. As already explained, this is straightforward for the ‘customary rules of interpretation of public international law’ which Article 3(2) DSU instructs WTO adjudicators to rely on in clarifying the provisions in WTO Agreements, including TRIPS.³³ And with regard to customary rules relating to dispute settlement and compliance, especially those on state responsibility deserve further scrutiny for their role relating to IP protection beyond borders.³⁴ However, perhaps the most relevant aspect of custom concerns the justifications or defences that a state may rely upon to limit the protection of IP rights in the public interest. It is this question about a customary right to regulate and its application in the context of international IP law to which this chapter now turns.

C. THE STATE’S RIGHT TO REGULATE AS A RULE OF CUSTOMARY INTERNATIONAL LAW

A useful starting point for appreciating a state’s customary right to act in the public interest is the protection of aliens (especially against injuries to their property) as part of customary international law. Initially in the form of general international law on all forms of protection available to foreign legal and natural persons in the host state, the so-called international ‘minimum standard of treatment’ (MST) has developed as the core substantive protection for foreign investors based on custom.³⁵ While ambiguity and controversies over the contours of the MST led especially capital-exporting states to demand treaty-based protection via international investment agreements (IIAs), the often expansive protections afforded under these treaties by investor-state dispute settlement (ISDS) tribunals have resulted in a push-back by

³² *Ibid.*, para. 7.581. In addition, the Panel disagreed that such practice could imply an agreement on the interpretation of TRIPS, hence lacking the subjective element which in custom is reflected by *pinion juris*.

³³ See Section B above, discussing the customary international law status in particular of Articles 31–33 VCLT and the use of these rules of interpretation in the context of TRIPS disputes.

³⁴ As mentioned in Section B, questions arise relating to the customary law on countermeasures in case the suspension of TRIPS obligations also affects other treaty commitments to protect IP, such as under the Paris or Berne Convention or IP Chapters in FTAs.

³⁵ Hobe, note 30, at pp. 9–14.

states, including by means of more concrete and narrow determinations of protection standards – including the MST.³⁶

Another expression of the ‘return of the state’³⁷ comes in the form of explicit recognition and concretisations, in IIAs as well as in ISDS awards, of a state’s right to regulate in the public interest, also referred to as ‘police powers’.³⁸ That right is thus not about customary protection of aliens and their property but the limits commonly accepted to such protection, based on the underlying notion of state sovereignty.³⁹ As the discussion below further indicates, this foundation of the right to regulate makes it particularly apt to limit not only customary but also treaty-based protections of investors and their assets.

Within its principal operational context of international investment law, the right to regulate (or ‘police powers’ doctrine)⁴⁰ has been accepted as forming part of custom.⁴¹ Various forms of state practice, often backed by express *opinio juris*, are commonly cited in support of this proposition,⁴² such as the provisions on

³⁶ On the scope of the customary protection, see Hobe, note 30, pp. 15–22. On the overall historical developments towards treaty standards via IIAs and the remaining role of custom, see Patrick Dumberry, *Customary International Law in International Economic Law, Encyclopaedia of International Economic Law* (Edward Elgar, 2017), 44–45. With a specific focus on fair and equitable treatment (FET), the MST, ISDS interpretations and state responses, see Klopschinski, Gibson and Grosse Ruse-Khan, note 30, 6.08–17. An example for state practice aiming to crystallise the contours of MST as part of custom is Article 9.6 of the CPTPP, read together with Annex 9-A to the CPTPP Investment Chapter, defining MST to include FET and full protection and security (FPS), which in turn are described in various subsections as including or not including certain elements of protection, with Annex 9-A confirming the Parties’ shared understanding of these protections and their limits reflecting custom.

³⁷ Jose Alvarez, *The Return of the State*, 20(2) *Minnesota Journal of International Law* 223 (2011).

³⁸ See generally Klopschinski, Gibson and Grosse Ruse-Khan, note 30, paras. 6.107–123.

³⁹ For a discussion on the foundations of the right to regulate in the concept of sovereignty, see Jorge Viñuales, *Sovereignty in Foreign Investment Law*, in Zachary Douglas, Joost Pauwelyn and Jorge E. Viñuales, eds. *The Foundations of International Investment Law: Bringing Theory into Practice* (Oxford University Press, 2014); Katja Ziegler and Domine Reserve, *Max Planck Encyclopaedia of Public International Law* (Oxford University Press, 2013); Cook, note 93, pp. 257, 261–263 (citing relevant WTO case-law).

⁴⁰ See for a general discussion Joel Trachtman, *The International Economic Law Revolution and the Right to Regulate* (Cameron May, 2005) and Catherine Titi, *The Right to Regulate in International Investment Law* (Nomos/Hart, 2014). Noam Zamir, *The Police Powers Doctrine in International Investment Law* (2017) 14(3) *Manchester Journal of International Economic Law* 318–337.

⁴¹ See generally Jorge Viñuales, *Customary Law in Investment Protection*, *Italian Yearbook of International Law* (2013/2014), pp. 23–48, who also discusses other expressions of state sovereignty within customary international law (such as necessity and the doctrine of countermeasures) and their role in framing investment protection standards, even if they are treaty-based. See also Dumberry, note 36, at 44; OECD, ‘Indirect Expropriation’ and the ‘Right to Regulate’ in International Investment Law, OECD Working Papers on International Investment, 2004/4 (Sept. 2004).

⁴² See for example the (relatively brief) discussion on state practice in *PMI v. Uruguay*, Award, para. 292–294.

expropriation in Annex B to the US Model BIT (2012), which are meant to mirror custom. The annex begins by emphasising that the parties understand that the substantive rules of BIT on expropriation are ‘intended to reflect customary international law concerning the obligation of States with respect to expropriation’; it then clarifies that ‘[e]xcept in rare circumstances, 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’.⁴³ Essentially identical text on the type of regulatory measures excluded from the notion of expropriation can be found in Annex 9-B on Expropriation in the CPTPP, and very similar formulations exist, for example, in the Canadian Model BIT,⁴⁴ the CETA,⁴⁵ the Indian Model BIT,⁴⁶ and Article 5(3) of the China – Turkey BIT⁴⁷ and Article 20(8) of the COMESA Investment Agreement⁴⁸. As early as 1961, the Harvard Draft Convention on the International Responsibility of States for Injury to Aliens excluded from wrongfulness ‘[a]n uncompensated taking of property of an alien or a deprivation of the use or enjoyment of property of an alien which results from . . . the action of the competent authorities of the State in the maintenance of public order, health, or morality’. This was subject to further conditions, such as non-discrimination, due process and non-arbitrariness.⁴⁹

Recent agreements such as CETA also show that the right to regulate is not limited to the expropriation standard.⁵⁰ And outside the specific investment law context, one can point to Article 1 of the 1st Protocol to the ECHR, which

⁴³ See US Model BIT (2012), Annex B – Expropriation, para. 1 and 4(b) available online at <https://ustr.gov/sites/default/files/BIT%20text%20for%20ACIEP%20Meeting.pdf>.

⁴⁴ See Article 9:3 Model FIPA (2021) available online at www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/fipa-apie/2021_model_fipa-2021_model_e_apie.aspx?lang=eng#article-9.

⁴⁵ See CETA, Annex 9-A on Expropriation, para. 3 available online at <https://data.consilium.europa.eu/doc/document/ST-10973-2016-ADD-3/en/pdf#page=64>. In addition, in Article 8(9) CETA on investment protection and regulatory measures, ‘the Parties reaffirm their right to regulate within their territories to achieve legitimate policy objectives, such as the protection of public health, safety, the environment or public morals, social or consumer protection or the promotion and protection of cultural diversity.’ The term ‘reaffirm’ shows that the Parties consider this right to exist regardless of its specific inclusion in the treaty.

⁴⁶ See Indian Model BIT (2016), Article 5(5) available online at https://dea.gov.in/sites/default/files/ModelBIT_Annex_o.pdf.

⁴⁷ See Article 5:3 of the China – Turkey BIT (2015) available online at <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/6085/download>.

⁴⁸ Investment Agreement for the Common Investment Area of the Common Market for Eastern and Southern Africa (COMESA), Article 20(8), which explicitly considers these exclusions of regulatory measures from expropriation as ‘[c]onsistent with the right of states to regulate and the customary international law principles on police powers’. Available online at <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/3092/download>.

⁴⁹ See Article 10(5) of the 1961 Harvard Draft Convention on the International Responsibility of States for Injury to Aliens.

