

Global Perspectives and Challenges for the Intellectual Property System

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Current Alliances in International Intellectual Property Lawmaking: The Emergence and Impact of Mega-Regionals

Edited by Pedro Roffe and Xavier Seuba

With contributions by

Thomas Cottier, Frederick M. Abbott, Mira Burri, Peter K. Yu,
Padmashree Gehl Sampath, Pedro Roffe and Xavier Seuba



International Centre for Trade
and Sustainable Development



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Abbreviations and Acronyms

ACTA	Anti-Counterfeiting Trade Agreement
APEC	Asia-Pacific Economic Cooperation
ASEAN	Association of Southeast Asian Nations
CAFTA-DR	Central America-Dominican Republic-United States Free Trade Agreement
CETA	Comprehensive Economic and Trade Agreement
CJEU	Court of Justice of the European Union
CMS	Centers for Medicare & Medicaid Services
CPC	Central Product Classification
CSFTA	China–Switzerland Free Trade Agreement
CSR	corporate social responsibility
DCMA	Digital Millennium Copyright Act
DSU	Dispute Settlement Understanding
EIA	economic integration agreement
EU	European Union
FTA	free trade agreement
FTAAP	Free Trade Area of the Asia-Pacific
G8	Group of Eight
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GDP	gross domestic product
GI	geographical indication
GPA	Government Procurement Agreement
GVC	global value chain
ICT	information and communication technology
IP	intellectual property
IPR	intellectual property right
ISDS	investor to state dispute settlement
ISP	internet service provider
KORUS	United States–Korea Free Trade Agreement
MFN	most favoured nation
NAFTA	North American Free Trade Agreement
NGO	non-governmental organisation
NT	national treatment
OECD	Organisation for Economic Co-operation and Development
OJEU	Official Journal of the European Union
PCT	Patent Cooperation Treaty
PPP	public-private partnerships
PTA	preferential trade agreement
PT&IA	plurilateral trade and investment agreement
RCEP	Regional Comprehensive Economic Partnership
RMI	rights management information
SDG	Sustainable Development Goal
TBT	Technical Barriers to Trade

TFA	Trade Facilitation Agreement
TIPP	Transatlantic Trade and Investment Partnership
TiSA	Trade in Services Agreement
TPP	Trans-Pacific Partnership
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TTIP	Transatlantic Trade and Investment Partnership
UK	United Kingdom
UN	United Nations
UNCITRAL	United Nations Commission on International Trade Law
US	United States
USITC	United States International Trade Commission
USTR	United States Trade Representative
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Foreword

The Center for International Intellectual Property Studies (CEIPI) and the International Centre for Trade and Sustainable Development (ICTSD) are pleased to present the fourth issue of the publication series on Global Perspectives and Challenges for the Intellectual Property System. This issue continues to develop what the publication series intends to provide: high quality academic and policy-oriented papers dealing with topics that are of global importance because of their normative pre-eminence, economic relevance and socioeconomic impact.

CEIPI and ICTSD decided to launch this common project convinced by the synergies existing between both organisations. We share a common interest in intellectual property (IP) as a tool for innovation, development and the pursuit of broader societal interests, being profoundly engaged in knowledgeable and informed reflection and international debates touching upon how intellectual property can fulfil these important goals. This series of papers aims, therefore, at provoking consideration of contemporary issues thanks to the collaboration of recognised scholars and experts, giving voice to them, enriching the academic debate and feeding policymakers with high quality materials.

The series wishes to reach a broader audience, ranging from academics to public officials, including civil society, experts, business advisers and the broad membership of the intellectual property community. We also have in mind the actual implementation of intellectual property—how IP works in practice—without losing sight of public policy objectives, including its intersection with innovation, creativity and sustainable development goals.

We sincerely hope you will find this fourth issue of the series, dealing with Current Alliances in International Intellectual Property Lawmaking: The Emergence and Impact of Mega-Regionals, a useful contribution to a better understanding of the complexities of the interface between intellectual property and trade issues in general.



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Introduction

Pedro Roffe and Xavier Seuba

The fourth issue of the series jointly published by the International Centre for Trade and Sustainable Development and the Center for International Intellectual Property Studies explores the impact of plurilateralism on intellectual property law. The chapters making up this volume review systemic, substantive and enforcement-related issues arising from plurilateralism, and do so by analysing the past, the current context and the most recently negotiated plurilateral trade agreements.

As noted in one of the contributions, times have clearly been turbulent for global trade. Mounting critiques on the apparent failure of trade to enhance productivity, investment and technology flows have only been met with a greater slump in the growth of global trade and the rise of protectionism. At the same time, the number of free trade agreements has burgeoned as a result of longstanding disagreements between countries at the multilateral level on a variety of issues. Data from the World Trade Organization highlight the growing number of regional trade agreements since 1995.

Against this backdrop, this volume gathers contributions by well-known researchers writing from distinctive perspectives and reflecting on the systemic consequences of plurilateralism and the implications of these trends for the international system. The analyses by Thomas Cottier, Frederick Abbott, Mira Burri, Peter Yu, Padmashree Gehl Sampath, Pedro Roffe and Xavier Seuba share, moreover, the broader policy interest of achieving a balance of interests and inclusiveness in the intellectual property system.

In "Embedding Intellectual Property in International Law," Thomas Cottier contextualises the expansion of intellectual property in the broader international legal order. The author addresses the question that has dominated the debate over intellectual property regulation for the last two decades, the search for balance between intellectual property and other social and economic interests. He does so by examining general principles of law and studying in depth three crucial interfaces: intellectual property and human rights, intellectual property and development, and intellectual property and trade. Analysis of regulation in trade, competition, human rights and development, as well as general principles of law and constitutional law, shows that international property rights "are embedded in a legal framework which partly allows a rebalancing of rights and obligations in the operation of intellectual property rights."

Thomas Cottier's analysis goes beyond the management of currently existing norms and introduces proposals for future lawmaking in the field of international intellectual property. Any new norms should address linkages with higher principles of the legal system, as well as other policy areas. This is particularly the case for fundamental rights, but also applies to competition and development. Ideas and approaches that span different areas should be integrated, in particular the issue of ceilings to intellectual property regulation and the progressive regulation and graduation of intellectual property norms. As the author sees it, "Perhaps, the impending failure to adopt mega-regional trade agreements limited to TRIPS-plus standards offers the option to further pursue the matter jointly in the WTO, WIPO and other specialised international fora."

Frederick Abbott analyses the evolution of provisions contained in United States trade treaties since the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and their impact on pharmaceutical products. The trend described is clear. While old agreements focused on intellectual property protection, more recent treaties broaden the scope and include regulatory standards. Likewise, they also include investor-to-state dispute settlement mechanisms that allow

private actors to initiate claims against host governments. The entire pharmaceutical chain, from innovation to access, is currently affected. New agreements encroach upon the prices of medicines, the treatment of pharmaceutical data, the definition of patentability standards, the acquisition of medicines by national authorities, insurance reimbursements, and the technical requirements for pharmaceutical products, among other relevant areas. This curtails national regulatory space and autonomy in the sphere of public health.

Preserving national space to manoeuvre and, ultimately, retaining the freedom associated with sovereignty are key tools for the future. Indeed, among the main recommendations made by Frederick Abbott, we would underline that "it is essential to adopt a formula in approving the agreement that is similar to the one adopted by the United States Congress to prevent the direct effect of the agreement in national law." In a similar vein, but referring to a different moment in the life of an international treaty, "the national government must retain the right to override the terms of the treaty within the national legislation," otherwise "the country risks being run by foreign trade negotiators and the private interests that drive them."

Mira Burri reflects upon the broader economy and governance changes triggered by digital technologies, and studies how trade, in particular trade in services, has been affected by the emergence of digital technologies. Her chapter thoroughly explores how the Trans-Pacific Partnership (TPP) Agreement addresses digital trade issues. The TPP is put into the context of the broader legal order and the regulation found in other international treaties. Relevant provisions in the domain of digital commerce in multilateral, bilateral and plurilateral agreements are introduced, and particular mention is made of upcoming mega-regional agreements: the Transatlantic Trade and Investment Partnership Agreement and the Trade in Services Agreement.

With the aim of fostering harmonisation and achieving legal interoperability in the field of digital governance, the TPP includes WTO-plus commitments, detailed rule-making of relevance to cross-border delivery of electronic services, as well as a number of non-trade issues, including consumer protection, privacy, and safeguards for the free flow of data. After carefully describing and analysing these aspects, Mira Burri underlines that the TPP has been the most ambitious effort so far to address digital economy issues. Among the novel and positive aspects, she underlines the ban on localisation measures, the subscription to a binding norm on free data flows with a potentially broad scope of application, and restrictions on forced disclosure of source code and on encryption requirements. Conversely, lack of legal certainty is also among the features of TPP regulation in this domain, but Mira Burri sees hope for improvement in this and other shortcomings in the current political context, looking to future agreements and the World Trade Organization's e-commerce programme.

Peter Yu examines the intellectual property chapter of the Regional Comprehensive Economic Partnership (RCEP), a powerful agreement under negotiation by Australia, China, India, Japan, New Zealand, South Korea and the members of the Association of Southeast Asian Nations. Leaks of the agreement "shed light on the future of intellectual property normsetting in the Asia-Pacific region" and reveal a broad coverage of intellectual property categories, enforcement mechanisms and policy-related aspects. In his analysis of the (bracketed) provisions, Peter Yu depicts a feature common to all intellectual property categories and enforcement remedies in RCEP: while a number of demanding obligations are put aside, other provisions integrating the most sophisticated intellectual property chapters of recent trade agreements are included. There are, however, also novelties—with

an uncertain future—in the text under negotiation, which broadly reflect the concerns of developing countries in areas such as genetic resources, traditional knowledge and special and differential treatment for developing countries.

Peter Yu forecasts three possible scenarios. In the first, the disagreement among RCEP members would lead to the abandonment of efforts to include an intellectual property chapter. While this scenario has strong grounds, Peter Yu is of the view that this will not happen. In the second possible scenario, the RCEP agreement would include an intellectual property chapter containing high protection and enforcement standards. Economic realities of the larger trade partners drawing together the RCEP and the fact that large developing country members “have begun to appreciate the strategic benefits of stronger intellectual property protection and enforcement” would favour this option. In the final scenario, China and India would push for an intellectual property chapter that contains much lower standards than those initially proposed by some negotiating parties. In this scenario, the chapter would “contain terms that offer more limited protection than the TPP intellectual property chapter, but still more expansive protection than the TRIPS Agreement or what is currently available in many Asian countries.” This, according to Peter Yu, is the most likely scenario.

Padmashree Gehl Sampath and Pedro Roffe review the trade agreements negotiated by the United States since the North American Free Trade Agreement (NAFTA), highlighting a clear trend of moving beyond traditional trade issues to include regulatory issues at greater length, following the tendency that began in the Uruguay Round of trade negotiations. Despite the withdrawal of the United States in January 2017, the TPP is a momentous achievement. It is now the first plurilateral agreement worldwide that contains the most advanced template on regulatory issues. The fact that the TPP now contains a regulatory framework that moves the regulatory regimes of all its members closer to that of the principal trade partner raises several questions. What is the future of the TPP's provisions that were rigorously negotiated between the original 12 countries? More importantly, can the TPP's regulatory stance be expected to become commonplace in other free trade agreements, both those negotiated by the United States in the future, including the current renegotiation of NAFTA, and those that will be proposed by the remaining TPP partners?

Gehl Sampath and Roffe, in this context, consider the new institutional architecture proposed by the TPP for regulatory harmonisation from the perspective of what it may hold for the future, both for those countries that are parties to the TPP and for those that are not. The chapter concludes with a scenario-building exercise post-TPP and presents some contrasting possibilities for global trade at the multilateral, bilateral and plurilateral levels. The co-authors conclude by asserting that, whatever the case, “the TPP is far from dead.”

In the final chapter of this volume, Xavier Seuba introduces the advances in the area of intellectual property enforcement since the adoption of the TRIPS Agreement. The author first analyses legal and conceptual aspects of enforcement. He underlines the relevance of taking into consideration the nature of enforcement norms as secondary norms, as well as the existence of horizontal, vertical and interpersonal provisions touching upon enforcement. Xavier Seuba argues that these apparently theoretical aspects impact on the daily identification and functioning of enforcement norms. Next, the chapter introduces general principles relating to enforcement set out in the TRIPS Agreement, and the WTO panel reports and mutually agreed solutions targeting intellectual property enforcement. Moving to trade agreements, it analyses how plurilateral attempts to strengthen intellectual

property enforcement have taken place in the context of a prolonged and intense wave of bilateral agreements that also strengthen civil, border and criminal enforcement, as well as enforcement in the digital environment.

Norms on enforcement can be adjusted to local conditions notwithstanding their international strengthening in recent years. Even more important, this final chapter of the volume emphasises that enforcement rules enable substantive norms to be fine-tuned, and also boost dynamism within the intellectual property system. Enforcement rules, together with rules on interpretation, open the space for dialogue and interaction between the intellectual property system and other legal regimes. Comparative intellectual property law and human rights law occupy a central space in that dialogue. They can both provide guidance in adjusting new norms on enforcement, and become part of the legal response to specific legal controversies involving enforcement norms. Contrary to what might be thought, enforcement is associated with dynamism and flexibility. Indeed, enforcement does not define a pre-established set of things or a final product. Instead, enforcement is a process of weighing and balancing rights and interests. In this dynamic context, when an intellectual property right is enforced, other norms and principles come into play, including values and legal interests found in other branches of the law.

It is hoped that this volume will help to clarify the important developments that have taken place in recent decades, beyond TRIPS, on the bilateral, regional and plurilateral fronts. More generally, it is also hoped that it can advance the growing debate on intellectual property and international trade and stimulate further research in order to bring systematisation to the analysis and a proper interaction between these developments and the multilateral system.

Embedding Intellectual Property in International Law

Thomas Cottier

1. Introduction*

The advent of TRIPS-plus provisions in preferential trade agreements (PTAs) and mega-regional agreements further reinforces the position of holders of exclusive rights, changing the balance of rights and obligations initially negotiated in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Paris and Berne Conventions as incorporated into the law of the World Trade Organization (WTO). Preferential trade agreements largely fail to right the balance, because of successful lobbying by industries of industrialised countries and a willingness of developing countries to envisage higher levels of protection in return for other market access rights and opportunities under the preferential agreement. This evolution reinforces the call to explore the implications of principles and rules outside specific intellectual property (IP) instruments in other parts of public international law, and WTO law in particular. Embedding protection for intellectual property rights (IPRs) in the overall body of international law, and related fields in domestic law, allows some rebalancing of recent developments in treaty law. It is not an easy task, however, in light of a long tradition of fragmentation and isolation of intellectual property within public international law.

The protection of intellectual property rights evolved as a separate and distinct area of public international law. Based upon bilateral treaties extending domestic protection to neighbouring countries in combating counterfeiting and piracy, the 1883 Paris Convention for the Protection of Industrial Property and the 1886 Berne Convention for the Protection of Literary and Artistic Works formed the very first multilateral agreements of international economic law, long before the post-World War II order brought about the advent of the General Agreement on Tariffs and Trade (GATT) and other multilateral agreements.¹ International intellectual property, however, led a life of its own. Largely ignored by the community of public international lawyers and scholars, it was dealt with as an appendix to domestic law, mainly of interest to commercial and private law practitioners organised in the International Association for the Protection of Intellectual Property (AIPPI).² It was largely absent from international arbitration, and no case relating to IPRs has been discussed before the International Court of Justice. The Geneva-based World Intellectual Property Organization (WIPO) developed in the footsteps of the International Bureau originally located in Berne. It produced subsequent amendments to the Paris and Berne Conventions, and new treaties open for signature on standards, registration procedures and classification.³ This body of law on intellectual property protection, with its global registration systems, is substantial. It clearly goes beyond the protection of real property in customary international law and in investment agreements in terms of scope, complexity and regulatory density.

The TRIPS Agreement of the World Trade Organization, negotiated during the 1986–1993 Uruguay Round of the GATT, incorporated substantive standards of the Paris and Berne Conventions and added additional protection disciplines. For the first time, it introduced procedural rights and

* This paper builds upon a keynote speech entitled "The Future of IP Issues in the Multilateral Trading System" delivered to the WTO@20 Symposium on the TRIPS Agreement for TRIPS Council Members and Observers, Geneva, 26 February 2015. I am much indebted to Pedro Roffe and to Xavier Seuba for valuable comments. The paper is dedicated in gratitude to my PhD students, past and present. They travelled with me and taught me in their respective specialised areas of research in international economic law.

1 "WTO Legal Texts," https://www.wto.org/english/docs_e/legal_e/legal_e.htm.

2 See <http://aippi.org/>.

3 WIPO Lex, <http://www.wipo.int/wipolex/en/>.

obligations in international law relating to the registration and enforcement of intellectual property in domestic law in order to improve disciplines in combating piracy and counterfeiting. The story has been told many times, and there is no need to repeat it.⁴ What is important to note, however, is that for the first time IPRs were integrated into the multilateral trading system and thus linked to principles and rules on trade in goods and services. They are subject to effective international dispute settlement and enforcement, with withdrawal of concessions in case of non-compliance. The WTO dispute settlement system commenced a long-term process of interpreting and applying IPR standards in line with the principles and rules on interpretation of the Vienna Convention on the Law of Treaties (VCLT), and the overall disciplines of WTO law, in particular the most favoured nation principle and the national treatment principle. With the increasing integration and recognition of international trade law in public international law, intellectual property protection has also become a fully recognised part of public international law, no longer limited to a highly specialised community of lawyers and economists.

Today, intellectual property is an important and well-established ingredient of international economic law. There are no convincing reasons to question its basic incorporation into the trading system and, more recently, into the law of international investment protection. IPRs are essential prerequisites of international trade and investment. The absence of standards, as well as excessive standards, act as non-tariff barriers to international trade in an integrating world of global value chains and trade mainly in components.⁵ The allocation of exclusive rights per se is not in contradiction to free trade, but forms part of the overall legal framework, similar to contract law and property protection in general. IPRs make an important contribution to legal security and thus are an important prerequisite of social and economic development. Yet what rightly provokes debate and controversy is the scope of rights, levels of harmonisation and the overall balance with competition, public policy goals and non-trade concerns. Intellectual property is closely linked to the evolution of technology and changes in market structures, which are always occurring and call for ongoing review and realignment of the scope of rights and the balance with the interests of competitors, consumers and public policy goals. Such goals are not confined to the field itself, but may be found outside of it, in other areas of law, such as human rights, trade law, competition law, or the law of investment protection. In other words, they are found throughout the legal order and need to be taken into account.

This paper seeks to identify and discuss components of the legal order in which intellectual property protection is embedded and thus has to be respected as an established feature. These components potentially play an important role in seeking an appropriate balance of exclusive rights and public and third party interests beyond the narrow confines of intellectual property legislation and treaty law. The paper does not aspire to be complete. For example, it does not cover the role of private international law and contracts in assessing voluntary licensing, or the role of torts in assessing damages for violations of intellectual property rights. The focus is on general principles of law and other areas of public international law. It essentially concentrates on intellectual property as part of international economic law.

4 Jayashree Watal and Anthony Taubman (eds), *The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations* (Geneva: World Trade Organization, 2015).

5 Deborah K. Elms and Patrick Low (eds), *Global Value Chains in a Changing World* (Geneva: World Trade Organization, 2013); Benno Ferrarini and David Hummels (eds), *Asia and Global Production Networks: Implications for Trade, Incomes and Economic Vulnerability* (Cheltenham: Edward Elgar, 2014).

The paper seeks to explore the role of general principles of law and linkages to human rights provisions and the Sustainable Development Goals (SDGs) of the United Nations. It discusses the impact of rules relating to GATT and the movement of goods, combating economic protectionism and rent-seeking, and the implications of the General Agreement on Trade in Services (GATS). It looks into the role of anti-trust rules and unfair competition disciplines; addresses investment protection and the relationship to real property; and finally, it addresses the problem of special and differential treatment of developing countries and how graduation could be brought about.

All these areas form part of the context of intellectual property protection. They are relevant in the process of the interpretation and application of rules, and in guiding future treaty-making and lawmaking in the field. The purpose of the paper is to provide a broad overview of all these components and to encourage further detailed research in different overlapping fields.

2. The Quest for Balance

2.1 Within the TRIPS Agreement

The balance between intellectual property protection and the interests of competitors and public policy goals is primarily addressed within IP legislation and IP treaties. This is equally true for the TRIPS Agreement.⁶ In the context of the Uruguay Round, the agreement embodies key interests of industrialised countries in strengthening intellectual property protection worldwide. It essentially protects First World assets, and an overall balance was sought in combination with concessions in trade in agriculture and textiles prior to the accession of China in 2001.⁷ This is not to say that the TRIPS Agreement does not also show inherent balancing. Largely built upon Western concepts of IPRs and domestic legislation, and taking into account concerns and interests of developing countries, the balance of rights and obligations within the TRIPS Agreement inherently translates into defining the scope of rights and the duration of rights, the latter particularly in patents, copyright and designs. The provisions on enforcing intellectual property rights carefully balance the interests of right holders and alleged infringers in terms of legal remedies and compensation for violations and alleged violations.

A balancing of interests in substantive standards can be seen in Article 6 of the TRIPS Agreement, which leaves members ample policy space in defining parallel trade in IP-protected goods. It can be seen in broad objectives and principles such as Articles 7 and 8, and the recognition of policy space for the application of competition policies in Article 40. These objectives, however, are locked in by treaty law and language and bound to respect the essence of intellectual property rights. Article 8 of the TRIPS Agreement thus allows for measures necessary to protect public health and nutrition, "provided that such measures are consistent with the provisions of the Agreement." Likewise, recourse to fair use exemptions must preserve the essence of exclusivity. Article 13 TRIPS provides for a tight three-step test and confines exceptions "to certain special cases which do not conflict with a normal

6 For an account of the agreement see Thomas Cottier, "The Agreement on Trade-Related Aspects of Intellectual Property Rights," in *The World Trade Organization: Legal, Economic and Political Analysis*, vol. 1, ed. Patrick F. J. Macrory, Arthur E. Appleton and Michael G. Plummer (pp. 1041–1120) (New York: Springer, 2005); Anthony Taubman, *A Practical Guide to Working with TRIPS* (Oxford: Oxford University Press, 2011).

7 See Frederick M. Abbott, "Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework," *Vanderbilt Journal of Transnational Law* 22, no. 4 (1989): 689–745; Thomas Cottier, "The Prospects for Intellectual Property in GATT," *Common Market Law Review* 28 (1991): 383–414.

exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.”⁸ Article 17 provides that fair use exemptions to trademarks “take account of the legitimate interests of the owner of the trademark and of third parties.” Article 30 TRIPS Agreement provides that fair use exemptions to patent rights “do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” The same test applies to industrial designs in Article 26(2) of the agreement. Other forms of intellectual property, in particular geographical indications (GIs) and layout designs (topographies) and trade secrets, undisclosed information and test data do not offer fair use exemptions in the TRIPS Agreement and the Treaty on Intellectual Property in Respect of Integrated Circuits, as incorporated. Article 31 allows for compulsory licensing, prescribing in detail procedural requirements to be met. Finally, the TRIPS Agreement does not include a general exception other than national security in Article 73. There is no horizontal provision comparable to Article XX GATT and Article XIV GATS in the TRIPS Agreement.

The incorporation of the Paris Convention and the Berne Convention into a single instrument in WTO law is not without tensions created by norms representing different stages of legal development. Perhaps the best example here is the problem of local working requirements in patent law. While Article 27(1) of the TRIPS Agreement requires non-discriminatory treatment of patents irrespective of the place of invention, the field of technology and whether products are imported or locally produced, Article 5A(2) of the Paris Convention allows members to issue compulsory licences to prevent the abuse of intellectual property rights, which is legally defined to include the failure to work. The right of a government, frequently found in domestic legislation, to oblige a right holder to operate the patent within its own jurisdiction, and thus to contribute to job creation and transfer of knowledge and transfer of technology, seems to conflict with Article 27(1) TRIPS Agreement and its trade-related approach. Whether or not products under patent protection are imported or locally produced does not matter under this provision. It is in accordance with contemporary perceptions of global value chains and international trade mainly consisting of trade in components produced in different countries prior to the assembly of a product destined for consumers. Inaction to work a patent may thus be justified by legitimate reasons and compulsory licences should be refused under Article 5(A)(4) of the Paris Convention. The matter, however, is unresolved and controversial.⁹ It may be argued that working consists both of import and production, and an abuse merely arises if a patent is used defensively with the intention not to be used and not to serve a particular market either by imports or local production. At the heart of the issue is the problem of transfer of technology and know-how and job creation.

Issues arising in the initial phase and the first 20 years of the WTO allowed the TRIPS Agreement (including Paris and Berne standards) to be dealt with in a largely self-contained manner. General precepts of GATT and WTO jurisprudence, mainly developed under GATT, were influential, but the influence did not extend to other instruments addressing IPRs.¹⁰ The WTO has no jurisdiction over other IPR agreements. It is thus unable to develop a comprehensive jurisprudence beyond

8 See United States – Section 11(5) of the *US Copyright Act*, paras 6.71–74, WT/DS160R (15 June 2000).

9 Thomas Cottier, Shaheez Lalani and Michelangelo Temmerman, “Use It or Lose It: Assessing the Compatibility of the Paris Convention and TRIPS Agreement with Respect to Local Working Requirements,” *Journal of International Economic Law* 17 (2014): 437–471.

10 For an excellent account of the case law, see Matthew Kennedy, *The WTO Dispute Settlement and the TRIPS Agreement: Applying Intellectual Property Standards in a Trade Law Framework* (Cambridge: Cambridge University Press, 2016).

considering such other agreements in the process of interpretation under Article 31(3)(c) of the Vienna Convention on the Law of Treaties. Moreover, public policy goals, enshrined in Articles 7 and 8 of the TRIPS Agreement, have remained without much influence.¹¹ The focus of the WTO Appellate Body, less so in panels of first instance, was on textual interpretation of the operational standards of the TRIPS Agreement, including the substantive provisions of the Paris and Berne Conventions.¹²

2.2 The Impact of Preferential Agreements

The shift of forum from the WTO to preferential trade agreements and plurilateral fora during the last 20 years, in particular in negotiations on the Trans-Pacific Partnership Agreement (TPP) and the Transatlantic Trade and Investment Partnership (TTIP), has led to strengthening intellectual property rights.¹³ Partly, TRIPS-plus provisions are necessary to complete the TRIPS Agreement and render provisions operational. This is particularly true in defining periods of exclusivity of test data under the incomplete Article 39(3) of the TRIPS Agreement. The main issue here merely relates to the proper duration of exclusivity without which the provision cannot be properly applied. Partly, however, they go beyond existing levels of protection and reduce existing flexibilities, in particular in patent law and plant variety protection.¹⁴ One would expect that these free trade agreements would remove barriers inherent to the territoriality of IPRs, creating free trade zones. None of them, however, addresses international exhaustion fostering parallel trade and competition. Some even impose national exhaustion. For example, the US–Morocco Free Trade Agreement states in Article 15.9(4) that exclusive rights “shall not be limited by the sale or distribution of that product outside its territory,” effectively imposing a national exhaustion rule.¹⁵ It would seem that demands of interest groups of right holders in Western countries are readily translated into legal disciplines, without proper checks and balances and due regard to implications not only for social and economic development, but also for innovation.¹⁶ Against this backdrop, scholars have called for ceilings to levels of intellectual property protection, so far without success.¹⁷

11 Cf. e.g. *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (17 March 2000).

12 The incorporation of the Paris Convention is addressed in *United States – Section 211 Omnibus Appropriation Act*, WT/DS176/AB/R (2 January 2002).

13 See Josef Drexler, Henning Grosse Ruse-Khan and Souheir Nadde-Phlix (eds), *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* (Heidelberg: Springer, 2014).

14 For an account see Thomas Cottier, “Intellectual Property and Megaregional Agreements: Progress and Opportunities Missed,” in *Mega-Regional Agreements: CETA, TTIP, TiSA: New Orientations for EU External Economic Relations*, ed. Stefan Griller, Walter Obwexer and Erich Vranes (Oxford: Oxford University Press, 2017); Thomas Cottier, Dannie Jost and Michelle Schupp, “Setting the Scene: The Prospects of TRIPS-Plus Protection in Future Mega Regionals,” in *Mega-Regional Trade Agreements and the Future of International Trade and Investment Law*, ed. Thilo Rensmann (New York: Springer, 2017).

15 Morocco FTA, Final Text, <https://ustr.gov/trade-agreements/free-trade-agreements/morocco-fta/final-text>; see Sarah R. Wasserman Rajec, “Free Trade in Patent Goods: International Exhaustion for Patents,” *Berkeley Technology Law Journal* 29 (2014): 317–376, at 355–356; see generally Christopher Heath and Anselm Kamperman Sanders (eds), *Intellectual Property and Free Trade Agreements* (Oxford: Hart, 2007).

16 Katrina Moberg, “Private Industry’s Impact on US Trade Law and International Intellectual Property Law: A Study of Post-TRIPS US Bilateral Agreements and the Capture of the USTR,” *Journal of the Patent and Trademark Office Society* 96, no. 2 (2014): 228.

17 Annette Kur and Henning Grosse Ruse-Khan, “Enough Is Enough—The Notion of Binding Ceilings in International Intellectual Property Protection,” in *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS*, ed. Annette Kur (pp. 359–407) (Cheltenham: Edward Elgar, 2011).

Preferential trade agreements normally do not further develop public policy goals or refine exceptions and fair use standards. Public policy interests, such as health care or access to information, have not been further elaborated and detailed. Critical voices warning that excessive levels of protection have a negative impact on innovation, let alone on distributional effects, have been largely left unheard in the political process.¹⁸ While in hindsight the TRIPS Agreement can be considered to be reasonably balanced, recent development and trends have dismantled and distorted its balance to the benefit of right holders. Most governments, at the end of the day, are simply willing to accept higher levels in return for market access rights to important export markets. At the same time, they may limit public resources allocated to the enforcement of intellectual property rights and thus seek to maintain a de facto balance between enhanced standards of protection and the needs of a developing country economy to engage in imitation.

2.3 Towards Investment Protection and Market Segmentation

An increasing shift to market segmentation and investment protection is behind these developments, due to high costs in research and marketing of products in global value chains. As production of goods has shifted to developing and emerging economies, research, development and marketing amount to an important source of income for industrialised and service-based economies. Enhanced protection of intangible information in different forms of intellectual property either serves to promote research and innovation and cultural works (patents, undisclosed information, copyright, designs), or to distinguish products and to inform consumers accordingly (trademarks, geographical indications).

Despite legal justification by the needs of innovation and consumer welfare, intellectual property protection is in reality as much motivated by market segmentation and the promotion and protection of investment. These motives have increasingly influenced the application and interpretation of intellectual property rights. The classical distinction between discoveries and inventions in patent law is increasingly blurred. Existing genes are eligible for biotechnology patents protection if used in a different than natural context.¹⁹ These developments can mainly be explained by high levels of investment in research and development. In copyright, levels of creativity are increasingly lowered, reflecting the shift of copyright protection into information technology, equally dependent upon high levels of investment. In database protection, at least in Europe, minimum levels of creativity are no longer required.²⁰ It essentially follows the sweat of the brow doctrine, still refuted in the United

18 Cf. Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005); the seminal work on the economics of IPRs by Keith Maskus, *Intellectual Property Rights in the Global Economy* (Washington, DC: Institute of International Economics, 2000); Keith Maskus, *Private Rights and Public Problems: The Global Economics in Intellectual Property in the 21st Century* (Washington, DC: Peterson Institute for International Economics, 2012); Christophe Geiger (ed.), *Research Handbook on Human Rights and Intellectual Property* (Cheltenham: Edward Elgar, 2015); Daniel Gervais, *International Intellectual Property: A Handbook of Contemporary Research* (Cheltenham: Edward Elgar 2015).

19 Howard Florey/Relaxin [1995] European Patent Office Rep. 541; for an analysis of the dichotomy, see Justine Pila, *The Requirement for an Invention in Patent Law* (Oxford: Oxford University Press, 2010), 221–224; for blurring lines, see also Michelangelo Temmerman, *Intellectual Property and Biodiversity: Rights to Animal Genetic Resources* (Alphen aan den Rijn: Wolters Kluwer, 2012); Geertrui van Overwalle, "Biotechnology and Patents: Global Standards, European Approaches and National Accents," in *Genetic Engineering and the World Trade System*, ed. Daniel Wüger and Thomas Cottier (pp. 77–108) (Cambridge: Cambridge University Press 2008).

20 Directive 96/9 EC of the European Parliament and of the Council of the EU of 11 March 1996 on the legal protection of

States.²¹ Much of trademark protection protects investment in marketing and advertising: at least as much as allowing the consumer to properly distinguish competing products. Recent developments see a shift of the IPR system to fostering the protection of investment and limiting competition by means of ever increasing levels of protection of IPRs.

It remains to be seen how these developments will affect welfare, growth and distribution in industrialised and developing countries alike. Yet it may be concluded at this stage that rebalancing can no longer be achieved within the system of intellectual property as such and on its own, but increasingly depends upon taking into account other areas of the law, both domestic and international. Increasing levels of protection render the embedding of intellectual property in the overall legal order more important than before. IPRs can no longer be dealt with in splendid isolation, but need to be construed and applied in the general context of law. This can best be achieved within the framework of domestic law under the umbrella of constitutional law and a uniform court system. It is more difficult to achieve in regional integration under preferential agreements, such as the North American Free Trade Agreement (NAFTA) and the European Union (EU). It is most difficult under the auspices of public international law—thus on the level where harnessing globalisation and effective checks and balances are most needed. The lack of a constitutional framework and the fragmentation of international law are major impediments in addressing balancing across different agreements.

2.4 The Impact of Fragmentation of Public International Law

The fragmentation of public international law in different fields and distinct fora renders the process of balancing more difficult.²² Unlike in domestic law and coherent legal systems, other areas of the law may not be taken into account on the international level due to limited and divided jurisdictions. Different institutions deal with the matter, and IPRs are far from being fully embedded in international law. The process is only at its beginnings, comparable to the early days of European Community law when IPRs—at the time a prerogative of member states—were found to interact with the principles and rules of competition law and the free movement of goods. The Court of Justice of the European Union (formerly the European Court of Justice) developed a fine balance between these different areas based upon a questionable distinction between the existence and the exercise of intellectual property rights.²³ Such exercise was subject to the prerogatives of free movement of goods, and resulted in particular in the doctrine of regional exhaustion and the need to increasingly harmonise intellectual property law.²⁴ Today, the EU enjoys full jurisdiction to enact legislative standards on intellectual property and balance exclusive rights and other parameters of

databases, OJ L. 077.

21 Feist Pubs., Inc. v. Rural Tel. Svc. Co., Inc., 499 U.S. 340 (1991).

22 Cf. 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, finalised by Martti Koskenniemi, UN General Assembly A/CN.4/L.682 (13 April 2006), http://legal.un.org/ilc/documentation/english/a_cn4_l682.pdf. For a comprehensive analysis of fragmentation and related theories, see Henning Grosse Ruse-Khan, *The Protection of Intellectual Property in International Law* (Oxford: Oxford University Press, 2016), 15–68.

23 See e.g. Paul Craig and Gráine de Búrca, *EC Law: Text, Cases, and Materials* (Oxford: Oxford University Press, 1997), 1027–1064, Case 56 and 58/64, Grundig/Consten, [1966] ECR 322; Case 119/75, Terrapin (Overseas) Ltd. v. Terranova Industrie C.A. Kupferer & Co [1976], ECR 1039.

24 See Ansgar Ohly and Justine Pila (eds), *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (Oxford: Oxford University Press, 2013).

the legal order.²⁵ Traditional fragmentation has been overcome.

At the level of international law, the fragmentation persists also in the context of treaty-making. The TRIPS Agreement was designed as a minimum standard. It allows increasing levels of protection in domestic law and other international agreements. TRIPS-plus standards in preferential trade agreements add to these standards, but are legally independent. Due to national treatment and most favoured nation obligations under Articles 3 and 4 of the TRIPS Agreement, bilaterally and preferentially agreed standards deploy general spillover effects and increase levels of protection de facto beyond the parties to a specific bilateral agreement. They lift all the boats in the water, and with them general levels of protection, in particular when such standards are agreed to by states representing large markets. Typically for behind-the-border issues, states adopt regulations compatible with preferential agreements and apply such regulations to all states alike. A country will not operate a dual system with special IP rules for a particular partner. Rather, it will adjust its standards to the higher requirements of the preferential trade agreement and apply them across the board to all right holders alike. PTAs thus increase levels of protection and affect the overall balance of rights and obligations in a significant way for all countries alike. TRIPS and preferential agreements thus jointly form what may be called the common law of intellectual property protection.²⁶ Eventually, bilateral standards, due to such effects, may find their way through negotiation back into multilateral agreements, in particular the TRIPS Agreement. The process may be compared to the formation of the Paris and Berne Conventions in the nineteenth century. Both agreements multilateralised standards previously introduced by means of bilateral agreements having general effects on domestic legislation.

TRIPS-plus standards in PTAs are introduced in a self-contained manner, detached from other parts of the WTO agreements. They follow calls for enhanced protection, but fail to take into account implications for the overall multilateral system at hand and its different regulatory areas and disciplines. They are, in other words, not embedded in the overall order of international economic law, but lead a life of their own. It is here that further work is needed. As much as in domestic law and European law, intellectual property needs to be applied and construed in the context of the overall order. Some elements will be found in international law, others in domestic law. Embedding intellectual property protection in the overall legal order will partly reinforce the position of right holders. Partly, however, it will contribute to bringing about a better balance of interests.

The point is that the operation of intellectual property rights is not confined to specific statutes and treaty provisions, but needs to consider pertinent principles and rules relating to other areas of the law. This is true both in domestic and international law, both requiring the awareness that IPR rules are embedded in the legal order at large and cannot be considered in isolation. Depending on the specific facts of particular cases, lawyers and judges need to apply the law in context and develop the ability to go beyond the provinces of intellectual property rights properly speaking in bringing about a proper balance of rights and obligations. Partly, these principles can be integrated in relevant rules. Mostly, they will exist independently, and the art of lawyering will consist of bringing together all these elements.

25 Article 118 Treaty on the Functioning of the European Union.

26 Thomas Cottier, "The Common Law of International Trade and the Future of the World Trade Organization," *Journal of International Economic Law* 18 (2015): 3–20.

3. General Principles of Law

The operation of intellectual property is subject to general principles of law which apply in a domestic context but also form part of public international law under Article 38(1)(c) of the Statute of the International Court of Justice.²⁷ They form part of the body of law which applies both in domestic and international relations.²⁸ They provide coherence to different layers of government and are of importance for the theory of multilayered governance and Global Administrative Law.²⁹ Linkages between intellectual property and its specialised rules, and general principles of law have not been sufficiently developed so far.³⁰ These principles, applying to lacunae and assisting the interpretation of broadly textured norms, offer an important and additional avenue to achieving an appropriate balance between rights and obligations under the facts of a particular case.

3.1 Equity and Good Faith

The principle of equity essentially stands for the proposition of achieving a fair and just result under the facts of a particular case.³¹ While aspiring to broad precepts of justice in international relations, the operation of equity in law, mainly focusing on maritime boundary delimitation, developed a particular methodology which can also be applied to international economic law. Based upon broad principles derived from the concept of the continental shelf and the exclusive economic zone as extensions of land masses, equitable principles have been developed including the identification of pertinent factors to be taken into account in assessing the claims of parties. Recourse to equitable principles amounts to a particular legal methodology suitable for complex configurations entailing conflicting interests and the need to balance them appropriately.³² This topical methodology can be deployed whenever the law refers to equity, for example requiring fair and equitable treatment in investment law. It can also be applied implicitly as a general principle of law. It has great potential to be applied in the field of intellectual property protection, not only in assessing compensation for compulsory licensing, but also in defining and refining the scope of rights and exemptions. Equity is also of great importance in procedural terms. The maxims of equity, developed in English law, have been largely adopted in international arbitration and may be called upon also in intellectual property

27 "[T]he general principles of law recognized by civilized nations"; http://legal.un.org/avl/pdf/ha/sicj/icj_statute_e.pdf. For a discussion see Giorgio Gaja, "General Principles of Law," in *Encyclopedia of Public International Law*, vol. 4 (pp. 370–377) (Oxford: Oxford University Press, 2012).

28 Hersch Lauterpacht, *Private Law Sources and Analogies of International Law* (Hamden, CT: Archon Books, 1927).

29 Christian Joerges and Ernst-Ulrich Petersmann (eds), *Constitutionalism, Multilevel Trade Governance and International Economic Law* (Oxford: Hart, 2011); Benedict Kinsbury, Nico Krish and Richard B. Stewart, "The Emergence of Global Administrative Law," *Law and Contemporary Problems* 68 (2005): 15–61.

30 A first attempt was made in Frederick M. Abbott, Thomas Cottier and Francis Gurry, *The International Intellectual Property System: Commentary and Materials*, vol. 1 (Boston: Kluwer Law International, 1999), 494–501, and subsequent editions.

31 See Francesco Francioni, "Equity in International Law," in *Encyclopedia of Public International Law*, vol. 3 (pp. 632–642) (Oxford: Oxford University Press, 2012).

32 See Thomas Cottier, *Equitable Principles of Maritime Boundary Delimitation: The Quest for Distributive Justice in International Law* (Cambridge: Cambridge University Press, 2015).

disputes.³³ For example, the maxim of clean hands allows objection to frivolous claims and conduct ignoring ethical standards and good faith. It offers an important avenue in combating the abuse of formally exclusive rights.

The principle of protecting legitimate expectations, emanating from good faith, is an important ingredient in assessing whether policies and policy changes introduced unduly frustrate right holders or third parties. Good faith is a free-standing principle of international law and domestic law, essentially derived from equity and designed to secure justice under the facts of a particular configuration and case.³⁴ Estoppel deploys binding effects on unilateral promises made and conduct engaged in if alterations harm others.³⁵ In WTO law, good faith depicts the prohibition of abuse of rights. It amounts to the protection of legitimate expectations as to the conditions of competition, being part of the doctrine of nullification and impairment of benefits.³⁶

3.2 Proportionality

The principle of proportionality displays different components which do not all have the same standing in international law.³⁷ Necessity amounts, in our view, to a principle of customary international law which has been applied to many areas and thus may be relevant in the field of intellectual property. It states that means applied should not exceed what is necessary to achieve a particular and defined goal. Other components of proportionality address whether a measure is suitable and able to achieve a particular goal, and foremost, whether the impact of the measure taken is commensurate with the importance of the regulatory goals. The latter strongly depends upon the context of a particular case and also standards of review applied in adjudication. As a general principle of law, it also applies to issues of intellectual property rights, for example in assessing restrictions on the use of trademarks and the policy goal at hand.³⁸ Such considerations do not depend upon explicit reference to proportionality in the text but can be introduced by referring to proportionality as a general principle of law applicable to the interpretation and application of specific treaty and legislative provisions.

3.3 Other Legal Principles

The principle of non-retroactivity is a general principle of law and does not allow the retroactive application of new legislation and treaty provisions to completed factual settings. For example, and in line with Article 70 TRIPS Agreement, the extension of the duration of protection cannot

33 See C. Wilfred Jenks, *The Prospects of International Adjudication* (London: Stevens, 1964), 316–427.

34 See Jörg Paul Müller, *Vertrauensschutz im Völkerrecht* (Cologne: Carl Heymann, 1971).

35 See Thomas Cottier and Jörg Paul Müller, "Estoppel," in *Encyclopedia of Public International Law*, vol. 3 (pp. 671–677) (Oxford: Oxford University Press, 2012).

36 Marion Panizzon, *Good Faith in the Jurisprudence of the WTO: The Protection of Legitimate Expectations, Good Faith Interpretation and Fair Dispute Settlement* (Oxford: Hart, 2006); see section 6.1 below.

37 See Thomas Cottier, Roberto Echandi, Rachel Liechti, Tetyana Payosova and Charlotte Sieber-Gasser, "The Principle of Proportionality in International Law: Foundations and Variations," *Journal of World Investment and Trade* 18 (2017) (forthcoming).

38 Cf. *Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7, 8 July 2016, <https://www.italaw.com/cases/460>; *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging* (WTO, DS 458, pending).

retroactively restore protection to information already in the public domain, which may thus be used by everybody. Article 18 of the Berne Convention as integrated into the TRIPS Agreement includes particular and limited exceptions to this principle in copyright. Yet, except for specific exceptions, the principle of non-retroactivity applies to all fields of IPRs, irrespective of whether this is positively stated in legislation.

The principle *ne bis in idem* does not allow an issue to be adjudicated twice. Once a matter is settled in court, it cannot be reopened unless new facts call for a revision of the ruling. Unless specific regulation allows reassessment and review of a case beyond the appeal mechanism, the principle provides for legal security. The principle also applies to intellectual property, both domestically and in international arbitration.

The principle of legality requires governmental action to be based upon law as a minimum standard.³⁹ It has hardly been called upon in the field of IPRs. Yet granting an exclusive and monopoly right requires a legal basis in domestic or international law (in monist countries). Administrative practices for the registration of rights short of a statutory basis may not meet legitimate expectations as to legal security.⁴⁰ Domestic law requirements may go beyond such minimum standards and require that a legal basis be found in acts passed by Parliament. Also, requirements as to the precision and density of the rule may exist. Loosely textured IPR norms restricting human rights may not suffice in certain jurisdictions. Such additional requirements do not (yet) exist in international law, but they influence the operation of IPRs under the constitutional law of individual countries.

More specific rules applicable to individual countries beyond international law may also apply under other provisions of constitutional law. It is recalled that the fundamental principle of free movement of goods significantly influences the exercise of intellectual property rights in the European Union and the European Economic Area under the Agreement on the European Economic Area (EEA). In federal states, commerce between states is subject to comparable rules, in particular the Interstate Commerce clause of the US Constitution or internal market regulation in Switzerland.⁴¹ Since intellectual property is mostly a matter of federal law, no particular restrictions and limitations on its exercise and enforcement generally are to be expected, but they cannot be excluded, in particular where restrictions are due to common law or particular state law, such as the protection from unfair competition which varies among different US states. Similar configurations also occur in other federations.

Finally, regulatory principles may influence the operation of intellectual property rights. The principle of transparency, also enshrined in Article 63 of the TRIPS Agreement, requires appropriate publication of laws, regulations and administrative and judicial rulings, or for them to be made otherwise available to right holders and third parties.⁴² Lack of publication may render the operation

39 Thomas Cottier, *Die Verfassung und das Erfordernis der gesetzlichen Grundlage*, 2nd edn (Diessenhofen: Rüegger, 1991).

40 Cf. in this context *India – Patent Protection for Pharmaceutical and Agricultural and Chemical Products*, WT/DS50/R (5 September 1997), WT DS50/AB/R (19 December 1997). While the ruling was based upon specific language of the TRIPS Agreement, the principle of legality may have offered an independent cause of action in this case.

41 See George Anderson (ed.), *Internal Markets and Multi-level Governance: The Experience of the European Union, Australia, Canada, Switzerland, and the United States* (Oxford: Oxford University Press, 2012).

42 Thomas Cottier and Michelangelo Temmerman, "Transparency and Intellectual Property Protection in International Law," in *Transparency in International Law*, ed. Andrea Bianchi and Anne Peters (pp. 197–220) (Cambridge: Cambridge University Press, 2013).

of the provision null and void, also violating the principle of legality discussed earlier. International agreements may provide for regulatory cooperation that also extends to the enforcement of intellectual property. In the European Union, this also entails harmonisation of intellectual property rights, and it will be interesting to see whether the approach will be extended to transatlantic relations under TTIP. Mutual recognition of rulings may exist under bilateral or multilateral agreements on administrative and judicial assistance. Parties to an agreement may agree to apply the principle of mutual recognition and equivalence not only to technical regulations and standards, but also to rules pertaining to intellectual property. This may entail the mutual or unilateral recognition of patents and trademarks issued by another state or international organisation, going beyond the rules of Article 4 and 4bis of the Paris Convention for the Protection of Industrial Property.

4. Human Rights

The fragmentation of public international law not only left trade outside of the core of public international law for decades, but also excluded closer interaction between trade and human rights.⁴³ The problem of securing drugs to combat human immunodeficiency virus and acquired immune deficiency syndrome (HIV/AIDS) in least developed countries in the wake of a spreading epidemic at the turn of the century triggered a lively debate on trade and human rights. It led to, and followed, the adoption of the 2001 Doha Declaration on the TRIPS Agreement and Public Health and its implementation mechanism based upon a waiver and subsequent amendment of Article 31(f) TRIPS Agreement which limits the granting of compulsory licensing essentially to the supply of the domestic market. The system adopted for pandemic drugs henceforth allows members to grant compulsory export licences under carefully circumscribed conditions.⁴⁴ While the system has only been applied once so far, it substantially increased the bargaining powers of governments in negotiating with original producers, which contributed to substantially lowering drug prices in the meantime. The issue of access to drugs induced extensive scholarly work in trade and human rights beyond the right to health.⁴⁵ It may have influenced WTO jurisprudence in invoking public morals in defence of non-trade concerns.⁴⁶ It prepared the ground for future invocation of labour standards and human rights. Particular and impressive scholarly efforts were made on human rights and intellectual property rights. The 2015 *Research Handbook* is an important milestone in this respect.⁴⁷

4.1 Substantive and Procedural Standards

43 Thomas Cottier, "Trade and Human Rights: A Relationship to Discover," *Journal of International Economic Law* 5 (2002): 111–132.

44 See e.g. Frederick M. Abbott and Jerome Reichman, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions," *Journal of International Economic Law* 10 (2007): 921–987. For a detailed analysis and case studies on access to medicines, with a particular focus on Global Administrative Law, see Rochelle C. Dreyfuss and César Rodríguez-Garavito (eds), *Balancing Wealth and Health: The Battle over Intellectual Property and Access to Medicines in Latin America* (Oxford: Oxford University Press, 2014).

45 Frederick M. Abbott, Christine Breining-Kaufmann and Thomas Cottier (eds), *International Trade and Human Rights: Foundations and Conceptual Issues* (Ann Arbor: University of Michigan Press, 2006); Thomas Cottier, Joost Pauwelyn and Elisabeth Bürgi, *Human Rights and International Trade* (Oxford: Oxford University Press, 2005).

46 See *European Communities – Measures Prohibiting the Importation and Marketing of Seal Products*, WT/DS 400/AB/R, WT/DS401/AB/R (5 May 2014).

