



A Handbook on Negotiating Development Oriented Intellectual Property Provisions in Trade and Investment Agreements

Henning Grosse Ruse-Khan and Teemu Alexander Puutio





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A HANDBOOK ON NEGOTIATING DEVELOPMENT ORIENTED INTELLECTUAL PROPERTY PROVISIONS IN TRADE AND INVESTMENT AGREEMENTS

Prepared for ARTNeT by

Henning Grosse Ruse-Khan and Teemu Alexander Puutio





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FOREWORD

As evidenced by the onset of the Fourth Industrial Revolution and the ever-increasing pace of industrial disruptions and innovations, technology and knowledge will be the undisputable drivers of the Asian century. Indeed, as countries inch closer towards harnessing the transformative powers of automation and digitization so must they also come to grips with an increasingly difficult regulative area governing inventions and innovative activity, namely, intellectual property.

While the importance of intellectual property is acknowledged and understood universally, the capacity to derive social and economic benefits remain distributed unequally. As is often the case, the Asia-Pacific region stands out as a region of superlatives and extraordinary variance with countries such as Japan and the Republic of Korea issuing more than a hundred thousand patents each year, with Nepal granting only two in 2015. Such differences in capacity to generate and attract innovation remain equally pervasive in other knowledge and technology intensive areas that rely on other forms of intellectual property such as trademarks, copyrights and industrial designs.

Rarely are the limits of these capacities tested as they are in free trade negotiations. Like this Handbook will show, intellectual property provisions have become a mainstay of modern trade agreements since the turn of the millennium, adding a new layer of complexity to negotiations that often present all-but-insurmountable challenges to even the most well-equipped nations. While global and regional economies continue on their, at times patchy, path towards harmonization and deeper integration, levelling the playing field for least developed countries and countries in transition to knowledge economies becomes a matter of supreme urgency if we are to expect equitable and sustainable outcomes from the process.

For the United Nations system to make good on its commitment to support its member states in implementing the Sustainable Development Goals, it must also take an active role in shaping the international discourse on science, technology and innovation policies. Drafted from the viewpoint of ensuring that countries with limited capacities and resources can achieve equitable trade negotiation outcomes in the area of intellectual property, this Handbook is a decisive step towards fulfilling that commitment.

Guided by the findings of leading academic authorities and research institutions, this Handbook establishes a firm basis for negotiators to formulate development-oriented intellectual property provisions. The Handbook also provides a robust benchmark based on an empirical analysis of intellectual property provisions utilized thus far in free trade agreements. Emerging as the output of an Asia-Pacific Research and Training Network on Trade (ARTNeT) initiative, the Handbook also joins the ranks of a wide array of demand-driven research created to enhance capacity of region to negotiate deep and development oriented preferential deals.

I hope this Handbook will be the catalyst Asia-Pacific needs to launch an era of modern trade agreements that strike the delicate balance of innovation, social equity and economic development analysis in a way that builds a sustainable future.

Shamshad Akhtar

Under-Secretary-General of the United Nations and Executive Secretary of ESCAP

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This publication "A Handbook on Negotiating Development Oriented Intellectual Property Provisions in Trade and Investment Agreements" was prepared by Dr. Henning Grosse Ruse-Khan, a Reader in International and European Intellectual Property Law, the Co-Director of CIPIL and the Fellow and Director of Studies, King's College, University of Cambridge and Mr. Teemu Alexander Puutio, Legal expert at the United Nations. The preparation of the publication and the related research and capacity building work was done under the substantive direction and guidance of Dr. Mia Mikic, Director of Trade, Investment and Innovation Division of the United Nations Economic and Social Commission for Asia and the Pacific and the Coordinator of Asia-Pacific Research and Training Network on Trade (ARTNeT).

The Handbook is the outcome of the ARTNeT secretariat's initiative introduced in 2012 concerning intellectual property rights for facilitating the Asia-Pacific growth of the innovation economy by means of capacity building, network building, research and norm advocacy. Production of knowledge products such as this Handbook is intended to help close the development gaps in the Asia-Pacific through enhanced use and understanding of IPRs especially in the context of preferential trade and investment liberalization. Special attention is given to the priority needs of developing and least developed countries in the Asia-Pacific region.

There are several objectives of the initiative which have been embedded in the production of this Handbook:

- To enhance regional awareness, knowledge and understanding of intellectual property rights and of their social and economic impacts;
- To build regional capacity to effectively manage and deal with intellectual property rights;
- To facilitate regional trade and investment by improved use of intellectual property rights; and
- To facilitate the development and implementation of effective and sustainable IPR norms, policies and measures within the Asia-Pacific region

It is hoped that this Handbook will contribute to better preparation of the negotiators and other stakeholders in the region to reach successful and sustainable outcomes in trade and investment agreement negotiations that involve intellectual property. The readers are also invited to use a training material on "Negotiating forward-looking IPRs clauses in bilateral and plurilateral free trade agreements for developing countries in Asia and the Pacific" prepared by Dr. Albert Hu, National University of Singapore under this initiative and available on the ARTNeT knowledge platform.

In addition to the authors of the Handbook, Dr. Grosse Ruse-Khan and Mr. Puutio, who generously shared their expertise and time to further this ARTNeT initiative, many people deserve to be thanked for their contributions to the implementation of the initiative and preparation of the Handbook for print. They include all members of the ARTNeT secretariat team, supporting staff and consultants of Trade, Investment and Innovation Division, and numerous interns who continue to support the ARTNeT cause even after completing their internships.

ABBREVIATIONS AND ACRONYMS

AB Panel or Appellate Body

ACP African, Caribbean and Pacific

ACTA Anti-Counterfeiting Trade Agreement

ASEAN Association of Southeast Asian Nations

ATRIP Advancement of Teaching and Research in Intellectual Property

BITs Bilateral Investment Treaties

BC Berne Convention

CAFTA-DR United States-Central America-Dominican Republic Free Trade

Agreement

CARIFORUM Caribbean Forum

CETA Comprehensive Economic and Trade Agreement

DSB Dispute Settlement Body

EC European Community

EFTA European Free Trade Association

EPA Economic Partnership Agreement

ESCAP Economic and Social Commission for Asia and the Pacific

EU European Union

FET Fair and Equitable Treatment

FPS Full Protection and Security

FTA Free Trade Agreement

GATT General Agreement on Tariffs and Trade (WTO)

Gls Geographical Indications

HIV/AIDS Immunodeficiency Virus and Acquired Immune Deficiency Syndrome

IIA International Investment Agreement

IP Intellectual Property

IPR Intellectual Property Rights

ISDS Investor-State Dispute Settlement

ISPs Internet Services Providers

MFN Most-Favoured-Nation

MPI Max Planck Institute

NAFTA North American Free Trade Agreement

NGO Non-Governmental Organization

NT National Treatment

PC Paris Convention

PM Philip Morris

RBC Revised Berne Convention

RTAs Regional Trade Agreements

SPS Sanitary and Phytosanitary

TCEs Traditional Cultural Expressions

TPP Trans-Pacific Partnership

TRIPS Trade-Related Aspects of Intellectual Property Rights

US United States

USTR United States Trade Representative

VCLT Vienna Convention on the Law of Treaties

WIPO World Intellectual Property Organisation

WTO World Trade Organization

EXECUTIVE SUMMARY

The drafting of the Handbook on negotiating development oriented intellectual property provisions in trade and investment agreements (Handbook here forth) was guided by the objective of supporting Asia and the Pacific economies in reaching successful and sustainable outcomes in trade agreement negotiations that involve intellectual property. To accomplish this objective, this Handbook first introduces the multilateral intellectual property system and explains the trends for additional intellectual property protection in international trade and investment agreements.

Chapter 1 presents the main international intellectual property treaties, with a focus on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and its main features, focusing particularly on the flexibilities afforded by TRIPS. In addition, the chapter introduces how intellectual property rights can be protected via international investment agreements (IIAs), in particular the public policy implications of such protection, using landmark disputes such as the Plain Packaging challenges mounted by Philip Morris in Uruguay and Australia.

Chapter 2 explores the topography of intellectual property inclusive trade agreements in Asia and the Pacific, based on the dataset created during the project. The chapter presents the stylized facts from the 91 Asia-Pacific trade agreements, in force in 2016, that contain intellectual property rights alongside brief narrative expositions of the findings based on the dataset.

Chapter 3 builds on the international intellectual property framework and the empirical foundation on intellectual property-inclusive agreements from the Asia-Pacific in order to recommend approaches for the negotiation, interpretation and implementation of intellectual property provisions in free trade and investment agreements. These recommendations further benefit from earlier research work by a broad range of intellectual property-experts in a project conducted at the Max Planck Institute for Innovation and Competition Law. They are primarily aimed at offering suggestions for retaining important flexibilities of the multilateral intellectual property treaty framework – so as to ensure that countries remain able to design an intellectual property system that suits local needs.

Chapter 4 concludes the Handbook by providing examples from state practice on provisions that can be used to integrate international intellectual property flexibilities into trade and investment agreements, and analyses which of those examples are fit for purpose.

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Chapter

1

THE MULTILATERAL INTELLECTUAL PROPERTY SYSTEM AND TRENDS FOR ADDITIONAL PROTECTION VIA FREE TRADE AGREEMENTS AND INTERNATIONAL INVESTMENT AGREEMENTS

his chapter sets out the wider, multilateral intellectual property (IP) treaty context within which current trade and investment agreements that include IP provisions are negotiated. This provides important background for the data presented in chapter 2, and the guidelines presented in chapter 3.

The chapter begins with an overview of the developments in international IP law (section 1). Within the wider international IP law, section 2 emphasizes the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which — as the most comprehensive international IP treaty with almost global membership — serves as multilateral framework for the bilateral or (mega-) regional IP and Investment Agreements which are at the heart of this Handbook. Next to a brief discussion of the main principles and objectives of TRIPS, the importance of the flexibilities inherent in the Agreement needs to be highlighted as an essential tool for states to achieve important public policy objectives.

Against this background, section 3 then discusses the tendencies for negotiating and agreeing to provisions in bilateral and regional agreements on IP that require contracting states to implement additional, stronger protection of IP rights in their national laws. Since the TRIPS Agreement functions as essential reference point in evaluating such provisions, those that offer additional or stronger protection compared to TRIPS provisions are commonly referred to as 'TRIPS-plus'.

Section 4 then moves on to discuss the phenomenon of protecting IP rights under international investment agreements (IIAs). There is a core distinction between the type of protection that results from international IP treaties, including those with TRIPS-plus provisions, and protection for IP rights as investments covered by an IIA which makes it necessary to treat these two types of international protections for IP rights separately, even if they occur in the same agreement (such as a comprehensive FTA with an IP and an investment chapter): while international IP treaties and IP chapters in FTAs contain obligations that require states to make available certain specific IP protections in national law (for example to protect software under copyright law, or to grant copyright holders exclusive control over making protected content available online), protecting IP rights via

IIAs or investment chapters in FTAs focuses on state measures that interfere with these rights (such as expropriating a patent holder).

The international IP obligations are specific to IP, and require domestic implementation in national IP laws. Investment protection for IP rights has to rely on general standards that under certain circumstances offer foreign investors protection against state conduct which usually needs to be arbitrary, discriminatory, or otherwise unfair.

A lot of IIAs and investment chapters in FTAs further allow protected foreign investors to bring proceedings against the host state in front of arbitration tribunals. Since some recent cases of Investor-State Dispute Settlement (ISDS) proceedings have involved IP rights, reliance on general investment standards to protect IP rights is not a mere theoretical possibility – but an issue that states are increasingly taking a fresh look at in negotiating IIAs or (re)drafting their model agreements in this context.

1. Overview of International Intellectual Property Treaty Developments

This section briefly sets out the multilateral IP treaty context within which current trade and investment agreements that include IP provisions are negotiated. Since goods and services that involve IP have been traded beyond national borders for centuries, those claiming IP rights have for a long time lobbied for effective mechanisms to protect their IP abroad. From the second half of the nineteenth century, these attempts have been increasingly successful. The conclusion of the Paris Convention for the Protection of Industrial Property in 1883 (covering, inter alia, patents, trademarks, and industrial designs) and the Berne Convention for the Protection of Literary and Artistic Works (covering essentially copyright) in 1885 are important landmarks in establishing an international IP system as these treaties – in revised forms – continue to apply and nowadays each bind more than 150 states.

The continued relevance of the Berne and the Paris Convention makes another point: The regulation of IP in the international arena is primarily based on international *treaties* that contain obligations on the protection and enforcement of IP rights of foreign right holders which the state parties must implement in their national laws. Hence, unless a state allows the direct application of international law in its domestic legal system, international IP treaties do not directly create IP rights.

For foreign right holders to benefit from international IP law, it usually must first be implemented in the national IP laws. Still, the primary purpose of international IP law is to protect the interests of right holders in the enforcement of their private rights across

borders: by creating international obligations for the protection of foreign right holders which states then must implement in their national laws.

While international IP treaties such as the Berne and Paris Convention do not create global IP rights, they nevertheless have facilitated the international protection of IP in significant ways:

- 1) In particular the Paris Convention contains provisions that make it easier for right holders to obtain protection abroad for their inventions by means of patents or their brands, logos and other signs to indicate the commercial origin of goods by means of trademarks. So-called 'rights of priority' ensure that a right holder who has filed an application for a registered IP right in one of contracting states has a priority to file, within a six or twelve month period, in other contracting states.
- 2) More importantly, both the Paris and the Berne Convention include the general principle of 'national treatment' whereby contracting states must, as regards the protection of IP covered under the respective treaty, offer the same protection to foreign right holders as they provide to their domestic ones. This cornerstone of international IP law that can be found in essentially all multilateral IP treaties is ensuring that there is no more discrimination of foreign right holders something that was commonplace in domestic IP laws prior to the international regulation of IP.
- 3) The third general element of the international IP system is perhaps the most important one: gradually and over time, international IP treaties have set more and more specific standards on how contracting state must protect the IP rights of foreign right holders. These so called 'minimum standards' cover questions of subject matter (what exactly must be protected under copyright, what falls as 'invention' under patent law?); the conditions for protection (under which requirements must countries grant patents to inventions, when does a sign deserve to be protected as a trademark?); the exclusive rights granted to the right holder (what kind of activity or conduct falls under the exclusive control of the IP owner?); the exceptions and limitations that are allowed for national laws (exempting use for the teaching or research purposes from copyright protection; granting a compulsory license to produce a patented product); and the enforcement of IP rights (what remedies must be available to right holders, do certain breaches of IP rights attract criminal liability?). Conceived as minimum standards which can (and frequently have) be superseded by stronger standards in subsequent treaties or national law developments, the concept of harmonisation so pursued has been a continuous trend towards increasing

levels of protection around the globe. The more detailed these international minimum standards have become over the last 150 years, the more has the flexibility of states decreased to design their domestic IP systems in accordance with domestic needs.

These progressive developments serve as important context for the guidelines in chapter 3. The next section focuses on the WTO TRIPS Agreement as the central multilateral treaty that frames the bilateral and regional treaties on IP which are at the heart of this Handbook.

2. An Introduction to the TRIPS Agreement

This section emphasizes the role of TRIPS as multilateral framework and the importance of its flexibilities. The TRIPS Agreement was negotiated during of the Uruguay Round of multilateral trade negotiations (1986-1993) within the context of the General Agreement on Tariffs and Trade (GATT). While developing countries had attempted to lower international levels of IP protection by requests for a revision of the Paris Convention in the 1980s, key industry groups in the United States – in particular the software and pharmaceutical industries – began to lobby for enhanced global IP protection as an international trade and competitiveness issue.

When industrialized countries realized that they would not be able to achieve higher levels of protection in the context of the Berne and Paris Conventions, they pushed for the inclusion of IP as a 'trade-related' topic in the Uruguay Round. The main argument was that insufficient levels of IP protection especially in emerging economies creates an unfair advantage for industries in these countries as they can freely copy and imitate the technologies and creations which are protected in the main IP-exporting countries. In the context of globalization, the decrease of trade barriers, the improved communication and transporting systems around the world, as well as an increasing global demand for technology-intensive goods and services was seen as crucial for right holders to receive protection in all markets abroad. Developing countries where initially very sceptical to accept the negotiation of a comprehensive IP agreement in the WTO context and demanded a much narrower mandate focusing on trade in counterfeits only. However, the comprehensive 'package deal' which was reached in the Uruguay Round included sufficient elements of interests for developing countries so that they were willing to swallow TRIPS as a bitter pill in exchange for enhanced market access for e.g. agricultural goods or textiles in industrialized countries.

Based on the concept of a 'single undertaking', membership in the WTO (offering market access preferences for goods and services) necessarily implies to sign up to the TRIPS Agreement, and hence an obligation to implement the comprehensive minimum standards of protection in all areas of IP the Agreement contains. This has made TRIPS the most important global standard for the protection of IP. As a WTO Agreement, compliance with TRIPS can be subject to proceedings in front of the WTO dispute settlement body. For the first time in the history of international IP law, a functioning system of settling disputes between states is available in case one contracting party is not satisfied with how another party has implemented the obligations to protect foreign right holders. In the first twenty years of WTO dispute settlement, only 34 (out of roughly 500) complaints have been brought that concern, *inter alia*, the TRIPS Agreement.¹ By mid 2017, the complaints related to TRIPS led to nine Panel reports; and of these three were appealed resulting in three Appellate Body Reports concerning TRIPS. That makes a total of 12 decisions on TRIPS – which is a very low amount if compared to the Panel and Appellate Body Reports generated in relation to matters concerning trade in goods.

2.1. Non-discrimination Principles (National Treatment, MFN)

Article 3 of TRIPS requires WTO members to provide treatment 'no less favourable' regarding the protection of IP rights covered under the Agreement to foreign nationals, in comparison to domestic nationals. This is subject to certain exceptions already provided in, respectively, the Paris Convention (in its 1967 version), the Berne Convention (in its 1971 version), the Rome Convention on the protection of rights related to copyright (1961) or the Treaty on Intellectual Property in Respect of Integrated Circuits (1989). As per footnote to Article 3, the 'protection' of IP means matters that affect the availability, acquisition, scope, maintenance and enforcement of IP rights as well as those matters affecting the use of IP rights specifically addressed in the TRIPS Agreement.

The scope of the national treatment obligation is further defined by the term 'intellectual property' as understood in TRIPS: it applies, by virtue of Article 1(2) TRIPS, only to those categories of IP rights which are covered by TRIPS. Those are, amongst other rights, copyrights, related rights of phonogram producers, performers and broadcasting organizations, trademarks, geographical indications, industrial designs, patents, and the protection for undisclosed information. Finally, the concept of 'treatment no less favourable'

¹ For a list of the 34 complaints which cite the TRIPS agreement in the request for consultations, see https://www.wto.org/english/tratop_e/dispu_e/dispu_e/dispu_e/dispu_e/dispu_e/dispu_e.htm.

has been defined by a WTO Panel in the *EC – Geographical Indications* dispute to include both *de jure* (based on the law or other measure as such) as well as *de facto* (based on how the law or other measure applies to foreign right holders in practice) discrimination. If there is no case of discrimination of a foreign right holder by virtue of a national IP law (which would be *de jure* discrimination), the relevant test for *de facto* discrimination is to ask whether the treatment in question modifies the effective equality of opportunities as regards the protection of intellectual property.

Cornerstone of international IP law since its multilateral inception with the Berne and Paris Convention (see section 1 above), the national treatment principle has important implications for the additional IP protections countries agree to in bilateral and regional treaties with provisions on IP. As long as the 'TRIPS-plus' protection under such a treaty falls within the categories of rights covered by TRIPS (covering essentially all major IP rights), and is a form of 'protection' within the meaning of footnote 3 to Article 3 TRIPS (which will be the case in almost all IP provisions in bilateral and regional agreements), any national implementation of such TRIPS-plus protection must in principle be made available to right holders from all other WTO Member countries.

This is because any implementing country, while technically only required to offer the TRIPS-plus protection to the right holders from the contracting states of the bilateral or regional treaty, will usually make this additional protection also available to its domestic right holders. Once it has done so, the national treatment obligation requires it to extend this protection to all WTO right holders. Effectively, the broad scope of the TRIPS national treatment obligation 'multilateralises' TRIPS-plus IP protection that is derived from a bilateral or regional treaty and would technically be limited to right holders from the contracting state(s). This far-reaching effect of the national treatment rule in TRIPS – together with an equivalent if not further effect of the most-favoured-nation principle (MFN) – should be borne in mind when negotiating and agreeing to TRIPS-plus provisions in bilateral and regional agreements.

The TRIPS Agreement's Article 4 on most-favoured-nation treatment provides that, with regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other members. It means that if two or more WTO Members agree – for example in a free trade agreement with an IP chapter – to grant their right holders higher levels of IP protection, this additional protection has to be made available immediately to the right holder from all other WTO Members.

There are certain exceptions to this obligation. Subparagraph (d) of that article, exempts any advantage, favour, privilege or immunity accorded by a member deriving from

international agreements related to the protection of intellectual property which entered into force before the WTO Agreement entered into force, provided that such agreements are notified to the TRIPS Council TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other members. Importantly however, there is no exception for Regional Trade Agreements (RTAs) as in Article XXIV GATT which allows the parties to retain the agreed trade preferences amongst themselves.

Given the practical implications of national treatment discussed above, the further practical effect of the MFN obligation in TRIPS is limited: based on national treatment under Article 3 TRIPS, all WTO Members must already grant right holders of other WTO Members the protection which they afford to their own nationals. It is only where a WTO Member grants more or stronger rights to foreigners – for example based on TRIPS-plus protections in an agreement which are not extended to the respective national right holders – that MFN can provide for additional protection which national treatment does not extend to.

The MFN rule however may become relevant in the context of protecting IP as an investment via an IIA or an investment chapter in a FTA: since investment protection is generally protection only for foreign investors, it is not a form of protection that would be extended to domestic investors. When applicable to IP rights, investment protection hence remains exclusive to the foreign investor that is covered *(rationae personae)* by the IIA. Where the type of protection the IIA affords to IP rights is considered as a form of 'protection' of 'intellectual property' that falls under Article 4 TRIPS (here the same definitions as discussed above for Article 3 apply), then this protection must be made available to right holders from all WTO Members. Chapter 3, section 2.2 will discuss the implications of this further.

2.2. Balancing and Public Interests - the Role of Articles 7 and 8 in TRIPS

Article 7 of TRIPS Agreement is entitled "Objectives", according to which the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

As will be explained in more detail in chapter 3, section 1.1, this provision can have important implications for IP provisions in bilateral and regional trade agreements. In a nutshell, the main idea is that because of their agreement – for the first time in the history

² See the Notifications under Article 4(d) TRIPS, http://www.wto.org/english/tratop_e/trips_e/trips_notif4_art4d_e.htm.

of international IP law – to establish a common objective for IP protection, WTO Members must now be careful not to derogate from TRIPS provisions that are an essential expression of this objective. As some TRIPS-plus provisions can be very one-sided in favour of the protection of right holders (and for example neglect the interests of users), the TRIPS objectives ensure that WTO Members then have the right to re-establish a balance of rights and obligations by introducing, for example, exceptions and limitations to the TRIPS-plus protections agreed under a bilateral or regional treaty.

Article 8 TRIPS, entitled "Principles", recognizes the rights of Members to adopt measures for public health and other public interest reasons and to prevent the abuse of intellectual property rights, provided that such measures are consistent with the provisions of the TRIPS Agreement. In the 2001 Doha Declaration on TRIPS and Public Health (see also section 1.2.3. below), all WTO Members agreed that the primary role for the balancing objectives in Article 7 and the public interest principles in Article 8 of TRIPS is to guide the interpretation of all TRIPS provisions in a balanced manner, in particular "supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." It means that especially the often ambiguous and open terms in the TRIPS Agreement (such as 'legitimate trade' in Article 41(1) TRIPS, 'unjustifiable' in Article 20 TRIPS or 'legitimate interests' in Articles 13, 17, 26(2) and 30 TRIPS) can be interpreted and implemented in a balanced way in the national law of WTO Member states, taking account not only of the interests of right holders, but equally of other stakeholders and the general public.