⁵⁰ See Article 8(9) CETA on investment protection and regulatory measures, cited in note 45.

emphasises that the human rights' protection of property 'shall not, however, in any way impair the right of a State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties.' While not all of these treaty provisions on the right to regulate make express reference to customary international law, they generally appear to reflect widespread and representative state practice. That remains true even if one might question whether this (treaty) practice is sufficiently consistent with regard to all contours of the right and can always be considered as being undertaken with a sense of a legal right beyond the treaty in question.⁵¹

A significant number of ISDS awards have also referred to the right to regulate and have frequently based its existence on customary international law, even where the applicable IIA does not contain a reference to that right. As this chapter cannot engage in a full review of ISDS cases on this topic, it is appropriate to focus on the main IP-related investment dispute where the right to regulate was invoked.

In *Philip Morris v. Uruguay*, the tribunal had to rule on claims that the host state's regulations, which in various ways limited the use of brands on tobacco packaging, constituted a breach of expropriation and fair and equitable treatment (FET) provisions in the Uruguay–Switzerland BIT.⁵² Uruguay countered that its measures had been designed to protect the public health of its citizens. The tribunal recognised that while the Philip Morris (PM) trademarks constitute a protected investment, neither under domestic law nor under applicable international (IP) treaties does the investor 'enjoy an absolute right of use, free of regulation – but only an exclusive right to exclude third parties from the market so that only the trademark holder has the possibility to use the trademark in commerce, subject to the State's regulatory power'.⁵³

On the expropriation claim, the tribunal held that not only had PM failed to show that there was a substantial deprivation of its protected investment (as there was no

⁵¹ As discussed further below, the scope of the right and the conditions for its exercise differ at times in certain relevant details, not only in the treaty provisions cited above but also in the way ISDS tribunals have considered them. Nevertheless, key elements of the right to regulate remain at its consistent core, namely the need to act to protect legitimate public welfare objectives and subjecting the right to conditions that prevent an abusive reliance on it (such as non-discrimination and/or good faith). The *pinion juris* element on the other hand can arguably be established if one recalls that the right to regulate is an expression of the basic and default notion of state sovereignty: as again further explained below, states will generally be aware of this right and will expect to be able to rely on it – unless and only to the extent they have explicitly agreed to limit their right to regulate in a particular way in a treaty.

⁵² *Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Uruguay (PMI v. Uruguay)*, ICSID Case No. ARB/10/7, Award, 8 July 2016. For a detailed discussion of this case see Klopschinski, Gibson and Grosse Ruse-Khan, note 30, para. 3.109–160; Prabhash Ranjan, Police Powers, Indirect Expropriation in International Investment Law and Article 31 (3)(c) of the VCLT: A Critique of Philip Morris v. Uruguay, (2019) 9 *Asian Journal of International Law* 98–124; Yannick Radi, CASE COMMENT: Philip Morris v. Uruguay. Regulatory Measures in International Investment Law: To Be or Not To Be Compensated? (2018) 33(1) *ICSID Review* 74–80.

⁵³ *PMI v. Uruguay*, Award, para. 271.

significant economic loss suffered in consequence of the tobacco packaging measures), but importantly also that ‘the adoption of the challenged Measures by Uruguay was a valid exercise of the State’s police powers, with the consequence of defeating the claim for expropriation under Article 5(1) of the BIT.’⁵⁴ Explaining that ‘[p]rotecting public health has since long been recognized as an essential manifestation of the State’s police power’,⁵⁵ the tribunal then systemically integrated the customary right to regulate into the investment protection provisions of the BIT. Even though these treaty provisions are not explicitly subject to the state’s police powers, an interpretation based on Article 31(3)c) VCLT allows for importing such powers from customary international law.⁵⁶ Those powers include a right to protect public health as a specific expression of a general right to regulate, which allows states to protect the public interest if the measures are ‘bona fide actions for the purpose of public welfare’. In other words, they cannot be ‘arbitrary and unnecessary’ but must be ‘directed to the [public welfare] end’ and ‘capable of contributing to its achievement’.⁵⁷ The tribunal found Uruguay’s tobacco packaging measures to meet these requirements and, as elaborated further in relation to the FET claim, highlighted the ‘margin of appreciation’ which regulatory authorities of the host state enjoy when making public policy determinations.⁵⁸ The tribunal continued that, as a matter of principle,

[t]he responsibility for public health measures rests with the government[,] and investment tribunals should pay great deference to governmental judgments of national needs in matters such as the protection of public health. In such cases respect is due to the discretionary exercise of sovereign power, not made irrationally and not exercised in bad faith . . . involving many complex factors.⁵⁹

In its analysis, the tribunal refers to a range of further ISDS decisions which have, in various ways, recognised the right to regulate. For example, the tribunal in *Saluka v. Czech Republic* stated:

⁵⁴ Ibid, para. 287. On the substantial deprivation standard and its application to PM’s investments, see paras. 274–286 and the discussion by Ranjan, note 52, 105–107.

⁵⁵ *PMI v. Uruguay*, Award, para. 291.

⁵⁶ Ibid, para. 290.

⁵⁷ Ibid, paras. 295, 298–306. For a comprehensive review of the tribunal’s approach to the police powers doctrine and a critique of its reliance on potentially different rules resulting from this doctrine, see Ranjan, note 52, 107–117.

⁵⁸ Ibid, para. 398. See also the general discussion, inspired by the *Philip Morris* award on the applicability of this concept in ISDS by Yuka Fukunaga, Margin of Appreciation as an Indicator of Judicial Deference: Is It Applicable to Investment Arbitration? (2019) 10 *Journal of International Dispute Settlement* 69.

⁵⁹ Ibid, para. 399 – referring further to *Electrabel SA v. Republic of Hungary (Electrabel)*, Decision on Jurisdiction, Applicability and Liability, ICSID Case No. ARB/ 07/ 19 (30 November 2012), para. 8.35; and *Saluka Investments BV (The Netherlands) v. Czech Republic (Saluka)*, UNCITRAL, Partial Award (17 March 2006), paras. 272–273. See however also the Dissenting Opinion of Gary Born on this particular point, *Philip Morris v. Uruguay*, ‘Concurring and Dissenting Opinion by Mr Gary Born’, paras. 87–88.

It is now established in international law that States are not liable to pay compensation to a foreign investor when, in the normal exercise of their regulatory powers, they adopt in a non-discriminatory manner bona fide regulations that are aimed to the general welfare. . . . [T]he principle that the State adopts general regulations that are ‘commonly accepted as within the police power of States’ forms part of customary international law today.⁶⁰

In *Tecmed v. Mexico*, the tribunal went as far as claiming that ‘[t]he principle that the State’s exercise of its sovereign power within the framework of its police power may cause economic damage to those subject to its powers as administrator without entitling them to any compensation whatsoever is undisputable.’⁶¹ And a tribunal established under North American Free Trade Agreement (NAFTA) Chapter 11 confirmed that ‘as a matter of general international law, a non-discriminatory regulation for a public purpose, which is enacted in accordance with due process and, which affects, inter alios, a foreign investor or investment is not deemed expropriatory’.⁶²

However, while other tribunals have taken a similar position,⁶³ there is also case law finding an expropriation, despite the measure being in support of a public welfare purpose. These cases often focus primarily on the detrimental effect of the measure on the investor’s assets.⁶⁴ Yet others have emphasised the limits of the right to regulate, in particular those which follow from specific obligations that states agreed to in an investment treaty.⁶⁵ In balancing the right to regulate with specific

⁶⁰ *Saluka v. Czech Republic*, para. 255, 260, 262.

⁶¹ *Tecnicas Medioambientales Tecmed SA v. United Mexican States (Tecmed)*, ICSID Case No. ARB(AF)/00/2, Award (29 May 2003), para. 119. That tribunal however went on to state that regulatory measures are not per se exempted from expropriation claims (para. 121); therefore, the tribunal adopted a proportionality test which – as discussed further below – balances the impact of the state action against its aims and the extent to which the action achieves those (para. 122).

⁶² *Methanex Corp. v. United States of America (Methanex)*, UNCITRAL, Award (3 August 2005), Part IV, Ch D, para. 7.

⁶³ See for example *Chemtura Corp. (formerly Crompton Corp.) v. Canada*, Final Award, ICGJ 464 (PCA 2010), para. 266; *Renée Rose Levy de Levi v. Peru*, ICSID Case No. ARB/10/17, Award, 26 February 2014, para. 476; *Pope and Talbot Inc v. Canada*, Interim Award, 26 June 2000, para. 96; for an extensive review of the early case-law and state practice (among NAFTA states in particular) confirming custom, see *Marvin Feldman v. Mexico*, ICSID Case No. ARB(AF)/99/1, Award, 16 December 2002, paras. 98–150.

⁶⁴ *Compañía del Desarrollo de Santa Elena, S.A. v. Costa Rica*, ICSID Case No. ARB/96/1, Final Award, 17 February 2000, paras. 71–72; *Metalclad Corporation v. Mexico*, ICSID Case No. ARB(AF)/97/1, Award, 30 August 2000, para. 103; *Vivendi Universal S.A. v. Argentina*, ICSID Case No. ARB/97/3, Award, 20 August 2007, para. 7.5.20; on this issue see generally the discussion in *Azurix Corp. v. Argentina (Azurix)*, ICSID Case No. ARB/01/12, Award, 14 July 2006, paras. 306–323.

