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The Impact of Free Trade Agreements on the Protection of Intellectual Property in the European Union

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Abstract

This thesis examines how modern free trade agreements (FTAs) influence intellectual property (IP) protection in the European Union (EU) and which legal challenges follow. It combines doctrinal analysis of EU secondary law and Court of Justice case law with a problem-driven comparison of IP chapters in CETA, the EU–Japan EPA, the EU–Korea FTA and the EU–Singapore FTA, while TTIP is used only as a counterfactual comparator. Four sectoral case studies (pharmaceuticals, digital/technology, creative industries, and geographical indications) trace how treaty commitments translate into concrete legal effects.

The thesis identifies three main impact channels. First, FTAs can export EU regulatory templates, reducing transaction costs and misappropriation risks in partner markets. Second, they can harden selected baseline choices in treaty form, thereby raising the political and legal cost of later recalibration. Third, they can also shift governance through committee-managed updating and dispute settlement, relocating parts of regulatory adjustment away from ordinary legislative processes.

These effects are constitutionally mediated. The Charter-based proportionality framework and the autonomy of EU law limit external "overreach": CJEU jurisprudence on Supplementary Protection Certificates (SPCs), copyright exceptions and intermediary liability, as well as *Opinion 1/17* on CETA's Investment Court System (ICS), confirm that treaty commitments cannot displace fundamental-rights safeguards or the Union's interpretative monopoly. Therefore, the core tension is not "more" or "less" IP protection in the abstract, but whether FTAs preserve meaningful regulatory space for public-interest measures in access-sensitive domains (public health, data protection, freedom of expression and cultural access).

The thesis recommends a differentiated and constitutionally reflexive FTA strategy: operational public-interest safeguards (health and digital enforcement), enhanced transparency and participation, autonomy-preserving dispute-settlement design, and sector-sensitive flexibility rather than uniform TRIPS-plus drafting.

Keywords: Free Trade Agreements, Intellectual Property, EU law, TRIPS-plus, supplementary protection certificates, intermediary liability, geographical indications, regulatory autonomy, Charter, CJEU.

Zusammenfassung

Diese Masterarbeit untersucht, wie moderne Freihandelsabkommen (FTAs) den Schutz geistigen Eigentums (IP) in der Europäischen Union (EU) beeinflussen und welche rechtlichen Konflikte daraus entstehen. Sie verbindet eine dogmatische Analyse des EU-Sekundärrechts und der EuGH-Rechtsprechung mit einem problemorientierten Vergleich der IP-Kapitel in CETA, EU–Japan EPA, EU–Korea FTA und EU–Singapur FTA, während TTIP lediglich als kontrafaktischer Referenzpunkt dient. Vier Fallstudien (Pharmazeutika, digitale/technologische Märkte, Kreativindustrien sowie geografische Angaben) zeigen, wie Vertragsverpflichtungen in konkrete Rechtswirkungen übersetzt werden.

Die Arbeit identifiziert drei Wirkungsmechanismen. Erstens können FTAs EU-Regulierungsmodelle exportieren und damit Transaktionskosten sowie Aneignungsrisiken in Partnerstaaten verringern. Zweitens können FTAs ausgewählte Basiskompromisse verfestigen, indem sie diese völkervertraglich „härten“ und dadurch spätere Neukalibrierungen erschweren. Drittens können FTAs Governance-Effekte erzeugen (Ausschüsse/Komitees, Streitbeilegung), die Teile der Anpassung aus den ordentlichen Gesetzgebungsprozessen heraus verlagern.
Diese Effekte werden verfassungsrechtlich vermittelt. Die Grundrechtecharta (Verhältnismäßigkeit) und das Autonomieprinzip begrenzen externes „Overreach“: EuGH-Rechtsprechung zu Supplementary Protection Certificates (SPCs), urheberrechtlichen Schranken und Intermediärhaftung sowie Gutachten 1/17 zum CETA- Investment Court System (ICS) zeigen, dass Vertragsbindungen Grundrechtsschutz und die Auslegungszuständigkeit des EuGH nicht verdrängen dürfen. Entscheidend ist daher nicht „mehr“ oder „weniger“ IP-Schutz im Abstrakten, sondern ob FTAs einen effektiven Regulierungsraum für Maßnahmen im öffentlichen Interesse sichern (Gesundheit, Datenschutz, Meinungsfreiheit, kultureller Zugang).

Empfohlen wird eine differenzierte, verfassungsreflexive FTA-Strategie: operative Schutzklauseln (Gesundheit und digitale Durchsetzung), mehr Transparenz und Beteiligung, autonomiewahrende Streitbeilegung und sektorenbezogene Flexibilität statt einheitlicher TRIPS-plus-Standards.

Schlagwörter: Freihandelsabkommen, geistiges Eigentum, Unionsrecht, TRIPS-plus, ergänzende Schutzzertifikate, Intermediärhaftung, geografische Herkunftsangaben, regulatorische Autonomie, Grundrechtecharta, EuGH.

Foreword

This thesis was written within the master's program in European and International Business Law (LL.M.) at the University of Vienna. My interest in the topic grew from the increasing constitutional and societal salience of "new generation" EU free trade agreements, particularly where intellectual property protection interacts with access to medicines, digital enforcement, and regulatory autonomy. Working at the interface between EU internal policy and external economic relations has also highlighted how the autonomy of EU law and the Charter of Fundamental Rights shape the legal space within which trade commitments operate.

I am grateful to my supervisor, Prof. Gabriel M. Lentner, for his thoughtful guidance and constructive feedback throughout the research and drafting process. I also thank Prof. Siegfried Fina and the program manager Dr. Maria Sturm for their support and practical assistance during my studies. I am especially thankful to my family for their encouragement and patience, especially during the writing period.

This work is dedicated to my parents, and especially to the memory of my father. Completing this mater's program alongside a full-time job and the responsibilities of fatherhood was not always easy. In Fact, it would not have been possible without the unwavering support of my wife and daughter. Therefore, I am especially grateful to them for their love, patience, unconditional support, and for making this journey possible.

List of Abbreviations

CCP	Common Commercial Policy (TFEU art 207)
CETA	Comprehensive Economic and Trade Agreement (EU–Canada)
CIPO	Canadian Intellectual Property Office
CJEU	Court of Justice of the European Union
DMCA	Digital Millennium Copyright Act (United States)
DRM	Digital rights management
DSA	Digital Services Act (Regulation (EU) 2022/2065)
DSM Directive	Directive (EU) 2019/790 on Copyright in the Digital Single Market
EPA	Economic Partnership Agreement
E-Commerce Directive	Directive 2000/31/EC on Electronic Commerce
ECLI	European Case Law Identifier
ECR	European Court Reports
Enforcement Directive	Directive 2004/48/EC on the Enforcement of IPRs
EPC	European Patent Convention
EPO	European Patent Office
EPRS	European Parliamentary Research Service
EU	European Union
EUIPO	European Union Intellectual Property Office
EUTM	European Union Trade Mark
EUTMR	Regulation (EU) 2017/1001 on the EU Trade Mark
EU–Japan EPA	Economic Partnership Agreement between the EU and Japan (in force 2019)
EU–Korea FTA	EU–Republic of Korea Free Trade Agreement (in force 2011)
EU–Singapore FTA (EUSFTA)	EU–Singapore Free Trade Agreement (in force 2019)
FDI	Foreign Direct Investment
FTA	Free Trade Agreement
GI	Geographical Indication
ICS	Investment Court System
ICT	Information and Communication Technology
InfoSoc Directive	Directive 2001/29/EC on Copyright in the Information Society

IP	Intellectual Property
IPR	Intellectual Property Right
OJ	Official Journal of the European Union
R&D	Research and Development
RCD	Registered Community Design
RMI	Rights-management information
SME	Small and Medium-sized Enterprise
SPC	Supplementary Protection Certificate
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
TPMs	Technological protection measures
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TRIPS-plus (TRIPS+)	Standards exceeding TRIPS minimum requirements
TTIP	Transatlantic Trade and Investment Partnership (proposed)
UP (Unitary Patent)	European patent with unitary effect (Reg (EU) 1257/2012; 1260/2012)
UPC	Unified Patent Court
UPC Agreement	Agreement on a Unified Patent Court
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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Declaration of Academic Integrity

I hereby confirm that I prepared this Master Thesis independently and on my own, by exclusive reliance on the tools and literature indicated therein. The sources of other people's work have been appropriately referenced. Quotation marks are used around materials written verbatim from other sources.
The thesis has not been submitted to any other examination board.

Vienna, 13 March 2026
Majed Rezko

Introduction

In a globalized economy, the protection of intellectual property (IP) is widely regarded as a cornerstone of international trade, innovation policy, and economic development. Intellectual property rights (IPRs) are considered to play a significant role in fostering creativity, technological advancement, and competitiveness by granting legal protection to inventions, literary and artistic works, trade marks, and other intangible assets used in commerce[1]. According to this prevailing view, by providing exclusive rights to creators and inventors over their creations, IP law underpins investment in research and creative activity, thereby facilitating cross-border knowledge exchange[2]. Hence, proponents argue that effective protection and enforcement of IPRs is essential not only to support economic prosperity and foster innovation as well as artistic expression within domestic markets, but also to promote international trade and investment. Based on empirical data from the European Patent Office (EPO)/European Union Intellectual Property Office (EUIPO) report, "taking both goods and services trade into account, in 2017–2019, 80.5% of EU imports and 80.1% of EU exports were generated by IPR-intensive industries"[3]. Nonetheless, a significant body of critical scholarship – especially within development studies and global-health discourse – contests these assumptions, cautioning that stronger IPRs can limit access to knowledge and essential medicines and do not necessarily translate into uniform developmental gains[4].This normative ambivalence situates IP protection at the intersection of economic liberalization and public-interest regulation, a tension that becomes especially pronounced in the European Union (EU)'s external trade policy.