2.3. Minimum Standards and Flexibilities in TRIPS

In respect of each of the main areas of intellectual property covered by the TRIPS Agreement, the Agreement sets out the minimum standards of protection to be provided by each Member. In the cases of patents and trademarks, each of the main elements of protection is defined: namely the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection. This brief overview cannot offer a further discussion of the individual TRIPS provision that cover these and other IP rights.⁴ Suffice to reiterate the very comprehensive nature of TRIPS as

Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, WT/MIN(01)/DEC/2 (20 November 2001), para. 4. Paragraph 5 a) provides: "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."

For such a discussion see for example the Handbook on the WTO TRIPS Agreement by Antony Taubman, Hannu Wager and Jayashree Watal (CUP, 2012). A great resource is also the ICTSD/UNCTAD Resource Book on TRIPS and Development – available online at https://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm.

the only multilateral treaty which covers essentially all relevant IP rights, and often sets out rules for all main elements of protecting an IP right. This is further complimented by a comprehensive part III of TRIPS on the enforcement of IP rights, setting out – for the first time in international IP law – detailed provisions on remedies for right holders in front of the domestic courts of WTO Members (such as the need to offer damages and injunctive relief to cease infringing activities), border measures to be imposed against the importation of counterfeit trademark goods pirated copyright goods, as well as obligations to introduce criminal law sanctions against grave violations of IP rights.

The Agreement further sets minimum standards by requiring, first, that the substantive obligations of the main conventions of the WIPO administered treaties, the Paris Convention for the Protection of Industrial Property (Paris Convention, PC) and the Berne Convention for the Protection of Literary and Artistic Works (revised Berne Convention, RBC) in their most recent versions must be complied with. With the exception of the provisions of the Berne Convention on moral rights (Article 6*bis*), all the main substantive provisions of these conventions are incorporated by reference and thus become obligations under the TRIPS Agreement between TRIPS Member countries.

This approach of incorporating the main provisions of the most important existing international IP treaties is often called the 'Convention-plus' principle. The relevant provisions are to be found in Articles 2.1 and 9.1 of the TRIPS Agreement, which relate, respectively, to the Paris Convention and to the Berne Convention. The importance of the Berne- and Paris-plus approach lies in the fact that compliance with the relevant provisions of these treaties can be litigated in WTO dispute settlement. TRIPS thereby turns the Berne and Paris Convention rules into enforceable obligations (in case the complaining party is economically strong enough to induce compliance of the responding party).

As mentioned above, the TRIPS Agreement adds a substantial number of additional obligations on matters where the pre-existing conventions are silent or were seen as being inadequate. The TRIPS Agreement is thus sometimes referred to as a Berne- and Paris-plus agreement: it is setting out comprehensive standards in all areas of IP protection and enforcement which bind all WTO Members and can be enforced via the WTO dispute settlement system.

At the same time, the need to consolidate the interests of IP importing and IP exporting countries during the TRIPS negotiations has found expression in the final text of the Agreement in form of a balance between the minimum standard obligations to protect IP and the policy space or 'flexibilities' TRIPS leaves to WTO Members in order to pursue public policies and serve the interests of users and the wider public on the domestic level. These flexibilities are included in various specific TRIPS rules and generally reflected in its

balancing objectives in Article 7 and the public interest principles in Article 8 (discussed above and in chapter 3, section 1.1). They sometimes are made very explicit (as in the right of each WTO Member to choose its national regime of exhaustion of IP rights, hence allowing parallel imports),⁵ and in other instances follow from the use on general an open terms in TRIPS provisions (such as legitimate interests, justifiability, *ordre public* and morality) that WTO Member can – within the limits of accepted principles of treaty interpretation in public international law – interpret and implement in accordance with their public policy preferences.

Accordingly, some examples for flexibilities in the patent-related provisions of TRIPS have the effect that WTO Members may take different approaches on the possible exceptions to patentability (regulated under Article 27:2, 3 TRIPS); implementing the general requirements for protection (such as novelty, inventive step and utility under Article 27:1 TRIPS); introducing exceptions to the exclusive rights granted to the patent holder (Article 30 TRIPS); allowing the importation and sale of patented products already placed on the market in another WTO Member (Article 6 TRIPS); and granting compulsory licenses on patented products or processes (Article 31 TRIPS).

On compulsory licenses, all WTO Members explicitly agreed in paragraph 5 of the Doha Declaration on TRIPS and Public Health that '[e]ach member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'; and that '[e]ach member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.'

These examples highlight the importance of TRIPS flexibilities as tools for states to pursue wider public policy goals and to protect not only the interests of IP owners, but also those of competitors, users, and the general public. Indeed, a United Nations report has concluded that: 'Flexibilities were included in TRIPS to allow States to take into consideration their economic and development needs. States need to take steps to facilitate the use of TRIPS flexibilities.'6

⁵ See Article 6 TRIPS and paragraph 5 of the Doha Declaration on TRIPS and Public Health (2001).

⁶ United Nations - Human Rights Council (2009), 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health', A/HRC/11/12, 31 March 2009, para. 96.

3. Tendencies for and Implications of TRIPS-plus Provisions in Bilateral and Regional Trade Agreements

This section describes tendencies for TRIPS-plus and their implications, in particular for the ability of WTO Members to rely on TRIPS flexibilities and more generally to design national IP systems to domestic development needs.

3.1. TRIPS-plus Protection

In the last 20 years since TRIPS entered into force, international IP law and policy has moved on. Apart from two multilateral agreements on copyright in the framework of the World Intellectual Property Organisation (WIPO),⁷ most new treaties on substantive standards for IP protection are of bilateral, plurilateral or regional character. Since the mid-nineties, countries interested in higher IP standards have successfully shifted IP negotiations away from WIPO and WTO towards FTAs.⁸

In this context, countries which are otherwise reluctant to agree to increase in IP protection are able to negotiate trade-offs such as obtaining (or avoid losing) preferential access to the markets of their FTA partners such as the United States, European Union or Japan. Since the early 1990ies, the number of bilateral or regional FTAs has increased tremendously.

Within the trade in goods, these agreements generally aim to rely on the Article XXIV GATT exception or specific development-related exceptions which allow preferential treatment for trading goods with developing or least developed countries (i.e. goods from developing countries can receive preferential market access as compared to other goods under certain conditions). Such preferential treatment would otherwise often amount to a breach of the

World Copyright Treaty (WCT) available at: http://www.wipo.int/treaties/en/ip/wct/trtdocs_wo033.html; WIPO Performances and Phonograms Treaty (WPPT) available at: http://www.wipo.int/treaties/en/ip/wppt/trtdocs_wo034.html.

On the notion of 'regime shifting' in international IP law see *L Helfer*, Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking. Yale Journal of International Law, Vol. 29, p. 1, 2004, available online at http://ssrn.com/abstract=459740; *P Yu*, Currents and Crosscurrents in the International Intellectual Property Regime. Loyola of Los Angeles Law Review, Vol. 38, 2004, available online at http://ssrn.com/abstract=578572.

Similar to the 'single undertaking' in the WTO, issues such as IP, trade in goods and services, investment and more recently even labour and environment are part of an overarching deal which hence allows for various *quid pro quo* trade-offs; see for example the subject matter covered in the first comprehensive Economic Partnership Agreement (EPA) which the European Community (EC, now EU) negotiated with the CARIFORUM group of Caribbean countries, Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part, (CEPA) signed in Bridgetown (Barbados) on 15 October 2008, Official Journal of the European Union (OJ) 2008 L 289/I/3 available at: http://trade.ec.europa.eu/doclib/docs/2008/february/tradoc_137971.pdf.

MFN principle set out in Article I GATT. Quasi in return for market access concessions for (developing) countries in areas of their interests, these FTAs however often also encompass chapters on IP protection which go beyond the obligations foreseen under the TRIPS Agreement.

Examples can be found primarily in bilateral or regional agreements which the EC, Japan, and the United States are entering into with developing and developed country trading partners. ¹⁰ Such TRIPS-plus obligations for additional IP protection usually reflect the interests of the IP dependant industries of the stronger trading partner and hence typically concern:

- stronger copyright protection in the digital, online environment (legal protection for technological protection measures and digital rights management systems, liability of internet service providers and other intermediaries such as search engines);
- stronger patent protection for bio- and pharma patents (extending patentable subject matter to plant and animals, allowing second use/indication patents, introducing additional protection certificates for pharmaceutical patents, test data exclusivity terms;
- stronger trademark- or geographical indication (GI) protection (establishing effective protection of trademarks on the Internet in particular relating to domain names (e.g. via WIPOs Uniform Dispute Resolution Process, UDRP); strengthening the protection of well-known marks against dilution; and/or establishing a register of protected indications of origin); and
- stronger IP enforcement mechanisms (including border measures for exports and goods in transit – applicable to any kind of suspected IP infringement; triple damage calculation; additional duties to provide information; ex officio actions; and extended criminal liability for various types of IP infringements).

This notion of TRIPS-plus IP protection has gained more and more attention in recent years. It is highly controversial among different interest groups, stakeholders, civil society and academia.

¹⁰ US Free Trade Agreements (FTAs) exist for example with Republic of Korea, Jordan, Singapore, Australia, Peru, Columbia or Chile; regional accords are NAFTA and CAFTA; the EC has signed the EC – CARIFORUM Economic Partnership Agreement (EPA) with the group of Caribbean Countries and various other EPAs and FTAs with different regional groups of African, Caribbean and Pacific (ACP) countries, as well as in Asia (Korea, Singapore) and Latin America; Japan has equally entered into so called Economic Partnership Agreements with several trading partners – especially in the Asian and Pacific region (such as Indonesia, Malaysia or the Philippines). While so called 'South-South' FTAs amongst developing countries are increasingly common, they seldom involve additional, TRIPS-plus obligations on IP protection.

3.2. Criticism

As indicated, the obligations in these FTAs to introduce standards of IP protection beyond those of the TRIPS Agreement are subject to criticism.¹¹ One central aspect of this critique is the fact that a lot of the TRIPS-plus standards reduce or eliminate the policy space TRIPS allows in the implementation of its obligations (TRIPS flexibilities).¹² The trend towards TRIPS-plus obligations in FTAs has also led to changes in the perception of TRIPS: Initially viewed by developing countries as primarily serving the interests of the IP exporting industries in the developed world, TRIPS is now often appraised for the flexibilities it offers.¹³ Demanders for stronger IP protection in turn initially celebrated the new international standards TRIPS has set – while later calling for new global 'gold standards' in areas such as IP enforcement.¹⁴ The TRIPS-plus trend is indicative for the long history of international IP protection whose development has primarily been a one-way route towards ever increasing levels of protection.¹⁵ This in turn creates the impression that international treaties on IP protection merely create a "floor" consisting of a minimum level of protection

¹¹ See United Nations Economic and Social Council – Sub-Commission on the Promotion and Protection of Human Rights (2001), 'The Impact of the Agreement on Trade Related Aspects of Intellectual Property Rights on Human Rights', (E/CN.4/Sub.2/2001/13) 27 June 2001, paras. 27-28; United Nations – Human Rights Council (2009), 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health', A/HRC/11/12, 31 March 2009, paras. 68-93; see generally Drahos, P. (2003), 'Expanding Intellectual Property's Empire: the Role of FTAs' – available at http://www.grain.org/rights_files/drahos-fta-2003-en.pdf.

In 2001, WTO unanimously recognized the importance of some of these flexibilities in the public health context in the Doha Declaration on TRIPS and Public Health; see WTO Ministerial Conference, Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), 20 November 2001.

¹³ WHO, Fifty-seventh World Health Assembly, WHA57.14: Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS, available at: http://apps.who.int/gb/ebwha/pdf_files/WHA57/A57_R14-en.pdf; United Nations – Human Rights Council (2009), note 9, paras. 25-55; see also various interventions by WTO Members in the 8-9 June 2010 TRIPS Council Meeting (Minutes of the TRIPS Council Meeting, IP/C/M/63, Agenda Item M (Enforcement Trends), at para. 252, 264-266, 272, 276, 291, 298, 300, 318, 319) which reflect primarily developing countries' concerns that TRIPS-plus standards undermine the 'flexibility', 'policy space' and 'balance' inherent in the TRIPS Agreement.

¹⁴ In relation to the Anti-Counterfeiting Trade Agreement (ACTA), the EU Commission explained the rationale for such a new agreement is to "establish new international norms, helping to create a new global gold standard on IPR enforcement"; see *EU Commission*, (2007) European Commission seeks mandate to negotiate major new international anti-counterfeiting pact, Press release of 23 October 2007 (IP/07/1573).

Once rights have been inscribed into the text of an IP convention, they basically become sacrosanct for now and the future. Revision conferences (with only a few remarkable exceptions of the Revision of the Berne Convention 1971 where an Annex addresses the option for developing countries to grant compulsory licenses mainly for translation purposes and the amendment of the TRIPS Agreement in the course of the Doha paragraph 6 solution; see General Council, Amendment of the TRIPS Agreement, WT/L/641, Dec. 8, 2005) have regularly served the purpose of further strengthening the position of right holders; hardly ever was an effort undertaken to question or curtail incumbent rules; see *Annette Kur and Henning Grosse Ruse – Khan*, Enough is Enough – The Notion of Binding Ceilings in International Intellectual Property Protection, (Max Planck Papers on Intell. Prop., Competition and Tax L., Research Paper No.09-01) (2008) *available at* http://ssrn.com/abstract=1326429.

which must be available in all national laws of the contracting parties (Taubmann, 2008)—without any apparent limitation as to the further extension of IP protection.¹⁶

Of course, agreeing to additional protection beyond the multilateral standards is usually based on trade-offs between the countries negotiating an FTA. Typically, IP obligations are requested for the benefit of IP-dependant export industries of one (or more) of the trading partners – and agreed by the other one(s) in exchange for commitments which benefit its own export industries, such as enhanced market access for goods or services. In 2017, WIPO counted 572 IP-related bilateral treaties – a significant portion of which are again agreements where enhanced IP protection and enforcement commitments accepted by one side function as a trade-off for concessions made by the other side.¹⁷

While this is not the place to question the overall welfare effects of such trade-offs or to engage in a detailed assessment of whether the benefits outweigh the losses that follow from such political decisions, the sustainability of such an approach from a long-term, global perspective generally appears doubtful: A trade concession obtained for agreeing to stronger IP rights usually derives its main economic value from being exclusive to the export industry of the country receiving this concession. Once the same or a similar concession is granted to competitors in third countries, the relative advantage is gone. That is why WTO law allows, under certain conditions, to shield further trade liberalisation in form of such concessions from the application of the most-favoured-nation (MFN) principle.¹⁸ In fact, the MFN exception creates the principal *raison d'être* for negotiating agreements – like RTAs and Customs Unions – that liberalise trade beyond the multilateral WTO standards.

Once however the IP-demanding country starts to grant equivalent trade concessions to other countries, the country which had agreed to higher IP standards risks to lose the economic benefits it hoped to obtain from the trade concession it initially obtained. This process of *preference erosion* calls the rationale for agreeing to higher IP standards as a part of a trade-off deal into question. This aside, IP standards driven by the export needs of another country hardly ever are those most suited to the domestic needs of innovators, creators, users and the general public.

¹⁶ On the question whether international IP law does – or should – contain also maximum standards or ceilings, see *Annette Kur and Henning Grosse Ruse – Khan*, as note 15 above.

¹⁷ See the WIPO lex website on IP-related bilateral treaties at http://www.wipo.int/wipolex/en/treaties/index_bilateral.jsp (accessed 6 April 2017).

See Articles I and XXIV of the General Agreement on Tariffs and Trade 1994 (GATT) (Marrakesh, 15 April 1994).

In addition, the tendency to include ever-more comprehensive and detailed provisions on IP in FTAs is in itself – that is regardless of their substance – very problematic. One example shall suffice here: the way we use copyrighted content has completely changed with the advent of the digital, network environment. One the one hand, identical digital copies produced by the click of a mouse and shared through global networks threaten exploitation opportunities of right holders. At the same time, in an age where any use of digital content implicates (temporary) reproductions, the traditional right to authorise reproduction of copyrighted works gives the copyright owner vast powers to control access to and use of such works that goes well beyond the analogue environment in which that right initially operated.

These sea-changes triggered some initial responses in the so called 'WIPO internet treaties' in 1996 – which now appear antiquated in the context of social media, user-generated content, and big data. It is naïve to assume that new responses developed today will continue to offer sensible solutions for the technologies that impact on IP tomorrow. This example shows that IP laws are particularly sensitive to changes in technology and how we use it. While TRIPS does not even attempt to deal with the 'digital revolution' or global communication networks, it generally provides for sufficient leeway to design national systems in accordance with domestic needs, and to adapt them to a changing technological environment. For example, under the so called three-step-test in Article 30 TRIPS, WTO Members can limit patent rights – such as by means of 'Bolar' and experimental use exceptions that can prove critical in enabling stop-gap adaptations while longer term solutions are sought.

Today's IP provisions in bilateral or regional agreements on the other hand are becoming ever more detailed, technology-specific and prescriptive. They are often transplants of comprehensive IP protection or enforcement approaches that are extracted from the domestic law of the IP-demanding country – without consideration whether they fit into the regulatory and technological environment of the receiving FTA partner country.

In addition, what is transplanted often leaves out the corresponding limits of IP protection and other checks and balances operating in the law of the transplanting country. If the provision is further not technologically neutral, the resulting transplant is bound to fail in providing any workable solution a few years down the line: For example, the detailed and lengthy provisions on the liability of internet services providers (ISPs) which are frequently among those transplanted via FTAs may have addressed most of the issues ISPs, content

¹⁹ See for example Articles 4, 5, 8, 11 and 12 WCT and the Agreed Statements to Articles 1(4), 10 in the WCT.

providers and internet users faced in the times when the European Union and the United States as the most common exporters of these rules drafted them (about 15 years ago).²⁰

These provisions may even be something one can still operationalise so as to cover quite a lot of today's problems – but they hardly will address the core legal questions that field will pose tomorrow. This example articulates the threats which an erosion of policy space via detailed and specific provisions in FTAs brings along – not only for the country importing such detailed rules, but also the country exporting them. Both risk to set out inflexible and uncompromising standards into the hard-to-amend rules in an international treaty.

3.3. Calls for Safeguarding TRIPS Flexibilities

In recent years, various international organizations, policy makers and NGOs have highlighted the importance of TRIPS flexibilities – especially in the public health and human rights context – and have called for safeguarding the right of WTO Members to exercise them against TRIPS-plus obligations in FTAs: On the international plane, the WHO emphasized that 'Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.' Further, the Fifty-seventh World Health Assembly urges WHO Members

as a matter of priority: (...) to take into account in bilateral trade agreements the flexibilities contained in the Agreement on Trade-related Aspects of Intellectual Property Rights and recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the World Trade Organization Ministerial Conference (Doha, 2001).²²

Similarly, the United Nations Special Rapporteur on right to health in his 2009 report explains '[f]lexibilities were included in TRIPS to allow States to take into consideration their economic and development needs. States need to take steps to facilitate the use of TRIPS

²⁰ See the 'notice and take-down' approach in the United States' Digital Millennium Copyright Act (DMCA), as well as the limitations on liability of Internet Service Providers (ISPs) in Articles 12-15 of the E-Commerce Directive 2000/31, and the respective 'transplants' of these approaches in EU and US FTAs, such as the US – Korea FTA, Chapter 18 (Intellectual Property Rights), Confirmation Letter (Limitations on Liability for Internet Service Providers), and, to a lesser extent, Article 11.47 of the EU – Singapore FTA.

²¹ WHO, Report of the Commission on Intellectual Property Rights, Innovation and Public Health (Geneva, 2006), Recommendation no: 4.26, http://www.who.int/intellectualproperty/documents/thereport/CIPIHReport23032006.pdf.

WHO, Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS, (Geneva, 2004, Resolution WHA57.14, Fifty-seventh World Health Assembly), http://apps.who.int/gb/ebwha/pdf_files/WHA57/A57_R14-en.pdf.

flexibilities.'²³ Because of this essential role of policy space within TRIPS, the Special Rapporteur demands that

'[de]veloping countries and LDCs should not introduce TRIPS-plus standards in their national laws. Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health.'²⁴

More recently, the United Nations General Assembly adopted a resolution where UN member states reaffirm

the right to use, to the fullest extent, the provisions contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Doha Declaration on the TRIPS Agreement and Public Health (...) which provide flexibilities for the protection of public health, and in particular to promote access to medicines for all.'²⁵

Finally, the September 2016 Report prepared by a High-Level Panel on Access to Medicines, convened by the United Nations Secretary-General, notes 'instances where undue political and economic have been used to dissuade governments from using [TRIPS] flexibilities' and states that such pressure 'violates the integrity and legitimacy of the system of legal rights and duties created by TRIPS'. ²⁶ It then points to WTO Members 'inalienable duty to protect health', and in this context demands that 'WTO Members must help safeguard the legitimate rights of individual Members to adopt and implement flexibilities in the TRIPS Agreement as reaffirmed by the Doha Declaration.'

Also important in this context are statements from those countries which so far have been the main demandeurs for TRIPS-plus provisions in FTAs. Already in 2007, the European Union Parliament stressed "that European IPR policy towards developing countries should not go beyond TRIPs Agreement obligations, but that it should instead encourage the use of TRIPs flexibilities."²⁷ Further, in the context of the European Union – India FTA negotiations, the European Commission reassured that

²³ United Nations – Human Rights Council (2009), 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health', A/HRC/11/12, 31 March 2009, para. 96

²⁴ Ibid, para.108.

²⁵ UN General Assembly 'Global health and foreign policy: health employment and economic growth', Resolution A/71/L.41 (8 December 2016), 5.

²⁶ High-Level Panel on Access to Medicines, Promoting Innovation and Access to Health Technologies, 14 September 2016 (United Nations, Geneva/New York, 2016), 26.

²⁷ European Parliament resolution of 22 May 2007 on Global Europe — external aspects of competitiveness (2006/2292(INI)), OJ C 102 E/128, para. 60.

"negotiations on intellectual property rights (IPR) are taken forward in the spirit of the Doha Declaration on the TRIPS Agreement and Public Health (...) The Commission has made it very clear that the provisions on IPR, in particular those on patents, must be implemented and interpreted in a way that does not impair the capacity of both parties to promote access to medicines in the developing world."²⁸

The European Union Commission further emphasised that it has proposed a "clause that will guarantee that no provision of the FTA will prevent India from using the flexibilities contained in the TRIPS Agreement"²⁹ as well as a "legally binding reference to the Doha Declaration on the TRIPS Agreement and Public Health".³⁰

Already in 2007 the United States Congress and the Bush administration reached a bipartisan compromise on a 'New Trade Policy for America' in 2007 which called for more balance on the position of the United States in FTA negotiations regarding issues related to IP, labour standards and the environment. In response to concerns over United States' FTAs undermining TRIPS flexibilities, the provisions on data exclusivity, patent extensions, and the linkage between patent protection and drug approval have been relaxed substantially; while the new template for FTAs now also included specific provisions on public health (*Roffe and Vivas-Eugui, 2007*). The latter state generally that the intellectual property chapter "does not prevent an FTA partner country from taking the necessary measures to protect public health." These changes were then incorporated in the then pending FTAs with Colombia, Peru and Panama.

Subsequently, the United States Trade Representative (USTR) affirmed, for example in the 2010 Special 301 Report on the protection of IP assets of United States companies abroad, that – in accordance with the Doha Declaration on TRIPS and Public Health – "the United

²⁸ Intellectual Property Watch, EU-India Trade Talks Resume Under Cloud of Concern for Public Health 27 April 2010, online available at http://www.ip-watch.org/weblog/2010/04/27/eu-india-trade-talks-resume-under-cloud-of-concern-for-public-health/.

²⁹ EU Commission, DG Trade: EU – India negotiations and access to medicines: Questions and Answers, p. 2, online available at http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146191.pdf.

³⁰ EU Commission, Letter of Karel De Gucht to MSF International, Brussels, 25 May 2010 – online available at http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146192.pdf.

³¹ Inside US Trade, Brand-Name Drug Industry Alarmed at IPR Precedent of FTA Template, May 18, 2007.

³² *P Roffe and D Vivas-Eugui*, as note 24 above. For a detailed analysis of these provisions, see section IV below. In the negotiations for a Trans-Pacific Partnership Agreement (TPP) however, USTR reportedly does not feel bound by this bipartisan compromise anymore; see *Sean Flynn*, USTR Considering Pharmaceutical Pricing Restrictions in TPP; Refuses to Follow May 10th Agreement on IP-Medicines Issues, IP Enforcement Mailing List, 8 February 2011 (on file with author).