⁶⁵ *ADC Affiliate Ltd and ADC and ADMC Management Ltd v. The Republic of Hungary (ADC)*, ICSID Case No. ARB/03/16 (Award 2 October 2006), para. 423–424.

treaty commitments to protect foreign investors, some tribunals have adopted proportionality tests, at times informed by the approach of the ECHR,⁶⁶ which demand some reasonable relationship of proportionality between the means employed and the aim to be realised.⁶⁷ In *El Paso v. Argentina*, the tribunal's balancing exercise considered whether 'the interference with private rights of the investors is disproportionate to the public interest'⁶⁸ – thereby adopting an approach that is more closely aligned with the deferential test in *PMI v. Uruguay*, which leaves room for a 'discretionary exercise of sovereign power' and only reviews whether a decision taken in the public interest is 'not made irrationally and not exercised in bad faith'.⁶⁹ Similar deferential approaches, at times specifically linked again to the notion of margin of appreciation adopted by the ECHR, have been adopted in relation to FET claims or other aspects of balancing international investment protection and the sovereign power of the state to regulate.⁷⁰

Retracing the nuanced differences in the case law, academic commentators refer to three lines of authority with regard to the method to draw a line between non-compensatory regulation and regulatory expropriation.⁷¹ While there seems to be

⁶⁶ See for example *James v. United Kingdom* (1986), ECtHR Judgment of 21 February 1986, para. 50, 63.

⁶⁷ *Azurix v. Argentina*, para. 311–312 (agreeing with the ECtHR that proportionality is lacking when the measure leads to an 'excessive burden' for the individual investor); *LG&E Energy v. Argentina*, 46 ILM 40 (2007), para. 189, 195 (balancing the 'degree of the measure's interference with the right of ownership and the power of the state to adopt its policies' – para. 189); see also *Continental Casualty Company v. The Argentine Republic (Continental Casualty)*, Award, ICSID Case No. ARB/03/9 (5 September 2008), para. 276; *Les Laboratoires Servier, S.A.S. Biofarma, S.A.S., Arts et Techniques du Progrès S.A.S. v. Poland (Servier)*, PCA (UNCITRAL), Final Award, 14 February 2012, para. 569; *Fireman's Fund Insurance Company v. Mexico*, ICSID Case No. ARB(AF)/02/01, Award, 17 July 2006, para. 176.

⁶⁸ *El Paso Energy International Company v. The Argentine Republic (El Paso)*, Award, ICSID Case No. ARB/03/15 (31 October 2011), para. 233. Similarly, the tribunal in *Servier v. Poland* (at para. 570) rephrased the (positively formulated) proportionality test into one case where it needed to determine whether the state had exercised its regulatory powers 'in bad faith, for some non-public purpose, or in a fashion that was either discriminatory or lacking in proportionality between the public purpose and the actions taken.'

⁶⁹ *PMI v. Uruguay*, Award, para. 399; see also the further discussion by the tribunal in paras. 409–410, 418–420.

⁷⁰ *Glamis Gold, Ltd v. The United States of America (Glamis Gold)*, UNCITRAL (NAFTA), Award (8 June 2009) para. 805; *Continental Casualty v. Argentina*, para. 199; *RWE Innogy GMBH & RWE Innogy AERSA SAU v. Kingdom of Spain (RWE)*, Decision on Jurisdiction, Liability and Certain Issues of Quantum, ICSID Case No. ARB/14/34 (30 December 2019), para. 553. See generally the discussion in Klopschinski, Gibson and Grosse Ruse-Khan, note 30, at paras. 6.114–123.

⁷¹ Ursula Kriebaum, Expropriation, in Bungenberg et al. (eds.) note 30, at 1001–1006, 1005. Along the lines discussed above, the author identifies cases that (1) primarily focus on the economic impact on the investor or (2) the nature of the regulatory measure, or (3) adopt some sort of a proportionality or reasonableness test to balance the investors' and the public's interests. See also Ranjan, note 52, at 107. For a similar but conceptually broader differentiation between the Hull formula (about the extent and criteria for compensation), the sole effect doctrine (focusing mainly on the effect on relevant assets) and the proportionality tests (which can also

some convergence on the basic proposition that '[i]t is an accepted principle of customary international law that where economic injury results from a bona fide non-discriminatory regulation within the police power of the State, compensation is not required',⁷² various differences on the exact (and potentially additional) conditions as well as on scope of the right to regulate remain.⁷³ Different views also exist on the interpretative methods used to import the right to regulate as a customary principle (in whatever exact form) into the specific treaty context. A particular question here is whether references to public welfare and non-discrimination as requirements for the legality of (compensatory) expropriation in the treaty bar an interpretative integration of police powers in order to exclude certain public welfare-oriented and non-discriminatory measures from the notion of (indirect) expropriation altogether.⁷⁴ And while authors have generally recognised an increased tendency to resort to the concept of police powers, Titi for example cautions – in the words of the Tribunal in *Saluka v. Czech Republic* – that 'international law has yet to identify in a comprehensive and definitive fashion precisely what regulations are considered "permissible" and "commonly accepted" as falling within the police or regulatory power of States and, thus, non-compensable'.⁷⁵

The overall picture that emerges from this necessarily brief review of state practice and opinio juris in recent investment treaties, the ISDS case law applying those treaties in light of what tribunals consider to constitute custom, and academic commentary hence is a somewhat blurry image of a right to regulate, the exact contours of which remain ambiguous. While its basic idea seems to receive increasing support from all sides, the scope and requirements of the right remain particularly elusive. Issues related to scope are: what type of public interests are covered and against which type of claims does the right apply? Issues related to the requirements include: subject to meeting which conditions exactly can the right be invoked? If the conditions include some sort of proportionality test, who decides on the balancing, and with what degree of deference to policy choices made by the host state? The answers remain unclear and are likely to differ depending on the specific (treaty) context. With this rather open assessment, the following section considers how this right might be invoked in the context of international IP treaties.

be seen as additional requirements, applied alongside the police powers doctrine), see Catherine Titi, Police Powers Doctrine and International Investment Law, in *General Principles of Law and International Investment Arbitration*, Andrea Gattini, Attila Tanzi and Filippo Fontanelli eds. (Brill, 2018) II.

⁷² OECD, 'Indirect Expropriation' and the 'Right to Regulate' in International Investment Law, OECD Working Papers on International Investment, 2004/4 (Sept. 2004) available online at <http://dx.doi.org/10.1787/780155872321>, p. 5, n. 10 (referring to several further sources).

⁷³ See in particular the critique by Radi, note 52, pp. 75–77, 78–80 and Ranjan, note 52, 107–117 concerning the reasoning in *PMI v. Uruguay* award in particular and of the ambiguities in the police powers doctrine more generally.

⁷⁴ See Radi, note 52, pp. 78–80, and Ranjan, note 52, 121–124.

⁷⁵ Titi, note 71, at III, citing *Saluka v. Czech Republic*, para. 263. See also her discussion of various specific open questions at IV.

D. SHOULD INTERNATIONAL IP TREATIES RECOGNISE AN INHERENT RIGHT TO REGULATE?

Based on the proposition that – despite its ambiguous contours – the right to regulate ‘reflect[s] the position under general international law’,⁷⁶ the remainder of this chapter considers the role of the right for international IP law – in particular, whether it can operate as an (implicit) limitation to obligations to protect IPRs under international IP treaties such as the TRIPS Agreement. This, in turn, requires addressing at least the following questions: (1) with regard to international obligations of protecting IP, what is the scope of a right to regulate? This is not so much the open question on the exact conditions under which the right can be exercised (as that arguably depends on the individual treaty context) – but concerns, as discussed below, conceptual differences between investment and IP protection in international law. Depending on the so determined scope of the right, a key further question is (2) whether states bound by international commitments to protect IP have contracted out of the right to regulate by agreeing to international IP treaties, in particular TRIPS.

And finally, one needs to consider, in case the right to regulate has not been waived in full by entering into a specific IP treaty, (3) what actually is its (residual) content? In particular, if the conditions under which it is meant to be exercised involve the balancing of different interest (for example under some sort of a proportionality test), can this be decided by international adjudicators? Or does the implementing state retain some degree of discretion or margin of appreciation to which adjudicators have to defer? Since answering most of the above questions will depend on the specific IP treaty context, the following discussion simply sketches the broader analytical parameters within which the questions can be addressed. And since – at the time of writing – the principal forum for adjudicating disputes over international IP commitments is (still) the WTO dispute settlement system, the discussion uses TRIPS as the main example.⁷⁷

I. *What Is the Operational Scope of a Right to Regulate in the Context of International IP Protection?*

When considering how (if at all) the right to regulate applies in the context of international IP law, one needs to keep key conceptual distinctions between IP and investment protection obligations in mind. As I have discussed in more detail elsewhere, international investment law operates primarily a form of protection against a state interfering with the protected assets of foreign investors (in form of

⁷⁶ *PMI v. Uruguay*, Award, para. 301.