As one of the world's largest economic blocs and a highly influential actor in shaping global trade rules[5], the EU has responded to these imperatives by developing a sophisticated and

[1] European Patent Office and European Union Intellectual Property Office, 'IPR-Intensive Industries and Economic Performance in the European Union - Industry-Level Analysis Report, Fourth Edition' (2022).
[2] World Intellectual Property Organization (WIPO), *World Intellectual Property Report 2024: Making Innovation Work for Development* (1st edn, WIPO 2024); European Patent Office and European Union Intellectual Property Office (n 1).
[3] European Patent Office and European Union Intellectual Property Office (n 1) 70.
[4] FM Abbott and JH Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 Journal of International Economic Law 921, 925; Susan K Sell (ed), *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press 2003); Daniel J Gervais (ed), *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-plus Era* (Second edition, Oxford University Press 2014) 39–40.
[5] Anu Bradford, *The Brussels Effect: How the European Union Rules the World* (Oxford University Press 2020) chs 2–3; European Commission, 'Trade Policy Review - An Open, Sustainable and Assertive Trade Policy'; European Council (Consilium), 'The EU's Role in Global Trade'

harmonized legal framework for IP protection, reflecting its dual ambition to stimulate economic growth and safeguard fundamental rights[6]. Yet, the landscape of IP protection in the EU is increasingly influenced by the expansion of modern Free Trade Agreements (FTAs), which extend far beyond traditional tariff reduction to encompass a broad range of regulatory disciplines.

Modern FTAs such as the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada, the EU-Japan Economic Partnership Agreement (EU–Japan EPA), the EU-Republic of Korea Free Trade Agreement (EU–Korea FTA) and the EU–Singapore Free Trade Agreement (EU–Singapore FTA) exemplify this trend toward embedding "TRIPS-plus" standards that often exceed the minimum requirements of the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These agreements are designed to promote regulatory convergence, enhance enforcement mechanisms, reduce trade barriers, and establish higher standards of IP protection among signatories[7]. Although these provisions promise to encourage trade and reinforce legal certainty, they also introduce new legal complexities and intensified debates about the appropriate balance between market integration, regulatory autonomy, and the protection of fundamental rights within the EU's constitutional order. Concerns have emerged, including challenges related to the harmonization of national laws across Member States, the enforcement of IPRs, the risk of regulatory fragmentation, and questions regarding compatibility with existing EU regulations, directives, and judicial interpretations. Furthermore, the introduction of investment protection and dispute settlement mechanisms – particularly under the Investment Court System (ICS) – has attracted constitutional scrutiny of their alignment with the Court of Justice of the European Union (CJEU)'s case law on the autonomy of EU law[8]. These tensions become especially evident in extremely sensitive domains such as pharmaceuticals, digital copyright, and geographical indications (GIs), where the interaction between trade liberalization and the protection of fundamental rights is most acute.

<https://www.consilium.europa.eu/en/infographics/the-eu-s-role-in-global-trade/> accessed 16 October 2025.

[6] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L157/45.

[7] Economic Partnership Agreement between the European Union and Japan [2018] OJ L330/3 ch 14; Free trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part [2011] OJ L127/6 ch 10; Free trade Agreement between the European Union and the Republic of Singapore [2019] OJ L294/3 ch 10; Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part [2017] OJ L11/23 ch 20.

[8] *Opinion 1/17 CETA EU:C:2019:341*; *Case C-284/16 Slovak Republic v Achmea BV EU:C:2018:158*.

Against this background, the thesis undertakes a critical analysis of the impact of modern FTAs on the protection of IP within the EU, focusing on the legal implications, emerging disputes, and constitutional limitations associated with such agreements. Accordingly, the analysis centers on the following key research question:
How do modern Free Trade Agreements influence the protection of intellectual property in the EU, and which legal challenges do they trigger?

To address this research question, the thesis adopts a qualitative, doctrinal legal research methodology, supplemented by elements of comparative and case study analysis. The research primarily involves a detailed examination of the legal texts of relevant FTAs, with emphasis on those currently in effect (CETA, EU–Japan EPA, EU–Korea FTA and E-Singapore FTA). Where analytically appropriate, draft textual proposals from the (ultimately not further pursued) Transatlantic Trade and Investment Partnership (TTIP) are employed illustratively as a counterfactual benchmark. This allows the study to evaluate how far current and prospective trade agreements extend, replicate, or challenge existing EU standards. Additionally, the research draws upon secondary sources such as academic literature, reports from EU institutions, and policy documents to contextualize the legal analysis and assess broader implications.

A structured comparative approach is applied throughout to identify both areas of alignment and divergences between FTA obligations and EU law. The analysis proceeds along four distinct dimensions. First, it reconstructs the relevant EU baseline – including secondary legislation, Charter rights, and case law of the CJEU – as the analytical foundation for understanding the subject matter. Second, it identifies the corresponding FTA commitments, including the direction and legal channel of their impact on that baseline. Third, it examines empirical and political responses at EU and Member State level. Finally, it assesses the resulting normative and constitutional implications, specifically for innovation, access to knowledge and medicines, and the protection of fundamental rights. This analytical framework is outlined in this Introduction and elaborated in Chapter 2. Then, it is subsequently operationalized through the doctrinal analysis in Chapter 3 and the sectoral case studies in Chapter 5, where it is applied explicitly under four headings (EU baseline; FTA commitments and direction of impact; empirical and political responses; normative and constitutional tensions).

The significance of this research lies in its potential to contribute to ongoing debates about the legitimacy, effectiveness, and future development of the EU's dual role as both a global standard-setter in IP law and a guardian of fundamental rights. By providing a critical evaluation of the strengths and weaknesses of current FTA provisions, the thesis aims to offer valuable insights for policymakers, legal practitioners, and scholars engaged in the evolving intersection between international trade law and IPRs within the EU and beyond.

To summarize, the thesis is divided into seven chapters. Chapter 1 sets out the internal legal and institutional framework governing IP protection in the EU. Chapter 2 traces the evolution and the design of modern FTAs and analyses their IP chapters, with particular attention to CETA and the EU's agreements with Japan, Korea and Singapore. Chapter 3 examines the interaction between these agreements and the EU acquis, focusing on harmonization dynamics, potential legal frictions and the treatment of IP as a protected "investment". Chapter 4 turns to competence questions and constitutional safeguards, especially the autonomy of EU law and the role of the Charter of Fundamental Rights. Chapter 5 develops four sectoral case studies – covering pharmaceuticals, digital technologies, creative industries and GIs – in order to demonstrate how FTA commitments operate in practice within specific regulatory contexts. Chapter 6 offers a critical evaluation of the existing regime and formulates proposals for the future development of EU legislation and treaty practice. Finally, Chapter 7 draws together the main findings, answers the central research question and reflects on the constitutional boundaries of the EU's external IP policy.

1 Legal Framework for Intellectual Property Protection in the European Union

1.1 Definition and Significance of Intellectual Property

IP refers to the exclusive rights granted to natural or legal persons over intangible creations, including inventions, literary and artistic works, symbols, names, and designs utilized in commerce[9]. Internationally and within the EU, these entitlements are derived from a variety of instruments and legal frameworks such as the Paris and Berne Conventions, the WTO TRIPS-Agreement, and EU secondary legislation[10]. In policy discourse, IPRs are often justified as mechanisms to stimulate innovation and creative activity by allowing rightsholders to appropriate returns on their investments, while simultaneously promoting disclosure and enabling licensing markets[11]. Concurrently, the strength, scope and design of such exclusivities are contested, and leading instruments expressly frame IP protection within broader public-interest objectives. This is reflected in TRIPS Articles 7-8, which emphasize that IPRs must contribute to social and economic welfare and allow Members to adopt measures to protect public health and other vital interests[12]. As Correa notes, these provisions operate as interpretative principles that condition the reading of substantive TRIPS obligations[13]. This dual nature – private reward balanced against public interest – remains central to the EU's constitutional approach to IP as will be explored in detail in the following chapters.

Legally, IPRs are conceived not as absolute monopolies but as limited exclusive entitlements that must be interpreted with regard to competing interests, including fundamental rights such

[9] Lionel Bently and others, *Intellectual Property Law* (6th edn, Oxford University Press 2022) 1–3; Fredrik Erixon and others, 'The Benefits of Intellectual Property Rights in EU Free Trade Agreements' (European Centre for International Political Economy (ECIPE) 2022) Occasional Paper No 3/2022 19; World Intellectual Property Organization (WIPO) (ed), *WIPO Intellectual Property Handbook: Policy, Law and Use* (2nd ed., reprint 2008, WIPO 2004) 3.