States respects a country's right to protect public health and, in particular, to promote access to medicines for all."³³ The report further assures that

"The United States will work to ensure that the provisions of our bilateral and regional trade agreements are consistent with these views and do not impede the taking of measures necessary to protect public health."³⁴

In sum, not only international organizations, their representatives and member states, but also the main state actors of TRIPS-plus FTAs have committed themselves to safeguarding TRIPS flexibilities – in particular those relevant in the public health context. Nevertheless, TRIPS-plus provisions in FTAs have continued to flourish (see the data discussed in chapter 2). At the same time, some FTAs contain general or specific clauses which go some way in 'safeguarding' flexibilities under TRIPS and other multilateral IP treaties such as the Berne or the Paris Convention. These are discussed further in chapters 3 and 4.

This brief review reiterates how important it is for a country negotiating IP provisions, especially in bilateral or regional trade agreements, to carefully assess the impact these provisions are likely to have on its ability to design national IP law and policy to cater its own development needs. While protections beyond the level of the TRIPS Agreement are not, per se, problematic in terms of the substance of IP protection or enforcement they oblige contracting parties to introduce, the impact this has on tailoring the national IP system to domestic needs is a general and systemic problem. This is especially so if the IP provisions are very detailed and comprehensive – and therefore leave little policy space for domestic implementation.

Since IP is an area where technological changes and the corresponding changes in how we use technology may require frequent changes to the law, detailed international treaty obligations are per se problematic – and have for good reasons generally been avoided in the multilateral IP treaties such as TRIPS, BC, and PC. As further expressed in the recommendations in chapter 3, section 1, countries should therefore be careful not to enter into too detailed or (technology) specific obligations on IP protection – they may soon be outdated and require a re-negotiation of the treaty. The next section moves on to briefly discuss IP protection under IIAs as another, quite different trend of additional (or perhaps better: alternative) means for the protection of IP.

³³ USTR, Special 301 Report (2010), at 13. The report further emphasizes that "the United States respects our trading partners' rights to grant compulsory licenses, in a manner consistent with the provisions of the TRIPS Agreement (...)"; ibid.

³⁴ Ibid

4. Intellectual Property Protection under International Investment Agreements

This section points to the somewhat distinct issues raised by international investment agreements (IIAs) pertaining to IP, and introduces some high-profile cases of Investor-State Dispute Settlement (ISDS) proceedings involving IP rights.

IIAs, in particular in the form of bilateral investment treaties (BITs), as well as investment chapters in FTAs, serve to protect investments made by investors from one contracting state (foreign investments) in the territory of another contracting state (host state) on par or even beyond the standards provided by customary international law.

Frequently, IIAs also provide a mechanism whereby foreign investors can pursue claims directly against a host state under an international arbitration, for the enforcement of the standards set out in the treaty (so that investors do not have to rely on their respective home states to espouse their claim). The core function of IIAs hence is to offer substantive and procedural protection to investors for their foreign investments against those types of host state measures that are in violation of obligations set out in the IIA, such as discriminatory measures, expropriation without compensation, or unfair or arbitrary treatment. The main rationale of this special system of protection is to promote inward foreign investment, which is commonly viewed as beneficial to the economic development of the host state.

Since most IIAs cover IP rights as a form of protected investment, they may offer an alternative form and venue for the protection of IP rights. Here, both relative in-vestment protection standards like national treatment and most-favoured-nation (MFN), as well as absolute standards like fair and equitable treatment, full protection and security, and the protection against expropriation, raise questions about the relationship with the 'traditional' international system of IP protection and its flexibilities.

Next to these substantive overlaps, differences in the judicial remedies of the two systems warrant attention: the common option in IIAs for investors to challenge state measures as inconsistent with investment standards in investor-state dispute settlement (ISDS) has no match in international IP law where, if at all, only states can bring a dispute over the compliance with IP treaty obligations. In some recent disputes, ISDS has served as a forum for claims based on investment standards applied to IP rights as protected investments. In addition, ISDS has been used by right holders to challenge host state compliance with 'traditional' international IP obligations (such as those in TRIPS, PC, or NAFTA chapter 17).

For a long time, the practical relevance of the IP and investment overlap seemed negligible. Since 2010, however, cases are emerging where right holders have relied on international investment protection to challenge various host state measures affecting IP rights. In the three most contested and publicly visible disputes, the measures challenged implement, directly or indirectly, important policy choices of the host state to protect public interests such as reducing tobacco consumption (by limiting the way logos and brand names can appear on packaging) or promoting access to medicines (by applying strict patentability requirements that often affect pharmaceutical products).

This section discusses the outcomes of these cases, and offers an overview how, in most of these cases, international investment protections are invoked to challenge these measures as *in breach of international IP treaties*. This reveals a trend whose implications are addressed in the guidelines in chapter 3, section 2, related to IP protection via IIAs. This Section however also looks at the so far only ISDS Award where a decision has been reached on claims of a breach of an international IP treaty: In *AHS vs Niger*, this claim has been rejected. It is therefore useful to contrast the arguments for rejecting this claim with the arguments raised in the three ongoing cases.

4.1. Plain Packaging Challenges in Philip Morris vs Uruguay and Philip Morris Asia vs Australia

Two of the pivotal cases involve the tobacco company Philip Morris and its ongoing battle against various attempts to limit the use of attractive logos, brands and other get-up on tobacco packaging. In 2010, three Philip Morris (PM) companies filed a request for arbitration under the Bilateral Investment Treaty (BIT) between Uruguay and Switzerland with the International Centre for the Settlement of Investment Disputes (ICSID),³⁵ alleging that Uruguay's limits on the use of trademarks on tobacco packaging 'have substantially damaged the value of the companies' investments in Uruguay and deprived them of the ability to use their brands and trademarks'.³⁶ These alleged deprivations of PM's IP rights were then argued to constitute breaches of Uruguay's obligations under the

³⁵ Philip Morris Brand Sàrl (Switzerland), Philip Morris Products S.A. (Switzerland) and Abal Hermanos S.A. (Uruguay) v Oriental Republic of Uruguay, [2009], ICSID Case No. ARB/10/7 (Philip Morris v Uruguay).

The two regulations challenged by PM concern an increase in the packaging space reserved for health warnings from 50 to 80% and a 'single representation requirement' that prohibits sales of more than one variation of cigarettes under a single brand name (as a response to so-called colour-coding where a particular variation of a brand suggests a 'light' product, etc). See Philip Morris International, Statement and background information regarding the company's Bilateral Investment Treaty (BIT) claim against the government of Uruguay, 5 Oct 2010, available: http://www.pmi.com/eng/media center/company statements/pages/uruguay bit claim.aspx.

Switzerland-Uruguay BIT, in particular with regard to expropriation under Article 5 and FET under Article 3(2) – thus entitling PM to compensation and damages.

After a July 2013 decision rejected Uruguay's objections against the jurisdiction of the ISDS tribunal,³⁷ the majority of the tribunal held in that the PM's claims were unfounded on the merits and therefore it dismissed the action.³⁸ With regard to the expropriation claim, the tribunal did not find that PM had offered sufficient evidence for a necessary 'substantial deprivation' of the value, use or enjoyment of PM's investments – for which the tribunal considered PM's business in Uruguay as a whole.³⁹ The majority of the tribunal also rejected the FET claim, acknowledging a 'margin of appreciation' on the side of the host state, to adopt measures to protect public health.⁴⁰ Crucially, in relation to the expropriation claim, the tribunal held that the fact that the Uruguayan measures had led to a decline of smoking, especially amongst young people, justified these measures as promoting public health.⁴¹

This finding is of systemic importance for claims that public interest-based measures limiting the protection of IP rights can amount to an expropriation. The tribunal unanimously found that under international law, states enjoy an inherent right to regulate – in a proportionate and non-discriminatory way – in order to protect public health. It said that 'the adoption of the Challenged Measures by Uruguay was a valid exercise of the State's police powers, with the consequence of defeating the claim for expropriation under Article 5(1) of the BIT.'⁴² The tribunal (consisting of very experienced international lawyers, one of which is now a judge at the International Court of Justice) reached this conclusion even though the expropriation provision of the relevant IIA, Article 5(1) of the Uruguay – Switzerland BIT, is not explicitly subject to the State's police powers. In doing so, it interpreted the notion of (indirect) expropriation in light of the state's right to regulate, which it considered to form part of customary international law of general nature.⁴³

³⁷ The tribunal rejected, inter alia, the argument that Philip Morris' business of selling tobacco products in Uruguay is not an 'investment' entitled to arbitration under Art. 25 of the ICSID Convention. The tribunal argued that for an investment to contribute to the host state's economic development (as any of the other 'Salini criteria') is not a 'mandatory legal requirement', but merely pointing to the typical features of an investment. See *Philip Morris v Uruguay*, Decision on Jurisdiction, 2 July 2013, para.204-210.

³⁸ Philip Morris v Uruguay, Award, 6 July 2016.

³⁹ Para.284 of the Award.

⁴⁰ Para.399 of the Award.

⁴¹ Para.306 of the Award

⁴² Para.287 of the Award.

⁴³ Para.290 of the Award. This approach is often referred to as 'systemic integration' and is based on Article 31(3) c) of the Vienna Convention of the Law of Treaties (VCLT).

It went on to conclude, reviewing a range of earlier ISDS Awards, that the police powers doctrine include a right of States to right to protect public health and that this right forms part of customary international law.⁴⁴ This right therefore generally applies in the relations between states, unless states have (in express terms) decided to exclude or limit this right. In fact, the balancing objectives in Article 7 TRIPS and the public interest principles in Article 8 TRIPS form a specific expression of this right to regulate in the international IP context

In a similar dispute, Philip Morris Asia (PMA), a company based in Hong Kong, China which – via the holding company PM Australia – owns the Australian company Philip Morris Limited (PML), initiated investment arbitration proceedings against Australia under the Hong Kong, China-Australia BIT (HK-AUS BIT) because of Australia's 'plain packaging' regulations. Those regulations (1) require tobacco product packaging to be in a particularly unappealing colour, (2) prohibit the use of graphic trademarks, and (3) restrict the use of word marks on tobacco product packaging to the effect that the brand, business, company or variant name may be displayed only in certain standard styles and positioning on the packaging.

The idea behind these rules is to reduce the attractiveness and appeal of tobacco products to consumers, increase the noticeability and effectiveness of mandated health warnings, and reduce the ability of the tobacco product and its packaging to mislead consumers about the harms of smoking. PMA claimed that it owns, via its Australian subsidiaries, trademarks such as Marlboro as well as 'copyright works, registered and unregistered designs; know-how; trade secrets; and overall get up of the product packaging ("intellectual property") on and in relation to Philip Morris' tobacco products and packaging'. It argued that this IP and the goodwill generated from its use in Australia are protected investments under the Hong Kong-Australia BIT.

⁴⁴ Para. 298 and 301 of the Award.

⁴⁵ See generally Andrew Mitchell and Tania Voon, 'Time to Quit? Assessing International Investment Claims Against Plain Packaging in Australia' 14(3) (2011) *Journal of International Economic Law* 515; Henning Grosse Ruse-Khan, 'Internationaler Investitionsschutz und geistiges Eigentum' 4(1) (2012) *Zeitschrift für Geistiges Eigentum*, 1.

⁴⁶ Parliament of the Commonwealth of Australia, House of Representatives, Tobacco Plain Packaging Bill 2011, 6 July 2011, clauses 19, 20, 21, 36. According to the Explanatory Memorandum to the Tobacco Plain Packaging Bill 2011 (6 July 2011), at 5, the Bill aims to 'to prevent trade marks from being used as design features to detract attention from health warnings, or otherwise to promote the use of tobacco products.'

⁴⁷ Philip Morris Asia, Written Notification of Claim to the Commonwealth of Australia pursuant to the Agreement between the Government of Hong Kong and the Government of Australia for the Promotion and Protection of Investments (27 June 2011), at 2.

Relying primarily on the FET standard, PMA claimed a 'legitimate expectation that Australia would comply with its international trade treaty obligations', in particular under TRIPS and the PC.⁴⁸ PMA has also argued that the umbrella clause in the Hong Kong-Australia BIT requires Australia to observe, as an obligation it has entered into with regard to investments of protected foreign investors, compliance with 'international obligations binding on the host state that affect the way in which property is treated in Australia'.⁴⁹

According to PMA, these obligations include those deriving from international IP treaties such as TRIPS and the PC. On 17 December 2015 however, the investment tribunal rejected its jurisdiction and dismissed PMA's claims on procedural grounds (*Hepburn and Peterson, 2015*). The claims have primarily been rejected because PMA had only obtained the relevant investments in Australia when it knew very well that Australia was about to introduce plain packaging for tobacco product. Essentially, Philip Morris had been 'treaty shopping' for an IIA that offered it investment protection and a forum to sue Australia – and this the tribunal considered to be an abuse of (procedural) rights, a misuse of the ISDS process.

While this effectively ends this ISDS complaint, it is nevertheless worth further exploring the arguments made to challenge compliance with international IP norms. Several countries around the globe, such as the United Kingdom, Norway, France, New Zealand and India have been considering to introduce plain packaging or similar measures. It may well be that measures introduced elsewhere will face a similar challenge under an applicable IIA. In light of the arguments made by PM and PMA so far, it is equally likely that such a challenge will also be based on alleged breaches of international IP norms that tobacco companies will try to 'import' into ISDS via routes such as FET and umbrella clauses. Insights from the arguments made in these disputes and the decision rendered will feed into the recommendations in chapter 3, section 2.

4.2. Patent Revocation Challenge in Eli Lilly vs Canada

A rather different investment dispute where again compliance with IP treaties has been challenged concerns the United States-based pharmaceutical company Eli Lilly and the revocation of two of its patents in Canada. In November 2012, Eli Lilly initiated ISDS proceedings under chapter 11 of NAFTA against Canada, following the invalidation of pharmaceutical patents for its drugs Strattera and Zyprexa by Canadian courts.⁵⁰

⁴⁸ Philip Morris Asia vs. Australia, Notice of Arbitration, 21 November 2011, at para.6.5 and 7.6-7.11.

⁴⁹ Ibid, at para.7.15-7.17; even prior to the decision on jurisdiction of 17 December 2015 mentioned in note 10, this claim apparently had been dropped by PMA – most likely for the reasons discussed in Part II 2).

⁵⁰ Eli Lilly and Company vs. Canada, Notice of Intent, 7 November 2012.

At the centre of the dispute is a 'promise doctrine' whereby Canadian courts take for granted what the patent application has described as the specific useful effect of the invention and require the applicant to show adequate support for that specific utility claimed in the application: If the applicant does not provide sufficient evidence, at the time of filing, for the promised utility the court has construed from the patent claims and description, the required disclosure is insufficient to support the 'promise' and the patent granted can be revoked.⁵¹

In order to justify a patent for a new use of a known substance and one for selecting a specific element from amongst a large group of known compounds, Eli Lilly had made specific utility claims in order to differentiate these applications from earlier patents – claims which Canadian Courts held to be insufficiently supported by evidence in the patent application. Lilly complained that the strict patentability standards resulting from the promise doctrine, as applied by the Canadian Courts since 2005, are *violating Canada's international IP obligations* under NAFTA, TRIPS and the Patent Cooperation Treaty (PCT). This in turn, Lilly argued, breaches NAFTA's investment chapter since 'Canada has a positive obligation to ensure Canadian law complies with NAFTA and the PCT, consistent with the reasonable investment-backed expectations of the investor.

Similar to the plain packaging disputes, the investor relied on the FET (and in this instance also on the expropriation) standard to claim a legitimate expectation that the host state complies with international IP norms. In *Eli Lilly vs Canada* however, a specific NAFTA clause ensures that the expropriation standard does not apply to certain IP limitations such as compulsory licenses or revocations of IP rights – as long as these limits are consistent with relevant international IP rules.⁵⁴ This clause, which also occurs in a range of other IIAs, offers an additional explanation why Lilly puts so much emphasis on a breach of IP treaty norms: unless Lilly can make a case that Canada's measures violate the relevant international IP provisions, it is effectively barred from invoking protection against expropriation for its patents. That in turn would significantly limit Lilly's ability to rely on one of its strongest arguments – the detrimental legal and economic effect the revocation has

⁵¹ In a June 2017 judgment, the Canadian Supreme Court however seems to have departed from the promise doctrine – see *AstraZeneca Canada Inc. v. Apotex Inc.* (2017 SCC 36). For a detailed discussion of the promise doctrine see *Richard Gold and Michael Shortt*, 'The Promise of the Patent in Canada and Around the World' 30(1) (2014) Canadian Intellectual Property Review 35, http://ssrn.com/abstract=2361146

⁵² See *Eli Lilly and Company v Teva Canada Limited*, 2011 FCA 220, affirming the earlier trial court decision (2010 FC 915) and *Eli Lilly Canada v Novopharm Limited*, 2012 FCA 232, again affirming the earlier trial court decision (2011 FC 1288).

⁵³ Eli Lilly vs. Canada, Notice of Arbitration, para.71, 77.

⁵⁴ See Art.1110(7) NAFTA, referring to the IP standards set out in Chapter 17 of NAFTA.

on its patents and their exploitation. Therefore, in order to keep the door open for these expropriation arguments, Eli Lilly first has to show a breach of Canada's IP obligations. Clauses such as Article 1110(7) NAFTA hence may serve as another 'door opener' to raise questions of compliance with international IP law in ISDS. As they ensure that expropriation protections do not undermine flexibilities on compulsory licenses and other limitations in the international IP order, they are referred to as *safeguard clauses*.

In March 2017, the tribunal issued its award, rejecting all claims by Eli Lilly.⁵⁵ At the heart of the decision are not so much the various contested claims about compliance of the promise doctrine with international IP norms and the role of safeguard clauses – instead, the tribunal found it most appropriate and judicially efficient to reject Lilly's claims primarily on factual grounds: even when assuming (in arguendo) that Eli Lilly is correct about the highly contested legal standards it had put forward for a breach of either the expropriation or the FET standard under NAFTA chapter 11, applied to judicial decisions of a court, Lilly could still not show that these standards had in fact been breached: the tribunal found that there had not been a dramatic change in the utility requirement in Canadian patent law (section VIII); and that the utility requirement, as applied to the relevant patents by Eli Lilly, is not arbitrary and/or discriminatory (section IX).⁵⁶ The decision is therefore less useful than the Uruguay Award in identifying the relevant legal standards of investment protection when applied to IP rights.

Nevertheless, the tribunal did make some important statements with regard to the scope of review an ISDS tribunal is meant to engage in when scrutinising national decisions of administrative bodies (such as Patent- or Trademark Offices) or courts for breaches of international investment standards:

'The Tribunal emphasizes that a NAFTA Chapter Eleven tribunal is not an appellate tier in respect of the decisions of the national judiciary. It is not the task of a NAFTA Chapter Eleven tribunal to review the findings of national courts and considerable deference is to be accorded to the conduct and decisions of such courts. It will accordingly only be in very exceptional circumstances, in which there is clear evidence of egregious and shocking conduct, that it will be appropriate for a NAFTA Chapter Eleven tribunal to assess such conduct against the obligations of the respondent State under NAFTA Article 1105(1).'

While decided on primarily on the basis of insufficient evidence to even meet the contested standards proposed by the investor, the Eli Lilly patent revocation case shows that invoking international IP norms and challenging host state compliance in ISDS is not a phenomenon

⁵⁵ Eli Lilly vs. Canada Case No. UNCT/14/2, Final Award, 16 March 2017.

⁵⁶ See Sections VIII and IX of the Award, in particular para. 386-389 and para. 442.

specific to tobacco packaging disputes. Since this line of argumentation appears in most of the publicly available IP-related investment disputes so far, it is not at all unlikely that similar claims will be made in future cases.

Finally, a less prominent ISDS dispute involving IP rights needs to be mentioned. Since the arbitrators refused to rule on the issue of compliance with an IP treaty in that case, it can be usefully compared with the arguments made in the disputes discussed so far. Taken together, the decisions allow to formulate some guidance for states in addressing the protection of IP rights via the standards of international investment law – be it in a self-standing BIT, or in an investment chapter of an FTA.

4.3. Unauthorised Use of Trademarks in AHS vs Niger

On 15 July 2013, ICSID released excerpts of an award in a case relating to the termination of an airport services concession in Niger in 2010. The dispute involved aviation handling service provider MMEA, a Luxembourg-registered company, and AHS, its Nigerian subsidiary, which jointly brought a claim against Niger in March 2011.⁵⁷ Under the concession, the claimants had provided airport cargo and ground services at Niamey International Airport in Niger.

When authorities terminated the concession and seized the claimants' bank accounts and equipment, AHS and MMEA initiated arbitration proceedings under ICSID.⁵⁸ In an award from July 2013, arbitrators considered the actions by Niger as expropriation and awarded 4.6 million Euros in compensation.⁵⁹ In the arbitration, AHS and MMEA also complained about infringements of its IP rights, in form of trademarks and trade names registered with OAPI, a regional IP Organization in Francophone Africa to which Niger is a Member. The complainants alleged that the new personnel employed by the Nigerien authorities, after seizing AHS' equipment, had continued to operate airport services using uniforms with IP protected trademarks and trade names registered for the claimants until early 2011.⁶⁰

⁵⁷ See the report by *Investment Arbitration Reporter*, Niger liable for expropriation of airport services concession, but no damages due for subsequent Misuse of Intellectual Property, 19 December 2013, – online available at http://www.iareporter.com/articles/20131219/.

⁵⁸ Ibid

⁵⁹ See AHS Niger and Menzies Middle East and Africa S.A. v. Republic of Niger (AHS vs Niger), ICSID Case No. ARB/11/11, Award of 15 July 2013.

⁶⁰ Ibid, at para.150.

The arbitrators found the arguments of the complainants with regard to this use of IP protected subject matter as not sufficient to establish a right to compensation: One the one hand, AHS and MMEA asserted that the use of their trademarks and trade names violated the Bangui Agreement, ⁶¹ a regional IP treaty which establishes a system of trademark protection. Crucially, while the complainants could show that Niger has ratified the Bangui Agreement, they were unable to explain how compliance with this Agreement mattered for the dispute. ⁶² In particular, the arbitration tribunal found that AHS and MMEA had not explained how it would be competent to hear arguments about a breach of the Bangui Agreement. The tribunal noted Article 47 of Annexe III of the Bangui Agreement that allocates jurisdiction for civil actions related to trademarks to civil courts; and further identifies the competent national courts in case of criminal actions, including defences based on the invalidity of the trademark. ⁶³

Apart from the alleged breach of the Bangui Agreement, the complainants argued that the use of their trade names and trademarks deceived the users of stop-over services by creating the impression that AHS was still responsible for low quality services performed by the stop-over assistance unit after seized by Niger.⁶⁴ AHS and MMEA argued that this negatively affected their reputation in Niger, relying on a service-audit performed by the company DHL in relation to the stop-over assistance unit. The arbitrators nevertheless found that AHS and MMEA were unable to show any consumer confusion between the services of the stop-over assistance unit after being seized and the services earlier provided by AHS Niger – so that no harm to reputation had been proven.⁶⁵

This brief review of the IP aspects in AHS vs Niger reveals that the arbitrators rejected the complainants' arguments based on breaches of international IP obligations (of Niger under the Bangui Agreement), and on infringements of the trademark rights owned by AHS and MMEA. While the latter was rejected on its merit (there was apparently insufficient evidence for showing consumer confusion, generally an essential element of trademark infringement), the alleged breach of an international IP treaty was rejected on *jurisdictional grounds*: The complainants had simply not provided any relevant arguments why compliance with the Bangui Agreement could be subject to arbitration.

⁶¹ Bangui Agreement Relating to the Creation of an African Intellectual Property Organization, Constituting a Revision of the Agreement Relating to the Creation of an African and Malagasy Office of Industrial Property, Bangui (Central African Republic), March 2, 1977.

⁶² AHS vs Niger, at para.152.

⁶³ Ibid.

⁶⁴ Ibid, at para.153.

⁶⁵ Ibid, at para.154.