47 Geiger, *Research Handbook on Human Rights and Intellectual Property*.

In interpreting and applying disciplines on IPRs in WTO law and preferential trade agreements, social and economic human rights will continue to be of paramount importance. Besides the right to health, the right to food and the right to life in general are of importance in assessing the scope and limitations of patents in pharmaceuticals, chemicals and foodstuffs. These rights may limit patent protection or undisclosed information, or copyright in view of the right to education and the right to information. They may also foster protection to encourage research and development in genetic engineering, however, making available more efficient and drought-resistant crops with the capacity to overcome hunger and malnutrition, or countering disinformation in the internet age. The relationship of IPRs and human rights is not a one-way street but must be considered case by case on the merits of the issue at hand.

Procedural human rights of due process, enshrined in Article 6 of the European Convention on Human Rights and other instruments, are of importance in improving procedures granting patent, trademark and design protection. They serve the protection not only of right holders, but also of competitors and consumers. Due process, and in particular the right to be heard of those affected, are relevant ingredients in refining procedures and ensuring that all sides have their day in court and are not overlooked. Finally, human rights are critical in assessing unfair competition rules referred to earlier. Whether or not conduct of companies under obligations of corporate social responsibility (CSR) is protected by freedom of speech, or whether it amounts to commercial speech subject to unfair competition, depends upon the interpretation of guarantees of freedom of speech and information enshrined in human rights instruments and constitutional law.

4.2 Property and Human Rights

Embedding intellectual property also raises the question of the extent to which IPRs amount to human rights in their own right. Article 27(2) of the Universal Declaration of Human Rights⁴⁸ is echoed in Article 15 of the International Covenant on Economic, Social and Cultural Rights, which includes the right to "benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he [or she] is the author."⁴⁹ The covenants, however, do not include the right to property as such. The right to property in Protocol (I) of the European Convention on Human Rights⁵⁰ was recognised and extended to IPRs, in particular trademark protection.⁵¹ It was argued that property rights form part of human rights.⁵² This translates into the need to balance the interests implied; this kind of balancing between IPRs and human rights is considered to be key. This approach actually dominates the interface of intellectual property and human rights in domestic and European Union case law.⁵³

48 "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he [or she] is the author"; <http://www.un.org/en/universal-declaration-human-rights/>.

49 See <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx>.

50 See <http://www.echr.coe.int/pages/home.aspx?p=basictexts>.

51 European Court of Human Rights, *Anheuser-Busch Inc. v. Portugal* [GC] no. 73049/01, 11 January 2007, paras 13–24, ECHR 2007-I.

52 See Petra Buck, *Geistiges Eigentum und Völkerrecht: Beiträge des Völkerrechts zur Fortentwicklung des Schutzes von geistigem Eigentum* (Berlin: Duncker & Humblot, 1994).

53 See Alexander Peukert, "The Fundamental Right to (Intellectual) Property and the Discretion of the Legislature," in Geiger, *Research Handbook on Human Rights and Intellectual Property* (pp. 132–148).

From a historical and functional point of view, however, IPRs respond to utilitarian concepts of enhancing the welfare of society at large, rather than primarily offering protection to individuals. Property, including IPRs, does not entail natural law (and thus characteristics pre-dating the state) which legislators need to respect and are unable to remove. They are, with David Hume, conventional in nature.⁵⁴ The protection of property in Protocol (I) of the European Convention on Human Rights presupposes the existence of a system of property created by legislation.⁵⁵ It is man-made. It does not reflect a human right to property entailed in natural law. In England, for example, the emergence of patent laws was a response to the granting of arbitrary royal privileges.⁵⁶ Rather, IPRs involve an obligation to seek and adjust a proper balance between conflicting interests in the course of never-ending technological developments. New forms of property protection may emerge, such as GIs, undisclosed information, integrated circuits, and in the future traditional knowledge. Others may disappear and be no longer used. Moreover, it would be difficult to generally assign human rights to juridical persons and multinational enterprises. They benefit from the protection of property as defined in legislation and case law, and they benefit from the procedural rights of Article 6 of the European Convention on Human Rights, which also applies to matters pertaining to intellectual property protection.

What then is the impact of Article 15 of the UN Covenant on Economic, Social and Cultural Rights? It is submitted that these rights are expressions of a right to personality, calling for the protection of interests closely relating to a particular natural person. They essentially translate into material and non-economic moral rights (recognised in copyright law), but also apply to rights of the personality in all forms of intellectual property protection. Statutory and conventional development of IPRs needs to take these elements into account, but may not exhaust the impact of Article 15. It is submitted that human rights are not linked to recognised right holders, but primarily protect the human dignity of individuals who have participated in the creative process. Human rights to creativity thus rebalance the rights of right holders (often juridical persons) with the interests of individuals who contributed in the creative process. Human rights, in other words, are important ingredients in defining the relationship of creative activity to right owners, and thus are in particular relevant in shaping the conditions of work for hire.

While IPRs thus are utilitarian and not based upon human rights, human rights are of paramount importance in providing goals and values which the overall IPR system should seek to implement. Human rights are one of the main components by which the legitimacy of the overall IP system should be assessed. They thus need to be taken into account in defining, interpreting and enforcing IPRs. Substantive and procedural rights define the benchmark by which outcomes are measured in terms of fairness, equity and justice. The right to life and health, the right to food, the right to education and other rights must play a key role in shaping and applying intellectual property rights. Partly, they overlap and are mutually supportive. Partly they conflict and intellectual property amounts to a restriction of human rights.

54 David Hume, *A Treatise of Human Nature* (1739); see "David Hume on Property as a Convention Which Gradually Emerges from Society," Online Library of Liberty, <http://oll.libertyfund.org/quotes/546>.

55 Peukert, "The Fundamental Right to (Intellectual) Property," 138.

56 Statute of Monopolies (1623), <http://www.legislation.gov.uk/aep/ja1/21/3>.

Importantly, in addressing such conflicts and tensions, human rights and property rights, as has been explained, are not on the same page and level. It is not simply a matter of balancing the two, but of adopting human rights as prime guidance in the process of shaping and applying intellectual property rights.⁵⁷ Rather, in case of conflict and diverging interests, it is a matter of making a legal justification for intellectual property rights which restrict human rights, calling for appropriate legal foundations, recognition of compelling public interests and respect for proportionality. This essentially amounts to a constitutional approach, requiring adequate legal foundations, public interest and the necessity (proportionality) of the regulation.⁵⁸

It is questionable whether the existing framework allows for sufficient flexibility to achieve this. Articles 7 and 8 of the TRIPS Agreement provide important doors of entry. However, the scope is limited as results must be compliant with the other provisions of the TRIPS Agreement. General exceptions allowing recourse to public morals do not exist as in the field of trade in goods and services. As levels of protection increase, it is important to consider these elements in future treaty-making and to provide for a clear basis which obliges legislators and adjudicators to consider human rights concerns in developing and assessing intellectual property standards and related procedures.

4.3 The Missing Pieces

In section 8, we shall briefly address real property in the context of investment protection, the main purpose of which is to protect foreign direct investment in real estate, translating into activities of resource extraction, or building industries in the production of goods and services. Other than that, it is striking to observe that public international law hardly deals with real estate.⁵⁹ Due to the principles of sovereignty over natural resources and territoriality, it is left to the nation-state. It is not protected in binding universal human rights agreements. Regulations under the umbrella of international law range from capitalist to socialist, even communist models of ownership of the means of production. Other than in the field of intellectual property, there are no transboundary transactions of real estate other than foreign direct investment.

At the same time, it should be recalled that the legal status of soil and real property plays an important role in international relations, ranging from fundamental geopolitical tensions to issues of social and economic development and thus private and official development assistance. Efforts to enhance the livelihood of rural populations and local farmers cannot be detached from real estate law. The lack of land titles prevents farmers and indigenous people from defending their core interests in land use and management. It bars them from mortgaging real property and soil and thus impedes investment. Resources spent in overseas development assistance on rural development may fail due to a lack of fundamentals, which, however, cannot be addressed in terms of international law. No binding international rules exist on land registration and zoning, and efforts to support countries in that respect all depend upon domestic law and voluntary compliance with development programmes. Climate change mitigation could be improved by binding land titles for indigenous peoples, beyond

57 See Lawrence R. Helfer, "Toward a Human Rights Framework for Intellectual Property," *UC Davis Law Review* 40 (2007): 971–1020. Cf. also Andrey R. Chapman, "The Human Rights Implications of Intellectual Property Rights," *Journal of International Economic Law* 5 (2002): 861–882.

58 See Peukert, "The Fundamental Right to (Intellectual) Property."

59 See Thomas Cottier, Katja Gehne and Maria Schultheiss, "The Protection of Property in International Law: The Missing Pieces," in *Coexistence, Cooperation and Solidarity: Liber Amicorum Rüdiger Wolfrum*, vol. 1, ed. Holger P. Hestermeyer et al. (pp. 367–396) (Leiden: Kluwer Law, 2012).

Article 26 of the 2007 UN Declaration on the Rights of Indigenous Peoples.⁶⁰ Finally, from the point of view of sustainable development and international trade in agricultural products, soil quality and care are of the utmost importance and an international concern. Countries depending upon food and feedstock imports have a stake and interest in sound soil management, preventing and remedying the deterioration of soil quality under principles of sustainable development. It hardly needs to be emphasised that the issue is of particular importance in the age of climate change and the need to cope with climate change adaptation mainly affecting agricultural production.

International law has a long way to go in developing a human right to personally used property, both real and movable. The discrepancy with the level of intellectual property protection is striking. Developing appropriate tools of international disciplines on domestic obligations, international cooperation and unilateral measures on soil and real property management under the emerging principle of common concern of humankind⁶¹ may also help to remedy some of the imbalances which are currently unsuccessfully addressed in agricultural trade and intellectual property protection relating to genetic resources for food and agriculture, the protection of traditional knowledge and the transfer of technology and know-how. We need to widen the options to avoid seeking solutions relating to property exclusively by using the tools of intellectual property. Efforts should not merely focus on plant variety protection, farmers' rights and genetic resources in patent law, onto GIs, labelling and trademark law and in the future to the protection of traditional knowledge. International law should also develop disciplines on land registration, sustainable soil management and the use of water resources in order to achieve an overall balance of the interests at stake. Disciplines on virtual water in international trade will assist in implementing and enforcing such disciplines.⁶²

5. Sustainable Development Goals

The 2015 Sustainable Development Goals, further developing the Millennium Development Goals, enshrine the basic philosophy of balancing economic, social and ecological goals in different walks of life important to developing countries and society at large. To a large extent, their content overlaps with social and economic human rights as enriched by environmental concerns not present when this generation of standards of justice and equity were drafted after World War II. The 2015 SDGs cover a wide field of human life and state ambitious goals: (1) No Poverty, (2) Zero Hunger, (3) Good Health and Well-Being, (4) Quality Education, (5) Gender Equality, (6) Clean Water and Sanitation, (7) Affordable Clean Energy, (8) Decent Work and Economic Growth, (9) Industry, Innovation and Infrastructure, (10) Reduced Inequalities, (11) Sustainable Cities and Communities, (12) Responsible Consumption and Production, (13) Climate Action, (14) Life below Water, (15) Life and Land, (16) Peace Justice and Institutions, (17) Partnership for the Goals.⁶³

The difference from human rights is essentially one of methodology and, partly, scope. While the

60 UNGA Res. 61/295 (13 September 2007), http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf.

61 Cf. Thomas Cottier, Philipp Aerni, Barış Karapınar, Sofya Matteotti, Joëlle de Sépibus and Anirudh Shingal, "The Principle of Common Concern and Climate Change," *Archiv des Völkerrechts* 52 (2014): 293–324.

62 See Fitzgerald Temmerman, "Trade in Water in International Law: Bulk Fresh Water, Irrigation Subsidies and Virtual Water," PhD thesis, University of Bern, 2015.

63 Resolution adopted by the General Assembly on 25 September 2015: "Transforming our World: The 2030 Agenda for Sustainable Development," UNGA Res. 70/1 (21 October 2015), http://www.unfpa.org/sites/default/files/resource-pdf/Resolution_A_RES_70_1_EN.pdf.

implementation of political and civil rights mainly depends on courts, and social and economic rights primarily upon legislation and domestic programmes, sustainable development goals set out benchmarks and make available international tools making it possible to measure and quantify progress made and identify shortcomings.⁶⁴ SDGs are not only informed by the efforts of civil society and non-governmental organisations supporting human rights and environmental goals, in particular mitigating climate change and adapting to climate change. They are essentially informed by working methods of the World Bank, United Nations organisations and national development agencies funded by taxpayers. From the point of view of international law, SDGs amount to soft law instruments which need to be taken into account in the interpretation of law. Compliance will depend upon specific programmes and commitments made which may trigger legal obligations in good faith and the doctrine of estoppel. By and large, however, it will not be a matter for the courts to secure implementation, but the political branches of government, national administrations and specialised international organisations.

Similar to human rights, SDGs should be taken into account in shaping intellectual property rights, in the process of interpretation and compliance. SDGs today provide the most important contemporary standards of justice and equity in international economic law. Again, Articles 7 and 8 of the TRIPS Agreement provide the basis to take SDGs into account. However, these provisions do not provide a basis to justify deviations from existing standards and rules, and the lack of general exceptions in the TRIPS Agreement may limit the opportunity to effectively take SDGs into account. Agreements such as preferential trade agreements, amendments to the TRIPS Agreement, but also IPR Conventions should introduce appropriate foundations which allow SDGs and human rights to be taken into account in specific regulatory areas. This is of importance in several areas relating to health, food and education, and climate change. It goes beyond the scope of this paper to engage in a detailed analysis. It should be highlighted, however, that SDGs will be of the utmost importance in developing new and effective disciplines on transfer of knowledge and technology on the basis of Articles 7 and 66(2) of the TRIPS Agreement in support of attaining the benchmarks defined by SDGs. Many of their goals cannot be achieved without enhancing the effort, and new tools need to be developed, such as tax incentives and framework rules for the operation of public-private partnerships (PPPs). Addressing intellectual property rights and PPPs has been one of the most difficult issues and so far has been left to a case-by-case approach, offering no transparency and sharing of mutual experience.

6. The Impact of International Trade Regulation

The overall system of the WTO provides equal conditions of competition and market access. The rules of the GATT 1994 and its specialised agreements protect tariff bindings and non-tariff barriers. They prevent and remedy protectionist, rent-seeking barriers to international trade while recognising legitimate non-trade concerns, such as public health, public morals or environmental standards in the process of sustainable development. The same philosophy applies, partly with different techniques due to the absence of tariffs, in the field of services.

Within the multilateral trading system, intellectual property rights are part of the law of non-

64 Cf. Resolution adopted by the General Assembly on 29 July 2016: "Follow-up and Review of the 2030 Agenda for Sustainable Development on the Global Level," UNGA Res. 70/299 (18 August 2016), https://www.cbd.int/doc/meetings/mar/soiom-2016-01/other/soiom-2016-01-desa-unga-a-70a_res_70_299-en.pdf.

tariff measures and a prerequisite of fair trade. If properly shaped, calibrated and balanced, they encourage and reward innovation, which in turn translates into increasing levels of international trade in exchanging goods and services. They allow consumers to distinguish different brands. They assist in excluding fake and dangerous products and combating counterfeiting and piracy. Trademark protection is an important ingredient in combating fake and dangerous drugs, often traded on the internet and otherwise difficult to attach. Lack of protection, as well as excessive protection, amounts to a distorting trade barrier. Again, IPRs pertain to the core of international trade regulation. IPRs thus need to be considered and respected in the interpretation of trade rules on goods and services. But this also implies that rules on goods and services need to be taken into account in interpreting and applying intellectual property rights beyond the confines of the TRIPS Agreement and TRIPS-plus disciplines in other agreements, in particular preferential trade agreements.

6.1 Non-discrimination, Nullification and Impairment

The general body of international trade law of the GATT has had significant influence in interpreting the TRIPS Agreement, taking into account the fact that the subjects of protection are not goods and services, but right holders, and thus natural and juridical persons.⁶⁵ While the doctrine of legitimate expectations as to conditions of competition developed in the context of Article III GATT on national treatment was unduly rejected by the Appellate Body in the early case law of *India – Patents*,⁶⁶ the paramount importance of de facto discrimination was recognised in *EC – Geographical Indications*.⁶⁷ Members of the WTO cannot hide behind formal concepts of national treatment if the regulation in fact deploys discriminatory effects. This case resulted in reducing discriminatory and protectionist practices in granting protection to geographical indications issued by the European Union. It brought about equal protection for domestic and foreign right holders, and overall balanced the existing system of protection.

Non-violation nullification and impairment of benefits, however, were excluded for political reasons by a moratorium, the legal effects of which have remained unclear. A majority of the WTO membership is afraid that non-violation complaints could instigate harassment beyond existing legal obligations. Another reason for exclusion was that the concept of non-violation is being misunderstood and the potential impact exaggerated. Strict legal requirements applied to non-violation complaints, in particular the non-foreseeability of a measure following agreed regulation,⁶⁸ hardly qualify for application in the field of IPRs. Within the detailed legal framework of the TRIPS Agreement it is difficult to imagine configurations of valid non-violation complaints. Most angles are covered by law. Perhaps the increase of price controls for products such as pharmaceutical and chemicals in the aftermath of patent protection are an area suitable for non-violation. Yet, even here, it will be difficult to comply with the legal test of non-foreseeability of the measure at hand if price controls have been in operation and increases of price controls are to be expected within a given

65 See Kennedy, *The WTO Dispute Settlement and the TRIPS Agreement*.

66 *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (19 December 1997); for a discussion, see Panizzon, *Good Faith in the Jurisprudence of the WTO*, 222–223.

67 *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS290/R (15 March 2005).

68 See Thomas Cottier and Krista Nadakavukaren Schefer, “Non-Violation Complaints in WTO/GATT Dispute Settlement: Past, Present and Future,” in *International Trade Law and the GATT/WTO Dispute Settlement System*, ed. Ernst-Ulrich Petersmann (pp. 145–183) (Leiden: Kluwer 1997).

national health system.

6.2 Exhaustion of Rights and Parallel Trade

Exhaustion of rights amounts to the most important and unresolved areas of interfacing TRIPS and GATT rules. Regulation of parallel trade, that is, the competition of original products placed in different markets and subsequently traded internationally, fundamentally defines to what extent free trade prevails over market segmentation.⁶⁹ Article 6 of the TRIPS Agreement leaves the matter to domestic policy space, subject to obligations of non-discrimination. Members are free to adopt rules of exhaustion which best serve their interests and industries. They may even adopt different rules for different forms of protection. A member may operate national exhaustion in patent law and international exhaustion in trademarks. In trademark law, Article 16 of the TRIPS Agreement implies the doctrine of international exhaustion for like products placed on different markets by the same multinational corporation. The provision allows the presumption to be rebutted that the use of the same trademark for identical goods and services results in a likelihood of confusion. Apparently, no such confusion exists for like products of the same company, provided that these products are physically identical. Since the TRIPS Agreement is a minimum standard, however, members are allowed to operate more stringent standards than under Article 16 TRIPS. The doctrine of regional exhaustion operating within the European Union is thus compatible with the provision.⁷⁰

The question arises as to whether such policy space is safeguarded under the TRIPS Agreement or possibly limited under the purview of the GATT 1994. Parallel trade depends upon the origin of the good, quite independently of the nationality of the right holder. It follows that national exhaustion (or regional exhaustion in the case of the EU) translates into quantitative restrictions applied to products imported. National or regional exhaustion in relation to third countries thus amounts to a violation of Article XI GATT, prohibiting quantitative restrictions on goods or transboundary services. The provision applies in its own right, irrespective of Articles 6 and 16 TRIPS Agreement.⁷¹ The operation of national or regional exhaustion thus depends upon exceptions under Article XX GATT. Such restrictions need to be necessary and comply with the requirements of the chapeau of the provision.

It may be argued that necessity can be readily established by invoking existing rules and practices of national exhaustion and thus the protection of existing intellectual property rights. It may also be argued, however, that necessity relates to the policy goals behind exhaustion and thus is open to weighing and balancing the impact of the measure and the policy goals. The effect of quantitative restrictions, market segmentation and price differentiation for original like products, resulting in higher pricing, thus must be balanced against the needs of industries to fund innovation and of consumers to be protected from deception as to the quality of the product.⁷² In pharmaceuticals, for

69 For a comprehensive analysis, see Irene Calboli and Edward Lee, *Research Handbook on Intellectual Property Exhaustion and Parallel Imports* (Cheltenham: Edward Elgar, 2016); Thomas Cottier and Matthias Oesch, *International Trade Regulation: Law and Policy in the WTO, the European Union and Switzerland* (Bern: Stämpfli, 2005), 936–939, 948–951, 953–958.

70 See Christiane Freytag, *Parallelimporte nach EG- und WTO-Recht* (Berlin: Duncker & Humblot, 2001).

71 But see Marco C. E. J Bronckers, "The Exhaustion of Patent Rights under World Trade Organization Law," *Journal of World Trade* 32, no. 5 (1998): 137–159.

72 For an excellent discussion under US patent law see Brief of Amicus Curiae (Frederick M. Abbott) in Support of Petitioner, *Impression Products Inc. v. Lexmark International, Inc.*, on Writ of Certiorari to the United States Court of Appeals for the Federal Circuit, United States Supreme Court, No 15-1189 (filed January 20, 2017;) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2906967. The US Supreme Court, in this case, essentially ruled on May 30, 2017 in favour of

example, it may be argued that price controls applicable to all products alike offer a viable and less intrusive alternative than quantitative restrictions imposed by right holders and enforced by states. In EU law, the rules on competition law and eventually of free movement of goods led to the finding that national exhaustion in intellectual property violates fundamental principles of EU law. Under GATT rules, the test may produce comparable results, although no concept of a common or internal market exists. The test may lead to different results in copyright, patents and trademarks, given possibly different motives for protection. National exhaustion in trademarks may not be considered a necessity to achieve the goal of product differentiation to the extent that original products effectively are the same. GATT may thus impose international exhaustion in this field. On the other hand, a price differential may be justified in patents in support of research and innovation and access to supplies by importing countries. Finally, national exhaustion needs to meet the standard of the chapeau of Article XX GATT, and avoid discriminatory treatment and disguised restrictions of trade.

In other words, the test applied to national exhaustion does not leave the matter entirely to members under Article 6 TRIPS. The two agreements are on a par, and TRIPS does not inherently prevail.⁷³ Both agreements need to be examined. Each of them applies in its own right and may impose stricter and thus under WTO law prevailing standards of protection than the other one. Applying GATT rules thus may lead to a more refined doctrine of exhaustion in the future, defining the parameters for patents and trademarks in their own ways. It may lead to a more refined balance of exclusive rights and market access in redefining the scope of intellectual property rights in the light of an open trading system. Members need to justify national exhaustion of rights, while under TRIPS they can freely choose to impose it and ban parallel imports from entering the market. Embedding the doctrine of exhaustion in the overall WTO framework may thus lead to different results than restricting considerations to the TRIPS Agreement and TRIPS-plus standards in preferential trade agreements. It may contribute to a better balance between exclusive rights and the interests of competitors and consumers.

Less is known about the impact of trade in services on the operation of IPRs. The structure of trade and the agreement is different from goods with the exception of transboundary mode 1 transactions, crossing borders. Unless the service produces a tangible good, it would seem that the doctrine of exhaustion has no role to play. The service and the provision of the service cannot be separated. Market access and non-discrimination are essentially defined by the schedules of commitment of each member. They may entail conditions and even quantitative restrictions under Article XVI. Article XIVbis GATS does not explicitly mention intellectual property in justifying exceptions, but it is included in legislation not incompatible with WTO law and measures necessary to prevent deceptive or fraudulent practices. Service-related patents (e.g. business models) and trademarks may thus justify restrictions on free movement of services and market access. The necessity test and proportionality, however, require recourse to the least intrusive measures and calibration which balances the impact and regulatory goals. In the absence of a particular case, the impact cannot be properly assessed. Overall it would seem that the GATS Agreement affects or modifies the operation of the TRIPS Agreement in a comparable manner to the potential effects of GATT on the operation

international exhaustion on the basis of the US Patent Act, https://www.supremecourt.gov/opinions/16pdf/15-1189_ebfj.pdf.

73 See *Canada – Certain Measures Concerning Periodicals*, WT/DS31/AB/R (30 June 1997); Cottier and Oesch, *International Trade Regulation*, 90–97.

of the exhaustion doctrine and on import restrictions.

7. Competition Law and Policy

7.1 Anti-trust Rules

Intellectual property rights amount to exclusive monopoly rights granted by the state to foster investment in research, development and marketing. They provide strong legal positions. They inherently restrict competition and market access of third parties. They create uneven playing fields in the process of negotiating voluntary licences. These effects may be excessive and even abusive. In domestic law, competition law is of importance in shaping the exercise of intellectual property rights. Abuses found may lead to damages or the granting of compulsory licensing, thus removing the exclusivity of intellectual property rights. Competition law, restricting freedom of contract and addressing cartels and the abuse of dominant positions as well as mergers and acquisitions, therefore amounts to an important check and balances IP rights and obligations. Article 8(2) of the TRIPS Agreement recognises the risk of abuse of rights and allows for appropriate remedies, provided that they are compatible with the provisions of the TRIPS Agreement. Article 40(1) more specifically recognises that "licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology."

Article 40(2) TRIPS Agreement explicitly allows members to adopt appropriate measures to prevent such practices. The agreement, by way of example, mentions exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing. The power also includes addressing the abuse of dominant positions. However, the provision requires that such measures are consistent with the other provisions of the TRIPS Agreement. While recourse to compulsory licensing under Article 31 TRIPS or exceptions under Article 30 TRIPS allow for adequate policy space, it is unclear to what extent other disciplines of competition policy may be restrained by Article 8(2) and Article 40 of the TRIPS Agreement.

The balance of intellectual property and competition is well developed in advanced jurisdictions, in particular in US and EU anti-trust rules. The US guidelines and EU regulations on block exemptions offer a certain amount of legal security in licensing intellectual property rights.⁷⁴ Important case law offers guidance as to the thresholds establishing an abuse of the dominant position granted by intellectual property rights.⁷⁵ Since the conclusion of the Uruguay Round, many countries have introduced disciplines on competition policy and may refer to such disciplines under the TRIPS Agreement. Issues relating to access to essential drugs were first addressed in South Africa, expounding the impact of competition law and policy.⁷⁶ Many countries, however, still lack adequate

74 US Department of Justice and Federal Trade Commission, "Antitrust Guidelines for the Licensing of Intellectual Property" (1995), <https://www.justice.gov/atr/archived-1995-antitrust-guidelines-licensing-intellectual-property>; Commission Regulation (EC) No. 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements, <http://www.wipo.int/wipolex/en/details.jsp?id=6390>; for a comprehensive analysis, see Andreas Heinemann, *Immaterialgüterschutz in der Wettbewerbsordnung* (Tübingen: Mohr Siebeck, 2002).

75 e.g. Case 241/91 and C-242/91 *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd v. Commission* [1995] ECR I 743 (Magill).

76 See Frederick Abbott, Sean Flynn, Carlos Correa, Jonathan Berger and Natasha Nyak, *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries* (New York: United Nations Development

disciplines and practices in order to bring about a proper balance. It should be recalled that the introduction and operation of anti-trust rules amounts to restricting freedom of contract and—other than intellectual property rights—is not generally supported by industries.

History shows that the introduction of effective disciplines on anti-trust often depends upon external pressures.⁷⁷ At the same time, large jurisdictions operating anti-trust rules with extraterritorial effects are not keen to engage international law disciplines. While part of the so-called Singapore issues, efforts to bring about such disciplines in the WTO have so far failed. Today, they are being pursued by the International Competition Network outside the WTO.⁷⁸ The Network has effectively supported countries in introducing legislation and developing expertise in the field. As many more countries have anti-trust rules today, the time has come to address binding common standards in the WTO. As countries develop their own anti-trust rules, regulatory cooperation and coherence may be warranted. The existence of extensive TRIPS and TRIPS-plus standards reinforces the need for effective tools balancing these rights, which, in international trade, depends upon effective international cooperation.⁷⁹ At the same time, developing countries may be worried that convergence will simply mean the adoption of US or European standards which may not sufficiently take into account the particular needs of developing countries. Evidently, WTO standards on competition policy cannot amount to simply copy-pasting existing domestic regulations, but must focus on core standards which allow countries to take appropriate measures to tame powerful positions based upon exclusive rights beyond the existing TRIPS Agreement. Moreover, it is necessary to develop mechanisms of mutual administrative and legal assistance in investigations, litigation and enforcement. Anti-trust investigations in a globalised economy strongly depend on mutual cooperation and law enforcement mechanisms.⁸⁰

Competition law thus amounts to an important ingredient in embedding intellectual property and to provide checks and balances. However, it cannot replace inherent and implied restrictions within IP law itself.⁸¹ It should be recalled that competition policy—with the exception of merger control—is reactive, costly and uncertain. It does not lend itself to defining and replacing the scope of IP rights in the first place.

7.2 The Need for Ceilings

The limited and ex post effects of competition law as a check on abuses of intellectual property are a main, but not exclusive, reason why international intellectual property agreements should not be limited to minimum standards, but also include maximum standards and thus ceilings of protection.⁸² The TRIPS Agreement states in its preamble that the agreement desires to ensure that

Programme, 2014), <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-competition-law-to-promote-access-to-medicine.html>.

77 Cf. David J. Gerber, *Law and Competition in the Twentieth Century Europe* (Oxford: Oxford University Press, 1998).

78 See <http://www.internationalcompetitionnetwork.org/>.

79 See David J. Gerber, *Global Competition: Law, Markets, and Globalization* (Oxford: Oxford University Press, 2012).

80 See Benoît Merkt, *Harmonisation internationale et entraide administrative internationale en droit de la concurrence* (Bern: Peter Lang, 2000).

81 See Eleanor Fox, "Can Antitrust Policy Protect the Global Commons from the Excesses of IPRs?" in *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*, ed. Keith E. Maskus and Jerome H. Reichman (pp. 758–773) (Cambridge: Cambridge University Press, 2005).

82 Kur and Grosse Ruse-Khan, "Enough Is Enough."

measures and procedures to enforce intellectual property rights not themselves become barriers to legitimate trade. The rules on enforcement in Articles 41–60 TRIPS thus partly contain such ceilings. To the extent that certain instruments are introduced, in particular on border measures, members are obliged to respect limitations which secure the balance of interests of right holders and importers affected by such measures. The agreement, however, does not go far enough, for example by clearly excluding the attachment of lawfully traded good in transit which potentially violate intellectual property rights in that market but are not likely to enter that market.⁸³ Moreover, the preamble in parallel does not recognise that substantive standards (other than for procedural standards) may amount to unnecessary barriers to trade. Instead, members of the WTO are free to adopt higher levels of protection unilaterally or as agreed in other agreements. It is necessary, with a view to establishing and maintaining a proper balance, to develop the idea that excessive protection may unduly restrict international trade and to contain levels of protection accordingly.

Unless the TRIPS Agreement is amended and introduces ceilings on substantive provisions, members may continue to increase levels of protection and TRIPS-plus provisions in bilateral and preferential agreements. These agreements are of equal standing and normally would not be questioned by the parties to them. Yet third parties may challenge domestic implementation of these standards in national legislation on the grounds that the standards due to ceilings are excessive and incompatible with the TRIPS Agreement. Violations found will give rise to withdrawal of concessions and thus may create incentives to suspend preferential agreements violating WTO law.

7.3 Unfair Competition Rules

Other than anti-trust rules, disciplines on unfair competition have established the principle of fairness in business dealings in relation to consumers and competitors. The concept imports moral and ethical standards into business law and practices. Given its vagueness and unpredictability, it has given rise to specific forms of intellectual property protection, the most recent additions explicitly referring to unfair competition being the protection of geographical indications and undisclosed information in Articles 22(2)(b) and 39(1) TRIPS Agreement. It is submitted that all forms of intellectual property protection, in particular patents, copyright and trademark protection operating on more specific rules than unfair competition, are conceptually rooted in this context and amount to *lex specialis* of unfair competition rules.

International law addresses unfair competition in Article 10bis of the Paris Convention as incorporated into the TRIPS Agreement.⁸⁴ Members are obliged to assure to nationals of other members effective protection from unfair competition. The general principle is stated in Article 10bis(2) of the Convention: "Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition." The provision, in particular and in a non-exhaustive manner, addresses acts creating confusion, recourse to false allegations discrediting a competitor, and indications or allegations which are liable to mislead the public as to the nature, the manufacturing process and the properties of a product.

83 Grosse Ruse-Khan, *The Protection of Intellectual Property*, 288–299.

84 For a comprehensive analysis see Christian Riffel, *Protection against Unfair Competition in the WTO TRIPS Agreement: The Scope and Prospects of Article 10bis of the Paris Convention for the Protection of Industrial Property* (Leiden: Brill Nijhoff, 2016).

The potential of unfair competition rules has largely remained untapped so far in balancing intellectual property rights. Despite the fact that the evolution of different forms of IP protection is founded upon unfair competition, the two disciplines have been dealt with separately. The theory prevailed that the two fields were mutually exclusive: facts dealt with under specific IPR rules exclude recourse to the general precepts of unfair competition law. This approach developed by domestic courts and by scholarship is not inherent in international law. Conduct in line with intellectual property disciplines may still amount to a violation of the basic precepts of justice and fairness of unfair competition rules. The different provisions of the TRIPS and substantive provisions of the Paris Agreement are on a par and need to be applied in a mutually compatible manner. For example, in assessing the relationship of trademarks and geographical indications, the principle could be of importance in avoiding consumer deception. The operation of unfair competition rules thus may significantly contribute to balancing the overall system of IPRs.

The unfair competition rules of Article 10bis Paris Convention are not self-executing. Members are required to implement appropriate disciplines in domestic law. However, the principle of fairness should be applied on the basis of the doctrine of consistent interpretation and may thus also influence the operation of domestic intellectual property rights. For example, if domestic law does not protect traditional knowledge and indigenous rights, exclusive rights ignoring the contributions of holders of traditional knowledge can be challenged on the basis of unfair competition rules before domestic courts. To the extent that domestic law does not extend to such protection, it could be challenged before a panel and the Appellate Body of the World Trade Organization. Outside the realm of IPs, unfair competition rules may also serve to enforce commitments made by companies under the framework of corporate social responsibility.⁸⁵ The failure of a company to live up to conduct and business practices and labour relations promised in a CSR statement published by the company amounts to consumer deception. It also creates distortions in competition with companies adhering to and implementing such standards.⁸⁶ Both amount to violations of principles of unfair competition which members of the WTO are obliged to address under Article 10bis of the Paris Convention, as incorporated in the TRIPS Agreement and thus subject to WTO dispute settlement.

Disciplines on unfair competition, finally, serve as a foundation to introduce new forms of IP protection beyond adjudication. Emerging disciplines on traditional knowledge are based upon fairness. The work of WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore is informed by unfair competition rules.⁸⁷ The idea of developing sui generis traditional knowledge rights is based upon unfair competition⁸⁸ and would add yet another new form of IP, along with the protection of GIs and undisclosed information. Future efforts may also relate to framing the enforcement of CSR standards, moving the field beyond soft law.

85 Thomas Cottier and Gabriela Wermelinger, "Implementing and Enforcing Corporate Social Responsibility: The Potential of Unfair Competition Rules in International Law," in *Corporate Social Responsibility: Verbindliche Standards des Wettbewerbsrechts*, ed. Reto M. Hilty and Frauke Henning-Bodewig (pp. 81–98) (Berlin: Springer, 2014).

86 Riffel, *Protection against Unfair Competition*, 107–133.

87 WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, <http://www.wipo.int/tk/en/igc/>.

88 Thomas Cottier, "The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law," *Journal of International Economic Law* 4 (1998): 555–584; Riffel, *Protection against Unfair Competition*, 134–259.

8. Investment Protection

Intellectual property, for a long time, did not figure prominently in international law of investment protection. Under customary law standards on compensation for lawful expropriation, it is unclear to what extent intellectual property forms part of protected property rights. In bilateral investment agreements, the issue is not dealt with uniformly. Some mention IPRs, some are silent and may or may not imply the inclusion of IPRs. For a long time, the issue was not addressed in private state arbitration.⁸⁹ Recent developments clearly see the explicit inclusion of IPRs in investment protection, commensurate with the implied shift to investment protection in IPR standards already discussed. Contemporary issues relate to the revocation of patents or strict limitations on trademark protection in the health sector. The Comprehensive Economic and Trade Agreement (CETA) explicitly addresses intellectual property rights and renders them subject to fair and equitable treatment, regulatory taking and expropriation newly defined within the agreement.⁹⁰ Moreover, these disciplines form part of the very same agreement which also contains rules on free trade and on intellectual property protection. The inclusion of all three areas raises interested issues of interaction. Should they be dealt with in isolation, or should the three components be applied and construed in combination, looking back and forth in the process of interpretation?

The CETA provides for a separate track in dispute settlement, and does not subject investment protection on IPRs to the dispute settlement system applicable to trade and IPR protection.⁹¹ The remedies are different. While investment protection addresses financial compensation for past unlawful acts, WTO law (and regional trade agreements) are forward looking and seek to adjust legislation and practices found to be incompatible with the treaty at hand. On substance, however, this does not exclude taking trade rules and IPR standards into account in adjudicating issues of fair and equitable treatment or regulatory takings. For example, in assessing restrictions on the use of trademark rights by governments, Article 20 TRIPS Agreement requires that the use of a trademark in the course of trade "shall not be unjustifiably encumbered by special requirements." This calls for taking into account standards developed on regulatory taking in investment protection. Conversely, assessing regulatory taking in investment protection arbitration requires taking into account Article 20 TRIPS. So far, this has not been the case in investment arbitration relating to plain packaging.⁹² It will be interesting to see to what extent WTO adjudication will establish the necessary bridges between trade and investment protection rules, also taking into account the increasing role of IPRs in fostering and protecting investment.⁹³ Linkages to investment protection in this context are likely to enhance the level of protection of IPRs. This shift makes it necessary to also enhance the role and impact of non-trade concerns, in particular the consideration of human rights and Sustainable Development Goals in the law of investment protection.

89 See Henning Grosse Ruse-Khan, "Investment Law and Intellectual Property Rights," in *International Investment Law: A Handbook*, ed. Marc Bungenberg, Jörn Griebel, Stephan Hobe and August Reinisch (pp. 1692–1713) (Oxford: Hart, 2015), 1709, note 22. See also *Journal of International Economic Law* 19 (2016): 87–277 (ed. Henning Grosse Ruse-Khan).

90 "CETA Chapter by Chapter": Chapter 8, Investment, <http://ec.europa.eu/trade/policy/in-focus/ceta/ceta-chapter-by-chapter/>.

91 "CETA Chapter by Chapter": Chapter 8, Investment.

92 See *Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay*.

93 See *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO, DS 458, pending.

9. Progressive Regulation and Graduation of IPRs

Other than the rules on goods and services, which are subject to individual schedules defining market access rights, intellectual property rights establish standards and rules applying horizontally to all parties and members alike, irrespective of levels of social and economic development and integration of a country in the world economy. True, the TRIPS Agreement in Part VI provides for a number of provisions on special and differential treatment for developing and least developed countries. Waivers exist in the field of patenting pharmaceutical and chemical products for least developed countries, which have been extended. No such exceptions, however, exist in other core substantive and procedural obligations. The TRIPS Agreement, for such reasons, has remained one of the most contentious agreements in the WTO, much more so than the GATT and GATS or the plurilateral Government Procurement Agreement which countries are free to adhere to or abstain from. Minimum TRIPS standards have a harmonising effect. Moreover, TRIPS-plus standards in preferential agreements apply across the board and increase levels of protection and requirements de facto for all countries alike. The agreement does not provide for progressive regulation and differentiated commitments.

The new Trade Facilitation Agreement (TFA), which entered into force on 22 February 2017, provides for a number of options which countries may choose in making commitments.⁹⁴ While this approach leaves decisions on graduation to members, another approach would trigger obligations within the agreement on the basis of economic thresholds and factors as defined ex ante.⁹⁵ Other than under the TFA, members would automatically graduate and incur obligations once these thresholds are met, for example obligations to introduce patent protection for pharmaceuticals and chemicals, or an obligation to provide protection for integrated circuits, or geographical indications and designs. Article 11 TRIPS Agreement provides a model to this effect. The introduction of protection of rentals, at the time (and no longer relevant due to information technology and online rentals), depended upon significant market shares. It states: "A Member shall be excepted from this obligation in respect of cinematographic works unless such rental has led to the widespread copying of such works which is materially impairing the exclusive right of reproduction conferred in that Member on authors and their successors in title." The same idea can be found in Article 27(5) of the Agreement on Subsidies and Countervailing Measures, which includes defined thresholds for specific countries. The provision states: "A developing country Member which has reached export competitiveness in any given product shall phase out its export subsidies for such product(s) over a period of two years." Annex VII of the agreement defines the thresholds for least developed countries benefiting from a period of eight years. It lists a number of countries and establishes a threshold of gross national product of \$1,000 per capita per annum.

This approach could also be developed and deployed in defining the kicking in of specific provisions calling for the protection of intellectual property rights. It will be objected that negotiating such thresholds is complex. It is submitted that this is not more difficult than in other areas, such as agriculture. Progressive regulation in IPRs offers a predictable approach, for example in addressing

94 WTO, "Trade Facilitation," https://www.wto.org/english/tratop_e/tradfa_e/tradfa_e.htm.

95 Thomas Cottier, "From Progressive Liberalization to Progressive Regulation in WTO Law," *Journal of International Economic Law* 4 (2006): 779–821; Thomas Cottier, "International Economic Law in Transition from Trade Liberalization to Trade Regulation," *Journal of International Economic Law* 17 (2014): 671–677.

the complex issue of pharmaceutical patents,⁹⁶ while taking into account that the primary needs of developing countries are not in the field of intellectual property rights and will be building up over time—not so differently from the history of industrialised countries in the nineteenth and twentieth centuries.

10. Conclusions

The examination of pertinent GATT rules, competition policy, unfair competition law, human rights and Sustainable Development Goals in soft law, but also recourse to general principles of law and domestic constitutional law, shows that IPRs are embedded in a legal framework which partly allows a rebalancing of rights and obligations in the operation of intellectual property rights. Article 31(3)(c) of the Vienna Convention on the Law of Treaties obliges account to be taken of other principles and rules of public international law in force between the parties to a dispute. WTO jurisprudence also requires account to be taken of soft law principles which influence the interpretation of IPR treaties. As a consequence, lawyers can no longer specialise solely in IPRs but need to take into account the broader framework and plead accordingly. They need to work in teams comprising different fields of law. The method is highly case specific and is most suitable for litigation before international and domestic judicial fora. It depends on the particular facts of a case and results cannot be readily generalised. It does not provide legal certainty and strongly depends upon case law.

Embedding intellectual property rights in the general framework of law therefore cannot dispense with seeking to rebalance rights and obligations in IP treaties and legislation itself. First, it is a matter of transparency. Second, case law and adjudication cannot replace the political process and will not be able to bring about and secure adequate levels of protection and enforcement on their own. Ever increasing levels of protection are detrimental to research and development and undermine the legitimacy of the overall system. The elements discussed in this paper indicate the bridges which should be built and used in courts, and which of the elements could be explicitly taken into account in future treaty-making. This is the task of the political process, of international negotiations, treaty-making and legislation at home. Moving from fragmentation to coherence, modern IP treaties should address the need to properly balance different interests, having recourse to a topical approach developed under the principle of equity in international law. They should address linkages with other policy areas, in particular human rights and general principles of law, and including competition policy, develop unfair competition rules, develop a framework for technology transfer and PPPs, introduce ceilings and adopt an approach of progressive regulation and graduation. None of this has been sufficiently conceptualised and should be part of a broad research agenda. Perhaps, the impending failure to adopt mega-regional trade agreements limited to TRIPS-plus standards offers the option to further pursue the matter jointly in the WTO, WIPO and other specialised international fora.

96 See Monirul Azam, *Intellectual Property and Public Health in the Developing World* (Cambridge: Open Book, 2016), discussing the case of Bangladesh.

The Evolution of Public Health Provisions in Preferential Trade and Investment Agreements of the United States

Frederick M. Abbott

1. Introduction

Bilateral, regional and plurilateral trade and investment agreements negotiated by the United States since the conclusion of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) limit public health regulatory autonomy. In negotiating plurilateral trade and investment agreements (PT&IAs), the immediate post-Uruguay Round negotiating objectives of the United States involved filling in perceived gaps left in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This included expanding the minimum scope of patent subject matter coverage, adding specificity regarding the criteria of patentability, requiring patent term extension, expanding the scope of obligations regarding protection of regulatory data through marketing exclusivity requirements, and bringing intellectual property (IP) disputes within the sphere of investor to state dispute settlement (ISDS). More recently, the PT&IA template advanced by the United States initiates a deeper intrusion into the public health regulatory arena. The new template provides for intervention by pharmaceutical originator companies into government decision-making regarding whether to include particular drugs in national health formularies, and into decisions regarding pricing. Such provisions appear in agreements concluded by the United States with Australia and South Korea, and are part of the Trans-Pacific Partnership (TPP) Agreement from which the United States withdrew its signature. The latest template extends a requirement of regulatory market exclusivity to the area of biologic drugs, effectively mandating delays in the introduction of biosimilar products whether or not they are protected by patent.

As a matter of US law and practice, the provisions of PT&IAs are not directly incorporated in national law. The US Congress must expressly implement relevant provisions, and private litigants are not authorised to initiate court claims based directly on PT&IA terms. Only legislatively implemented provisions are subject to enforcement through the courts. There is, however, a prospective caveat to this general rule. In a case currently pending before the US Supreme Court—involving the appropriate rule of exhaustion (national or international) with respect to patents—an argument is raised that the United States must adopt a rule that is incorporated in a few PT&IAs, or otherwise find itself in breach of its international obligations. A Supreme Court decision following that argument would create a new situation in US law bringing about a form of direct effect through an indirect mechanism.

President Trump has signalled an intention to negotiate, and renegotiate, trade deals in a way more favourable to the United States, suggesting that the USA has been unfairly taken advantage of in prior trade deals. This may come as a surprise to trade negotiators of other countries. At the same time, the President has expressed strong dissatisfaction with high pharmaceutical prices. It is unclear at this moment how these signals will be translated into future US trade negotiating positions. But, it would be surprising if the result is a relaxation of demands with respect to protection of intellectual property, including regulatory exclusivity, or a relaxation of the push towards regulatory intrusion. Countries negotiating and implementing PT&IAs with the United States should remain cautious in accepting obligations that may be directly effective in national law. The model of the United States requiring legislative transformation or implementation remains the prudent approach, allowing the legislature to do what it can to maintain a domestic balance that favours the interests of consumers and patients.

2. Evolution

2.1 Negotiations and Agreements Preceding Conclusion of the TRIPS Agreement

The United States was an architect of the WTO TRIPS Agreement, initiating its policy drive in the late 1970s, moving towards the GATT in the early 1980s, and completing the TRIPS framework by late 1993.¹ The provisions of the TRIPS Agreement and the effect of those provisions on public health are the subject of an extensive literature, not to be repeated here.²

Prior to the TRIPS Agreement, the United States had negotiated bilateral investment treaties that included intangible property as a form of investment, and that subjected unlawful takings to third-party dispute settlement.³ The negotiation of such provisions generated little discussion or controversy within the United States.

The first US “free trade agreement” was negotiated with Israel and entered into force on 1 January 1985, but included only a cursory reference to intellectual property, and no provisions on investment or third-party dispute settlement related to that.⁴ The Canada–US Free Trade Agreement, entering into force on 1 January 1989, currently suspended, did not contain provisions regarding intellectual property, and did not in its investment chapter expressly refer to intellectual property or intangible property. In addition, there was no formal mechanism for third-party dispute settlement.⁵ However, the United States had long expressed concern regarding Canada’s compulsory licensing system with respect to pharmaceutical patents that effectively provided licences of right. Canada initially amended its Patent Act in 1987, among other reasons, to address those concerns. It was in 1992, during the North American Free Trade Agreement (NAFTA) and TRIPS negotiations, that Canada enacted legislation that effectively eliminated this “alternative” compulsory licensing regime for pharmaceuticals.⁶

The United States, Canada and Mexico initiated negotiation of the NAFTA in 1991, the agreement was signed at the end of 1992, ratified in 1993, and entered into force on January 1, 1994.⁷ The intellectual

1 Frederick M. Abbott, “Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework,” *Vanderbilt Journal of Transnational Law* 22, no. 4 (1989): 689, <https://ssrn.com/abstract=1918346>; UNCTAD-ICTSD, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement*, last updated 1 June 2005, <https://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm>.

2 See, including for references, Frederick Abbott, “Trade in Medicines,” in *Trade and Health: Building a National Strategy*, ed. R. Smith et al. (pp. 117–140) (Geneva: World Health Organization, 2015), <https://ssrn.com/abstract=2659277>.

3 Lahra Liberti, “Intellectual Property Rights in International Investment Agreements: An Overview,” *OECD Working Papers on International Investment*, 2010/01 (Paris: OECD, 2010), <http://dx.doi.org/10.1787/5kmfq1njz135-en>.

4 Agreement on the Establishment of a Free Trade Area between the Government of Israel and the Government of the United States of America, signature 22 April 1985, entry into force 19 August 1985, http://www.sice.oas.org/Trade/US-Israel/index_e.asp.

5 Canada–US Free Trade Agreement: <http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/us-eu.aspx?lang=eng>; <http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/us-eu.aspx?lang=eng>.

6 See Kristen Douglas and Célia Jutras, “Patent Protection for Pharmaceutical Products in Canada—Chronology of Significant Events,” Canadian Parliamentary Information and Research Service, PRB 99-46E (2008), <http://www.loppar.gc.ca/content/lop/ResearchPublications/prb9946-e.pdf>.

7 Frederick M. Abbott, *Law and Policy of Regional Integration: The NAFTA and Western Hemispheric Integration in the World Trade Organization System* (Dordrecht: M. Nijhoff, 1995), ch. 1; Frederick M. Abbott, “The North American Integration Regime and Its Implications for the World Trading System,” in *The EU, the WTO, and the NAFTA: Towards a Common Law of International Trade*, ed. Joseph H. H. Weiler (pp. 169–200) (Oxford: Oxford University Press, 2000).

property chapter of the NAFTA was negotiated contemporaneously with the TRIPS Agreement, and the negotiators for each of the parties was well aware of the provisions under negotiation at the GATT. While NAFTA may have been negotiated for its own sake, it was also a US "bargaining chip" during the Uruguay Round as US negotiators pointed out that regional arrangements were an alternative should other countries not want to make concessions at the GATT. These concessions included the TRIPS Agreement.