[10] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299; Berne Convention for the Protection of Literary and Artistic Works (Paris Act, 24 July 1971, as amended 28 September 1979) 1161 UNTS 3; Paris Convention for the Protection of Industrial Property (Stockholm Act, 14 July 1967, as amended 28 September 1979) 1967 828 UNTS 305; Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the Harmonisation of Certain Aspects of Copyright and Related Rights in the Information Society [2001] OJ L167/10,; Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L157/45; Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark [2017] OJ L154/1.

[11] World Intellectual Property Organization (WIPO) (n 9) 3; Keith E Maskus, *Intellectual Property Rights in the Global Economy* (Inst for Internat Economics 2000) ch 5.

[12] TRIPS Agreement arts 7–8.

[13] Carlos María Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Second edition, Oxford University Press 2020) ch 4.

as freedom of expression and access to information[14]. This principle has been endorsed repeatedly by the CJEU, which frames IP protection as a system of "fair balance" rather than unqualified exclusivity [15]. Leading EU scholarship has reinforced this approach, treating IP as a field of careful calibration in which limitations, exceptions, and users' interests play a constitutive role in shaping the scope of protection[16]. Conversely, critical scholars have warned that expansive protection risks enclosing the public domain and constraining the conditions for follow-on innovation, thereby undermining the very processes of creativity and knowledge diffusion that IP is intended to foster[17].

Politically, IP has become a strategic component of trade governance and an instrument of regulatory power. Bradford describes this phenomenon as the "Brussels Effect", capturing how EU rules – including those on IP – are effectively exported when firms worldwide adopt them to secure access to the EU market[18]. Under this dynamic, the EU's external IP policy functions both as a projection of its internal regulatory model and as a negotiation tool to obtain reciprocal protection abroad.

In fact, a substantial critical literature situates IP chapters in trade agreements within North–South distributive politics and private interest mobilization. Susan K. Sell argues that developed countries, above all the United States (US) and the EU, use IP provisions in trade agreements to protect their economic interests and exert global influence[19]. For instance, in trade negotiations such as those involving the WTO or bilateral agreements like CETA, IP protection often becomes a contentious issue, manifesting power imbalances between developed and developing nations[20]. Other critical voices, such as Ruth Okediji and Amy Kapczynski, have also underscored the distributive politics of IP. Okediji locates developing

[14] Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the Harmonisation of Certain Aspects of Copyright and Related Rights in the Information Society [2001] OJ L167/10,; Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC [2019] OJ L130/92; Charter of Fundamental Rights of the European Union [2012] OJ C326/391.

[15] Charter of Fundamental Rights of the European Union [2012] OJ C326/391 art 11,17; *Case C-70/10 Scarlet Extended SA v Société belge des auteurs, compositeurs et éditeurs SCRL (SABAM) EU:C:2011:771*; *Case C-360/10 Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM) v Netlog NV EU:C:2012:85*.

[16] Christophe Geiger and Elena Izyumenko, 'Copyright on the Human Rights' Trial: Redefining the Boundaries of Exclusivity Through Freedom of Expression' (2014) 45 IIC – International Review of Intellectual Property and Competition Law 316.

[17] James Boyle, *Public Domain: Enclosing the Commons of the Mind* (Yale University Press 2008) chs 3–4; Amy Kapczynski, 'Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector' (2009) 97 California Law Review 1571, 1588–1600.

[18] Bradford (n 5) ch 2,5-6.

[19] Sell (n 4).

[20] ibid.

country participation in the global IP system within competing "human rights, cultural, and welfare-enhancing" narratives that challenge OECD dominance[21]. Kapczynski extends this critical perspective by analyzing the emergence of the "Access to Knowledge (A2K)" movement, which re-conceptualizes IP as a site of democratic contestation[22]. In other words, developing countries often claim that strong IPR regimes favor wealthy nations by restricting access to knowledge and technology, while proponents in developed states advocate robust protection as a prerequisite for global trade and innovation[23]. Together, these perspectives contend that IP norms negotiated through FTAs are not merely technical trade provisions, but rather, they reflect deeper ideological conflicts over knowledge governance and global equity.

From an economic standpoint, the justification for implementing protective IP policies is firmly rooted in foundational economic theories. These theoretical frameworks are frequently invoked by policymakers and negotiators to support the inclusion of strong IP provisions, often presenting them as a precondition for technology transfer and sustainable growth. One influential example within this field is the growth theory developed by Joseph Schumpeter. In his seminal work, Schumpeter argues that temporary monopolies serve as incentives for firms to invest in research and development (R&D) driving industrial expansion[24].

Moreover, trade negotiators and policymakers often draw upon complementary theories of trade and investment. According to neoclassical trade theory, robust IPRs can reduce transaction costs and expand market access by standardizing standards across jurisdictions. It is widely argued in the literature on foreign direct investment (FDI) that multinational enterprises are more inclined to transfer technology and establish subsidiaries in environments where their intangible assets are legally protected. Empirical studies, such cross-country analysis conducted by Gould and Gruben, are regularly cited in support of this argument, demonstrating a positive correlation between IPR protection and higher growth rates in open economies[25]. Similarly, Keith Maskus asserts that IPRs are a critical driver of innovation, contributing to economic development by incentivizing firms to invest in R&D and enabling technological diffusion through FDI[26]. Maskus also underscores the role of IPRs in enabling access to international

[21] Ruth L Okediji, 'The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System' (2003) 7 Singapore Journal of International & Comparative Law 315, 317–319.
[22] Amy Kapczynski, 'The Access to Knowledge Mobilization and the New Politics of Intellectual Property.' (2008) 117 Yale Law Journal 804, 806-810,820-859.
[23] Gervais (n 4) 39–40.
[24] Joseph A Schumpeter, *Capitalism, Socialism and Democracy* (Routledge 2010).
[25] David M Gould and William C Gruben, 'The Role of Intellectual Property Rights in Economic Growth' (1996) 48 (2) Journal of Development Economics 323.
[26] Maskus (n 11) ch 5.

markets, as firms operating under robust IP protection frameworks are more likely to participate in trade and engage in cross-border licensing[27].

This relationship is especially clear in the context of the EU, which considers IPRs as central to its strategies for fostering economic growth and technological advancement as well. According to the 2022 EPO-EUIPO report over the 2017–2019 period, IP-intensive industries contributed 47.1% of the EU's GDP, generating around €6.4 trillion annually[28]. Likewise, they accounted for 29.7% of direct employment, equating to more than 61 million jobs[29]. Beyond providing direct employment, IPR-intensive industries contribute to further job opportunities in non-IPR-intensive fields, as they depend on these sectors for the supply of necessary goods and services[30]. Including these indirect effects, IPR-intensive total employment impact rises to over 81 million jobs or 39.4% of the EU workforce[31]. At the firm level, companies operating within IPR-intensive sectors consistently exhibit superior economic performance[32]. The report states that firms owning patents, trade marks, or designs outperform their counterparts in terms of productivity and competitiveness. For instance, wages in IPR-intensive industries are 41% higher compared to non-IPR-intensive sectors, reflecting the tangible benefits of IP protection in creating high-value employment opportunities[33]. This effect is most marked in technology-intensive and knowledge-driven industries, where the capacity for innovation is essential to achieving market leadership and attracting investment.

Overall, IP is conceptualized within the EU as a strategic asset for economic and competitive advancement, rather than merely a legal right. Data from the EPO and EUIPO reveal the significant economic impact of IP-intensive industries on GDP, employment, and firm-level performance. These figures, widely referenced in policy contexts, reflect the EU's rationale for advocating "TRIPS-plus" standards in its external trade agreements.

In spite of that, countervailing economic arguments highlight the contextual nature of these effects. Chu, Cozzi, and Galli explore the dynamic relationship between IPRs and economic growth, offering a nuanced view that emphasizes stage dependency[34]. Drawing on their analysis, the strength of IPR regimes must align with a country's level of economic

[27] Keith E Maskus, 'Intellectual Property Rights and Economic Development' (2000) 32 (3) Case Western Reserve Journal of International Law 471, 471–506.
[28] European Patent Office and European Union Intellectual Property Office (n 1) 17–19.
[29] ibid.
[30] ibid.
[31] ibid.
[32] ibid 20–21.
[33] ibid.
[34] Angus C Chu, Guido Cozzi and Silvia Galli, 'Stage-Dependent Intellectual Property Rights' (2014) 106 Journal of Development Economics 239, 239–249.

development. In emerging economies, moderate levels of IPR protection may be preferable, as overly stringent regimes can stifle domestic innovation and hinder knowledge spillovers[35]. On the contrary, in advanced economies, effective IP systems are regarded as indispensable for sustaining high levels of research activity and technological progress[36]. This stage-dependent perspective underscores the importance of designing IPR policies that are tailored to specific developmental contexts in order to maximize their positive impact on economic growth[37].
As a result, "economists and legal scholars have argued that nations should adopt strong IPR policies as a matter of promoting economic growth. But the governments of some states at a lower level of economic development might perceive the benefits of a weak IPR regime as being greater than the benefits derived from enacting a strong regime"[38].