⁷⁷ As discussed below, the analysis also applies to the Paris and Berne Convention rules incorporated into TRIPS, and – depending on the individual treaty at issue – may apply analogously to commitments in IP chapters in FTAs, especially if these chapters refer to TRIPS.

taking property, or treating its owner unfairly).⁷⁸ On the other hand, international IP law essentially obligates states to protect, by means of private rights, various forms of ‘creations of the mind’ as a specific type of intangible asset against unauthorised exploitation and use by third (usually private) parties.⁷⁹ In short: investment protection primarily operates within the vertical relations between a state and a foreign private party, whereas IP law regulates the horizontal relations between private parties. While the discussion below shows that this characterisation of the modes of protection in international investment and IP law is not absolute, the principal question that emerges from it is whether the right to regulate solely applies to measures where the state directly interferes with a protected asset. Or can it also be applied to the regulation of private rights between private parties?

As a basic proposition, one may argue that if the internationally recognised objective of IP rights and their protection is to promote public welfare aims,⁸⁰ then, as a matter of principle, the power of the state to regulate in the public interest continues to apply to at least the same extent – if not more – as when the state directly interferes with private property. Regardless of the endless debates about the purpose of IP protection, within the context of TRIPS, IP rights – even as private rights – are not an end in themselves (and hence not primarily for the benefit of IP owners) but serve as tools to balance the incentive to innovate with the need to maximise access to intangibles with a public good character.⁸¹

Against this background, there is no argument of principle whereby the regulation of private party relations should be outside the scope of the state’s power to act in the public interest. The intangible nature of what domestic IP laws define as works, inventions, signs or other protectable subject matter inherently entails the need to make policy choices about the availability, conditions, scope and limits of IP

⁷⁸ Henning Grosse Ruse-Khan, *Protecting Intellectual Property through Trade and Investment Agreements: Concepts, Norm-setting, and Dispute Settlement*, in *Research Handbook on Intellectual Property and Investment Law*, Christophe Geiger ed. (Edward Elgar Publishing, 2020) pp. 11–47; University of Cambridge Faculty of Law Research Paper No. 14/2019, online at <https://ssrn.com/abstract=3393645>.

⁷⁹ As the Preamble to the TRIPS Agreement recognises, IP rights are ‘private rights’ which however serve ‘public policy objectives’. See also the further discussion in Grosse Ruse-Khan, note 78.

⁸⁰ See, next to the Preamble cited above, the ‘objectives’ set out in Article 7 TRIPS whereby the ‘protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare’.

⁸¹ In economic terms, intangible creations of the mind (such as those captured by the legal concept of a ‘work’, an ‘invention’ or a ‘sign’) are public goods because they have non-rival characteristics (that is, my use of a specific creation of the mind, for example a literary work, does not prevent someone else’s use of that same work, at the same time) and non-exclusive characteristics (this means that legal protections aside, for example via exclusive rights, the further utilisation and dissemination of an intangible creation of the mind cannot be controlled once it has been made available to others).

protection. And the overarching utilitarian objectives for such protection in the TRIPS Agreement necessarily include the basic idea that the state designs and tailors the legal framework for IP subject matter in the public interest. A right to regulate is therefore not only very much possible for the regulation of private rights in private law relations but is arguably inherent in the very nature of IP. In the context of regulating intangible creations of the mind, such a right hence goes beyond the ability of the state to – for example – expropriate assets in the public interest. While the contours of the right of course need to be properly construed in light of the treaty commitments to protect the IP of foreign right holders, there is no reason why the right to regulate would not also operate within the typical domain of IP protection.

A comparative look back in time at international investment (and human right to property) protection confirms the basic proposition above. Whereas the protection of property assets under international law is primarily conceived as protection against state interference, when that expands to cover a duty to protect property then there is no convincing reason that such a duty is not equally, or more, subject to the state's right to regulate. The generally rather limited scope of a duty to protect (in contrast to a duty not to interfere) in itself is an expression of sovereignty and the right to regulate. Such a duty is usually construed narrowly in terms of what states actually have to do to protect against third-party interferences with property, and this narrow scope in itself leaves sufficient policy space for the state to regulate.⁸² But even where a duty to act exists, there is no principal reason why the right to regulate should not be generally available for the state to act, while taking the interests of the public and other specific groups into consideration.⁸³ Again, much will depend on the specific treaty commitments undertaken and the extent to which they can be

⁸² In international investment law, the 'full protection and security' standard owed by the host state to protect investors against third-party acts generally only entails a duty of due diligence, subject to proportionality and the respective level of development of the host state (see generally Christoph Schreuer, *Full Protection and Security* 1(2) *Journal of International Dispute Settlement* 353, 353 (2010); Klopschinski, Gibson and Grosse Ruse-Khan, note 30, paras. 6.02–07, 6.85–93). And while the (human) right to property under Article 1 P1 ECHR was also construed to cover a duty to protect IP in *Anheuser Busch v. Portugal* (Judgment of the ECtHR Grand Chamber, 11 January 2007), the ECtHR equally highlighted its limited review of domestic measures involving the application of domestic (IP) laws protecting against other private parties (which only checks whether such measures are manifestly unreasonable or arbitrary). Similarly, the CJEU has interpreted Article 17(2) EU Charter to oblige EU Member States to 'ensure the effective exercise' of IP rights vis-à-vis third parties, but also held that this is limited by the rights of others (see for example the CJEU Judgment in *Coty Germany v. Parfümerie Akzente*, Case C-230/16, 6 December 2017).

⁸³ Confirmation for this point can be found for example in Article 8:9 CETA whereby the contracting parties generally reaffirm their right to regulate in relation to all obligations to protect the foreign investor – hence including CETA's narrowly defined full protection and security standard in Article 8:10.5; on the public policy defences and/or justifications in the context of FET, see generally Klopschinski, Gibson and Grosse Ruse-Khan, note 30, at 6.107–123.

construed as exhaustive *lex specialis*, whereby states have contracted out of their police powers. The next section considers this point in more detail.

Finally, the international IP system also addresses situations where the state might want to directly interfere with property. Generally, the idea that IP rights are merely negative rights to exclude third parties from utilising protected subject matter without authorisation (rather than rights which entail a claim against the state for its undistorted exploitation or use) will often make state interference (in a mere negative right) dispensable.⁸⁴ That is because owning a copyright in a cinematographic work with sexual explicit content, for example, does not entail a right to object to state restrictions on how the work can be distributed, shown in cinemas or otherwise made available to the public; similarly, a patent for a medicine does not prevent state regulatory approval requirements (for example to show the safety and efficacy of the patented medicine). The international IP system acknowledges this core limit of IP rights as merely negative rights in various forms – for example in defining the scope of exclusivity (e.g. in Articles 14, 16 and 28 TRIPS), or in the express recognition of the state's right to 'censor' and otherwise restrict the utilisation of copyrighted works in Article 17 BC.⁸⁵ However, in particular for trademarks, the idea that protected signs are in principle meant to be used in commerce to indicate the (commercial) origin of goods or services requires that the negative rights character is not absolute. Again, the international IP system accounts for this – not in the form of a 'right to use' but via a limited protection against trademark use restrictions which are 'unjustifiable'.⁸⁶

In sum then, the analysis shows that international commitments to protect IP rights are subject to the basic concept of a right to regulate, both with regard to regulating private law relations and by addressing direct state interferences with property. The key question that hence arises is whether this right has been exhaustively addressed in the relevant IP treaties, or whether those treaties leave room for the basic recognition of this right under customary international law.

II. *Have States Contracted Out of Their Police Powers by Agreeing to International IP Treaties?*

The debates in international investment law about the exact contours of a right to regulate – which, in its basic conception, receives widespread recognition and

⁸⁴ As discussed further below, this point is further reflected in Article 8(1) TRIPS, whereby the state may adopt measures that protect (for example) public health, but only if they are otherwise consistent with TRIPS, including its provisions on the grant of rights to exclude others.

⁸⁵ On the scope of exclusivity under Article 16 TRIPS, see *Australia – Plain Packaging* (Panel Report, at 7.1993–2031 and Appellate Body Report, at 6.581–586); on Article 17 BC, see *China – IPRs*, para. 7.131–132. See also Section E of this chapter on the extent to which these specific treaty provisions reflecting the right to regulate are exhaustive *lex specialis*.