The intellectual property chapter of the NAFTA introduced protection of regulatory data for pharmaceuticals as the subject of trade agreement.⁸ While the initial form was softer than those later included in bilateral/regional PT&IAs, it was stronger than the provision in the TRIPS Agreement because it included an express requirement for market exclusivity, with a presumption regarding the appropriate duration. In addition, NAFTA included a commitment by Mexico to pharmaceutical product patent "pipeline" protection pursuant to which US and Canadian pharmaceutical patent owners were authorised to obtain corresponding patents in Mexico for the duration of the pending patent terms, provided that the subject pharmaceutical products had not previously been marketed in Mexico.⁹ The regulatory exclusivity provision in the NAFTA did not appear to generate public controversy at the time it was concluded.¹⁰ The pipeline provision raised concerns among other GATT Contracting Parties because there was no mechanism for extension to non-NAFTA countries. And, because Mexican nationals would not benefit from the pipeline provision in Mexico, this is cited as one of the reasons why the most favoured nation provision is included in the TRIPS Agreement (along with a US–China bilateral agreement that gave certain rights to US nationals that were better than those granted to Chinese nationals).

8 Article 1711: Trade Secrets, NAFTA:

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.

9 Article 1709: Patents, NAFTA:

4. If a Party has not made available product patent protection for pharmaceutical or agricultural chemicals commensurate with paragraph 1:

(a) as of January 1, 1992, for subject matter that relates to naturally occurring substances prepared or produced by, or significantly derived from, microbiological processes and intended for food or medicine, and

(b) as of July 1, 1991, for any other subject matter,

that Party shall provide to the inventor of any such product or its assignee the means to obtain product patent protection for such product for the unexpired term of the patent for such product granted in another Party, as long as the product has not been marketed in the Party providing protection under this paragraph and the person seeking such protection makes a timely request.

10 However, Canada did not initially implement the regulatory exclusivity requirement in a way preferred by the United States, giving rise to some follow-on controversy. See *Bayer Inc. v. The Attorney General of Canada and The Minister of Health and Apotex Inc and Novopharm Limited*, A-679-98, 19990519, para. 4.

It is worth noting that Mexico revised its national patent law to allow pharmaceutical product patenting in 1991, prior to conclusion of the NAFTA, but apparently at the urging of the US government, and as context for the NAFTA negotiations.¹¹

In addition to the patent and regulatory data provisions, the NAFTA included an investment chapter and third-party investor to state dispute settlement either through the International Centre for Settlement of Investment Disputes or under the rules of the United Nations Commission on International Trade Law (UNCITRAL).¹² There is no direct link in the intellectual property chapter to the investment chapter. The definition of investment refers to "intangible property."¹³ The investment chapter, in Article 1110(7), introduces language that purports to remove compulsory licensing from the subject matter of ISDS, though in a way that nevertheless permits arbitration regarding whether the licensing complied with IP chapter rules:

This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property).

In this specific way, the investment chapter expressly links to the intellectual property chapter.

A notable development regarding the NAFTA investment and intellectual property chapters is the claim brought by the US-based pharmaceutical company Eli Lilly against the government of Canada in 2012, which claim was rejected by a NAFTA-UNCITRAL arbitration panel in early 2017. Eli Lilly invoked the takings provisions in the NAFTA investment chapter as grounds for challenge of a determination of patent invalidity by Canadian federal courts regarding two Eli Lilly patents.¹⁴ The Eli Lilly complaint and subsequent proceedings against the government of Canada provided a stark illustration of why governments and other stakeholders have become increasingly concerned about the potential scope of ISDS obligations in PT&IAs. Eli Lilly's complaint was nothing more than an attempt to appeal ordinary adverse patent determinations by Canadian federal courts to a non-Canadian arbitral body, accompanied by demands for an extraordinary level of compensation (US\$500 million). It also represented an effort to pressure the Canadian government to modify Canadian patent law. Canada was in the fortunate position to have the financial and human resources

11 Mexico, Industrial Property Law of 25 June 1991, subsequently amended, at <http://www.wipo.int/edocs/lexdocs/laws/en/mx/mx113en.pdf>. Kenneth C. Shadlen, "Intellectual Property for Development in Mexico," in *The Future of North American Trade Policy: Lessons from NAFTA*, Pardee Center Task Force Report, November 2009, at 53, 57; Edwin S. Flores Troy (Student Note), "The Development of Modern Frameworks for Patent Protection: Mexico, a Model for Reform," *Texas Intellectual Property Law Journal* 6, no. 2 (1998): 133.

12 Frederick M. Abbott, "The North American Free Trade Agreement (NAFTA): Structure, Dispute Settlement and Case Law" (1 June 2014), in *Max Planck Encyclopedia of Public International Law*, gen. ed. Rüdiger Wolfrum (Oxford: Oxford University Press, 2012; updated 2014), vol. 7, p. 776, <https://ssrn.com/abstract=2080209>.

13 Article 1139(g), NAFTA, includes among defined investments "(g) real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes." Regarding the standard of protection to be provided by the host country, Article 1105(1) provides: "Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security."

14 Frederick M. Abbott, "Introductory Remarks by Frederick M. Abbott," *Proceedings of the ASIL Annual Meeting* 108 (2014): 311–313, doi:10.5305/procanmeetasil.108.0311; Jerome H. Reichman, "Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection," *Proceedings of the ASIL Annual Meeting* 108 (2014): 313–317, doi:10.5305/procanmeetasil.108.0313.

available to defend itself properly. For developing countries, taking on a well-capitalised originator pharmaceutical company in an international arbitration will place strain on government resources, regardless of the merits of the case.

The process of approval of the NAFTA in the United States was politically controversial. However, at the relevant time, neither the investment chapter nor ISDS provisions were the substantial subject matter of that controversy. The main focus was on labour rights and environmental protection, in addition to the general question whether NAFTA would result in a transfer of US jobs to Mexico.¹⁵ Notably, H. Ross Perot, a successful Texas businessman, ran a third-party presidential campaign against George H. W. Bush and Bill Clinton principally on the argument that approval of NAFTA would create "a giant sucking sound going south" in terms of American jobs.¹⁶

At the time the GATT Tokyo Round (1979) was concluded, the US Congress began to incorporate in its trade agreement approval legislation provisions expressly barring the agreements from "self-executing" or direct effect in the law of the United States, and precluding individuals from initiating court actions on the basis of the relevant trade agreement. Such a provision was included in the legislation approving and implementing the NAFTA,¹⁷ along with a so-called "Statement of Administrative Action" which is a formal document transmitted by the Executive Branch along with the proposed approval legislation that states the Executive's interpretation of the agreement and is binding on the Executive.¹⁸

2.2 The WTO TRIPS Agreement

The US pharmaceutical industry was a major force behind TRIPS Agreement demands, and the industry accomplished several of its principal objectives in the TRIPS Agreement. Foremost was establishing the obligation on all WTO members to provide pharmaceutical product patent protection, albeit with transition arrangements. The minimum patent term of 20 years from the date of filing substantially extended duration for many countries. However, various compromises were required to bring along the most important developing countries (from an economic standpoint), such as Brazil and India. Probably the most important from the industry standpoint was the relatively soft nature of the commitment in Article 39.3 regarding protection of regulatory data. The United States and European Union (then European Community) had sought a requirement for regulatory market exclusivity, including a minimum duration, but were unable to secure this concession.¹⁹ The provisions regarding exceptions and compulsory licensing were less strict than the United States

15 See Abbott, *Law and Policy of Regional Integration*, ch. 1.

16 Ross Perot "Giant Sucking Sound," 15 October 1992, C-SPAN clip of presidential candidates' debate, <https://www.c-span.org/video/?c4554632/ross-perot-giant-sucking-sound>.

17 A "light" form of the preclusion of direct effect was used to approve the US–Israel Free Trade Agreement in 1985. Description of implementing procedure in Approval of United States–Israel Trade Agreement, Report of the Senate Finance Committee, Senate Report 99–55, May 15, 1985, p. 6 <https://www.finance.senate.gov/imo/media/doc/srpt99-55.pdf>.

18 The inclusion of the Statement of Administrative Action is a practice that grew out of a dispute between the US Senate and President Reagan regarding interpretation of the US–Russia Anti-Ballistic Missile (ABM) Treaty of 1972. President Reagan asserted an interpretation of the treaty that had been specifically disclaimed before the Senate by the US Department of State when it was initially approved and ratified. Congress thereafter insisted upon a formal binding record of agency interpretations. The Statement of Administrative Action of the Executive with respect to approval of the Uruguay Round agreements in the United States played a role in the decision of the WTO panel in the US–Section 301 case; *United States – Sections 301–310 of the Trade Act of 1974*, Report of the Panel, WT/DS152/R, 22 December 1999.

19 See UNCTAD–ICTSD, *Resource Book on TRIPS and Development*, 525–526.

would have preferred. While the TRIPS Agreement referred to the basic criteria of patenting, it did not incorporate express definitions of those criteria. The US pharmaceutical industry was opposed to international exhaustion and potential parallel importation of patented pharmaceuticals, and the TRIPS Agreement left that matter open.²⁰ While the US pharmaceutical industry had accomplished its fundamental objectives with the TRIPS Agreement, it was an incomplete success.

The TRIPS Agreement entered into force on 1 January 1995. The originator pharmaceutical industry may have initially envisaged progressive tightening of IP rules at the new WTO, but the prospect to secure additional concessions at the WTO was surrendered when the industry initiated a lawsuit against Nelson Mandela following adoption by South Africa of the Medicines and Related Substances Controls Amendment Act of 1997 (including the provision authorising the Minister of Health to approve parallel importation of patented medicines).

During the multi-year battle with South Africa and the international community of non-governmental organisations (NGOs), the pharmaceutical industry turned its attention to bilateral and regional agreements. The Doha Declaration on the TRIPS Agreement and Public Health was adopted in November 2001 as a direct response to the litigation in South Africa and would play an ongoing role in respect to bilateral and regional agreements.²¹

2.3 First Generation Post-TRIPS PT&IAs

The first major success from the industry standpoint was negotiation of the Central America Free Trade Agreement (CAFTA)–Dominican Republic–US (DR-US),²² concluded in 2004, entering into force 2006–2009.²³ These negotiations were quite interesting from a political standpoint. Between the conclusion of the TRIPS Agreement in 1993 and the negotiating timeframe of the CAFTA-DR a powerful coalition of NGOs, academic experts and developing country governments had turned their attention to the IP provisions in trade agreements as potential obstacles to the accomplishment of important public health objectives. Central American governments received expert external advice regarding the potential impact of the IP chapter, especially, on public health in that region. NGOs were successful in generating political opposition to rules that would inhibit access to medicines. Yet, despite these “headwinds,” the trade and investment benefits of entering into the agreement persuaded the governments of the CAFTA-DR countries to largely accept US pharmaceutical industry-backed demands. A new “template” was now in evidence that secured substantial concessions for the US pharmaceutical industry. That template has continued to evolve through the TPP text, though its foundations can be directly traced to the CAFTA-DR.

20 Compare Frederick M. Abbott, “First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation,” *Journal of International Economic Law* 1, no. 4 (1998): 607–636, <https://ssrn.com/abstract=915046>, and Harvey E. Bale, Jr, “The Conflicts between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals,” *Journal of International Economic Law* 1, no. 4 (1999): 637.

21 Frederick M. Abbott, “The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO,” *Journal of International Economic Law* 5 (2002): 469, <https://ssrn.com/abstract=1493725>.

22 Central America–Dominican Republic–United States Free Trade Agreement (CAFTA-DR), http://www.sice.oas.org/Trade/CAFTA/CAFTADR_e/CAFTADRin_e.asp.

23 Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements*, Occasional Paper No. 14, Quaker United Nations Office (Geneva), April 2004, <https://ssrn.com/abstract=1977300>.

The CAFTA-DR also was the first US-negotiated PT&IA to include a side letter referencing the Doha Declaration on the TRIPS Agreement and Public Health, though in a less well articulated form than subsequent such side letters.²⁴

Twists and turns were navigated on the US-led PT&IA road during and following the negotiation of CAFTA-DR. From the standpoint of the pharmaceutical industry, the US–Morocco text represented a zenith in the sense that the Kingdom appeared to have little interest in making demands, so the then industry wish list was largely incorporated into the text.²⁵ On the other side, among the earlier agreements, Chile and Jordan actively resisted demands affecting the pharmaceutical sector, perhaps because each country had a large and successful generics industry which pressured their respective governments.²⁶ Chile and Jordan accepted TRIPS-plus pharmaceutical-related commitments, but each with some concessions from the United States regarding its preferred template. Colombia, Peru and Panama were each pressured by US negotiators to accept restrictive templates, but were then the beneficiaries of objections by the US Democratic Party, and a bipartisan congressional agreement regarding modifications.²⁷ The terms were amended in favour of relaxing the restrictive rules prior to entry into force of the agreements.²⁸

2.4 Second Generation Preferential Trade and Investment Agreements

2.4.1 Australia and South Korea

A new template began to emerge in negotiations between the United States, on one side, and higher income countries, notably Australia²⁹ and South Korea.³⁰ In these cases, the US pharmaceutical

24 CAFTA-DR, "Understanding Regarding Certain Public Health Measures," 5 August 2004.

25 United States–Morocco Free Trade Agreement, entry into force, 1 January 2006, https://ustr.gov/sites/default/files/uploads/agreements/fta/morocco/asset_upload_file118_3819.pdf.

26 Regarding Chile, see Pedro Roffe, "Bilateral Agreements and a TRIPS-plus World: The Chile-USA Free Trade Agreement," *TRIPS Issues Papers* No. 4, Quaker United Nations Office, Geneva (2004), <http://www.quno.org/sites/default/files/resources/Bilateral%2BAgreements%2Band%2BTRIPS%2Bplus%2BEnglish.pdf>.

27 Binyamin Appelbaum and Jennifer Steinhauer, "Congress Ends 5-Year Standoff on Trade Deals in Rare Accord," *New York Times*, 12 October 2011.

28 See Tove Iren S. Gerhardsen, "Observers Watchful of US Trade Impact on Medicines Access," *IP-Watch*, 24 July 2007, <http://www.ip-watch.org/2007/07/24/observers-watchful-of-us-trade-impact-on-medicines-access/>.

29 US–Australia, Annex 2-C and Side Letter, http://sice.oas.org/Trade/US-AusFTAFinal/chapter1_13.asp#ANNEX_2C:

Annex 2-C, Pharmaceuticals

2. Transparency

To the extent that a Party's federal healthcare authorities operate or maintain procedures for listing new pharmaceuticals or indications for reimbursement purposes, or for setting the amount of reimbursement for pharmaceuticals, under its federal healthcare programs, it shall:

- (a) ensure that consideration of all formal proposals for listing are completed within a specified time;
- (b) disclose procedural rules, methodologies, principles, and guidelines used to assess a proposal;
- (c) afford applicants timely opportunities to provide comments at relevant points in the process;
- (d) provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities;
- (e) provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law; and
- (f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.

30 US–South Korea, Chapter Five: Pharmaceutical Products and Medical Devices, http://sice.oas.org/TPD/USA_KOR/Draft_text_0607_e/asset_upload_file899_12703.pdf.

industry became more aggressive with respect to demands regarding the broader regulatory structure surrounding pharmaceuticals, including determinations by public health authorities regarding insurance reimbursement and pricing issues. This was an important set of developments representing a deeper intrusion into international public health regulatory structure and decision-making. This new form of intrusion was introduced as a template for the TPP negotiations.

The new template with Australia and South Korea requires that pharmaceutical companies have a right to challenge determinations regarding whether purchases of particular drugs will be reimbursed by national health schemes. The public health authorities make these determinations on the basis of comparative efficacy and cost, among other factors, and these determinations are now subject to challenge. The companies may ultimately be able to force the Australian and South Korean governments to reimburse for expensive new drugs, notwithstanding the initial decisions of the public health authority.³¹

The pharmaceutical companies argue that these measures are important to promote transparency and fairness. However, it should be apparent that the prospects of facing time-consuming litigation involving pharmaceutical industry lawyers will pressure public health authorities to lean towards approval so as to avoid it. Because the industry uses advertising and promotion to stimulate physician prescribing, once a drug is approved there is a substantial possibility that it will be prescribed, typically without great attention to the ultimate budgetary imposition on the government (or private patients). Given that sovereign governments would typically guard the regulatory discretion of their public health authorities, it is naturally surprising that Australia and South Korea would accept these provisions, and it shows the extent of the pressure that can be brought to bear.

2.4.2 *The Trans-Pacific Partnership*

The TPP was projected to initially encompass 12 countries, making it a substantially wider arrangement than previous PT&IAs of the United States. In this regard, the TPP is sometimes referred to as a

31 US–South Korea provides:

ARTICLE 5.2: ACCESS TO INNOVATION

To the extent that health care authorities at a Party's central level of government operate or maintain procedures for listing pharmaceutical products, medical devices, or indications for reimbursement, or setting the amount of reimbursement for pharmaceutical products or medical devices, under health care programs operated by its central level of government, the Party shall:

- (a) ensure that the procedures, rules, criteria, and guidelines that apply to the listing of pharmaceutical products, medical devices, or indications for reimbursement, or setting the amount of reimbursement for pharmaceutical products or medical devices are fair, reasonable, and non-discriminatory;
- (b) ensure that the Party's determination, if any, of the reimbursement amount for a pharmaceutical product or medical device, once approved by the appropriate regulatory authority as safe and effective, is based on competitive market-derived prices; or if its determination is not based on competitive market-derived prices, then that Party shall:
 - (i) appropriately recognize the value of the patented pharmaceutical product or medical device in the amount of reimbursement it provides;
 - (ii) permit a manufacturer of the pharmaceutical product or medical device to apply, based on evidence of safety or efficacy, for an increased amount of reimbursement over that provided for comparator products, if any, used to determine the amount of reimbursement; and
 - (iii) permit a manufacturer of the pharmaceutical product or medical device, after a decision on a reimbursement amount is made, to apply for an increased amount of reimbursement for the product based on evidence the manufacturer provides on the product's safety or efficacy; and
- (c) permit a manufacturer of the pharmaceutical product or medical device to apply for reimbursement of additional medical indications for the product, based on evidence the manufacturer provides on the product's safety or efficacy.

"mega-regional." With respect to pharmaceuticals and IP, the TPP text incorporated new template elements, though more in the nature of an evolution than a sharp break from the prior template.

For the first time the text of an PT&IA would explicitly extend regulatory marketing exclusivity to biologic pharmaceuticals.³² The extension to biologic pharmaceuticals would entail a substantially longer duration than prior PT&IAs with respect to pharmaceuticals created through synthetic organic chemistry. The extension to biologic pharmaceuticals is important on several counts. First, Article 39.3 of the TRIPS Agreement imposes a requirement for pharmaceutical regulatory data protection with respect to "new chemical entities."³³ On its face, this language does not encompass biologic drugs which are outside the ordinary definition of chemical entities. In this regard, the TPP extension addresses what to the pharmaceutical industry is a significant gap in the TRIPS Agreement. At the same time, of course, for countries that may wish to allow accelerated follow-on introduction of biologics, this extension creates a genuine obstacle.

Second, negotiation of the duration of the biologics exclusivity period was perhaps the most controversial part of the TPP negotiations, or at least among the top few. Ultimately, the parties agreed upon an eight-year period of market exclusivity that, in response to demands from Australia regarding the way its regulatory system operates, include an alternative "5+3" formulation that is understood to effectively correspond to an eight-year term.³⁴ The situation in the United States was "peculiar" at best in that the Obama Administration under industry pressure lobbied for a 12-year exclusivity period, which corresponds to the internal US legislation, while domestically the same

32 TPP, Article 18.52: Biologics:

1. With regard to protecting new biologics, a Party shall either:

(a) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively,

(b) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection:

(i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least five years from the date of first marketing approval of that product in that Party,

(ii) through other measures, and

(iii) recognising that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.

2. For the purposes of this Section, each Party shall apply this Article to, at a minimum, a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.

3. Recognising that international and domestic regulation of new pharmaceutical products that are or contain a biologic is in a formative stage and that market circumstances may evolve over time, the Parties shall consult after 10 years from the date of entry into force of this Agreement, or as otherwise decided by the Commission, to review the period of exclusivity provided in paragraph 1 and the scope of application provided in paragraph 2, with a view to providing effective incentives for the development of new pharmaceutical products that are or contain a biologic, as well as with a view to facilitating the timely availability of follow-on biosimilars, and to ensuring that the scope of application remains consistent with international developments regarding approval of additional categories of new pharmaceutical products that are or contain a biologic.

33 Article 39.3, TRIPS Agreement: "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize *new chemical entities*" (emphasis added).

34 The provision embodying the 5+3 alternative is not a model of clarity, and foreseeably might lead to disputes among governments and/or other stakeholders.

Obama Administration was pressing to reduce the exclusivity duration to seven years.³⁵ Basically, the Executive was negotiating internationally for an agreement that would contradict its own internal legislative preference.

In other matters regarding the template, TPP parties would need to provide patents for new uses of known products, or new methods of use of previously known compounds.³⁶ This is consistent with prior US PT&IAs. A provision that would have effectively negated the type of provision that India adopted as section 3(d) of its Patent Act—requiring new forms of known pharmaceutical substances to evidence a significant enhancement in efficacy from known use³⁷—was not part of the final text.

The TPP requires parties to link registered patents with drug regulatory approval, providing at least a notice and opportunity to seek a preliminary injunction, or alternatively simply to block approval based on a patent.³⁸ Though the drafting of this requirement may include somewhat more extensive obligations than earlier template versions, this is not a new development. Linkage presents the largest scale problem for the countries with the least well developed legal systems: countries where preliminary injunctions may last for a decade because there is no one that can effectively challenge them.

There is a requirement that customs authorities will have ex officio power to seize goods in transit based on suspicion of trademark infringement. Patents are not specifically covered in this provision in the TPP.³⁹

There is a criminal trademark provision that makes it illegal to repackage and relabel using a registered trademark of a party.⁴⁰ This provision, not much mentioned, could raise substantial obstacles to parallel trade worldwide. There is, for example, US jurisprudence to the effect that reusing an existing "non-original" trademark may, in fact, constitute trademark infringement.⁴¹

The TPP investment chapter enumerates intellectual property as protected investment, authorises investor to state dispute settlement, and includes a now-standard compulsory licensing exemption that is contingent on TRIPS Agreement compliance.⁴²

There is a "Transparency and Anti-Corruption" chapter of the TPP, which includes an annex which gives private third parties the right to challenge decisions by national health authorities about the drugs

35 Peter Gosselin, "Obama Pushes Trade Partners for Drug Rules He Opposes in U.S.," *Pharmaceutical Law & Industry Report* (Bloomberg BNA), 10 July 2015.

36 TPP, Article 18.37.2.

37 Trans-Pacific Partnership Intellectual Property Rights Chapter, Draft, 10 February 2011, ARTICLE 8: PATENTS

1. Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. In addition, the Parties confirm that: patents shall be available or any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, **even if such invention does not result in the enhancement of the known efficacy of that product.** [bold added]

38 TPP, Article 18.51: Measures Relating to the Marketing of Certain Pharmaceutical Products.

39 TPP, Article 18.76.5.

40 TPP, Article 18.77.3.

41 See *Lever Brothers v. United States*, 981 F.2d 1330 (D.C. Cir. 1993).

42 TPP, Article 9.1: Definitions, "investment," para. f.

that are listed on their reimbursement formularies, burdening health ministers in determinations regarding what drugs should and should not be on their formularies.⁴³ This is modelled on the Australia/South Korea template discussed earlier, although it includes less precise reference (i.e. ambiguous) regarding challenging of prices than was included in the US–Australia and US–South Korea FTAs. This provision is further discussed below.

The TPP IP chapter recognises the importance of the Doha Declaration and that nothing in the agreement will prevent governments from addressing public health,⁴⁴ but it does not indicate how conflicts with the Doha Declaration will be resolved. There is no specific mechanism to do that.

3. Relationship to Domestic Law

3.1 The International Plane

When an international trade agreement enters into force it has legal effects in terms of relations between the contracting parties, that is, rights and obligations on the international plane.⁴⁵ Typically disputes between the parties regarding the interpretation and application of the agreement will be settled by some form of arbitration involving a panel of experts appointed through a process prescribed in the agreement.⁴⁶ Upon a finding that a party has acted contrary to the terms of the agreement, there will usually be a directive to that party to bring its measures into conformity. If the defaulting party does not remedy its measures, there may be a further mechanism allowing for adjustment of obligations through the withdrawal of trade concessions or compensation.⁴⁷ This type of state to state dispute settlement mechanism is incorporated in the PT&IAs negotiated by the United States.

A PT&IA may include additional specific forms of state to state mechanisms for settling disputes, such as making specific provision for experts on a particular subject matter to issue some type of report around which the parties can pursue discussion prior to more formal dispute settlement.⁴⁸

The PT&IAs negotiated by the United States in recent years also include investor to state dispute settlement mechanisms that allow private actors to initiate claims against host governments for interference with property rights, including expropriation.⁴⁹ These ISDS mechanisms typically do not require a state party that is found to have violated private rights to modify any governmental measures. Rather, the remedy is payment of compensation.

43 TPP, ANNEX 26-A. TRANSPARENCY AND PROCEDURAL FAIRNESS FOR PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES.

44 Article 18.6: Understandings Regarding Certain Public Health Measures.

45 See Vienna Convention on the Law of Treaties, Article 26 ("Every treaty in force is binding upon the parties to it and must be performed by them in good faith").

46 While treaties relating to public international law are often subject to dispute settlement by the International Court of Justice, international agreements in the sphere of trade are traditionally subject to an internally defined dispute settlement mechanism, including for the WTO the arrangement established by the Dispute Settlement Understanding (DSU) (Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 to the Agreement Establishing the World Trade Organization).

47 See, e.g., WTO DSU, Articles 19–22.

48 See, e.g., North American Agreement on Labor Cooperation, Supplemental Agreement to the NAFTA, entry into force 1 January 1994, <http://www.sice.oas.org/trade/nafta/Labor1.asp>.

49 See Abbott, "The North American Free Trade Agreement (NAFTA)."

3.2 The Domestic Plane

Whether and how the terms of an international trade agreement become part of the domestic law of a contracting party is a matter of constitutional law in each state.⁵⁰ The national constitution essentially mediates the relationship between international and domestic law. Some countries follow a “monist” tradition in which international agreements become part of national law without additional action on the part of a legislative or parliamentary body. Some countries follow a “dualist” tradition in which the terms of the international agreement must be incorporated by a legislative act into domestic law, so-called “transformation.” Some countries, including the United States and the European Union follow a quasi-dualist approach in which the courts decide whether a particular international agreement is directly effective in national/regional law, or whether legislative action is required to transform its provisions into domestic law. This may entail examining the terms, structure and spirit of the agreement, including any express indications regarding the intent of the parties with respect to direct effect.

Though seemingly esoteric, the question whether an international trade agreement is directly effective in national law may entail very significant practical consequences. For example, the doctrines surrounding direct effect played a central role in the 2017 decision by the United Kingdom Supreme Court holding that an Act of Parliament was required to authorise the Prime Minister to provide notice under Article 50 of the Treaty on the Functioning of the European Union that the UK would exit the European Union.⁵¹ It is particularly important in the area of public health where national laws and policies are carefully constructed to address the interests of citizens, and where changes based on trade negotiations may reflect different interest constellations than internal stakeholder discussions.

To illustrate the important role that direct effect may have, the pharmaceutical firm Novartis brought suit against the Indian government alleging that section 3(d) of the amended Patent Act (2005) contravened India's obligations under TRIPS. Because India follows a dualist model, as does the United Kingdom, the High Court in India rejected the allegation of TRIPS inconsistency on grounds that the TRIPS Agreement is not directly effective in Indian law.⁵²

In a 2006 Issue Paper for ICTSD, this author described the relationship between trade agreements and domestic law from the perspective of the United States.⁵³ The US Constitution has a general provision regarding the relationship between treaties and domestic law (i.e., treaties are the supreme law of the land).⁵⁴ The Supreme Court has generally interpreted that to establish the possibility of direct effect, but determining the matter on a case-by-case basis. In terms of trade

50 See generally, *Parliamentary Participation in the Making and Operation of Treaties*, ed. Stefan A. Riesenfeld and Frederick M. Abbott (Dordrecht: M. Nijhoff, 1991).

51 *R v. Secretary of State for Exiting the European Union*, [2017] UKSC 5, 24 January 2017.

52 *Novartis v. Union of India*, High Court at Madras, dated 06.08.2007, W.P. Nos. 24759 and 24760 of 2006.

53 Frederick M. Abbott, *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of US Federal Law*, Issue Paper No. 12, UNCTAD-ICTSD Project on IPRs and Sustainable Development, February 2006, <https://ssrn.com/abstract=1912621>.

54 US Constitution, Article VI:

This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.

agreements, the US Congress has a special role because Article 1, section 8 of the Constitution provides that Congress has the power to regulate commerce with foreign nations.⁵⁵ For trade agreements, the President requires congressional assent to bring these agreements into force, and the Congress has the power to determine whether or not a trade agreement will have direct effect in the law of the United States. As noted earlier, since the conclusion of the GATT Tokyo Round, the Congress has legislated against the direct effect of trade agreements, including the PT&IAs. As a corollary, the Congress has legislated that decisions of dispute settlement bodies within such trade agreements do not have direct effect in US law.

In principle, this would suggest that changes to domestic law in the United States would come about only through congressional legislation amending federal law. This premise, however, does not reflect the complete picture. As this contribution is written, the US Supreme Court has before it a case regarding exhaustion of patent rights, asking whether the US follows a doctrine of international or national exhaustion with respect to patents.⁵⁶ The Supreme Court has decided in favour of international exhaustion regarding copyright⁵⁷ and trademark (for commonly controlled enterprises),⁵⁸ but the Court of Appeals for the Federal Circuit held in favour of national exhaustion for patents in 2001,⁵⁹ and recently affirmed that decision in *Lexmark International v. Impression Products*.⁶⁰ The Supreme Court granted certiorari and will decide the case later in 2017. The Supreme Court will decide whether the United States follows a doctrine of international or national exhaustion with respect to patents.

The US Congress has not expressly addressed the exhaustion question with respect to patents. There is case-law precedent in US law favouring international exhaustion, prior to the 2001 decision of the Federal Circuit.⁶¹ As a practical matter, in light of the lack of congressional direction the Supreme Court will essentially be deciding the question as a matter of policy, though it will certainly couch its decision in legal terms.

In its decision affirming national exhaustion, the Federal Circuit said that three free trade agreements (FTAs) entered into by the United States (US–Morocco, US–Australia and US–Singapore) obligate the United States to enforce a rule of national exhaustion of patents. The Federal Circuit did not say that the agreements are directly effective in the law of the United States, which clearly is precluded by the legislative acts approving the agreements. However, the Federal Circuit said that the United States would be in breach of its obligations under the agreements if it followed a rule of international exhaustion of patents.

To begin with, the three PT&IAs in question do not obligate any of the contracting parties to forgo international patent exhaustion.⁶² They provide that the parties must have a mechanism to prevent

55 US Constitution, Article I, §8, cl. 3: "The Congress shall have power ... To regulate commerce with foreign nations."

56 *Impression Products v. Lexmark International*, S. Ct. No. 15-1189, cert. granted 2016.

57 *Kirtsaeng v. John Wiley & Sons, Inc.*, U.S. ___, 133 S.Ct. 1351 (2013).

58 *Kmart v. Cartier*, 486 U.S. 281 (1988).

59 *Jazz Photo Corp. v. International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001).

60 *Lexmark International, Inc. v. Impression Products, Inc.*, 816 F.3d 721 (Fed. Cir. 2016).

61 See *Fuji Photo Film Co. v. Jazz Photo Corp.*, 249 F.Supp.2d 434, 452 (D.N.J.2003).

62 See Brief of Amicus Curiae (Frederick M. Abbott) in Support of Petitioner in *Impression Products v. Lexmark International*, US Supreme Court, No. 15-1189, filed 20 January 2017, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2906967.

importation of patented products put on the market outside their countries, but they expressly authorise the enforcement of contractual restrictions as a means of accomplishing this objective. So, even if the Supreme Court decides that US law should be compatible with the three trade agreements, this does not mean that it must adopt a rule of international exhaustion.

In addition, subsequent to congressional approval and entry into force of these three trade agreements, Congress began to preclude the Executive from incorporating similar language in subsequent free trade agreements. In that regard, these three agreements can be considered “outliers” and inconsistent with current congressional policy preferences.

Mainly because of the factor that the agreements do not mandate international exhaustion, it is doubtful that the Supreme Court will decide that they control the outcome of this case. But, reliance by the Federal Circuit on the terms of the PT&IAs in reaching its decision illustrates the risk that is inherent in public-health related provisions in international trade agreements. In other words, there is not only a risk that Congress will transform an obligation in the PT&IA into federal law, but a further risk that the federal courts will consider the provisions of such an agreement to obligate a particular decision, even if the relevant rule is not directly effective.

Another important constitutional doctrine in the United States is the “last in time rule” between congressional legislation and international agreements. The latter of the two rules governs. This means that even after the United States has entered into a trade agreement, the Congress may adopt legislation inconsistent with that agreement, and the congressional legislation will prevail as a matter of constitutional interpretation. The United States may then be in breach of the trade agreement in relation to other state parties to the agreement, but that is a distinct matter. In other words, Congress may choose to adopt legislation inconsistent with an existing trade agreement, and the congressional action will prevail.

4. The Political Dynamics of Modifying Domestic Law Through Trade Agreements

The interests taken into account by trade negotiators in reaching an international agreement are different than those taken into account by national legislators acting in the domestic context. In trade negotiations, each government is bargaining for concessions. The fundamental idea behind a comprehensive free trade agreement is that governments will concede preferences in some areas to obtain benefits in other areas. The GATT Uruguay Round negotiations were premised on the idea that bargaining for cross-concessions (e.g., agriculture for intellectual property) would facilitate a successful conclusion.

The trade bargaining arena gives particular industry groups an avenue for achieving objectives that might not otherwise be achievable if directly approaching a foreign national legislature through lobbying or otherwise. As an example, it is doubtful that Australia or South Korea would have agreed to permit foreign pharmaceutical companies to challenge administrative decisions regarding insurance reimbursement had such a demand been placed outside their PT&IA negotiations with the United States.

By the same token, however, industry groups that might find it difficult to achieve certain domestic objectives directly may find it useful to approach those objectives through the “backdoor” of free trade agreement negotiations. In some cases, an impact on domestic law might be an unforeseen or “surplus” benefit from the negotiations with foreign trading partners.

The 2006 Issue Paper regarding PT&IAs in US domestic law pointed to a number of differences between the terms of the trade agreements and US federal law. Of interest regarding public health these included provisions with respect to:

- patent term extension
- regulatory review exception
- patent–regulatory review linkage
- compulsory transfer of trade secret
- parallel importation
- enforcement, including damages calculations

There is not a conflict between the provisions of the TPP providing for a minimum eight-year term of market exclusivity for biologic products and current US law. US federal law provides for a 12-year exclusivity term.⁶³ However, the fact that the TPP would lock in an eight-year marketing exclusivity term for biologics—bearing in mind that the United States has withdrawn its signature—would act as a substantial constraint on the United States with respect to future modifications of that term. To be clear, the United States follows a “last in time” rule in respect to the relationship between international agreements and legislation. Congress may adopt legislation that is inconsistent with an existing international agreement, and the congressional legislation prevails as a matter of constitutional interpretation. No doubt, if there was a move in the Congress to reduce the exclusivity term, the biologics industry would assert that it was precluded from doing so by the terms of the agreement, and would suggest broader potential harm to US economic relations. But, as a practical matter it seems unlikely that other parties to the TPP, with the possible exception of Japan, would be concerned about this since the other countries were essentially pressured into accepting the exclusivity commitment.

One of the second generation provisions in the TPP regarding pharmaceuticals is found in the Transparency and Anti-Corruption Chapter 26, Annex 26-A, “Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices.” This provision requires that when a party’s national healthcare authorities “operate or maintain procedures for listing new pharmaceutical products or medical devices for reimbursement purposes, or setting the amount of such reimbursement,” government shall:⁶⁴

- (a) ensure that consideration of all formal and duly formulated proposals for such listing of pharmaceutical products or medical devices for reimbursement is completed within a specified period of time;
- (b) disclose procedural rules, methodologies, principles, and guidelines used to assess such proposals;

63 42 U.S. Code § 262—Regulation of biological products, at subsection (k)(7).

64 This provision does not apply to government procurement as such (see footnote 11 in TPP text).

- (c) afford applicants, and where appropriate, the public, timely opportunities to provide comments at relevant points in the decision-making process;
- (d) provide applicants with written information sufficient to comprehend the basis for recommendations or determinations regarding the listing of new pharmaceutical products or medical devices for reimbursement by national health care authorities;
- (e) *make available*:
 - (i) *an independent review process; or*
 - (ii) *an internal review process, such as by the same expert or group of experts that made the recommendation or determination, provided that such a review process includes, at a minimum, a substantive reconsideration of the application and that may be invoked at the request of an applicant directly affected by such recommendation or determination by a Party's national health care authorities not to list a pharmaceutical or medical device for reimbursement; and*
- (f) provide written information to the public regarding such recommendations or determinations, while protecting information considered to be confidential under the Party's law. (Paragraph 26-A.2: Procedural Fairness; emphasis added, footnotes omitted)

The annex provides a mechanism for "consultation" regarding issues that may arise in the context of implementing its requirements. The annex is specifically exempted from the general dispute settlement chapter 28 of the TPP.⁶⁵

The national healthcare authorities of the parties are specifically identified.⁶⁶ For the United States, it is the Centers for Medicare & Medicaid Services (CMS), with respect to CMS's role in making Medicare national coverage determinations. For Australia, as an example, it is the Pharmaceutical Benefits Advisory Committee, with respect to listing of products for reimbursement under the Pharmaceutical Benefits Scheme.

Annex 26-A, as quoted above, delineates a new level of regulatory intrusion in PT&IAs, although similar models already were used in the US–Australia and US–South Korea FTAs.⁶⁷ The US Medicare pharmaceutical benefits system is complex. The vast majority of determinations regarding what drugs are available under the large Part D government-subsidised system are made by private insurance companies.⁶⁸ However, the plans offered by the private insurance companies must meet

65 TPP, Paragraph 26-A.6: Disputes

The dispute settlement procedures provided for in Chapter 28 (Dispute Settlement) shall not apply to this Annex.

66 TPP, Schedule to Annex 26-A.

67 In describing the obligations of the United States under the FTA with Australia, the United States Trade Representative (USTR) notes that the Pharmaceutical Annex expressly excludes procurement by the US Veterans Administration and the Department of Defense, and suggests that Medicare procurement should not be affected because this is done by state officials, not the federal government. But, it notes that the transparency obligations may be applicable. USTR, US–Australia Free Trade Agreement—Questions and Answers about Pharmaceuticals, July 2004, <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/archives/2004/july/us-australia-free-trade-agreement-questions-and>. There is no similar statement regarding the US–South Korea FTA.

68 *Medicare Prescription Drug Benefit Manual*, Chapter 6—Part D Drugs and Formulary Requirements (Rev. 18, 01-15-16), at 30.2—Provision of an Adequate Formulary, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

guidelines established by the CMS. It is not entirely clear how the requirement established by the TPP to provide regulatory access to government decision-making regarding reimbursement will function. Conceptually, pharmaceutical companies could use the TPP obligation as a mechanism for challenging CMS approvals of pharmaceutical benefit plans offered by private insurance companies. Medicare also provides under Part B coverage of drugs that are administered in doctors' offices, including many of the more expensive cancer treatments,⁶⁹ as to which CMS makes determinations regarding coverage, and as to which it has proposed to limit prices.⁷⁰ The pharmaceutical industry in the United States would appreciate a strong avenue to challenge CMS, which could come through the TPP obligation.

The pharmaceutical industry has managed to cross a threshold by inserting into PT&IAs provisions that obligate governments to provide them access to challenge national government benefit plan determinations regarding listings on formularies and prices. Since the inception of bilateral and regional negotiations to supplement the rules of the TRIPS Agreement and other multilateral rules there has been a progressive encroachment into national regulatory space in the field of public health. This continues a trend of viewing national government regulation as a part of reciprocal bargaining subject matter in trade negotiations. This began in the context of second-generation trade barriers at the GATT when the organisation began to seriously tackle barriers to market penetration posed by technical regulations and sanitary and phytosanitary regulations. It progressed through more detailed rules adopted during the Uruguay Round, and the third generation of alleged trade barriers posed by inadequate protection of intellectual property rights. Now, with challenges to legislation regulating tobacco packaging and national court decisions regarding patentability, the focus has more intensively turned to challenging national rules that may restrict market penetration on the basis of legitimate regulatory concerns. What is the alternative? If governments are allowed to pursue regulation solely to favour national goods and services providers, the basic concept underlying a liberal trading order breaks down. On the other hand, deep foreign intrusion into decision-making directed towards protecting the public has adverse consequences. Ultimately the system must be balanced if it is going to allow for economic efficiency gains while protecting public interests.

For the individual government that is a party to a PT&IA with the United States, it is essential to adopt a formula in approving the agreement that is similar to the one adopted by the US Congress to prevent the direct effect of the agreement in national law. The national legislature must act to transform the PT&IA in the interests of the nation. Otherwise, foreign companies can directly tie up the government in litigation based on claims under their own interpretations of the agreement. Even if the government ultimately prevails, or a private counterparty, the litigation may drain resources. In addition, the national government must retain the right to override the terms of the treaty within the national legislation, regardless of the consequences on the international plane as between the PT&IA parties. Otherwise, the country risks being run by foreign trade negotiators and the private interests that drive them.

69 Medicare.gov, "What Part B Covers," <https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html>.

70 Sarah Karlin-Smith and Brett Norman, "Pharma Unleashes on Part B Demo," Politico Prescription Pulse, 9 May 2016.

The Regulatory Framework for Digital Trade in the Trans-Pacific Partnership Agreement

Mira Burri

1. Introduction

The emergence of digital technologies and their wide adoption have triggered multiple changes in essentially all facets of societal life.¹ Trade too has been affected.² Online shopping is perhaps the first and most everyday example that comes to mind, but some transformations go deeper. The characteristics of digital technologies, which allow all types of information—be it text, picture, or video—to be expressed in binary digits, in a line of zeroes and ones, and the instantaneous communication to large and globally dispersed audiences that the internet enables, have had important effects on trade in services. We experience the process of “servicification,” whereby there is an increase in the use, output and sale of services, and these are also increasingly traded across borders.³ A related example particularly relevant to trade in information technology products has to do with the emergence of “global value chains” (GVCs), which mobilise a large number of producers and service providers based in different countries that are often remote from one another. Beyond these instances, it has been argued that digital technologies profoundly change the entire economy and innovation space.⁴ The importance of data, and now more recently Big Data, is critical in this transformation, and even greater changes are anticipated.⁵

Digitisation has had an impact on the economy, on social and cultural practices, but also on law and patterns of governance in general. Legal institutions face various challenges, related, among other things, to design and enforcement. Many of the existing rules no longer provide appropriate answers. Digital technology undermines, for instance, traditional perceptions of copyright on authorship and exclusivity. It renders classic distinctions between goods and services obsolete. It has also been observed that law in the conventional sense of acts of the legislature or treaties between sovereign nations has been challenged and often supplanted by new modes of control. Prominent among these new models is regulation through code, where diverse mechanisms controlling access and use are embedded directly into the software or the device and in effect enforce certain legal standards.⁶

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- 1 See e.g. Yochai Benkler, *The Wealth of Networks: How Social Production Transforms Markets and Freedom* (New Haven: Yale University Press, 2006); Jonathan L. Zittrain, *The Future of the Internet—and How to Stop It* (New Haven: Yale University Press, 2008); Richard S. Whitt, “A Deference to Protocol: Fashioning a Three-Dimensional Public Policy Framework for the Internet Age,” *Cardozo Arts and Entertainment Law Journal* 31 (2013): 689–768, at 717–729.
 - 2 See e.g. Mira Burri and Thomas Cottier (eds), *Trade Governance in the Digital Age* (Cambridge: Cambridge University Press, 2012); Anupam Chander, *The Electronic Silk Road: How the Web Binds the World in Commerce* (New Haven: Yale University Press, 2013). For a brief overview with regard to trade, see Joshua Paul Meltzer, “The Internet, Cross-Border Data Flows and International Trade,” *Asia and the Pacific Policy Studies* 2 (2015): 90–102.
 - 3 See e.g. Swedish National Board of Trade, *Everybody Is in Services: The Impact of Servicification in Manufacturing on Trade and Trade Policy* (Stockholm: National Board of Trade, 2012); Magnus Lodefalk, “The Role of Services for Manufacturing Firm Exports,” *Review of World Economics* 150 (2014): 59–82; Rainer Lanz and Andreas Maurer, “Services and Global Value Chains—Some Evidence on Servicification of Manufacturing and Services Networks,” *WTO Working Paper ERSD 3* (2015); Pierre Sauvé and Martin Roy (eds), *Research Handbook on Trade in Services* (Cheltenham: Edward Elgar, 2016).
 - 4 See e.g. Yochai Benkler, “Growth-Oriented Law for the Networked Information Economy: Emphasizing Freedom to Operate over Power to Appropriate,” in Kauffman Taskforce on Law, Innovation and Growth, *Rules for Growth: Promoting Innovation and Growth through Legal Reform* (pp. 313–342) (Kansas City: Kauffman Foundation, 2011); Urs Gasser and John Palfrey, “Fostering Innovation and Trade in the Global Information Society: The Different Facets and Roles of Interoperability,” in *Trade Governance in the Digital Age*, ed. Mira Burri and Thomas Cottier (pp. 123–153) (Cambridge: Cambridge University Press, 2012).
 - 5 James Manyika et al., *Big Data: The Next Frontier for Innovation, Competition, and Productivity* (Washington, DC: McKinsey Global Institute, 2011); Viktor Mayer-Schönberger and Kenneth Cukier, *Big Data: A Revolution That Will Transform How We Live, Work, and Think* (New York: Eamon Dolan/Houghton Mifflin Harcourt, 2013).
 - 6 Lawrence Lessig, *Code and Other Laws of Cyberspace* (New York: Basic Books, 1999); Lawrence Lessig, *Code: Version 2.0* (New York: Basic Books, 2006). Briefly, also, Mira Burri, “Controlling New Media (without the Law),” in *Handbook of Media Law*, ed. Monroe Price and Stefaan Verhulst (pp. 327–342) (Abingdon: Routledge, 2012).

Private ordering has also proliferated and created a new legal layer built around contractual, often asymmetrical, relationships (examples are the end-user agreements by large online platforms, such as Facebook or YouTube).⁷ Governance models have in general become less state-centred, and there are new regulatory forms that involve multiple stakeholders, with varied types of controlling functions entrusted to the state.⁸

Against this backdrop of broader economy and governance changes triggered by digital technologies, it is the purpose of this chapter to explore the Trans-Pacific Partnership (TPP) Agreement, as one of the most recent and big trade deals, and to see how it addresses digital trade issues. We also seek to contextualise the TPP provisions: that is why, in the first part of the chapter, we present the current state of World Trade Organization (WTO) law, as well as the progress made in other free trade agreements (FTAs) prior to the TPP. After a careful analysis of the different TPP provisions, we briefly compare these with what there is on the negotiating table of other “mega-regionals” by looking at the Transatlantic Trade and Investment Partnership (TTIP) Agreement and the Trade in Services Agreement (TiSA) and their provisions in the domain of digital commerce.⁹ The chapter concludes with a critical appraisal of the TPP and the current overall state of the governance of cross-border data flows.

2. The WTO: A Case of Failed Adaptation

While the TPP is the focus of this chapter, we cannot simply ignore the multilateral forum of the WTO. On the one hand, WTO law matters in its own right as a set of hard and enforceable rules on trade in goods and services and intellectual property (IP) protection.¹⁰ On the other hand, the TPP and other FTAs are in many senses only an addition to these rules.

The WTO Agreements, the fundamental bases of international trade law, were adopted during the Uruguay Round in 1994.¹¹ Despite a few updates—such as the Information Technology Agreement and the Fourth Protocol on Basic Telecommunications Services—the WTO rules have so far not reacted in a forward-looking manner to the various changes triggered by the internet. One could, of

7 See e.g. Yochai Benkler, “An Unhurried View of Private Ordering in Information Transactions,” *Vanderbilt Law Review* 53, no. 6 (2000): 2063–2080.

8 Viktor Mayer-Schönberger, “The Shape of Governance: Analyzing the World of Internet Regulation,” *Virginia Journal of International Law* 43 (2003): 605–673; Christopher T. Marsden, *Internet Co-Regulation: European Law, Regulatory Governance and Legitimacy in Cyberspace* (Cambridge: Cambridge University Press, 2011).

9 One could also mention the Regional Comprehensive Economic Partnership (RCEP), which is a negotiation led by the Association of Southeast Asian Nations (ASEAN) aiming to enhance economic integration and cooperation between the ten members of ASEAN and six countries with which ASEAN has FTAs (Australia, China, India, Japan, Korea and New Zealand). The chapter does not cover these agreements.

10 For an introduction to the law of the WTO and its most important tenets, see e.g. Peter van den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization*, 3rd edn (Cambridge: Cambridge University Press, 2013); Petros C. Mavroidis, George A. Bermann and Mark Wu, *The Law of the World Trade Organization: Documents, Cases, and Analysis*, 2nd edn (Eagan, MN: West, 2013).

11 Agreement Establishing the World Trade Organization with Understanding on the Rules and Procedures Governing the Settlement of Disputes and Trade Policy Review Mechanism, Marrakesh, 15 April 1994, 1867 U.N.T.S. 154; 33 I.L.M. 1144 (1994), entered into force 1 January 1995 (hereinafter the Marrakesh Agreement); General Agreement on Tariffs and Trade 1994, 1867 U.N.T.S. 187; 33 I.L.M. 1153 (1994), entered into force 1 January 1995 (hereinafter GATT); General Agreement on Trade in Services, 1869 U.N.T.S. 183; 33 I.L.M. 1167 (1994), entered into force 1 January 1995 (hereinafter GATS); Agreement on Trade-Related Aspects of Intellectual Property Rights, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (1994), entered into force 1 January 1995 (hereinafter TRIPS), all collectively referred to as the WTO Agreements.

course, argue that laws need not change with each and every new technological invention.¹² Indeed, the law of the WTO may lend credence to such an argument because it possesses intrinsic flexibility and resilience, both in the substance and in the procedure. The WTO is based on powerful principles of non-discrimination, such as the most favoured nation (MFN) and the national treatment (NT) obligations,¹³ which could potentially address technological developments better than new made-to-measure regulatory acts that may often be adopted as a reaction to strong vested interests. WTO law also often tackles issues in a technologically neutral way—for instance, with regard to the application of the basic principles with regard to standards,¹⁴ trade facilitation,¹⁵ subsidies,¹⁶ and government procurement.¹⁷ There are, additionally, horizontally applicable provisions, such as those regarding transparency (Article III GATS) and domestic regulation (Article VI GATS)¹⁸ that may have the potential, if properly implemented, to deal with many digital trade concerns.