In conclusion, the politics of IP in trade agreements are characterized by complexity and diversity, making it impossible to distill them into a single unified narrative. On the one hand, OECD actors rely on mainstream economic theories to promote strong IP protection policies. On the other hand, critical scholars and voices from developing countries draw attention to the distributive consequences of stringent IP standards, situating them within broader North-South asymmetries. These competing viewpoints shape the negotiation and design of IP chapters in modern FTAs and frame the analytical baseline for this thesis. Against this background, the present thesis does not attempt to resolve the empirical validity of these broader debates. Instead, the following sections examine how these justificatory narratives are operationalized within the EU legal order and projected through its external trade instruments.

1.2 Overview of Relevant EU Regulations and Directives

This section identifies the key EU instruments that constitute the internal "baseline" against which FTA IP commitments are assessed. Rather than cataloguing rules exhaustively, it highlights the legal parameters that FTAs may, export to partner jurisdictions, harden through treaty form, or re-route into governance/implementation channels that affect the EU's capacity to recalibrate its internal balances (developed in Chapters 3-4).

[35] ibid.
[36] ibid.
[37] ibid.
[38] Daniel J Gervais (ed), *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-plus Era* (Second edition, Oxford University Press 2014) 27.

1.2.1 Directive 2001/29/EC and Directive (EU) 2019/790 (Copyright and the Digital Single Market)

Directive 2001/29/EC, commonly referred to as the Information Society (InfoSoc) Directive, harmonizes key aspects of copyright and related rights across Member States considering the rapid technological developments associated with the digital environment. The directive grants authors exclusive rights to authorize or prohibit the reproduction and communication of their works to the public, including making them available online[39]. It also establishes legal safeguards against the circumvention of effective technological measures employed by rightsholders to protect their content, such as encryption and digital rights management (DRM) technologies[40].

While the directive establishes exclusive rights for authors, it also specifies exceptions and limitations intended to safeguard public interests. These include allowances for private copying, use for the benefit of people with disabilities, and certain uses for educational or research-related purposes, among others[41]. These exceptions reflect the directive's attempt to balance the protection of IPRs with access to knowledge and information in a digital society, which form the backbone of the CJEU's "fair balance" case law[42].

The directive, further, underscores the importance of effective enforcement mechanisms, encouraging Member States to adopt legal remedies against copyright infringements, including the distribution of counterfeit goods[43].

In response to the evolving digital landscape, Directive (EU) 2019/790 on Copyright in the Digital Single Market (DSM Directive) complements and updates this framework[44]. Notably, Article 17 introduces a new liability regime for online content-sharing service providers, obliging platforms to obtain licenses or ensure the removal of unauthorized content, a significant shift from the principles established in the 2001 directive[45]. Additionally, the DSM

[39] Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the Harmonisation of Certain Aspects of Copyright and Related Rights in the Information Society [2001] OJ L167/10, arts 2–4.
[40] ibid ,art 6.
[41] ibid ,art 5.
[42] *Case C-201/13 Johan Deckmyn and Vrijheidsfonds VZW v Helena Vandersteen and Others EU:C:2014:2132*; *Case C-70/10 Scarlet Extended SA v Société belge des auteurs, compositeurs et éditeurs SCRL (SABAM) EU:C:2011:771* (n 15); *Case C-360/10 Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM) v Netlog NV EU:C:2012:85* (n 15).
[43] Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the Harmonisation of Certain Aspects of Copyright and Related Rights in the Information Society [2001] OJ L167/10, art 8.
[44] Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC [2019] OJ L130/92.
[45] ibid ,art 17.

Directive strengthens the legal foundation for text and data mining and expands user rights in educational and research contexts[46]. While the InfoSoc Directive remains in force and continues to shape national laws and case law, the adoption of the DSM Directive signals a substantial step toward modernizing EU copyright law to better align with the realities of the digital single market.

In this thesis, the significance of these instruments lies in their role in constitutionalizing the internal balance (exclusive rights + enforceable exceptions) that FTA digital-enforcement clauses may exert indirect pressure on. The legal question is not whether enforcement is "strengthened", but whether external commitments risk hardening enforcement expectations in ways that compress the practical effectiveness of Charter-sensitive exceptions (see §§3.1-3.2; Chapter 4).

1.2.2 Regulation (EU) No 2017/1001 on the European Union Trade Mark

Regulation (EU) No 2017/1001 (EUTMR) constitutes the core legal instrument governing the registration, administration, and enforcement of trade marks within the EU. Through this regulation, businesses can obtain trade mark protection in all EU Member States via a single application submitted to the EUIPO, thus eliminating the need for multiple national filings and reducing administrative burdens[47].

The EUTMR confers exclusive legal protection on an EU trade mark proprietor, specifically granting the right to prevent third parties from using identical or similar signs for identical or similar goods and services that may cause confusion[48]. This protection extends to combating counterfeiting, unauthorized commercial use, and misleading marketing practices. Importantly, Article 60(1)(b) addresses the issue of bad-faith applications, allowing trade marks to be declared invalid where there is evidence that the applicant acted dishonestly or with the intention of undermining legitimate commercial interests[49].

Moreover, the regulation provides comprehensive mechanisms for enforcing trade mark rights, such as the ability to initiate civil proceedings against infringers and to seek remedies like injunctions, damages, and the destruction of infringing goods[50].

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[46] ibid ,art 3.
[47] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark [2017] OJ L154/1 art ,art 1.
[48] ibid ,art 9.
[49] ibid ,art 60(1)(b).
[50] ibid ,arts 122-124.

For the purposes of this thesis, the EUTMR is relevant as part of the internal acquis – indirectly shaped by FTA commitments on trade-mark enforcement and border measures – and as a benchmark for trade-mark-style protection of GIs in external agreements. Accordingly, it provides an internal reference point for evaluating when FTA GI clauses and coexistence solutions function as "trade mark analogues" that may diverge from, or interact uneasily with, the EU's own GI logic (see §3.2; §5.4).

1.2.3 Directive 2004/48/EC on the Enforcement of Intellectual Property Rights (the Enforcement Directive)

Directive 2004/48/EC on the enforcement of IPRs approximates legislative systems across the EU with respect to civil enforcement of IPRs. It establishes "minimum standards" that all Member States must implement in their national legal systems concerning civil enforcement mechanisms[51]. Among its core provisions are effective and proportionate remedies, such as 'injunctions'[52], 'corrective measures' including destruction or recall of infringing goods[53], and the award of 'damages' to compensate for the harm caused by the infringement[54].
The Directive's provisions apply to all IPRs covered by Union law or by Member States' national laws, with particular focus on civil-law procedures, and the CJEU has interpreted them in a series of judgments on proportionality and due process.

In brief, the Enforcement Directive provides the internal benchmark for assessing whether FTA enforcement clauses – civil, administrative and border measures – are compatible with the Union's proportionality requirements and fundamental-rights safeguards. Given the prevalence of the Directive's terminology in numerous FTA enforcement chapters, the analytical issue is not "more enforcement", but whether treaty framing can harden remedy expectations in Charter-sensitive contexts and thereby affect the EU's room for later recalibration (see §§3.1-3.2; Chapter 4).

[51] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L157/45.
[52] ibid ,art 11.
[53] ibid ,art 10.
[54] ibid ,art 13.

1.2.4 Regulation (EU) No 1257/2012 and the Agreement on a Unified Patent Court (Unitary Patent Package)

The Unitary Patent Package, comprising Regulation (EU) No 1257/2012, Regulation (EU) No 1260/2012, and the Agreement on a Unified Patent Court (UPC Agreement), represents a significant development in EU IP framework regarding the harmonization and efficiency of patent protection[55]. Under Article 2, the Regulation introduces a system where a European patent, once granted by the EPO under the European Patent Convention (EPC), can benefit from 'unitary effect' across all participating EU Member States[56]. Article 3 defines this unitary effect as uniform protection and equal legal effect in all the Member States that have signed and ratified the Regulation and the UPC Agreement[57].

The UPC Agreement, signed on 19 February 2013, complements unitary patent protection by creating a 'Unified Patent Court' – a specialized judicial body endowed with exclusive competence to adjudicate disputes arising from European patents both with and without unitary effect[58]. Articles 1-3 of the Agreement define the Court's legal status, its competence, and its jurisdictional scope[59]. This UPC system is designed to streamline litigation by enabling a single court ruling to have effect in all participating states, thus avoiding parallel litigation in multiple jurisdictions and minimizing the risk of inconsistent decisions.

For the present purposes, the Unitary Patent Package is relevant as an illustration of how internal market integration and external competitiveness concerns shape the EU's patent architecture, and as a comparator for specialized adjudicatory mechanisms in investment and FTA-related dispute settlement that are examined in later chapters. It also serves as an internal comparator for the "institutional design" question raised by investment adjudication in FTAs: specialized adjudication is not per se problematic, but it must operate within autonomy constraints and constitutional safeguards (see Chapter 4).

1.2.5 Directive 98/44/EC on the Legal Protection of Biotechnological Inventions

Directive 98/44/EC provides a harmonized legal framework for the patentability and protection of biotechnological innovations within the EU. Its main objective is to foster investment and research in the biotechnology sector by providing legal certainty and consistent standards for

[55] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L361/1.
[56] ibid ,art 2.
[57] ibid ,art 3.
[58] Agreement on a Unified Patent Court [2013] OJ C175/1.
[59] ibid ,arts 1-3.

the protection of such inventions across all Member States[60]. Under Article 1(1), Member States are required to protect biotechnological inventions under national patent law, aligning them with the general rules of patentability[61]. The Directive defines the criteria for patentability in Article 3(1), stipulating that biotechnological inventions are patentable if they are 'new', involve an 'inventive step', and are 'susceptible to industrial application', consistent with general patent law principles[62].