This points to the key difference between this case and the other disputes described above: In *Lilly vs Canada* and in the tobacco packaging disputes, investors have relied on various arguments and investment standards that establish grounds for linking breaches of international IP rules with the protection of foreign investments. Essentially, an investment 'hook' – such as umbrella or safeguard clauses, FET or expropriation standards – is necessary to import international IP norms into ISDS so that compliance with them may be reviewed. General references to international law as (part of) the applicable law, such as in Article 42 ICSID, are insufficient for this purpose.

4.4. Connecting the Cases: Attempts of Challenging Compliance with Intellectual Property Treaties via ISDS

The emerging cases on IP as protected investment reviewed in this section reveal that investors often try to invoke international IP norms in investment disputes that involve IP rights. Various routes have been employed to challenge compliance of the host state measure at stake with IP treaties. Although the total number of publicly available challenges is few, it seems quite likely that future cases involving IP rights will also involve challenges that are primarily based on breaches of international IP norms.

This is compounded by the fact that there is – compared to the number of substantive protections in IIAs – a much greater number of specific international IP obligations that result from the core multilateral treaties with almost universal membership as well as from an ever-increasing amount of IP provisions in FTAs. If those FTAs include detailed and comprehensive provisions as described above, right holders may attempt to seek opportunities to enforce them.

Rights holders will find it relatively easy to allege a breach of an international IP provision — but in international IP law, they lack a forum to litigate them. ISDS offers them a forum; and the broad and ambiguous protections in IIAs such as FET, expropriation or umbrella clauses invite them to re-package an alleged violation of a specific IP norm as breach of an IIA protection. Taken together, this offers a truly unique and unprecedented opportunity for private right holders to challenge national IP laws in a way not seen before. In contrast, 'traditional' invocations of expropriation and FET standards have not fared well in the plain packaging and patent revocation disputes discussed above.

For this reason, chapter 3, section 2 includes suggestions for host states to draft IIA provisions in a way which does not allow misuse of investment protection to challenge compliance with international IP norms. It also offers guidance on how to ensure that investment protections do not override accepted flexibilities in the international IP system, and generally allow the host state to retain the policy space under that system to develop domestic IP law based on domestic needs.

Chapter

2

EMPIRICAL REVIEW AND CURRENT TOPOGRAPHY OF AGREEMENTS: STYLIZED FACTS FOR UNDERSTANDING THE NOODLE BOWL

After an introduction to the background and trends of international IP treaties, including a thorough examination of the TRIPS Agreement (all of which negotiators should be aware of in order to negotiate IP protection in trade and investment agreements effectively), we proceed to examine the topography of IP related trade agreements which for the purposes of this chapter are held to include bi- and plurilateral trade agreements regardless of whether they are designated as regional, preferential or free trade agreements.

The objective of this chapter is firstly to inform readers of how Asia-Pacific ecobnomies have approached IP rights in trade agreements in the past. This will be accomplished by means of presenting stylized facts derived from a ESCAP database of IP rights in trade agreements first established by T. Alexander Puutio and Luca Parisotto. Secondly, this chapter aims to provide readers, and trade negotiators in particular, with an understanding of what types of provisions their peers have negotiated and what their negotiation partners have sought in previous engagements. Accordingly, this chapter will showcase the types of provisions agreed upon by different categories of states, namely developed and developing, and whether there are discernible differences in the strength of these provisions. While the dataset encompasses all available trade agreements globally, the chapter will focus on Asia-Pacific economies and their trade agreement partners in other regions.

1. Differing Capacities to be Involved

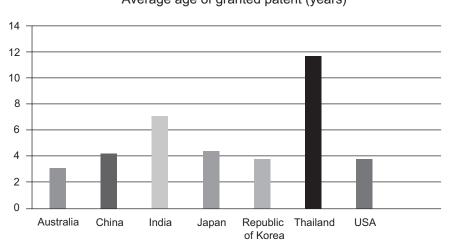
As all modern trade negotiators know well, trade agreements are no longer only about tariffs restricting market access. Today, trade negotiators have to be concerned with sanitary and phytosanitary (SPS) standards, customs cooperation and foreign investment rules and a wealth of other highly technical provisions that regulate trade in different ways. Since the signing of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994, more issues were added to already long negotiating mandates including very controversial IP rights. Over last 17 years, IP rights) have seen a rise from a near obscurity to being an almost mandatory part of modern trade agreements. As further discussed in chapter 1, section 3, this rise has been fast, and

with the growing importance of knowledge-based industries that momentum is only increasing.

The mere speed of these developments is making more difficult to properly assess the reasons why IP has been incorporated into trade agreements in the first place as well as what effects their sudden emergence is creating. The indecisiveness over what global IP standards should look like make the situation even more complex – particularly so for developing countries that have recently found themselves thrown into the deep waters of an increasing amount of international obligations for protecting intellectual property rights.

In regions such as Asia and the Pacific governmental capabilities to deal with IP are far from being equally distributed. While no official metrics exist, this inequality proxied e.g. by the efficiency of patent offices. For instance, where the average patent issued by the Australian patent office is slightly over three years old, its peers from Thailand are almost twelve years of age (figure 1).

Figure 1. Average age of granted patent (years)



Average age of granted patent (years)

Source: The Long Wait for Innovation: The Global Patent Pendency Problem, Mark Schultz, Kevin Madigan, 2016.

Significant differences exist in other areas relevant for forming the necessary capacity to successfully negotiate IP inclusive trade agreements. Firstly, and most obviously, countries have very different financial capacities to support negotiations and the related institutional arrangements. These pecuniary inequalities greatly tilt the playing field in favour of states

that can afford cadres of government officials and external consultants whom are instrumental in ensuring informed negotiation strategies and the capacity to pull them through.

Secondly, Asia-Pacific economies vary greatly in their homegrown academic capabilities, essential for example for formulating and conducting accurate impact assessments. In fact, the academic prowess of Asia-Pacific nations is so deeply concentrated in the Republic of Korea, Japan, Australia, Singapore and China that the first developing country to reach the list of top innovative universities in the region is India's IIT at number 71 (table 1).

Table 1. Asia-Pacific universities innovativeness rankings by Reuters

1	KAIST	Republic of Korea
2	Seoul National University	Republic of Korea
3	University of Tokyo	Japan
4	Pohang University of Science and Technology (POSTECH)	Republic of Korea
5	Sungkyunkwan University	Republic of Korea
6	Tsinghua University	China
7	Tohoku University	Japan
8	Kyoto University	Japan
9	Osaka University	Japan
10	Hanyang University	Republic of Korea
71	Indian Institutes of Technology System (IIT)	India

Source: Authors' compilation from Reuters 2017 Study on most innovative Asia-Pacific universities.

2. Why These Differences Matter and What to Do About Them

Vast differences in negotiation capacities hampers the internal development of IPRs regimes as well as the likelihood of successful trade negotiations where developing countries are often confronted with legal transplants which reflect the policies drafted in favour of their more developed negotiation partner – or are little more than a copy and paste exercise of domestic IP provisions of that partner.

While precious little can be done to alleviate resource and institutional deficiencies, much can be accomplished in terms of leveling the playing field through other means. For instance, as Moerland alludes to in her recent paper, developing countries could greatly increase the likelihood of negotiation success by enhancing the *transparency* of the overall process (Moerland, 2017).⁶⁶ In particular, she notes that a lack of transparency hinder the

⁶⁶ The following subsection refers to Anke Moerland, 2017.

availability of third party information and advice – something which is particularly crucial in case domestic stakeholders lack expertise or the ability to make their voices heard. Furthermore, domestic civil society organizations can often tab into a well-connected network of NGOs and other civil society organizations and individual who have experience and expertise of dealing with IP in developing countries, perhaps even similarly situated developing countries. Such extended means of seeking input allows developing country negotiators to base their decisions on more information – not only related to their own domestic context, but perhaps also on experiences from similarly situated countries which have already signed up to IP provisions in FTAs.

As a matter of process, third party inputs can be specifically invited, and their emergence can be greatly facilitated by opening up various parts of the negotiation process, including the mandate, drafts and preparatory discussions. The benefits of enhanced transparency for developing states are twofold. First, its provides for better informed and more successful negotiation outcomes. Secondly, it ensures domestic industry buy-in and respect for the outcomes and their implementation process.

A particularly important, albeit indirect, outcome of transparency and third-party involvement is the typically increased flexibility of the rules negotiated, given that the outcome is shaped by a wider array of socio-economic situations and requirements. In the case of developing countries, these flexibilities should account for the need to efficiently catch up with information and knowledge economies espoused by developed states, and abide by the public-interest flexibilities included in TRIPS. In an area such as IP where protected technology and the way we use is changing rapidly, it is essential to have rules that are flexible enough to deal with tomorrow's technology, and tomorrow's uses – in particular if these rules are part of an international agreement that is not meant to be re-negotiated every time such change occurs.

Developing states have other tools for leveling the playing field at their disposal as well. To begin with, Moerland notes the potency of *impact assessments* which can significantly improve the bargaining power and leverage held by the negotiation team. Optimally, the assessment would be tailor-made for the proposed agreement, and would critically asses the implications of the particular IP demands on various areas of public life, the realization of human rights and the institutional, financial and practical burdens implementation would impose. Such impact assessment have not only been suggested in relation to FTAs, but also other areas of international economic law (in particular in relation to investment

protection).⁶⁷ They are also good practice in the legislative implementation of IP protection in national law.⁶⁸

Furthermore, negotiators can improve outcomes by knowing their domestic preferences and the limits of their national win-set by heart as they enter the negotiations, and be ready to effectively represent this set when seated at the negotiation table – even to the extent of occasionally feigning the level of capacities involved as a strategic move. In addition, developing nations should be adamant in their requests for interference-free support for the implementation of any IP related concessions made in the course of the negotiations.

As a corollary, developed states should refrain from imposing themselves into the implementation process, and should not wield their financial and political influence to interfere with the national discourse on implementation – specifically in situations where the transparency of the negotiation process has been limited.

Where these suggestions go unheeded a plethora of issues are bound to arise. In the case of multilateral negotiations such as the Trans-Pacific Partnership (TPP), recent commentary notes that imbalances and procedural misgivings have led to the lack of clarity and coherence in the IPRs rules greatly detracting from the prior aspirations set out for now all-but-defunct agreement. Other recent examples include the failed ACTA negotiations, the downturn of which began after vocal calls for more balanced involvement of less-capable countries involved in the European Union negotiation bloc. The eventual rejection of ACTA by the European Parliament has been, to a large extent, the outcome of political pressure from street protests in Europe, from NGOs and civil society, as well as from hundred of thousands European citizens that feared ACTA would unduly interfere with fundamental freedoms and civil rights. This in turn to a large extent has been due to the lack of transparency which had been endemic in the early stages of ACTA negotiations and which had allowed urban myths about rules mandating the seizure of mobile phones or laptops (in order to check for copyright infringing content) to flourish. All this shows the importance of transparency and inclusive stakeholder participation in the negotiation of IP provisions in FTAs.

⁶⁷ See for example the General Comment No. 24 (2017) on State obligations under the ICESCR in the context of business activities which states in para.13: 'The conclusion of [trade and investment] treaties should therefore be preceded by **human rights impact assessments** that take into account both the positive and negative human rights impact of trade and investment treaties, including the contribution of such treaties to the realisation of the right to development. Such impacts on human rights of the implementation of the agreements should be regularly assessed, to allow for the adoption of any corrective measures that may be required.'

⁶⁸ See for example the Impact Assessment required under EU Directives on Copyright and Neighbouring Rights – for example in Art.12:1 of the Directive 2001/29/EC on Copyright in the Information Society.

From a civil engagement point of view, bilateral engagements subject poorly prepared partners to even greater dangers. As exemplified by the 'November exchange', even developed countries such as Australia are not exempt for potential peril of unwarranted interference. In the example at hand, the United States interference garnered wide-spread scorn after conditioning the effectuation of the United States-Australia FTA on the passing of additional copyright legislation which was not subjected to the processes Australia had maintained throughout the negotiations (Kelsey, 2015).

3. A Mapping of the Asia-Pacific Trade Agreements and Their IPRs Contents

For some time, Asia and the Pacific has been the most dynamic region in terms of economic growth (ESCAP, 2016) and, as a result, among the most appealing in terms of a prospective region with which to forge a closer economic relationship. This natural appeal of the region combined with the inability to conclude the Doha Round has led to a dramatic increase in the number of trade agreements in the region (Kawai and Wignaraja, 2010).

As of November 2016, a total of 167 agreements involving Asia-Pacific countries were in force, with an additional 94 agreements pending ratification or currently in negotiation (figure 2). Out the agreements currently in force in the Asia and the Pacific, a total of 91 - or 54 per cent - includes IP in one form or another (figure 3). This share is particularly impressive when contrasted with the fact IPRs inclusive trade agreements have emerged only in the 1990's, or two decades after the region first became active in terms of trade agreements.

The few agreements signed prior to TRIPS cover IPRs in a superficial manner; and IPRs have been seriously discussed only after TRIPS. The full-speed proliferation of IPR-inclusive agreements only started after 2000, prior to which only six IPR-inclusive trade agreements had been signed.

Regardless of their expeditious emergence, provisions on IPRs are present only in approximate 30 per cent of all regional trade agreements around the globe. Taking the growing importance of IPRs for the industries of regional emerging and already established heavyweights such as Australia, China, India, Japan and the Republic of Korea, the upward trend is likely to continue. However, the pace of proliferation may well be tempered by the current political climate where the benefits of globalization are being questioned with increasing intensity. While this climate has led to a halt in the pursuit of mega-regional agreements such as the TPP, it remains unclear – at the time of writing – what such a trend would mean for bilateral or plurilateral FTAs in the Asia-Pacific region.

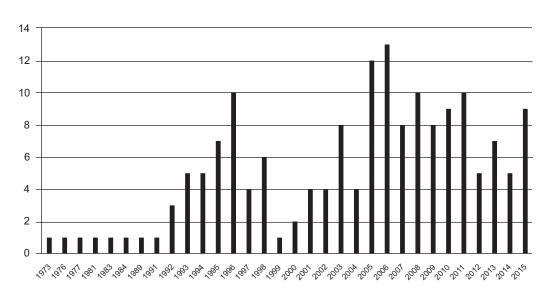
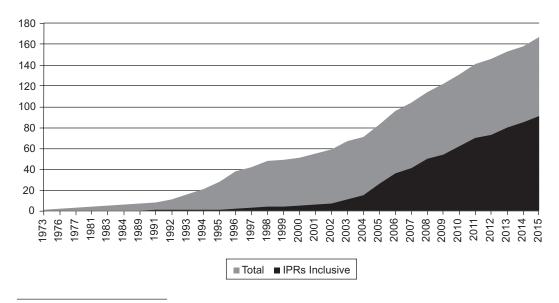


Figure 2. Number of new trade agreements per year⁶⁹

Figure 3. Cumulative number of trade agreements involving Asia-Pacific countries since 1973



⁶⁹ Source for this and remainder of figures in this chapter are based on the authors' compilation derived from the Puutio-Parisotto Dataset, 2016.

One way forward is alluded to by the Regional Comprehensive Economic Partnership agreement, which has been under negotiation by ASEAN members, Australia, China, India, Japan, New Zealand, and the Republic of Korea since 2011. First, the agreement sidesteps many current political quagmires by focusing on the ASEAN core and its regional cohabitants in a concentric model often explained as 'ASEAN plus X' without involvement of traditional trade agreement superpowers like the United States and the European Union. As a consequence, the negotiations have taken a markedly more consensus based track, where concessions revolve around terms more familiar to developing nations. For example, countries such as India have thus far successfully fought off the inclusion of terms on government procurement which have become more prevalent in treaties negotiated with developed nations elsewhere.

The proliferation of IPR-inclusive trade agreements in the region has led to 32 members being involved in IPRs inclusive trade agreements. The median amount of IPR-inclusive agreements is 5, with Turkey ranking top at 21, mainly due to its heavy involvement with the European continent. However, in terms of the amount and complexity of the IPRs provisions involved, Singapore, the Republic of Korea and Japan are among the most active in the region with 17, 13 and 13 IP-inclusive agreements respectively. In the group of developing countries, China leads with nine agreements.

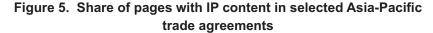
With whom are these connections shared? A total of 18 agreements are with bilateral or plurilateral partners in Latin America, with 17 involving partners on the European continent. The United States is involved in four bilateral agreements, being the most significant partner in North-America.

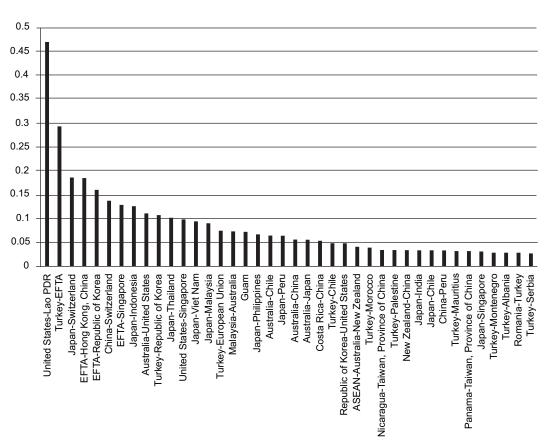
These figures show the heavy interest that the developed countries in the Western hemisphere have in the Asia-Pacific region. The reason why developed economies are interested in the region is natural. Recent economic analysis has shown that as the level of IPRs protection increases so does the amount of royalties and licensing receipts (Koff, 2011). However, this is no proof of causation and could equally as well be a sign of o-development of IP related industries and domestic pressure for more stringent IP norms.

The effect of higher IP protection can be negative for exporters as well: it has been shown that increased IP protection in the ASEAN-5 may reduce China's exports to said countries (Yong, Yew and Yan, 2009). Possible reasons for the drop of exports include the share of imitation goods which would be barred from market entry with higher IPR protection.

From 1992 onwards, initially all the IP-inclusive trade agreements affecting the region were signed with Western partners; it was only in 2002 when the first intra-regional trade agreement was signed between Japan and Singapore. After 2002 the Asia-Pacific

countries, led by Australia, China, Japan, the Republic of Korea and Singapore, picked up the pace, and at the end of November 2016, 32 per cent of all IP-inclusive trade agreements were exclusively signed by members of the same region. Out of these intra-regional treaties, 28 per cent are between developed countries, 65 per cent between developed and developing, with the remaining 6 per cent between developing countries alone. At the same time as the Asia-Pacific countries became active within their own region they began creating connections with another dynamic region, Latin-America. Today, 18 IP inclusive agreements between Asia-Pacific and Latin-American countries are in effect, out of which nine are with Chile alone.





As expected, there is significant variance between any two IP inclusive agreement. For instance, while one agreement may contain a significant amount of IP provisions, there may be little to none practical obligations contained within them. Likewise, the amount of 'real estate' devoted to IP differs greatly from agreement to agreement. One admittedly crude way of uncovering these differences is to examine how large of a share do IP related pages make of the total of the agreement.

While the clear majority of agreements contain between two to ten per cent of IP as a share of the total, a handful of treaties stand out from the crowd, the 2015 United States-Lao agreement of which 46 per cent(!) relates to IPs key among them. Other significantly IP-inclusive treaties include treaties mainly those driven by EFTA, such as the Turkey-EFTA (29 per cent), and Japan such as the Japan-Switzerland treaty (18 per cent). In general, even the most IP-savvy Asia-Pacific countries such as Japan, the Republic of Korea, Singapore and Australia showcase significant flexibility in signing both treaties that encompass large swathes of IP and those that do not include much of them, as exemplified by e.g. the Japan-Chile and Singapore-Australia agreements with three and two percent of IP contents respectively. While the measure is agnostic to the actual contents and strictness of the provisions, the fact that a country is willing to entertain agreements of varying amounts of IPRs does show that significant amounts of IP related provisions are not a threshold question without which the treaty would not exist as is often seen to be the case with modern European Union and United States agreements. Given the trends noted above and the continued roll-out of the fourth industrial revolution inclusive of its knowledge-laden effects, it is safe to assume that IP related provisions will become increasingly pivotal in future agreements. Particular areas of increased activity will undoubtedly include crossborder enforcement and all IP instruments related to e-commerce driven expansion of international consumer-goods trade. At the same time, provisions concerning more backward-looking IP instruments such as traditional knowledge and plant-based biological assets will continue to rise in importance as developing nations find their voice in the multilateral and bilateral fora.

4. Provision Specific Mapping

In order to create a thorough measure of the coverage of these agreements we divided the various aspects of IP protection in 93 different issues. Of these 93 issues, the most frequent provisions are found in the category of general commitments. By far the most frequently added provision involves a general commitment to cooperation which has been included in 68 per cent of the Asia-Pacific agreements in force today. Other typical provision are the establishment of focal points and commitments to increasing transparency and awareness, to which 37 per cent, 32 per cent and 30 per cent of agreements refer to respectively.

4.1. General Commitments

In addition to general commitments, agreements often reiterate previous commitments made in the form of treaties and multilateral agreements (table 2). While such provisions do not establish new commitments on their own they can be valuable in setting a preambular background for interpretation (see the further discussion in chapter 3, section 1, and chapter 4). In addition, such reference can – depending on how it is phrased – serve as an obligation to comply with the referenced set of rules (which often does not have a self-standing dispute settlement system). The effect of this inclusion by reference then can be that compliance with the referenced rules becomes an actionable obligation under the dispute settlement system established by the trade agreement. A prominent early example of this is the inclusion of core provisions of the Berne Convention on the Protection of Literary and Artistic Works (BC) and the Paris Convention for the Protection of Industrial Property (PC) into the TRIPS Agreement.

Table 2. General commitments

General commitments	Number	Per cent
Cooperation commitment	62	68
Establishing focal points	34	37
Transparency	30	32
Building awareness on IPRs	28	30
Information sharing	22	24
Establishment of cooperative body	21	23
Promotion of innovation	17	18
Cooperation on streamlining of procedural measures	15	16
Technical assistance	15	16
Harmonization	5	5
Support to small and medium enterprises	2	2

4.2. International treaties and WTO principles

The most frequently mentioned agreement is TRIPS, with 79 per cent of agreements including either a reference of a reiteration of commitments to its landmark provisions (table 3). Other common treaty-references include the Paris and Berne conventions with 25 per cent of agreements mentioning them specifically. The least common commitments referred to are specific European Union legislations and the Convention on biological diversity which are mentioned in only 2 per cent of the agreements in force.

Table 3. International treaties

International treaties	Number	Per cent
TRIPS	72	79
General reference to multilateral agreements	28	30
Paris Convention	23	25
Berne convention	23	25
WIPO Copyright Treaty	20	21
WIPO Performance and Phonograms Treaty	18	19
Madrid Protocol	14	15
Locarno/Nice/Strasbourg and Vienna agreement	14	15
Patent Cooperation Treaty	13	14
Rome Convention	11	12
Budapest Treaty	9	9
Hague Agreement concerning the international registration of industrial designs	7	7
Patent Law Treaty	6	6
Geneva Convention for the protection of producers of phonograms	5	5
Brussels Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite	5	5
Singapore Treaty	5	5
Trademark Law Treaty	4	4
Specific EU legislation	4	4
WIPO Convention	2	2
Convention of Biological Diversity	2	2

The final generic category we examined involves WTO principles (table 4). Out of the 91 agreements that involved IP, 30 per cent commit to national treatment. In addition, 26 per cent commit to to non-discrimination as a general term, e.g. in connection to digital products or expropriation related to IP in specific agreements such as the United States – Australia FTA, and 16 per cent to most-favoured-nation treatment in the realm of IPRs.

Table 4. WTO principles

WTO principles	Number	Per cent
National treatment	28	30
Non-discrimination (as a general term)	24	26
MFN	15	16

4.3. Copyrights

IP-inclusive trade agreements are of course not limited to references to or re-castings of existing obligations. On the contrary, many of the agreements touch upon important aspects such as patent, copyright, and trademark protection as well as enforcement measures, accession to other international IP treaties, and other emerging issues such as government procurement of software. Perhaps the most typical category is copyrights, which was first referred to in the Asia-Pacific in 1992. Dividing countries into developed and developing categories, we note that there is significant variance in the propensity to include language concerning specific copyright issues.