Moreover, in terms of evolution of norms, it can be argued that the WTO possesses the unrivalled advantage of an effective dispute settlement. There is strong evidence in the WTO jurisprudence for both the capacity of the dispute settlement system and for the relevance of the internet in trade conflicts.¹⁹ *The US – Gambling* case is illuminating in this context. Not only did this first “GATS only”

12 See, famously, Frank H. Easterbrook, “Cyberspace and the Law of the Horse,” *University of Chicago Legal Forum* (1996): 207–216.

13 The MFN principle is enshrined in Article I GATT, Article II GATS and Article IV TRIPS. The NT obligation can be found in Article III GATT, Article XVII GATS and Article III TRIPS.

14 The WTO does not have a standard-setting capacity itself but its Agreement on Technical Barriers to Trade (TBT) assesses the compatibility of domestic regulations and standards with WTO law. Overall, the TBT Agreement limits the regulatory space available to states to implement standards as barriers to trade. Next to encouraged subscription to international standards, it includes far-reaching non-discrimination and transparency norms, as well as procedural safeguards. See respectively Articles 2.1 and 2.2 TBT, Articles 2.9, 2.10, 2.11, 2.12, 4.1 and 10 TBT.

15 The WTO Agreement on Trade Facilitation, which was agreed upon in the 2013 Bali Ministerial Conference is an important customs reform that reduces the burden of administrative and customs controls at the border and makes procedures and officials more transparent, efficient and accountable. It requires, for example, WTO members to publish information on all laws, regulations and procedures affecting trade, including transit procedures, duty rates and import fees. Most of this information must be made available on the internet. The agreement would also speed up procedures by providing, for instance, for a one-stop shop for documentation and for expedited release of goods through air cargo facilities. The Trade Facilitation Agreement entered into force on 22 February 2017. See WTO General Council, Protocol Amending the Marrakesh Agreement Establishing the World Trade Organization, Decision of 27 November 2014, WT/L/940 (2014). On trade facilitation under the WTO, see http://www.wto.org/english/tratop_e/tradfa_e/tradfa_e.htm.

16 The WTO Agreement on Subsidies and Countervailing Measures disciplines the use of subsidies and regulates the actions countries can take to counter the effects of subsidies. Under the agreement, a country can use the WTO's dispute settlement procedure to seek the withdrawal of the subsidy or the removal of its adverse effects. Or the country can launch its own investigation and ultimately charge extra duty (“countervailing duty”) on subsidised imports that are found to be hurting domestic producers. There is no comparable agreement for trade in services; just a duty to negotiate under the GATS “built-in agenda” (Article XV GATS).

17 The WTO Government Procurement Agreement (GPA) seeks openness of the procurement market. It is a plurilateral agreement that binds and benefits only its signatories (Switzerland as well as the European Union (EU) are members). The revised GPA, which entered into force on 6 April 2014, is a further reaching effort that establishes standards of non-discrimination, transparency and procedural fairness in public procurement. The text of the revised agreement is available at https://www.wto.org/english/tratop_e/gproc_e/gp_gpa_e.htm.

18 See e.g. Panagiotis Delimatsis, *International Trade in Services and Domestic Regulations: Necessity, Transparency, and Regulatory Diversity* (Cambridge: Cambridge University Press, 2007).

19 In fact, all major GATS cases have had a substantial internet-related element. See WTO Panel Report, *Mexico – Measures Affecting Telecommunications Services (Mexico – Telecommunications)*, WT/DS204/R, adopted 2 April 2004; Panel Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services (US – Gambling)*, WT/DS285/R, adopted 10 November 2004; Appellate Body Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services (US – Gambling)*, WT/DS285/AB/R, adopted 7 April 2005; Panel Report, *China – Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products (China –*

case confirm that GATS commitments apply to electronically supplied services, but it also clarified key notions of services regulation, such as likeness and the scope of the “public morals/public order” defence under the general exceptions of Article XIV GATS.²⁰

Unfortunately, such a positive picture of the WTO and its relevance for digital trade does not reflect reality. Indeed, there are many causes for worry and scepticism. Some relate to the ways WTO rules, in particular the GATS provisions, were designed, allowing WTO members to tailor their commitments.²¹ Others relate to old (pre-internet) classifications of goods, services, and sectors upon which these commitments were based and which are becoming increasingly disconnected from trade practices.²² Many of the contentious issues, which often block digital trade negotiations, stem however from more fundamental policy and cultural divergences. They translate into different “trade and ...” pairs,²³ which render solution-finding processes hard and protracted, especially when the views of dominant actors—the United States and the European Union—diverge.²⁴

This situation has induced legal uncertainty. For instance, as the WTO law presently stands, we are unsure whether online games should be categorised as goods or services.²⁵ Even where no physical medium is involved and we decide consequently to apply the GATS, the classification puzzle is by no means solved. Online games, as a new type of content platform, could be potentially fitted into the discrete categories of computer and related services, value-added telecommunications services, entertainment, or audiovisual services. We are unsure, when there is an electronic data flow intrinsic to the service, whether to classify this flow separately, or as part of the traditional services.²⁶

Classification is by no means trivial,²⁷ as each category implies a completely different set of duties and/or flexibilities. If online platforms and the services they offer were classified as computer services,

Publications and Audiovisual Products), WT/DS363/R, adopted 12 August 2009; Appellate Body Report, *China – Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products (China – Publications and Audiovisual Products)*, WT/DS363/AB/R, adopted 21 December 2009; WTO Panel Report, *China – Certain Measures Affecting Electronic Payment Services (China – Electronic Payment Services)*, WT/DS413/R, adopted 31 August 2012.

- 20 Mark Krjewski, “Playing by the Rules of the Game? Specific Commitments after *US – Gambling and Betting* and the Current GATS Negotiations,” *Legal Issues of Economic Integration* 32 (2005): 417–447; Sacha Wunsch-Vincent, “The Internet, Cross-Border Trade in Services, and the GATS: Lessons from *US – Gambling*,” *World Trade Review* 3 (2006): 1–37; Panagiotis Delimatsis, “Don’t Gamble with GATS—The Interaction between Articles VI, XVI, XVII and XVIII GATS in the Light of the *US – Gambling Case*,” *Journal of World Trade* 40 (2006): 1059–1080.
- 21 See e.g. Rudolf Adlung, “Trade Liberalisation under the GATS: An Odyssey?” in *GATS and the Regulation of International Trade in Services*, ed. Marion Panizzon, Nicole Pohl and Pierre Sauvé (pp. 209–231) (Cambridge: Cambridge University Press, 2008); Juan A. Marchetti and Martin Roy, “Services Liberalization in the WTO and in PTAs,” in *Opening Markets for Trade in Services: Countries and Sectors in Bilateral and WTO Negotiations*, ed. Juan A. Marchetti and Martin Roy (pp. 61–112) (Cambridge: Cambridge University Press, 2009).
- 22 See e.g. Burri and Cottier, *Trade Governance in the Digital Age*.
- 23 See e.g. Andrew T. F. Lang, “Reflecting on ‘Linkage’: Cognitive and Institutional Change in the International Trading System,” *Modern Law Review* 70, no. 4 (2007): 523–549.
- 24 The trade and culture debate is illustrative in this context. See e.g. Mira Burri, Christoph Graber and Thomas Steiner, “The Protection and Promotion of Cultural Diversity in a Digital Networked Environment: Mapping Possible Advances to Coherence,” in *The Prospects of International Trade Regulation*, ed. Thomas Cottier and Panagiotis Delimatsis (pp. 369–393) (Cambridge: Cambridge University Press, 2011).
- 25 See e.g. Rolf H. Weber and Mira Burri, *Classification of Services in the Digital Economy* (Berlin: Springer, 2012).
- 26 For a discussion of the application of technology neutrality to services classification, see Shin-yi Peng, “GATS and the Over-the-Top Services: A Legal Outlook,” *Journal of World Trade* 50, no. 1 (2016): 21–46.
- 27 See Weber and Burri, *Classification of Services in the Digital Economy*.

states would lack any wiggle-room whatsoever and would have to grant full access to foreign services and services suppliers and treat them as they treat domestic ones because of the high level of existing commitments under the GATS of virtually all WTO members.²⁸ The evolutionary interpretation of schedules of specific commitments, as affirmed in *China – Publications and Audiovisual Products*, while genuinely a positive development, does not necessarily help much to achieve legal certainty in such situations.²⁹

The classification dilemma, particularly critical for digital trade, is an illuminating example of this state of paralysis but far from the only one. Many other issues discussed in the framework of the 1998 WTO Work Programme on Electronic Commerce have been left without a solution or even a clarification.³⁰ There is, for instance, still no agreement on a permanent duty-free moratorium on electronic transmissions and their content. The moratorium has only been temporarily extended several times, the last time for a period of two years following a decision taken during the Nairobi Ministerial Conference in 2015.³¹

It should be stressed in this context that addressing the issues raised by the Work Programme on E-Commerce may now be simply insufficient or even futile. Since the programme was launched in 1998, the picture has changed in many critical respects. The significance of digital trade, both in its contribution to the economic growth of many countries and the preoccupation of governments with digital trade-related policies, has grown exponentially.³² This progress and changing interests relate to new, previously unknown or not fully developed technological applications, such as mobile telephony or cloud computing, which have become important platforms for business.³³ The overall transformation relates to the new centrality of the internet as the essential foundation for innovation and its deep economic, social, and cultural implications.³⁴ These changes have also been associated with a new palette of measures that inhibit digital trade. An enquiry by the United States International Trade Commission compiled a useful taxonomy of such measures.³⁵ Some measures can be grouped under the so-called "digital trade localisation measures" or "localisation barriers to trade." They encompass, among others, requirements for localisation of data servers, certain local

28 This is true not only because of traditional media policies but also because of newly adopted ones. The promotion of local content in digitally delivered services is not limited to Europe either. The Chinese Ministry of Culture reportedly has classified online games as "cultural products" and has intensely supported the domestic industry. See United States International Trade Commission, *Digital Trade in the US and Global Economies*, Part 1 (Washington, DC: United States International Trade Commission, 2013), 5–7.

29 In *China – Publications and Audiovisual Products* (at para. 396), the Appellate Body found that the terms in China's Schedule "are sufficiently generic that what they apply to may change over time."

30 Sacha Wunsch-Vincent and Arno Hold, "Towards Coherent Rules for Digital Trade: Building on Efforts in Multilateral versus Preferential Trade Negotiations," in *Trade Governance in the Digital Age*, ed. Mira Burri and Thomas Cottier (pp. 179–221) (Cambridge: Cambridge University Press, 2012), 181.

31 WTO, Ministerial Decision on Work Programme on Electronic Commerce, adopted on 19 December 2015 at the Tenth WTO Ministerial Conference in Nairobi, WT/MIN(15)/42 (2015).

32 United States International Trade Commission (USITC), *Digital Trade in the US and Global Economies, Part 1*, Investigation No. 332–531 (Washington, DC: USITC, 2013).

33 See e.g. WTO, Communication from the European Union and the United States: Contribution to the Work Programme on Electronic Commerce, S/C/W/338 (2011).

34 Benkler, *The Wealth of Networks*; Chander, *The Electronic Silk Road*.

35 See USITC, *Digital Trade in the US and Global Economies, Part 1*, as well as USITC, *Digital Trade in the US and Global Economies, Part 2*, Investigation No 332–540 (Washington, DC: USITC, 2014).

content policies, or discrimination against digital services or providers not locally based.³⁶ Other measures are not related strictly to trade: censorship, divergent approaches to data privacy, and IP protection adopted by different countries nonetheless disrupt digital trade, increase the cost of doing business, and hinder innovation.³⁷

Overall, while it can be maintained that the WTO Agreements have fairly comprehensive rules and that digital trade can be subsumed under the law of the GATT and the GATS, it is also evident that legal adaptation under the auspices of the WTO has not progressed. Despite the utility of the WTO's dispute settlement, judicial transplants cannot replace political consensus on the substance, particularly in a complex and highly technical domain such as digital trade. As the Doha negotiations continue to make little progress, the multilateral venue of legal rule-making has been seriously undermined and this has triggered forum-shopping: bilaterally, regionally, or through plurilateral initiatives. It can be argued that the TPP is the pinnacle of these efforts. Before we look at those provisions of the TPP that address digital trade issues, it can be useful to take a look at the previous FTAs. This will allow us to trace the origins of some digital trade rules and to understand the success and the failures of the TPP.

3. Experience Gathered in Regional and Bilateral Agreements Before the TPP

The regulatory environment for digital trade has been substantially influenced by FTAs, and in particular by those led by the United States. The United States has endorsed and attempted to ensure implementation of its so-called "Digital Agenda"³⁸ through the FTA channel. The agreements reached since 2002 with Australia, Bahrain, Chile, Morocco, Oman, Peru, Singapore, the Central American countries,³⁹ and more recently with Panama, Colombia and South Korea, all contain critical WTO-plus provisions in the broader field of digital trade.⁴⁰ The emergent regulatory template on digital issues is not, however, limited to US agreements but has diffused and can be found in other FTAs as well, such as Singapore–Australia, Thailand–Australia, Thailand–New Zealand, New Zealand–Singapore, India–Singapore, Japan–Singapore and South Korea–Singapore.⁴¹ The implemented US template regulates key aspects of digital trade in (i) specifically dedicated e-commerce chapters, (ii) the chapters on cross-border supply of services, as well as in (iii) information and communication technology (ICT) cooperation, and (iv) intellectual property chapters.

3.1 E-Commerce Chapters

The first category of FTA chapters, which focuses exclusively on matters of electronic commerce, represents a clear attempt to compensate for the lack of progress in the WTO and remedy the ensuing uncertainties. These chapters directly or indirectly address many of the questions of the

36 For a country survey, see Anupam Chander and Uyên P. Lê, "Data Nationalism," *Emory Law Journal* 64 (2015): 677–739.

37 USITC, *Digital Trade in the US and Global Economies*, Part 1; Chander and Lê, "Data Nationalism."

38 See Sacha Wunsch-Vincent, "The Digital Trade Agenda of the US: Parallel Tracks of Bilateral, Regional and Multilateral Liberalization," *Aussenwirtschaft* 1 (2003): 7–46.

39 The CAFTA-DR includes Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and the Dominican Republic.

40 Wunsch-Vincent and Hold, "Towards Coherent Rules for Digital Trade."

41 Wunsch-Vincent and Hold, "Towards Coherent Rules for Digital Trade."

WTO e-commerce programme⁴² that have been discussed but still remain open.⁴³ This includes a clear definition of "digital products," which treats digital products delivered offline equally with those delivered online, so that technological neutrality is ensured. The chapters also recognise the applicability of WTO rules to electronic commerce,⁴⁴ and establish an express and permanent duty-free moratorium on the import or export of digital products by electronic transmission.⁴⁵ Critically, the e-commerce chapters ensure both MFN and NT for digital products trade; discrimination is banned on the basis that digital products are "created, produced, published, stored, transmitted, contracted for, commissioned, or first made available on commercial terms outside the country's territory" or their "author, performer, producer, developer, or distributor is a person of another party or a non-party."⁴⁶

However, the seemingly far-reaching provisions of the e-commerce chapters need to be qualified. They appear legally inferior to the rest of the free trade agreement, as they are "subject to any other relevant provisions, exceptions, or non-conforming measures set forth in other Chapters or Annexes of this Agreement."⁴⁷ In case of a conflict, the provisions of the e-commerce chapters will thus be overridden.

3.2 Chapters on Cross-Border Supply of Services

The depth of the commitments made in the e-commerce chapters is contingent on the services chapters. In most US-led FTAs, the chapters on cross-border trade in services are very liberal. Among other things, and pertinently for our discussion, they use a negative-list approach for the undertaking of commitments. This means that no measures inconsistent with national treatment are maintained, except where specifically provided for. While the negative approach does not in itself influence the content or the quality of the obligations undertaken,⁴⁸ it does indirectly tackle the problem of outdated (and politically contentious) classification issues, as well as ensures, in principle, coverage for future digital services. In addition, the FTAs address still existing MFN exemptions under the WTO regime, and ensure that these exemptions are dropped. Many of the FTAs also address and expressly ban the newer generation of digital trade barriers, which prescribe certain local content or presence elements, as we will discuss in more detail later.

42 WTO General Council, Work Programme on Electronic Commerce, WT/L/274 (1998).

43 Sacha Wunsch-Vincent, *The WTO, the Internet and Digital Products: EC and US Perspectives* (Oxford: Hart, 2006).

44 See e.g. US–Singapore FTA, Article 14.1; US–Australia FTA, Article 16.1.

45 See e.g. US–Singapore FTA, Article 14.3, para. 1; US–Chile FTA, Article 15.3. It is also clear that the zero duty obligation applies to the content of the digital transmission, namely digital products. It appears, however, that the moratorium does not apply to digitally delivered services.

46 See e.g. US–Singapore FTA, Article 14.3; US–Australia FTA, Article 16.4. In many FTAs digital products must not be fully produced and exported through one of the contracting parties of the bilateral FTAs to benefit from the non-discrimination obligations. This is an interesting way to avoid complex rules of origin. See Wunsch-Vincent and Hold, "Towards Coherent Rules for Digital Trade," 201.

47 See e.g. US–Chile FTA, Article 15.2; US–Singapore FTA, Article 14.2.

48 Rudolf Adlung and Hamid Mamdouh, "How to Design Trade Agreements in Services: Top Down or Bottom Up?" *WTO Staff Working Paper 8* (2013). The authors suggest that what matters for the level of liberalisation is not negotiating or scheduling techniques, but the political impetus that the governments concerned are ready to generate; see also, in this sense, Submission by Switzerland: Possible Operationalization of a Hybrid Schedule, Really Good Friends – Meeting of 5 November 2012, Plurilateral Initiative on Trade in Services, 10 October 2012.

3.3 ICT Cooperation

In addition to the topics of market access and equal treatment that are core to trade agreements, many FTA partners have sought the conclusion of additional understandings on e-commerce, as part of the e-commerce chapters or in a discrete form.⁴⁹ These cover different cooperation initiatives in the broader information technology policy field, such as those for telecommunications policy, information technology standards and interoperability, cybersecurity, electronic signatures and payments, paperless trading, self-regulation and e-government projects. On the other hand, the joint understandings try to achieve some common ground rules for the digital marketplace, where increasingly inadequate and incompatible national regulations are seen as an important digital trade barrier.⁵⁰ There is no uniform format for attaining this objective. Some of the agreed digital trade principles are general, while others are fairly detailed and far-reaching. In particular, the provisions on authentication mandating certain technological and legal requirements, interoperability and non-discrimination, work on mutual recognition and international standards, as well as on consumer protection⁵¹ and privacy standards, can be truly powerful and demand changes in domestic law and policies.

The US–South Korea FTA is perhaps the most advanced in this regard. It includes “Principles on Access to and Use of the Internet for Electronic Commerce,” which details rights for consumers to (a) access and use services and digital products of their choice; (b) run applications and services of their choice; (c) connect their choice of devices to the internet; and (d) have the benefit of competition among network providers, application and service providers, and content providers.⁵² Next to these fairly solid safeguards against censorship and other types of constraints on access and use, the US–South Korea FTA provides for free cross-border information flows, obliging the parties, albeit in a non-binding manner, “to refrain from imposing or maintaining unnecessary barriers to electronic information flows across borders.”⁵³

3.4 Intellectual Property Chapters

Many relevant digital trade provisions are to be found in the IP chapters of FTAs. These include a number of TRIPS-plus (i.e., standards that go beyond TRIPS) and TRIPS-extra (i.e., new areas previously not covered by TRIPS) provisions.⁵⁴ Over the past decade, FTAs have become a primary

49 Very often there are joint statements on e-commerce that are agreed upon bilaterally and regionally. See e.g. Asia-Pacific Economic Cooperation, “Statement to Implement APEC Policies on Trade and the Digital Economy,” Leader’s Declaration, 27 October 2002, Los Cabos.

50 Wunsch-Vincent and Hold, “Towards Coherent Rules for Digital Trade,” 204–211. For comparative data, see USITC, *Digital Trade in the US and Global Economies, Part 1*.

51 The US–Australia FTA includes, for instance, detailed additional obligations on cross-border consumer protection, also referring to the 2003 OECD Guidelines for Protecting Consumers from Fraudulent and Deceptive Commercial Practices across Borders (see US–Australia, Chapter 14 on competition-related matters, Article 2). The same is true for the US–South Korea agreement, which next to Article 15.5 on online consumer protection includes detailed rules in its chapter on competition, at Article 16.6.

52 US–South Korea, Article 15.7.

53 US–South Korea, Article 15.8: “Recognizing the importance of the free flow of information in facilitating trade, and acknowledging the importance of protecting personal information, the Parties shall endeavor to refrain from imposing or maintaining unnecessary barriers to electronic information flows across borders.”

54 See e.g. John Braithwaite and Peter Drahos, “Ratcheting Up and Driving Down Global Regulatory Standards,” *Development* 42, no. 4 (1999): 109–114; Susan K. Sell, “The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play,” *PJIP Research Paper* 15 (2010): 1–22; Neil W. Netanel, “Why Has Copyright Expanded? Analysis and Critique,” in *New Directions in Copyright Law: Vol. 6*, ed. Fiona Macmillan (pp. 3–34) (Cheltenham: Edward Elgar, 2007).

venue for implementing IP rules to protect content online.⁵⁵ The level of detail and the strength of protection have steadily increased—from the early US-led agreements, such as US–Jordan, to more recent ones, such as the US–South Korea FTA.⁵⁶

The IP chapters secure adherence to, or at least compliance (without formal ratification) with the WIPO Internet Treaties.⁵⁷ Going even further than the WIPO Copyright Treaty, the bilateral and regional agreements ensure implementation of technical protection measures and digital rights management systems to prevent unauthorised digital copying. The flexibility in the implementation of the WIPO Copyright Treaty is in many senses reduced as the FTAs demand legal remedies against circumventing technical protection measures, as well as against devices used for that purpose (independent of the intended use of the device). Many of the FTAs also regulate the liability of internet service providers (ISPs) and contain additional provisions on the enforcement of copyright online.⁵⁸

3.5 Looking at Some Non-US Agreements

The United States has clearly been leading as a legal entrepreneur with regard to digital trade. While, as noted, the US template and different provisions from it have spread in non-US agreements, it is fair to add that not all countries have strategies with regard to digital issues. Many remain involved, although not actively, in the WTO e-commerce programme but do not pursue insertion of digital trade provisions in FTAs. This is true for many developing countries because of their limited regulatory capacities but it is also true for developed countries, such as the European Free Trade Association members. The European Union has been more proactive but certainly not to the extent of the US.

Apart from the generic differences between the EU and the US approaches to FTAs, the EU template with regard to digital trade is not as coherent as that of the United States.⁵⁹ It has also developed and changed over time, with regard to both dedicated provisions on electronic commerce, as well as services and IP rules of relevance to digital trade.

The agreement with Chile (signed in 2002) was the first to include substantial e-commerce provisions, but the language was cautious and limited to soft cooperation pledges in the services chapter⁶⁰ and in the fields of information technology, information society and telecommunications.⁶¹ In more recent agreements, such as the EU–South Korea FTA (signed in 2009), the language is much more concrete

55 Netanel, "Why Has Copyright Expanded?"

56 Wunsch-Vincent and Hold, "Towards Coherent Rules for Digital Trade," 211.

57 The WIPO Internet Treaties encompass the WIPO Copyright Treaty and the WIPO Performance and Phonograms Treaty. See WIPO Copyright Treaty, 20 December 1996, WIPO Publication No. 226, (1997) 36 ILM 65, entered into force 6 March 2002, and WIPO Performances and Phonograms Treaty, 20 December 1996, WIPO Publication No. 227, (1997) 36 ILM 76, entered into force 20 May 2002.

58 Wunsch-Vincent and Hold, "Towards Coherent Rules for Digital Trade," 211–215.

59 EU FTAs tend, for instance, to cover more WTO-plus areas but have less liberal commitments. For detailed analysis, see Henrik Horn, Petros C. Mavroidis and André Sapir, *Beyond the WTO? An Anatomy of EU and US Preferential Trade Agreements* (Brussels: Bruegel Print, 2009).

60 EU–Chile FTA, Article 102. The agreement states: "The inclusion of this provision in this Chapter is made without prejudice of the Chilean position on the question of whether or not electronic commerce should be considered as a supply of services."

61 EU–Chile FTA, Article 37.

and binding. It imitates some of the provisions of the US template and confirms the applicability of the WTO Agreements to measures affecting electronic commerce, as well as subscribing to a permanent duty-free moratorium on electronic transmissions.⁶² Particularly insistent on data protection policies, the EU has also sought commitment of its FTA partners to compatibility with the international standards of data protection.⁶³ Cooperation is increasingly framed in more concrete terms and includes mutual recognition of electronic signatures certificates, coordination on internet service providers' liability, consumer protection, and paperless trading.⁶⁴

The most recent EU agreement with Canada—the Comprehensive Economic and Trade Agreement (CETA)⁶⁵—goes a step further. The CETA provisions concern commitments ensuring (a) clarity, transparency and predictability in their domestic regulatory frameworks; (b) interoperability, innovation and competition in facilitating electronic commerce; as well as (c) facilitating the use of electronic commerce by small and medium-sized enterprises.⁶⁶ The EU has succeeded in deepening the privacy commitments. The CETA has a specific provision discussing trust and confidence in electronic commerce, which obliges the parties to adopt or maintain laws, regulations or administrative measures for the protection of personal information of users engaged in electronic commerce in consideration of international data protection standards.⁶⁷

With regard to cross-border trade in services, the EU's traditional approach has been to follow the GATS model and only make positive (and relatively conservative) commitments, whereby different services sectors and subsectors are listed and the commitments for national treatment and market access specified. The level of commitments has largely mirrored the offers made by the EU during the Doha Round, so, unlike the US, the EU has not gone substantially GATS-plus in its FTAs. For telecommunications services, an additional commitment on number portability is included.⁶⁸ For the computer services sector, the provisions foresee deep liberalisation of all computer and related services at the two-digit Central Product Classification (CPC) 84 level, while excluding core content services delivered electronically (e.g., financial or audiovisual services).⁶⁹ The EU experimented with a negative list of commitments for the first time with the CETA. This marks a turn in the EU's FTA strategies and it remains to be seen whether this will be a continued effort or it was merely suitable for Canada as a trading partner with similar priorities and sensitivities. It should be stressed that even in this case and as a reflection of Canada's and the EU's continuing pro-cultural stance, some sectors are a priori excluded. For the EU, these are audiovisual services; for Canada, the caveat relates to its

62 EU–South Korea FTA, Article 7.48.

63 EU–South Korea FTA, Article 7.48.

64 EU–South Korea FTA, Article 7.49.

65 CETA was signed in 2014 and adopted by the Council and signed at the EU–Canada Summit on 30 October 2016. CETA's consolidated text is available at <http://data.consilium.europa.eu/doc/document/ST-10973-2016-IN17/en/pdf>.

66 CETA, Article 16.5.

67 CETA, Article 16.4.

68 CETA, Article 15.10. Number portability has been a common commitment in all FTAs, while missing from the WTO Reference Paper on Basic Telecommunications Services.

69 EU–South Korea FTA, Article 7.25, in a way identical to the EU's Doha Round offer; see WTO, Understanding on the Scope of Coverage of CPC 84—Computer and Related Services, Communication from Albania, Australia, Canada, Chile, Colombia, Croatia, the European Communities, Hong Kong China, Japan, Mexico, Norway, Peru, the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu, Turkey and the United States, TN/S/W/60, S/CSC/W/51 (2007).

"cultural industries."⁷⁰ In addition, there is an annex attached to the services chapter which sets out an understanding on new services not classified in the UN Provisional CPC in its 1991 version, as used during the Uruguay Round negotiations. The understanding specifies that the commitments made do not apply in respect to any measure relating to a new service that cannot be classified under the CPC.⁷¹ Parties have an obligation to notify the other party about such new services and enter into negotiations to incorporate the new service into the scope of the agreement, at the request of one of the parties.⁷² This is an extremely cautious approach to future innovation, as it prevents coverage being automatic and may also involve a burdensome and costly administration of the FTA. It also diverges from the current US practice.

The convergence between the EU and the US templates is most pronounced with regard to the chapters on intellectual property protection. Since the EU–Chile FTA, and in particular in the EU–CARIFORUM⁷³ and EU–South Korea, the EU has included a number of TRIPS-plus provisions.⁷⁴ Digital copyright norms (compliance with the WIPO Internet Treaties; provisions on technological protection measures and ISP liability) have become an intrinsic element of the EU deals too.⁷⁵

4. The Trans-Pacific Partnership Agreement

It is clear from this discussion that the TPP did not come out of the blue but was meant to build upon existing FTA provisions. The expectations for the TPP in its legal design and impact were great, however. It was supposed to be a "twenty-first century" trade agreement that would match contemporary global trade better than the mercantilist and bricks-and-mortar WTO Agreements.⁷⁶ It was only logical, in this sense, that sizeable weight was given in the negotiations to digital trade. In terms of the breadth and depth of the commitments, the United States Trade Representative strove to substantially exceed the "gold standard" created by the US–South Korea FTA. The final text of the TPP entails some successes in this regard, as well as some failings.

70 CETA, Chapter 32 "Exceptions." If we compare this with the W/120 classification for audiovisual services, which includes motion picture and video tape production and distribution services, motion picture projection service, radio and television services, radio and television transmission services and sound recording, the scope of "cultural industries" is somewhat broader.

71 CETA, Annex 9-B – Understanding on new services not classified in the United Nations provisional central product classification (CPC), 1991, para. 1.

72 It is clarified that this regime does not apply to an existing service that could be classified under the CPC but that could not previously be provided on a cross-border basis due to lack of technical feasibility. CETA, Annex 9-B, para. 4.

73 In October 2008, Antigua and Barbuda, the Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Jamaica, Saint Lucia, Saint Vincent and the Grenadines, Saint Kitts and Nevis, Surinam, Trinidad, Tobago, and the Dominican Republic signed with the EU the CARIFORUM–EU Economic Partnership Agreement. Haiti signed the agreement in December 2009, but is not yet applying it pending ratification.

74 Henning Grosse Ruse-Khan, "Access to Knowledge under the International Copyright Regime, the WIPO Development Agenda and the European Communities' New External Trade and IP Policy," in *Research Handbook on the Future of EU Copyright*, ed. Estelle Derclaye (pp. 574–612) (Cheltenham: Edward Elgar, 2009); Josef Drexler, Henning Grosse Ruse-Khan and Souheir Nadde-Phlix (eds), *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* (Berlin: Springer, 2014).

75 Wunsch-Vincent and Hold, "Towards Coherent Rules for Digital Trade"; Grosse Ruse-Khan, "Access to Knowledge"; Drexler, Grosse Ruse-Khan and Nadde-Phlix, *EU Bilateral Trade Agreements and Intellectual Property*.

76 See e.g. Claude Barfield, "The Trans-Pacific Partnership: A Model for Twenty-First-Century Trade Agreements?" *International Economic Outlook 2*, American Enterprise Institute, June 2011. The United States Trade Representative (USTR) had various such references on its dedicated TPP website—these have now been removed.

4.1 The IP Chapter

Among its successes, the TPP heightened standards in the field of intellectual property protection.⁷⁷ For instance, and borrowing from earlier US agreements such as NAFTA,⁷⁸ the TPP defines "intellectual property" as an asset that can be subject to the investor–state dispute settlement, which essentially envisages an opportunity for companies to sue states for introducing rules that may harm the exploitation of IP rights.⁷⁹ The TPP also provides for heightened protection of trade secrets,⁸⁰ particularly mentioning that unauthorised and wilful misappropriation and the fraudulent disclosure of a trade secret, "including by means of a computer system," are to be criminalised in the domestic laws of all TPP countries.⁸¹

The IP chapter particularly aims to facilitate "legitimate digital trade," and diffuses the digital copyright rules, as applied in the US especially through the Digital Millennium Copyright Act (DMCA).⁸² Yet, while the USTR claims that the TPP is the first FTA to clarify that IP enforcement should be available against infringement in the digital environment,⁸³ this is merely a promotional statement rather than something that reflects the truth. In fact, many of the measures, such as the prevention of circumvention of technological protection mechanisms, have been spelled out in other trade agreements, such as that with South Korea, and are prescribed by the 1996 WIPO Internet Treaties and, later on, by the Anti-Counterfeiting Trade Agreement (ACTA).⁸⁴ In contrast, reflecting the strong influence of the IP lobby, Article 18.28(1)(b) TPP does include a novelty by requiring that each party's system for the management of its country-code top-level domain (ccTLD) names provide "online public access to a reliable and accurate database of contact information concerning domain name registrants in accordance with each Party's law and relevant administrator policies regarding protection of privacy and personal data." This has been controversial because of online harassment issues and can be interpreted as a serious intervention into the area of internet governance, which is based on a more open, multi-stakeholder approach.⁸⁵ The practical effect of having this norm is, however, as yet uncertain.

The changes in the regulation of internet service providers⁸⁶ are also important to note, as ISPs are critical intermediaries in the online environment that enable and condition the access and distribution

77 TPP, Chapter 18. See also Sean M. Flynn, Brook Baker, Margot Kaminski and Jimmy Koo, "The US Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement," *American University International Law Review* 28, no. 1 (2012): 105–202.

78 North American Free Trade Agreement (NAFTA), 32 I.L.M. 289 (1993) and 32 I.L.M. 605 (1993), at Chapter XVII. See also NAFTA and Imtiaz Hussain, *Reevaluating NAFTA: Theory and Practice* (Berlin: Springer, 2012), esp. 83–92.

79 Article 9.1. TPP.

80 Article 18.78 TPP.

81 Article 18.78(2) TPP.

82 Pub. L. No. 105-304, 112 Stat. 2860, 28 October 1998.

83 TPP, Chapter on Intellectual Property, at Introduction.

84 Flynn, Baker, Kaminski and Koo, "The US Proposal"; also David S. Levine, "Bring in the Nerds: Secrecy, National Security, and the Creation of International Intellectual Property Law," *Cardozo Arts and Entertainment Journal* 30 (2012): 105–151.

85 See e.g. Mira Burri, "The WTO as an Actor of Global Internet Governance," in *The Institutions of Global Internet Governance*, ed. William Drake and Mira Burri (Cambridge: Cambridge University Press, forthcoming).

86 An ISP is defined broadly as (a) a provider of online services for the transmission, routing, or providing of connections for digital online communications, between or among points specified by a user, of material of the user's choosing, undertaking the function in Article 18.82.2(a) (Legal Remedies and Safe Harbours); or (b) a provider of online services undertaking the functions in Article 18.82.2(c) or Article 18.82.2(d). For greater certainty, Internet Service Provider includes a provider of the services listed above that engages in caching carried out through an automated process. See Article 18.82.1 TPP.

of information.⁸⁷ The TPP framework for “legal remedies and safe harbours” requires putting in place “legal incentives” for ISPs to deter or to take action to deter “unauthorised storage and copying of copyrighted materials.”⁸⁸ The ISPs are required to expeditiously remove or disable access to material residing on their networks or systems that infringes copyright once they have received information or knowledge regarding such infringement or where there are facts or circumstances from which the infringement is apparent, such as when they receive a notice.⁸⁹ The TPP in effect harmonises the “notice and takedown” system of administering ISPs’ liability for copyright infringement for all TPP countries, very much in line with existing US standards imposed by the DMCA. There is still an exception for the somewhat softer “notice and notice” regime of Canada,⁹⁰ as well as for the notification system followed by Chile.⁹¹ Countries without such a system so far, like Brunei, Malaysia, Mexico, New Zealand and Vietnam, would need to adopt the “notice and takedown” mechanism.

The TPP does include some language with regard to the link between ISP liability and privacy protection but the relationship seems to work to the benefit of the copyright holder. On the one hand, Article 18.82.7 says that legal procedures for administering ISP liability should be “consistent with the principles of due process and privacy”; on the other hand, the provision permits “a copyright owner that has made a legally sufficient claim of copyright infringement to obtain expeditiously from an Internet Service Provider information in the provider’s possession identifying the alleged infringer in cases in which the information is sought for the purpose of protection or enforcing that copyright.”⁹²

4.2 The E-Commerce Chapter

The TPP chapter on e-commerce is clearly the most comprehensive so far. It comprises 18 articles and includes new features that in effect signal an expansion of the US template for digital trade. New issues covered by the TPP include provisions on domestic electronic transactions framework, personal information protection, internet interconnection charge sharing, location of computing facilities, unsolicited commercial electronic messages, source code, and dispute settlement.⁹³ We will go on to look more closely at them.

The TPP explicitly seeks to restrict the use of data localisation measures. Article 14.13(2) prohibits the parties from requiring a “covered person to use or locate computing facilities in that Party’s territory as a condition for conducting business in that territory.” The soft language from US–South Korea on free data flows is now framed as a hard rule: “Each Party shall allow the cross-border transfer of information by electronic means, including personal information, when this activity is

87 See e.g. Jack M. Balkin “Media Access: A Question of Design,” *George Washington Law Review* 76, no. 4 (2008): 101–118; Jeremy F. De Beer and Christopher D. Clemmer, “Global Trends in Online Copyright Enforcement: A Non-Neutral Role for Network Intermediaries?” *Journal of Law, Science and Technology* 49 (2009): 375–409; also Sonia S. Katyal, “Filtering, Piracy, Surveillance and Disobedience,” *Columbia Journal of Law and the Arts* 32, no. 4 (2009): 401–426; Urs Gasser and Wolfgang Schulz (eds), *Governance of Online Intermediaries: Observations from a Series of National Case Studies* (Cambridge, MA: Berkman Center for Internet and Society, 2015).

88 Article 18.82.1(a) TPP.

89 Article 18.82.3(a) TPP.

90 TPP, Annex 18-E.

91 TPP, Annex 18-F.

92 Article 18.82.7 TPP.

93 TPP Articles 14.5, 14.8, 14.12, 14.13, 14.14, 14.17 and 14.18 respectively.

for the conduct of the business of a covered person."⁹⁴ The rule has a broad scope and most data transferred over the internet are likely to be covered, although the word "for" may suggest the need for some causality between the flow of data and the business of the covered person.

Measures restricting digital flows or localisation requirements under Article 14.13 TPP are permitted only if they do not amount to "arbitrary or unjustifiable discrimination or a disguised restriction on trade" and do not "impose restrictions on transfers of information greater than are required to achieve the objective."⁹⁵ These non-discriminatory conditions are similar to the strict test formulated by the GATS Article XIV and GATT Article XX, a test that is supposed to balance trade and non-trade interests but is also extremely hard to pass.⁹⁶ The TPP test differs from the WTO norms in one significant element: while there is a list of public policy objectives in the GATT and the GATS, the TPP provides no such enumeration and simply speaks of a "legitimate public policy objective."⁹⁷ This permits more regulatory autonomy for the TPP signatories. However, it also may lead to abuses and overall legal uncertainty.

Further, it should be noted that the ban on localisation measures is somewhat softened with regard to financial services and institutions.⁹⁸ An annex to the financial services chapter has a separate data transfer requirement, whereby certain restrictions on data flows may apply for the protection of privacy or confidentiality of individual records, or for prudential reasons.⁹⁹ Government procurement is also excluded.¹⁰⁰

Pursuant to Article 14.17, a TPP member may not require the transfer of, or access to, source code of software owned by a person of another party as a condition for the import, distribution, sale or use of such software, or of products containing such software, in its territory. The prohibition applies, however, only to mass-market software or products containing such software.¹⁰¹ This means that tailor-made products will be excluded, as well as software used for critical infrastructure and those in commercially negotiated contracts.¹⁰² The aim of this provision is to protect software companies and address their concerns about loss of IP or cracks in the security of their proprietary code,¹⁰³ its real effect is, however, hard to predict.

These provisions illustrate an interesting development because it is evident that they do not simply entail a clarification of existing bans on discrimination, nor do they merely set higher standards, as is

94 Article 14.11(2) TPP.

95 Article 14.11(3) TPP.

96 See e.g. Henrik Andersen, "Protection of Non-Trade Values in WTO Appellate Body Jurisprudence: Exceptions, Economic Arguments, and Eluding Questions," *Journal of International Economic Law* 18 (2015): 383–405.

97 Article 14.11(3) TPP.

98 See the definition of "a covered person" in Article 14.1, which is said to exclude a "financial institution" and a "cross-border financial service supplier."

99 The provision reads: "Each Party shall allow a financial institution of another Party to transfer information in electronic or other form, into and out of its territory, for data processing if such processing is required in the institution's ordinary course of business."

100 Article 14.8(3) TPP.

101 Article 14.17(2) TPP.

102 Article 14.17(2) TPP.

103 It is interesting to note that China does demand access to source code from software producers selling in its market, so this provision may be interpreted as a reaction to this.

generally anticipated from trade agreements. Rather, they shape the regulatory space domestically and may actually lower certain standards. Commitments to lower standards of protection are particularly palpable in the field of privacy and data protection.

Article 14.8(2) requires every TPP party to “adopt or maintain a legal framework that provides for the protection of the personal information of the users of electronic commerce.” No standards or benchmarks for the legal framework have been specified, except for a general requirement that TPP parties “take into account principles or guidelines of relevant international bodies.”¹⁰⁴ A footnote provides some clarification in saying: “For greater certainty, a Party may comply with the obligation in this paragraph by adopting or maintaining measures such as a comprehensive privacy, personal information or personal data protection laws, sector-specific laws covering privacy, or laws that provide for the enforcement of voluntary undertakings by enterprises relating to privacy.”¹⁰⁵

Parties are also invited to promote compatibility between their data protection regimes, by essentially treating lower standards as equivalent.¹⁰⁶ Overall, the goal seems to be to prioritise trade over privacy rights. This commitment is clearly pushed by the US, which subscribes to relatively weak and patchy protection of privacy, and could lose the privilege of free transatlantic data transfer as a consequence of the judgment of the Court of Justice of the European Union that struck down the EU–US Safe Harbor Agreement.¹⁰⁷

While attention is (understandably) focused on data protection, it should be noted that the TPP provisions on consumer protection¹⁰⁸ and spam control¹⁰⁹ are also fairly weak. The same is true for the newly introduced rules on cybersecurity. Article 14.16 is non-binding and identifies a relatively limited scope of activities for cooperation, in situations of “malicious intrusions” or “dissemination of malicious code,” and capacity-building of governmental bodies dealing with cybersecurity incidents.

Net neutrality is another important digital economy topic that has been given specific attention in the TPP, although the rules so created are non-binding in nature. Article 14.10 titled “Principles on Access to and Use of the Internet for Electronic Commerce” states:

Subject to applicable policies, laws and regulations, the Parties recognise the benefits of consumers in their territories having the ability to: (a) access and use services and applications of a consumer’s choice available on the Internet, subject to reasonable network management; (b) connect the end-user devices of a consumer’s choice to the Internet, provided that such devices do not harm the network; and (c) access information on the network management practices of a consumer’s Internet access service supplier.

While it is commendable that net neutrality is endorsed, this comes with many reservations, as evidenced by this provision, from the domestic laws of TPP countries; from undefined situations

104 Article 14.8(2) TPP.

105 Article 14.8(2) TPP, footnote 6.

106 Article 14.8(5) TPP.

107 C-362/14, *Maximilian Schrems v. Data Protection Commissioner*, judgment of 6 October 2015, ECLI:EU:C:2015:650.

108 Article Article 14.7 TPP..

109 Article 14.14 TPP.

that call for “reasonable network management;”¹¹⁰ or from exclusive services. The obligations are ultimately weak and not linked to legal remedies for situations such as blocking or filtering content. It is unlikely that the TPP would lead to a uniform approach with regard to net neutrality across TPP countries.

4.3 Provisions Scattered in Other TPP Chapters That Matter for Digital Trade

The presentation so far is not exhaustive and there are a number of other provisions scattered in the chapters of the TPP that matter for digital trade. In general, the higher level of liberalisation achieved in some of the services sectors relevant for digital trade, such as telecommunications, computer and related, and media services, matters.¹¹¹ We only highlight here a few of those norms in the context of telecommunications and technical barriers to trade.

The TPP telecommunications chapter is very comprehensive and goes beyond what we have under the GATS with the Annex on Telecommunications and the Reference Paper.¹¹² It is very detailed and seeks to ensure a level playing field for telecommunication services and service suppliers. There is a general recognition of the liberal approach towards regulation, whereby the TPP parties recognise the value of competitive markets to deliver a wide choice in the supply of telecommunications services and to enhance consumer welfare, and that economic regulation may not be needed if there is effective competition or if a service is new to a market.¹¹³ The provisions on access and use of public telecommunications services are strengthened by including, for instance, number portability¹¹⁴ and enhanced transparency requirements.¹¹⁵ Article 13.23 is new and seeks to ensure flexibility in the choice of technology. Suppliers of public telecommunications services choose “the technologies they wish to use to supply their services, subject to requirements necessary to satisfy legitimate public policy interests, provided that any measure restricting that choice is not prepared, adopted or applied in a manner that creates unnecessary obstacles to trade.”¹¹⁶

The second provision to mention comes from Chapter 18 on technical barriers to trade and relates to encryption standards. It is a reaction to a practice by several countries that impose direct bans on encrypted products or set specific technical regulations that restrict the sale of encrypted products.¹¹⁷ China is a prominent, but not the only example in this context with its attempt to enforce an indigenous standard for wireless networks: the WAPI standard, which was a proprietary standard

110 Article 14.10(a) TPP. Footnote 7 to this paragraph specifies: “The Parties recognise that an Internet access service supplier that offers its subscribers certain content on an exclusive basis would not be acting contrary to this principle.”

111 TPP, Chapters 10 and 13.

112 For analysis of the WTO rules on communications services, see e.g. Mira Burri, “The Law of the World Trade Organization and the Communications Law of the European Community: On a Path of Harmony or Discord?” *Journal of World Trade* 41 (2007): 833–878.

113 Article 13.3 TPP.

114 Article 13.5.4 TPP.

115 Article 13.22 TPP.

116 Paragraph 2 clarifies that when a party finances the development of advanced networks, it may make its financing conditional on the use of technologies that meet its specific public policy interests. It is clarified further in a footnote that “advanced networks” includes broadband networks.

117 See generally Branislav Hazucha, “Technical Barriers to Trade in Information and Communication Technologies,” in *Research Handbook on the WTO and Technical Barriers to Trade*, ed. Tracey Epps and Michael J. Trebilcock (pp. 525–565) (Cheltenham: Edward Elgar, 2013).

diverging from the internationally agreed upon Wi-Fi.¹¹⁸ It is apparent that such measures create barriers to trade, increase compliance costs, may lead to forced disclosure of IP, or other data, and may overall harm innovation.

Annex 8-B, Section A.3 addresses such concerns. Pursuant to it, with respect to a product that uses cryptography and is designed for commercial applications,

no Party shall impose or maintain a technical regulation or conformity assessment procedure that requires a manufacturer or supplier of the product, as a condition of the manufacture, sale, distribution, import or use of the product, to: (a) transfer or provide access to a particular technology, production process or other information, for example, a private key or other secret parameter, algorithm specification or other design detail, that is proprietary to the manufacturer or supplier and relates to the cryptography in the product, to the Party or a person in the Party's territory; (b) partner with a person in its territory; or (c) use or integrate a particular cryptographic algorithm or cipher, other than where the manufacture, sale, distribution, import or use of the product is by or for the government of the Party.

The provision does not prevent law enforcement actions¹¹⁹ and does not apply to networks owned or controlled by the government,¹²⁰ or to government measures related to supervision, investigation, or examination of financial institutions or markets.¹²¹ Despite these exceptions, by banning the forced provision of encryption keys or the adoption of indigenous standards, the TPP seems to properly address this newer kind of digital trade barrier and cater well for the growing concerns of large companies like IBM and Microsoft that thrive on free data flows with less governmental intervention.

5. Comparing the TPP With Other “Mega-Regionals”

5.1 Transatlantic Trade and Investment Partnership Agreement

There is great ambition, as well as plenty of uncertainty as to the contents of the trade deal between the big trading powers of the United States and the EU. A key cross-cutting trade issue to both the TPP and the TTIP, next to comprehensive and robust market liberalisation, has been the quest for regulatory convergence that promotes more seamless and efficient trade among the partners and ensures competitiveness and business facilitation.¹²² The TTIP negotiators have repeatedly underscored this goal and have sought to reduce the differences in regulations and standards by promoting greater compatibility, transparency, and cooperation, while maintaining high levels of health, safety, and environmental protection.¹²³ They wish to develop rules, principles and new

118 See Christopher S. Gibson, “Globalization and the Technology Standards Game: Balancing Concerns of Protectionism and Intellectual Property in International Standards,” *Berkeley Technology Law Journal* 22 (2007): 1403–1484, at 1475. The case did not reach the WTO dispute settlement and was settled diplomatically, as China decided to forbear from mandating the WAPI standard.

119 TPP, Annex 8-B, Section A.5.

120 TPP, Annex 8-B, Section A.4.

121 TPP, Annex 8-B, Section A.4.

122 See e.g. Jonathan B. Wiener and Alberto Alemanno, “The Future of International Regulatory Cooperation: TTIP as a Learning Process toward a Global Policy Laboratory,” *Law and Contemporary Problems* 78 (2015): 103–136.

123 Wiener and Alemanno, “The Future of International Regulatory Cooperation.”

modes of cooperation on issues of global concern, including intellectual property and market-based disciplines addressing state-owned enterprises and discriminatory localisation barriers to trade.

Yet, there are many areas of contestation, some affecting digital trade.¹²⁴ Traditionally, ever since the days of the France-led "exception culturelle" campaign during the Uruguay Round of the WTO negotiations,¹²⁵ a major battlefield between the US and the EU has been audiovisual services.¹²⁶ These (including online media services) are presently excluded from the negotiating mandate of the European Commission, as a result of the sizeable pressure of the European Parliament. As maintained by the Parliament, this exclusion is necessary to safeguard the "cultural exception" and protect the cultural and linguistic diversity of the EU countries.¹²⁷ Public services in general have been a major source of preoccupation in recent debates in Europe.¹²⁸ Another hotly discussed and contentious topic facing intense civil society objections is intellectual property rights. The fear from the EU side is that the IP maximalist agenda of the Anti-Counterfeiting Trade Agreement,¹²⁹ as well as that of the domestically unsuccessful US legislative initiatives, the Stop Online Piracy Act and the Protect IP Act,¹³⁰ will in many aspects be replicated in the TTIP.¹³¹ Digital copyright is part of these efforts and it remains to be seen how far-reaching the adopted rules will be, especially if we consider the current efforts of the EU to reform its own copyright rules as part of its Digital Single Market Strategy.¹³² While on some issues, such as intermediaries' liability, there seems to be a move towards current US legal practice, on other issues, such as publishers' rights,¹³³ there is clear divergence.