A crucial feature of the Directive is its emphasis on ethical boundaries. Article 6(1) excludes inventions whose 'commercial exploitation would be contrary to ordre public or morality' from patentability[63]. Notably, Article 6(2)(c) expressly prohibits the patenting of 'uses of human embryos for industrial or commercial purposes', highlighting the EU's commitment to upholding ethical standards in scientific and commercial practices[64].

Moreover, the Directive addresses the scope of protection for biological material. Article 5(2) establishes that 'an element isolated from the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention – even if it previously occurred in nature – provided that it meets the patentability criteria' [65]. However, Recital 23 clarifies that 'a mere discovery of a DNA sequence without indication of a function is not patentable'[66], thereby balancing innovation incentives with the need to prevent the monopolization of fundamental natural elements.

In terms of accessibility, the Directive makes clear in Article 12 that a 'compulsory licensing system must be available for situations in which a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, or vice versa'[67]. This provision supports the public interest by ensuring that critical technologies or resources remain available despite overlapping rights.

This instrument is relevant in sectors where trade commitments intersect with ethical limits on patentability and access to technologies in agriculture and health. Thus, it feeds into the analysis of how far FTAs may affect the Union's regulatory autonomy in ethically sensitive areas. In FTA terms, it underscores a fundamental design constraint: external IP commitments should

[60] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L213/13 ,rec 3.
[61] ibid ,art 1(1).
[62] ibid ,art 3(1).
[63] ibid ,art 6(1).
[64] ibid ,art 6(2)(c).
[65] ibid ,art 5(2).
[66] ibid ,rec 23.
[67] ibid ,art 12.

not harden contested ethical boundaries in ways that diminish the EU's capacity to uphold (or adapt) morality-based exclusions and access safeguards within its constitutional framework (see Chapter 4).

1.2.6 Regulation (EU) No 608/2013 concerning Customs Enforcement of Intellectual Property Rights

Regulation (EU) No 608/2013 lays down the rules governing customs enforcement of IPRs within the EU. Its primary objective is to provide a uniform legal framework that enables customs authorities to take proactive measures in order to detect and take action against goods suspected of infringing IPRs during importation, exportation, re-exportation, entry into or exit from the Union customs territory, or in transit, thereby strengthening the EU's capacity to prevent the circulation of counterfeit and pirated goods[68].

Under Article 3, rights holders, their representatives, and authorized users may submit applications requesting customs intervention. These applications must include evidence of ownership of the intellectual property rights concerned and relevant information to assist customs in identifying infringing goods[69]. Once an application is granted, customs authorities are empowered, pursuant to Article 17, to suspend the release of or detain goods suspected of infringing rights, pending further investigation[70].

This Regulation functions as the internal template for border-enforcement provisions in FTAs and will be used as a benchmark when assessing whether FTA commitments reinforce, duplicate or go beyond existing EU standards. Analytically, border measures illustrate how treaty commitments can export an enforcement template while shifting practical burden to administrative implementation and proportionality-sensitive safeguards in domestic procedures (see §3.1; Chapter 4).

1.2.7 Regulation (EC) No 469/2009 and Regulation (EU) 2019/933 (Supplementary Protection Certificates)

Regulation (EC) No 469/2009 concerning the supplementary protection certificate (SPC) for medicinal products establishes a sui generis right designed to compensate pharmaceutical patent

[68] Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003 [2013] OJ L 181/15 art 1, rec 1.
[69] ibid ,art 3.
[70] ibid ,art 17.

holders for the effective loss of patent term caused by lengthy marketing-authorization procedures. Under Articles 4 and 5, the SPC extends the protection conferred by the basic patent to the authorized medicinal product, conferring the same rights and obligations[71]. Under Article 13, the duration of the SPC is limited to a maximum of five years, thereby prolonging the period of market exclusivity beyond the standard twenty-year patent term[72].
By Regulation (EU) 2019/933, the SPC Regulation was amended to include a narrowly defined manufacturing waiver. This provision permits EU-based manufacturers of generics and biosimilars to produce for export to third-country markets and to stockpile for EU market entry immediately after SPC expiry[73]. The amendment reflects the EU's effort to recalibrate the balance between originator rights and the competitiveness of follow-on producers. This illustrates the evolving and dynamic character of the Union's pharmaceutical IP regime.

For the purposes of this thesis, the SPC framework is a key component of the internal acquis against which the patent-term restoration obligations in CETA and related pharmaceutical provisions in other FTAs are assessed. It provides an example of how finely tuned internal mechanisms may be affected when analogous standards are "locked in" at treaty level.
The scope and duration of SPCs have been refined by the CJEU in a series of judgments, including *Seattle Genetics (Case C-471/14), Teva v Gilead (Case C-121/17)* and *Santen (Case C-673/18)*[74]. Collectively, this case law underscores that SPCs are closely linked to EU pharmaceutical regulation and that their detailed configuration reflects ongoing legislative and judicial calibration.

Taken together, these instruments constitute the core of the EU's IP acquis. They define the scope of exclusive rights, the main exceptions and limitations, and the available enforcement mechanisms. They will serve as the reference framework for evaluating the substantive, procedural, and institutional consequences of modern FTA IP provisions in subsequent chapters. Crucially, they also define the internal "moving parts" that FTAs may stabilize externally. This line of inquiry is pursued subsequently, with the aim of ascertaining the

[71] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1 arts 4–5.
[72] ibid 13.
[73] Regulation (EU) 2019/933 of the European Parliament and of the Council - of 20 May 2019 - amending Regulation (EC) No 469 / 2009 concerning the supplementary protection certificate for medicinal products [2019] OJ L153/1 art 5(2).
[74] *Case C-471/14 Seattle Genetics Inc v Österreichisches Patentamt EU:C:2015:659*; *Case C-121/17 Teva UK Ltd and Others v Gilead Sciences Inc EU:C:2018:585*; *Case C-673/18 Santen SAS v Directeur général de l'INPI EU:C:2020:531*.

circumstances under which such stabilization strengthens legal certainty and diminishes constitutionally legitimate recalibration space (see Chapters 3-4).

1.3 Institutions and Mechanisms for Intellectual Property Protection in the EU

The institutional architecture of EU IP protection combines supranational and national actors. At Union level, specialized offices administer unitary rights and gather evidence on the economic role of IP-intensive industries, while the CJEU ensures the uniform interpretation of the acquis. National offices and customs authorities implement and enforce these rules on the ground. This subsection briefly presents the main institutions referenced that will feature in the analysis.

1.3.1 European Patent Office (EPO)

The EPO is a key institution in the European IP landscape, responsible for the examination and granting of patents under the EPC of 1973. Although the EPO is not an EU institution in the strict sense – it operates under the framework of the European Patent Organization, an independent intergovernmental body – it plays a fundamental role in facilitating patent protection across Europe[75]. The EPO administers a centralized filing and examination procedure by which applicants may obtain patent rights in multiple contracting states through a single European patent application.

In recent years, the EPO has also been instrumental in supporting the implementation of the Unitary Patent system, by administering European patents with unitary effect[76]. The grant practice of the EPO and the jurisprudence of its Boards of Appeal form a key component of the normative and practical framework, within which EU legislative measures and FTA commitments concerning patents operate.

1.3.2 European Union Intellectual Property Office (EUIPO)

The EUIPO is the central authority responsible for the registration and administration of trade marks and designs that are valid throughout the entire EU. Established in 1994 and based in Alicante, Spain, the EUIPO manages the EU Trade Mark (EUTM) and the Registered

[75] Convention on the Grant of European Patents (European Patent Convention) 1973.
[76] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L361/1.

Community Design (RCD) systems, offering businesses and individuals a unified, cost-effective mechanism for securing IP protection across all EU Member States[77].

Beyond its core registration functions, the EUIPO hosts the European Observatory on Infringements of IPRs, which brings together public and private stakeholders to strengthen cooperation, raise awareness, and develop strategies to combat IP infringements such as counterfeiting and piracy[78].

Last, the EUIPO also contributes significantly to evidence-based policymaking within the EU by conducting research and publishing studies on the economic and social impact of IPRs. These activities inform both internal legislative reforms and external trade policy, where the economic weight of IP-intensive sectors is often invoked to justify ambitious IP chapters in FTAs.

1.3.3 Court of Justice of the European Union (CJEU)

The CJEU serves as the supreme judicial authority in the EU responsible for ensuring the uniform interpretation and application of EU law, including in the field of IP. Its role is critical in safeguarding the coherence of the EU's legal framework and providing authoritative guidance on complex legal questions related to IPRs across all Member States[79].

In the context of IP protection, the CJEU adjudicates disputes arising from the interpretation of EU legislation, such as directives and regulations governing trade marks, designs, patents, and copyright. Through its preliminary-ruling jurisdiction, the CJEU developed key doctrines on the "fair balance" between IP and fundamental rights, on the interpretation and availability of supplementary protection certificates, and on the protection of geographical indications. The Court's case law provides the constitutional and doctrinal framework within which FTA commitments must operate and against which their compatibility is assessed (see Chapters 3–5).