Furthermore, we note that when references are made, the strength of the language used differs greatly depending on the development stage of the partners involved. In measuring the strength of individual provisions, a structured measure was used according to which no mentions receive a score of 0, a mere mention a score of 1, particular definitions a score of 2, and actionable obligations or commitments a score of 3.

For developed-developed paired agreements the data shows that general copyright related commitments and related rights provisions are most common in all 'strengths' of the provisions (table 5a). Areas such as the protection of computer programs and databases, encryption measures and satellites emerge as clearly reserved issues where only weak language has been included to date. Government use on the other hand is noteworthy as a provision that has been included in its strong form with increasing prevalence in the past decade.

The effect of involving developing countries on the prevalence and strength of copyright provisions is immediate and two-fold (table 5b). First, the number of categories in which provisions are found decreases, with issues such as sound recordings having no specific

Developed-Developed	Weak (per cent)	Medium (per cent)	Strong (per cent)
Copyrights-General	27	5	33
Related rights	33	5	22
Protection of computer programs, databases	11	0	0
Sound recordings	5	5	5
DRM, Encryption etc.	11	0	0
Satellite signals	11	5	0
Government use of software	0	0	5

Table 5a. Copyrights, Developed-Developed

clauses at all. Second, where provisions are found, they are less prevalent across agreements and their strength shifts towards weaker clauses with no actionable commitments. As expected, the effect intensifies when only developing countries are involved, with all but the general, related rights and protection of computer databases and programmes disappearing totally (table 5c).

Table 5b. Copyrights, Developed-Developing

Developed-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Copyrights-General	11	5	11
Related rights	16	0	5
Protection of computer programs, databases	5	0	0
Sound recordings	0	0	0
DRM, Encryption etc.	0	11	0
Satellite signals	5	0	0
Government use of software	0	0	0

Table 5c. Copyrights, Developing-Developing

Developing-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Copyrights-General	5	0	0
Related rights	5	0	5
Protection of computer programs, databases	5	0	0
Sound recordings	0	0	0
DRM, Encryption etc.	0	0	0
Satellite signals	0	0	0
Government use of software	0	0	0

4.4. Patents

Another common category is patents, which covers a variety of issues ranging from general commitments to specific rules on compulsory licensing, patentability and the treatment of new uses of known substances (sometimes referred to as ever-greening). Within the category of developed-developed pairings, strong commitments were most likely to pertain to patentability criteria and exceptions thereto, new plant varieties and test data exclusivity periods with five to eleven per cent of intra-category agreements containing such clauses. In the category of developed-developing paired agreements, strong patent protection

clauses were included in particular in agreements signed by the United States, European Union, Australia and the Republic of Korea. Provisions such as novelty grace periods, the length of patent protection periods and compulsory licensing appear in 27 to 38 per cent of agreements, but only in weak forms that have little actionable consequences (table 6a).

As with copyrights, the involvement of developing countries decreases the prevalence and strength of terms overall (table 6b). However, there are a few interesting 'anomalies' which buck the trend. Key among them is the fact that test data exclusivity and data protection provisions are contained in their strong form in 11 per cent of developing-developed paired agreements, whereas no developed-developed agreements include such forms. Another noteworthy fact is that developed-developing paired treaties have included a significant amount of utility model clauses, 55 per cent medium and 5 per cent strong, while similar clauses are much rarer in developed-developed pairings. Furthermore, compulsory licensing clauses appear in 33 per cent of the agreements in their weak form, with no strong form commitments, typically reaffirming TRIPS provisions.

The effect of involving only developing countries is as potent as possible – no patent clauses are involved in any meaningful form that would register on the scaling metric used (table 6c).

Table 6a. Patents, Developed-Developed

Developed-Developed	Weak (per cent)	Medium (per cent)	Strong (per cent)
Patents-General	11	11	38
New plant varieties	0	0	5
Utility models	27	11	0
Specific pharmaceutical provisions	23	0	0
Specific exclusions from patentability	38	0	0
Exceptions to patent rights	16	5	11
New use	22	0	0
Patentability criteria	16	0	11
Test data exclusivity-data protection	27	0	5
Patent linkages	0	11	0
Novelty grace period	0	5	0
Patent term extensions	38	0	0
Patenting period-general	33	0	0
Compulsory licensing	38	0	0
Generic Entry	0	0	0
Parallel importing	22	0	0
Ordre public exemptions	27	0	0

Table 6b. Patents, Developed-Developing

Developed-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Patents-General	11	11	5
New plant varieties	0	0	0
Utility models	55	5	5
Specific pharmaceutical provisions	16	0	5
Specific exclusions from patentability	5	0	0
Exceptions to patent rights	0	0	0
New use	0	0	0
Patentability criteria	0	11	0
Test data exclusivity-data protection	0	0	11
Patent linkages	0	0	0
Novelty grace period	0	0	0
Term extensions of patent protection	0	0	0
Patenting period-general	0	0	0
Compulsory licensing	33	0	0
Generic Entry	0	0	0
Parallel importing	0	0	0
Ordre public exemptions	0	0	0

Table 6c. Patents, Developing-Developing

Developing-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Patents-General	0	0	0
Utility models	0	0	0
New plant varieties	0	0	0
Specific pharmaceutical provisions	0	0	0
Specific exclusions from patentability	0	0	0
Exceptions to patent rights	0	0	0
New use	0	0	0
Patentability criteria	0	0	0
Test data exclusivity-data protection	0	0	0
Patent linkages	0	0	0
Novelty grace period	0	0	0
Term extensions of patent protection	0	0	0
Patenting period-general	0	0	0
Compulsory licensing	0	0	0
Generic Entry	0	0	0
Parallel importing	0	0	0
Ordre public exemptions	0	0	0

4.5. Geographical indications

In terms of specific IPR protection instruments, geographical indications (GIs) appear surprisingly frequently. One reason for the frequent inclusion of GIs is the relative 'scarcity' of existing international agreements concerning them when compared with the relative abundance of multilateral agreements on patents, trademarks and copyrights. This scarcity, combined with the impasse at the Doha Rounds, imposes natural pressure for countries that want to extend the reach of GI legislation to do so in the bilateral forum. These pressures are further increased by the strong divisions on GIs within the traditional pro-IP camp formed by the United States on the one hand, and the European Union (and EFTA and Switzerland) on the other.

Between themselves, developed countries have included both general language concerning GIs as well as specifying certain GIs in annexes to be protected upon signature (table 7a). As expected, the stronger clauses are included in treaties where the European Union, EFTA or Switzerland are among the contracting parties. However, countries such as Australia, the Republic of Korea and Singapore also successfully included provisions on GI protection, even when dealing with traditionally GIs-opposed states such as the United States. It is noteworthy that 27 per cent of agreements include strong form provisions on GIs and 5 per cent enumerate specific GIs for protection. When developing countries are involved, 11 per cent of agreements include strong form GIs clauses (table 7b).

Table 7a. Geographical indications, Developed-Developed

Developed-Developed	Weak (per cent)	Medium (per cent)	Strong (per cent)
Geographical indications-General	5	16	27
Appellation of origins	11	5	0
Protected GIs specified in annex	5		

Table 7b. Geographical indications, Developed-Developing

Developed-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Geographical indications-General	27	0	11
Appellation of origins	5	0	0
Protected GIs specified in annex	0		

While often thought to be most relevant to agricultural economies strongly relied upon by many developing countries, GIs are rare in developing-developing country agreements with only 6 per cent including weak form language (table 7c). This may be explained by the complexities of establishing effective GIs regimes which require significant institutional efforts. It may also be explained by the fact that GIs are not sufficiently relevant in intradeveloping-country trade.

Table 7c. Geographical indications, Developing-Developing

Developing-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Geographical indications-General	6	0	0
Appellation of origins	0	0	0
Protected GIs specified in annex	0		

4.6. Trademarks and Designs

While trademarks are among the most approachable forms of IP, they are surprisingly scarce as IP provision in free trade agreements in the region. As expected, developed countries are most frequent users of trademark provisions, but even in their case strong form provisions are rare (table 8a). In fact, they are only found in somewhat related areas such as domain names and industrial designs where five per cent of agreements include such strong form provisions. When negotiating with developing countries, developed partners have included strong form trademark provision into 11 per cent of the agreements – a marked increase from none at all when dealing within their own group (table 8b).

Table 8a. Trademarks, Developed-Developed

Developed-Developed	Weak (per cent)	Medium (per cent)	Strong (per cent)
Trademarks-General	16	0	0
Collective marks	0	0	0
Country names	0	0	5
Non-traditional trademarks	27	11	0
Designs-General	11	11	0
Layout designs, integrated circuits	16	5	0
Provisions specific to industrial designs	22	16	5
Domain names	5	0	5

Table 8b. Trademarks, Developed-Developing

Developed-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Trademarks-General	5	5	11
Collective marks	0	0	0
Country names	0	0	0
Non-traditional trademarks	0	0	0
Designs-General	0	11	0
Layout designs, integrated circuits	11	5	0
Provisions specific to industrial designs	11	11	0
Domain names	0	0	0

Thus far developing countries have had little appetite for trademark provisions within their own group, with only weak form provisions in five per cent of agreements covering general trademarks, layout designs and industrial designs (table 8c).

Table 8c. Trademarks, Developed-Developing

Developed-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Trademarks-General	5	0	0
Collective marks	0	0	0
Country names	0	0	0
Non-traditional trademarks	0	0	0
Designs-General	0	0	0
Layout designs, integrated circuits	5	0	0
Provisions specific to industrial designs	5	0	0
Domain names	0	0	0

4.7. Traditional Knowledge, Traditional Cultural Expressions (Folklore), Genetic Resources

While traditional knowledge and traditional cultural expressions (TCEs) or folklore are often on the agenda in multilateral negotiations and discussions driven by developing countries, they have not found their way to trade agreements between developing countries alone. On the contrary, traditional knowledge and folklore are most prevalent between developed-developed paired agreements, where weak, medium and strong form commitments are all equally prevalent with 11 per cent of agreements – all involving either New Zealand or

European Union as one treaty partner (table 9a). Genetic resources behave similarly, however no strong form commitments have been made to date, with most provisions being limited to an exchange of views and cooperation, e.g. within the WIPO setting, as is the case with the European Union-Republic of Korea agreement.

Table 9a. Traditional Knowledge, Traditional Cultural Expressions (Folklore), Genetic Resources, Developed-Developed

Developed-Developed	Weak (per cent)	Medium (per cent)	Strong (per cent)
Traditional knowledge	11	11	11
Folklore	11	11	11
Genetic resources	11	11	0

When developing countries become involved with developed, we note a drop in the prevalence of TCE/folklore-related provisions from 11 per cent to 5 per cent across all forms (table 9b). Genetic resource provisions weaken as well, with the only medium forms found in the China-Republic of Korea agreement which reaffirms the Convention on Biological Diversity and establishes venues for discussions. No provisions were found in developing-developing paired agreements (table 9c).

Table 9b. Traditional Knowledge, Traditional Cultural Expressions (Folklore), Genetic Resources, Developed-Developing

Developed-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Traditional knowledge	11	11	11
Folklore	5	5	5
Genetic resources	11	5	0

Table 9c. Traditional Knowledge, Traditional Cultural Expressions (Folklore), Genetic Resources, Developing-Developing

Developing-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Traditional knowledge	0	0	0
Folklore	0	0	0
Genetic resources	0	0	0

In terms of examples of concrete clauses on traditional knowledge, the China-Republic of Korea agreement contains medium strength provisions that re-establish the related TRIPS rules in Article 27.3(b) and specifically allow each country to 'adopt or maintain measures to promote the conservation of biological diversity and the equitable sharing of benefits' arising from traditional knowledge. While the drafters included folklore in the same chapter heading, no individual provisions were given to folklore, leaving the question whether traditional knowledge provisions apply to folklore, mutatis mutantis, open for interpretation. The European Union-Republic of Korea treaty handles folklore similarly, mandating only the exchange of views on folklore within the established venues of WTO and WIPO. An example of weak-form provisions can be found in the New Zealand – Hong Kong agreement which notes only that the contracting parties may 'establish appropriate measures to protect genetic resources, traditional knowledge and traditional cultural expressions or folklore.'

4.8. Trade Secrets, Consumer Protection, Government Procurement and Unfair Competition

In addition to 'vintage' IP such as patents and copyrights, modern trade agreements often contain commitments on a variety of emerging issues such as trade secrets, consumer protection and unfair competition provisions. We find that the emergence of such topics is driven by developed-developed paired agreements, and note that as expected with emerging topics strong form commitments are rare with the emphasis on weak form non-actionable provisions. In fact, only 5 per cent of developed-developed agreements contain either strong form trade secret or abuse of IP provisions (table 10a).

We also include analysis on government procurement, which some developed nations have included in their agreements in a way that has enforcement-type interactions with IP. For instance, in the United States-Singapore agreement, the parties stipulate that 'Each Party shall issue appropriate laws, orders, regulations, administrative, or executive decrees mandating that all government agencies use computer software only as authorized by the right holder. Such measures shall actively regulate the acquisition and management of software for such government use, which may take the form of procedures, such as preparing and maintaining inventories (...)'.

Abuse of IP in this connection refers to various international obligations, such as those contained in TRIPS and the Paris Convention, and other circumstances where IP-holders may abuse their rights. For example, the United States-Australia agreement obliges its parties to provide judicial authorities with the procedural means to require a showing of sufficient proof prior to injections based in IP to prevent abuse. An example of weak-form

Table 10a. Traditional Knowledge, Traditional Cultural Expressions (Folklore), Genetic Resources, Developed-Developed

Developed-Developed	Weak (per cent)	Medium (per cent)	Strong (per cent)
Trade secrets	22	0	5
Government procurement	22	0	0
Abuse of IPRs	5	0	5
Unfair competition	33	0	0
Consumer protection	0	0	0

provisions is found in the China-Switzerland agreement that enable both parties to take appropriate measures to prevent the abuse of IPRs in restraint of trade and technology transfer, aligned with TRIPS 8.2.

Again, as the involvement of developing nations increases the prevalence and strength of commitments decrease, all the way to the developing-developing paired agreements where the only provisions are on trade secrets, found in 5 per cent of treaties (table 10b and table 10c).

Table 10b. Traditional Knowledge, Traditional Cultural Expressions (Folklore), Genetic Resources, Developed-Developing

Developed-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Trade secrets	5	0	5
Government procurement	11	5	0
Abuse of IPRs	16	0	0
Unfair competition	5	5	5
Consumer protection	5	0	0

Table 10c. Traditional Knowledge, Traditional Cultural Expressions (Folklore), Genetic Resources, Developing-Developing

Developing-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Trade secrets	5	0	0
Government procurement	0	0	0
Abuse of IPRs	0	0	0
Unfair competition	0	0	0
Consumer protection	0	0	0

4.9. Enforcement and Dispute Settlement Connected to Intellectual Property

As other authors have duly pointed out, a significant portion of the agreements in force today also contain provisions aimed at ensuring compliance, including provisions on cooperation, negotiation and dispute settlement (Valdes, McCann 2014.) Among the most frequently provided for issues are border measures and civil and criminal penalties, which are included in their strong form in 16 per cent, 11 per cent and 16 per cent of developeddeveloped paired agreements respectively (table 11a). On the other hand, service provider liability suggesting sensitivities and complexities in the subject matter itself. Similar reservations seem to exist in the area of dispute settlement, both between the contracting parties and investors and the state, which admittedly go beyond matters of pure enforcement. An example of ISDS provisions that have interactions with IP can be found e.g. in the United States-Australia agreement. First, the agreement includes IP within the definition of investments. Second, in the chapter on investments the parties stipulated that 'If a Party considers that there has been a change in circumstances affecting the settlement of disputes on matters within the scope of this Chapter and that, in light of such change, the Parties should consider allowing an investor of a Party to submit to arbitration with the other Party a claim regarding a matter within the scope of this chapter, the Party may request consultations with the other Party on the subject, including the development of procedures that may be appropriate.' Given the combination of non-commitment and not directly IP related language the provision was marked as a weak ISDS clause.

Enforcement and dispute resolution related provisions are often approached with significant reservations given that they have the power to curtail core areas of what is held as traditional sovereignty of nations. Accordingly, we see significant decreases across all provision types as developing nations become involved, with virtually no provisions being entertained in developing-developing paired agreements (table 11b and table 11c).

Table 11a. Enforcement and dispute resolution, Developed-Developed

Developed-Developed	Weak (per cent)	Medium (per cent)	Strong (per cent)
Border measures	16	5	16
Penalties-general	5	5	11
Criminal measures	16	5	16
Civil measures	16	5	16
Provisional measures	5	11	5
Service provider liability	11	22	0
State-to-State dispute settlement	22	0	5
Investor state dispute settlement	5	0	0

Table 11b. Enforcement and dispute resolution, Developed-Developing

Developed-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Border measures	5	5	11
Penalties-general	11	6	0
Criminal measures	5	5	5
Civil measures	0	5	5
Provisional measures	0	11	0
Service provider liability	0	11	0
State-to-State dispute settlement	11	5	0
Investor state dispute settlement	0	0	0

Table 11c. Enforcement and dispute resolution,

Developing-Developing

Developing-Developing	Weak (per cent)	Medium (per cent)	Strong (per cent)
Border measures	0	0	0
Penalties-general	5	0	0
Criminal measures	0	0	0
Civil measures	0	0	0
Provisional measures	0	0	0
Service provider liability	0	0	0
State-to-State dispute settlement	0	0	0
Investor state dispute settlement	0	0	0

4.10. Intellectual property as an investment

On a connected note, there are marked differences in whether intellectual property is defined as an investment within the scope of the treaty to begin with. Where only developed states are involved, 61 per cent of agreements define IP as an investment (table 12). When developed states negotiate with developing, the figure is drops to 38 per cent. Perhaps unsurprisingly, IP has not been defined as an investment in any of the currently in force developing-developing paired agreements. What may be surprising for many is that investor-state dispute settlement issues are not as prevalent as the global discourse would afford one to think, appearing only in 5 per cent of developed-developed paired agreements. Whether and how FTAs that include IP as an investment address issues such as expropriation, national treatment and other relevant governmental actions within the investment related chapters of these agreements will be further assessed in future papers.

Based on the nevertheless quite significant amount of agreements that include IP as a form of investment, chapter 3 section 2 includes guidelines on how countries may wish to address the IP-investment interface in FTAs.

Table 12. IP defined as an investment

IP defined as an investment	per cent
Developed-Developed	61
Developed-Developing	38
Developing-Developing	0

Chapter

3

RECOMMENDED APPROACHES FOR THE NEGOTIATION, INTERPRETATION AND IMPLEMENTATION OF INTELLECTUAL PROPERTY PROVISIONS

B ased on chapters 1 and 2 above, and on earlier research described below, this chapter offers recommendations for approaching IP protection in the context of trade agreements. In section 1, this concerns 'traditional' IP provisions in FTAs, described further in chapter 1, section 3; and analyzed (with a focus on the Asia-Pacific region) in chapter 2. The recommendations in section 2 on the other hand concern IP protection via investment protections – either in stand-alone BITs or in investment chapters in FTAs.

The recommendations in section 1 below are based on several years of research, in three main projects, on IP provisions in bilateral and regional agreements at the Max Planck Institute (MPI) for Innovation and Competition (formerly MPI for Intellectual Property and Competition Law). A project addressing the 'noodle bowl' of FTAs in the Asia-Pacific region, examined the political economy of continuously strengthening IP protection and enforcement provisions in these FTAs from an interdisciplinary perspective (Antons, 2011).

The main focus of another research project concerned a new generation of bilateral and regional agreements pursued by the European Union. Examples are the Economic Partnership Agreement (EPA) signed in October 2008 with the group of CARIFORUM countries (European Union-CARIFORUM EPA) and the trade agreement the European Union concluded with Colombia and Peru in June 2012. At the core has been the question whether the IP provisions found in this new generation of European Union agreements actually live up to the development rhetoric and take into account the specific developmental needs of the European Union contracting partners (Drexl, Grosse Ruse – Khan, Nadde-Phlix). This question becomes particularly acute in the framework of redefined trade relations between the European Union and the group of African, Caribbean and Pacific (ACP) states which includes a large number of very poor countries in Africa. The examples of good (and not so good) practice examples of clauses in FTAs that retain flexibilities from the multilateral IP treaty system (in particular TRIPS) discussed in chapter 4 are largely based on research conducted for this project.

The insights gained in the course of these projects then led a group of researchers at the MPI and from all over the world to go one step further and develop a set of *Principles for*

Intellectual Property Provisions in Bilateral and Regional Agreements.⁷⁰ The Principles aim to provide a concise analysis of what the drafters perceive to be the core problems with IP provisions in these agreements and try to offer solutions and ideas on how these problems can be addressed. They have been first presented to the public at the Annual Conference of the International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP) in Oxford, United Kingdom, 23-26 June 2013.⁷¹ For these guidelines, the Principles have served as the key input, but have been re-assessed in light of the data generated on IP in FTAs in the Asia-Pacific, and are expanded and tailored to serve as guidelines for negotiating IP provisions in FTAs.

1. Intellectual Property Chapters in Trade Agreements

1.1. The Continued Relevance of the Multilateral IP Treaty Framework for Bilateral and Regional Agreements

Background and wider context: Since the early 1990s, the world has witnessed an unprecedented inclusion of IP provisions in trade and other agreements that are outside the traditional domain of international IP law. As chapter 2 explains further, in the Asia-Pacific region, way more than half out of a total of 160 plus agreements include IP provisions. Those agreements (here referred to as FTAs) cover a wide range of issues and allow for deals in which IP provisions are agreed in exchange for trade preferences and other advantages. On both sides, these deals are driven by export interests and other objectives external to the IP system rather than the common goal to achieve a mutually advantageous, balanced regulation of IP among the parties. As chapter 1, section 3 suggests, the expected benefits in form of preferential market access or other trade preferences (which can be in principle shielded from the WTO MFN rule) are likely to erode once the FTA partner agrees to grant similar preferences to other countries. Countries which consider to agree to IP provisions in FTAs primarily in exchange for trade preferences in other areas therefore may

Next to this author who acted as project coordinator, Mor Bakhoum (MPI), Jeremy de Beer (University of Ottawa), Carlos Correa (University of Buenos Aires), Graeme Dinwoodie (Oxford University), Josef Drexl (MPI), Susy Frankel (Victoria University of Wellington), Sean Flynn (American University, Washington), Holger Hestermeyer (Max-Planck-Institute for International Law), Reto Hilty (MPI), Thomas Jaeger (MPI), Annette Kur (MPI), Kaya Köklü (MPI), Mathias Lamping, (MPI), Bryan Mercurio (The Chinese University of Hong Kong), Souheir Nadde-Phlix (MPI), Pedro Roffe (International Centre for Trade and Sustainable Development), Xavier Seuba (Université de Strasbourg), and Peter Yu (Drake University) contributed to the drafting of the principles. The Principles can be downloaded at http://www.ip.mpg.de/files/pdf2/Principles_for_IP_provisions_in_Bilateral_and_Regional_Agreements_final1.pdf.

⁷¹ The conference website can be found at http://www.law.ox.ac.uk/conferences/atrip/index.php; the homepage of ATRIP is at http://www.atrip.org/.

wish to consider carefully whether these preferences are in fact long-lasting and sustainable.

Most of these FTAs in which IP serves as a trade-off are negotiated on the bilateral or regional level. These agreements increasingly contain provisions on the protection and enforcement of IP that are more extensive than the multilateral standards contained in the Paris and Berne Conventions as well as the WTO TRIPS Agreement. Furthermore, the trade-off nature of agreeing to IP in FTAs means that while these agreements may pursue an overall balance of concessions, they usually do not lead to international IP rules that address the interests of all countries affected. As further outlined in more detail below, countries should therefore carefully judge the extent to which the proposed IP rules serve the interests of their domestic constituencies, for example by means of transparent access to documents, consultations with relevant stakeholders before and during negotiations, as well as impact assessments.

Continuous extension of IP protection and enforcement increases the potential for law and policy conflicts with other rules of international law that aim to protect public health, the environment, biological diversity, food security, access to knowledge and human rights. IP provisions in FTAs hence need to be considered and negotiated with the broader international law context in mind. While most international rules are usually drafted in a sufficiently broad fashion that allows a mutual coherent application and interpretation vis-à-vis other international rules, the trend for ever-more detailed and comprehensive IP provisions in FTAs (discussed further below) may make mutual coherence more difficult to achieve. In order to clarify the continued relevance of other international obligations and to highlight the need for a mutual supportive interpretation, countries should consider an express general clause which emphasises that the FTA (and its IP provisions) need to be applied, interpreted and implemented in light of key other agreement to which both FTA partners are party.