Data protection will likely be the most contentious question, with possible spillover effects to other issue areas. Here, the approaches of the US and EU towards the protection

124 See e.g. Andrea Renda and Christopher Yoo, "Telecommunications and Internet Services: The Digital Side of the TTIP," *CEPS Special Report* No. 112, July 2015.

125 See e.g. Mira Burri, "Trade versus Culture: The Policy of Cultural Exception and the World Trade Organization," in *Palgrave Handbook of European Media Policy*, ed. Karen Donders, Caroline Pauwels and Jan Loisen (pp. 478–492) (Basingstoke: Palgrave Macmillan, 2013).

126 Burri, "Trade versus Culture."

127 European Parliament, Resolution on EU Trade and Investment Negotiations with the United States of America (2013/2558(RSP)), paras 11–12.

128 See e.g. Markus Krajewski and Britta Kynast, *Impact of the Transatlantic Trade and Investment Partnership (TTIP) on the Legal Framework for Public Services in Europe* (Düsseldorf: Hans-Böckler-Stiftung, 2014).

129 Peter K. Yu, "ACTA and Its Complex Politics," *WIPO Journal* 3 (2011): 1–16; Daniel Gervais, "Country Clubs, Empiricism, Blogs and Innovation: The Future of International Intellectual Property Norm Making in the Wake of ACTA," in *Trade Governance in the Digital Age*, ed. Mira Burri and Thomas Cottier (pp. 323–343) (Cambridge: Cambridge University Press, 2012); Levine, "Bring in the Nerds."

130 Stop Online Piracy Act (SOPA), H.R. 3261 and Protect IP Act (Preventing Real Online Threats to Economic Creativity and Theft of Intellectual Property Act, or PIPA), S. 968. The SOPA/PIPA legislation aimed in essence to expand the ability of US law enforcement to fight online trafficking, also beyond the US national jurisdiction. After opposition by academics, corporations and civil society representatives, both bills were dropped. See e.g. Mark A. Lemley, David S. Levine, and David G. Post, "Don't Break the Internet," *Stanford Law Review* 64 (2012): 34–38.

131 Flynn, Baker, Kaminski and Koo, "The US Proposal."

132 European Commission, A Digital Single Market Strategy for Europe, COM(2015) 192 final, 6 May 2015.

133 See European Commission, Proposal for a Directive of the European Parliament and of the Council on copyright in the Digital Single Market, COM(2016) 593 final.

of privacy are at this stage hardly reconcilable.¹³⁴ The new EU General Data Protection Regulation,¹³⁵ which will be enforced as of May 2018, subscribes to a particularly high standard of privacy protection, as embedded in the Charter of Fundamental Rights of the EU. It seeks to endorse this not only within the borders of the Union but also for cross-border data transfers containing personal data.¹³⁶ The leaked TTIP text exposes yet again the divergence between the US and the EU on data protection. There is no agreement on data flows between the negotiating parties, despite signals of US willingness to tolerate the exclusion of audiovisual media services from the scope of the trade deal. Overall, the leaked TTIP reveals no substantial progress on digital issues so far. E-labelling (setting standards for providing product information to consumers in electronic format that replaces labels) and e-accessibility (facilitating ICT use for people with disabilities) seem to be the low hanging fruit but these are issues of very little impact on the practical reality of digital trade.

5.2 Trade in Services Agreement

A third important digital trade agreement evolving outside the WTO umbrella is the Trade in Services Agreement (TiSA) currently being negotiated. The TiSA is meant to provide deeper market access in the services sector, where liberalisation is still quite low, despite the substantial gains from trade expected.¹³⁷ TiSA, launched in early 2013, has been supported by the United States, the EU, Japan, and other countries that are part of the group "Really good friends of services."¹³⁸ The impact of TiSA can be substantial because not only do some of the most important market economies support TiSA, in effect covering over 70 percent of world services trade, but TiSA also aims at high market access commitments and at adding a layer of deeper regulatory arrangements.¹³⁹

Despite a number of leaks,¹⁴⁰ as well as publication of some countries' offers,¹⁴¹ the final outcome is uncertain. It appears so far that TiSA has adopted a hybrid approach towards commitments. This entails a negative type of commitment for MFN and NT but positive for market access. Parties are also discussing the inclusion of so-called "standstill" and "ratchet" clauses. Under a standstill clause, members would agree not to create new obstacles to services trade and preserve the

134 See e.g. Paul M. Schwartz, "The EU–US Privacy Collision: A Turn to Institutions and Procedures," *Harvard Law Review* 126 (2013): 1966–2009; Paul M. Schwartz and Daniel J. Solove, "Reconciling Personal Information in the United States and European Union," *California Law Review* 102 (2014): 877–916.

135 Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L [2016] 119/1.

136 See e.g. Mira Burri and Rahel Schär, "The Reform of the EU Data Protection Framework: Outlining Key Changes and Assessing Their Fitness for a Data-Driven Economy," *Journal of Information Policy* 6 (2016): 479–511.

137 For an overview, see Juan A. Marchetti and Martin Roy (eds), *Opening Markets for Trade in Services: Countries and Sectors in Bilateral and WTO Negotiations* (Cambridge: Cambridge University Press, 2009).

138 Current negotiating parties include Australia, Canada, Chile, Chinese Taipei (Taiwan), Colombia, Costa Rica, Hong Kong, Iceland, Israel, Japan, Liechtenstein, Mexico, New Zealand, Norway, Pakistan, Panama, Paraguay, Peru, South Korea, Switzerland, Turkey, the US and the EU.

139 Juan A. Marchetti and Martin Roy, "The TiSA Initiative: An Overview of Market Access Issues," *WTO Staff Working Paper ERSD-2013-11* (2013), 27.

140 See Wikileaks, at <https://wikileaks.org/tisa/>.

141 See e.g. for Switzerland, the information provided by the State Secretariat for Economic Affairs, https://www.seco.admin.ch/seco/de/home/Aussenwirtschaftspolitik_Wirtschaftliche_Zusammenarbeit/Wirtschaftsbeziehungen/Internationaler_Handel_mit_Dienstleistungen/TISA/Schweiz_und_TiSA.html.

current level of liberalisation. With the ratchet clause, in cases where one participating member improves services market access on its own, that newly liberalised access would then be accorded to other parties to the deal, and become permanent.¹⁴²

In terms of the depth of liberalisation, there is an effort to reach the level of best FTA commitments in all sectors. Even if this is achieved, it may not be sufficient to address the pertinent digital trade issues. The reason is that, despite the far-reaching US FTAs, past FTA negotiations involving other TiSA participants have not made significant progress in liberalising sensitive sectors, such as audiovisual services. The EU and Canada are highly unlikely to give up their policy space in these sectors,¹⁴³ which again brings back the "old" GATS problems and the trade versus culture dilemma of the Uruguay Round of negotiations.¹⁴⁴ The Swiss initial offer under TiSA confirms this, as Switzerland has tabled no GATS-plus commitments for audiovisual services.¹⁴⁵

Regarding digital trade specifically, there is a willingness to curb protectionism and ban localisation requirements, be it with regard to presence, technology or content. We see expressions of this willingness in the texts of the annex on telecommunications, which reiterates and goes beyond the WTO Annex on Telecommunications and the Reference Paper. The negotiations have also evolved over time and this is discernible in the newer texts of the chapter on electronic commerce and the annex on localisation measures.

The chapter on electronic commerce has a broad scope and should apply to measures affecting trade in services using or enabled by electronic means. Financial services and government procurement are likely to be excluded, although the United States is pushing for softer language in this respect. There is still much contestation on the article on the movement of information. The US, together with Japan and Canada, suggest: "No Party may prevent a service supplier of another Party from transferring, accessing processing or storing information, including personal information, within or outside the Party's territory, where such activity is carried out in connection with the conduct of the service supplier's business."¹⁴⁶ Many countries consider exceptions or conditions to this ban, so as to allow more domestic flexibility. For instance, Hong Kong has proposed: "There should be a balance between free movement of information across borders and protection of personal data. Advancing the former cause should be without prejudice to safeguarding the latter right."¹⁴⁷ In Hong Kong, the Personal Data Ordinance requires that certain conditions (e.g. written consent) be met before a transfer of personal data to a place outside Hong Kong can be made. Switzerland subscribes to a more general but also very broad exception in the sense that each party can apply its own regulatory regime concerning the transfer of data and personal data by electronic means.¹⁴⁸ The

142 For a good explanation, see Submission by Switzerland: Possible Operationalization of a Hybrid Schedule, as well as Submission by Switzerland: Provisions on Scheduling of Commitments, Really Good Friends—Meeting of 29 April to 3 May 2013, Agreement on Trade in Services (TiSA), 30 April 2013.

143 Marchetti and Roy, *Opening Markets for Trade in Services*, 18.

144 Burri, "Trade versus Culture."

145 See Switzerland, Swiss Initial Offer, Really Good Friends, Trade in Services Agreement, 30 January 2014.

146 Article 2.1 TiSA chapter on Electronic Commerce.

147 Article 2.1 TiSA chapter on Electronic Commerce, proposal by Hong Kong.

148 Article 2.2 TiSA chapter on Electronic Commerce. See also Submission by Switzerland: Provisions on Trade-related Principles for Information and Communication Technology Services (ICT Principles), Really Good Friends—Meeting of 18 March 2013, Plurilateral Initiative on Trade in Services, 13 February 2013.

diverging approaches between the TiSA parties with regard to data protection are further exposed in the following provisions on online consumer protection and personal information protection.¹⁴⁹ While the language on spam is similarly, as under the TPP, rather weak,¹⁵⁰ the provisions on open networks, network access and use, and on location of computing facilities, although still contentious, reveal an effort to create more binding rules.¹⁵¹ Article 7 proposes:

Each Party recognises that consumers in its territory, subject to applicable laws, and regulations, should be able to: (a) access and use services and applications of their choice available on the Internet, subject to reasonable network management; (b) connect their choice of devices to the Internet, provided that such devices do not harm the network; and (c) have access to information on network management practices of their Internet access service suppliers.¹⁵²

This language, if it survives the negotiations, has stronger elements on net neutrality than the accepted TPP norm. With regard to the location of computing facilities addressed in Article 8, the United States is pushing for a ban on requiring a service supplier, as a condition for supplying a service, to use or locate computing facilities in the party's territory.¹⁵³ Again, the provision is under debate. There seems to be more agreement with regard to the prohibition of customs duties imposed on electronic transactions (Article 10), as well as to the softer norms on international cooperation (Article 11) and on electronic authentication and signatures (Article 9).

An important breakthrough in the TiSA negotiations with regard to digital trade has been the annex on localisation measures. While it is framed in a broader, technologically neutral manner, it addresses important digital economy issues and the localisation requirement increasingly used in this context. The annex seeks to ban local presence, local context, and other performance requirements. To allow such far-reaching commitments, the annex provides for a "grandfathering" clause for those localisation measures that are inscribed in the schedules of specific commitments, as well as for exceptions on security grounds, for financial services, and government procurement.¹⁵⁴

There is much promise in these provisions to horizontally address core issues of digital trade and provide for legal certainty for the free flow of data. However, as many controversial questions remain open and as the political climate is hard to predict, the outcome of the TiSA negotiations is uncertain.

6. Appraisal of the TPP in the Context of Digital Trade Governance

In the preceding sections, we saw that in the face of failing legal adaptation under the auspices of the WTO, much has happened in preferential trade venues, and the TPP has been the most ambitious effort to address digital economy issues. It includes a number of WTO-plus commitments and detailed rule-making of relevance to cross-border delivery of electronic services. In addition

149 Articles 3 and 4 TiSA chapter on Electronic Commerce.

150 Article 5 TiSA chapter on Electronic Commerce.

151 Articles 7 and 8 TiSA chapter on Electronic Commerce.

152 Article 7 TiSA chapter on Electronic Commerce.

153 Article 8 TiSA chapter on Electronic Commerce.

154 Articles X.4 and X.5 TiSA annex on Localization Measures.

and perhaps more importantly, certain non-trade issues, such as consumer protection, privacy, and safeguards for the free flow of data, are addressed in an attempt to achieve a basic level of harmonisation, or at least legal interoperability, in the field of digital governance. When compared with the ongoing negotiations under the auspices of TTIP and TiSA, it can be argued that the TPP standards are particularly high and unlikely to be reached by the mentioned agreements. The TPP template with regard to digital trade is distinct not only in its high standards but also in the breadth of issues covered that matter more or less immediately for the contemporary digital economy. The TPP has also been innovative. Some research shows that the language of the TPP electronic commerce chapter overlaps only some 27 percent with the language of previous US FTAs.¹⁵⁵ Although quantity is not a direct signal as to quality, in the depth of the commitments undertaken we did see some new as well as far-reaching provisions. The clear ban on localisation measures and the subscription to a binding norm on free data flows with a potentially broad scope of application are unprecedented. Restrictions on forced disclosure of source code and on encryption requirements are entirely novel.

Despite all these virtues, legal certainty may nonetheless be lacking, primarily because the TPP does not provide answers to some of the contestations intrinsic to the digital space, such as that between free data flows and data protection. Nor does it put forward a clear exceptions rule that may appropriately reconcile economic and non-economic interests, while ensuring non-discrimination.

Apart from this legal design critique, it should be pointed out that the nature of the digital economy and its demands for seamlessness and interoperability¹⁵⁶ is such that the multilateral forum makes more sense. So, states acting as legal entrepreneurs must contemplate ways of testing discrete rules and arrangements with regard to digital trade in FTAs and subsequently multilateralise the progress made there.¹⁵⁷ Now, after the withdrawal of the United States from the TPP,¹⁵⁸ there may be a window of opportunity opening in this regard. The efforts under the WTO e-commerce programme may be reinigorated towards some actual results.¹⁵⁹ The TPP template for digital trade will probably diffuse, even if these efforts yet again prove futile, as signalled by the recent amendment of the Singapore–Australia FTA,¹⁶⁰ which imitates the TPP electronic commerce chapter. We can only hope that in future agreements the line between data protection and data protectionism will be more clearly drawn, so as to allow digital innovation while safeguarding important public interest objectives, such as the protection of privacy.¹⁶¹

155 Todd Allee and Andrew Lugg, "Who Wrote the Rules for the Trans-Pacific Partnership?" *Research and Politics* (2016): 1–9.

156 Gasser and Palfrey, "Fostering Innovation and Trade."

157 Herman suggests "bottom-up multilateralisation," whereby FTAs' e-commerce undertakings and provisions are extended to a larger number of partners, and "top-down multilateralisation," which advances e-commerce provisions, commitments and common learning to the WTO level. See Lior Herman, "Multilateralising Regionalism: The Case of E-Commerce," *OECD Trade Policy Working Paper* 99 (2010); also Robert Howse, "Regulatory Cooperation, Regional Trade Agreements, and World Trade Law: Conflict or Complementarity?" *Law and Contemporary Problems* 78 (2015): 137–151.

158 The White House Office of the Press Secretary, Presidential Memorandum Regarding Withdrawal of the United States from the Trans-Pacific Partnership Negotiations and Agreement, 23 January 2017, <https://www.whitehouse.gov/the-press-office/2017/01/23/presidential-memorandum-regarding-withdrawal-united-states-trans-pacific>.

159 See e.g. WTO Work Programme on E-Commerce, Non-Paper from the United States, WTO Doc. JOB/GC/94 (2016); WTO Work Programme on E-Commerce, Non-Paper from Brazil, WTO Doc. JOB/GC/98 (2016); WTO Work Programme on E-Commerce, Communication from Canada, Chile, Colombia, Côte d'Ivoire, the European Union, the Republic of Korea, Mexico, Paraguay and Singapore, Trade Policy, the WTO and the Digital Economy, WTO Doc. JOB/GC/97/Rev.1 (2016).

160 See Agreement to Amend the Singapore–Australia Free Trade Agreement (signed 13 October 2016), Chapter 14, <http://dfat.gov.au/trade/agreements/safta/official-documents/Pages/default.aspx>.

161 Chander and Lê, "Data Nationalism."

The RCEP and Intellectual Property Normsetting in the Asia-Pacific

Peter K. Yu

1. Introduction*

As far as mega-regional trade agreements and non-multilateral intellectual property normsetting are concerned, considerable media, policy and scholarly attention has been devoted to the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership (TTIP). Receiving significantly, and unduly, less attention is the Regional Comprehensive Economic Partnership (RCEP), which is currently being negotiated between Australia, China, India, Japan, New Zealand, South Korea and the 10 members of the Association of Southeast Asian Nations (ASEAN).¹ Launched in November 2012 under the ASEAN+6 framework, the RCEP negotiations built on past trade and non-trade discussions between ASEAN and its six major Asia-Pacific neighbours.

Although the RCEP has been seldom analysed until recently, its negotiations are important for at least three reasons. First, this partnership is important globally. The 16 RCEP negotiating parties "account for almost half of the world's population, almost 30 per cent of global GDP [gross domestic product] and over a quarter of world exports."² These figures compare favourably with those relating to the TPP, which was originally created to cover "40% of global GDP and some 30% of worldwide trade in both goods and services."³ Second, the RCEP is highly important within the Asia-Pacific region. Once established, this partnership will cover not only China and India but also two high-income Asian economies (Japan and South Korea) and six other TPP partners (Australia, Brunei Darussalam, Malaysia, New Zealand, Singapore and Vietnam). Third, the RCEP could serve as a viable alternative to the TPP and has become increasingly important following the United States' decision to withdraw from the pact. Given the Trump administration's position and the other negotiating parties' inability hitherto to resuscitate the partnership,⁴ the TPP has now seemingly been placed on life support.⁵ Unless the remaining partners can move the pact forward without the participation of the United States, the TPP Agreement will likely meet the same fate as the widely criticised Anti-Counterfeiting Trade Agreement (ACTA). Despite its adoption in April 2011, ACTA has thus far been ratified by only one country—Japan, the country of depository.

This article examines the RCEP with a focus on the intellectual property norms it seeks to develop. It begins by briefly discussing the partnership's historical origins and ongoing negotiations. It then examines the latest leaked draft of the RCEP intellectual property chapter. This article concludes by exploring three scenarios concerning the chapter's future. A close examination of these scenarios is

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- 1 The 10 current ASEAN members are Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam. They negotiate as a bloc in the RCEP negotiations.
- 2 Department of Foreign Affairs and Trade (Australia), "Regional Comprehensive Economic Partnership," <http://dfat.gov.au/trade/agreements/rcep/pages/regional-comprehensive-economic-partnership.aspx>.
- 3 David A. Gantz, "The TPP and RCEP: Mega-Trade Agreements for the Pacific Rim," *Arizona Journal of International and Comparative Law* 33, no. 1 (2016): 59.
- 4 Shortly after the United States withdrew, Australia, Japan, Singapore and New Zealand explored ways to resuscitate the agreement. These efforts, however, did not bear fruit. At the time of writing, only Japan and New Zealand have ratified the agreement. No other country is actively pursuing any effort to do the same. Nevertheless, at a May 2017 APEC meeting in Hanoi, Vietnam, the remaining TPP partners reaffirmed their commitment to the pact and agreed to explore the development of a process to move it forward even without the participation of the United States.
- 5 Peter K. Yu, "Thinking about the Trans-Pacific Partnership (and a Mega-regional Agreement on Life Support)," *SMU Science and Technology Law Review* 21 (2017): forthcoming.

instructive, as it will shed light on the future of intellectual property normsetting in the Asia-Pacific region.

2. Historical Origins and Ongoing Negotiations

Although the RCEP negotiations were launched in November 2012, more than two years after the beginning of the TPP negotiations, they were established not solely as a reactive response or defensive measure. Instead, the RCEP negotiations built on prior efforts at various fora to facilitate economic integration and cooperation in the Asia-Pacific region. These fora include ASEAN+3 (ASEAN, China, Japan and South Korea), ASEAN+6 (ASEAN+3, Australia, India and New Zealand) and the Asia-Pacific Economic Cooperation (APEC) Forum.

In October 2001, the East Asian Vision Group, which was charged with “develop[ing] a road map to guide future regional cooperation,”⁶ recommended to ASEAN+3 leaders the establishment of the East Asia Free Trade Area.⁷ Although China strongly supported this proposal, Japan and other Asian countries had serious reservations about China’s potential dominance in this pact.

Five years later, Japan advanced an alternative proposal concerning the Comprehensive Economic Partnership in East Asia.⁸ Covering not only ASEAN+3 members but also the three remaining ASEAN+6 members (Australia, India and New Zealand), this partnership would dilute China’s influence in the regional pact while adding to the mix a major source of natural resources—namely, Australia.

Around that time, APEC members also actively explored regional integration and cooperation efforts. In November 2006, APEC began studying the concept of a Free Trade Area of the Asia-Pacific (FTAAP).⁹ Three years later, APEC leaders pledged to create an agreement to realise this conceptual vision. As Fred Bergsten observed at that time, the proposed pact could provide a wide variety of benefits to both the Asia-Pacific region and the global economy.¹⁰ Since then, APEC leaders have endorsed various declarations laying down the incremental steps needed to realise the FTAAP. These documents include the “Pathways to FTAAP,” which was adopted in November 2010, and the “Beijing Roadmap for APEC’s Contribution to the Realization of the FTAAP,” which was released four years later.¹¹

In November 2011, ASEAN, with the support of both China and Japan, proposed to merge the initiatives concerning the East Asia Free Trade Area and the Comprehensive Economic Partnership

6 Mark Beeson, *Institutions of the Asia-Pacific: ASEAN, APEC and Beyond* (London: Routledge, 2009), 78.

7 Shujiro Urata, “Japan’s FTA Strategy and a Free Trade Area of the Asia-Pacific,” in *An APEC Trade Agenda? The Political Economy of a Free Trade Area of the Asia-Pacific*, ed. Charles E. Morrison and Eduardo Pedrosa (Singapore: ISEAS, 2007), 106.

8 Meredith Kolsky Lewis, “Achieving a Free Trade Area of the Asia-Pacific: Does the TPP Present the Most Attractive Path?” in *The Trans-Pacific Partnership: A Quest for a Twenty-First Century Trade Agreement*, ed. C. L. Lim, Deborah Kay Elms and Patrick Low (Cambridge: Cambridge University Press, 2012), 228; Urata, “Japan’s FTA Strategy,” 106–107.

9 Lewis, “Achieving a Free Trade Area of the Asia-Pacific,” 223.

10 C. Fred Bergsten, “A Free Trade Area of the Asia-Pacific in the Wake of the Faltering Doha Round: Trade Policy Alternatives for APEC,” in *An APEC Trade Agenda?*, ed. Morrison and Pedrosa, 32–33.

11 “Pathways to FTAAP,” 14 November 2010, http://www.apec.org/meeting-papers/leaders-declarations/2010/2010_aelm/pathways-to-ftaap.aspx; “The Beijing Roadmap for APEC’s Contribution to the Realization of the FTAAP,” 11 November 2014, http://www.apec.org/Meeting-Papers/Leaders-Declarations/2014/2014_aelm/2014_aelm_annexa.aspx.

in East Asia to form the RCEP.¹² At the 19th ASEAN Summit in Bali, Indonesia, ASEAN leaders adopted the "Framework for Regional Comprehensive Economic Partnership."¹³ Formal negotiations were finally launched in November 2012 at the 21st ASEAN Summit in Phnom Penh, Cambodia. As ASEAN+6 leaders declared at that time, the RCEP negotiations were established to

Achieve a modern, comprehensive, high-quality and mutually beneficial economic partnership agreement establishing an open trade and investment environment in the region to facilitate the expansion of regional trade and investment and contribute to global economic growth and development; [and]

Boost economic growth and equitable economic development, advance economic cooperation and broaden and deepen integration in the region through the RCEP, which will build upon our existing economic linkages.¹⁴

Although the ASEAN+6 leaders' joint declaration did not specifically mention the TPP, there is no denying that the development of this United States–led partnership has greatly accelerated the RCEP negotiations. The latter negotiations were particularly urgent when two major ASEAN+6 economies, China and India, were intentionally excluded from the TPP.¹⁵ Also excluded were other key ASEAN+6 members, such as Indonesia, the Philippines, South Korea and Thailand. While some of these countries had been invited to the TPP negotiations but declined to participate,¹⁶ others were simply ignored or left out.

Undoubtedly, there were both economic and non-economic reasons for not inviting these countries to the TPP negotiations. Yet, the outcome was the same: while the excluded countries could still join the partnership once it had been established, they would not be able to shape the standards involved. Instead, they could only accept the final terms as agreed upon by the original negotiating parties. Such an outcome was highly unattractive, if not unacceptable, to large Asian economies such as China and India. It is therefore unsurprising that these countries have turned their time, attention and energy towards the RCEP to develop regional standards based on their own preferences and experiences.¹⁷

12 Shintaro Hamanaka, "Trans-Pacific Partnership versus Regional Comprehensive Economic Partnership: Control of Membership and Agenda Setting," *Asian Development Bank Working Paper Series on Regional Economic Integration* 146 (2014): 11, https://aric.adb.org/pdf/workingpaper/WP146_Hamanaka_Trans-Pacific_Partnership.pdf; Ganeshan Wignaraja, "The Regional Comprehensive Economic Partnership: An Initial Assessment," in *New Directions in Asia-Pacific Economic Integration*, ed. Tang Guoqiang and Peter A. Petri (Honolulu: East-West Center, 2014), 94.

13 "ASEAN Community in a Global Community of Nations': Chair's Statement of the 19th ASEAN Summit," 17 November 2011, <http://www.asean.org/wp-content/uploads/archive/documents/19th%20summit/CS.pdf>; "ASEAN Framework for Regional Comprehensive Economic Partnership," 12 June 2012, http://asean.org/?static_post=asean-framework-for-regional-comprehensive-economic-partnership.

14 "Joint Declaration on the Launch of Negotiations for the Regional Comprehensive Economic Partnership," 20 November 2012, <http://dfat.gov.au/trade/agreements/rcep/news/Documents/joint-declaration-on-the-launch-of-negotiations-for-the-regional-comprehensive-economic-partnership.pdf>.

15 Peter K. Yu, "TPP and Trans-Pacific Perplexities," *Fordham International Law Journal* 37, no. 4 (2014): 1132–1163.

16 Yoo Choonsik, "South Korea Moves Closer to Joining TPP Trade Talks," *Reuters*, 29 November 2013, <http://www.reuters.com/article/us-korea-trade-tpp-idUSBRE9AS06M20131129>; Alan Raybould, "Thailand Says to Join Trans-Pacific Partnership Trade Talks," *Reuters*, 18 November 2012, <http://www.reuters.com/article/us-asia-obama-trade-idUSBRE8AH06R20121118>.

17 Hamanaka, "Trans-Pacific Partnership," 12–15.

At the time of writing, ASEAN+6 members have already entered into 19 rounds of negotiations. Since the first round in May 2013 in Bandar Seri Begawan, Brunei Darussalam, negotiations have been held around the Asia-Pacific region—in Brisbane, Kuala Lumpur, Nanning, Singapore, Greater Noida, Kyoto, Bangkok, Nay Pyi Taw, Busan, Perth, Auckland, Ho Chi Minh City, Tianjin, Kobe, Manila and Hyderabad. Seven ministerial meetings, including both regular and intersessional, have also been held in Bandar Seri Begawan, Nay Pyi Taw, Kuala Lumpur, Kuala Lumpur, Vientiane, Cebu and Hanoi, respectively.

Although no draft text has thus far been officially released to the public, Knowledge Ecology International made the leaked texts of some chapters available online. Among these leaked drafts are the 15 October 2015 version of the proposed RCEP intellectual property chapter,¹⁸ the original proposed intellectual property chapters from ASEAN, India, Japan and South Korea,¹⁹ as well as the proposed RCEP investment chapter.²⁰ Even though this investment chapter does not focus specifically on intellectual property issues, the investor–state dispute settlement mechanism it seeks to establish will have serious ramifications for regional intellectual property developments.

Once the RCEP Agreement is completed, the final text is anticipated to cover a wide range of areas, including “trade in goods, trade in services, investment, economic and technical cooperation, intellectual property, competition [and] dispute settlement.”²¹ Beyond these areas, working or sub-working groups have also been established to address rules of origin; customs procedures and trade facilitation; legal and institutional issues; sanitary and phytosanitary measures; standards, technical regulations and conformity assessment procedures; electronic commerce; financial services; and telecommunications.²²

Given this large number of working and sub-working groups, it remains to be seen whether their establishment will result in the creation of standalone chapters in each specific area. Regardless of how the final agreement is structured, however, that agreement is likely to be as ambitious as the TPP Agreement, whose final text contains 30 different chapters. In light of this expansive and comprehensive coverage, questions have already been raised about the potential rivalry, compatibility and complementarity between these two mega-regional agreements.

3. Draft Intellectual Property Chapter

When ASEAN leaders adopted the “Framework for Regional Comprehensive Economic Partnership” in November 2011, it was unclear—at least to outsiders—whether the agreement would include an intellectual property chapter. Such potential omission was plausible considering the wide variation in intellectual property protection and enforcement among ASEAN+6 members.

18 “2015 Oct 15 Version: RCEP IP Chapter,” *Knowledge Ecology International*, 19 April 2016, <http://keionline.org/node/2472>.

19 “2014 Oct 3 Version: Korea Proposal for RECP IP Chapter (Regional Comprehensive Economic Partnership),” *Knowledge Ecology International*, 3 June 2015, <http://keionline.org/node/2239>; “2014 Oct 3 Version: Regional Comprehensive Economic Partnership, Japan IPR Proposals, RCEP,” *Knowledge Ecology International*, 9 February 2015, <http://keionline.org/node/2173>; “2014 Oct 10: ASEAN Proposals for RECP IP Chapter, also India,” *Knowledge Ecology International*, 8 June 2015, <http://keionline.org/node/2241>.

20 “2015 Oct 16 Version: RCEP Draft Text for Investment Chapter,” *Knowledge Ecology International*, 21 April 2016, <http://keionline.org/node/2474>.

21 “Guiding Principles and Objectives for Negotiating the Regional Comprehensive Economic Partnership,” 30 August 2012, <http://dfat.gov.au/trade/agreements/rcep/Documents/guiding-principles-rcep.pdf>.

22 Department of Foreign Affairs and Trade (Australia), “Previous Negotiating Rounds and Ministerial Meetings,” <http://dfat.gov.au/trade/agreements/rcep/news/Pages/previous-negotiating-rounds-and-ministerial-meetings.aspx>.

By the time ASEAN+6 leaders adopted the "Guiding Principles and Objectives for Negotiating the Regional Comprehensive Economic Partnership" (Guiding Principles) in August 2012, however, it became clear that the RCEP Agreement would contain an intellectual property chapter, or at least some intellectual property provisions. As Part V of the Guiding Principles declared, "The text on intellectual property in the RCEP will aim to reduce [intellectual property]-related barriers to trade and investment by promoting economic integration and cooperation in the utilization, protection and enforcement of intellectual property rights."

At the third round of the RCEP negotiations in Kuala Lumpur in January 2014, the negotiators finally agreed to establish a working group on intellectual property. As shown by leaked documents, ASEAN, India, Japan and South Korea began submitting draft negotiating texts for the proposed intellectual property chapter only shortly before the sixth round of the RCEP negotiations in Greater Noida, India in December 2014. According to the brief meeting notes that the Australian Department of Foreign Affairs and Trade provides online, this negotiation round—which followed immediately from the Second RCEP Ministerial Meeting in Nay Pyi Taw, Myanmar—was the first time the working groups "made progress on draft chapter text."²³ It is therefore very likely that draft negotiating texts only began to emerge at this stage, even though the meeting notes did mention that intellectual property issues were discussed as early as the second round.

At the time of writing, the draft text of the RCEP intellectual property chapter has not yet been officially released. Nevertheless, several documents have already been leaked to the public via the internet. Based on the latest leaked text, dated 15 October 2015, the intellectual property chapter may include 13 sections: (1) general provisions and basic principles; (2) copyright and related rights; (3) trademarks; (4) geographical indications; (5) patents; (6) industrial designs; (7) genetic resources, traditional knowledge and folklore; (8) unfair competition; (9) enforcement of intellectual property rights; (10) cooperation and consultation; (11) transparency; (12) transitional period and transitional arrangements; and (13) procedural matters.

Although this article does not offer detailed explorations of each of these sections, it highlights the key provisions concerning the four main branches of intellectual property law as well as the enforcement of intellectual property rights. When analysing the draft RCEP intellectual property chapter, it is worth recalling that other draft RCEP chapters, such as those on investment and electronic commerce, could include provisions relevant to intellectual property rights. For example, the TPP investment chapter, which seeks to establish an investor–state dispute settlement mechanism, became highly controversial after Eli Lilly and Philip Morris used similar mechanisms in bilateral or regional trade agreements to address their intellectual property disputes.²⁴

3.1 Copyright and Related Rights

The draft RCEP intellectual property chapter includes the usual language found in free trade agreements (FTAs) requiring the accession to the two internet treaties of the World Intellectual

23 Department of Foreign Affairs and Trade (Australia), "Previous Negotiating Rounds and Ministerial Meetings."

24 On these disputes and the use of the investor–state dispute settlement mechanism, see Cynthia M. Ho, "Sovereignty under Siege: Corporate Challenges to Domestic Intellectual Property Decisions," *Berkeley Technology Law Journal* 30, no. 1 (2015): 213–304; Ruth L. Okediji, "Is Intellectual Property 'Investment'? *Eli Lilly v. Canada* and the International Intellectual Property System," *University of Pennsylvania Journal of International Law* 35, no. 4 (2014): 1121–1138; Peter K. Yu, "The Investment-Related Aspects of Intellectual Property Rights," *American University Law Review* 66, no. 3 (2017): 829–910.

Property Organization (WIPO)—the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty (Draft Article 1.7.6(g)–(h)). Going beyond the terms of the TPP Agreement, the draft chapter also requires accession to the Beijing Treaty on Audiovisual Performances, the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (Rome Convention) and the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled (Draft Article 1.7.6(h)–(*ibis*)).

In addition, the draft RCEP intellectual property chapter includes the usual provisions on technological protection measures and electronic rights management information (Draft Articles 2.3, 2.3*bis* and 2.3*ter*), which are both significantly shorter and more flexible than their counterparts in the TPP Agreement. Targeting online streaming and other new means of digital communication, the draft chapter also includes provisions addressing the unauthorised communication, or the making available, of a copyright work to the public (Draft Article 2.1.1–2). The push for such provisions is understandable considering the recent copyright infringement litigation concerning works disseminated through streaming or other digital technologies.²⁵

Among the negotiating parties, there was some effort—notably by Australia—to push for stronger language on copyright limitations and exceptions beyond the mere recitation of the three-step test in the TRIPS Agreement and the WIPO Copyright Treaty. Article 2.5.3 of the leaked draft states:

Each party shall endeavour to provide an appropriate balance in its copyright and related rights system by providing limitations and exceptions ... for legitimate purposes including education, research, criticism, comment, news reporting, libraries and archives and facilitating access for persons with disability.

The purposes listed in this provision are very similar to those found in the preamble of the US fair use provision.²⁶

Like the TPP intellectual property chapter, the draft RCEP chapter includes a provision prohibiting government use of infringing computer software (Draft Article 2.4). Unlike the TPP chapter, however, the RCEP chapter does not extend the copyright term beyond the life of the author plus 50 years—the minimum required by the Berne Convention for the Protection of Literary and Artistic Works. The draft RCEP chapter also does not include detailed TPP-like provisions on internet service providers, secondary liability for copyright infringement, and the notice-and-takedown mechanism (although those provisions could easily have been negotiated as part of the yet-to-be-disclosed electronic commerce chapter, if that chapter indeed exists).

To the disappointment of consumer advocates and civil society organisations, South Korea proposed language requiring countries to “take effective measures to curtail repetitive infringement of copyright and related rights on the Internet or other digital network” (Draft Article 9*quinquies*.3). In addition, Japan called for the disclosure of information concerning the accounts of allegedly infringing internet subscribers (Draft Article 9*quinquies*.4). It further advanced a footnote supporting

25 Among the leading cases in this area are *American Broadcasting Companies v. Aereo, Inc.* before the US Supreme Court, *ITV Broadcasting Ltd v. TVCatchup Ltd* before the Court of Justice of the European Union and the “Maneki TV” case before the Japanese Supreme Court.

26 Copyright Act 1976 17 USC § 107.

"a regime providing for limitations on the liability of, or on the remedies available against, online service providers while preserving the legitimate interests of [the] right holder" (Draft Article 9*quinquies*.2, fn. 43).

Even more disturbing, the draft RCEP intellectual property chapter offers stronger and more expansive protection to broadcasters than the TPP intellectual property chapter, covering such issues as the unauthorised retransmission of television signals over the internet (Draft Article 2.6). As Jeremy Malcolm commented,

Based on the current text proposals, [the] RCEP may actually impose more stringent protections for broadcasters than the TPP does. The TPP allows authors, performers and producers to control the broadcast of their work, but it does not bestow any independent powers over those works upon broadcasters. [The] RCEP, in contrast, could create such new powers; potentially providing broadcasters with a 50 year monopoly over the retransmission of broadcast signals, including retransmission of those signals over the Internet.²⁷

3.2 Trademarks

The draft RCEP intellectual property chapter includes the usual language requiring accession to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks, the Singapore Treaty on the Law of Trademarks and the Trademark Law Treaty (Draft Article 1.7.6(d)–(e)). The draft chapter also includes provisions broadening the protectable subject matter of trademark, thereby extending protection to sound and scent marks and signs in three-dimensional shapes (Draft Article 3.1.2–3).

In addition, the draft RCEP intellectual property chapter covers the procedural improvements relating to trademark application and registration (Draft Articles 3.4, 3.5 and 3.5*bis*), including the maintenance of "a trademark classification system that is consistent with the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks" (Draft Article 3.3). The draft chapter, however, does not include extensive TPP-like language on domain names, in particular names in country-code top-level domains.

Among the RCEP negotiating parties, disagreement remains over the extent of protection for well-known trademarks, including protection through the recognition of the WIPO Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks (Draft Article 3.10.3). The parties also strongly disagree on ways to address the relationship between trademarks and geographical indications as well as the latter's eligibility for trademark protection (Draft Articles 3.2, 3.9 and 4.1). The current geographical indications provisions in the draft RCEP intellectual property chapter (Draft Section 4) are significantly shorter than those in the TPP Agreement.

3.3 Patents

The draft RCEP intellectual property chapter includes the usual FTA provisions concerning the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV), the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes

27 Jeremy Malcolm, "RCEP: The Other Closed-Door Agreement to Compromise Users' Rights," *Electronic Frontier Foundation*, 20 April 2016, <https://www.eff.org/deeplinks/2016/04/rcep-other-closed-door-agreement-compromise-users-rights>.

of Patent Procedure, the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (Draft Article 1.7.6(a), (b), (j) and (k)). The draft chapter also includes the usual—and usually ineffective—language concerning the Doha Declaration on the TRIPS Agreement and Public Health and the Protocol Amending the TRIPS Agreement, which took effect on 23 January 2017 (Draft Article 1.7.1–4).

Like those in the TPP Agreement, the draft patent provisions cover both substantive rights and procedural issues, including those concerning patent application and examination and the maintenance of “a patent classification system that is consistent with the Strasbourg Agreement Concerning the International Patent Classification” (Draft Article 5.18). Although Japan initially called for the protection of new uses for, or new forms of, known substances, directly undercutting section 3(d) of the Indian Patents (Amendment) Act of 2005,²⁸ the draft chapter does not offer such protection. Nevertheless, there remains continued disagreement between the RCEP negotiating parties over the appropriate standards concerning worldwide novelty for patents (Draft Article 5.12), patent term restoration (or extension) as compensation for the time lost due to unreasonable regulatory delay (Draft Article 5.13), patents for new plant varieties (Draft Article 5.19) and the handling of patent-related information disclosed during the one-year grace period (Draft Article 5.14).

3.4 Trade Secrets and Undisclosed Information

The relevant provisions in this area are included in both the patent and unfair competition sections of the draft RCEP intellectual property chapter. The patent section includes a TRIPS-plus provision requiring the introduction of a data exclusivity regime, which prevents the reliance on clinical trial data submitted for the marketing approval of pharmaceuticals (Draft Article 5.16). However, no provision focuses specifically on biologic medicines, a highly contentious and controversial topic during the TPP negotiations.²⁹

Compared with those in the patents section, the provisions in the unfair competition section do not seem to go significantly beyond the requirements of Article 39 of the TRIPS Agreement (Draft Section 8). Nevertheless, some civil society organisations have considered the RCEP negotiators’ “failure to explicitly address the need for exceptions to trade secret protection for whistleblowers, journalists, and other disclosures in the public interest ... [a] missed opportunity.”³⁰

3.5 Intellectual Property Enforcement

The draft RCEP intellectual property chapter includes the usual provisions concerning civil, criminal and administrative procedures and remedies, as well as provisional and border measures (Draft Section 9). Although a considerable portion of the draft language in the enforcement section merely reaffirms the existing rights and obligations under the TRIPS Agreement, the proposed language increases the obligations concerning the seizure and destruction of allegedly infringing goods, including the grant of authority to take ex officio action (Draft Article 9ter.5) and to seize or destroy

28 “Draft Text on Areas Not Covered in the Possible Common Elements from the 2nd WGIP [Working Group on Intellectual Property]: Submitted by Japan,” 3 October 2014, http://keionline.org/sites/default/files/RCEP_WGIP_JP_Revised_Draft_Text_3Oct2014.pdf.

29 Burcu Kilic and Courtney Pine, “Decision Time on Biologics Exclusivity: Eight Years Is No Compromise,” *Intellectual Property Watch*, 27 July 2015, <http://www.ip-watch.org/2015/07/27/decision-time-on-biologics-exclusivity-eight-years-is-no-compromise/>.

30 Malcolm, “RCEP.”

the materials or implements used to create infringing goods (Draft Articles 9*bis*.5, 9*bis*.6, 9*bis*.10 and 9*quater*.6). The draft chapter also seeks to empower judicial authorities to determine damages for intellectual property infringement based on lost profits, the market price or the suggested retail price (Draft Article 9*bis*.2(i)).

Like the TPP intellectual property chapter, the draft RCEP chapter calls for criminal procedures and penalties for unauthorised camcording in cinemas (Draft Article 9*quinquies*.5). Unlike their counterparts in the TPP, however, the draft RCEP provisions on criminal procedures and penalties are not extensive. They do not apply to either trade secret infringement or the circumvention of technological protection measures. The draft provisions on border measures are also less detailed and less invasive (Draft Article 9*ter*).

At the time when the leaked draft was being negotiated, the RCEP negotiating parties still strongly disagreed on the appropriate standards concerning criminal liability for aiding and abetting (Draft Article 9*quater*.4), the award of attorneys' fees (Draft Article 9*bis*.4) and obligations relating to intellectual property enforcement in the digital environment (Draft Article 9*quinquies*). Facing strong opposition from its negotiating partners, South Korea remained the lone party calling for the provision of pre-established damages (Draft Article 9*bis*.3).

3.6 Summary

When all of these five sections are taken together, much of the language in the draft RCEP intellectual property chapter resembles the language found in either the TRIPS Agreement or the TPP Agreement. Nevertheless, the draft RCEP chapter includes provisions that are different from those in these earlier agreements. For instance, it includes a section on genetic resources, traditional knowledge and folklore (Draft Section 7), which is more lengthy and detailed than the one found in the TPP Agreement. The language in that section can be traced back to India's 10-paragraph original proposal.³¹ Despite opposition from Australia, India, Japan, New Zealand and South Korea, China also proposed language on the disclosure of origin or source of genetic resources (Draft Article 7.1). The proposed language resembles Article 26 of the Chinese Patent Law, which requires patent applicants to disclose the traditional knowledge and genetic resources used in their inventions.

In addition, the RCEP negotiators debated whether Draft Section 12 should be about transitional periods and arrangements or about special and differential treatment. The recognition of the need for special and differential treatment is especially attractive to the developing country members of ASEAN+6, which have consistently benefited from such treatment. Cases in point are the early harvest programmes in the ASEAN–China Free Trade Area, which provided for the early opening of markets for select goods and services.³²

Special and differential treatment is also necessitated by the existence of least developed countries in the RCEP—namely, Cambodia, Laos and Myanmar, three of the four newest ASEAN members.³³ Thanks to a June 2013 TRIPS Council decision, the TRIPS transition period for these countries has

31 "Working Draft of IPR Chapter from India: RCEP Negotiations," <http://keionline.org/sites/default/files/06-RCEP-TNC6-WGIP3-IN-IP-Draft.pdf>.

32 Peter K. Yu, "Sinic Trade Agreements," *U.C. Davis Law Review* 44, no. 3 (2011): 996–997.

33 Shujiro Urata, "A Stages Approach to Regional Economic Integration in Asia Pacific: The RCEP, TPP, and FTAAP," in *New Directions in Asia-Pacific Economic Integration*, ed. Tang and Petri, 127.

now been extended to 1 July 2021.³⁴ The TPP, by contrast, does not include any least developed countries (even though its intellectual property chapter does offer transition periods to six of the 12 TPP partners—namely, Brunei Darussalam, Malaysia, Mexico, New Zealand, Peru and Vietnam).

In sum, the draft RCEP intellectual property chapter, like any other treaty in the middle of the negotiation process, includes a wide variety of bracketed texts. While some of the draft provisions are stronger than, or similar to, what is found in the TPP Agreement, other language is much weaker. The draft text also includes language that cannot be found in the TPP Agreement or other TRIPS-plus FTAs.³⁵ Given that “nothing is agreed until everything is agreed”³⁶—a favourite aphorism of treaty negotiators and other government officials—it remains to be seen what the intellectual property provisions in the final RCEP Agreement will look like, or even whether the agreement will include an intellectual property chapter.

Despite this uncertainty, it is quite possible that much of the bracketed language in the draft intellectual property provisions will be retained or only slightly altered at the end of the negotiations. If so, the final RCEP Agreement will indeed require the poorer ASEAN+6 members to offer higher levels of intellectual property protection and enforcement than the TRIPS Agreement currently requires. It is therefore understandable why the draft RCEP intellectual property chapter has sparked major concerns among policymakers, commentators, activists, consumer advocates and civil society organisations, especially in regard to the chapter’s potential deleterious impact on access to essential medicines and digital communication.³⁷

4. Three Future Scenarios

Although nobody at this point can predict how the RCEP negotiations will play out—or whether the final agreement, once completed, will ever enter into force—one can easily anticipate three scenarios concerning the future of the RCEP intellectual property chapter. A close examination of these scenarios is instructive, as it will shed light on the future of intellectual property normsetting in the Asia-Pacific region. This section discusses and assesses each scenario in turn.

4.1 Scenario 1: No Intellectual Property Chapter

In the first scenario, the wide disagreement among ASEAN+6 members could eventually cause them to abandon efforts to include an intellectual property chapter in the RCEP Agreement. Although highly unlikely, this scenario is still plausible in view of the diverse, highly uneven and rapidly changing intellectual property developments in the Asia-Pacific region.³⁸

34 Council for Trade-Related Aspects of Intellectual Property Rights, “Extension of the Transition Period under Article 66.1 for Least Developed Country Members: Decision of the Council for TRIPS of 11 June 2013,” 11 June 2013, IP/C/64.

35 Malcolm, “RCEP.”

36 Henrique C. Moraes, “Dealing with Forum Shopping: Some Lessons from the Negotiation on SECURE at the World Customs Organization,” in *Intellectual Property Enforcement: International Perspectives*, ed. Li Xuan and Carlos Correa (Cheltenham: Edward Elgar, 2009), 176.

37 “2015 Oct 15 Version: RCEP IP Chapter”; Malcolm, “RCEP”; “New Threat against Affordable Medicines in Trade Negotiations with India and ASEAN,” *Médecins Sans Frontières*, 21 April 2016, <http://msfaccess.org/about-us/media-room/press-releases/new-threat-against-affordable-medicines-trade-negotiations-india->

38 Peter K. Yu, “Clusters and Links in Asian Intellectual Property Law and Policy,” in *Routledge Handbook on Asian Law*, ed. Christoph Antons (London: Routledge, 2017), 148; Peter K. Yu, “Intellectual Property and Asian Values,” *Marquette Intellectual Property Law Review* 16, no. 2 (2012): 339–370.

For example, some ASEAN+6 members are far behind others in protecting and enforcing intellectual property rights. As a result, they continue to struggle with massive piracy and counterfeiting problems. Such problems not only have slowed down the development of their domestic intellectual property industries, but they have also created considerable demands on enforcement resources—resources that these countries either do not have or are reluctant to provide at the expense of other equally or more pressing public needs.³⁹

Many other ASEAN+6 members have also struggled with problems concerning access to essential medicines, educational materials, computer software, information technology, scientific and technical knowledge, and patented seeds and foodstuffs. Because higher standards of intellectual property protection and enforcement would limit access to these much-needed materials, these countries simply do not see such higher standards as in their best interest. In their view, whatever benefits those standards provide will be far outweighed by the costs of stronger intellectual property protection and enforcement and by the adverse impact in areas not driven by intellectual property industries. After all, many ASEAN+6 economies still rely heavily on agriculture and industrial production.

To further complicate matters, the very strong preference of ASEAN—and, to a lesser extent, ASEAN+6 members—to achieve solutions based on the ASEAN Way has made it particularly difficult for the more powerful ASEAN+6 members, such as Japan or South Korea, to shove their high intellectual property standards down the throats of their less powerful neighbours. As Amitav Acharya described: “The ASEAN Way ... is a claim about a process of regional interactions and cooperation based on discre[et]ness, informality, consensus building and non-confrontation styles which are often contrasted with the adversarial posturing, majority vote and other legalistic decision-making procedures in Western multilateral negotiations.”⁴⁰ While this harmonious approach to regional cooperation has facilitated diplomacy and enhanced security, it has also slowed down the negotiation process, resulting in what Mark Beeson has described as “accommodating the slowest ship in the convoy.”⁴¹ Thus, if the RCEP is to be negotiated in the ASEAN Way, it is unclear whether the RCEP participating members will eventually reach a consensus on an intellectual property chapter.

Despite all of these considerations, there are at least three reasons why the RCEP Agreement will most likely contain an intellectual property chapter in the end. First, when ASEAN+6 members adopted the Guiding Principles in August 2012, they agreed to include an intellectual property text in the RCEP Agreement (Section V). After the establishment of the Working Group on Intellectual Property at the third round of the RCEP negotiations in January 2014, that group has also worked actively to develop the draft text of the intellectual property chapter. Absent any catastrophic developments in the RCEP negotiations, the time and effort invested in this working group are just too substantial for the chapter to be abandoned at this late stage.

Second, given the importance of intellectual property industries to countries such as Australia, Japan, New Zealand and South Korea, it is very unlikely that these countries will be content with

39 Peter K. Yu, “Enforcement, Economics and Estimates,” *WIPO Journal* 2, no. 1 (2010): 3–4.

40 Amitav Acharya, *Constructing a Security Community in Southeast Asia: ASEAN and the Problem of Regional Order*, 3rd edn (London: Routledge, 2014), 79.