1.3.4 National Intellectual Property Offices and Customs Authorities

Alongside EU-level institutions, the national IP offices of each Member State play a crucial role in the protection and enforcement of IPRs within the EU. These offices are responsible for

[77] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark [2017] OJ L154/1 art 151.

[78] European Union Intellectual Property Office (EUIPO), 'Consolidated Annual Activity Report' (2023) 12–13; Appendix F-2.

[79] Paul P Craig and Gráinne De Búrca, *EU Law: Text, Cases, and Materials* (8th edn, Oxford University Press 2024) 95–110; Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/1 art 267.

the registration of IPRs, apply EU-derived standards and cooperate with the EUIPO, EPO and EU Observatory[80]. National customs authorities acting under Regulation (EU) No 608/2013, constitute the first line of defense against counterfeit and pirated goods at the EU's external borders.

These national actors are central to the implementation of FTA commitments because border-enforcement and civil-remedy clauses ultimately depend on domestic procedures, capacity and resources. For this reason, they constitute the operational interface between the EU's external IP policy and the day-to-day enforcement of rights.

1.3.5 Unified Patent Court (UPC)

The UPC represents a major development in the European patent system, offering a centralized judicial forum for patent litigation across contracting Member States. Established under the Agreement on a Unified Patent Court, the UPC has exclusive jurisdiction over disputes concerning European patents and European patents with unitary effect, aiming to reduce fragmentation in patent enforcement and strengthen legal predictability for rights holders[81].

Although the UPC is an intra-EU instrument, its creation is often framed in terms of enhancing the EU's global competitiveness and providing an efficient enforcement environment for innovators. It therefore illustrates how internal institutional design and external trade objectives interact in the patent field

Overall, this institutional constellation underpins the EU's capacity both to implement its internal IP acquis and to project its regulatory preferences externally through FTAs. The following chapters examine how modern FTAs interact with this legal and institutional framework and to what extent they reinforce or destabilize the balances it embodies.

[80] Commission Recommendation (EU) 2024/915 of 19 March 2024 on measures to combat counterfeiting and enhance the enforcement of intellectual property rights [2024] OJ L 2024/915 rec 19, 40.

[81] Agreement on a Unified Patent Court [2013] OJ C175/1.

2 Modern Free Trade Agreements and Their Provisions on Intellectual Property Protection

In recent decades, modern FTAs have evolved beyond their traditional focus on reducing tariffs and trade barriers, with IP protection emerging as a key component. The integration of detailed IP chapters reflects the shift toward regulatory trade policy, particularly for economies with strong IP-intensive industries such as the EU. Modern FTAs seek to harmonize IP standards, strengthen enforcement mechanisms, and foster cooperation between signatory parties, thereby facilitating cross-border trade, technological exchange, and investment.

This chapter provides an overview of the key features of IP provisions in modern FTAs, focusing on their objectives, practical implications, and the legal and policy debates they have generated. Special attention is given to recent agreements CETA, the EU–Japan EPA, the EU–Korea FTA and the EU–Singapore FTA, which demonstrate the policy trade-offs and implementation challenges inherent in incorporating IP protection into modern trade agreements. The following discussion situates these agreements within the EU acquis (Chapter 1) and prefigures the doctrinal and constitutional tensions examined in Chapters 3-5.

2.1 The Evolution and Scope of Modern FTAs

Modern FTAs represent a new generation of international trade instruments that extend far beyond market access disciplines. Since the early 2000s, they have increasingly functioned as vehicles of regulatory cooperation, embedding disciplines in areas such as investment protection, competition law, labor rights, environmental sustainability, and digital trade[82]. This shift reflects the reality that trade today is deeply intertwined with global value chains and knowledge-intensive industries, where regulatory alignment is as important as tariff reduction. Within this broader regulatory scope, IP protection has emerged as one of the most prominent components of modern FTAs. Its prominence can be explained by three main factors. First, the global economy has become increasingly reliant on intangible assets, from pharmaceuticals and digital technologies to cultural goods and branding. Second, the limitations of multilateral frameworks such as the TRIPS Agreement have led advanced economies, with the EU among

[82] Pedro Roffe, 'Intellectual Property Chapters in Free Trade Agreements: Their Significance and Systemic Implications' in Josef Drexl, Henning Grosse Ruse - Khan and Souheir Nadde-Phlix (eds), *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* (Springer 2016) 17–40;
Marco M.Aleman, 'Impact of TRIPS-Plus Obligations in Economic Partnership- and Free Trade Agreements on International IP Law' in Josef Drexl, Henning Grosse Ruse - Khan and Souheir Nadde-Phlix (eds), *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* (Springer 2016) 61–85.

them, to pursue "TRIPS-plus" standards through bilateral and regional trade agreements. As Daniel Gervais observes, the proliferation of such agreements reflects the strategic use of FTAs to embed higher IP standards where TRIPS left flexibilities[83]. This trend is further confirmed in Peter Yu's analysis, which shows how perceived gaps in TRIPS have triggered increasingly stringent "TRIPS-plus" standards in FTAs[84]. Third, as discussed in §1.1, IP protection is viewed by policymakers as both a tool to secure competitive advantages for domestic industries and a bargaining chip in broader trade negotiations[85].

The EU has embraced a distinctive approach by utilizing FTAs to advance its regulatory preferences on a global scale, thereby strengthening its position as a "rule exporter" in the realm of international trade[86]. Hoekman and Kostecki describe this process as part of the political economy of trade, in which preferential agreements extend regulatory agendas beyond the multilateral system[87]. Complementing this, Horn, Mavroidis and Sapir provide empirical evidence of how EU and US FTAs embed far-reaching provisions, including in IP, that functionally go "beyond the WTO" in setting global standards[88]. Consequently, the EU has played a leading role in the incorporation of extensive IP provisions into modern FTAs. Its "new generation" FTAs attest to the transformation of IP chapters into comprehensive frameworks in themselves. These agreements regulate not only patents, trade marks, and copyrights but also areas such as GIs, digital enforcement mechanisms, and pharmaceutical data protection. Given these points, the EU pursues a dual strategy through the embedding of IP standards into trade agreements. Firstly, it seeks to harmonize legal regimes across partner countries. Secondly, it aims to export its regulatory model on a global scale. At the same time, as later chapters demonstrate, this outward-looking strategy also generates internal questions about sovereignty, regulatory space and the protection of fundamental rights.

Beyond the EU, the increasing incorporation of IP provisions in FTAs has also sparked considerable debate among policymakers, civil society groups, scholars, and stakeholders, many of whom represent perspectives from the Global South. As discussed in §1.1 and analyzed

[83] Gervais (n 38) 3–5.
[84] Peter K Yu, 'TRIPs and Its Discontents' (2006) 10 Marq. Intellectual Property L. Rev. 369, 383–385.
[85] Sell (n 4).
[86] Bradford (n 5) chs 2–3; European Commission, 'Trade Policy Review' (n 5); European Council (Consilium) (n 5).
[87] Bernard M Hoekman and Michel Kostecki, *The Political Economy of the World Trading System: The WTO and Beyond* (3rd ed, Oxford University Press 2009) ch 10.
[88] Henrik Horn, Petros C Mavroidis and André Sapir, 'Beyond the WTO? An Anatomy of EU and US Preferential Trade Agreements' (2010) 33 The World Economy 1565.

in more detail in §2.3, provisions that exceed TRIPS minimum standards are often perceived as reflecting the regulatory preferences of industrialized economies and as imposing IP models that do not necessarily correspond to the developmental needs or institutional capacities of lower-income countries.

In sum, despite the potential to strengthen legal protection for IPRs at the international level, modern FTAs risk deepening existing global asymmetries in access to knowledge and innovation. This duality remains a persistent tension in contemporary trade-policy discourse and underlines the need for a more balanced and context-sensitive approach to the design and implementation of IP provisions in trade agreements. The broader implications of this strategy – including questions of sovereignty, access to essential goods, and the balance between private rights and public interests – are examined in §2.3.

2.2 Detailed Analysis of Intellectual Property Provisions in Modern FTAs

This section identifies the FTA IP commitments that are most relevant to the research question. Namely, clauses that either (i) export the EU's internal templates (enforcement, GIs), (ii) harden time-bound exclusivities (pharmaceutical incentives), or (iii) shift calibration into treaty governance (lists, committees, dispute settlement). Therefore, the focus is on the direction and channel of impact, rather than on comprehensive treaty description (see Chapters 3-5).

The Comprehensive Economic and Trade Agreement between the EU and Canada

CETA stands as a paradigmatic example of a modern FTA that includes detailed and far-reaching provisions on IP. In other words, it functions as a central reference point because it combines TRIPS-plus pharmaceutical incentives, expansive GI recognition, and a detailed enforcement architecture in a single "template" agreement. Concluded in 2016 and provisionally applied since 2017, CETA reflects the strategic importance of IP in fostering innovation, facilitating trade, and ensuring the competitiveness of knowledge-based economies[89].