Continued Relevance of the Multilateral IP Framework: The multilateral framework, in particular the TRIPS Agreement and the Berne and Paris Convention rules it incorporates, does not only contain minimum standards of IP protection. It also includes norms that provide for policy space in domestic implementation ("flexibilities") and obligations that place limits on IP protection ("ceilings"). The TRIPS Agreement can be understood to pursue a certain balance between those elements. This balance forms part of the negotiated consensus of all WTO Members. It is reflected in the object and purpose of the Agreement, as embodied in Articles 7 and 8 TRIPS. These provisions guide the interpretation and implementation of the TRIPS Agreement.

As a multilateral agreement, TRIPS establishes a framework that IP provisions in bilateral and regional agreements amongst WTO Members may not contravene. Based on general international law principles⁷² on the modification (for example via FTAs) of a multilateral treaty (such as TRIPS), IP standards in such agreements should not affect core TRIPS flexibilities, derogation from which is incompatible with the effective operation of the object and purpose of TRIPS, as embodied in its Articles 7 and 8. This means that flexibilities crucial for the balance that Article 7 establishes, as well as those essential for the public interest principles set out in Article 8, should not be restricted. These are in particular flexibilities that support designing domestic IP systems to be 'conducive to social and economic welfare' (Article 7 TRIPS). In order to highlight and clarify the continued importance of TRIPS, countries may wish to include a general provision to this effect. section 1.6 below offers more guidance on this; while chapter 2, section 4.2 shows state practice in the Asia-Pacific, and chapter 4 offers examples of good (and not so good) practice in this regard.

Addressing the Erosion of Multilateral Policy Space: IP protection and enforcement rules in bilateral and regional FTAs tend to erode the policy space inherent in the TRIPS Agreement. States bound by such rules are less able to tailor their IP laws to fit their domestic environment and to adapt them to changing circumstances. These trends also affect current and future multilateral initiatives in international IP law.

As discussed in chapter 1, section 3, IP provisions in FTAs have become increasingly detailed and prescriptive. Anecdotal evidence from chapter 2 (for example on recent FTAs that devote almost 50 per cent of its content to IP issues) supports this. Some of the more detailed and comprehensive IP provisions are transplanting specific protection and enforcement standards from the domestic IP system of the IP-demanding country, while disregarding the exceptions, limitations and other checks and balances from that same system. Countries should be aware that implementing these transplants will often not suit domestic needs and will further constrain policy space.

Given the difficulty to amend or withdraw from international treaties, agreeing to detailed IP obligations in bilateral and regional agreements has far-reaching consequences. Countries risk that these obligations will be cast in stone – with few options to adapt to changing economic, technological or other societal needs on the domestic level. As explained further in chapter 1, section 3 and chapter 2, section 2, it is especially crucial in the IP context to ensure that the rules agreed in an international treaty are sufficiently flexible and

⁷² See Art.41 of the Vienna Convention on the Law of Treaties (VCLT).

technology-neutral: given that IP covers areas which are particularly fast-moving and dynamic in terms of technology-developments and also in how we use the protected subject matter, countries should generally avoid too specific commitments and reject provisions which are transplants of specific approaches in the domestic law of the country proposing this provision.

At the very least, they should:

- (1) ensure that any detailed, specific set of rules is subject to an impact assessment three or five years after the rules have been implemented into domestic law; and
- (2) include a clause with explicit recognition that relevant flexibilities within the international IP system can be applied to these specific IP commitments in the FTA.⁷³

Implementing the detailed and comprehensive IP obligations from FTAs often requires the re-allocation of financial and human resources and places additional burdens on the legislative, administrative and judicial infrastructure. It may affect the ability of the implementing country to protect the public interest. Countries should consider these costs within their overall cost-benefit analysis, ideally via a careful impact assessment, and judge them against the risk of eroding preferences – preferences that may serve as the main motivation for entering into the FTA.

1.2. Transparency, Inclusiveness and Equal Participation

The current process of negotiating FTAs frequently lacks transparency, inclusiveness and equal participation of stakeholders and the public. These democratic deficits cannot be corrected by parliamentary ratification or implementation processes without a meaningful option to influence the treaty text or its implementation. This is especially acute if detailed and prescriptive transplants are included in these agreements.

As explained in chapter 2, section 2, it is important to ensure transparency, inclusiveness and equal opportunities for all stakeholders to participate in:

- (1) setting and shaping a domestic IP strategy in general and a specific agenda for including IP rules in an FTA in particular;
- (2) the negotiating process, especially by offering an opportunity to comment on draft provisions and proposals on IP; and
- (3) the domestic implementation process of FTA provisions on IP.

On further discussion of relevant State Practice on such clauses see Chapter 4.

This is not only a matter of democratic and consultative governance, but facilitates crucial input from non-governmental sectors – which can help to address inequalities in the IP-expertise between the countries negotiating an FTA. Such an approach can further help to design domestic implementation towards domestic needs identified in the consultative process, and support industry and users' acceptance and familiarity with the rules once applicable as domestic IP laws.

Based on this general suggestion in favour of transparency, inclusiveness and equal participation, the next sections indicate how these elements can be given effect in the process from setting a negotiation mandate, via the negotiation period, to ratifying and implementing the negotiated outcome.

1.3. Negotiation Mandate and Strategy

Countries demanding additional IP protection should take international principles of development cooperation, the recommendations of the WIPO Development Agenda and the level of development of their negotiating partner into account and adjust their demands accordingly.

The text of the negotiation mandate should be openly available to the public in the negotiating countries. For all domestic stakeholders and interested parties with a significant local connection, there should be a meaningful opportunity to raise concerns and influence the negotiation process.

Countries facing IP demands should aim to develop their own pro-active agenda on IP issues in a consultative and participatory domestic process, outlined in section 1.2 above. They should ensure that their agenda on IP issues reflects not only concerns of local industries and domestic right holders, but also considers the interests of competitors and users, as well as the general public. Such an agenda should not only encompass areas where specific types of IP protection and enforcement can be beneficial, but may include identifying limits for additional IP protection and enforcement, especially limits motivated by the protection of public interests.

1.4. Negotiation Process

The negotiations should be conducted, as far as their nature makes it possible, in an open and transparent manner. They should allow for participation by all stakeholders in the negotiating countries that are potentially affected by the agreement in an open and non-discriminatory manner. In particular, right-holder and industry groups should not enjoy preferential treatment over other stakeholders.

All stakeholders from the negotiating countries should have meaningful and equal opportunities to comment on draft texts. Since an ex-post consent to the final text of an FTA is generally not a sufficient means for ensuring democratic decision-making (see chapter 1, section 3), publicly elected bodies that have to approve a final text should be consulted during the negotiating process.

Each negotiating country should evaluate, for example in the form of impact assessments or by means of consultations, the IP demands they face in terms of their implications for public interests, the realization of human rights, and the financial burdens and implementation costs they entail.

No country should demand or agree to any IP provision that has not been subject to a public negotiation process in which a full range of stakeholders has had the opportunity to review and comment on the wording of the provision. Meeting these requirements may not always be easy, in particular in circumstances where productive interfaces between the public sector and civil society have not beeen previously cultivated in the area o IP. States finding themselves in such situtations are not without hope however. On the contrary, in the recent decades a wide array of international support structures has arisen within intergovernmental organizations such as WIPO and in the purely non-profit sphere – all of which can be tapped for support in organizing consultations and impact assessments. At the same time, such states would do well by embarking on a longer journey towards establishing homegrown public and private institutional capacity by various means such as grant funding for think-tanks and frequent involvenment of civil society entities in transparent assessment briefings.

1.5. Negotiated Outcome

Room for Domestic Implementation: If parties agree on IP provisions containing protection or enforcement obligations stronger than those of the TRIPS Agreement, these provisions should nevertheless be sufficiently flexible to take into account the socio-economic situation and needs of both parties. To this effect, countries may wish to consider incorporating references to specific TRIPS flexibilities, or include a general clause which allows the FTA IP provisions to be interpreted and implemented in light of the objectives and principles of the TRIPS Agreement (as further discussed below, and with examples of state practice in chapter 4).

Inclusion by Reference: If the parties agree to include other international IP agreements, guidelines, recommendations or model rules into the FTA by reference, they should be clear about the effect of such an inclusion, in particular with regard to options of bringing a complaint about an alleged breach of a rule so included in front of any dispute settlement

system established by the FTA. Countries should also be clear whether they include a static or dynamic reference to other IP provisions – in particular when those provisions are potentially subject to change.

Countries should consider the long-term consequences, via impact assessments and consultative processes, for the public interest and their domestic IP system in case they accept IP demands in exchange for obtaining trade preferences or other benefits. They should also be aware that such benefits are likely to be progressively eroded whenever their trade partners offer equivalent or greater benefits to third countries (see also above, and chapter 1 section 3).

Wider International Law Context: The negotiated outcome should respect all international obligations of the parties, in particular those relating to the protection of human rights, biological diversity, the environment, food security and public health. It should allow countries to adopt exceptions and limitations necessary for giving effect to such concerns. In order to clarify this, countries may wish to consider including a general clause which emphasises that the FTA (and its IP provisions) need to be applied, interpreted and implemented in light of key other agreements to which both FTA partners are party (see also section 1.1 above).

TRIPS Flexibilities: The negotiated outcome should not undermine the ability of WTO Members to rely on the public-interest-related flexibilities in the TRIPS Agreement, including those mentioned in the Doha Declaration on TRIPS and Public Health. Countries should include an express reference to the Doha Declaration, Articles 7 and 8 TRIPS as guides for the interpretation of the FTA IP chapter, and to other existing international flexibilities they deem particularly important. While provisions from multilateral IP treaties that apply in the relations of the parties in principle continue to apply (as discussed further in section 1.6 below), a clarifying clause to this effect can be useful to emphasise the importance the parties give to specific provisions, and to remove any doubts about the continued application in the context of the FTA. Unless the parties intend otherwise, such clauses should be formulated in an open way – so that they are not understood as excluding provisions which have not been explicitly referred to.

Transition Periods and Review Clauses: IP obligations in bilateral and regional FTAs should allow for appropriate transition periods and include a review clause whereby the impact of their implementation is comprehensively assessed. These assessments should focus on the effect of the implementation on all stakeholders and take their comments into account. Bilateral and regional FTAs could include provisions on establishing an institutional setting within which an impact assessment for all parties is conducted; and should include an option for re-negotiating IP provisions in light of an impact assessment.

1.6. Interpretation and Implementation

Background and wider International Law Context: Based on general international law principles of treaty interpretation set out in particular in Article 31:3c) VCLT, IP provisions in bilateral and regional agreements have to be interpreted and implemented in the context of other relevant rules of international law, including those on the protection of public health, the environment, biological diversity or human rights, applicable in relation between the parties. Provisions from multilateral treaties, including those on IP, applicable in the relations of the parties therefore continue to apply and serve as interpretative context – unless the FTA parties have expressed their common intention to contract out of these provision. Countries therefore do not need to include particular clauses to achieve the default outcome above. They however may include a general provision emphasising the importance of particular treaties (such as the CBD or its Nagoya Protocol) or individual provisions they consider to be of particular relevance for guiding the interpretation and implementation of the FTA IP provisions.

Objectives and Principles of TRIPS: In the TRIPS Agreement, the principal way to balance the interests of rights holders and users of IP, as well as to give effect to public interests such as health and protecting the environment, is by means of treaty interpretation and implementation. The Doha Declaration confirms this in paragraph 4 and 5a) by highlighting the role of the objectives and principles expressed in Articles 7 and 8 TRIPS. Since these provisions serve as relevant context for FTAs between WTO Members (and are often also incorporated by references to TRIPS), the interpretation and implementation of such FTAs should also be based on the balancing objective and public interest principles embodied in Articles 7 and 8 TRIPS. Accordingly, IP provisions in these agreements should be construed to provide sufficient policy space to implement the balance that these Articles call for. This means that when countries implement specific provisions serving the interests of right-holders, the implementing country generally maintains the right to draft exceptions and limitations necessary for restoring the balance of Article 7.

'Multilateralising' Flexibilities: The notion of protection and enforcement of IP should be understood to encompass also exceptions, limitations and other rules that balance the interests of rights holders against those of users, competitors and the general public. This wider notion allows for an equally wider understanding of national treatment and most-favoured-nation treatment in international IP law. Countries facing IP demands would then be able to rely on concessions regarding exceptions and limitations obtained by other countries in similar situations: When a country has agreed to a specific exception or limitation to IP protection or enforcement in a bilateral or regional agreement, it should also offer this to any other country with which it has concluded a bilateral or regional agreement,

if that other country is at a similar stage of development as the country to which the exception or limitation is granted.

Neutral Technical Assistance: IP-demanding countries should provide unconditional financial and impartial technical support for implementing the IP obligations they have asked for. This support should in no way attempt to reduce the policy space in deciding how to implement IP provisions.

Implementation Process: Countries should consult all interested domestic parties through open and transparent processes in order to implement international IP provisions in the light of their domestic needs. To achieve this, they should take into account all available flexibilities to the necessary extent. They should conduct impact assessments which show how the domestic implementation of the FTA's IP provisions affects rights holders, competitors, other users and the public at large.

No Unilateral Certification Processes: IP-demanding countries should not employ unilateral certification or other assessment processes in order to influence the implementation of IP obligations; nor should those countries unilaterally withhold or withdraw benefits unless an independent process has established a breach of obligations of the bilateral or regional agreement.

Re-negotiations: Countries should consider re-negotiating existing bilateral and regional agreements whose IP provisions do not conform with these recommendations; in particular those which undermine recognised TRIPS flexibilities or in which the contracting party makes concessions to other countries at a similar stage of development for additional exceptions and limitations to IP protection and enforcement.

2. Intellectual Property Provisions in Investment Agreements

International Investment Agreements (IIAs), in particular in form of BITs as well as Investment Chapters in FTAs, often include IP rights as a protected investment by means of an express definition of investment. Even where that is not the case, a broad general understanding of investment is likely to cover IP rights. Once an IIA covers IP rights as an investment, the question arises how the general standards of investment protection apply to IP rights: if the IIA contains an Investor-State Dispute Settlement (ISDS) system, a foreign investor owning IP rights in the host state can rely on both relative investment protection standards like national treatment and MFN as well as absolute standards like 'fair and equitable treatment' (FET), 'full protection and security' (FPS) and the protection against expropriation.

For states negotiating IIAs, awareness of the implications of these protections applied to IP rights is crucial. In particular, states may wish to ensure that these protections are compatible with and do not override accepted flexibilities of the international IP system – such as on compulsory licensing and other limits to IP protection in the TRIPS Agreement. States also should be aware of the tendencies for investors to rely on FET or expropriation standards in order to claim breaches of international IP norms in ISDS, as the cases discussed in chapter 1, section 1.4 indicate. They may wish to include specific clauses which prevent this – along the lines of the European Union and Canada in CETA.

This section offers guidance on how States can address the protection of IP under IIAs. It begins with some suggestions for whether and how IP can be covered as a protected investment (section 2.1); how to ensure that relative standards of protection do not override accepted limits to national treatment and MFN under the international IP system (section 2.2); and similarly, how to ensure that standards such as FET, FPS and the protection against expropriation recognise important flexibilities within the international IP system (section 2.3). It finally offers some suggestions how States can minimise chances that investors can litigate compliance with international IP norms in ISDS (section 2.4).

2.1. IPRs as Protected Investments

Background: Already in the first BIT, signed between Germany and Pakistan in 1959, the definition of investment under Article 8 included 'assets such as (...) patents and technical knowledge'. Today, the model BITs of most countries address IP (Lahra and Liberti, 2009). The 2012 United States Model BIT for example provides in its investment definition in Article 1 that 'forms that an investment may take include (...) intellectual property rights.' While the approach in BITs differs in so far as some contain merely a general reference to 'intellectual property rights' and others include a (generally non-exhaustive) list of types of IPRs, empirical research shows that BITs generally include IP rights as a form of investment.⁷⁴ Further, a lot of FTAs negotiated between developed and developing countries contain an investment chapter. For example, under Article 10.28(f) of the CAFTA-DR⁷⁵, Article 10.27(f) of the Chile–United States FTA⁷⁶, Article 10.28(f) of the Peru-United

⁷⁴ For a comprehensive study on how BITs cover IP rights as protected investment see Rachel Lavery, 'Coverage of Intellectual Property Rights in International Investment Agreements: An Empirical Analysis of Definitions in a Sample of Bilateral Investment Treaties and Free Trade Agreements' (2009) 6 TDM, 1, 4-7 and Annex 1. The author observes that although few BITs do not explicitly address IP rights, this does not necessarily mean that they do not cover IP since BITs generally provide that the lists of covered investments are not exhaustive.

The United States—Central America—Dominican Republic Free Trade Agreement, 28 January 2004, (2004) 43 ILM 514.

⁷⁶ Chile-US Free Trade Agreement, 6 June 2003, (2003) 42 ILM 1026.

States Trade Promotion Agreement (TPA)⁷⁷, the definition for investment includes 'intellectual property rights'. Also recent European Union FTAs – such as CETA – and Japanese FTAs – such as the J-EPA with Indonesia⁷⁸ – include an investment chapter which again covers IP rights as protected investment.⁷⁹

Excluding IP Rights from Investment Protection: Countries negotiating an IIA with a developed country should therefore be aware that there will be a general expectation to cover IP rights within the definition of investment. Excluding IP rights hence may not be easy to achieve. Also, a country that does not wish to protect IP via investment standards should try to include an express exclusion to this effect, since a broad general definition of investment – as in Article 1139 NAFTA – have been understood to cover IP rights, for example in the *Eli Lilly vs Canada* arbitration.

Developing countries negotiating an IIA another developing countries in particular may wish to consider an *express exclusion of IP rights* from the scope of investment protection. This would ensure that all potential problems which otherwise need to be addressed by specific clauses can be avoided. This does not leave a foreign investor owning IP rights without protection as the investor can still rely on the general standards of protection with regard to his business activities in the host state. Since investment protection generally is a protection against state interference, it will usually not be of help in typical IP infringement scenarios that usually concern the unauthorised use of IP by private parties in the host state.

Limited Inclusions of IP Rights: In case an express exclusion of IP rights from the scope of investment protection is not desirable or not achievable, countries should consider an appropriate qualification when including IP rights in the definition of an investment. This can be in form of *general requirements for what constitutes a protected investment*: Article 1 of the 2012 United States Model BIT for example defines investment as 'every asset that an investor owns or controls, directly or indirectly, that has the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk'. IP rights are merely listed as one form 'that an investment may take'. Such an approach ensures that simply holding an IP right as such does not qualify for protection under an IIA.

Peru–US Trade Promotion Agreement, 12 April 2006.

Agreement between Japan and the Republic of Indonesia for an Economic Partnership, 1 July 2008.

⁷⁹ J-EPA Art. 58(f)(vi) refers to 'intellectual property rights, including copyrights, patent rights and rights relating to utility models, trademarks, industrial designs, layout-designs of integrated circuits, new varieties of plants, trade names, indications of source or geographical indications and undisclosed information.'

In this context, countries may also wish to include a requirement that the investment needs to make a *positive contribution to the development of the host state*. The public policy considerations which justify granting IP rights – as expressed in Article 7 TRIPS – support this: IP rights serve a utilitarian goal, they are a means to an end. If countries wish to take this approach, they should include an express requirement to this effect. While investment tribunals have in some cases deduced similar requirements from the definition of an investment under Article 25 ICSID,⁸⁰ the tribunal in the *PM vs Uruguay* plain packaging arbitration explicitly rejected the need to identify a positive contribution to the host state's development as a fixed requirement under Article 25 ICSID and emphasised that the Parties to an IIA are free to introduce such a limit in their definition of investment.⁸¹

Finally, countries should include, in their definition of investment, *references to the domestic law of the host State*. For example, they may wish to generally require that 'investments have been admitted in accordance with the law and regulations of the contracting party in which territory the investment was carried out'⁸² or even demand that IP rights are only protected as 'investments' if they are 'admitted' by the relevant Contracting Party 'subject to its law and investment policies applicable from time to time'.⁸³

Such references ensure that there is no doubt about the crucial role of the domestic IP law of the host state in determining existence, validity, conditions for, scope, and limits to IP rights. While the principle of territoriality that governs IP rights makes any other approach very difficult to imagine, countries should, for reasons of clarity, include a reference to the domestic law of the host state. As further discussed in section 2.3, this has also been one of the insights from the Eli Lilly case which led Canada and the European Union to include a similar clause into CETA.

2.2. Safeguarding Limits to National Treatment and MFN

Background: As described in chapter 1 section 1.2, obligations to grant national treatment (NT) are at the core of the international IP law tradition. Provisions like Article 5(1) of the Berne Convention and Article 2(1) of the Paris Convention aim to prevent the discrimination of foreign right holders – something that was widespread to promote domestic production or publication, facilitate technological progress by imitating foreign

⁸⁰ See the leading case, *Salini Costruttori S.p.A. and Italstrade S.p.A. v. Kingdom of Morocco*, Decision on Jurisdiction 31 July 2001 (ICSID Case No. ARB/00/4, 42 ILM 609 (2003)).

⁸¹ See *Philip Morris vs Uruguay*, Decision on Jurisdiction (2 July 2013), para. 197-208.

⁸² Art. I(2) of the Chile-Egypt BIT (1999).

⁸³ Art.1(e) Hong Kong-Australia BIT.

inventions or copying foreign literature and to advantage one's own national inventors and creators.

At the same time, international IP treaties have always allowed reciprocity as an exception to national treatment in areas where the differences in domestic law are so grave that an unconditional national treatment rule would allow right holders from low-protection countries to 'free-ride' on stronger rights in high-protection countries. ⁸⁴ For example, any party to the Berne Convention can exceed the minimum standard of 50 years of copyright protection after the death of the author without the need to grant this longer term to 'foreign' works. ⁸⁵ The TRIPS Agreement carefully maintains these exceptions to national treatment in its Article 3, and also upholds them in Article 4 on MFN.

Safeguarding Limits to National Treatment and MFN: Against this context, an important consideration for countries negotiating IIAs which include IP as protected investment should be to ensure that these accepted limits on NT and MFN are not undermined by unqualified national treatment or MFN rules in IIAs. This can be achieved by means of a specific clause as in Article 14:4 of the 2012 United States Model BIT which provides that the NT and MFN standards in the IIA 'do not apply to any measure covered by an exception to, or derogation from, the obligations under Articles 3 or 4 of the TRIPS Agreement.'

The downside of such a clause is that it could be used by investors to challenge, in ISDS proceedings, whether the host state measure complained about is, in fact, 'covered by an exception to (...) TRIPS'. The tribunal charged to decide the case may then feel compelled to (at least indirectly) assess whether the host state has acted TRIPS compliant – something which falls in the exclusive domain of WTO dispute settlement.

Two options exist to overcome this problem:

The countries negotiating the IIA may include an express provision to the effect that if the investor challenges the relevant host state measure as not covered by a (reciprocity) exception in TRIPS, BC or PC, this matter can only be decided by a WTO Panel – if the investor's home state decides to bring a complaint in front of the WTO Dispute Settlement Body (DSB). Unless the home state agrees to do this and the WTO Panel or Appellate Body (AB) decides in favour of a breach, the NT or MFN claim cannot prevail. This option however would involve significant delays, and would make protection of the investor wholly dependent on the will of the home state.

⁸⁴ The limited operation of reciprocity in turn aimed to induce countries to harmonise their laws towards the higher protection standard.

See Art. 7(1) and (8) of the Berne Convention.

A hence more realistic (and less drastic) option would be to include, into the NT and MFN provision in the relevant IIA, an express reference to the limits to NT and MFN under TRIPS, the BC, and PC. This reference needs to be carefully drafted not to include, as a condition, the compliance with TRIPS rules. Instead, the express reference to TRIPS or other international IP treaties should be in form of interpretative guidance: 'In case the protected investment is an IP right, the protection of national treatment and MFN under the [IIA] needs to be construed in light of the relevant provisions of TRIPS, the BC and PC.' While retaining core limits of from the international IP system, those are not applied, but merely relied on as interpretative guidance.