41 Beeson, *Institutions of the Asia-Pacific*, 32.

a regional trade and investment agreement that does not contain an intellectual property chapter. If these countries threaten to pull out of the RCEP negotiations, the key question for the remaining ASEAN+6 members will no longer be about whether the agreement should omit an intellectual property chapter, but whether such omission is so important to them that they would rather lose the entire regional pact or the participation of key neighbours in this pact than include the chapter.

Third, apart from the developed country members of ASEAN+6, China, India and other emerging countries in the region—or what I have called “middle intellectual property powers”⁴²—have begun to appreciate the strategic benefits of stronger intellectual property protection and enforcement. Although these countries have yet to embrace the very high protection and enforcement standards found in the European Union, Japan or the United States, they now welcome standards that are higher than those currently available in the Asia-Pacific region. These countries are therefore unlikely to block the inclusion of an intellectual property chapter in the RCEP Agreement.

4.2 Scenario 2: A TPP-Like Intellectual Property Chapter

In the second scenario, the RCEP Agreement will include an intellectual property chapter containing high protection and enforcement standards, similar to those found in the TPP Agreement. A key rationale behind such inclusion is that, if the RCEP is to successfully compete with the TPP as a viable alternative for setting trade norms in the Asia-Pacific region—at least before the United States' withdrawal—it will need to provide effective standards in the intellectual property area. Otherwise, it will lose the support of those economies that are driven heavily by intellectual property and technology industries—both within ASEAN+6 and outside.

Even if the TPP were dead, as many policymakers and commentators fear,⁴³ the RCEP would still need to provide standards that were high enough to entice existing TPP partners to embrace the partnership as a dominant forum for setting regional intellectual property norms. Without such participation, a new regional pact could easily emerge to take the TPP's place as a rival pact. Such emergence would be particularly likely should the Trump administration change its course or be satisfied with the new arrangement.

More importantly, the RCEP intellectual property chapter may have already garnered the support of not only the developed country members of ASEAN+6 but also their developing country counterparts. It is no surprise that Japan advanced at the RCEP negotiations a very detailed proposal for an intellectual property chapter. After all, the country has the strongest and most sophisticated economy in Asia, with a GDP per capita of US\$32,477.22 in 2015, as estimated by the World Bank. It also has a well-functioning intellectual property system. According to WIPO statistics, Japan currently ranks second in terms of international patent applications filed through the PCT, behind only the United States.⁴⁴

42 Peter K. Yu, “The Middle Intellectual Property Powers,” in *Law and Development in Middle-Income Countries: Avoiding the Middle-Income Trap*, ed. Randall Peerenboom and Tom Ginsburg (New York: Cambridge University Press, 2014), 84.

43 Joshua Berlinger, “TPP Unravels: Where the 11 Other Countries Go from Here,” *CNN*, 24 January 2017, <http://www.cnn.com/2017/01/24/asia/tpp-other-11-countries-what-next/>; Kaori Kaneko and Yoshifumi Takemoto, “Japan Ratifies TPP Trade Pact to Fly the Flag for Free Trade,” *Reuters*, 9 December 2016, <http://www.reuters.com/article/us-japan-tpp-idUSKBN13Y0CU>.

44 WIPO, “Who Filed the Most PCT Patent Applications in 2016?” 15 March 2017, http://www.wipo.int/export/sites/www/ipstats/en/docs/infographic_pct_2016.pdf.

In addition, Japan originated the proposal to establish ACTA. Conceived as a “Treaty on Non-Proliferation of Counterfeits and Pirated Goods,” that proposal for an anti-counterfeiting treaty was advanced by Prime Minister Junichiro Koizumi at the June 2005 G8 meeting in Gleneagles, Scotland.⁴⁵ As a TPP member, Japan also has a strong interest in ensuring that the intellectual property standards in the RCEP Agreement are comparable to those found in the TPP Agreement. From a business standpoint, it would be a major nightmare for Japanese firms to juggle two very different sets of standards within the Asia-Pacific region.

Like Japan, South Korea's economy is highly developed, with a GDP per capita of US\$27,221.53 in 2015, as estimated by the World Bank. The country also has a well-functioning intellectual property system and a highly successful home electronics industry, with Samsung and LG being household names. Since May 2007, the Korean Intellectual Property Office has actively engaged the European Patent Office, the Japan Patent Office, the United States Patent and Trademark Office and the State Intellectual Property Office of China to identify ways to streamline and harmonise their patent examination systems. According to WIPO, South Korea currently has the world's fifth largest volume of PCT applications, behind the United States, Japan, China and Germany.⁴⁶ Among corporate applicants, LG and Samsung rank fifth and ninth in the world, respectively.

Moreover, the Korea–United States Free Trade Agreement, which entered into force in March 2012, requires South Korea to adopt some of the world's highest intellectual property standards. To the extent that these standards have increased the costs of its goods and services and thereby undercut its global competitiveness, South Korea will have a strong incentive to level the playing field by introducing similar cost-raising standards to other ASEAN+6 members through the RCEP. As Jeremy Malcolm lamented,

Far from setting up a positive alternative to the TPP, South Korea is channeling the [US Trade Representative] at its worst here—what on earth are they thinking? The answer may be that, having been pushed into accepting unfavorably strict copyright, patent, and trademark rules in the process of negotiating its 2012 free trade agreement with the United States, Korea considers that it would be at a disadvantage if other countries were not subject to the same restrictions.⁴⁷

Together with Australia, Japan and New Zealand—the three other ASEAN+6 members of the Organisation for Economic Co-operation and Development (OECD)—South Korea will be able to form a Developed Country Quad within ASEAN+6. As far as the RCEP is concerned, this group of countries will be powerful enough to push actively for high standards of intellectual property protection and enforcement. Given the similarities between these standards and those found in the TPP Agreement, the four ASEAN members that are also TPP partners—Brunei Darussalam, Malaysia, Singapore and Vietnam—may also choose to support the inclusion of TPP-like standards in the RCEP.

The most interesting developments leading up to this second scenario, however, concern the large developing country members of ASEAN+6, such as China, India, Indonesia, the Philippines and Thailand.

45 Peter K. Yu, “Six Secret (and Now Open) Fears of ACTA,” *SMU Law Review* 64, no. 3 (2011): 980–983.

46 WIPO, “Who Filed the Most PCT Patent Applications in 2016?”

47 Jeremy Malcolm, “Meet RCEP, a Trade Agreement in Asia That's Even Worse than TPP or ACTA,” *Electronic Frontier Foundation*, 4 June 2015, <https://www.eff.org/deeplinks/2015/06/just-when-you-thought-no-trade-agreement-could-be-worse-tpp-meet-rcep>.

As noted earlier, China, India and other emerging countries in the Asia-Pacific region have begun to appreciate the strategic benefits of stronger intellectual property protection and enforcement.

A case in point is China. Once a technologically backward country that relied heavily on piracy and counterfeiting to catch up, China now ranks third in terms of PCT applications, behind only the United States and Japan.⁴⁸ Among corporate applicants, ZTE Corporation and Huawei Technologies also rank the first and second in the world, respectively. As regards trademark protection, China currently has the world's fourth largest volume of international trademark applications filed under the Madrid system.⁴⁹

To be sure, China, India and other emerging countries in the region may still find the intellectual property standards proposed by Australia, Japan, New Zealand and South Korea higher than they would prefer. Nevertheless, they may not find those standards highly objectionable, especially if they manage to secure greater concessions in other trade or trade-related areas. After all, these emerging countries are now growing rapidly in both economic and technological terms. Their intellectual property standards have therefore been slowly elevated to match their changing local conditions. It will be only a matter of time before these standards catch up with those found in their more developed neighbours.

Some leaders in these emerging countries may also welcome new RCEP requirements for stronger intellectual property protection and enforcement. After all, those requirements will provide these leaders with the much-needed external push to accelerate domestic intellectual property reforms.⁵⁰ In China, for instance, the standards required by the TRIPS Agreement and the push for accession to the World Trade Organization (WTO) led to a complete overhaul of its copyright, patent and trademark laws in the early 2000s.⁵¹ To many reformist leaders, having their hands tied by international treaties can sometimes be used as an effective weapon against hardline leaders and conservative critics at home.

To be sure, the weaker and poorer ASEAN+6 members may still be reluctant to accept an intellectual property chapter with high protection and enforcement standards. Nevertheless, the benefits they will secure from the RCEP in other trade or trade-related areas may more than compensate for their losses in the intellectual property area. To a large extent, the trade-offs in the RCEP may not be that different from the trade-offs they have experienced in the WTO.

From a Realist standpoint, many of these poorer and weaker countries also have very limited power or recourse if their more powerful neighbours insist on including an intellectual property chapter with high protection and enforcement standards. For the former, it is just not a viable option to lose the new trade and trade-related benefits provided by Australia, China, India, Japan, New Zealand, South Korea and other more powerful neighbours through the RCEP.

48 WIPO, "Who Filed the Most PCT Patent Applications in 2016?"

49 WIPO, "Who Filed the Most Madrid Trademark Applications in 2016?" 15 March 2017, http://www.wipo.int/export/sites/www/ipstats/en/docs/infographic_madrid_2016.pdf.

50 Peter K. Yu, "Intellectual Property, Economic Development, and the China Puzzle," in *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era*, ed. Daniel J. Gervais, 1st edn (Oxford: Oxford University Press, 2007), 192.

51 Peter K. Yu, "The Transplant and Transformation of Intellectual Property Laws in China," in *Governance of Intellectual Property Rights in China and Europe*, ed. Nari Lee, Niklas Bruun and Li Mingde (Cheltenham: Edward Elgar, 2016), 26.

Although it is still possible that the RCEP Agreement will include a TPP-like intellectual property chapter, it is unlikely that the agreement will do so, considering that the FTAs China and India have thus far entered into do not include similarly high protection and enforcement standards.

If the RCEP Agreement included TPP-like standards, these powerful developing countries would have to completely overhaul their intellectual property systems—an outcome they have fought very hard at the WTO and WIPO to avoid.⁵² Given the pivotal roles China and India have played in the RCEP negotiations, it is just difficult to imagine that these countries would suddenly welcome requirements they had adamantly opposed in major international fora. It is also very unlikely that Australia, Japan, New Zealand and South Korea could force these powerful emerging countries to accept the heightened requirements on a take-it-or-leave-it basis.

Nevertheless, if these developed countries managed to convince China and India to support the inclusion of an intellectual property chapter with high TPP-like intellectual property standards, or if China and India changed their minds (due perhaps to changing economic and technological conditions), the RCEP intellectual property chapter would facilitate greater harmonisation of protection and enforcement standards at both the regional and global levels. Within the Asia-Pacific region, these new standards would help pave the way for the establishment of the FTAAP. Other countries in the region would warmly welcome such harmonisation, considering that many of them remain reluctant to support—and, for some, even unable to afford—two expansive yet differing regional trade pacts.⁵³

Across the world, the new RCEP standards would help accelerate international harmonisation of intellectual property standards at both the WTO and WIPO. As the TRIPS negotiations have demonstrated, multilateral standards tend to be developed by securing a consensus among the key negotiating parties first before slowly extending those standards to other members of the international community.⁵⁴ The harmonisation facilitated by the RCEP would therefore be highly important, especially in view of the current deadlock between developed and developing countries in the Doha Development Round of Trade Negotiations.

4.3 Scenario 3: A TPP-Lite Intellectual Property Chapter

In the final scenario, China and India will push for an intellectual property chapter that contains much lower standards than those initially proposed by Japan and South Korea and now supported by other developed country members of ASEAN+6. While these proposals may have provided useful starting points for the working group on intellectual property, the remaining RCEP negotiating parties—led by China and India, perhaps—have actively bargained down the terms of the draft intellectual property chapter. In the end, this chapter will contain terms that offer more limited protection than the TPP intellectual property chapter, but still more expansive protection than the TRIPS Agreement or what is currently available in many Asian countries.

52 Peter K. Yu, "TRIPS and Its Achilles' Heel," *Journal of Intellectual Property Law* 18, no. 2 (2011): 518–520.

53 Lewis, "Achieving a Free Trade Area of the Asia-Pacific," 231; Meredith Kolsky Lewis, "The TPP and the RCEP (ASEAN+6) as Potential Paths toward Deeper Asian Economic Integration," *Asian Journal of the WTO and International Health Law and Policy* 8, no. 2 (2013): 369–370.

54 Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (London: Routledge, 2002); Susan K. Sell, *Private Power, Public Law* (Cambridge: Cambridge University Press, 2003), 96–120.

This scenario is the most likely and is already happening. The terms of the RCEP intellectual property chapter will be even more diluted if the negotiations have to conclude soon—that is, before China, India and other emerging countries further elevate their intellectual property standards to match their rapidly changing local conditions. After all, the current standards in these countries are still quite close to those of the developing country members of ASEAN+6.

This final scenario also reflects the approach currently taken by both China and India in their FTA negotiations. If one is interested in the type of intellectual property provisions that will find their way to the final text of the RCEP Agreement, a good starting point will be the China–Switzerland Free Trade Agreement (CSFTA) or the European Union–India Free Trade Agreement.

Take the CSFTA, for example. Although China was somewhat reluctant to include an expansive intellectual property chapter in its early FTAs—such as those with Chile, Pakistan, New Zealand and Singapore—the CSFTA contains a significantly more detailed intellectual property chapter.⁵⁵ The inclusion of such a lengthy chapter is perhaps due to Switzerland's insistence on high standards of intellectual property protection and enforcement, especially after the very limited success, if not failure, of the ACTA negotiations. The existence of such a chapter is also attributable to the timing of the CSFTA, which was signed in July 2013, as opposed to the mid to late 2000s. By then, China had already had its National Intellectual Property Strategy in place for five years. The country had also completely overhauled its patent law and was only a few weeks away from adopting the third amendment to its trademark law.⁵⁶

Indeed, the CSFTA bears a remarkable resemblance to the current leaked draft of the RCEP intellectual property chapter. Although the former includes provisions found in the TRIPS Agreement and other TRIPS-plus FTAs, some of its provisions are quite unique. Article 11.9 of the CSFTA, for instance, offers language on the disclosure of origin or source of genetic resources. Article 11.9 also calls for efforts "to enhance a mutually supportive relationship between the TRIPS Agreement and the Convention on Biological Diversity, regarding genetic resources and traditional knowledge."

In sum, like the CSFTA, the RCEP intellectual property chapter is likely to contain lower standards than those found in the TPP Agreement. It may also include language that is not found in that agreement or other TRIPS-plus FTAs. Only time will tell whether the intellectual property standards in the RCEP Agreement will complement or conflict with those found in the TPP Agreement. If conflicts indeed arise, the resulting inconsistencies and tensions may precipitate what I have described as the "battle of the FTAs."⁵⁷ In this battle, the TPP and the RCEP will further polarise ASEAN+6 members while fragmenting the regional and international trading and intellectual property systems.

Given ASEAN's reluctance to pick between the United States and their powerful Asian neighbours⁵⁸ and given the inability of many ASEAN members to afford two expansive yet conflicting sets of

55 Peter K. Yu, "Sinic Trade Agreements and China's Global Intellectual Property Strategy," in *Intellectual Property and Free Trade Agreements in the Asia-Pacific Region*, ed. Christoph Antons and Reto M. Hilty (Berlin: Springer, 2015), 264–265.

56 The third amendment to the Chinese Patent Law was adopted in December 2008, and the third amendment to the Chinese Trademark Law was adopted in August 2013, a month after the signature of the CSFTA.

57 Yu, "Sinic Trade Agreements," 1018–1027.

58 Ellen L. Frost, "China's Commercial Diplomacy in Asia: Promise or Threat?" in *China's Rise and the Balance of Influence in Asia*, ed. William W. Keller and Thomas G. Rawski (Pittsburgh: University of Pittsburgh Press, 2007), 105; David Shambaugh, "Introduction: The Rise of China and Asia's New Dynamics," in *Power Shift: China and Asia's New Dynamics*, ed. David Shambaugh (Berkeley: University of California Press, 2006), 17; Yu, "TPP and Trans-Pacific Perplexities," 1151.

regional trade and trade-related standards, the TPP and RCEP may eventually be combined in the name of the FTAAP. It is indeed no surprise that “[a]n analyst with the Asian Development Bank has [already] predicted that ASEAN+6 and the TPP will ultimately merge together.”⁵⁹

5. Conclusion

Regardless of which future scenario one finds the most likely, the RCEP will raise important questions about the future of intellectual property normsetting in the Asia-Pacific region and about the future levels of protection and enforcement that will be found in intellectual property systems across this region. That the RCEP negotiations have involved many different trade and trade-related areas will also drive ASEAN+6 members to think more deeply about the future directions of both their national economy and the overall regional economy.

Given that intellectual property will remain a crucial part of the economy in the twenty-first century and that its importance can only grow with time, ASEAN+6 members will squander a major opportunity to harmonise regional intellectual property standards if the RCEP Agreement does not include an intellectual property chapter. If the standards in this chapter are set too high, however, they will also hurt themselves by impeding future development, eroding global competitiveness and jeopardising access to essential medicines, educational materials and information technology. In view of these immense challenges and the high stakes involved, it is high time that policymakers, commentators, activists, consumer advocates and civil society organisations paid greater attention to the RCEP negotiations.

59 Lewis, “Achieving a Free Trade Area of the Asia-Pacific,” 235.

The Trans-Pacific Partnership Agreement: A Stroke of Genius or a Tragedy of Sorts?

Padmashree Gehl Sampath and Pedro Roffe

1. Introduction

Recent times have clearly been turbulent for global trade. The slowdown in multilateral negotiations has been accompanied by a rise in the number of free trade agreements (FTAs), of a bilateral, plurilateral or regional nature¹ and new trade alliances. Such agreements have burgeoned with new provisions going further than those of the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and on topics that have been subject to longstanding disagreements between countries at the multilateral level. Data from the WTO on regional trade agreements highlight the growing number since 1995. As of 20 June 2017, there were 279 agreements in force corresponding to 445 notifications from members, taking goods, services and accession into account separately. This, according to some studies, corresponds to over 10 FTA partners per country as early as 2010.²

Among all current FTAs, the Trans-Pacific Partnership Agreement (TPP) stands out as the first and the most comprehensive plurilateral trade agreement, putting forward an ambitious regulatory agenda. Characterised as the “twenty-first century agreement,” the TPP negotiations reached a climax with its final adoption by the trade ministers of the negotiating partners: Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States of America and Vietnam. Although the influence and the geopolitical consequences of the agreement changed drastically once the US withdrew on 23 January 2017, the TPP remains a template to contend with.

Almost all trade agreements negotiated by the US since the North American Free Trade Agreement (NAFTA) have shown a clear trend of moving beyond traditional trade issues (such as tariffs) to include regulatory issues at greater length. This follows the tendency that began in the Uruguay Round of trade negotiations leading to the establishment of the World Trade Organization. Over time, if one views the evolution of FTAs, the trend has been one of gradual but definitive regulatory strengthening: from NAFTA to the United States–Korea Free Trade Agreement (KORUS). Although the TPP builds on the regulatory provisions of KORUS (in fact, most of the provisions are very similar), KORUS was only bilateral, and the TPP extends a plurilateral status to these provisions. A closer review of the negotiation of the TPP sheds light on the fact that the main endeavour of the US during the negotiation process was to align the regulatory regimes of all 12 trading partners more closely with its domestic institutional framework for trade, investment, intellectual property (IP) and electronic commerce. For the US, the key interest was to transplant its legal framework and grant it a wider status and acceptance among its partners in the process of a progressive harmonisation of regulatory questions,³ making the TPP the “pivot to

1 “Regional” and “plurilateral” are often used interchangeably in the literature to denote the emergence of regionalism. But in some parts of the literature, “regional” agreements are used to denote the rise of regional integration in the geographical sense (such as the Association of Southeast Asian Nations (ASEAN) or the Common Market for Eastern and Southern Africa), whereas plurilateral agreements are those which, while creating a regional/preferential trading zone, do not restrict themselves to any particular geographical or other considerations.

2 A dedicated database of regional trade agreements is at <http://rtais.wto.org/UI/PublicAllRTAList.aspx>. Chen and Joshi estimate that, as opposed to 1991, when each country had on average only 1.8 FTA partners, in 2005 the average of FTA partners per country had risen to 9.9; see M. X. Chen and S. Joshi, “Third-Country Effects on the Formation of Free Trade Agreements,” *Journal of International Economics* 82 (2010): 238–248, at 238. See also Xavier Seuba, “Intellectual Property in Preferential Trade Agreements: What Treaties, What Content?” *Journal of World Intellectual Property* 16, nos 5–6 (2013): 1–22.

3 For the principal trade negotiating objectives of the US, refer to the Bipartisan Congressional Trade Priorities and Accountability Act of 2015, <https://www.govtrack.us/congress/bills/114/s995>.

Asia.¹⁴ For the other Asian countries negotiating the TPP, it was supposed to leverage trade gains to guard against the ever-expanding rise and reach of China.

Despite the withdrawal of the US in January 2017, the TPP is a momentous achievement. It is now the only plurilateral agreement worldwide that contains the most advanced template on regulatory issues. The fact that the TPP now contains a regulatory framework that moves the regulatory regimes of all its members closer to that of the US, although the US is no longer a party to the agreement, is a contradiction of sorts. It also raises several serious questions: What is the future of the TPP's provisions so rigorously negotiated between the countries? More importantly, can the TPP's regulatory stance be expected to become commonplace in other FTAs, both those negotiated by the US and those that will be proposed by TPP existing partners? In other words, has the US, in absentia, achieved a coup of sorts?

This paper discusses the new institutional architecture proposed by the TPP for regulatory harmonisation from the perspective of what it may hold for the future, for those countries which are party to the TPP and for those which are not. Section 2 of the paper analyses the key components of the TPP, trying to set out what the agreement consolidates in two key areas, investment and intellectual property, with a view to assessing their implications for the TPP member countries, and as a new standard on regulatory reform. Section 3 discusses what this might mean for the member countries of the TPP and other non-member countries for the future, in terms of global trade, with concrete examples such as e-commerce. In Section 4, we conclude with a scenario-building exercise post-TPP and present the contrasting possibilities for global trade as we move ahead in the coming months and years.

2. The Key Components of the TPP: A Baseline Analysis

The origins of the TPP go back to the P3 group (Chile, New Zealand and Singapore), which later became the P4 with the inclusion of Brunei Darussalam in setting up the Trans-Pacific Strategic Economic Partnership Agreement, also known as P4. It was the first plurilateral trade agreement ever signed by countries across the Pacific, aiming to eliminate 90 percent of tariffs among members, and it had a modest approach to regulatory issues, focusing mostly on traditional trade issues. In late 2009, the United States decided to be part of this negotiating group as a core member, thereby renaming the agreement the Trans-Pacific Partnership.

Tracing the negotiations since the US joined, one finds a change in pace and tone, with the strong trade agenda of the US influencing the move towards the progressive harmonisation of key regulatory issues in a systematic manner. Table 1 traces the changes in the FTAs and their coverage since the Marrakesh Treaty of 1994, from what was commonplace in first generation FTAs such as the NAFTA, to the expansion in second generation FTAs, to evolve into the current generation.⁵ Given that the TPP consolidates the regulatory harmonisation contained in most other previous FTAs negotiated

4 A. Smith, "How Trump Killed Obama's Vaunted Trade Deal—and Why It Could Affect the US for Decades," *Business Insider UK*, 8 February 2017.

5 For the purposes of our analysis, the second generation of US FTAs represents those negotiated after NAFTA with a number of countries in early 2000 (e.g., Australia, Bahrain, Chile, CAFTA-DR, Jordan, Morocco, Singapore), expanding the coverage of issues by including, among others, full treatment of the digital environment, electronic commerce, pharmaceutical issues and the reinforcing of enforcement provisions; see United States Trade Representative (USTR), "Free Trade Agreements," at <https://ustr.gov/trade-agreements/free-trade-agreements>.

by the US, particularly the KORUS,⁶ at a plurilateral level, the table uses the TPP as the exemplar of third generation FTAs.

For the purpose of our analysis, table 1 shows selected core regulatory themes covered by the TPP, namely investment, intellectual property, regulatory matters in areas such as pharmaceuticals and e-commerce and how each of these has evolved over time particularly since the Marrakesh Agreement of 1994 establishing the World Trade Organization.

Table 1: Evolution of treatment of selected regulatory issues in trade agreements since the Marrakesh Treaty of 1994

Marrakesh Treaty (1994)	First generation FTAs (e.g. NAFTA)	Current generation FTAs (e.g. TPP)
<p>Investment</p> <p>Follows a long series of bilateral investment treaties setting standards of treatment and protection of foreign investors. Marrakesh did not incorporate a precise treaty on investment but included related questions such as services, trade-related investment measures and IP</p>	<p>Part Five of NAFTA includes Chapter Eleven on Investment, being the first comprehensive trade agreement to incorporate investment among traditional trade issues and new trade-related issues.</p> <p>Most favoured nation (MFN) treatment is accorded to investors and to investments of investors of another party and, in like circumstances, to investors of a non-party with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.</p>	<p>TPP provides a more detailed treatment of investment issues. There are 30 provisions compared to 20 in NAFTA.</p> <p>It includes MFN but clarifies that this treatment does not encompass international dispute resolution procedures or mechanisms.</p> <p>TPP is more specific with respect to minimum standard of treatment (Article 9.6).</p> <p>It includes Annex 9-B on Expropriation, particularly on indirect measures equivalent to direct expropriation and effects of non-discriminatory regulatory measures that are aimed at protecting legitimate public welfare objectives.</p>
<p>Electronic commerce</p> <p>Marrakesh did not incorporate matters related to the digital environment</p>	<p>Not included.</p>	<p>Electronic commerce is an important component of the TPP.</p>
<p>Intellectual property</p> <p>TRIPS provides minimum standards of protection and enforcement</p>	<p>NAFTA negotiated at the time of TRIPS includes provisions that go beyond TRIPS.</p>	<p>Comprehensive treatment of IP issues including 83 provisions compared to 21 in NAFTA.</p>
<p><i>Patentable subject matter:</i> patents available in all technological fields</p>	<p>Similar to TRIPS.</p>	<p>Ratification of TRIPS and expanded to new uses of a known product, new methods of using a known product, or new processes of using a known product.</p>
<p><i>Minimum protection:</i> patents for 20 years</p>	<p>Term of protection at least 20 years from the date of filing or 17 years from the date of grant. Term may be extended to compensate for delays caused by regulatory approval processes.</p>	<p>Compensation or restoration of duration in cases of administrative delays or sanitary permits.</p> <p>TPP is more precise and uses mandatory language for term adjustment for unreasonable granting authority delays and adjustment for unreasonable curtailment of patent term in case of marketing approval.</p>

6 For KORUS, see USTR, KORUS FTA, at <https://ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text>.

Table 1: *Continued*

Marrakesh Treaty (1994)	First generation FTAs (e.g. NAFTA)	Current generation FTAs (e.g. TPP)
<i>Patents on plants and animals:</i> can be excluded from protection	Similar to TRIPS.	A party may exclude from patentability plants other than microorganisms. However, each party confirms that patents are available at least for inventions that are derived from plants.
<i>Undisclosed information:</i> including data submitted for the marketing of pharmaceuticals—to be protected against unfair competition	No person other than the person who submitted data for marketing approval may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time. A reasonable period shall normally mean not less than five years, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any party implementing abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.	– Exclusive protection for at least five years for new uses and protection of biologics for five to eight years. – Linkage between marketing approval and patent term.
<i>Copyright term of duration:</i> 50 years when term is calculated on a basis other than the life of natural person	Similar to TRIPS	Term of protection of a work, performance or phonogram is to be calculated: (a) on the basis of the life of a natural person, not less than the life of the author and 70 years after the author's death; and (b) on a basis other than the life of a natural person, the term shall be: (i) not less than 70 years from the end of the calendar year of the first authorised publication of the work, performance or phonogram; or (ii) failing such authorised publication within 25 years from the creation of the work, performance or phonogram, not less than 70 years from the end of the calendar year of the creation of the work, performance or phonogram.
<i>Digital environment:</i> not included in the copyright provisions	NAFTA negotiated at the time of TRIPS did not cover this aspect.	Extensive protection of copyright including both traditional and digital forms of expression. Special provisions on technological protection measures, rights management information and internet service providers.
<i>Geographical indications (GIs):</i> special protection in the case of wines and spirits and an agenda on future international negotiations	GIs are dealt with briefly in Article 1712, NAFTA, in line generally with TRIPS.	Lengthy treatment of GIs with emphasis on recognition that they may be protected through a trademark or sui generis system or other legal means.

Table 1: *Continued*

Marrakesh Treaty (1994)	First generation FTAs (e.g. NAFTA)	Current generation FTAs (e.g. TPP)
<i>Enforcement:</i> comprehensive regime on enforcement of intellectual property rights	NAFTA follows scheme and broad focus of TRIPS.	<ul style="list-style-type: none"> – Expansion of minimum standards by making mandatory provisions considered optional under TRIPS. – Enlarged border enforcement. – Expanding enforcement provisions to the digital environment. – Enlarged criminal enforcement including trade secrets.
Technical barriers to trade and pharmaceuticals Not dealt specifically	No specific provisions.	TPP includes important regulatory questions not covered in earlier trade agreements. Chapter on Technical Barriers to Trade includes Annex 8-C dealing with pharmaceuticals. Annex applies to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation and notification procedures of central government bodies that may affect trade in pharmaceutical products between the parties.
Transparency and procedural fairness for pharmaceutical products and medical devices Not dealt specifically	No specific provisions.	Transparency and anti-corruption covered by Chapter 26 of TPP includes Annex 26-A on transparency and procedural fairness for pharmaceutical products and medical devices. Annex underlines the commitment of the parties to “facilitating high-quality health care and continued improvements in public health for their nationals, including patients and the public.” The focus of the Annex is on reimbursement issues under national care programmes providing guidelines to be followed by parties.

Source: Compiled by the authors from a review of FTAs, 1990–2017.

As the table sets out, the details provided in the TPP are extensive. In areas such as investment and intellectual property, as well as regulatory issues on pharmaceutical products and medical devices, the changes in the TPP expand and strengthen the regulatory level to something very different from what it was before.⁷ The real question that stands out in the signed agreement is the following: What are these changes and what does this amount to for countries? The following subsections provide an analysis of what the chapters in the TPP dealing with investment and intellectual property represent in terms of regulatory harmonisation, and the potential issues they raise.

⁷ The area of e-commerce is also covered extensively, as discussed in Box 2 of this paper.

2.1 The Investment Chapter

The TPP's investment chapter consolidates several issues that have been part of previous US agreements, particularly KORUS.⁸ The TPP includes a comprehensive definition of investment covering every tangible and intangible asset that an investor owns or control, directly or indirectly, "such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk."⁹ The agreement lists examples of forms of investment covered, such as financial instruments, contracts, intellectual property rights, licences, authorisations, permits, and broadly "other tangible or intangible, movable or immovable property, and related property rights, such as leases, mortgages, liens and pledges."

All the investments covered by the agreement are subject to well-known trade and investment principles such as national treatment and most favoured nation treatment. But it also accords minimum standards of treatment in accordance with customary international law principles, including fair and equitable treatment and full protection and security, to those investments covered by the agreement.¹⁰

A positive and interesting change in the TPP is the coverage of expropriation and compensation. This, while being an important element of the US agenda since NAFTA, has become the subject of debate in recent years, particularly after the recent disputes between investors and states in the Philip Morris cases with Australia and Uruguay.¹¹ These cases raised questions as to the boundaries of the regulatory power of the state and the circumstances under which an indirect expropriation might have an effect equivalent to direct expropriation. In the two cases, investors questioned state actions on the grounds that restrictions (trademarks in the case of Philip Morris and patents in the case of Eli Lilly) constituted an indirect but legitimate appropriation of the assets that should have accrued to the investors.

Generally speaking, the TPP prohibits parties from expropriating or nationalising any investment covered by the agreement directly or indirectly through measures that equal expropriation or nationalisation without clear compensation.¹² But the agreement clarifies that this requires a case-by-case and fact-based inquiry allowing for a certain amount of discretion.¹³ It also creates an exception, namely that "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

8 The TPP's investment chapter builds on previous trade and investment agreements negotiated in the past by the US with at least 10 countries which are members of the TPP (Australia, Brunei Darussalam, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam) and particularly on the latest KORUS agreement negotiated with Korea and concluded in 2012.

9 See Article 9.1, TPP. For a full text of the agreement see the legally verified text released on 26 January 2016, at <https://www.mfat.govt.nz/en/about-us/who-we-are/treaties/trans-pacific-partnership-agreement-tpp/text-of-the-trans-pacific-partnership>.

10 See Article 9.6, TPP.

11 See arbitral award in Philip Morris and Oriental Republic of Uruguay, International Centre for Settlement of Investment Disputes, ICSID Case No. ARB/10/7, 26 September 2016, at http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C1000/DC9013_En.pdf.

12 See Article 9.8.1, TPP.

13 See Annex 9-B, Expropriation, TPP.

not constitute indirect expropriations, *except in rare circumstances*.¹⁴ This provision is a clear step forward in that it clearly allows states certain degrees of freedom in cases seen as affecting public health, safety and the environment.

The agreement specifies that these provisions shall not apply to the issuance of compulsory licences granted in accordance with the TRIPS Agreement, or to the revocation, limitation or creation of intellectual property rights, to the extent that the issuance, revocation, limitation or creation is consistent with the provision on intellectual property of the TPP and the TRIPS Agreement.¹⁵ The NAFTA contained a similar provision,¹⁶ but left out the decision of what constitutes situations in which these provisions can be implemented in the countries. This ambiguity was the cause for disputes, as, for example, in the case of Eli Lilly and the government of Canada that was recently settled in favour of Canada in the context of NAFTA.¹⁷ The TPP moves this discussion one step forward by clarifying that the revocation of patents as explained in the agreement falls under the regulatory power of the states, and should not be disputed. This is a timely and positive clarification as far as this area is concerned.

There are two more noteworthy aspects of the investment chapter. The first concerns investor–state dispute settlement. This is once again a vestige of previous agreements negotiated by the US, giving investors the recourse to sue governments in front of international arbitration tribunals.

The second relates to performance requirements, where the TPP consolidates earlier precedents on performance requirements from all other trade agreements. It forbids the enforcement of requirements, commitments or contractual undertakings in a wide variety of cases, such as: to export a given level or percentage of goods or services; to achieve a given level or percentage of domestic content; to purchase, use or accord a preference to goods produced in its territory, or to purchase goods from persons in its territory; to relate in any way the volume or value of imports to the volume or value of exports or to the amount of foreign exchange inflows associated with the investment; to transfer a particular technology, a production process or other proprietary knowledge to a person in its territory; to supply exclusively from the territory of the party the goods that the investment produces or the services that it supplies to a specific regional market or to the world market. These measures, however, do not apply to government procurement.¹⁸

A primary reading of the performance requirement provision indicates a reduction of what is considered to be policy space in industrial policy, given that countries are unable to specify domestic content in any way. It further limits the two primary mechanisms that were considered pathways of technology transfer, namely foreign direct investment and intellectual property rights (IPRs), by stating clearly that investment cannot be linked to the performance requirement of transfer of technology. This, however, had no bearing on indirect, technology spillovers (through tacit know-how, or movement of personnel, etc.) as the main channel of technology transfer through investment and IPRs.

14 Annex 9-B, 3.B, emphasis added, TPP.

15 The actual wording in TPP is inspired by KORUS, Article 11.6.5.

16 Article 1110.7, NAFTA.

17 See final award in *Eli Lilly v. Canada*, 16 March 2017, http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C3544/DC10133_En.pdf.

18 See Article 9.10, TPP.

2.2 Intellectual Property

In general, intellectual property has been a controversial component of trade agreements and an important bargaining chip used by advanced economies to achieve final results in these agreements. Intellectual property retained its customary status of being the most controversial issue in the negotiations of the TPP as well. This is also the main area where the negotiating mandate of the US to replicate the high standards of protection and enforcement of its national laws in FTAs stands out.¹⁹ During the negotiation of the TPP, questions related to public health attracted particular attention because of its social implications and warnings issued by civil society groups on the potential impacts of TPP in threatening access to health.²⁰ These calls were due not only to the strengthening of patent protection but to the inclusion of technical and regulatory standards relating to pharmaceutical products.

But more generally speaking, in the IPRs chapter, the TPP consolidates the progress made in all other trade agreements in two ways. First, it often sets out new rules that have clarified and strengthened the enforcement-related standards in the TRIPS Agreement. Second, in many cases, it sets out enforcement norms that cover areas that were previously ambiguous (or not regulated) in the TRIPS Agreement. New norms on enforcement raise questions because of the general inclination to—mostly or solely—reflect the interests of right holders. This imbalance generally generates tensions *vis-à-vis* the protection of priority legal interests (health, privacy, access to information) and the objective of the multilateral trade system to promote free trade, on the one hand, and the preservation of the public interest of the member countries, on the other.²¹

With respect to public interest concerns, the TPP presents an attractive repackaging of IP issues, through introductory provisions on objectives, principles and general understanding of the underlying policy objectives of national IP systems.²² As a response to the public health concerns raised at the time of the WTO Ministerial Declaration on Public Health, the TPP unmistakably states that the TPP provisions “do not and should not prevent a Party from taking measures to protect public health” in line with commitments made in the WTO.²³ But, on the whole, although there are provisions that seek to balance IPRs with economic, social and national interests (see section 3.2 of this paper), the TPP managed to accomplish, among other things, what the failed Anti-Counterfeiting Trade Agreement (ACTA) negotiations could not do on enforcement issues, and in general consolidated perceived ambiguous provisions in TRIPS, a number of which were of a controversial character during the TPP negotiating process. These are presented here.

19 The TPP negotiating mandate of the US executive was precisely one of “ensuring that the provisions of any trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law.” See Section 5 on the principal objectives of the US regarding trade-related intellectual property issues, in H.R.2146—114th Congress (2015–2016), at <https://www.congress.gov/bill/114th-congress/house-bill/2146/text/pl>.

20 “The big losers in the TPP are patients and treatment providers in developing countries. Although the text has improved over the initial demands, the TPP will still go down in history as the worst trade agreement for access to medicines in developing countries, which will be forced to change their laws to incorporate abusive intellectual property protections for pharmaceutical companies”; statement by Médecins Sans Frontières on the conclusion of negotiations of the TPP in Atlanta, 5 October 2015, at <http://www.doctorswithoutborders.org/article/statement-msf-conclusion-tpp-negotiations-atlanta>.

21 See the chapter by Xavier Seuba in this volume providing a detailed analysis of enforcement issues in trade agreements.

22 See Section A of Chapter 18, TPP.

23 See Article 18.6 (Understandings Regarding Certain Health Measures), TPP.

2.2.1 Cooperation in the area of traditional knowledge

The TPP stresses that its members "shall endeavour to cooperate on IP matters through appropriate coordination, training and exchange of information between the respective IP offices, or other institutions."²⁴

In the case of traditional knowledge, the principal emphasis, however, is on pursuing quality patent examination on issues such as determination of prior art, including prior art disclosures that may have a bearing on patentability; the use of databases or digital libraries containing traditional knowledge associated with genetic resources; and cooperation in the training of patent examiners in the examination of related traditional knowledge issues.²⁵ Thus, in effect, the emphasis is on ensuring better examination of patents as the key means to secure the right of communities on traditional knowledge. This, while being one view on the topic, shies away from substantive negotiating issues on traditional knowledge associated with genetic resources that have occupied the recent attention of discussions in the WTO and World Intellectual Property Organization (WIPO),²⁶ including considering the demand made by several member states on the need to provide for a sui generis right to traditional knowledge that recognises the particular features of such knowledge and allows the communities a longer-term right structure for them.

2.2.2 Trademarks

In the case of trademarks, the TPP broadens the scope of different types of trademarks, and when compared to the TRIPS Agreement, it sets out the following additional standards.²⁷ To begin with, it stipulates that the registration of trademarks does not need to cover signs that are visually perceptible, and extends the notion of trademarks to sounds, scent marks, collective marks and certification marks.²⁸ Well-known trademarks receive extensive coverage, including the stipulation that "no Party shall require as a condition for determining that a trademark is well-known that the trademark has been registered in the Party or in another jurisdiction, included on a list of well-known trademarks, or given prior recognition as a well-known trademark."²⁹

At the same time, there is need to provide for appropriate measures to refuse an application or cancel the registration and prohibit the use of a trademark that is identical or similar to a well-known mark for identical or similar goods or services, if the use of that trademark is likely to cause confusion with the prior well-known trademark. Such measures might include cases in which the subsequent trademark is likely to deceive. It also sets out procedural aspects of examination; opposition and cancellation include the use and encouragement of electronic means.

24 Cooperation could cover broad areas, including developments in domestic and international IP policy; education and awareness relating to IP; science, technology and innovation activities, and the generation, transfer and dissemination of technology; policies involving the use of IP for research, innovation and economic growth; see Article 18.13, TPP.

25 See Article 18.16, TPP.

26 See Daniel E. Robinson, Ahmed Abdel-Latif and Pedro Roffe (eds), *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Abingdon: Routledge, 2017).

27 Trademarks are dealt in Section C of Chapter 18, see Articles 18.18–18.28, TPP.

28 The agreement stipulates that registration cannot be denied only on the ground that the sign of which it is composed is a sound.

29 Article 18.22, TPP.

The TPP consolidates in this section the expansion of the coverage of trademarks since the adoption of the TRIPS Agreement, particularly in the case of well-known marks and more importantly by reinforcing related enforcement measures with respect to counterfeit or confusingly similar trademarks in provisions dealing with border measures³⁰ and criminal procedures in cases of wilful trademark counterfeiting, which has repercussions for a number of ongoing debates.

2.2.3 Geographical indications

The TPP, influenced by the US view on these matters, provides that geographical indications (GIs) may be protected by a trademark or sui generis system or other legal means.³¹ There is obviously an attempt at a balancing act in the agreement with respect to providing safeguards to ease tensions between trademarks and geographical indications, as has been the case in multilateral discussions in the WTO or as compared to trade agreements where the European Union (EU) is a party. The TPP, however, plainly exports the US approach to GIs. This approach contrasts with that of the EU, which in its trade agreements seeks to transplant its GI culture to third countries. Susy Frankel explains this dichotomy lucidly:

The approach of trying to force a one-size-fits-all model is certainly not the exclusive domain of the European Union in its trade agreements. While the United States does not seek to export GI laws through its trade agreements, it does export its view of how trademark law should dominate and how GIs, if and where they exist, should not trump trademarks, but rather trademarks should prevail over GIs.³²

The TPP accomplishes this goal by underscoring that grounds of opposition and cancellation include situations where the GI is likely to cause confusion with a trademark that is the subject of a pre-existing good faith pending application or registration in the territory of the host country; when it is likely to cause confusion with a pre-existing trademark, the rights to which have been acquired in accordance with domestic law; and when the GI is a term customary in common language as the common name for the relevant good in the territory of the party.

On possible conflicts with other trade agreements subscribed to by a party, the TPP attempts to deal with this in a lengthy provision on "International Agreements" that recognises the pre-eminence of agreements concluded or agreed, ratified or entered into force prior to the TPP conclusion, ratification or entry into force.³³ This provision aims at easing tensions that might arise between countries that have negotiated or are in the process of negotiating with the EU trade agreements incorporating provisions on GIs that respond to the traditional line of expanding the coverage of GIs beyond agricultural products and wine and spirits. In practice, however, it is to be expected that countries that have signed FTAs with both the US and the EU will experience difficulties in the implementation of these different approaches to dealing with GIs.

30 Article 18.76, TPP.

31 For geographical indications, see Section E, Articles 18.30–18.36, TPP.

32 S. Frankel, "Geographical Indications and Mega-Regional Trade Agreements and Negotiations," in *Geographical Indications at the Crossroads of Trade, Development, and Culture: Focus on Asia-Pacific*, ed. I. Calboli and W. L. Ng-Loy (pp. 147–167) (Cambridge: Cambridge University Press, 2017).

33 Article 18.36.6, TPP.

2.2.4 General provisions on patents

Perhaps one of the most controversial areas in the negotiations was related to the provisions of the agreement on patents and undisclosed test or other data, where the TPP includes detailed provisions, consolidating earlier trade agreements signed with a great number of TPP members.

The opening section in this part of the agreement includes provisions on patentable subject matter; grace period; patent revocation; exceptions; other use without authorisation of the right holder (compulsory licensing); patent filing, amendments and observations and publication of patent applications; and patent term adjustment for unreasonable granting authority delays.³⁴

Salient changes in the TPP compared to TRIPS are the following:

- Patents are now available for new uses of a known product, new methods of using a known product, or new processes of using a known product.
- Plants other than microorganisms may be excluded from patentability. However, there is a commitment that patents are available at least for inventions that are derived from plants.
- In cases of unreasonable delays in the issuance of patents and at the request of the patent owner, there should be an adjustment of the term to compensate for such delays.³⁵

The TPP does not alter the general standards for patentability—novelty, inventive step and industrial application—inscribed in earlier generations of FTAs, but, as described, it extends the availability of patents for inventions related to new uses, new methods, or new processes using a known product. This provision can be considered equivalent to “evergreening” and thus lowering the standards of patentability, with the proviso that members have the chance to “limit those new processes to those that do not claim the use of the product as such.”³⁶

2.2.5 Measures relating to agricultural chemical products

In the area of agricultural chemical products, the TPP doesn't chart new ground when compared to earlier bilateral trade agreements that most members of the TPP were party to, but elevates the provisions to the plurilateral level for the first time.³⁷ Compared with the TRIPS Agreement, the agreement consolidates the marketing approval and market exclusivity requirements to a certain extent, thereby providing for much stronger protection.

In particular, in cases of marketing approval for a new agricultural chemical product, the TPP deems the submission of undisclosed test or other data concerning the safety and efficacy of the product *unusable* by third parties, without the consent of the person that previously submitted such information, in marketing the same or a similar product on the basis of that information or the marketing approval granted to the person that submitted such test or other data for at least 10 years from the date of marketing approval of the new agricultural chemical product in the territory of the host country.

34 See Section F, Subsection A (General Patents), Articles 18.37–18.46, TPP.

35 The agreement clarifies that an unreasonable delay shall include a delay of more than five years from the date of filing of the application, or three years after a request for examination of the application has been made, whichever is later.

36 Article 18.37.2, TPP.

37 See Article 18.47, TPP.

The TPP adds a further obligation, which is not common in agreements of the earlier generation, providing that the market exclusivity is extended to the submission of evidence of a prior marketing approval of the product in another territory, for at least 10 years from the date of marketing approval of the new agricultural chemical product in the territory of the host country.

This market exclusivity provision is highly interesting from the perspective that it strengthens the extent of protection provided by patents. Since market exclusivity (exclusive market for the product that the protection is extended to) can be much stronger than patent protection (where the protected product still competes with others already existing in that product category), it is open to review what the competitive effects of the provision are, in a dynamic sense. More importantly, it seems likely that it could provide a venue for firms with valuable inventions to strategically target market segmentation in TPP member countries.

2.2.6 Measures relating to pharmaceutical products

In the section on pharmaceutical products,³⁸ the agreement covers important issues that have a direct bearing on access to these products, such as patent term adjustment for unreasonable curtailment;³⁹ regulatory review exception; protection of undisclosed test or other data; biologics; definition of new pharmaceutical product;⁴⁰ measures relating to the marketing of certain pharmaceutical products; and alteration of period of protection. Following sections deal selectively with some of these questions that are relatively new and go beyond what was prescribed in TRIPS.⁴¹

Protection of undisclosed test or other data

The TPP expands the protection of undisclosed data⁴² to new situations that were not previously covered in earlier trade agreements until KORUS. This protection is now accorded to new clinical information in support of previously approved products covering new indications or formulations, with the proviso that countries may take measures to protect public health in accordance with the WTO Declaration on TRIPS and Public Health.

These provisions apply to the entry into the market of competitive products, in the following ways:

38 Articles 18.48–18.54, TPP.

39 Contrary to TRIPS, which did not deal with this matter, but as in the case of earlier trade agreements, the TPP provides for more detailed principles to adjust the patent to compensate for unreasonable curtailment of the effective duration of the patent as a result of marketing approval. Best efforts should be made to process applications for marketing approval of pharmaceutical products in an efficient and timely manner. In implementing this obligation, countries may provide for conditions and limitations, provided that they continue to give effect to this obligation. With the objective of avoiding unreasonable curtailment of the effective patent term, countries may adopt or maintain procedures that expedite the processing of marketing applications. (Article 18.48, TPP.)

40 "A new pharmaceutical product means a pharmaceutical product that does not contain a chemical entity that has been previously approved in that Party" (Article 18.52, TPP).

41 See the chapter by Frederick Abbott in this volume, on a detailed review of the evolution of the pharmaceutical issues in FTAs negotiated by the US. See also on the TPP and access to medicines, Raquel Artecona and Rosine M. Plank-Brumback, "Access to Medicines and Incentives for Innovation: The Balance Struck in the Trans-Pacific Partnership (TPP) on Intellectual Property (Patent and Data Exclusivity) Protection for Pharmaceutical Products," ECLAC Office in Washington, DC, November 2016; Carlos M. Correa, "Intellectual Property in the Trans-Pacific Partnership: Increasing the Barriers for the Access to Affordable Medicines," Research Paper 62R, South Centre, July 2017.

42 See Article 18.50, TPP.

- The submission of undisclosed test or other data concerning the safety and efficacy of the product cannot be used by third persons, for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the host country, without the consent of the person that previously submitted such information, to market the same or a similar product.
- The same principle applies to the submission of evidence of prior marketing approval of the product in another territory. The five years applies from the date of marketing approval of the new pharmaceutical product in the territory of the host party.
- The same protection against the use by third persons applies for a period of at least three years with respect to new clinical information submitted in support of a marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration; or, alternatively, for a period of at least five years to new pharmaceutical products that contain a chemical entity that has not been previously approved in that country.

While these provisions allow countries to take measures to protect public health in accordance with the WTO 2001 Ministerial Declaration, parties will have to do so in a very subtle and innovative way to overcome the constraints they impose on the entry into the market of competitive products. These provisions certainly help reinforce the position of established pharmaceutical firms.

Biologics

The TPP introduces innovative provisions on the protection of new biologics that were not present in any of the earlier trade agreements. In fact, this is one area that divided trading partners and they were unable to find a solution until the very end of the negotiations. The duration of the protection was one of the main obstacles, with the US favouring a protection ranging from 8 to 12 years. Most of the other partners considered it unnecessary to make a distinct case for biologics different from the one on non-biological products. The final outcome negotiated is a new standard, although ambiguous. The TPP now provides for protection of biologics, which was earlier not a subject matter for protection, for a mandatory minimum of five years. It allows, however, the possibility of providing protection for anything up to eight years if members choose to do so.