The IP chapter of CETA builds upon the commitments of both parties under the TRIPS Agreement, while introducing so-called "TRIPS-plus" obligations aimed at strengthening IP protection and enforcement. These commitments are shaped by the broader objectives of

[89] Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part [2017] OJ L11/23 ch 20.

regulatory coherence, legal certainty for investors, and the safeguarding of IP-intensive industries. As later chapters will show, these provisions are particularly significant where they interact with sensitive sectors such as healthcare and agriculture. For the purposes of this study, CETA's significance lies not only in its ability to "raise" protection standards, but also in its capacity to stabilize selected external baselines, consequently increasing the cost of later internal recalibration in sensitive fields (see §§3.1–3.2; §5.1)

CETA contains specific provisions regarding the protection of pharmaceutical patents. One of the most notable is patent term restoration or "sui generis protection", which allows for the extension of patent duration to compensate for time lost during the marketing approval process[90]. This measure is intended to encourage innovation in the pharmaceutical sector by providing a longer period of market exclusivity.
Indeed, CETA introduces a treaty-based mechanism for compensating regulatory delay. This mechanism operates alongside the Union's SPC regime and has implications for future legislative flexibility, which are examined in more detail in Chapter 3 and §5.1.

Apart from pharmaceutical patents, CETA also consolidates the protection afforded to GIs, a category of IP that designates goods by place of origin and associates them with specific qualities or reputational value derived from their geographical provenance. The Agreement's annex enumerates over 170 protected EU GIs alongside several Canadian GIs, prohibiting their imitation, translation, or evocation in the Canadian market[91]. From a legal perspective, the CETA list of GIs projects core elements of the EU's evocation-based protection model beyond the minimum standards set by TRIPS, while at the same time accommodating Canadian partner concerns through coexistence clauses for certain prior trade marks and generic terms. The key point for the research question is the governance channel. List-based protection and coexistence solutions can stabilize contested boundary choices (genericness, coexistence) outside ordinary EU legislative revision, thereby creating a potential coherence tension with the internal "high protection" GI baseline (see §3.2; §5.4). The practical and distributive effects of these choices are addressed in the agri-food case study (§ 5.4).

In addition to its focus on patents and GIs, CETA's IP chapter establishes a detailed enforcement regime designed to bolster the remedies and procedural tools available to IP

[90] ibid 20.27.
[91] ibid Annex 20-A.

rightsholders. This regime comprises measures related to civil procedures and remedies, border enforcement, and criminal sanctions for counterfeiting and piracy[92]. Notably, the agreement emphasizes the role of customs authorities in seizing infringing goods and provides deterrent-level penalties for willful IP violations[93]. Here, the analytic issue is the interaction between enforcement export and constitutional limits. The agreement can reinforce an enforcement-capable template abroad, but implementation and interpretative practice must remain compatible with proportionality and Charter-sensitive safeguards that structure EU enforcement doctrine (see Chapter 4). The extent to which this enhanced enforcement architecture serves to promote innovation and trade, as opposed to engendering risks of over-enforcement and imposing disproportionate burdens on smaller actors, is analyzed in greater depth in the following chapters.

In general, scholarship on "mega-regional" IP chapters supports the reading of CETA as a treaty-level hardening device rather than mere convergence. Cottier's analysis underscores how pharmaceutical incentives and enforcement clauses can narrow domestic regulatory flexibility[94]. On the contrary, *Opinion 1/17* (CETA/ICS) establishes the constitutional constraint that external commitments affecting fundamental EU competences are acceptable only if the autonomy of the EU legal order and the EU institutions' determination of the level of public-interest protection are preserved (see Chapter 4)[95].

EU–Japan Economic Partnership Agreement

The EU–Japan EPA, which entered into force on 1 February 2019, shares the EU's mega-regional architecture exemplified by CETA. It covers trade in goods and services, government procurement, IP, regulatory cooperation, and sustainable development, but differs in its sectoral priorities[96]. The EPA places relatively greater emphasis on agri-food market access, regulatory cooperation in sectors such as automotive and pharmaceuticals, and detailed sustainability and governance provisions, whereas CETA devotes more attention to investment protection and dispute settlement mechanisms[97].

[92] ibid 20, Sec. C-D.
[93] ibid 20.32–20.50.
[94] Thomas Cottier, 'Intellectual Property and Mega-Regional Trade Agreements: Progress and Opportunities Missed' in Stefan Griller, Walter Obwexer and Erich Vranes (eds), *Mega-regional trade agreements: CETA, TTIP, and TiSA: new orientations for EU external economic relations* (First edition, Oxford University Press 2017) 163–164.
[95] *Opinion 1/17 CETA EU:C:2019:341* (n 8).
[96] Economic Partnership Agreement between the European Union and Japan [2018] OJ L330/3.
[97] ibid 14.

In the copyright field, article 14.13 of the EU–Japan EPA obliges each party to ensure a term of protection of at least seventy years after the death of the author for most works. Although the details of implementation remain a matter of domestic law, the EPA consolidates this convergence by embedding high-standard copyright disciplines and establishing cooperation mechanisms between the parties. For EU cultural and creative industries, this reduces regulatory divergence in key export markets for audiovisual and publishing content and facilitates cross-border rights clearance, even though significant differences remain in the design of exceptions and limitations, collective management structures and platform regulation. For this thesis, the main relevance lies in the externalization of a long-duration baseline. Although the EPA does not amend EU law, it entrenches "life + 70" as a bilateral benchmark in a major market, thereby raising the justificatory threshold for later reopening of term-length debates (see §5.3).

Beyond the domain of copyright, the EPA's IP chapter contains provisions on enforcement, trade marks, designs and trade secrets that closely align with the foundational principles of the Union's internal framework and the orientation of the Enforcement Directive, including requirements on civil procedures, provisional measures and damages[98]. In the pharmaceutical area, the agreement establishes minimum common rules on the protection of undisclosed test data while leaving politically sensitive parameters – such as the precise duration and scope of protection – largely to domestic legislation[99]. Compared with CETA – whose Chapter 20 and pharmaceutical provisions (notably Articles 20.27 and 20.29) introduce a sui generis patent-term restoration mechanism and detailed TRIPS-plus rules on test-data protection – the EPA adopts a more restrained approach to pharmaceutical exclusivity. Article 14.37 of the EPA imposes a baseline obligation to protect undisclosed tests or other data for a minimum period of six years, expressly linking protection to the periods provided under each Party's domestic law at the time of entry into force. The EPA, thus, does not create any additional treaty-based obligation on patent-term restoration. This difference reflects, inter alia, Japan's pre-existing domestic framework for patent-term extension and data protection rather than a deliberate move toward significantly higher exclusivity standards in the EPA itself. From an analytical point of view, the EPA thus operates primarily through export and convergence (reducing divergence) rather than through hardening EU-internal incentive settings, which helps explain why its main

[98] ibid.
[99] ibid 14.36-14.37.

"constitutional pressure" is more visible in copyright or cultural circulation than in pharmaceutical recalibration (see Chapters 3 and 5).

A further distinctive feature of the EPA is its broad protection of geographical indications. The agreement recognizes an extensive and expandable list of EU GIs for wines, spirits and agri-food products, thereby extending EU-style GI protection into one of Asia's largest consumer markets and reinforcing the international visibility of European regional brands[100]. At the same time, the EPA accommodates Japanese concerns through specific coexistence and phasing-in arrangements, illustrating the negotiated nature of GI export strategies and the compromises required when transposing the Union's internal model into different legal and cultural environments[101]. This demonstrates the EU's diversified export strategy, wherein robust formal GI recognition is complemented by negotiated accommodations. This dynamic is also evident in the GI case study, manifesting as sources of distributive and coherence tensions, discussed in §5.4.

From the perspective of IP-in-trade scholarship, the EPA illustrates how long-term protection standards can become entrenched through bilateral benchmark-setting. Peter K. Yu's account of TRIPS-plus dynamics explains why term-length convergence matters even without formal EU-law amendment, while the Court's ruling in *Deckmyn* (C-201/13) signals that any spill-over into enforcement or exception design must remain compatible with Charter-sensitive balancing as discussed in the later Chapters 3-5[102].

Viewed from the Union's perspective, the EPA performs three main functions in the field of intellectual property. First, it attenuates regulatory divergence in key IP-intensive sectors – above all copyright and GIs – thereby facilitating cross-border exploitation of European catalogues and agri-food brands. Second, it consolidates Japan as a partner that shares a broadly comparable approach to enforcement and to the institutional role of IP in innovation policy, while still leaving room for differences in exceptions, collective management and platform regulation. Third, it offers a reference point for the Union's engagement with other Asian partners, signaling that high IP standards and GI recognition can be combined with differentiated treatment in more sensitive areas such as pharmaceuticals. This combination of

[100] ibid 14, sec b, sub-3; Annex 14-B.
[101] ibid 14.27.
[102] Yu (n 84) 383–385; *Case C-201/13 Johan Deckmyn and Vrijheidsfonds VZW v Helena Vandersteen and Others EU:C:2014:2132* (n 42).

convergence and calibrated flexibility is important for the sector-specific analyses developed in Chapter 5.