⁸⁶ See Article 20 TRIPS and the further discussion in Section E.

acceptance – show that the perhaps most important question concerns the relation between a state’s customary police powers and the specific treaty commitments the state has entered into.⁸⁷ When considering this question in the context of international IP law, our focus on TRIPS as part of the WTO legal order means that the analysis has to address: (1) the role that customary international law in general can play within WTO law, and (2) the role a customary right to regulate can play with regard to TRIPS in particular.

In an area that sometimes has been referred to as a ‘self-contained regime’ where rules are essentially derived from the WTO’s own ‘covered agreements’, custom might be argued to play little, if any, role. A default assumption may be to consider a treaty rule to supersede an equivalent rule of custom. But general international law practice and scholarship tell us that unless there is clear evidence (usually in form of an express treaty rule) that the state parties wished to contract out of custom, customary international law principles and rules apply – at least as a source of guiding treaty interpretation. For example, on the applicability of the local remedies rule, the ICJ stated that it ‘finds itself unable to accept that an important principle of customary international law could be held to have been tacitly dispensed with, in the absence of any words making clear the intention to do so.’⁸⁸ The ILC explains the continued role of custom in a world dominated by treaties in similar terms in its report on fragmentation: ‘It is in the nature of “general law to apply generally” – namely inasmuch as it has not been specifically excluded. It cannot plausibly be claimed that these parts of the law – “important principles” as the [ICJ] put it – have validity only as they have been “incorporated” into the relevant regime.’⁸⁹

The basic starting point therefore is that rules of custom (or general international law, as these terms are sometimes used interchangeably) apply – unless there is clear evidence that states, for example by including specific terms in a treaty, wished to contract out of these rules. One then needs to positively identify state intent to exclude a rule of custom – rather than an intention to retain that rule as soon as related treaty rules exist.

What do these insights from general international law mean for WTO law and in particular the IP treaties incorporated into the WTO legal order? In the words of the ILC, there is ‘little reason of principle’⁹⁰ to depart from the above-described principle when applying and interpreting the rules of TRIPS and the IP treaties it

⁸⁷ See Section C, and in particular the critique by Ranjan, note 52, and Radi, note 52, about the need to define the right and its interpretative role in light of the specific treaty rules on expropriation, and whether those rules already recognise public welfare and other elements of the host state’s police power.

⁸⁸ *Elettronica Sicula S.p.A. (ELSI) (United States of America v. Italy)*, ICJ Reports 1989 p. 42, para. 50.

⁸⁹ International Law Commission, *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law* (Report of the Study Group of the International Law Commission, 13 April 2006, UN Doc A/ CN.4/ L.682), para. 185.

⁹⁰ *Ibid.*, para. 169.

incorporates. While WTO dispute settlement is no forum of universal jurisdiction, the Appellate Body has, even in its very first decision, confirmed that WTO law does not operate in ‘clinical isolation’⁹¹ from other rules of international law. When Panels and the Appellate Body consider claims under the covered agreements (rather than based on non-WTO rules), they must construe the rights and obligations flowing from WTO rules ‘within the overall context of general international law’.⁹² In several decisions, WTO adjudicators have accepted and applied this approach.⁹³ In as much as WTO law therefore does not constitute a self-contained regime per se, the same must be true for other WIPO-administered treaties and indeed the (internal and external) conduct of international organisations that deal with IP, such as the European Patent Office (EPO). While one can for example point to the WIPO Global Challenges Division as evidence of engagement with the outer (international law) environment,⁹⁴ such evidence is not required for relying on custom and other generally applicable rules of international law. As the default rule is continued relevance, one would need to show that for example by agreeing to the Patent Cooperation Treaty or by setting up the EPO, contracting states wanted to create self-contained regimes.

Specifically on the WTO members’ police powers, WTO Panels and the Appellate Body have generally recognised a ‘sovereign right to regulate’,⁹⁵ but have underscored that this right needs to be exercised in accordance with the state’s international obligations. With regard to services trade, the Panel in *US – Gambling* held that ‘[m]embers maintain the sovereign right to regulate within the parameters

⁹¹ *United States – Standards for Reformulated and Conventional Gasoline (US – Gasoline)*, Appellate Body Report (29 April 1996, WT/DS2/AB/R), p. 16.

⁹² ILC Report, note 89, para. 170.

⁹³ See for example the decisions *Korea – Government Procurement*, Panel Report (19 January 2000, WT/DS163/R), para. 7.96 where the Panel states:

We take note that Article 3(2) of the DSU requires that we seek within the context of a particular dispute to clarify the existing provisions of the WTO agreements in accordance with customary international law rules of interpretation of public international law. However, the relationship of the WTO agreements to customary international law is broader than this. *Customary international law applies generally to the economic relations between WTO members*. Such international law applies to the extent that the WTO treaty agreements do not ‘contract out’ from it. To put it another way, to the extent that there is no conflict or inconsistency, or an expression in a covered WTO agreement that applies differently, we are of the view that the customary rules of international law apply to the WTO treaties and to the process of treaty formation under the WTO (emphasis added).

See also *US – Antidumping and Countervailing Duties*, Appellate Body Report (11 March 2011, WT/DS379/R/AB), para. 316; and generally Graham Cook, *A Digest of WTO Jurisprudence on Public International Law Concepts and Principles* (Cambridge University Press, 2015), pp. 234–244, in particular the case law at pp. 240–242.

⁹⁴ See the WIPO webpages of its Global Challenges Division at www.wipo.int/about-wipo/en/activities_by_unit/index.jsp?id=56.

⁹⁵ Generally, see Cook, note 93, pp. 261–263.

of Article VI of the GATS. Members' regulatory sovereignty is an essential pillar of the progressive liberalization of trade in services, but this sovereignty ends whenever rights of other Members under the GATS are impaired.⁹⁶ On trade in goods, the Appellate Body stated that 'the object and purpose of the TBT Agreement is to strike a balance between, on the one hand, the objective of trade liberalization and, on the other hand, Members' right to regulate'.⁹⁷ In terms of how such a balance is to be struck by means of appropriately construing WTO commitments, the Panel in *China – Rare Earths*

agree[d] with China that an interpretation of the covered agreements that resulted in sovereign States being legally prevented from taking measures that are necessary to protect the environment or human, animal or plant life or health would likely be inconsistent with the object and purpose of the WTO Agreement. In the Panel's view, such a result could even rise to the level of being "manifestly absurd or unreasonable".⁹⁸

The conclusion then is that as part of custom, WTO members generally retain their police powers unless there is clear evidence that it has been specifically contracted out in a WTO Agreement. Hence one needs to positively identify states' intent to exclude the right to regulate, rather than an intention to retain their police powers as soon as relevant treaty rules exist. In the context of WTO dispute settlement, where the competence of adjudicators is limited to deciding claims about consistency with 'the covered [WTO] Agreements',⁹⁹ even relatively conservative views allow the importation of custom via treaty interpretation, including on the basis of Article 31:3 c) VCLT.

The analysis in Section I suggests that there is no reason of principle for the right to regulate not also to apply to international IP protection – although the specific IP treaty commitments are of course essential in determining the extent to which the WTO members' police power has been contracted out. In *China – IPRs*, China highlighted 'the right of governments to take the necessary steps to maintain public order', as reflected in Article 17 BC, and which arguably was 'not affected by the [author's] rights given by the Convention'.¹⁰⁰ The Panel generally agreed with this interpretation, explaining that:

⁹⁶ *US – Gambling*, Panel Report (WT/DS/285/R, 10 November 2004), para. 6.316.

⁹⁷ *US – Measures affecting the Production and Sale of Clove Cigarettes (US – Clove Cigarettes)*, Appellate Body Report (WT/DS/406/R/AB, 4 April 2012), para. 174; see also *US – Import Prohibition of certain Shrimp and Shrimp Products*, Appellate Body Report (WT/DS/58/AB/R, 12 October 1998), para. 185 and *US – Clove Cigarettes*, Panel Report (2 September 2011), para. 7.2.

⁹⁸ *China – Measures Related to the Exportation of Rare Earths, Tungsten and Molybdenum (China – Rare Earths)*, Panel Report (WT/DS/431/R, 26 March 2014), para. 7.111.

⁹⁹ See Article 3(2) DSU.

¹⁰⁰ *China – IPRs*, para. 7.131.