The text also provides for a review of the situation in 10 years, given that international and domestic regulation of new pharmaceutical products that are or contain a biologic is at a formative stage and that market circumstances may evolve over time.⁴³

43 See Article 18.51: Biologics, TPP:

"1. With regard to protecting new biologics, a Party shall either:

(a) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively,

(b) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection:

(i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least five years from the date of first marketing approval of that product in that Party,

(ii) through other measures, and

Measures relating to the marketing of certain pharmaceutical products

The TPP provides special measures that need to be adopted as a condition for marketing approval to rely on evidence or information concerning the safety and efficacy of a product previously approved, such as evidence of prior marketing approval by the host country party or in another territory.⁴⁴ This is not new; it follows what has already been ongoing in other trade agreements. In these situations, it calls for measures that offer sufficient notice and opportunities to the patent holder to be informed of marketing approvals required by third parties and adequate procedures, including preliminary injunctions for the resolution of disputes concerning the validity or infringement of applicable patents. This creates a clear “linkage” between marketing approval and the status of a patent.

No alteration of the period of protection of undisclosed data

The TPP clarifies—as in the cases of KORUS and the FTA with Peru—that the period of protection afforded to undisclosed test or other data including biologics is not affected in the event that the related patent protection terminates on a date earlier than the period of protection for undisclosed data.⁴⁵

2.2.7 Copyright

Copyright is a relatively long section in the TPP,⁴⁶ which consolidates what has been achieved—beyond the TRIPS Agreement—in earlier trade agreements in terms of reinforcing and strengthening the rights of right holders, particularly those pertaining to the digital sphere. The agreement reinforces the right of reproduction in terms giving authors, performers and producers of phonograms “the exclusive right to authorise or prohibit all reproduction of their works, performances or phonograms in any manner or form, including in electronic form.”⁴⁷ The same applies to the right of communication to the public, and the right of distribution. Special clarifications are made with respect to related rights with attention to the exclusive rights of performers to authorise or prohibit certain acts of broadcasting, communication to the public, and fixation of their unfixed performances.⁴⁸

(iii) recognising that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.

2. For the purposes of this Section, each Party shall apply this Article to, at a minimum, a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.

3. Recognising that international and domestic regulation of new pharmaceutical products that are or contain a biologic is in a formative stage and that market circumstances may evolve over time, the Parties shall consult after 10 years from the date of entry into force of this Agreement, or as otherwise decided by the Commission, to review the period of exclusivity provided in paragraph 1 and the scope of application provided in paragraph 2, with a view to providing effective incentives for the development of new pharmaceutical products that are or contain a biologic, as well as with a view to facilitating the timely availability of follow-on biosimilars, and to ensuring that the scope of application remains consistent with international developments regarding approval of additional categories of new pharmaceutical products that are or contain a biologic.”

44 Article 18.51, TPP.

45 See Article 18.54, TPP.

46 Copyright and related rights are dealt with in Section H, Articles 18.57–18.70, TPP.

47 Article 18.58, TPP.

48 Article 18.62, TPP.

By the same token, in line with the earlier generation of trade agreements, the TPP reaffirms that there is no hierarchy between the rights of the author of work embodied in phonograms and those of a performer or producers.⁴⁹

With respect to the term of protection for copyright and related rights, contrary to initial proposals to fix duration between 90 and 110 years, the final text adds 20 years of protection to the minimum standard in TRIPS. In a trend that is in line with earlier trade agreements, the TPP provides a protection period of 70 years after the author's death in the case of natural persons and no less than 70 years in the case of legal persons.⁵⁰

But, in an unprecedented manner, the TPP offers an interesting provision on the balance of rights in copyright and related rights. In line with US law, it validates the goal of achieving an appropriate balance in its rights system, among other things by means of limitations or exceptions, including those for the digital environment, for "purposes such as, but not limited to: criticism; comment; news reporting; teaching, scholarship, research, and other similar purposes; and facilitating access to published works for persons who are blind, visually impaired or otherwise print disabled."⁵¹ Scholars have highlighted this progressive evolution in the TPP with respect to earlier trade agreements of the first or second generation by transplanting in the TPP the fair use concept.⁵²

Trade agreements have not shied away from dealing with matters related to the digital environment, which was not touched upon in TRIPS. In that tradition, the TPP deals extensively with the circumvention of effective technological protection measures;⁵³ adequate and effective legal remedies to protect rights management information (RMI);⁵⁴ and internet service providers (in Section J of the TPP chapter on IP).⁵⁵ All these provisions, together with those on enforcement, are related to and supportive of the principles and standards established on electronic commerce in the agreement.

49 For example, the need for the authorisation of the author does not cease to exist because the authorisation of the performer or producer is also required; and otherwise, the need for the authorisation of the performer or producer does not cease to exist because the authorisation of the author is also required (Article 18.61). In an extension of this non-hierarchical character of rights, the TPP provides that any person acquiring or holding any economic right in a work, performance or phonogram: may freely and separately transfer that right by contract; and by virtue of contract shall be able to exercise that right in that person's own name and enjoy fully the benefits derived from that right. See Article 18.67, TPP.

50 Article 18.63, TPP.

51 Article 18.66, TPP.

52 Jonathan Band, "Evolution of the Copyright Exceptions and Limitations Provision in the Trans-Pacific Partnership Agreement" (11 November 2015), at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2689251.

53 "Effective technological measure means any effective technology, device, or component that, in the normal course of its operation, controls access to a protected work, performance, or phonogram, or protects copyright or related rights related to a work, performance or phonogram" (Article 18.68.5, TPP).

54 "RMI means:

(a) information that identifies a work, performance or phonogram, the author of the work, the performer of the performance or the producer of the phonogram; or the owner of any right in the work, performance or phonogram;

(b) information about the terms and conditions of the use of the work, performance or phonogram; or

(c) any numbers or codes that represent the information referred to in subparagraphs (a) and (b),

if any of these items is attached to a copy of the work, performance or phonogram or appears in connection with the communication or making available of a work, performance or phonogram to the public" (Article 18.69.4, TPP).

55 See Articles 18.81–18.82, TPP.

2.2.8 Enforcement

The enforcement section (Section I) is one of the longest in the TPP, including almost 15 pages of text, and broadens the provisions in the TRIPS Agreement.⁵⁶ The TPP consolidates the gains made in earlier trade agreements, including KORUS and the failed plurilateral ACTA treaty, but moves issues forward, characterised by some as securing an “ACTA-plus” enforcement framework.⁵⁷

The enforcement machinery broadly follows the TRIPS structure, covering a number of issues ranging from general provisions;⁵⁸ civil and administrative procedures and remedies;⁵⁹ provisional measures;⁶⁰ special requirements related to border measures; criminal procedures and penalties;⁶¹ trade secrets;⁶² protection of encrypted program-carrying satellite and cable signals;⁶³ to government use of software.⁶⁴ But the TPP is far less ambiguous in these matters, building on earlier agreements, but expanding and strengthening the enforcement procedures to permit effective action in case of infringement of these rights, “including expeditious remedies to prevent infringements and remedies that constitute a deterrent to future infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and provide for safeguards against their abuse.”⁶⁵

A novel subject matter in the TPP on which it extends enforcement when compared to earlier trade agreements is trade secrets. It provides for criminal procedures and penalties in cases such as the unauthorised and wilful access to a trade secret held in a computer system; the unauthorised and wilful misappropriation of a trade secret, including by means of a computer system; or the fraudulent disclosure, or alternatively, the unauthorised and wilful disclosure, of a trade secret, including by means of a computer system.⁶⁶ The agreement emphasises that those acts should be for purpose of “commercial advantage or financial gain” or to “injure the owner of such trade secret.”

3. Open Questions for Policy in the Aftermath Of TPP

There are several open questions for policy at the national and international levels if the TPP is considered in conjunction with where we are today in multilateral negotiations. These relate to the implications of the emergence of such a “mega” regional agreement, and the future of trade and

56 See Section I of Chapter 18, Articles 18.71–18.80, TPP. See also the chapter by Xavier Seuba in this volume providing a detailed analysis of enforcement issues.

57 See Pedro Roffe and Xavier Seuba (eds), *The ACTA and the Plurilateral Enforcement Agenda: Genesis and Aftermath* (Cambridge: Cambridge University Press, 2015).

58 Article 18.71, TPP.

59 Article 18.74, TPP.

60 See Article 18.75, TPP.

61 See Article 18.77, TPP.

62 See Article 18.78, TPP.

63 See Article 18.79, TPP.

64 See Article 18.80, TPP.

65 Article 18.71.1, TPP.

66 See Article 18.78, TPP.

policy space of countries. In this section, we seek to raise the most pertinent concerns in this regard for both members and non-members of the TPP.

3.1 Is This a Gradual Blurring of Free Market and Regulatory Issues?

In keeping with the earlier FTAs, the TPP also comes with the underlying presumption that the free market/common market access issues will be treated differentially from regulatory measures. In other words, that conventional trade issues—such as tariffs and barriers to trade—can be used to create a preferential market, but the regulatory framework that is set out in the agreement is expected to be implemented by all its member countries subject to the transition arrangements agreed by countries as part of the agreement. This would also mean that within the TPP countries, these regulatory reforms would be applicable in the same way to one and all (due to the MFN principle), thereby also extending to all non-members.

But it would be important to note at this point that there are a number of issues that are blurry and have the potential to change the fundamental rules of the game.

To begin with, there are numerous areas where the TPP tries to regulate what has traditionally been thought to be in the trade domain. An example in point is that of technical barriers to trade, on which there is an entire annex in the agreement covering health-related questions (see Box 1).⁶⁷ The inclusion of such topics in the regulatory domain signals a shift in the traditional balance between trade and regulatory issues set out by the Uruguay Round. It goes to the heart of the main conundrum that has occupied economists studying the impact of preferential trading agreements on world trade flows and welfare.⁶⁸ Bhagwati calls these the static issues (what is the direct impact of the creation of preferential trading zones on welfare) and asks how they impact on or set incentives for further liberalisation on a non-discriminatory basis (from a dynamic perspective).⁶⁹ Previous analyses have argued that FTAs can be building blocks for global trade in a dynamic perspective, not only furthering the interests of countries which engage in them, but also facilitating multilateral negotiations.⁷⁰ Whether similar conclusions can be drawn in the context of the TPP, which contains a much more comprehensive framework, with lesser exceptions for liberalisation commitments and more extensive changes to domestic practices⁷¹ remains a matter for economic analysis when sufficient data are available on its effects on its member countries in the future.

67 See Annex 8-C, TPP.

68 J. Bhagwati, "Regionalism and Multilateralism: An Overview," in *New Dimensions in Regional Integration*, ed. J. De Melo and A. Panagariya (Cambridge: Cambridge University Press, 1993); A. Panagariya, "Preferential Trade Liberalization: Traditional Theory and New Developments," *Journal of Economic Literature* 38 (2000): 287–331.

69 Bhagwati, "Regionalism and Multilateralism."

70 P. Aghion et al., "Negotiating Free Trade," *Journal of International Economics* 73 (2007): 1–30; K. Saggi and H. M. Yildaz, "Bilateral Trade Agreements and the Feasibility of Multilateral Free Trade," *Review of International Economics* 19, no. 2 (2011): 356–373.

71 J. J. Schott., "Understanding the Transatlantic Pacific Partnership: An Overview," Working Paper, Peterson Institute of International Economics, 2016 (on file with the authors).

Box 1: Blurring trade and regulatory issues: the case of technical barriers to trade

Annex 8-C of the TPP applies to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation and notification procedures of central government bodies that may affect trade in pharmaceutical products between the parties.^a It further obliges the member parties to collaborate through relevant international initiatives, such as those aimed at harmonisation, as well as regional initiatives that support those international initiatives to improve the alignment of their respective regulations and regulatory activities for pharmaceutical products.

It stipulates:

- (a) Guidelines on market authorisation for pharmaceutical products that should include, among others: information on pre-clinical and clinical data, on safety and efficacy; information on the manufacturing quality of the product; and labelling information related to the safety, efficacy and use of the product.
- (b) Marketing authorisation for a pharmaceutical product should be decided within a reasonable period of time and provide at least that:
 - Any marketing authorisation determination is subject to an appeal or review process that may be invoked at the request of the applicant.
 - In case of periodic reauthorisation for a pharmaceutical product the pharmaceutical product should remain on its market pending a decision on the periodic reauthorisation.

- a The annex does not apply to a technical specification prepared by a governmental entity for its production or consumption requirements or a sanitary or phytosanitary measure.

There is reason to suspect that these trade-offs for individual countries, as well as global trade, might be different in the future when considered in a dynamic perspective for at least a few preliminary reasons. First, what we have now is a free trade zone with a relatively higher level of regulatory standards (especially in terms of IPR protection). Since, in many cases, the form of market exclusivity granted by the TPP in the case of pharmaceuticals can be much stronger than patent protection (where the protected product still competes with other products in that category), the effects of such provisions on competition in the in-country markets in the TPP countries, in a dynamic sense, are open to review. It seems likely that it could provide an opportunity for firms with valuable inventions to strategically target market segmentation in such product categories in TPP member countries. Furthermore, this offers firms that already have incumbent advantages or seek such advantages a larger sphere of IP and related protection (market approval, market exclusivity and related provisions) that preserves their market-specific advantages in the wider regional zone.⁷² By doing so, it is not just using preferential trade measures to the advantage of the regional zone, but also the regulatory measures to assist technologically advanced firms from within the zone in preserving their market returns and IPR-related rents for a longer period of time, thereby reducing the threat of competition from outside firms which seek to enter the technological and product market in these product categories.

Secondly, the TPP template paves the way for the inclusion of other strategic links between regulatory matters and trade gains in more pervasive ways in an effort to curb trade deficits, or improve

72 Gehl Sampath and Park use data from the database of the Bureau of Economic Analysis, US Department of Commerce, of US multinationals and their subsidiaries in India, Brazil and China to show that patents in the pharmaceutical, chemical, and information and communication technology sectors lead to market concentration in these sectors with related anti-competitive effects. They also find that the rate of return of firms for a 1% increase in patent protection (due to regulatory reforms) is over 2% when measured against the firm's productivity; see P. Gehl Sampath and W. Park, "How Patents Can Facilitate Market Concentration," UNCTAD Discussion Paper (2017, forthcoming).

national trade balances, in line with the new proposed objectives for the NAFTA renegotiations.⁷³ Such requirements are potentially problematic because they link trade even more closely with the fiscal and eventually the financial independence of countries.

3.2 Is This a New Institutional Architecture, a Blueprint for a Common Multilateral Future?

When the US withdrew from the TPP, a large number of scholars and global trade activists heaved a sigh of relief. The view that the TPP would end up creating a free trade zone that cordons off 40 percent of global GDP and one-third of world trade⁷⁴ with preferential rules was accompanied by an apprehension that such a "mega" regional would eventually increase incentives for outside countries to seek accession to this free trade area. It was widely feared that the deal would eventually have resulted in creating a parallel regulatory framework governing global trade, legitimising the standards of the TPP as an alternative later-day clarification to the TRIPS Agreement in many ways.

The withdrawal of the US notwithstanding, given that the US still endorses the same regulatory framework within its boundaries, the TPP is a compelling alternative to the multilateral institutional architecture as far as regulatory reforms are concerned. It therefore remains a framework that continues to be in force in countries that account for 40 percent of world trade. Moreover, it contains the most comprehensive coverage to date of many of the questions that have been part of long drawn-out battles between countries, including e-commerce, with clear definitions that are enforceable, alongside a strong enforcement apparatus. Therefore, it remains a standard to contend with in multilateral negotiations due to the extensive nature of these sections in the TPP.⁷⁵ In this sense, there is a real possibility of the "bandwagon" effect that scholars have previously warned about where the provisions proposed by the trade giants have the propensity to influence the other nations to follow.⁷⁶

E-commerce is an area where this potential will be tested in the immediate future, when the topic may be negotiated by countries at the 11th WTO Ministerial in Argentina in December 2017. Due to the comprehensive character of the TPP's provisions (Box 2), and the broad consensus reached by the negotiating parties, the TPP template can be expected to have a profound influence on future negotiations on electronic commerce.⁷⁷ Some other areas where the TPP's regulatory framework may be put forward as a template by its current signatories at the multilateral level include the protection of pharmaceutical products (including biologics), traditional knowledge, copyrights and enforcement issues.

73 See USTR, "Summary of Objectives for the NAFTA Renegotiation," 17 July 2017, at <https://ustr.gov/sites/default/files/files/Press/Releases/NAFTAObjectives.pdf>.

74 K. Granville, "What Is the TPP: Behind the Trade Deal That Died," *New York Times*, 23 January 2017.

75 See Summers for a discussion of how regional trade agreements facilitate multilateral negotiation by consolidating the common interests of its member countries; L. H. Summers, "Regionalism and the World Trading System: Policy Implications of Trade and Currency Zones," Federal Reserve Bank, Kansas City, 1991.

76 R. Baldwin and D. Jaimovich, "Are Free Trade Agreements Contagious?" *Journal of International Economics* 88 (2012): 1–16.

77 See, for example, "Trump Administration Draft Notice of Intent to Renegotiate NAFTA," where two main objectives are addressed: "Seek commitments from the NAFTA countries not to impose custom duties on digital products or unjustifiably discriminate among products delivered electronically.

Seek to ensure that the NAFTA countries refrain from implementing measures that impede digital trade in goods and services, restrict cross-border data flows, or require local storage or processing of data, including with respect to financial services, and that where legitimate policy objectives require domestic regulations that may affect such trade or flows, obtain commitments that any domestic regulations are the least trade restrictive, non-discriminatory, and transparent, and promote an open market environment." At <http://infojustice.org/archives/37955>.

Box 2: E-commerce: Can the TPP set the standard at the WTO Ministerial?

The TPP provides for the most comprehensive coverage of “e-commerce” compared to earlier trade agreements negotiated since 1994, recognising “the economic growth and opportunities provided by electronic commerce and the importance of frameworks that promote consumer confidence in electronic commerce and of avoiding unnecessary barriers to its use and development.”^a For the United States Trade Representative (USTR), one major accomplishment of the TPP was the e-commerce component that, among others, commits parties “to ensuring free flow of the global information and data that drive the Internet and the digital economy, subject to legitimate public policy objectives such as personal information protection.”^b

It is not new that FTAs of earlier generations included related digital trade issues to ensure the implementation of a digital agenda that could not be achieved in the multilateral system.^c Earlier FTAs made some progress on cross-border trade and a general permanent duty-free moratorium on the import or export of digital products and electronic transmission.^d Intellectual property related matters were already covered in these earlier FTAs with an important bearing on e-commerce through issues such as adherence to the WIPO Internet Treaties of 1996; technological protection measures and rights management information; encrypted satellite signals; domain names; government use of software; and internet service providers. Chapter 14 of TPP, however, is by far the most extensive.^e

The TPP establishes the following governing principles to guide electronic commerce:

- No customs duties on electronic transactions.
- Non-discriminatory treatment of digital products in terms of no less favourable treatment than that accorded to other like digital products.
- The maintenance of a domestic legal framework governing electronic transactions that, among other things, should avoid unnecessary regulatory burdens.
- No denial of the legal validity of a signature solely on the basis that it is in electronic form.
- The adoption and maintenance of transparent effective measures to protect consumers from fraudulent and deceptive commercial activities.
- Recognition of the economic and social benefits of protecting personal information of users to enhance consumer confidence in electronic commerce.
- Paperless trading by making trade administrative documents available in electronic form and as legal equivalents of the paper version of those documents.
- Principles on access to and use of the internet for electronic commerce by, inter alia, recognising the ability and choice of consumers to access and use services and applications available on the internet.
- Recognition that states may have their own regulatory requirements concerning the transfer of information by electronic means but allowing the cross-border transfer of information by electronic means, including personal information, when this activity is for the conduct of business.
- States may have their own regulatory requirements regarding the use of computing facilities, including requirements that seek to ensure the security and confidentiality of communications; however, there should be no requirement to use or locate computing facilities in a host territory as a condition for conducting business in that territory.
- States need to adopt measures regarding unsolicited commercial electronic messages by, among other things, providing legal recourse against such suppliers.
- The recognition of the global nature of electronic commerce and thus the need for international cooperation to assist, for example, small and medium-sized enterprises in overcoming obstacles to its use and cooperation on cybersecurity matters.
- There is no obligation to require the transfer of, or access to, source code of software owned by a person of another state, as a condition for the import, distribution, sale or use of such software, or of products containing such software, in its territory.^f

a Article 14.2.1, TPP.

b USTR, “Summary of the Trans-Pacific Partnership Agreement,” Press Release, October 2015, <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/summary-trans-pacific-partnership>.

c See S. Wunsch-Vincent and A. Hold, “Towards Coherent Rules for Digital Trade: Building on Efforts,” in *Trade Governance in the Digital Age*, ed. M. Burri and T. Cottier (pp. 179–221) (Cambridge: Cambridge University Press, 2012).

d Wunsch-Vincent and Hold, “Towards Coherent Rules for Digital Trade.” See also the chapter by Mira Burri in this volume, dealing with the topic extensively and highlighting that “the TPP template with regard to digital trade is distinct not only in its high standards but also in the breadth of issues covered that matter more or less immediately for the contemporary digital economy.”

e Chapter 14 of KORUS on electronic commerce is not as inclusive as Chapter 14 in the TPP.

f See Article 14.17, TPP, clarifying that software in these cases is limited to mass-market software or products containing such software and does not include software used for critical infrastructure.

3.3 Are There New Negotiating Trade-offs for Developing Countries?

The TPP proposes a form of regionalism that raises several questions for developing countries. It is the first regional trade agreement between members that are not at similar levels of development (or bound by similar economic and regional interests, such as the EU or ASEAN), yet it creates a significant economic bloc with deep regulatory harmonisation. It establishes a form of "open" as opposed to "closed" regionalism,⁷⁸ in the sense that there seems to be the possibility for other countries to join, and accession is not restricted based on a regional, geographical or other consideration.

There seem to be provisions in the TPP that cater to differences in development levels and public interest concerns. The TPP in its introductory part reproduces Articles 7 and 8 of the TRIPS Agreement on objectives and principles and additionally recognises the need to promote innovation and creativity; facilitate diffusion of information, knowledge, technology, culture and the arts; and foster competition and open and efficient markets.⁷⁹ It recognises the obligation of parties to ratify or accede to international agreements on protection and cooperation in diverse areas of IP, including a number of WIPO administered treaties.⁸⁰ As a response to the public health concerns raised at the time of the WTO Ministerial Declaration on Public Health, the TPP unmistakably states that the TPP provisions "do not and should not prevent a Party from taking measures to protect public health" in line with commitments made in the WTO.⁸¹

But, at the same time, any new members—should they choose to join the agreement—will not be able to renegotiate the text; rather, they are takers of the regulatory standards that are currently set out by those that negotiated it. As a result, there is no choice of "sequential bargaining," which is considered to be a main advantage of FTAs when compared with multilateral bargaining.⁸² While this may not be such a problem for some countries, it will limit the choices for many other developing countries that choose to join later, especially if they have economic structures that are different from those developing countries that are already party to the agreement. Economic structures of countries can differ if they are strongly embedded in natural resources, have endemic weaknesses in their industrial sectors (especially manufacturing), or have weak scientific infrastructure, among other factors. These factors may imply differential trade-offs for countries, with little room to manoeuvre, as the lengthy review of the TPP's provisions in Section 2 of this paper has highlighted wherever possible.

For example, the performance requirements in the investment section limit countries in what is considered policy space in traditional industrial policy. As a result, although investment and IPRs can be linked explicitly with any domestic requirement for transfer of technology/local content, for the TPP countries, investment is expected to promote technology transfer and spillovers through tacit know-how transfer at the enterprise level, brain gain, and other such mechanisms that are more indirect. This, while being effective, works only when there is some level of technology absorption

78 S. S. Yi, "Endogenous Formation of Customs Unions under Imperfect Competition: Open Regionalism Is Good," *Journal of International Economics* 41 (1996): 153–177.

79 See Article 18.4, TPP.

80 For example, Paris and Berne Conventions and facilitation and classification treaties (e.g., Patent Cooperation Treaty, Madrid Protocol), Article 18.7, TPP.

81 See Article 18.6, TPP.

82 See Aghion et al., "Negotiating Free Trade."

capacity and a wider enabling context with industrial capabilities.⁸³ Other degrees of freedom that are important for countries that have had long-term difficulties in promoting sustained industrialisation can be reduced or eliminated through clear definitions and specifications of terms of protection for many IP provisions when compared to the TRIPS Agreement, raising doubts as to whether this could be beneficial to all countries.⁸⁴

4. Future Scenarios in the Post-TPP World: Some Food for Thought

In the preceding discussion, this paper has presented a large number of dilemmas raised by the TPP for its own member countries, non-member countries and multilateral trade. Despite our best efforts, we have only been able to point to these many issues, and there is a need for further research on these and other aspects that we could not focus on entirely.

To return to the questions that this paper began with, the TPP's provisions rigorously negotiated between the countries are still intact, and are expected to be implemented in its member countries. It is a fact that they are left saddled with a US-led regulatory template, but whether the trade-offs for the remaining countries are different in the aftermath of the exit of the US (and preferential access to its market), and how they will reassess their costs and benefits of being in the TPP remains to be seen. On the question of whether the TPP's regulatory stance will become commonplace in other FTAs, both those negotiated by the US and those that will be proposed by its existing partners, we find in the affirmative as well.

We envision the following scenarios, all of which sketch alternative visions of a post-TPP world.

A first scenario is that the remaining countries continue to implement the TPP in the absence of the US, and use it as a template in other bilateral and plurilateral agreements with other countries.

A second scenario is indeed that, as suggested by the Trump administration, the US negotiates bilateral arrangements with some if not all of the TPP countries, and other countries in general. In these cases, it is likely that "TPP-plus" or "TPP-extra" standards will emerge, as the US seeks to ratchet up its stance further on several provisions. The recently released USTR "Summary of Objectives for the NAFTA Renegotiation" supports this scenario, particularly with respect to e-commerce,⁸⁵ investment,⁸⁶

83 See P. Gehl Sampath and P. Roffe, *Unpacking the International Technology Transfer Controversy: Fifty Years and Beyond, Working Paper*, International Centre for Trade and Sustainable Development, Geneva, 2012.

84 See Saggi and Yıldaz, "Bilateral Trade Agreements"; O. S. Dahi and F. Demir, "Preferential Trade Agreements and Manufactured Goods Exports: Does It Matter Whom You PTA With?" *Applied Economics* 45, no. 34 (2013): 4754–4772.

85 USTR, "Summary of Objectives for the NAFTA Renegotiation," released 17 July 2017. The summary, for example, refers to the following objectives in the case of e-commerce: secure commitments not to impose customs duties on digital products (e.g., software, music, video, e-books); ensure non-discriminatory treatment of digital products transmitted electronically and guarantee that these products will not face government-sanctioned discrimination based on the nationality or territory in which the product is produced; establish rules to ensure that NAFTA countries do not impose measures that restrict cross-border data flows and do not require the use or installation of local computing facilities; establish rules to prevent governments from mandating the disclosure of computer source code.

86 On investment: establish rules that reduce or eliminate barriers to US investment in all sectors in the NAFTA countries; secure for US investors in the NAFTA countries important rights consistent with US legal principles and practice, while ensuring that NAFTA country investors in the United States are not accorded greater substantive rights than domestic investors.

intellectual property;⁸⁷ and settlement of disputes.⁸⁸ In such a case, the TPP may become the more generous default position for countries to propose as a counter.

A third scenario concerns the pivotal role played by the US in the past in catalysing FTAs. This role could well be shepherded by the EU. To some extent, it could be argued that this is already taking place in light of the ongoing negotiations with countries in the Common Market of the South (MERCOSUR) and China. In this scenario, the EU could be complemented by initiatives of the emerging economies to launch plurilateral agreements that are more tuned to their needs.

A fourth scenario to expect would be that the TPP becomes an important regulatory template to contend with at the multilateral level, especially given that countries at widely differing levels of development have already endorsed it. This could lead to new rifts on where countries stand on key IP, investment and trade issues. Questions that remain in this context are the previous discussions on policy space and whether the need to create special concessions for levels of development is not so important any more. Where do we go from here on these issues, at the multilateral level? These are extremely important issues to consider for countries in order to be well prepared for future negotiations.

All of these are nail-biting outcomes that can be disputed, discussed or expanded upon. Whatever the case, the TPP is far from dead.

87 On intellectual property: ensure provisions governing intellectual property rights reflect a standard of protection similar to that found in US law; provide strong protection and enforcement for new and emerging technologies and new methods of transmitting and distributing products embodying intellectual property, including in a manner that facilitates legitimate digital trade; prevent or eliminate discrimination with respect to matters affecting the availability, acquisition, scope, maintenance, use, and enforcement of intellectual property rights; ensure standards of protection and enforcement that keep pace with technological developments, and in particular ensure that right holders have the legal and technological means to control the use of their works through the internet and other global communication media, and to prevent the unauthorised use of their works; provide strong standards enforcement of intellectual property rights, including by requiring accessible, expeditious, and effective civil, administrative, and criminal enforcement mechanisms; prevent or eliminate government involvement in the violation of intellectual property rights, including cybertheft and piracy; secure fair, equitable, and non-discriminatory market access opportunities for United States persons that rely upon intellectual property protection; respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001, and to ensure that trade agreements foster innovation and promote access to medicines; prevent the undermining of market access for U.S. products through the improper use of a country's system for protecting or recognising geographical indications, including failing to ensure transparency and procedural fairness and protecting generic terms.

88 With respect to disputes: encourage the early identification and settlement of disputes through consultation and other mechanisms; establish a dispute settlement mechanism that is effective, timely, and in which panel determinations are based on the provisions of the Agreement and the submissions of the parties and are provided in a reasoned manner; establish a dispute settlement process that is transparent by: requiring that parties' submissions be made publicly available; requiring that hearings be open to the public; enquiring that final determinations by a panel be made publicly available; and ensuring that non-governmental entities have the right to request making written submissions to a panel.

International Intellectual Property Enforcement: From Multilateralism to Plurilateralism and Bilateralism

Xavier Seuba

1. Setting the Scene

Norms on enforcement enable the effectiveness of norms establishing substantive rights and obligations. They set up the mechanisms that compel observance of the rights conferred by each intellectual property category and "permit effective action against any act of infringement of intellectual property rights."¹ Materialising substantive entitlements is their most visible function, but their importance goes well beyond that purpose. Indeed, norms on enforcement play a crucial systemic role, since it is in the combination of primary and secondary norms, the latter including norms on enforcement, that the constitutive characteristic of the legal system lies.²

The existence of two groups of norms of different nature which relate to each other introduces the idea of dynamism. In effect, enforcement is not a mechanical process and does not define a pre-established set of things. Instead, enforcement is a process of weighing and balancing rights and interests of different nature. Secondary norms enable that functioning and may open the door to various results. This dialogue takes place in the context of adjudication, but also of interpretation and legal change. Adjudication, interpretation and legal change are, in fact, the three fields of action of secondary norms.

While the relationship between enforcement rules and substantive rights is inextricable, it has many different grades, to the extent that enforcement options are many and may importantly shape substantive rights. The *eBay, Inc., v. MercExchange* litigation is a good case in point. In *eBay*, the Supreme Court of Justice of the United States differentiated "the creation of a right" from "the provision of remedies for violations of that right."³ This apparently trivial observation was, however, the basis for reversing the practice of United States courts of granting permanent injunctions almost automatically once patent infringement had been found. As a consequence, a powerful remedy such as an injunction would not necessarily follow the right to exclude.⁴ Other norms and principles, including values and legal interests found in other branches of the law, come into play. In the case of injunctions, this enables the transformation of the right to exclude into a right to receive compensation.

While these features revolve around the very nature of rights and obligations and could seem overly theoretical, they acquire great relevance in present international intellectual property lawmaking. The expansion of enforcement as an area of international regulation is one of the prominent trends since the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Such an expansion is part of a broader agenda comprising policy, normative and institutional initiatives for the protection of intellectual property rights. From the standpoint of their legal nature, norms of enforcement are secondary norms, usually secondary norms of adjudication. However, when observed from this angle, some norms adopted in the context of that broader enforcement agenda have a contested nature.

1 Article 41 of the TRIPS Agreement.

2 H. L. A. Hart, *The Concept of Law*, 2nd edn (Oxford: Oxford University Press, 1997).

3 *eBay, Inc., v. MercExchange, LLC*, 126 S.Ct. 1837 (2006), at 1840.

4 J. D. Sarnoff, "Flexible Application of Injunctive Relief in Intellectual Property Enforcement (with Reference to Lessons from the Emerging US Jurisprudence)," in *Intellectual Property Enforcement: International Perspectives*, ed. C. Correa and X. Li (Cheltenham: Edward Elgar, 2009), 103.

Whereas the nature of civil, border and criminal enforcement norms is not open to question, other cases are dubious. This applies particularly to the case of "enforcement" norms that not only enforce existing rights, but create new substantive rights. It is also the case for norms that transfer the responsibility to enforce intellectual property rights from the right holder to third parties. Likewise, inbuilt mechanisms in digital technologies to have intellectual property rights enforced by design also escape traditional legal accounts of the nature of norms. Expansion of the legal standing is a fourth area of debate. Finally, in that broader context of "frontier" enforcement norms, international enforcement mechanisms relating to intellectual property treaties deserve closer inspection, as well.

This chapter introduces the advances experienced in the plurilateral and bilateral normative context in the area of intellectual property enforcement. In order to do this, the multilateral setting is first addressed. This is the reason why it is particularly relevant to clarify the last area of contention mentioned,⁵ namely, whether norms found in international treaties and relating to enforcement can be actually considered intellectual property enforcement norms.

2. Enforcement of International Treaties and Enforcement of Intellectual Property Rights

Enforcement provisions enacted in international treaties pertain to two distinct realms. First, treaties frequently contain norms dealing with the enforcement of intellectual property in the national context and regulate civil, criminal and border enforcement remedies. Second, treaties also enshrine norms concerning the enforcement of the treaty itself. The latter include dispute settlement provisions as well as other mechanisms to supervise the fulfilment of the treaty, such as cooperation and exchange of information.

Keeping with the Hartian divide between primary and secondary norms, civil, criminal and border enforcement provisions are ascribed to the group of secondary norms in national legal systems. By contrast, norms that relate to the enforcement of a treaty are also secondary norms, but secondary norms of public international law. Provisions on treaty enforcement and articles on the enforcement of intellectual property rights differ in several respects. For instance, provisions on treaty enforcement shape the relations between states and infringement gives place to international responsibility of the state, whereas articles on intellectual property enforcement are meant to shape interpersonal relations and their actual infringement results in intellectual property violations.

The Anti-Counterfeiting Trade Agreement (ACTA) is a good example of a treaty laying down both types of provisions. Its Chapter II enshrines intellectual property enforcement obligations intended to apply to the relations between private parties. It regulates civil, administrative and criminal enforcement, as well as enforcement in the digital environment. By contrast, ACTA Chapter IV is devoted to international cooperation in the area of enforcement⁶ and Chapter V

5 The other areas are analysed in X. Seuba, *The Global Regime for the Enforcement of Intellectual Property Rights* (Cambridge: Cambridge University Press, 2017).

6 It regulates law enforcement cooperation with respect to criminal enforcement and border measures, information sharing, capacity building and technical assistance. See, respectively, Articles 33, 34, and 35 of ACTA.

includes institutional arrangements and sets up the ACTA Committee.⁷ Thus, even if Chapters IV and V are intended to promote the fulfilment of commitments in the intellectual property domain, they are specifically crafted to shape the behaviour of member states.

Obligations of horizontal nature rule the relations between contracting member states. This applies, for instance, to the obligation to communicate to the other treaty members information on the national efforts undertaken for the enforcement of intellectual property rights, commonly found in treaties. Instead, in vertical provisions states agree to regulate their relations with legal or natural persons in a specific manner. An example of an enforcement provision of a vertical nature would be TRIPS Agreement Article 42, which establishes that "Members shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement." Finally, in a third class of provisions, interpersonal provisions, states undertake to shape the relationship between private parties in a particular fashion. This applies, for instance, to provisions allowing the substitution of remedies such as injunctions by pecuniary compensation, a possibility found both in national and international law.⁸

These differences do not alter the state-centred nature of treaty norms. Instead, they just reflect the content of the compromises undertaken by states. They do not alter, either, the direct applicability of international law by national courts, which is a matter of local law. In this respect, depending on the specific wording of the provision and the national approach to the direct applicability of international law, an intellectual property enforcement provision of a vertical or interpersonal nature may be directly invoked in national litigation. That is, international norms on intellectual property enforcement can determine the relations between right holders, alleged infringers and users in daily litigation. This has, for instance, been the case in the Netherlands with regard to the TRIPS Agreement article on damages,⁹ and in Poland¹⁰ and Argentina in relation to the TRIPS Agreement article on provisional measures.¹¹ By contrast, the Court of Justice of the European Union has rejected the direct application of the very same article on interim injunctions.¹² While keeping due respect for national choices in the direct application of intellectual property provisions found in international treaties, these are conceived to shape national legal orders rather than becoming the primary source of litigation.

7 The ACTA Committee has been tasked to "review the implementation and operation of this Agreement." See Article 36 ACTA.

8 For instance, Article 159 EU-CARIFORUM States free trade agreement (FTA) and economic integration agreement (EIA) (2008) establishes that "in appropriate cases and at the request of the person liable to be subject to the measures provided for in Part III of the TRIPS Agreement and in this Chapter, the competent judicial authorities may order pecuniary compensation to be paid to the injured party instead of applying the measures provided for in Part III of the TRIPS Agreement or in this Chapter if that person acted unintentionally and without negligence, if execution of the measures in question would cause him disproportionate harm and if pecuniary compensation to the injured party appears reasonably satisfactory."

9 See Supreme Court, 19 December 2003, LJN AF9714, para. 5.2.3; quoted from D. Sloss, *The Role of Domestic Courts in Treaty Enforcement: A Comparative Study* (Cambridge: Cambridge University Press, 2009), 368.

10 Sloss, *The Role of Domestic Courts*, 395.

11 For a collection of an important number of cases where Article 50 of the TRIPS Agreement was directly invoked in Argentina, see M. Genovesi and J. Kors, "Medidas cautelares," in *Patentes de Invención: Diez Años de Jurisprudencia*, ed. J. Kors (pp. 153–181) (Buenos Aires: La Ley, 2005).

12 CJEU, Case C-300/98 and C-392/98 *Parfums Christian Dior SA v. Tuk Consultancy*, 2000.

3. Evolution of The International Codification of Enforcement

Obligations dealing with domestic enforcement of intellectual property rights have become a common feature of international agreements. Their international codification has changed the historical neglect of this important area of regulation, and has done so with a level of detail not found in other areas of international law. As a result, a loosely organised regime has emerged, where both repetitive and conflictive norms coexist. This piece identifies international treaties touching upon intellectual property enforcement, and introduces the objectives and main obligations established therein.

The identification of treaties depending on whether they are multilateral or bilateral is a first step in building a picture of the current international normative architecture for the enforcement of intellectual property rights. Multilateral treaties¹³ can be further differentiated into regional and plurilateral agreements, that is, open only to a select group of states. From the substantive point of view, enforcement-related treaties may be differentiated depending on whether they only regulate intellectual property or address other subjects as well, particularly trade in goods. The nature of the norms enshrined in the treaty (civil, criminal or administrative) is an additional criterion for classification, although treaties regulating enforcement generally do not restrict their reach to just one type of enforcement.

National governments have been traditionally unwilling to surrender sovereignty over the implementation of intellectual property rights.¹⁴ This reluctance was evident in the old intellectual property conventions, which contain very few articles on enforcement of rights.¹⁵

In the late 1970s and early 1980s, industrialised nations manifested their discontent with the perceived lack of effective enforcement within some countries. They held that inadequate enforcement amounted to a trade barrier, since exports were substituted by locally manufactured infringing products.¹⁶ Counterfeiting was a central topic of discussion during the 1973–1979 Tokyo Round of the General Agreement on Tariffs and Trade (GATT),¹⁷ although the practical effects in terms of normative changes were still meagre.¹⁸ In any case, since that moment the "lack of an international discipline on sanctions and remedies for tackling counterfeiting and piracy"¹⁹ has been on the international normative agenda.

13 Those concluded between three or more states. See A. Aust, *Modern Treaty Law and Practice*, 2nd edn (Cambridge: Cambridge University Press, 2007), 10.

14 See F. M. Abbott, "Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health," *ICTSD Issue Paper 24* (Geneva: International Centre for Trade and Sustainable Development, 2009), 6–7.

15 See T. Dreier, "TRIPS and the Enforcement of Intellectual Property Rights," in *From GATT to TRIPS: The Agreement on Trade-Related Aspects of Intellectual Property Rights*, ed. F. K. Beier and G. Schriker (Munich: Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, 1996), 249.

16 See M. C. E. J. Bronckers, D. W. F. Verkade and N. M. McNelis, *TRIPS Agreement: Enforcement of Intellectual Property Rights* (Luxembourg: Office for Official Communications of the European Communities, 2000), 10.

17 Scholars noted that "as early as 1978, the USA and the European Community had taken the initiative in proposing an agreement on counterfeiting in the Tokyo Round." See J. Reinbothe and A. Howard, "The State of Play in the Negotiations on TRIPS (GATT/Uruguay Round)," *European Intellectual Property Review* 5 (1991): 157.

18 See M. Blakeney, "International Intellectual Property Jurisprudence after TRIPS," in *Intellectual Property in the New Millennium*, ed. D. Vaver and L. Bentley (Cambridge: Cambridge University Press, 2004), 10.

19 See J. Reinbothe, "The EU Enforcement Directive 2004/48/EC as a Tool for Copyright Enforcement," in *Copyright Enforcement and the Internet*, ed. I. A. Stamatoudi (The Hague: Kluwer Law International, 2010), 7; Reinbothe and Howard, "The State of Play," 157.

Domestic enforcement of intellectual property rights was at the heart of the Uruguay Round negotiations,²⁰ as finally reflected in Part III of the TRIPS Agreement. Specifically devoted to enforcement, this part did not attempt to achieve full harmonisation. Instead, it established general standards²¹ to be implemented according to the method chosen by each member state, often leaving judges ample discretion to ponder different legal interests involved in adjudication. At the time when the TRIPS Agreement was adopted, national differences were very relevant, which made it unfeasible to adopt a uniform set of rules or the universal recognition and execution of national rulings.²² Instead, the goal of the TRIPS Agreement was to agree on the first international and comprehensive set of norms on enforcement,²³ generally modelled on the national laws existing in developed countries. This was considered "one of the most spectacular merits of the WTO TRIPS Agreement"²⁴ and "perhaps the most significant milestone in TRIPS."²⁵

Notwithstanding these achievements, intellectual property enforcement did not disappear from international norm-making. Countries that had promoted the adoption of the TRIPS Agreement strived to enhance the international normative *acquis* on intellectual property enforcement. As with many other areas of intellectual property regulation, enforcement was the object of careful attention in the numerous bilateral and plurilateral trade agreements. The reason may be found in the relative disenchantment with respect to enforcement norms found in the TRIPS Agreement.

In effect, even if the enforcement regime in the TRIPS Agreement was initially considered revolutionary, with the passage of time its norms were criticised by some for being crafted as too broad legal standards.²⁶ In fact, criticism of TRIPS Part III was not entirely new. A number of early commentators claimed that the ambiguity of these rules would "make it harder for mediators or dispute-settlement panels to pin down clear-cut violations,"²⁷ something that would "greatly disappoint rightholders in the developed countries."²⁸ Even if the reality is far more complex and TRIPS enforcement provisions

20 See Dreier, "TRIPS," 249; T. P. Stewart, *The GATT Uruguay Round: A Negotiating History* (The Hague: Kluwer Law International, 1993), 463, 466.

21 These standards were something more than "a bullet point list of required elements for an IPR [intellectual property right] enforcement system."

22 See Dreier, "TRIPS," 254.

23 "One of the major reasons for the conclusion of the TRIPS Agreement was the desire to set out a minimum set of procedures and remedies that judicial, border and other competent authorities must have available to them." See WTO Panel, *China – Intellectual Property Rights*, para. 7.241; J. Watal, "US–China Intellectual Property Dispute: A Comment on the Interpretation of the TRIPS Enforcement Provisions," *Journal of World Intellectual Property* 13 (2010): 604; C. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford: Oxford University Press, 2007), 409; H. Grosse Ruse-Khan, "Criminal Enforcement and International IP Law," in *Criminal Enforcement of Intellectual Property: A Handbook of Contemporary Research*, ed. C. Geiger (Cheltenham: Edward Elgar, 2012), 171.

24 See Reinbothe, "The EU Enforcement Directive 2004/48/EC," 5.

25 See M. L. Cordray, "GATT v. WIPO," *Journal of the Patent and Trademark Office Society* 76 (1994): 135.

26 See "USTR Official Predicts Difficulty in Forcing Compliance with TRIPS," *Inside US Trade*, 16 July 1999, citing Mr Papovich; quoted from Watal, "US–China Intellectual Property Dispute," 607.

27 See J. H. Reichman and D. Lange, "Bargaining around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions," *Duke Journal of Comparative and International Law* 9 (1998): 35. It has also been affirmed that the enforcement norms of the TRIPS Agreement were "new and primitive." See P. K. Yu, "The TRIPS Enforcement Dispute," *Nebraska Law Review* 89 (2011): 1046–1131, at 1048.

28 See Reichman and Lange, "Bargaining around the TRIPS Agreement," 38–39; T. P. Trainer, "Intellectual Property Enforcement: A Reality Gap (Insufficient Assistance, Ineffective Implementation)," *John Marshall Review of Intellectual Property Law* 8 (2008): 47.

satisfied the large majority of World Trade Organization (WTO) members, more and more treaties have been adopted since then to remedy the alleged shortcomings, transform what in the TRIPS Agreement were permissions into obligations, and convert provisions drafted in open terms into detailed articles.

While there are cases of treaties of a bilateral nature exclusively dealing with intellectual property, these are relatively unusual. In the majority of cases, intellectual property provisions are enshrined in treaties of broader economic or commercial scope. By and large, the most important strategy for intellectual property codification has been the conclusion of preferential trade agreements (PTAs).²⁹ While this is not a strictly new phenomenon, trade agreements have become a major source of international intellectual property regulation.³⁰ Some treaties enshrine very complete intellectual property enforcement statutes, while others contain a reduced number of provisions dealing with specific mechanisms, notably border measures.

Turning to plurilaterals, ACTA tried to introduce a major systemic shift. ACTA was akin to a framework agreement, which opened new avenues for the intellectual property enforcement agenda. There is a general perception that ACTA constituted just a springboard for new initiatives to expand enforcement standards. The "vague and uncertain nature of some provisions and the lack of clear limits,"³¹ as well as ACTA's inbuilt mechanisms would have permitted moving in that direction. Even if the implementation of the treaty failed, ACTA is shaping new bilateral and plurilateral initiatives and has been used as a standard to assess other countries' performance in the context of unilateral evaluations.

A similar assessment can be made with respect to the Trans-Pacific Partnership (TPP) Agreement, a new failed plurilateral initiative. In light of current circumstances, it is highly unlikely that the TPP will ever be adopted in its original form and by the original signatory member states. However, its intellectual property content is still highly relevant. Two reasons sustain that holding. First, it will be interesting to see whether intellectual property provisions are amended in non-US centred versions of the agreement. Second, a scenario even more likely than in the case of ACTA is that new US bilateral agreements take the TPP as the basis of new negotiations.

4. Multilateral Treaties

4.1 Before and after TRIPS

The TRIPS agreement epitomises all advances made in the international regulation of international property enforcement. In reality, there was not much before in the multilateral context, and there has not been much afterwards either.

29 These include bilateral and plurilateral trade agreements as well as customs unions, economic integration agreements and partial scope agreements. See Article XXIV paras 8(a) and 8(b) of GATT 1994; Article V of the General Agreement on Trade in Services, and para. 4(a) of the Enabling Clause.

30 See X. Seuba, "Intellectual Property in Preferential Trade Agreements: What Treaties, What Content?" *Journal of World Intellectual Property* 16 (2013): 240–261.

31 See C. Geiger, "Assessing the Implications of ACTA for the European Union: Legitimate Aim but Wrong Means," in *The ACTA and the Plurilateral Enforcement Agenda: Genesis and Aftermath*, ed. P. Roffe and X. Seuba (Cambridge: Cambridge University Press, 2015), 323.

Intellectual property enforcement was generally ignored in multilateral treaties, the most prominent examples being the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works. These conventions contain very little guidance as to the specific means for intellectual property enforcement.³² The provisions enshrined therein are limited in number and scope, afford a great margin of discretion and have had a limited impact.³³ The Paris and Berne Conventions contain no references to general goals or principles relating to enforcement. References to remedies indeed exist, but they are occasional. This is the case for injunctions for specific rights and situations, the seizure of imported goods, some procedural rights and references to norms on legal standing.³⁴ Certainly, the Berne and Paris conventions did not provide "governments with the necessary guidance concerning appropriate and modern" enforcement standards.³⁵

Before jumping into the content of the TRIPS Agreement, it is worth mentioning the most important multilateral treaties adopted after TRIPS in the area of enforcement. These are the World Intellectual Property Organization (WIPO) internet treaties, namely the 1996 Copyright Treaty and Performances and Phonograms Treaty. The TRIPS Agreement was outdated in this particular domain as soon as it entered into force, since it did not address enforcement on the internet. The WIPO internet treaties had been negotiated in parallel to the conclusion of the TRIPS Agreement,³⁶ were adopted just one year after the TRIPS Agreement, and entered into force in 2002. Since then, PTAs and regional treaties have actively promoted the adoption of the WIPO internet treaties and have expanded on the obligations set forth therein.

The WIPO internet treaties codified the first attempts to respond to online infringement of intellectual property rights,³⁷ in particular copyright, which were made by means of technological protection measures against unauthorised access and copying, as well as electronic rights management information.³⁸ Technological protection measures and electronic rights management information are usually jointly referred to as digital rights management;³⁹ however, they "raise different legal

32 See D. Gervais, "Criminal Enforcement in the US and Canada," in *Criminal Enforcement of Intellectual Property*, ed. Geiger, 269.

33 See P. K. Yu, "Shaping Chinese Criminal Enforcement Norms through the TRIPS Agreement," in *Criminal Enforcement of Intellectual Property*, ed. Geiger, 287.

34 See in detail, Seuba, *The Global Regime*.

35 See World Intellectual Property Organization, *WIPO Intellectual Property Handbook: Policy, Law and Use* (Geneva: World Intellectual Property Organization, 2004), 214.

36 See J. Reinbothe and S. von Lewinski, *The WIPO Treaties 1996: The WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty: Commentary and Legal Analysis* (London: Butterworths Lexis Nexis, 2002).