This outcome can also be achieved if ISDS tribunals are bold enough to step out of the narrow confines of the IIA: based on general international law, the interpretation of the relevant national treatment provision in IIAs should always be conducted in light of Article 31(3) (c) of the VCLT. As soon as both parties to the IIA are members of the WTO, the Paris or Berne Union, the reciprocity exceptions to the national treatment obligations in TRIPS, the Paris or the Berne Convention may be considered as 'relevant rules of international law applicable in the relations between the parties.'

A similar approach, taken in *PM vs Uruguay*, had ensured that the term (indirect) expropriation is construed in light of the 'right to regulate' as part of customary international law. 86 As a form of *lex specialis* for the protection of IP rights related investments, TRIPS, BC or PC rules hence should affect the interpretation of national treatment obligations in IIAs so that the recognised exceptions in international IP law are carried over into international investment law. However, if countries wish to be sure of such limits, they may better include an express guiding role of the relevant TRIPS rules.

2.3. Ensuring a Balanced Scope for Investment Standards of FET, FPS, and Protection against Expropriation

Background: In international investment law, ISDS practice and commentary has attempted to clarify the rather ambiguous notion of fair and equitable treatment (FET) by resorting to a number of (partly overlapping) elements such as reasonableness, consistency, non-discrimination, transparency, due process and proportionality in domestic decision-making; as well as the protection of legitimate expectations and protection against bad faith, coercion, threats and harassment.

⁸⁶ See Chapter 1 Section 1.4 above.

While the FET standard operates highly context-specific, three factors can be identified as a rough guiding parameters: (1) a violation of domestic law by the host state as such is not sufficient for a FET breach; (2) FET however can be breached without the need to show bad faith on the side of the host state; and (3) the protection of legitimate expectations of the investor, if at all accepted, must be balanced against the legitimate right of the host state to regulate in the public interest. In the IP context, legitimate expectations of the IP-owning investor, and the right to regulate are key issues.

The protection against expropriation in turn often focuses, in IP cases, on how to deal with compulsory licences, revocations and invalidations of IP rights, and other limits to the scope of the rights: when can such measures be considered as (indirect) expropriations? Finally, with regard to IP rights as investments, discussions on Full Protection and Security (FPS) then link to steps the host state has to take to protect such rights against infringements by third parties.

These guidelines do not offer the space for a comprehensive coverage of all aspects of FET, FPS or expropriation that may be of relevance for the protection of IP rights as investments. Instead, the suggestions below focus on options for states to constrain an overbroad notion of protecting legitimate expectations or for determining indirect expropriation. They aim to ensure that investment protections are not invoked to prevent the dynamic development of domestic IP laws by local courts and administrative agencies (such as patent offices); and that the state's right to regulate as well as accepted flexibilities under the international IP system are duly taken into account. In addition, section 2.4 below addresses ways to ensure that FET or expropriation standards are further not applied to allow the investor to challenge the host state's compliance with international IP norms in ISDS proceedings.

Negotiating more specific protections under FET: As the Eli Lilly arbitration shows, the broad and open concept of FET has been relied on to challenge specific developments of domestic IP law, in particular by courts and IP offices. While Eli Lilly was eventually not successful, this case was mainly decided on the facts with little guidance on how FET applies to IP rights. Therefore, if countries are willing to agree to include FET as a standard of protection, they might wish to further qualify what is understood by FET, or at least indicate what FET is not meant to interfere with.

The approach taken by the NAFTA Trade Commission – which in July 2001 issued a statement expressing the common position of NAFTA Parties that the FET (and FPS) standards 'do not require treatment in addition to or beyond that which is required by the customary international law minimum standard of treatment of aliens' – is not very helpful. As the Eli Lilly arbitration and other cases indicate, this simply shifts the debate whether the

international minimum standard encompasses protection of, for example, legitimate expectations.

Countries wishing to retain control over the remaining policy space available to develop their domestic IP laws might then include specific qualifications of the FET and FPS standards: Article 8.10.2 CETA for example enumerates specific circumstances which constitute a breach of FET, including

- '(a) denial of justice in criminal, civil or administrative proceedings;
- (b) fundamental breach of due process, including a fundamental breach of transparency, in judicial and administrative proceedings;
- (c) manifest arbitrariness;
- (d) targeted discrimination on manifestly wrongful grounds, such as gender, race or religious belief;
- (e) abusive treatment of investors, such as coercion, duress and harassment'.

Further notable approaches in Article 8.10 CETA that countries may wish to consider are to allow the IIA/FTA Parties to dynamically develop the content of the FET standard via a specialized committee formed by the Parties. And they may wish to clarify that the breach of an international treaty provision or a domestic law as such does not amount to a breach of FET. This may be helpful to overcome arguments that an (alleged) breach of an international IP treaty rule violates legitimate expectations of the investor.

Upholding the right to regulate: For greater certainty, countries should further consider including general or IP-specific references to their right to regulate under customary international law. While the tribunal in *PM vs Uruguay* relied on this right without the need for an express reference, this was focused on the expropriation claims. Again, CETA serves as useful example for a general reference: Under Article 8.9.1, the Parties 'reaffirm their right to regulate within their territories to achieve legitimate policy objectives, such as the protection of public health, safety, the environment or public morals, social or consumer protection or the promotion and protection of cultural diversity.'

In Article 8.9.2, they highlight that 'the mere fact that a Party regulates, including through a modification to its laws, in a manner which negatively affects an investment or interferes with an investor's expectations, including its expectations of profits, does not amount to a breach of an obligation under this Section.' As chapter 1 section 1.3 has shown, the reference to the right to dynamically develop domestic law is of particular importance in the IP context where countries need to retain flexibility to adapt to changing technologies and other IP-protected subject matter, and the way we use it. Countries introducing such

clarifications should make clear that they cover all standards of investment protection not just expropriation or FET.

Limiting the concept of legitimate expectations: Countries not willing or able to exclude the concept of legitimate expectations from the protection of FET may wish to consider an express clarification that such protection cannot be based on the mere grant of an IP right – such that the invalidation, revocation or other limitation of the right per se amounts to a breach of FET or serves as an indicator for expropriation. Protections of FET claimed for IP rights that have been invalidated or limited should be limited to protections of due process, the right to be heard, or against denial of justice – rather than offering an opportunity for the investor to have the application of domestic law reviewed, or tested against international IP norms for which no or only state-to-state dispute settlement exist.

FET protection hence should essentially focus on the process of granting, administering, and invalidating IP rights – and should not interfere with the dynamic development of the substance of IP laws. The latter is sufficiently regulated by means of the specific multilateral and (if applicable) regional or bilateral IP treaties. In order to ensure clarity on this point, a statement on competence of national IP offices and courts, also relevant for section 2.4, can be helpful: based on the experience in the Eli Lilly arbitration, the Parties of CETA included an express statement clarifying that ISDS is 'not an appeal mechanism for the decisions of domestic courts' and 'that the domestic courts of each Party are responsible for the determination of the existence and validity of intellectual property rights.'⁸⁷

Protections against indirect expropriation should – next to being accompanied by a general reference to the right to regulate – be based on a range of factors which are applied to define indirect expropriation. Such factors can include, but should not be limited to the economic effect of the measure. They should also incorporate the nature or character of the measure and a clarifying statement whereby as a matter of principle, non-discriminatory measures that are designed and applied to protect legitimate public welfare objectives, such as health, safety and the environment, do not constitute indirect expropriations.

⁸⁷ See ANNEX 8-D – JOINT DECLARATION CONCERNING ARTICLE 8.12.6 which states in full: 'Mindful that the Tribunal for the resolution of investment disputes between investors and states is meant to enforce the obligations referred to in Article 8.18.1, and is not an appeal mechanism for the decisions of domestic courts, the Parties recall that the domestic courts of each Party are responsible for the determination of the existence and validity of intellectual property rights. The Parties further recognise that each Party shall be free to determine the appropriate method of implementing the provisions of this Agreement regarding intellectual property within their own legal system and practice. The Parties agree to review the relation between intellectual property rights and investment disciplines within three years after entry into force of this Agreement or at the request of a Party. Further to this review and to the extent required, the Parties may issue binding interpretations to ensure the proper interpretation of the scope of investment protection under this Agreement in accordance with the provisions of Article 8.31.3.'

If countries wish to include the protection of legitimate expectations as a further factor for determining indirect expropriation, a clarification when, in the IP context, such expectations are 'legitimate' may be useful: as suggested above, the mere grant of an IP right never serves as basis for an expectation that this right is sacrosanct and not subject to invalidation, cancelation or other forms of limitations such as compulsory licenses. section 4 below covers the specific issue of linking to the internationally accepted flexibilities with regard to compulsory licenses and other accepted IP limitations in more detail.

Flexibilities on IP enforcement measures: On the sometimes separately regulated concept of Full Protection and Security (FPS), countries may wish to include a clarification that FPS does not require the host state to ensure that IP rights of the investor will not be infringed by third parties, nor does it require specific IP enforcement remedies to be available to the investor. This shields against expansive interpretations of FPS where an investor might try to argue that FPS covers a duty of the host state to take active, concrete and/or effective steps against third party infringement of IP rights. The easiest way to achieve this would be to limit FPS to physical security of investors and covered investments. Otherwise, an IP-specific clarification suggested above should be included. Countries should however be careful how they include specific references to TRIPS flexibilities (as in Article 41:5 TRIPS): they need to ensure that an express incorporation of these and other TRIPS flexibilities does not serve as tool to import these norms into ISDS complaints where the investor then alleges a breach of TRIPS norms. Instead, the approach chosen above where the ISDS tribunal is urged to construe the broad and open investment standard in light of relevant TRIPS provisions, especially its flexibilities, should be preferred.

2.4. Preventing ISDS over International IP Provisions

Background: As the discussion of the IP ISDS cases in chapter 1 section 1.4 has shown, a key element of most complaints brought by IP-owning investors was to allege a breach of various international IP provisions – usually through the vehicle of either the expropriation or the FET standard. Often, the concept of legitimate expectations was relied on to claim that a host state measure breaches an international IP treaty provision (such as rules on patentability under TRIPS or NAFTA, or on use restrictions for trademarks in TRIPS and the PC), and that such a breach interferes with the legitimate expectation the investor has that the host state complies with the relevant international IP treaty. The outcome of such a line of arguments would be that an ISDS tribunal has to rule in compliance with an international IP treaty.

In a somewhat different context, also clauses in IIAs that try to ensure that protection against expropriation does not override accepted flexibilities in the international IP system invite for challenging compliance with international IP rules in ISDS: based on earlier examples in Article 1110:7 NAFTA and corresponding rules in the United States Model BIT, Article 8.12.5 CETA states that expropriation protection 'does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, to the extent that such issuance is consistent with the TRIPS Agreement.' In the Eli Lilly arbitration, this type of clause was used by the investor to argue that since Canada's law breached relevant international IP rules, it amounted to an expropriation. Even if this argument is flawed on several levels, countries may wish to take steps in order to pre-empt such claims.

Pre-empting claims for breaches of international IP treaties (while safeguarding internationally recognized flexibilities on limits to IP rights): Countries should consider introducing clauses that purport to safeguard flexibilities of international IP treaty framework, such as on compulsory licensing and other forms of accepted limitations of IP protection, against being undermined by a broad application of international investment protection standards, such as expropriation, FET, FPS, or non-discrimination standards (see section 2.2 above). They should however try achieve this goal without inviting the investor to challenge compliance with the international IP rules setting out the relevant flexibilities in ISDS. Countries therefore may wish to consider an alternative to the provision set out above – by including a clause that does not establish consistency with international IP rules as benchmark, but relies on these rules to guide the understanding of the investment protection standards.

A clause to this effect could be formulated along the following lines: 'When protection is sought for IP rights as an investment, in interpreting the standards of protection for investors under this agreement, a tribunal shall be guided by the relevant flexibilities and other provisions in applicable international IP treaties.' This ensures that IP flexibilities guide the construction of investment protection standards. It essentially has a mere clarifying and emphasizing role, since the same result would already follow from treaty interpretation principles expressed in Article 31:3c) VCLT. An express rule however would ensure that these principles are in fact applied; and that an ISDS tribunal will give them appropriate weight in the interpretation process.

Such a provision is to be preferred over clauses in CETA which had been drafted in response to Eli Lilly claims for an expropriation based on a breach of international IP rules, as mentioned above. Article 8.12.6 CETA states: 'For greater certainty, the revocation, limitation or creation of intellectual property rights, to the extent that these measures are consistent with the TRIPS Agreement and Chapter Twenty (Intellectual Property), do not constitute expropriation.

Moreover, a determination that these measures are inconsistent with the TRIPS Agreement or Chapter Twenty (Intellectual Property) does not establish an expropriation.' While this ensures that expropriation claims are pre-empted by showing TRIPS consistency (while at the same time they cannot be based on TRIPS violations), the clause again does not prevent an ISDS tribunal to examine compliance with TRIPS (but in fact seems to presume that the tribunal makes such 'determinations'). For this reason, a general interpretative rule that directs a ISDS tribunal to interpret investment standards in IP cases in light of the international IP rules is certainly to be preferred.

Chapter

4

AN ANALYSIS OF GOOD (AND NOT SO GOOD) PRACTICES ON FLEXIBILITY CLAUSES

This section focuses on presenting and analyzing examples from FTA state practice that go some way to ensure flexibilities of the multilateral system (in particular TRIPS) are upheld, that introduce other forms of policy space, or that can be used to this effect. The examples are taken from Agreements that are not specific to the Asia-Pacific, so as to offer a broader perspective on the options available, and to show good (and not so good) practice in terms of retaining flexibility in drafting domestic IP law in accordance with domestic needs.

1. FTA Clauses Affirming WTO/TRIPS (Rights and) Obligations

The first and most traditional group of FTA clauses that are examined here generally affirm the parties' intentions to act consistent with WTO obligations in general or with those deriving from TRIPS in particular. In most instances this affirmation also extends to rights granted under the WTO/TRIPS Agreements.

Affirming WTO/TRIPS Obligations Only: A prominent example where the conflict rule refers to WTO/TRIPS obligations only is Art.1 ACTA which states: "Nothing in this Agreement shall derogate from any obligation of a Party with respect to any other Party under existing agreements, including the TRIPS Agreement." First and foremost, a treaty containing such a clause would hence have to be interpreted in a manner consistent with TRIPS. If that is not possible, such a clause expresses the intention of the negotiating parties not to derogate from any WTO/TRIPS obligations. Interestingly in this specific case, the final ACTA text uses only the term 'obligations'—not 'rights and obligations' as earlier versions of ACTA did. This indicates that—from its own perspective—ACTA prevails over

Based on the July 2010 ACTA text, Article 1 (RELATION TO OTHER AGREEMENTS) stated that "nothing in this Agreement shall derogate from [EU/NZ/Sing: any existing rights and] any obligation of a Party with respect to another Party under existing agreements, including the WTO Agreement of Trade related Aspects of Intellectual Property Rights." See ACTA – July 1 draft, Anti-Counterfeiting Trade Agreement Informal Predecisional/ Deliberative Draft: July 1, 2010, Art.1.1.

optional TRIPS flexibilities. The same result will in principle be the outcome for similar clauses which only refer to obligations owed under TRIPS.⁸⁹

Affirming WTO/TRIPS Rights and Obligations: In all United States FTAs examined for this research, the conflict clause however concerns both *rights and* obligations under WTO/TRIPS. The contracting parties usually include a general provision where they assert "existing rights and obligations with respect to each other under existing bilateral and multilateral agreements to which both Parties are party, including the WTO Agreement". ⁹⁰ In addition, in an IP-specific rule in some FTAs the "parties affirm their rights and obligations with respect to each other under the TRIPS Agreement". ⁹¹

Similarly, some clauses used in European Union FTAs refer to both "rights and obligations between the Parties under the TRIPS Agreement". Purthermore, most Japanese FTAs contain such a clause – however often with the addition that "[i]n the event of any inconsistency between this Agreement and the WTO Agreement, the WTO Agreement shall prevail to the extent of the inconsistency". For the purpose of this analysis the main question is whether such an express conflict clause, or the further inclusion of treaty rights under WTO/TRIPS Agreements, can function to safeguard TRIPS flexibilities as far as their operation is undermined by FTA provisions that introduce additional IP protection or enforcement obligations which go beyond TRIPS (in this section referred to as 'TRIPS-plus').

Analysis: For the following reasons however, it appears unlikely that the clauses above will function as effective means to safeguard policy space under TRIPS. First, the contracting parties may understand the term 'rights and obligations' with respect to each other as describing a (treaty) obligation in international law from a dual perspective where the obligation of one party is a right of another party.⁹⁴ Then the term would still only apply to

⁸⁹ See for example Art.139:1 of the EU – CARIFORUM EPA and Art.170:1 (a) (i) of the EU – Chile Association Agreement in which the contracting parties express their intention to "[e]nsure adequate and effective implementation of the obligations arising from (...) TRIPS".

⁹⁰ Art.1.1:2 US Singapore FTA, Art.1.1:2 US Australia FTA, Art.1.2:1 US Bahrain FTA, Art.1.2:1 US – Morocco FTA, Art.1.2:1 US – Oman FTA, Art.1.2 US Jordan FTA, Art.1.3:1 US – CAFTA-DR, Art.1.3:1 US Panama TPA, Art.1.3 US – Chile FTA, Art.1.2 US – Colombia FTA, Art.1.2:1 US – Korea FTA, Art.1.2:1 US Peru TPA.

⁹¹ See Art.17.1:3 of the US – Australia FTA, Art.15.1:7 US – CAFTA-DR, Art.1.3, Ch 17 (IP) preamble, Art.17.1:5 US Chile FTA (nothing shall derogate from), Art.16.1:6 US – Colombia FTA, Art.18.1:2 US – Korea FTA.

⁹² See Art.189:1 EU – Columbia. Peru FTA.

⁹³ See Article 12 Japan-Indonesia FTA (2007), Article 11 Japan-Thailand FTA, Article 11 Japan-Philippines FTA (2006), Article 11 Japan-Malaysia EPA (2005), Article 9 Japan – Vietnam EPA.

⁹⁴ For example, the obligation not to introduce a system of international exhaustion in the domestic law of one contracting party can be viewed as a right of the other contracting party to demand that no such system of exhaustion is provided in domestic law.

obligations under international treaties – but not function as a safeguard for TRIPS flexibilities, understood as optional rights under an IP treaty to rely on the option(s) provided by the respective rule (such as to introduce an exception to patent rights, or issue a compulsory licence).

Second, even if one considers that a more probable reading of the term 'rights' includes also TRIPS flexibilities, it is limited to rights which the FTA parties owe to another. If these countries agree in the FTA to waive their rights under TRIPS (by introducing TRIPS-plus FTA provision which limit or exclude the use of such a flexibility), this would arguably not derogate from a treaty right affirmed in these conflict clauses: the argument is that a right can be exercised – but is not derogated from if the Parties agree not to exercise it.

This argument also applies to the explicit conflict clauses in most Japanese FTAs which give preference to the WTO Agreement to the extent of any inconsistency with the FTA: Inconsistency with TRIPS (as an agreement annexed to the WTO Agreement) does not exist where the contracting parties agree not to exercise a right under TRIPS.

Finally, as far as FTAs contain specific TRIPS-plus rules whose interpretation necessarily leads to an outcome that undermines the exercise of TRIPS flexibilities, the operation of the conflict rules described above cannot lead to a result which renders the specific TRIPS-plus provision inutile or ineffective. ⁹⁵ It hence remains rather doubtful that the FTA clauses simply affirming 'rights and obligations' can operate to prevent specific TRIPS-plus rules in FTAs from undermining TRIPS flexibilities. Only where TRIPS-plus provisions are open-textured or ambiguous in their impact on TRIPS, such conflict clauses demand an interpretation which safeguards TRIPS flexibilities. ⁹⁶

This follows from the application of the principle of good faith in treaty interpretation (as embodied in Art.31(1) VCLT) which is *inter alia* an expression of the principle of *pacta sunt servanda* (Art. 26 VCLT) that in turn embodies the principle of effectiveness, see *Yearbook of the International Law Commission*, The International Law Commission's Commentary on Art. 27 to 29 of its Final Draft Articles on the Law of Treaties, Vol. II (1966), at 219 and *I Sinclair*, The Vienna Convention on the Law of Treaties (2nd Ed, Manchester, 1984), at 119-120. Notions of good faith and of giving effect to each provision of the treaty prohibit an interpretation of one treaty provision which renders another treaty provision ineffective or inutile. Compare also *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, Appellate Body Report WT/DS58/AB/R (6 November 1998), at para. 121.

This result however already follows from the principle of harmonious interpretation as discussed in Chapter 3, Section 1.1 above. The same is true for the more specific Art.189 EU – Columbia, Peru FTA which further provides "the provisions of this Title shall complement and specify the rights and obligations between the Parties under the TRIPS Agreement and other multilateral treaties related to intellectual property in force among the Parties and therefore *no provision of this Title will contradict or be detrimental to the provisions of such multilateral agreements.*" (emphasis added): Apart from expressing the principle of *lex specialis*, the provision calls – to the extent possible – for a harmonious interpretation which takes TRIPS flexibilities into account.

In sum, these traditional FTA conflict clauses cannot be applied to uphold an optional provision in TRIPS which the IP Chapter provisions of that very same FTA override. Countries implementing the suggestions in chapter 3 section 1 in favour of retaining the policy space available under TRIPS should therefore opt for more specific clauses discussed below.

2. References to the Doha Declaration

Another type of provisions that appears in the more recent United States and European Union FTAs are those which contain various types of references to the Doha Declaration on TRIPS and Public Health. Since the Doha Declaration in paragraph 5 lists some of the most important flexibilities that TRIPS contains in relation to public health matters in particular, 97 such provisions could function to uphold these flexibilities over TRIPS-plus provisions in FTAs.

General Doha References: The first category of 'Doha-references' are of general nature. The FTA contracting parties are "recognising the principles set out in", ⁹⁸ "affirm their commitment to", ⁹⁹ or "recognise the importance of ¹⁰⁰ the Doha Declaration. In the same vain, in the ACTA preamble the negotiating parties agree to ACTA while: "*Recognizing* the principles set out in the Doha Declaration on the TRIPS Agreement and Public Health, adopted on November 14, 2001, by the WTO at the Fourth WTO Ministerial Conference, held in Doha, Qatar". ¹⁰¹ The principles expressed in the Doha Declaration include a public health supportive interpretation and implementation of TRIPS. ¹⁰² In this connection, WTO Members reaffirmed "the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose." ¹⁰³

Hence, such general references to the Doha Declaration in FTAs can primarily function as a tool which demands an *interpretation and implementation* of FTA provisions that does not undermine the flexibilities listed in the Doha Declaration. Similar to the WTO/TRIPS consistency clauses discussed above, this may work well in cases of open and ambiguous TRIPS-plus obligations in FTAs where an interpretation based on Articles 7 and 8 TRIPS

⁹⁷ Compare Chapter 1, Section 2 and 3 above.

⁹⁸ See the preamble to Chapter 17 (Intellectual Property) in the US – Chile FTA.

⁹⁹ See Art.16.13:1 US Colombia FTA, Art.16.13:1 US Peru TPA, Art.18.11:1 US – Korea FTA.

¹⁰⁰ See Art.147 B EU CARIFORUM EPA.

¹⁰¹ See ACTA Preamble.

¹⁰² See para.4 of the Doha Declaration on TRIPS and Public Health (2001) stating that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

¹⁰³ Ibid.

can significantly affect the meaning of the relevant obligation.¹⁰⁴ It will however not be particularly helpful in the vast amount of cases where specific and concise TRIPS-plus provisions in FTAs curtail or inhibit the reliance on TRIPS flexibilities.¹⁰⁵

Consistency with Doha: A more promising clause is Article 190:2 of the European Union – Colombia Peru FTA which states:

"The Parties recognize the importance of the Doha Declaration and especially the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by the Ministerial Conference of the World Trade Organization and its subsequent developments. In this sense, *in interpreting and implementing the rights and obligations under this Title, the Parties shall ensure consistency with this Declaration.*" ¹⁰⁶

Again, it emphasizes interpretation and implementation of the FTA primary as field of operation for 'recognising' the importance of the Doha Declaration for the FTA. However, beyond the general Doha-references discussed above, the parties are under a binding legal obligation to "ensure consistency" with the Doha Declaration. A problem then arises if such a clause has to be operationalised in relation to a TRIPS-plus rule in a FTA that limits flexibilities under Doha. How can this clause be aligned with a specific TRIPS-plus FTA obligation in case the latter undermine the use of any of the flexibilities listed in the Doha Declaration?