[a] government's right to permit, to control, or to prohibit the circulation, presentation, or exhibition of a work may interfere with the exercise of certain rights with respect to a protected work by the copyright owner or a third party authorized by the copyright owner. However, there is no reason to suppose that censorship will eliminate those rights entirely with respect to a particular work.¹⁰¹

In *EC – GIs*, responding to the European Community's argument that since TRIPS lacked a general exception clause akin to Article XX GATT it should be allowed to import and rely on Article XX GATT as defence against a TRIPS violation, the Panel countered as follows:

the TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of negative rights to prevent certain acts. This fundamental feature of intellectual property protection inherently grants Members freedom to pursue legitimate public policy objectives since many measures to attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement.¹⁰²

These Panel findings in *China – IPRs* and *EC – GIs* confirm the analysis in Section I that the negative rights nature of IP protection under TRIPS is a reflection of the right to regulate.¹⁰³ And where TRIPS does offer some protection against state interferences with IP owners' ability to use protected subject matter, the Panel and Appellate Body in *Australia – Plain Packaging* construed the relevant TRIPS commitments in a way that aligns with WTO members' customary police powers.¹⁰⁴

The discussion so far shows that WTO adjudication in general and with regard to TRIPS in particular has applied and interpreted relevant treaty commitments to protect IP in light of a right to regulate – even if the adjudicators have not always referred to the customary international law status of the right. With regard to situations where state measures interfere with IP assets (in that the utilisation of

¹⁰¹ *China – IPRs*, para. 7.132.

¹⁰² *European Communities – Geographical Indications (EC– GIs)*, Panel Report (15 March 2005, WT/DS/174R), para. 7.210.

¹⁰³ In *Australia – Plain Packaging*, the Panel (see para. 7.1916–2031) and the rejection by the Appellate Body (para. 6.581–86) of claims that the exclusive rights set out Article 16 TRIPS should be construed to prevent restrictions on use which may, gradually and over time, affect the distinctiveness of a mark further confirm the WTO Members' police power: such a broad reading of trademark rights would operate to limit or even prevent restrictions on the use of the protected subject matter without any balancing test, while Article 20 TRIPS explicitly subjects such restrictions to a test of justifiability. Only a narrow reading of the scope of the exclusive rights as mere negative rights hence ensures that public policy measures which affect the (unhindered) use of IP-protected subject matter are not caught by provisions setting out the IP owner's right to exclude others.

¹⁰⁴ As discussed further below, the notion of 'justifiability' in Article 20 TRIPS has been interpreted in light of a 'right of WTO Members to adopt measures for the protection of certain societal interests that may adversely affect [trademark] use'; see *Australia – Plain Packaging*, Panel Report, para. 7.2429.

IP-protected subject matter is restricted), WTO members therefore have not contracted out of their police powers. However, what about a right to regulate IP rights as 'private rights' and how they operate in private law relations? Do treaty commitments to grant and protect these rights (for defined subject matter and subject to certain requirements as well as with certain allowed exceptions, limitation and duration) offer sufficient evidence that WTO members have contracted out of the right to regulate IP in its principal private law domain? Section I showed that, based on the intangible character of IP subject matter and the utilitarian aims of IP protection, a right to regulate follows from the very nature of IP. And as I have argued elsewhere, for state measures which delineate the scope of protection of private rights vis-à-vis the rights of others and the general public to use IP-protected subject matter (such as patented drugs), the negative rights character of IP rights is not sufficient to secure a WTO member's police powers.¹⁰⁵ The long-standing debates on access to medicines show that the protection of public health will often require limiting IP protection in order to facilitate the access to essential goods (such as medicines and other health related technologies) via subject matter exclusions, exceptions and limitations, compulsory licences and so on.

Of course, with Articles 27, 30 and 31 for example, the TRIPS Agreement contains a range of provisions allowing WTO members to adopt access-enhancing measures. But there is no indication that their mere existence exhaustively covers the right to regulate – in other words, that WTO members intended to contract out of their customary police powers by signing up to TRIPS. That follows first of all from recognising the appropriate point of departure for this analysis: as discussed above, the general position in international law is that one needs to positively identify state intent to exclude a rule of custom – rather than an intention to retain that rule as soon as related treaty rules exist.¹⁰⁶ Second, and arguably more importantly, the relevant treaty provisions and their application by WTO members strongly support a continued role for the right to regulate. In the specific TRIPS context, most of the treaty provisions addressing access-enhancing measures contain key terms that are broad, open and undefined – which in turn have commonly been understood and implemented to include policy space for WTO members to protect public interests, including (for example) access to medicines.¹⁰⁷

¹⁰⁵ See Grosse Ruse-Khan, *The Protection of Intellectual Property in International Law* (Oxford University Press, 2016), para. 13.17–21.

¹⁰⁶ See Section I.

¹⁰⁷ A full discussion of this topic is beyond the scope of this chapter, but it is beyond doubt that TRIPS commitments to grant patents for all 'inventions' that are 'new', 'inventive' (i.e. 'non-obvious') and 'industrially applicable' (i.e. 'useful') have not harmonised notions such as invention, novelty, or inventive step. This follows not only from the significantly diverging state practice in implementing these concepts but also in the (failed) attempts to address and harmonise some of them in the Substantive Patent Law Treaty (SPLT). This lack of uniformity in implementing such broad and open terms in TRIPS also applies to other IP commitments, including those under the Paris and Berne Conventions.

The most widespread, representative and consistent state practice recognising this policy space is reflected in the Doha Declaration on TRIPS and Public Health, adopted at the Doha Ministerial Conference in November 2001. Here, all WTO members 'reaffirm[ed] the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.'¹⁰⁸ In the terms of the ILC Conclusions, the Doha Declaration constitutes a resolution adopted at an intergovernmental conference that provides evidence for determining the existence and content of a rule of custom.¹⁰⁹ Since the Declaration was adopted by consensus of all WTO members and is not intended to amend TRIPS,¹¹⁰ it also includes evidence of states' *opinio juris* for a customary right to regulate within TRIPS. That is to say, the Declaration reflects a sense of all WTO members of a legal right to adopt measures in the public interest – even though they have committed to TRIPS and its obligations to protect IP. In para. 4 of the Declaration, all WTO members

agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment 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.¹¹¹

The negotiation history of the Declaration offers further support for states' *opinio juris* that TRIPS does not prevent domestic measures to protect public interests.¹¹²

¹⁰⁸ Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) (Doha, 14 November 2001, WT/MIN(01)/DEC/2), para. 4. The purpose referred to in para. 4 is, as para. 1–3 elucidates, to address 'public health problems', in particular the need to 'promote access to medicines for all'. On the negotiation history see Grosse Ruse-Khan, note 105, para. 12.27–29, and generally Holger Hestermeyer, *Human Rights and the WTO – The Case of Patents and Access to Medicines* (Oxford University Press, 2007); Frederick Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO* (2002) 5(2) *Journal of International Economic Law* 469.

¹⁰⁹ See the ILC Draft conclusions, note 19, Conclusion 12.2, at 147–148.

¹¹⁰ In the existing literature, the main emphasis is on the legal status of the Declaration (as an instrument amending the TRIPS Agreement, an authoritative interpretation within Article IX of the WTO Agreement, or an agreement on the interpretation of TRIPS under Article 31(3) a) VCLT): see Steve Charnovitz, *The Legal Status of the Doha Declarations* (2002) 5(2) *Journal of International Economic Law* 211; Daya Shanker, *The Vienna Convention on the Law of Treaties, the Dispute Settlement of the WTO and the Doha Declaration on the TRIPS Agreement* (2002) 36(4) *Journal of World Trade* 763; James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties* (2002) 15(2) *Harvard Journal of Law and Technology* 292. This was a point the AB in *Australia – Plain Packaging* declined to rule on (see Appellate Body Report, para. 6.657).

¹¹¹ Doha Declaration, para. 4.

¹¹² See the Interventions by Argentina, Ecuador (stressing that private rights are subject to public interest measures); Barbados, Canada, Kenya, Norway, Switzerland and Ecuador (emphasising the need to balance IP rights and public interests measures, in particular to protect public health); the United States, Uganda, Brazil, the EU, Hungary and Pakistan (highlighting that

Subsequent IP treaty commitments – in particular IP Chapters in FTAs – as well as resolutions of international organisations have frequently referred to and reiterated the importance of the Doha Declaration. As I have discussed in detail elsewhere, FTA contracting parties are, for example, ‘recognising the principles set out in’, ‘affirm their commitment to’, or ‘recognise the importance of the Doha Declaration.’¹¹³ Parties have also agreed that in interpreting and implementing their FTA IP rules, they ‘shall ensure consistency’ with the Doha Declaration.¹¹⁴ And some FTAs contain language identical or at least equivalent to the right to protect public health referenced in paragraph 4 of Doha¹¹⁵ – in the round indicating that the right to regulate as affirmed in the Declaration continues to apply, despite generally more extensive commitments to protect IP under FTAs.