37 The WIPO internet treaties require states to "ensure that enforcement procedures are available under their law so as to permit effective action against any act of infringement of rights covered by this Treaty, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements." See Article 14.2 WIPO Copyright Treaty and Article 23.2 WIPO Performances and Phonograms Treaty.

38 According to WIPO, "'the answer to the machine is in the machine.' This 'answer' to the problems raised by the 'machine'—by the computer and the related elements of information and telecommunication technologies—... consists in technological protection measures (such as encryption of the protected material) and electronic rights management information (such as digital identifiers) to be included in the 'machine.'" See WIPO, *Guide to the Copyright and Related Rights Treaties Administered by WIPO and Glossary of Copyright and Related Rights Terms* (Geneva: World Intellectual Property Organization, 2003), 216.

39 See M. Ficsor, "Protection of 'DRM' under the WIPO 'Internet Treaties': Interpretation, Implementation and Application," in *Copyright Enforcement and the Internet*, ed. Stamatoudi, 257–258.

issues" and the WIPO internet treaties regulate them separately.⁴⁰ In any case, the WIPO internet treaties order states to adopt legal protection and effective legal remedies on technological measures and electronic rights management information, but they do not mandate detailed legal remedies or enforcement mechanisms relating to domestic implementation.

4.2 Content and Objectives of the TRIPS Agreement Part on Enforcement

Part III of the TRIPS Agreement is devoted to intellectual property enforcement within national jurisdictions. Five sections make up this part, and address general obligations, civil and administrative enforcement, provisional measures, border measures and criminal enforcement. The 20 articles contained in Part III create a relatively sophisticated reference for WTO members, while leaving a considerable margin of manoeuvre to national implementation. In terms of content, the provisions of the TRIPS Agreement on enforcement can be divided into three groups depending on their expected outcome.

First, some articles state how enforcement must be put into practice, and use an imperative terminology. An example is Article 41.1 of the TRIPS Agreement, which establishes that the members of the WTO "shall ensure that enforcement procedures as specified in this Part are available." While "shall" provisions abound in Part III, and touch upon the rights both of the right holder and the alleged infringer,⁴¹ subsequent treaties regulating enforcement of intellectual property rights include an even higher number of imperative provisions.

In other cases, the TRIPS Agreement instructs members to empower their courts to do something or to adopt certain decisions, but it does not prescribe a specific result. In fact, this is the most common type of provision in the Agreement, and is generally introduced under a construction stating that "judicial authorities shall have the authority to ..."⁴² When passing sentences, judges take into consideration the entire legal order, including obligations belonging to areas of law distinct from intellectual property. It is in this context that such an authority to adopt, or not, certain decisions must be understood.

Finally, the TRIPS Agreement also proposes some further possibilities of enforcement, but leaves their implementation to the discretion of the WTO members. When this is the case, usual expressions are "Members may provide that the judicial authorities shall have the authority to ..." or "Members may authorise the judicial authorities to ..."⁴³

The first section of Part III of the TRIPS Agreement, on general obligations, incorporates crucial articles shaping the implementation of all enforcement-related articles in the Agreement. Article 41, on general obligations, is particularly important since it clarifies the goals and sets out the principles for the interpretation and implementation of the entire Part III. Several subsections of Article 41 have been transplanted to numerous plurilateral and bilateral agreements.⁴⁴

40 Ficsor, "Protection of 'DRM,'" 258.

41 See, respectively, Articles 41.1–4, 42.1, 46, 49, 50.4, 50.6, 50.8, 51, 52, 54, 55, 58, 59, 61 TRIPS Agreement.

42 See Articles 43.1, 44.1, 45.1, 46, 47, 48.1, 50.1, 50.2, 50.3, 50.7, 53.1, 56, 59 TRIPS Agreement.

43 See also Articles 44.2, 45.2, 47, 48.1, 51, 50.5, 57, 60 TRIPS Agreement.

44 This is interesting, because the transplanted subsections have their origin in the North American Free Trade Agreement (NAFTA). In this sense, compare Article 41 of the TRIPS Agreement with Article 1714 of the NAFTA FTA and EIA (1994).

The “primary obligation”⁴⁵ of WTO members in the area of enforcement is to set up effective methods for the enforcement of intellectual property rights, as mandates in Article 41.1 of the TRIPS Agreement. Whether this is an obligation of result or an obligation of means has been the subject of debate. In our view, the TRIPS Agreement enshrines commitments of a different nature and most of the times the emphasis is rather on the tools than on specific results. In some cases, the provisions of the agreement lay down clear and immediately enforceable mandates, while in other cases the text is open and the possibilities for implementation are many. It is important to keep in mind that the TRIPS Agreement was not conceived as a tool to ensure full harmonisation and homogeneous implementation of enforcement obligations. On the contrary, it is an instrument that lays down minimum standards and commits parties to an overall satisfactory level of intellectual property enforcement.⁴⁶

Article 41.1 of the TRIPS Agreement must be read in light of the private nature of intellectual property rights and in conjunction with Article 41.5, which states that nothing in the agreement “creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and enforcement of law in general.”⁴⁷ The latter is commonly regarded as a concession made to developing countries,⁴⁸ which wanted to contextualise the new obligations in the broader framework of general law enforcement⁴⁹ and pre-empt demands for resources to set up specialised courts or strengthen intellectual property enforcement.⁵⁰ This provision is frequently invoked in policy-related forums, under the general understanding that it “should temper IPR owners’ expectations.”⁵¹

The WTO Panel report in the *China – Intellectual Property Rights* case has been interpreted as giving meaningful impact to Article 41.5 as a justification for non-compliance. Whereas the WTO Panel made clear that it does not establish a general permission to infringe, it also stated that “Article 41.5 is an important provision in the overall balance of rights and obligations in Part III of the TRIPS Agreement.”⁵² However, the WTO Panel noted that Article 41.5 refers to the deployment of resources for enforcement of intellectual property rights, but does not impact on or detract from the standard set for enforcement in any particular provision.⁵³ The WTO Panel seems to disentangle resource considerations and fulfilment of the norms. This is particularly important in light of the manifold economic implications of enforcement norms, including the considerable expense required for their

45 See F. M. Abbott, “WTO Dispute Settlement Practice Relating to the Agreement on Trade-Related Intellectual Property Rights,” in *The WTO Dispute Settlement System: 1995–2003*, ed. F. Ortino and E.-U. Petersmann (The Hague: Kluwer Law International, 2004), 427.

46 See Bronckers, Verkade and McNelis, *TRIPS Agreement: Enforcement*, 14.

47 See, as well, Article 2.2 ACTA.

48 See T. P. Stewart, *The GATT Uruguay Round: A Negotiating History* (The Hague: Kluwer Law International, 1993), 541; UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (Cambridge: Cambridge University Press, 2005), 585.

49 See Watal, “US–China Intellectual Property Dispute,” 337.

50 See P. K. Yu, “Are Developing Countries Playing a Better TRIPS Game?” *UCLA Journal of International Law and Foreign Affairs* 16 (2011): 326.

51 See Trainer, “Intellectual Property Enforcement,” 51.

52 See WTO Panel, *China – Intellectual Property Rights*, WT/DS362/R, 26 January 2009, para. 7.594.

53 See Watal, “US–China Intellectual Property Dispute,” 610.

implementation. Fulfilling this obligation while simultaneously making use of the right not to modify the distribution of resources seems difficult to reconcile.⁵⁴

Enforcement provisions in the TRIPS Agreement set up "minimum standards of due process"⁵⁵ that crystallise general principles of law,⁵⁶ such as general principles on judicial procedure widely accepted in domestic legal orders. Inherent components of the right to a fair trial mentioned in Articles 41 and 42 include the right to a reasoned sentence in writing, the right to a procedure and sentence within a reasonable time limit, the right to affordable procedures, the right to be heard, the right to a review, the right to a timely and detailed written notice, the right to representation by independent legal counsel, and the right to procedures without burdensome requirements concerning mandatory personal appearances. That is, they set up a very complete charter touching upon due process standards and lay down fundamental due process principles that may have decisive effects on the adjustment of enforcement procedures to the requirements resulting from the right to a fair trial. In particular, the TRIPS Agreement sets forth the principles of equity and fairness in enforcement procedures, which apply to all parties in a dispute.⁵⁷

The general provisions and basic principles of the TRIPS Agreement impact on Part III of the agreement. The potential of Articles 7 and 8 of the agreement is vast and has been explored in great depth by doctrine⁵⁸ and some WTO case law.⁵⁹ Moreover, these articles are repeatedly quoted in policy statements in multilateral fora,⁶⁰ mostly by developing countries,⁶¹ and in some intellectual property chapters of PTAs.⁶² Although some caution must be expressed concerning their practical impact, the principles and objectives enshrined in Articles 7 and 8 are relevant for enforcement-related obligations. This is particularly the case for references made in Article 7 to the link between intellectual property enforcement and the promotion of technological innovation, the transfer and dissemination of technology, the mutual advantage of producers and users, social and economic welfare, and the balance of rights and obligations. The reference made to taking equally into account the legitimate interests of intellectual property owners and those of their competitors should be

54 See X. Seuba, "Checks and Balances in the Intellectual Property Enforcement Field: Reconstructing EU Trade Agreements," in *Constructing European Intellectual Property: Achievements and New Perspectives*, ed. C. Geiger (Cheltenham: Edward Elgar, 2013), 417–418.

55 See Reichman and Lange, "Bargaining around the TRIPS Agreement," 34.

56 See Blakeney, "International Intellectual Property Jurisprudence," 7.

57 See UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, 582; J. Straus, "Reversal of the Burden of Proof, the Principle of 'Fair and Equitable Procedures' and Preliminary Injunctions under the TRIPS Agreement," *Journal of World Intellectual Property* 3 (2000): 811; C. Heath, "Comparative Overview and the TRIPS Enforcement Provisions," in *Patent Enforcement Worldwide: A Survey of 15 Countries: Writings in Honour of Dieter Stauder*, 2nd edn, ed. C. Heath and L. Petit (Oxford: Hart, 2005), 12.

58 See P. K. Yu, "The Graduated Response," *Florida Law Review* 62 (2010): 1373–1430; H. Grosse Ruse-Khan, "A Comparative Analysis of Policy Space in WTO Law," *Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series* 02-02 (2008); repr. in *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS*, ed. A. Kur (pp. 167–207) (Cheltenham: Edward Elgar, 2011).

59 See WTO Dispute Settlement Panel, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, 17 March 2000, para. 7.26, stating that the goals and limitations stated in Articles 7 and 8.1 must be borne in mind when interpreting Article 30 of the TRIPS Agreement on exceptions.

60 See Recommendation 45, WIPO Development Agenda (2007), A/43/16, Annex A.

61 See Request for Consultations by India, *European Union and a Member State – Seizure of Generic Drugs in Transit*, WT/DS408/1, 19 May 2010, p. 3.

62 See Article 139.2 EU–CARIFORUM States FTA and EIA (2008); Article 195 EU–Colombia and Peru FTA and EIA (2013).

especially meaningful in the area of enforcement,⁶³ both when regulating and adjudicating. In this regard, the account to the principle of equality of arms and, therefore, to the guarantees of the right to a fair trial seems clear.

4.3 Dispute Settlement and TRIPS Agreement Enforcement Provisions

TRIPS Agreement articles on intellectual property enforcement have been litigated in several WTO disputes, either as the main intellectual property area at issue or as a subsidiary object of concern in the context of broader cases. The reports drafted by WTO panels and the—rare but existing—decisions of the Appellate Body that allude to the TRIPS Agreement intellectual property enforcement provisions have had an important impact. Amendments to national laws have been adopted in the areas of civil, border and criminal enforcement in response to decisions of dispute settlement bodies and to mutually agreed solutions. Likewise, mutually agreed solutions have anticipated normative changes in regional and international fora.

Before moving to specific civil, criminal and border enforcement provisions, a short reference will be made to Article 41 of the TRIPS, which establishes overarching obligations of relevance in all enforcement areas. This article has been invoked in several cases. Mention was already made in the previous section to the interpretation given by the panel in the *China – Intellectual Property Rights* dispute to the meaning of “effectiveness” in the context of the TRIPS Agreement, and the understanding that the demand of effectiveness involves an obligation to make the remedies available to the parties. On a different subject, but also involving Article 41, in *EC – Trademarks and Geographical Indications* the application of Part III in a dispute concerning registration of geographical indications was raised. The panel confirmed that the obligations enshrined in Part III are applicable to all intellectual property rights covered by the agreement by virtue of Article 1.2, and that geographical indications are included.⁶⁴ However, the panel noted that the dispute related to acquisition of intellectual property rights, a subject regulated in Part IV of the TRIPS Agreement.

The link established between Part III and the intellectual property rights covered by the agreement was also relevant in the *US – Section 211 Appropriations Act* dispute. In that case, the Appellate Body concluded that trade names are covered under the TRIPS Agreement.⁶⁵ While the controversy mainly revolved around substantive aspects,⁶⁶ both the panel and the Appellate Body dealt with TRIPS

63 See Straus, “Reversal of the Burden of Proof,” 808.

64 *EC – Trademarks and Geographical Indications*, WT/DS290/R, 15 March 2005, para. 7.731

65 Because Paris Convention, Article 8 covering trade names is explicitly incorporated into TRIPS Article 2.1. *US – Section 211 Appropriations Act*, WT/DS176/AB/R, 2 January 2002, paras 333 and 338. The scope of “intellectual property” covered by the TRIPS Agreement goes beyond the categories enumerated in Part II. First, it must be noticed that TRIPS “categories” do not necessarily coincide with the headings of Sections 1 through 7 of Part II, but with the categories that are the *subject* of those sections. This is the case of plant variety protection, for example, which does not have a specific section in the TRIPS Agreement but must be protected pursuant to TRIPS Article 27.3(c). Second, as the Appellate Body noted regarding trade names, other intellectual property types also fall within the scope of “intellectual property” protection regulated in the TRIPS Agreement, even if they are not explicitly mentioned; TRIPS Agreement Article 2.1 reference to Articles 1 through 12, and Article 19, of the Paris Convention, which results in the protection of not only trade names but also utility models. Third, TRIPS Agreement does not protect all currently existing forms of intellectual property protection. This affects categories that have been developed with particular emphasis by both developing and developed nations. In the first group, mention must be made to the *sui generis* protection of traditional knowledge, while in the second group mention can be made of the protection of non-original databases.

66 The panel and Appellate Body found that the TRIPS Agreement and Berne Convention regulate the properties of trademarks themselves, but not ownership of trademarks.

Agreement Article 42, which addresses the requirements of "fair and equitable procedures" in the context of civil enforcement. The Appellate Body found that the United States measure at issue (the Section 211 Appropriations Act) was not inconsistent with Article 42, as it gave right holders access to civil judicial procedures, as required under Article 42, which is a provision on procedural obligations, while the United States Act affects substantive rights.

The impact of disputes concerning the TRIPS Agreement does not depend on having a report adopted by a panel. On different occasions, normative changes at the national level have been adopted because a mutually agreed solution has been adopted. This has been the case in the areas of civil, border and criminal enforcement alike.

Regarding civil enforcement, provisional measures are a case in point. In disputes initiated by the United States and targeting Argentina, Sweden and Denmark, a mutually agreed solution that required the amendment of national laws was reached. In the Argentinean case, the agreement with the United States included an amendment of the regulation concerning interim injunctions. The amended Argentinean legislation had to include the *fumus boni iuris* and *periculum in mora* principles, an evaluation of the balance of interest in the award of an interim injunction, other guarantees set forth in TRIPS Agreement Article 50, and the possibility of continuing with the alleged infringing activity if a caution was paid.⁶⁷ It would seem that both Argentina and the United States used the controversy to reflect about the key aspects of a balanced regime for the award of interim injunctions. The Swedish and Danish cases were closely connected and resulted in the amendment of the relevant laws as far as provisional measures for the preservation of evidence were concerned. Denmark and Sweden adopted bills providing that, in case of threat of infringement, courts may order a search for infringing materials, documents or other relevant evidence. The search may be ordered *inaudita altera parte* if there is a risk that materials or documents could be removed, destroyed or altered.⁶⁸

Something similar can be said regarding border enforcement. In 2010, Brazil and India requested consultations with the European Union (EU) and the Netherlands regarding repeated seizures on patent infringement grounds of generic drugs originating in third countries but transiting the Netherlands. In July 2011, an understanding between India and the European Union was reached. The agreement established that the mere fact that medicines transit European territory, and that there is a patent applicable in this territory, does not constitute enough grounds for the intervention of customs authorities. However, if there is a substantial likelihood of diversion of such medicines on to the EU market, customs authorities may take action. Subsequently, in 2012, the European Union adopted guidelines implementing the understanding and giving examples of possible indications of risk of diversion. This very same approach was adopted in the new European regulation concerning border measures.

Disputes relating to criminal enforcement of intellectual property rights have also resulted in a mutually agreed solution linked to the amendment of national legislation. In March 1998, the United States denounced the regular broadcasting by Greek TV stations of copyrighted motion

67 Argentina – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals—Argentina – Certain Measures on the Protection of Patents and Test Data, Notification of Mutually Agreed Solution, WT/DS171/3, WT/DS196/4, IP/D/18/Add.1, IP/D/22/Add.1, 20 June 2002.

68 Sweden – Measures Affecting the Enforcement of Intellectual Property Rights, Notification of Mutually-Agreed Solution, WT/DS86/2 IP/D/10/Add.1, 11 December 1998; Denmark – Measures Affecting the Enforcement of Intellectual Property Rights, Notification of Mutually-Agreed Solution, WT/DS83/2 IP/D/9/Add.1, 13 June 2001.

pictures and television programmes without the authorisation of copyright owners. Six months later, a new law was adopted in Greece. The law ordered the imposition of criminal sanctions for copyright counterfeiting and the possibility of closing down TV stations that infringed intellectual property rights. In March 2001, a mutually agreed solution between Greece, the United States and Europe recognised the satisfaction of the United States with the law and measures adopted. In that agreement, Greece undertook to maintain current legislation and continue with the effective actions adopted since the new law was adopted.⁶⁹

Among the cases that have made its way through a panel or the Appellate Body, the one exclusively dealing with enforcement is *China – Intellectual Property Rights*. The measures at issue in that case were the thresholds for criminal procedures and penalties for infringement of intellectual property, the disposal of infringing goods confiscated by customs authorities, and the denial of protection and enforcement to works not authorised for publication or distribution within China. With respect to the numerical thresholds for finding criminal liability, the panel did not validate such thresholds but underlined that TRIPS does not order the criminalisation of all copyright and trademark infringements and that the key notion in that context is one of “commercial scale”⁷⁰ On a different matter, the panel also made clear that the conditions set forth in the border measures section apply to imports but not to exports. It also noted that auctioning goods seized on importation is not contrary to the TRIPS Agreement, but doing so in a way that the product can be reused merely by removing the trademark is. As to the denial of copyright protection, the panel underlined that the circulation of protected works can be prohibited, but this does not allow not granting copyright protection to prohibited works.

5. Here Come the (Failed) Plurilaterals

The two plurilateral attempts to strengthen intellectual property enforcement standards took place in the context of a prolonged and intense wave of bilateral agreements. In effect, the 20 years that elapsed between the TRIPS Agreement entering into force and President Trump withdrawing from TPP included 15 years of increasingly demanding bilateralism. Still, the close interplay between plurilateral, bilateral and multilateral negotiations reflects broader trends in international relations, which ultimately mirror countries' expectations, power and economic and social realities.

In 1994 many countries probably thought the TRIPS agreement was a good compromise because it would put an end to bilateral pressures.⁷⁰ The reality has been different, however, and the move towards increased standards of intellectual property protection has continued in both bilateral and plurilateral fora. Whether countries concluding these treaties see new intellectual property standards as a realist approach to trade and power relations or, instead, they are convinced about the interest of those standards to the local economy is open to question. The response to that dilemma will probably differ from country to country, but resorting to plurilateral and bilateral negotiations is the technique followed by intellectual property *demandeurs* when their views do not succeed at the multilateral level.

69 *Greece – Enforcement of Intellectual Property Rights for Motion Pictures and Television Programs, Notification of Mutually Agreed Solution*, WT/DS125/2 IP/D/14/Add.1, 26 March 2001.

70 See A. Taubman, *A Practical Guide to Working with TRIPS* (Cambridge: Cambridge University Press, 2012).

ACTA is a plurilateral treaty on intellectual property enforcement negotiated between a closed group of nations and signed in 2011.⁷¹ The ratification of the agreement was rejected by the European Parliament in 2012, however, a rebuff that in practical terms meant the end of ACTA as an international treaty. Nevertheless, the agreement erected the most complete international regime on intellectual property enforcement developed so far, and the provisions set forth therein heavily influence intellectual property enforcement standards adopted in subsequent plurilateral and bilateral agreements.

The name of this international treaty is certainly misleading, since ACTA is not just concerned with trade or trademarks, as the reference to "trade agreement" and "counterfeiting" would suggest. Instead, it is the only international treaty ever adopted with exclusive focus on intellectual property enforcement, and more particularly on the enforcement of all intellectual property rights that are the subject of Sections 1 through 7 of the TRIPS Agreement.

From a normative point of view, ACTA has two notable characteristics. First, in relation to civil, criminal and border enforcement it incorporates the obligations set forth in the TRIPS Agreement but remains silent on the many instances where this agreement codifies the rights of alleged infringers. Second, ACTA strengthens the standards of protection for right holders and creates new rights in areas not specifically regulated in the TRIPS Agreement, such as the digital environment. However, ACTA introduces as well general provisions to guide interpretation, and incorporates by reference important TRIPS principles, including those set forth in TRIPS Articles 7 and 8. Numerous provisions of ACTA are drafted in either permissive or ambiguous terms or do not mention other rights and interests at stake. This is the reason why Articles 7 and 8 of the TRIPS Agreement could play a quasi-legislative function in the context of ACTA or in subsequent treaties merely copying ACTA provisions.

While civil enforcement provisions of ACTA essentially restate what was already available to right holders in signatory member states, the conflict between legal traditions became evident when trying to go beyond some remedies. In this respect, the limits of intellectual property harmonisation were particularly clear with respect to the award of damages, where continental law and common law traditions clash and offer very different options, conceiving damages only from the compensatory point of view in the first case, or from both a compensatory and punitive function in the second case.

As far as border enforcement is concerned, ACTA introduced relevant changes. It essentially expanded border enforcement obligations and ordered control of both importation—as prescribed by the TRIPS Agreement—and exportation. It recognised, moreover, the possibility of controlling transit, while allowing parties to exclude the control of goods protected by patents and trade secrets. The combination of such recognition and the power not to exclude patents can be read as a permission to control the transit of patented goods, even if this possibility was a matter of national and international debate and rejection during ACTA negotiations.

Criminal enforcement was the area attracting most concern, however. The articles adopted in ACTA were too vague when analysed from the point of view of fair trial standards. The inclusion of vague

71 On 1 October 2011, in Tokyo, eight representatives of the negotiating countries signed ACTA, namely Australia, Canada, Japan, Republic of Korea, Morocco, New Zealand, Republic of Singapore, and the United States. The European Union and 22 of its member states (Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovenia, Spain, Sweden, United Kingdom) signed the treaty on 26 January 2012, and the United Mexican States signed on 12 July 2012.

provisions impacting on fundamental rights and personal freedoms was the chief argument made by the global movement for rejecting the agreement. Together with the lack of transparency for most of the ACTA negotiation process, such ambiguity—which also characterises many PTAs—heavily influenced the negative vote of the European Parliament.

The origins of the TPP are found in the P4 trading group, set up in 2005 by Chile, Brunei Darussalam, Singapore and New Zealand. In 2009 the United States joined the P4 negotiations, followed later on by a larger group of nations with the view of becoming a major trading block.⁷² Once negotiations concluded, the TPP became the most sophisticated trade agreement enshrining intellectual property standards, including enforcement standards, and was signed in February 2016. Even though candidates in the US presidential elections in 2016 expressed their dissatisfaction with the TPP, their concerns were unrelated to the intellectual property chapter. As is well known, President Trump withdrew from the TPP in January 2017. "Great thing for the American worker what we just did," he said.⁷³ Nonetheless, as happens with ACTA, the TPP is the basis for future bilateral treaties and the new benchmark for intellectual property negotiations.

The TPP section on enforcement⁷⁴ includes general principles and detailed articles touching upon civil, criminal and border enforcement. It also enshrines important references to enforcement of intellectual property rights in the digital domain. It largely builds upon previous agreements, in particular ACTA⁷⁵ and the trade agreement between the United States and the Republic of Korea. Even though in some specific respects the TPP goes beyond these treaties, in some other instances it is a more balanced text and includes checks and balances frequently absent in PTAs. This is particularly the case with the general provisions of the TPP intellectual property chapter, where a number of guarantees and basic principles missing in PTAs are enacted.

Take, for instance, the references to fair trial and fair trial principles. In much the same way as ACTA did, and in many respects also reiterating the TRIPS Agreement, the TPP establishes that enforcement procedures shall be fair and equitable, not be "unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays."⁷⁶ This is an improvement over many PTAs, which remain silent in this regard. Interestingly, given the scope of the TPP, it also extends fair trial principles to the digital environment.

The article on distribution of resources and intellectual property enforcement confirms what was already agreed in ACTA and the TRIPS Agreement, and improves the text of a number of PTAs.⁷⁷ Essentially, it restates the latitude that states have when deciding how to allocate resources for

72 These countries are Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States, and Viet Nam.

73 "Trump Executive Order Pulls Out of TPP Trade Deal," *BBC News*, <http://www.bbc.com/news/world-us-canada-38721056>.

74 See Section I of Chapter 18 of the TPP.

75 The influence of ACTA over the TPP is apparent. The provision relating to proportionality is a case in point. In both treaties the reference to proportionality is almost identical. See Article 18.71.5 TPP.

76 See Article 18.71.3 TPP. See also Article 6.2 ACTA and Article 41.2 TRIPS Agreement.

77 Article 18.71.4 of the TPP says that Section I does not create any obligation "to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general" and does not create any obligation "with respect to the distribution of resources as between the enforcement of intellectual property rights and the enforcement of law in general."

enforcing intellectual property rights, and repeats that states are not obliged to create specialised bodies for the enforcement of those rights. While comments made above on Article 41.5 of the TRIPS Agreement and Article 2.2 of ACTA are applicable in this context, the text of the TPP may represent an unexpected development. Indeed, the express recognition of flexibility may contradict PTAs concluded by TPP members stating that distribution of resources does not justify lack of enforcement.⁷⁸

General provisions of the enforcement section of the TPP restate as well some of the "ceilings" and guarantees set forth in the TRIPS Agreement, in particular that enforcement procedures must "be applied in such a manner as to avoid the creation of barriers to legitimate trade" and that "safeguards against their abuse" must be provided.⁷⁹ Institutional and scholar references made to the relevance of the ceilings established in the TRIPS Agreement are also applicable with respect to the TPP. In this regard, former WTO Director General Pascal Lamy noted that while the TRIPS Agreement does not preclude its members from introducing additional measures to protect intellectual property, such protection cannot contravene the agreement.⁸⁰

However, as happens with other treaties adopted after the TRIPS Agreement, a troubling feature of the TPP is the lack of reference to the rights and guarantees that protect all parties, not just right holders. There are several, not particularly complex mechanisms to redress this neglect, including the adoption of the missing guarantees when passing national laws or resorting to systemic interpretation. However, the partial transplantation of intellectual property statutes in the TPP and similar agreements supports their portrayal as texts essentially conceived from the lenses of right holders' rights, with little interest in other relevant actors and the functioning of the intellectual property system as a whole.

6. Relevance of Enforcement Norms in Preferential Trade Agreements

Since the mid 1990s the number of PTAs has constantly grown, particularly after the TRIPS Agreement was adopted. PTAs have been considered an ideal tool to foster increased protection of intellectual property while negotiations in other fora make no progress. PTAs have been a leading source of new normative commitments in the area of intellectual property enforcement. Beginning with the United States, and soon thereafter with the European Union, the main trading powers have made intellectual property enforcement a prominent component of the PTAs negotiated in the last 10 years.

78 This is the case for Peru, Chile and Singapore. In the PTA with Chile it is stated that "The distribution of resources for the enforcement of intellectual property rights shall not excuse a Party from compliance with the provisions of this Article."

79 See Article 18.71.1 TPP.

80 See letter from Pascal Lamy, Director General of the World Trade Organization, to members of the European Parliament, 4 May 2010, http://keionline.org/sites/default/files/WTO-Lamy_Answer-to-MEP-letter.pdf. For a doctrinal elaboration of the TRIPS Agreement as a treaty establishing ceilings, see P. K. Yu, "TRIPs and Its Discontents," *Marquette Intellectual Property Law Review* 10 (2006): 402; G. Dinwoodie, "The International Intellectual Property Law System: New Actors, New Institutions, New Sources," *Marquette Intellectual Property Law Review* 10 (2006): 214; H. Grosse Ruse-Khan, "A Trade Agreement Creating Barriers to International Trade? ACTA Border Measures and Goods in Transit," *American University International Law Review* 26 (2011): 653–657; A. Kur and H. Grosse Ruse-Khan, "Enough Is Enough: The Notion of Binding Ceilings in International Intellectual Property Protection," *Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series* 09-01 (2008).

The interest in enforcement should come as no surprise. The Trade Promotion Authority Act of the United States established that the purpose of the United States in the area of enforcement is "providing strong enforcement of intellectual property rights, including through accessible, expeditious, and effective civil, administrative, and criminal enforcement mechanisms."⁸¹ In a similar vein, the European Union has also made clear in 2004 and 2014 policy documents (the "strategies" for the enforcement of intellectual property rights in third countries) that intellectual property rights enforcement is a priority target of the PTAs it negotiates.⁸²

Of course, not all PTAs that regulate intellectual property address enforcement,⁸³ and not all agreements that regulate enforcement do it with the same intensity. A differentiation can be made between treaties that make a general reference to intellectual property enforcement⁸⁴ and those that regulate this area in detail.⁸⁵

81 See Trade Act of 1974, 19 USC § 3802, 4. A(v).

82 See European Commission, "Strategy for the Enforcement of Intellectual Property Rights in Third Countries," *Official Journal of the European Union* (OJEU) 2005/C 129/3. The European Commission adopted a revised Strategy for the Enforcement of Intellectual Property Rights in Third Countries in 2014. See European Commission, "Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Trade, Growth and Intellectual Property—Strategy for the Protection and Enforcement of Intellectual Property Rights in Third Countries," COM(2014) 389 final.

83 This is the case of the agreements concluded in ASEAN–China FTA and EIA (2005/2007); ASEAN–Australia–New Zealand FTA and EIA (2010); ASEAN–Republic of Korea FTA and EIA (2010/2009); Canada–Chile FTA and EIA (1997); Canada–Costa Rica FTA (2002); Canada–Peru FTA and EIA (2009); Caribbean Community and Common Market Customs Union (CU) and EIA (1973/2002); Chile–Costa Rica (Chile–Central America) FTA and EIA (2002); Chile–El Salvador (Chile–Central America) FTA and EIA (2002); Chile–Guatemala (Chile–Central America) FTA and EIA (2010); Chile–Honduras (Chile–Central America) FTA and EIA (2008); Chile–Nicaragua (Chile–Central America) FTA and EIA (2012); Panama–Chile FTA and EIA (2008); China–Hong Kong FTA and EIA (2003); Egypt–Turkey FTA (2007); EU–Egypt FTA (2004); EU–Palestinian Authority FTA (1997); Faroe Islands–Norway FTA (1993); Gulf Cooperation Council CU (2003); India–Singapore FTA and EIA (2005); Israel–Mexico FTA (2000); Pakistan–Malaysia FTA and EIA (2008); Panama–Honduras (Panama–Central America) FTA and EIA (2009); Peru–Chile FTA and EIA (2009); Southern African Development Community FTA (2000); Southern Common Market (MERCOSUR) CU and EIA (1991/2005); Turkey–Jordan FTA (2011); Turkey–Palestinian Authority FTA (2005); Turkey–Syria FTA (2007); Turkey–Tunisia FTA (2005); Ukraine–Former Yugoslav Republic of Macedonia FTA (2001); Ukraine–Moldova FTA (2005); US–Israel FTA (1985).

84 See EU–Mexico FTA and EIA (2000); EU–Montenegro FTA and EIA (2008/2010); EU–Morocco FTA (2000); EU–Serbia FTA and EIA (2010/2013); EU–Tunisia FTA (1998); EU–Turkey CU (1996); European Economic Area EIA (1994); European Free Trade Association FTA and EIA (1960/2002); Hong Kong, China–New Zealand FTA and EIA (2011); India–Japan FTA and EIA (2011); Republic of Korea–Chile FTA and EIA (2004); Republic of Korea–India FTA and EIA (2010); Republic of Korea–Singapore FTA and EIA (2006); Panama–Costa Rica (Panama–Central America) FTA and EIA (2008); Panama–El Salvador (Panama–Central America) FTA and EIA (2003); Turkey–Albania FTA (2008); Turkey–Bosnia and Herzegovina FTA (2003); Turkey–Croatia FTA (2003); Turkey–Former Yugoslav Republic of Macedonia FTA (2000); Turkey–Georgia FTA (2008); Turkey–Israel FTA (1997); Turkey–Montenegro FTA (2010); Turkey–Morocco FTA (2006); Turkey–Serbia FTA (2010).

85 See Andean Community CU (1988); Australia–Chile FTA and EIA (2009); Chile–China FTA and EIA (2006/2010); Chile–Japan FTA and EIA (2007); Chile–Mexico FTA and EIA (1999); China–Costa Rica FTA and EIA (2011); Colombia–Mexico FTA and EIA (1995); Costa Rica–Mexico FTA and EIA (1995); CAFTA–DR–US FTA and EIA (2006); EC Treaty CU and EIA (1958); EFTA–Albania FTA (2010); EFTA–Colombia FTA and EIA (2011); EFTA–Hong Kong, China FTA and EIA (2012); EFTA–Mexico FTA and EIA (2001); EFTA–Montenegro FTA (2012); EFTA–Peru FTA (2011); EFTA–Serbia FTA (2010); EFTA–Ukraine FTA and EIA (2012); EU–CARIFORUM States FTA and EIA (2008); EU–Colombia and Peru FTA and EIA (2013); EU–Republic of Korea FTA and EIA (2011); Japan–Indonesia FTA and EIA (2008); Japan–Malaysia FTA and EIA (2006); Japan–Peru FTA and EIA (2012); Japan–Philippines FTA and EIA (2008); Japan–Switzerland FTA and EIA (2009); Japan–Thailand FTA and EIA (2007); Japan–Viet Nam FTA and EIA (2009); Republic of Korea–US FTA and EIA (2012); Mexico–El Salvador FTA and EIA (2001); Mexico–Guatemala FTA and EIA (2001); Mexico–Honduras FTA and EIA (2001); Mexico–Nicaragua FTA and EIA (1998); Nicaragua–Chinese Taipei FTA and EIA (2008); NAFTA FTA and EIA (1994); Pakistan–China FTA and EIA (2007/2009); Panama–Peru FTA and EIA (2012); Panama–Chinese Taipei FTA and EIA (2004); Peru–China FTA and EIA (2010); Peru–Republic of Korea FTA and EIA (2011); Singapore–Australia FTA and EIA (2003); Thailand–Australia FTA and EIA (2005); US–Australia FTA and EIA (2005); US–Bahrain FTA and EIA (2006); US–Chile FTA and EIA (2004); US–Colombia FTA and EIA (2012); US–Jordan FTA and EIA (2001); US–Morocco FTA and EIA (2006); US–Panama FTA and EIA (2012); US–Oman FTA and EIA (2009); US–Peru FTA and EIA (2009); US–Singapore FTA and EIA (2004).

Treaties can also be identified depending on the area or areas of intellectual property enforcement that they regulate, namely civil,⁸⁶ criminal,⁸⁷ border,⁸⁸ and digital⁸⁹ enforcement.

One of the major changes after the TRIPS Agreement is the regulation of intellectual property enforcement in the digital domain. Since the adoption of the WIPO internet treaties in 1996, many PTAs have included an obligation to ratify treaties related to digital enforcement. In other cases, treaties directly regulate the digital enforcement measures to be adopted and address in particular anti-circumvention of effective technological measures and electronic rights management information.⁹⁰

As regards border enforcement, numerous treaties contain measures that potentially affect goods protected by intellectual property rights. These are measures of a general nature, however,

86 See Andean Community CU (1988); Australia–Chile FTA and EIA (2009); Chile–Japan FTA and EIA (2007); Chile–Mexico FTA and EIA (1999); Colombia–Mexico FTA and EIA (1995); Costa Rica–Mexico FTA and EIA (1995); CAFTA–DR–US FTA and EIA (2006); EC Treaty CU and EIA (1958); EFTA–Colombia FTA and EIA (2011); EFTA–Mexico FTA and EIA (2001); EFTA–Montenegro FTA (2012); EFTA–Peru FTA (2011); EU–CARIFORUM States FTA and EIA (2008); EU–Colombia and Peru FTA and EIA (2013); EU–Republic of Korea FTA and EIA (2011); Japan–Indonesia FTA and EIA (2008); Japan–Malaysia FTA and EIA (2006); Japan–Peru FTA and EIA (2012); Japan–Philippines FTA and EIA (2008); Japan–Switzerland FTA and EIA (2009); Japan–Thailand FTA and EIA (2007); Japan–Viet Nam FTA and EIA (2009); Republic of Korea–US FTA and EIA (2012); Mexico–El Salvador FTA and EIA (2001); Mexico–Guatemala FTA and EIA (2001); Mexico–Honduras FTA and EIA (2001); Mexico–Nicaragua FTA and EIA (1998); NAFTA FTA and EIA (1994); US–Australia FTA and EIA (2005); US–Bahrain FTA and EIA (2006); US–Chile FTA and EIA (2004); US–Colombia FTA and EIA (2012); US–Jordan FTA and EIA (2001); US–Morocco FTA and EIA (2006); US–Panama FTA and EIA (2012); US–Oman FTA and EIA (2009); US–Peru FTA and EIA (2009); US–Singapore FTA and EIA (2004).

87 See Andean Community CU (1988); Australia–Chile FTA and EIA (2009); Chile–Japan FTA and EIA (2007); Chile–Mexico FTA and EIA (1999); Colombia–Mexico FTA and EIA (1995); Costa Rica–Mexico FTA and EIA (1995); CAFTA–DR–US FTA and EIA (2006); EC Treaty CU and EIA (1958); EFTA–Mexico FTA and EIA (2001); EFTA–Montenegro FTA (2012); EU–CARIFORUM States FTA and EIA (2008); EU–Colombia and Peru FTA and EIA (2013); EU–Republic of Korea FTA and EIA (2011); Japan–Indonesia FTA and EIA (2008); Japan–Malaysia FTA and EIA (2006); Japan–Peru FTA and EIA (2012); Japan–Philippines FTA and EIA (2008); Japan–Switzerland FTA and EIA (2009); Japan–Thailand FTA and EIA (2007); Japan–Viet Nam FTA and EIA (2009); Republic of Korea–US FTA and EIA (2012); Mexico–El Salvador FTA and EIA (2001); Mexico–Guatemala FTA and EIA (2001); Mexico–Honduras FTA and EIA (2001); Mexico–Nicaragua FTA and EIA (1998); NAFTA FTA and EIA (1994); US–Australia FTA and EIA (2005); US–Bahrain FTA and EIA (2006); US–Chile FTA and EIA (2004); US–Colombia FTA and EIA (2012); US–Jordan FTA and EIA (2001); US–Morocco FTA and EIA (2006); US–Panama FTA and EIA (2012); US–Oman FTA and EIA (2009); US–Peru FTA and EIA (2009); US–Singapore FTA and EIA (2004).

88 See EFTA–Albania FTA (2010); Andean Community CU (1988); Australia–Chile FTA and EIA (2009); Chile–Japan FTA and EIA (2007); Chile–Mexico FTA and EIA (1999); China–Costa Rica FTA and EIA (2011); Colombia–Mexico FTA and EIA (1995); Costa Rica–Mexico FTA and EIA (1995); CAFTA–DR–US FTA and EIA (2006); EC Treaty CU and EIA (1958); EFTA–Colombia FTA and EIA (2011); EFTA–Hong Kong, China FTA and EIA (2012); EFTA–Mexico FTA and EIA (2001); EFTA–Montenegro FTA (2012); EFTA–Peru FTA (2011); EFTA–Serbia FTA (2010); EFTA–Ukraine FTA and EIA (2012); EU–CARIFORUM States FTA and EIA (2008); EU–Colombia and Peru FTA and EIA (2013); EU–Republic of Korea FTA and EIA (2011); Japan–Indonesia FTA and EIA (2008); Japan–Malaysia FTA and EIA (2006); Japan–Peru FTA and EIA (2012); Japan–Philippines FTA and EIA (2008); Japan–Switzerland FTA and EIA (2009); Japan–Thailand FTA and EIA (2007); Japan–Viet Nam FTA and EIA (2009); Republic of Korea–US FTA and EIA (2012); Mexico–El Salvador FTA and EIA (2001); Mexico–Guatemala FTA and EIA (2001); Mexico–Honduras FTA and EIA (2001); Mexico–Nicaragua FTA and EIA (1998); NAFTA FTA and EIA (1994); Pakistan–China FTA and EIA (2007/2009); Panama–Peru FTA and EIA (2012); Panama–Chinese Taipei FTA and EIA (2004); Peru–Republic of Korea FTA and EIA (2011); Peru–China FTA and EIA (2010); Singapore–Australia FTA and EIA (2003); Thailand–Australia FTA and EIA (2005); US–Australia FTA and EIA (2005); US–Bahrain FTA and EIA (2006); US–Chile FTA and EIA (2004); US–Colombia FTA and EIA (2012); US–Jordan FTA and EIA (2001); US–Morocco FTA and EIA (2006); US–Panama FTA and EIA (2012); US–Oman FTA and EIA (2009); US–Peru FTA and EIA (2009); US–Singapore FTA and EIA (2004).

89 See Australia–Chile FTA and EIA (2009); CAFTA–DR–US FTA and EIA (2006); EC Treaty CU and EIA (1958); EU–Colombia and Peru FTA and EIA (2013); EU–Republic of Korea FTA and EIA (2011); Japan–Peru FTA and EIA (2012); Japan–Switzerland FTA and EIA (2009); Republic of Korea–US FTA and EIA (2012); Mexico–Nicaragua FTA and EIA (1998); NAFTA FTA and EIA (1994); US–Australia FTA and EIA (2005); US–Bahrain FTA and EIA (2006); US–Chile FTA and EIA (2004); US–Colombia FTA and EIA (2012); US–Morocco FTA and EIA (2006); US–Panama FTA and EIA (2012); US–Oman FTA and EIA (2009); US–Peru FTA and EIA (2009); US–Singapore FTA and EIA (2004).

90 See preceding note on the treaties directly regulating digital enforcement, excepting the EC Treaty CU and EIA (1958), Mexico–Nicaragua FTA and EIA (1998) and NAFTA FTA and EIA (1994).

such as the inspection of goods entering the country. However, many other treaties regulate the specific relationship between intellectual property rights and border measures. Fundamentally, these treaties expand both the categories of intellectual property rights—eventually all of them—and the border situations that are the object of control: importation, exportation and transit.

The diversity existing across PTAs regulating intellectual property enforcement makes it impossible to generalise about the content of the general provisions specifically targeting these enforcement measures. Probably the only valid generalisation is that, in the majority of cases, there is no section on general provisions for intellectual property enforcement. The PTAs promoted by the United States and the European Union are an exception, however, as they often enshrine some general principles and understandings on how enforcement should be implemented, and coincide in aspects such as mandating *ex officio* action in the context of border and criminal enforcement, or requiring final decisions on the merits of a case be made in writing.

Agreements concluded by the United States commonly mention the possibility of providing more extensive enforcement of intellectual property rights under its law than required by the treaty, providing that “the more extensive protection does not contravene” the PTA itself.⁹¹ This is reminiscent of the construction of Article 1.1 of the TRIPS Agreement, generally presented as the provision limiting the ever increasing protection of intellectual property rights.

Due process and fair trial standards are also commonly mentioned in bilateral treaties promoted by the United States in the context of intellectual property enforcement. In some cases, the incorporation of due process principles is made in general terms. On other occasions, however, only specific aspects relating to due process are mentioned. This is the case of the right to have judicial decisions and administrative rulings related to the enforcement of intellectual property rights in writing, published or “available to the public, in its national language in such a manner as to enable governments and right holders to become acquainted with them.”⁹² As mentioned, ACTA and TPP have generally improved references to fair trial principles in international agreements relating to intellectual property rights.

One of the central elements of Article 41 of the TRIPS Agreement is the affirmation in paragraph 5 that nothing in the agreement “creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and enforcement of law in general.” While some PTAs transplant this provision,⁹³ the actual implications of Article 41.5 are contentious.⁹⁴ Some PTAs have tried to make sure that references of this type do not impact on the actual respect of substantive rights. Hence, in some PTAs it is stated that “Parties understand

91 See Article 18.1.5 Republic of Korea–US FTA and EIA (2012); Article 17.1 US–Australia FTA and EIA (2005); Article 14.1.4 US–Bahrain FTA and EIA (2006); Article 15.1.4 US–Morocco FTA and EIA (2006); Article 16.1.7 US–Peru FTA and EIA (2009); Article 16.1.7 US–Colombia FTA and EIA (2012).

92 See Article 18.10.1 Republic of Korea–US FTA and EIA (2012); Article 17.11.2 US–Australia FTA and EIA (2005); Article 14.10.1 US–Bahrain FTA and EIA (2006); Article 15.11.1 US–Morocco FTA and EIA (2006); Article 16.11.2 US–Peru FTA and EIA (2009); Article 16.11.2 US–Colombia FTA and EIA (2012); Article 15.11.3 US–Panama FTA and EIA (2012); Articles 16.9.1 and 16.9.2 US–Singapore FTA and EIA (2004); Article 17.1.12 US–Chile FTA and EIA (2004).

93 See Article 234.4 EU–Colombia and Peru FTA and EIA (2013).

94 See section 4.2 of this paper.

that a decision that a Party makes on the distribution of enforcement resources shall not excuse that Party from complying with the provisions of this Chapter.”⁹⁵

In the case of the European Union, only treaties concluded after the adoption of the 2005 Strategy for the Enforcement of Intellectual Property Rights include a detailed regulation on intellectual property, including intellectual property enforcement. Whenever an article on general obligations concerning enforcement is incorporated, it is modelled upon Article 3 of the EU Enforcement Directive.⁹⁶

7. Conclusion

This chapter has introduced the international normative framework for the enforcement of intellectual property rights. It has done so briefly and underlying the relevance of the systemic aspects and the nature of enforcement norms. It has also depicted the evolution of the international regulation of intellectual property enforcement and described current advances in the multilateral, plurilateral and bilateral fora.

With respect to the systemic aspects and the nature of enforcement norms, conceptual and contextual aspects influence the functioning and impact of norms integrating the international regime for the enforcement of intellectual property rights. Enforcement norms are secondary norms, frequently secondary norms of adjudication, and shape the functioning and scope of primary norms. Crucially, they allow adjustment and enable dynamism, and put primary norms into a relationship with a broader set of norms and circumstances, such as socioeconomic determinants and human rights entitlements.

Static depiction of intellectual property does correspond with the variety of outcomes possible when intellectual property rights and the mechanisms to make them tangible are related to each other. That is, when the intellectual property regime actually works. In this sense, intellectual property enforcement does not evoke the image of a frozen world or an automated process. As a matter of fact, enforcement options are frequently multiple and the work of a judge frequently resembles that of a potter who moulds clay and assembles pieces with the tools and under the conditions given him by the legal system .

While simple, this view has important consequences both in the legal domain and in the economics of intellectual property. Unequivocal enforcement scenarios where options are reduced to one idealised situation must be discarded. However, presently, when estimates on the scale and impact of intellectual property infringement are produced, a concrete view on the content of remedies and the level of enforcement is implicit—but never specified. Studies and estimates of the impact of intellectual property infringement would do well to acknowledge this complexity and specify, in their methodology, which assumptions are made regarding enforcement.

95 See Article 14.10.3 US–Bahrain FTA and EIA (2006); Article 15.11.3 US–Morocco FTA and EIA (2006); Article 16.11.4 US–Peru FTA and EIA (2009); Article 16.11.4 US–Colombia FTA and EIA (2012); Article 15.11.2 US–Panama FTA and EIA (2012); Article 16.9.4 US–Singapore FTA and EIA (2004); Article 17.11.2 US–Chile FTA and EIA (2004).

96 See Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the Enforcement of Intellectual Property Rights (*OJEU* L 157 of 30 April 2004), *OJEU* L 195 of 2 June 2004.

Some final remarks follow concerning a legislative technique frequently used to promote the adoption of international norms in the area of enforcement, and also regarding specific topics relating to civil, criminal and border enforcement.

First, there are clear limits to international harmonisation of intellectual property enforcement norms. Take the example of the award of damages in the event of intellectual property infringement. The limits of harmonisation via transplantation become apparent in light of conflicting international normative initiatives and technical cooperation activities that promote contradictory punitive and compensatory approaches to the award of damages

Second, in other areas of civil enforcement, the potential for improvement is important. This particularly applies to provisions that have been poorly drafted in bilateral and plurilateral treaties, which are frequently vague or lack balance. The right to information, measures for the preservation of evidence and injunctions—both final and interim—are cases in point. A useful approach to remedy poor drafting is found in informed implementation, and for that purpose comparative intellectual property law and fundamental rights can be extremely useful and lead to balanced national regimes that respond to local circumstances and legal traditions.

Third, by opening rigid approaches to systemic and dynamic readings of intellectual property obligations a more commensurate outcome can be achieved. Injunctions are a clear example of the relevance of the concept of public interest defended by the United States Supreme Court and the notion of proportionality developed by the Court of Justice of the European Union.

Fourth, in the case of criminal enforcement, international codification has proved that it will hardly find the indispensable balance between respecting national sovereignty—which generally results in a broad drafting of international obligations—and proposing the concise wording that the principle of legal certainty requires. This is the reason why criminal enforcement is an area that should be largely left to states to regulate.

Finally, concerning border enforcement, there is still space to refine border enforcement and harmoniously combine free trade principles with intellectual property protection and the protection of some other public policy interests. The Court of Justice of the European Union has given guidance of the criteria that should be met when interfering in the free flow of products in transit. To the proven risk of diversion onto the internal market, countries may decide to add other criteria, such as the plain risk for public health that some counterfeit products may pose.

For a number of reasons, including the varying national approaches to the incorporation of international law and the content of the texts implementing international obligations, judges are faced with the actual adjudication of intellectual property disputes using new intellectual property enforcement tools. National judges have to receive the message that they are not just executing norms but actually implementing the weighing and balancing process referred to in this paper, and that the entire legal order and broader societal objectives and principles are relevant for that purpose.

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