An example for such apparent contradiction is Article 224 of the European Union – Peru, Colombia FTA which demands a minimum of 5 years of test data exclusivity for pharmaceutical products. This TRIPS-plus rule can prevent Peru or Colombia to effectively exercise the compulsory licensing flexibilities set out in the Doha Declaration. Such flexibilities to freely determine the grounds for compulsory licenses are *de facto* useless when, based on test data exclusivity, no generic production can take place to improve affordable access to medicines. To resolve this conflict, the Doha-reference in Article 190:2 should be understood to allow a wide understanding of the "Exceptions for reasons of public interest, situations of national emergency or extreme urgency, when it is necessary to allow access to those data to third parties" foreseen in Article 224:4. To live up

¹⁰⁴ See the discussion in Chapter 1 Section 2, and Chapter 3, Section 1.1.

See the discussion about increasingly comprehensive and detailed IP provisions in FTAs in Chapter 1, Section 3. As argued in section 1 above, general conflict clauses in FTAs, including these general references to the Doha Declaration, cannot lead to a result which renders the specific TRIPS-plus FTA provisions inutile or ineffective.

¹⁰⁶ Art. 190:2 of the European Union – Colombia Peru FTA (emphasis added).

¹⁰⁷ See Art. 224:2 of the European Union – Colombia Peru FTA.

to the obligation to 'ensure consistency' with the Doha Declaration, these exceptions must allow a real and effective use of all the TRIPS flexibilities mentioned in the Doha Declaration. 108

In sum, the added value of Doha-references such as Article 192:2 of the European Union – Colombia, Peru FTA is that they are more concrete and specific in indicating *how* the Doha Declaration is relevant for the FTA. They are hence more effective to safeguard TRIPS flexibilities because they have a greater impact on the appropriate understanding of TRIPS-plus FTA provisions: Since even a concise and detailed TRIPS-plus provision in an FTA will seldom explicitly prohibit reliance on any of the four TRIPS flexibilities mentioned in the Doha Declaration, FTA provisions may not undermine those flexibilities.

(Conditional) Allowances for Measures to Protect Public Health: Yet another category of Doha-references in FTAs appear particularly promising at first sight. They allow that "a Party may take measures to protect public health in accordance with (...) the Declaration on the TRIPS Agreement and Public Health". However, this clause is subject to further conditions: it is "Notwithstanding subparagraphs (a), (b), and (c)" of the relevant TRIPS-plus FTA rule which in essence obliges the FTA contracting parties to introduce a "reasonable period" of test data exclusivity.

That normally is to be understood as five years. 110 Hence the right to rely on TRIPS flexibilities which flows from these Doha-references is subject to not interfering with the specific obligation to introduce test data exclusivity. In the FTAs used as examples here, the Doha reference is positioned in the last subparagraph of the FTA test data provision. This indicates that it only applies to this provision, so that one may question what independent value it can have after all: One possibility would be to interpret the 'notwithstanding test' in a way that any measure taken cannot affect the protection for test data at all.

A more liberal reading however would allow for taking any measure in accordance with the Doha Declaration (e.g. a compulsory license based on Article 31 TRIPS) as long it is within the interpretative boundaries of the provision on test data. Here, a wider understanding of terms such as 'reasonable period' and 'normally' in the test data provision could allow for compulsory licenses for a patented drug as a form of exceptional, public health motivated

¹⁰⁸ In the context of the European Union – India FTA, the European Union Commission confirms this result by assuring that "Data exclusivity will not hamper the effective use of a compulsory licence. (...) More specifically, in case of conflict between data exclusivity rules and compulsory licensing, the latter would override the former." See European Union Commission, as note 18 above, at 2.

¹⁰⁹ See Art. 16.10:2 e) United States – Colombia FTA, Art. 16.10:2 e) United States – Peru TPA, Art. 18.9:3 United States – Republic of Korea FTA.

¹¹⁰ See Art. 16.10:2 b) United States – Colombia FTA, Art. 16.10:2 b) United States – Peru TPA, Art. 18.9:2 United States – Republic of Korea FTA.

situation which does not interfere with the 'reasonable' test data exclusivity period. Again, appropriate solutions depend heavily on an implementation and interpretation which adopts creative ways to give effect to the Doha-references.

Incorporating Language from Doha: Finally, some of the recent FTAs contain language which is similar with or identical to parts of the Doha Declaration. For example, a section in the "Understanding Regarding Certain Public Health Measures" in several recent United States FTAs states:

The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all.¹¹¹

In a similar manner, Article 139:2 of the EC – CARIFORUM EPA assures that "Nothing in this Agreement shall be construed as to impair the capacity of the Parties and the Signatory CARIFORUM States to promote access to medicines." ¹¹²

A detailed analysis of all of the implications of these provisions is well beyond the scope of this chapter. Compared to the Doha-references, they re-iterate important principles of the Doha Declaration and transplant them into the FTA context instead of indirectly referring to them or to the flexibilities mentioned in the Declaration. While this may be less effective for safeguarding these flexibilities against TRIPS-plus FTA provisions, the Doha-language transplanted here can have an even further-reaching impact on the FTA obligations. It may entail a right of the contracting parties to adopt public health or nutrition protecting measures – even if these measures are inconsistent with individual IP obligations in the FTA. Or it can be understood to mean that such individual obligations must be *interpreted*

¹¹¹ See Art. 16.13:2 United States – Colombia, Art. 16.13:2 United States – Peru TPA, Art. 18.13:2 United States – Republic of Korea FTA (emphasis added) which are, in the emphasized parts, almost identical to para. 4 of the Doha Declaration.

¹¹² See Art. 139:2 European Union – CARIFORUM EPA which also has the same core meaning as para. 4 of the Doha Declaration.

¹¹³ For a more detailed analysis of Art. 139:2 European Union – CARIFORUM EPA see *H Grosse Ruse-Khan*, The Concept of Sustainable Development in International IP Law – New Approaches from EU Economic Partnership Agreements? (January 25, 2010), Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper No. 10-04, at 22-24 – online available at http://ssrn.com/abstract=1542486.

and implemented in a way that allows domestic measures to protect public health and nutrition.

Analysis: Given the reference to interpretation and implementation as the means for ensuring the right to protect public health in the United States FTA quote above, the latter option appears preferable. Also for the European Union EPA provision, its title ("Nature and Scope of Obligations")¹¹⁴ speaks for an interpretative function of that provision: The nature and scope individual IP obligations in the EPA must be so that they allow the protection of public health and nutrition and must not impair access to medicines.¹¹⁵

In sum, the various types of Doha-references in FTAs can go a certain way to safeguard TRIPS flexibilities. The extent to which they can perform such a safeguarding function depends on the type of reference at hand. In general, the main feature of the Doha Declaration is to create policy space within TRIPS mainly *by interpretation and implementation*. ¹¹⁶

This equally affects the role Doha-references can play in TRIPS-plus FTAs: they primarily function as a tool which demands an interpretation and implementation of FTA provisions that does not undermine the flexibilities listed in the Doha Declaration. Doha references thus guide the general notion of 'harmonious interpretation' amongst different rules of international (IP) law towards an understanding which recognises TRIPS flexibilities. The more specific the TRIPS-plus obligations in FTAs are however, the fewer are the options for such an interpretative approach. On the other hand, the more specific and demanding a clause refers to the Doha Declaration, the more effective it is in safeguarding TRIPS flexibilities. Countries should therefore carefully consider which type of Doha reference may be most suitable in the specific FTA context they are negotiating.

Legal Status and Role of the Doha Declaration: Beyond its role as a potential safeguard for TRIPS flexibilities, another important effect of the Doha-references is that they establish a (legal) relationship between the Doha Declaration and the FTA IP provisions. Depending on the type of Doha reference, this is instrumental in clarifying the legal status of the Doha Declaration as an interpretative instrument as well as a source of law in its own right.¹¹⁷

¹¹⁴ See Art. 139:2 EU CARIFORUM EPA.

¹¹⁵ H Grosse Ruse-Khan, supra note 123, at 23.

¹¹⁶ See para. 4 of the Doha Declaration.

¹¹⁷ On the debate about the legal status of the Doha Declaration see *F Abbot*, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) *JIEL* 469, at 491-492; *H Grosse Ruse – Khan*, 'Proportionality and Balancing within the Objectives of Intellectual Property Protection', in P Torremanns (ed), *Intellectual Property and Human Rights* (Kluwer, London, 2008), 161-194, at 184; See in general *S Charnovitz*, 'The Legal Status of the Doha Declarations', 5 *JIEL* (2/2002), 211.

Again: the more concrete and specific a FTA refers to the Doha Declaration, the greater will be its relevance for the interpretation of the FTA IP provisions. Furthermore, those FTAs which transplant parts of the Doha Declaration into the FTA treaty text 'internalise' and integrate the Doha Declaration to become part of treaty law. The Doha Declaration hence is upgraded from a mere source of external guidance (relevant for interpretation)¹¹⁸ to a being a part of the treaty provisions. As part of treaty law, it is part of the treaty's rights and obligations and can therefore have a greater and more direct impact on IP obligations in FTAs.¹¹⁹

3. References to (Specific) TRIPS Flexibilities

The third and final category of rules examined here are those which refer to specific TRIPS provisions that offer policy space or to TRIPS flexibilities in general. A good example for the latter category is Article 190:1 of the European Union – Peru, Colombia FTA which states:

With due regard to the provisions of this Title, each Party may, in formulating or amending its laws and regulations, make use of the exceptions and flexibilities permitted by the multilateral intellectual property agreements; particularly when adopting measures necessary to protect public health, to guarantee access to medicines and nutrition.¹²⁰

The highlighted text in italics gives a first impression that Article 190:1 allows the FTA parties to rely on exceptions and flexibilities permitted by any multilateral IP treaty – including TRIPS. Although the provision contains several ambiguities (what constitutes an exception – and, more importantly, what is a 'flexibility'?), this fact arguably works in favour of the FTA party invoking this provision: The absence of any definition of the term 'flexibilities' allows each party significant discretion to rely on more or less any provision in an international IP agreement which offers more policy space than the FTA provisions.

Subjecting Flexibilities to FTA provisions: Against this background, the chapeau clause 'With due regard to the provisions of this Title' functions to limit the policy space to rely on anything understood as 'flexibility' in international IP law. Making use of TRIPS flexibilities hence cannot override TRIPS-plus clauses in the FTA. This means that where FTA provisions contain detailed and concrete obligations to protect IP rights, they prevail over

¹¹⁸ In the context of TRIPS, the Doha Declaration should be understood as an "subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions" in the sense of Art.31:3(a) VCLT which hence "shall be taken into account, together with the context" in the process of TRIPS interpretation; see *H Grosse Ruse – Khan*, ibid.

¹¹⁹ The author wants to thank Margaret Chon for emphasising this point in discussions on this research.

¹²⁰ Emphasis added.

the permission to rely on exceptions and flexibilities to the extent of a conflict. It however also means that where those obligations are ambiguous or of general nature, they must be interpreted in light of the right to rely on (TRIPS) flexibilities. Wherever possible, provisions like Article 190:1 thus allow an interpretation and implementation of the FTA obligations that aligns with the existing exceptions and flexibilities in multilateral IP treaties.

A similar approach is taken in Article 17.4:10c) of the United States – Australia FTA which allows the contracting parties to rely on exceptions and limitations under TRIPS and other international IP treaties. It provides: "unless otherwise specifically provided in this Chapter, nothing in this Article shall be construed as reducing or extending the scope of applicability of the limitations and exceptions permitted under the agreements referred to in Articles 17.1.2 and 17.1.4 and the TRIPS Agreement." The impact of this provision is however more limited: Firstly, it only applies to copyright protection obligations in Article 17.4 of the FTA. Secondly, it refers to exceptions and limitations only – not to the broader notion of flexibilities. Article 17.4:10c) hence merely allows to rely on copyright exceptions and limitations contained in, *inter alia*, the Berne Convention and TRIPS – and only to the extent that the FTA IP chapter does not specifically provide otherwise. Since the latter is the case in particular for exceptions to the protection of technological protection measures and digital rights management information, ¹²² its practical importance is rather limited.

Test Data Exclusivity: Another example is Article 15 of an early draft text for an European Union – India FTA, stating that "Each Party in its laws and regulations shall provide for protection of undisclosed information *in accordance with and subject to the flexibilities in the TRIPS agreement.*" Again, the field of operation for this clause is limited because it applies only to the protection of undisclosed information. The obligation to provide for this form of IP protection however is made subject to the right to rely on TRIPS flexibilities.¹²³

It means that for example the protection of test data submitted for obtaining marketing approval for pharmaceutical products cannot interfere with the public health related flexibilities of TRIPS – such as the right to grant compulsory licenses. In order to give effect to this clause, it further should be understood so that patent-related flexibilities in TRIPS impose limits to the protection of undisclosed information and that the latter cannot make

¹²¹ See also the arguments to the same effect in relation to the Doha-reference in Art.190:2 of the same EU – Peru, Colombia FTA made in section 2. above.

¹²² See Art.17.4:7(e) and (f) and Art.17.4:8(b) of the US – Australia FTA.

¹²³ A narrower reading of this provision would merely refer to the flexibilities inherent in the TRIPS provision on protecting undisclosed information (Art.39), in particular the discretion to define what amounts to 'unfair commercial use' under Art. 39:3 TRIPS.

the former meaningless.¹²⁴ The European Union Commission has confirmed such an interpretation in a Question and Answer paper on the European Union – India FTA to allay fears and concerns expressed by civil society groups over the impact that FTA might have on access to medicines in India and other developing countries which rely on India for affordable medicines. The paper states:

"Data exclusivity will not hamper the effective use of a compulsory licence. The European Union has proposed a clause that will guarantee that no provision of the FTA will prevent India from using the flexibilities contained in the TRIPS Agreement. More specifically, in case of conflict between data exclusivity rules and compulsory licensing, the latter would override the former." ¹²⁵

References to TRIPS Objectives and Principles: ACTA offers another, different example for clauses referring to TRIPS flexibilities. Its Article 2:3 (NATURE AND SCOPE OF OBLIGATIONS) states: "The objectives and principles set forth in Part I of the TRIPS Agreement, in particular in Articles 7 and 8, shall apply, *mutatis mutandis*, to this Agreement." While the reference to Articles 7, 8 TRIPS is one to specific TRIPS provisions, those are primarily relevant for a public interest based interpretation and implementation of other TRIPS provisions. Since the objectives and principles embodied in Articles 7 and 8 TRIPS apply horizontally to all TRIPS obligations, their application in ACTA via reference equally affects the understanding of all ACTA provisions. The fact that Article 2 ACTA defines the 'nature and scope of obligations' in ACTA further underlines this: The nature and scope of ACTA obligations is, *inter alia*, determined by an interpretation and implementation based on the principles and objectives embodied in Articles 7 and 8 TRIPS.

In sum, the reference to Articles 7 and 8 TRIPS within an FTA can have an important emphasising effect for those FTA parties aiming to implement the agreement based on the balancing objectives and public interest principles embodied in those TRIPS provisions. Its

¹²⁴ This follows from the principle of effectiveness (effet utile) as embodied in the notion of 'good faith' in Art. 31:1 VCLT; see the further references supra note 105.

EU Commission, DG Trade: EU – India negotiations and access to medicines: Questions and Answers, p. 2, online available at http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146191.pdf.

Para. 5 a) of the Doha Declaration emphasizes the role of Art. 7, 8 TRIPS for treaty interpretation: "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles." See also *H Grosse Ruse – Khan*, supra note 127, at 181-183; and generally *P Yu*, The Objectives and Principles of the TRIPs Agreement (May 4, 2009), Houston Law Review, Vol. 46, pp. 797-1046, 2009 – online available at http://ssrn.com/abstract=1398746.

¹²⁷ Since the ACTA Preamble refers to the Doha Declaration, one can safely conclude that the role para. 5 a) of the Doha Declaration foresees for Art. 7, 8 TRIPS also applies for ACTA.

¹²⁸ Art. 2 ACTA has as its title: "NATURE AND SCOPE OF OBLIGATIONS".

main effect will again be on open and ambiguous provisions in ACTA – while it is less likely to impact on most of the concise and detailed TRIPS-plus provisions.¹²⁹

References to Other Specific TRIPS Flexibilities: While these more general references to exceptions and flexibilities primarily stem from the newer generation of European Union FTAs, some United States FTAs also contain references to specific TRIPS flexibilities. In relation to the scope of patentable subject matter, the United States – CAFTA DR, United States – Colombia FTA and United States – Peru TPA all contain the following clause:

"Nothing in this Chapter shall be construed to prevent a Party from excluding inventions from patentability as set out in Articles 27.2 and 27.3 of the TRIPS Agreement. Notwithstanding the foregoing, any Party that does not provide patent protection for plants by the date of entry into force of this Agreement shall undertake all reasonable efforts to make such patent protection available. Any Party that provides patent protection for plants or animals on or after the date of entry into force of this Agreement shall maintain such protection." ¹³⁰

Analysis: The first sentence clarifies that the IP FTA obligations shall not be understood in a way that affects the flexibilities in Article 27:2, 3 TRIPS to exclude certain inventions from patentability. The right to exercise these flexibilities hence prevails over any TRIPS-plus provisions which might suggest otherwise. Where such provisions exist, they would have to be interpreted in a manner which allows relying on Art. 27:2, 3 TRIPS. The language used in the first sentence thus appears as an effective way to safeguard (specific) TRIPS flexibilities.

However, sentences 2 and 3 qualify the right to rely on Article 27:2, 3 TRIPS: Regarding the patentability of plants, the contracting parties must 'undertake all reasonable efforts' to foresee such protection in their national laws. Legally, this does not seem to affect the safeguard of the first sentence in a meaningful way. FTA parties should be able to decide autonomously what 'reasonable efforts' they undertake and they could arguably use internal opposition as an excuse for not (yet) providing patents for plants. The more decisive qualification is contained in the third sentence whereby any FTA party that already foresees patents for plants or animals must maintain this level of protection. This 'freezes' domestic TRIPS-plus laws and does not allow FTA parties to rely on the flexibilities in Article 27:2, 3 TRIPS to change their law. Such 'freeze-clauses' thus prevent countries from exercising existing flexibilities to adapt their IP system to the changing economic,

¹²⁹ See also Chapter 3, Sections 1.1, 1.5 and 1.6.

¹³⁰ See Art. 15.9 US CAFTA DR, Art. 16.9:2 United States – Colombia FTA, Art. 16.9:2 United States – Peru TPA. (emphasis added).

technological and societal context. Given the importance of being able to dynamically adapt the domestic IP framework, countries should carefully consider the implications of such clauses, and generally refrain from agreeing to them.

Intellectual Property – Investment Related Flexibilities: Further examples for FTA clauses upholding specific TRIPS flexibilities can be found in basically all investment chapters of Unite States FTAs¹³¹ They primarily relate to prohibitions of expropriation and technology transfer requirements and define the relation of those general investment protection standards to specific exceptions and limitations allowed under TRIPS.¹³² Identical provisions exist in the 2012 United States Model for a BIT and in recent United States BITs.¹³³ These clauses aim to ensure that investment standards – especially relating to (indirect) expropriation – do not interfere with the exercise of TRIPS flexibilities. As discussed in chapter 3 sections 2.3 and 2.4, they however might invite IP-owning investors to challenge compliance with the respective TRIPS flexibilities within ISDS proceedings.¹³⁴ Countries should therefore rather opt for clauses that ensure investment standards are understood and applied in a way that relevant TRIPS flexibilities remain effective.¹³⁵

¹³¹ See Art.10.6:5 and Art.10.8:3 (b) i) US Morocco FTA, Art.10.6:5 and Art.10.8:3 (b) i) US Oman FTA, Art.11.7:5 and Art.11.9:3 (b) i) US Australia FTA, Art.15.6:5 and Art.15.8:3 (b) i) US Singapore FTA, Art.10.7:5 and Art.10.9:3 (b) i) US CAFTA, Art.10.7:5 and Art.10.9:3 (b) i) US Panama TPA, Art.10.9:5 and Art.10.5:3 (b) i) US Chile FTA, Art.10.7:5 and Art.10.9:3 (b) i) US Colombia FTA, Art.10.7:5 and Art.10.9:3 (b) i) US Peru TPA, Art.11.6:5 and Art.11.8:3 (b) i) US Korea FTA; as well as Art. 82.5 JAPAN – CHILE FTA (2007).

The standard provision on expropriation states that it "does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter Seventeen (Intellectual Property Rights)" (emphasis added); see e.g. Art.10.7:5 US CAFTA DR. The prohibition to impose certain technology- or other proprietary knowledge transfer conditions usually does not apply "when a Party authorizes use of an intellectual property right in accordance with Article 31 of the TRIPS Agreement, or to measures requiring the disclosure of proprietary information that fall within the scope of, and are consistent with, Article 39 of the TRIPS Agreement"; see Art.15.8:3 (b) i) US Singapore FTA.

¹³³ See Art.6.5 of the 2012 US Model BIT. Accordingly, the standards on expropriation do "not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement." Under Art.6:5 of the recent US – Uruguay and US – Rwanda BITs, this type of safeguard clause extends further to cover not only compulsory licenses, but also "the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with the TRIPS Agreement." See for a further discussion: Chapter 1 Section 4, and Chapter 3 Section 2.3 and 2.4.

¹³⁴ But these clauses allow investors to raise the issue of TRIPS consistency in ISDS proceedings. Distinct to the WTO dispute settlement system, private parties therefore can challenge the compliance of domestic laws with the TRIPS Agreement in front of international (quasi) judicial bodies. This implies a significant departure from the WTO/TRIPS system which in turn challenges the substantive coherence established by these consistency clauses in the first place; for a detailed discussion see *H Grosse Ruse – Khan*, The protection of intellectual property in international law (OUP, 2016), Chapter 7.

¹³⁵ See Chapter 3 Section 2.4.

Conclusion for Chapter 4: In sum, references to TRIPS flexibilities are often 'subject to' TRIPS-plus FTA obligations which limit their application and hence the ability to safeguard the flexibilities declared applicable. In cases of *general* references, their main role is to ensure – to the extent possible – coherence between TRIPS-plus FTA obligations and the right to use TRIPS flexibilities. Their effectiveness as a TRIPS flexibility safeguard can be significantly enhanced where TRIPS-plus obligations are made 'subject to' the right to use TRIPS flexibilities. This has the following effect: instead of limiting the operation of the reference-clause by the TRIPS-plus obligations in the FTA, such obligations then are limited by TRIPS flexibilities. If countries wish to give preference to TRIPS flexibilities over FTA TRIPS-plus obligations, they might consider a general clause that makes obligations for protecting and enforcing IP rights subject to the right to use flexibilities in TRIPS in general, or to use specific, enumerated flexibilities (such as on those on compulsory licensing, exhaustion, or patentable subject matter).

Clauses with *specific* references to TRIPS flexibilities in turn are more likely to allow the referenced flexibility to prevail over TRIPS-plus FTA obligations. Effective for example would be clauses referring to specific TRIPS flexibilities in a way that 'nothing in the FTA IP provisions shall be construed to prevent' a FTA party from relying on a specific TRIPS provision. Countries wishing to ensure that they can continue to rely on specific flexibilities therefore should consider a clarifying clause along the lines of the above.

Another, more general implication of these specific references is that they can operate to integrate the referred flexibility into the FTA. Similar to the references to the Doha Declaration, the TRIPS flexibility then becomes part of the treaty's rights and obligations and can therefore have a greater and more direct impact on IP obligations in FTAs. Referring to Articles 7 and 8 TRIPS, perhaps with the clarification that these provisions are meant to operate as object and purpose guiding the interpretation of the FTA IP provisions, will include these core horizontal flexibilities into the FTA and ensure that the FTA parties can interpret and implement their agreement in line with the key multilateral IP flexibilities.

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