Furthermore, in the United Nations, the General Assembly adopted a resolution on ‘Global health and foreign policy’ in 2016, [r]eaffirming the right to use, to the fullest extent, the provisions contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Doha Declaration on the TRIPS Agreement and Public Health . . . which provide flexibilities for the protection of public health, and in particular to promote access to medicines for all.¹¹⁶

More recently, the COVID-19 pandemic has placed global access to medical technology, not only vaccines but also personal protective equipment and ventilators, among others, at the centre of attention. As one of many responses, in the

TRIPS, due to its flexibilities, does not prevent public health measures); Chile, India, Tanzania (on behalf of LDC WTO members); Ecuador (pointing to WTO Members’ right to adopt measures under Article 8 TRIPS); Cuba, Egypt, the EU, Hungary, India, the United States, Nigeria, Pakistan and Switzerland (stressing flexibilities within TRIPS to interpret and implement the agreement to protect public interests); Ecuador, Egypt, the EU and Malaysia (on behalf of ASEAN countries); and Norway, Pakistan and Kenya (emphasising the utilitarian objectives of IP protection and enforcement, as set out in Article 7 TRIPS) at the TRIPS Council Meeting in June 2001 (IP/M/31, 18 June 2001). This was prior to the adoption of the Doha Declaration. See also the interventions by Brazil, Zimbabwe, the United States, Canada, the Czech Republic, Egypt, the EU, Hong Kong (China), Hungary, India, Indonesia, Japan, Kenya, Malaysia, New Zealand, Norway, Peru and Switzerland at a subsequent TRIPS Council Meeting in September 2001 (IP/M/33, 19/09/2001) – on various ways in which TRIPS can be construed so that it retains flexibility to regulate in the public interest, especially to facilitate access to medicines.

¹¹³ See the Preamble to Chapter 17 (Intellectual Property) in the US–Chile FTA; Art 16.13.1 US–Colombia FTA, Art 16.13.1 US–Peru TPA, Art 18.11.1 US–Korea FTA and Art 18.6.1 CPTPP; and Art 147 B EU–CARIFORUM EPA. See generally Grosse Ruse-Khan, note 105, para. 5.69–74.

¹¹⁴ Article 190:2 of the EU–Colombia Peru FTA.

¹¹⁵ See the discussion in Grosse Ruse-Khan, note 105, para. 5.72.

¹¹⁶ UN Resolution, adopted by the General Assembly on 15 December 2016 – Global health and foreign policy: Health employment and economic growth (A/71/L.41, 17 January 2017). See also the almost identical language on the right to use TRIPS flexibilities for access to medicines in the resolution of the Human Rights Council, ‘The right of everyone to the enjoyment of the highest attainable standard of physical and mental health in the implementation of the 2030 Agenda for Sustainable Development’, 21 June 2017, item 3.b.

'Rome Declaration' by the G20 countries adopted in May 2021, signatory states agreed to facilitate the global distribution of medical technologies, not least by 'working consistently within the TRIPS agreement and the 2001 Doha Declaration'.¹¹⁷

Overall, while individual invocations of Doha vary, all share the basic idea of using the Declaration as a central reference point for how WTO members can protect public interests such as health in a manner that is consistent with TRIPS (and FTA). And most refer to a 'right' of states to protect health within the framework of TRIPS. Applying the ILC Conclusions, these references in treaties subsequent to TRIPS further support the argument of a rule of custom that is 'codified' (in the form of Doha references) in a treaty rule (namely, those FTA provision referring to Doha).¹¹⁸ The references in the United Nations' and other resolutions of international organisations offer additional evidence for the existence and content of customary police powers remaining, in spite of treaty commitments to protect IP. With these constant recognitions of the right to regulate in mind, the final section below considers the residual scope of this right in the context of TRIPS.

III. *The Contours of WTO Members' Police Powers in Light of TRIPS*

The discussion in Section C on the role of a customary right to regulate and its exact contours in international investment law has shown that much depends on the specific treaty commitments undertaken by the state invoking the right. Attempting to offer some parameters for addressing the same issues in the context of TRIPS hence should start with the relevant obligations to protect IP under the WTO framework. Very much hence depends on the individual TRIPS (or other IP treaty) commitment and the extent to which this already implements a WTO member's police powers – that is, how far the specific treaty rules at issue offer evidence of the contracting parties' intent to contract out of custom. Such an individual assessment cannot be undertaken here. The principal approach, however, has been confirmed by WTO members in the Doha Declaration. After affirming that TRIPS 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health' and that all TRIPS flexibilities should be used for this purpose, WTO members highlight these flexibilities to include, first and foremost, that '[i]n applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.'¹¹⁹ The WTO members then go on to highlight specific interpretative flexibilities regarding compulsory licensing and exhaustion. Furthermore, under

¹¹⁷ G20 'Rome Declaration', adopted at the Global Health Summit in Rome on 21 May 2021.

¹¹⁸ See ILC's Draft conclusions, note 19, Conclusion 11:1(a) and 2, pp. 143–146.

¹¹⁹ Doha Declaration, para. 5 (a).

the so-called ‘paragraph six mechanism’, they eventually negotiated a waiver to a TRIPS provision whose operation stood in the way of an effective use of compulsory licensing for public health.¹²⁰

The main mechanism for realising a right to regulate within TRIPS is thus by means of an interpretation and implementation of its provisions which afford sufficient policy space for WTO members to protect public interests such as health. This in turn should be achieved by the full use of TRIPS flexibilities, especially those listed in paragraph 5(a)–(d) of the Doha Declaration. As I have discussed in detail elsewhere, because of its horizontal operational effect, the most important flexibility here is interpreting and implementing TRIPS commitments in light of the agreement’s object and purpose, set out in its ‘Objectives’ in Article 7 and ‘Principles’ in Article 8(1).¹²¹

In short, that flexibility follows from (1) the interpretative relevance that Article 31 (1) VCLT (reflecting customary international law principles of treaty interpretation) affords to these provisions as expression of treaty object and purpose of TRIPS; and from (2) the substance of Articles 7 and 8. The interpretative role of Articles 7 and 8 has to be appreciated relative to other factors informing the interpretation exercise, especially ordinary meaning and context. The more ambiguous and multilayered a provision’s common understanding in relation to the treaty is, the more it needs further determination and concretisation by the treaty’s objective – so that policy space via treaty interpretation depends significantly on the terms at issue.¹²² The substance of Article 7 and especially 8(1) TRIPS then further determines the contours of a right to regulate and reflects the two basic rationales for invoking police powers in relation to IP protection, as discussed in Section I: namely, a state (1) interfering with IP rights to protect the public interest (reflected in the public interest principles of Article 8(1)); and (2) regulating the scope of protection as well as its limits in relations between private parties (as set out in the balancing objectives of Article 7).¹²³

The basic concept that emerges is one of a right to regulate which has to be actioned via treaty interpretation, with an important role for the TRIPS object and

¹²⁰ See Doha Declaration, para. 5 (b)–(d) and 6, and the outcome of these negotiations in the form of Article 31bis TRIPS.

¹²¹ See generally Grosse Ruse-Khan, note 105, Chapter 13 of that book.

¹²² See the discussion and examples in Grosse Ruse-Khan, note 105, 13.28, 13.52–56.

¹²³ This finds further support in the origins and negotiation history of Article 8:1 and Article 7. As I discuss in more detail elsewhere, the origins of both provisions lie in a 1989 submission of India referring to the ‘primacy of public interest’ as a ‘principle which is closely related to the balance of rights and obligations’ of IP owners. Under this principle ‘[t]he state has the inherent right to take measures in public interest abridging the rights of holders of intellectual property rights’ – not least because these rights have utilitarian functions; see Uruguay Round of Multilateral Trade Negotiations, Communication from India, Applicability of the Basic Principles of the GATT and of Relevant International Intellectual Property Conventions (5 September 1989, MTN.GNG/NG11/W/39), para. 13–14 and the discussion in Grosse Ruse-Khan, note 105, para. 13.06–09 and 13.36–38.

purpose as set out in Articles 7 and 8 – relative to other interpretative elements. The public interest principles in Article 8(1) confirm the customary police powers of WTO members and crystallise their contours: members may take measures ‘necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development’. Since those measures also must be ‘consistent with the provisions of [TRIPS]’, the policy space to adopt them lies within the interpretative flexibilities provided by individual TRIPS commitments, construed in light of the TRIPS object and purpose. The balancing objectives in Article 7 in turn call for IP protection and enforcement to ‘contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare’.

Broad and open concepts (such as ‘invention’, ‘novelty’ in Article 27, ‘distinctiveness’ in Article 15, or ‘expressions’ – in contrast to ideas – in Article 9) that are commonly used in TRIPS leave it for WTO members to determine their specific meaning and to align the associated interests of IP owners, users and society; hence, the balancing that Article 7 calls for primarily occurs on the level of domestic implementation.¹²⁴ From a right-to-regulate perspective, WTO members have retained sovereignty to ‘customise’ IP protection and to balance all affected interests – unless individual TRIPS provisions entail concrete commitments where no (or few) interpretative flexibilities remain.

Finally, this policy space for tailoring IP protection in line with competing interests and different stakeholders on the domestic level is reinforced by the basic notion of territoriality. The fact that despite almost 150 years of international harmonisation of IP protection, the competence to grant rights over intangible assets remains with the individual nation state is in itself a strong indicator of the right to regulate on the domestic level, not only via norm-setting that builds on the interpretative policy space left by often broad concepts in treaty commitments but also by the principal competence of domestic agencies and courts to apply and adjudicate these norms. While of course territoriality has been (partially) done away with in the case of significantly enhanced socio-economic integration (as in the European Union),¹²⁵ its continued existence within TRIPS and TRIPS-plus frameworks confirms the police and regulatory powers of the state granting, delineating and limiting IP rights.

In sum, the reference to both Article 7 and 8 in Doha’s emphasis on the TRIPS object and purpose highlights the two related but distinct aspects of the right to regulate IP protection. Adopting public interest measures within the contours of

¹²⁴ For a detailed discussion, see Grosse Ruse-Khan, note 105, para. 13.40–45.

¹²⁵ See for example the EU-wide trademark and design rights which are granted by EU institutions and enforced by domestic agencies and courts, subject to a final review by EU courts.

Article 8; and shaping IP protection to facilitate socio-economic welfare aims via Article 7. Crystallising the scope and content of a WTO member's regulatory powers then should be a matter of characterising a domestic measure as primarily within the ambit of Article 7 or 8 TRIPS. A measure that is predominantly delineating or balancing the interests of IP owners, competitors or users falls rather under Article 7; and it is that provision's terms which serve as principal interpretative guides for construing individual TRIPS commitments that may be implicated by the measure at issue.¹²⁶ Article 8 on the other hand concerns measures taken to protect general public interests such as health or the environment.

Here, one should further differentiate between two types of TRIPS provisions implicated by the measure: (1) a TRIPS provision that has an 'internal' public interest test – such as 'unjustifiable' in case of trademark use restrictions under Article 20, in contrast to (2) a TRIPS provision which lacks such a test or equivalent internal mechanism. Interpreting the proper meaning of the latter in light of Article 8(1) then requires importing the necessity test inherent in Article 8(1),¹²⁷ whereas construing a provision with an internalised (and hence *lex specialis*) public interest test usually will lead to that test's ordinary meaning and context to dominate over the object and purpose reflected in Article 8(1) TRIPS. As confirmed in the *Plain Packaging* litigation by both Panel and Appellate Body, a specific test in an individual TRIPS commitment replaces the general one in Article 8(1).¹²⁸ The contours of the right to regulate in the context of international IP law hence are framed by three key parameters:

- (1) Within TRIPS, the pre-existing IP treaties it incorporates and the subsequent FTAs which refer to it, the customary right continues to exist. It is to be effected by means of a flexible interpretation and domestic implementation of individual treaty commitments to protect IP rights.
- (2) That policy space is determined by the interpretative role of the TRIPS object and purpose – relative to the importance of the ordinary meaning and context of the treaty rules at issue. The more open and broad the key terms in these treaty commitments are, the more room remains for the individual WTO member's police powers.

¹²⁶ For a detailed discussion, see Grosse Ruse-Khan, note 105, para. 13.46–57.

¹²⁷ Again, for a discussion on how the necessity test under Article 8(1) operates in light of the specific terms used in that provision and in particular on the policy space left for WTO members, see Grosse Ruse-Khan, note 105, at 13.10–12.

¹²⁸ See *Australia – Plain Packaging*, Panel Report, at 7.2395, 7.2429–2430, 7.2598–2604; as confirmed by the Appellate Body Report, at 6.651–655. In their analysis, both the Panel and the AB also confirmed the 'margin of discretion' (Appellate Body Report, at para. 6.651) available to WTO members to choose a measure they deem appropriate to meet the policy objective they wish to pursue.

- (3) Because Articles 7 and 8 TRIPS address different aspects of these powers to regulate, a domestic measure should be characterised as to which aspect of the TRIPS object and purpose the measure primarily reflects. Broadly speaking, the TRIPS compliance of measures undertaken to protect a general public interest such as health or the environment (and curtailing IP rights accordingly) should be construed in light of Article 8(1) and especially its necessity test – unless the relevant individual TRIPS commitment offers a more specific public interest test. By contrast, the TRIPS consistency of measures balancing the interests of IP owners, competitors or users (and delineating the content and limits of IP rights accordingly) needs to be determined first and foremost under Article 7.

E. CONCLUSIONS

As an area where norm-setting seems *prima facie* driven primarily by treaties, international IP law appears to leave little room for custom or general principles of law. But if one looks beyond the primary rules that define the protection of IP rights beyond borders, there is ample space for other sources of law – for example with regard to treaty interpretation and state responsibility. In the broader context of treaty rules interacting with custom and general principles, this chapter has reviewed the role that remains for a customary right of states to adopt measures protecting public interests once those states have agreed to protect the IP rights of foreigners. The chapter has shown that the principal difficulty in identifying custom to protect foreign IP via state practice and *opinio juris* does not apply to this right to regulate, which emanates from basic concepts of sovereignty. The right to regulate has received widespread recognition in other areas of international economic law, even though its exact contours remain somewhat blurry and in turn have to rely heavily on further determination in reference to the specific commitments to protect the assets of foreigners.

Considering how a state's customary police powers apply in the specific IP treaty context (in particular, the TRIPS Agreement), an important insight from general international law is the continued relevance of custom – unless there is clear evidence that contracting states intended to contract out of custom. This point not only has specific implications for appreciating the contours of a right to regulate in light of relevant IP treaty rules, which are considered above in detail. On a more fundamental level, it reminds us of the continued relevance and 'background functionality' of the general – even where detailed rules have been set, usually in favour of the specific interests of IP owners.

The *raison d'être* to coordinate IP protection beyond borders essentially relies on treaties as a specific legal tool to achieve its principal purpose of protecting IP owners abroad. However, in doing so, this legal protection necessarily becomes a segment of

a wider universe. Therefore, appreciating international IP law, as a whole, means viewing the field contextually – that is, as part of a broader operating system, epistemic community or project (depending on how one prefers to characterise international law). Without this contextual perspective, international IP protection will necessarily appear self-contained, and one misses those elements that exist simply because coordinating protection beyond borders relies on the functionality of international law. For our specific question about the role of customary international law, this means that disregarding custom implies not fully accounting for the broader contextual framework within which international IP treaties operate – which in turn leads to further self-isolation and containment of the international IP system.

For a state's residual police powers to protect public interests, despite specific treaty commitments, this broader view ensures that the default position is not contracting out and self-containment but continued relevance. Custom can therefore retain its role and – in the specific WTO–TRIPS context – serve an interpretative function, unless there is clear evidence that the treaty rules under interpretation exhaustively cover a WTO member's right to regulate. The Doha Declaration as well as Articles 7 and 8 TRIPS confirm this point and offer further guidance on the contours of the right.

The amount of policy space to (1) interfere with IP rights to protect public interests recognised under Article 8, and (2) balance the interests of various stakeholders in line with Article 7 then is driven by the interpretative role of the TRIPS object and purpose, as well as the degree of openness and ambiguity in the treaty terms under interpretation. Given that the key concepts set out in TRIPS remain undefined and have been implemented in diverse ways for decades (if not centuries), WTO members retain quite some flexibility. And while FTAs tend to include more concrete and detailed commitments to protect foreign IP, their frequent references to Doha and/or Articles 7 and 8 suggest that the same principles apply.

However, practically, perhaps the most important point concerns actually utilising the right to regulate, on the ground. Whether it is about access to patented medicines, regulating the use of (tobacco) brands on products, or setting 'safe harbours' from copyright liability, it is within the domestic IP system that measures are adopted and where they can have an impact. This of course follows primarily from the notion of territoriality (which in itself secures significant policy space to regulate). In addition, it also follows from the optional character of most provisions that allow to limit IP rights. Since the *raison d'être* has generally been to coordinate protection (rather than its limits) beyond borders, contracting states are usually not obliged (under the IP system) to exercise their police or regulatory powers.

Again, however, a broader contextual view can shift the perspective: taking account of other legal orders within international law might point to (treaty or customary) rules or general principles which demand state action. The duty to respect, protect and fulfil the right to health under Article 12 of the International

Covenant on Economic Social and Cultural Rights,¹²⁹ for example, then appears as the flipside of the recognition in the Doha Declaration of a ‘right to protect public health’. No matter how much recognition to these ‘external’ norms may be given on the international level, it will be domestic implementation and the effect given at that level that eventually count. With this in mind, the international dimension of a right to regulate – be it based on custom or explicitly set out in treaty terms – is only the prerequisite for actual and concrete action on the domestic level, where intangible ‘creations of the mind’ are turned into legally recognised assets with a concrete scope, limits and duration.

¹²⁹ International Covenant on Economic, Social and Cultural Rights (ICESCR) (New York, 16 December 1966, 993 UNTS 3).