EU–Korea Free Trade Agreement

The EU–Korea FTA, provisionally applied since 2011 and entered fully in force since 2015, was the first of the EU's "new generation" FTAs concluded under the Global Europe strategy and the Union's first comprehensive FTA with an Asian partner[103]. Substantively, it contains an extensive IP chapter which builds on TRIPS and selected WIPO conventions and has been widely described as an ambitious attempt to export EU-style IP standards to a key high-technology economy[104]. The IP chapter covers copyright and related rights, trade marks, designs, patents, trade secrets and geographical indications, and is complemented by a detailed section on enforcement[105]. In copyright and related rights, the agreement confirms protection for authors, performers and producers, including provisions on technological protection measures and rights-management information[106]. In trade marks and designs, it requires the parties to provide registration and enforcement systems broadly aligned with EU practice[107]. The enforcement section reflects the structure and many of the concepts of Directive 2004/48/EC, including rules on evidence, provisional and precautionary measures, injunctions, corrective measures and damages, thereby promoting convergence with the Union's internal "minimum standards" for civil IP enforcement[108]. For customs enforcement, the FTA supplements TRIPS border-measure obligations with additional commitments and cooperation between customs authorities, reflecting EU priorities in relation to counterfeit high-technology and branded consumer goods[109]. From the perspective of the research question, the relevance of this agreement lies in its role as an early export template. It anticipates enforcement structures later refined in CETA and provides a platform for examining how EU-style enforcement as well

[103] Free trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part [2011] OJ L127/6; European Commission (ed), *The EU-Korea Free Trade Agreement in Practice* (Publications Office 2011) 3.
[104] Free trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part [2011] OJ L127/6 ch 10; European Commission, *The EU-Korea Free Trade Agreement in Practice* (n 103) 3.
[105] Free trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part [2011] OJ L127/6 ch 10.
[106] ibid 10, s B, sub-A.
[107] ibid 10, s B, sub-B and sub-D.
[108] ibid 10, s C; Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L157/45.
[109] Free trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part [2011] OJ L127/6 art 6.13, 10.67.

as intermediary-safe-harbor (in the digital field) concepts travel through treaty practice (see §§3.1-3.2; §5.2).

For the digital and technology sectors, the agreement aims to create a predictable legal environment for European and Korean firms by clarifying protection for computer programs, databases and undisclosed information[110]. These provisions sit against ongoing debates within the EU about the proper scope of patentability for computer-implemented inventions and the balance between robust trade secret protection and regulatory transparency in areas such as health and environmental regulation. In doctrinal terms, the FTA itself does not resolve those internal controversies, but it contributes to consolidating a high-protection baseline for software-related subject matter and confidential business information in the Union's external relations. In other words, the pivotal analytical observation is that such clauses seldom "modify" EU internal law in a direct manner. Instead, they serve to stabilize an external high-protection baseline that can exert influence on the political cost associated with internal reform proposals (e.g. in areas such as transparency, trade secrets, or platform enforcement design), which must remain Charter-consistent (see Chapter 4).

In the field of GIs, the EU–Korea FTA adopts a more selective approach than later agreements such as CETA and the EU–Japan EPA. At entry into force, it recognized around 160 EU GIs for wines, spirits and certain agri-food products, alongside a small number of Korean indications, with scope for subsequent additions through a joint committee[111]. The level of protection broadly follows EU practice – extending beyond mere protection against misleading use to cover evocation and translation – yet the more limited product coverage and the calibrated coexistence solutions for pre-existing uses illustrate the negotiated nature of GI export strategies at this earlier stage of the EU's FTA practice[112]. This illustrates the governance channel in earlier form. Committee-based updating facilitates expansion but also shifts part of GI calibration into treaty practice rather than internal legislative amendment (see §5.4).

Generally speaking, the EU–Korea FTA can be read as an early export template in the sense described by Horn, Mavroidis and Sapir ("beyond the WTO" commitments), but its relevance for digital-enforcement models is legally constrained by the CJEU's prohibition on general

[110] ibid 10.2, 7.25.
[111] ibid 10.18-10.26, Annex 10-A and 10-B.
[112] ibid.

monitoring in *Scarlet Extended* (C-70/10), which operates as a constitutional ceiling for intermediary-centered enforcement models later examined in §5.2[113].

From an EU perspective, the EU–Korea FTA therefore performs a dual function in the IP field. It operates as an early "prototype" of the comprehensive IP chapters that become more elaborate in CETA and the EU–Japan EPA, particularly with respect to enforcement and GIs, while simultaneously reflecting the experimentation and sector-specific trade-offs characteristic of the Union's first new-generation agreement in Asia. These themes reappear in the analysis of harmonization and conflict in Chapter 3 and in the digital and GI case studies in Chapter 5.

EU–Singapore Free Trade Agreement

The EU–Singapore FTA, in force since 2019, occupies a strategic position in the Union's trade network with Southeast Asia[114]. Singapore's role as a regional logistics and services hub makes the agreement particularly relevant for the external projection of EU IP rules in supply-chain and digital contexts.

In institutional terms, the agreement follows the "post-*Opinion 2/15*" architecture regarding the competence-sensitive treaty design, whereby trade and IP disciplines are enshrined within an EU-only FTA, while investment protection and dispute settlement are addressed in a discrete, mixed Investment Protection Agreement[115]. This structural separation reflects the refined allocation of competences under Article 207 TFEU and *Opinion 2/15*, which is relevant for the constitutional analysis developed in Chapter 4. Within the scope of the thesis, this matter is of consequence because competence-sensitive design choices are themselves part of the constitutional "effects" of modern FTAs. In Fact, treaty architecture can mitigate autonomy and competence friction while still exporting detailed IP templates (see Chapter 4).

Substantively, the IP chapter consolidates a high level of protection across copyrights, trade marks, designs, patents and GIs, broadly mirroring the orientation of the Enforcement Directive and CETA. Like CETA and the EU–Japan EPA, it uses annexed lists to secure recognition of a significant number of EU GIs in a key export market, with protection extending beyond direct misuse to forms of imitation and evocation as defined in the treaty text[116]. These commitments

[113] Horn, Mavroidis and Sapir (n 88); *Case C-70/10 Scarlet Extended SA v Société belge des auteurs, compositeurs et éditeurs SCRL (SABAM) EU:C:2011:771* (n 15).
[114] Free trade Agreement between the European Union and the Republic of Singapore [2019] OJ L294/3.
[115] *Opinion 2/15 EU–Singapore FTA EU:C:2017:376*.
[116] Free trade Agreement between the European Union and the Republic of Singapore [2019] OJ L294/3 art 10.17–10.22 and Annexes 10-A, 10-B.

support the external effectiveness of the EU GI regime and provide a direct treaty basis for the GI case study in §5.4.

In the digital environment, the agreement places particular emphasis on enforcement and the protection of technological measures and rights-management information. It obliges the parties to provide effective civil remedies and deterrent-level damages for online infringement and to protect technological protection measures and rights-management information against circumvention and removal[117]. At the same time, the text is drafted to remain compatible with the Union's internal standards on intermediary liability and data protection. The enforcement section requires that IPRs be supported by effective civil procedures and remedies, while also containing an express safeguard that implementation must respect each party's framework on the processing of personal data[118]. From a legal-analytical standpoint, the agreement illustrates the EU's "balanced template" claim in the digital field – strong enforcement expectations combined with safeguards – raising the downstream question of whether implementation practices preserve the internal Charter-sensitive balance developed in EU law (see §5.2).

Within the scope of this thesis, the EU–Singapore FTA is therefore significant less for introducing novel IP concepts than for projecting a high-protection, enforcement-oriented model into a pivotal regional hub. Its combination of detailed enforcement rules, GI recognition and digital-environment clauses illustrates how the Union adapts a relatively stable IP template to the specific economic profile of a partner economy whose importance lies as much in its gateway function for the wider region as in its domestic market. These features provide a useful contrast to the more pharmaceutical- and GI-centered design of CETA and the copyright-focused convergence with Japan, and they feed into the sectoral analysis of digital enforcement and GIs in Chapter 5.

Considered in comparative perspective, these four agreements demonstrate a consistent yet differentiated EU strategy of negotiating TRIPS-plus IP standards with major trading partners, while tailoring sectoral emphasis – pharmaceuticals, GIs, digital enforcement and creative industries – to the economic profile and regulatory preferences of each partner. CETA occupies a central place in this matrix as the most far-reaching template in pharmaceuticals, GIs and enforcement. The EU–Japan EPA foregrounds copyright and cultural industries alongside an

[117] ibid 10.09-10.10.
[118] ibid sec. C, art. 8.54.

expansive GI list, whereas the EU–Korea FTA, which predates CETA, serves as an early laboratory for digital and enforcement provisions in a high-technology context and the EU–Singapore FTA consolidates a high-protection, enforcement-oriented model in a regional trade and logistics hub.

In Summary, The EU–Singapore model also elucidates the dynamic interplay between treaty architecture and constitutional limitations. *Opinion 2/15* explains the post-split design choice, while Geiger's critique of investment protection and IP underscores the necessity of drafting dispute-settlement and enforcement clauses to avoid compressing Charter-consistent regulatory space even when the trade/IP component is EU-only (see Chapter 4)[119].

Taken together, these treaties show that there is no single, monolithic "EU IP model" exported identically in every agreement. Rather, the Union has progressively developed an IP chapter architecture – most clearly visible in CETA – characterized by a standalone IP chapter, detailed enforcement provisions and annexed GI lists, and has subsequently adapted this template in light of partner-specific priorities and political-economy constraints. The EU–Korea FTA appears in this trajectory as a precursor that anticipates several design choices later refined in CETA, the EU–Japan EPA and the EU–Singapore FTA. The following chapters examine how this differentiated export strategy interacts with the EU's internal legal order and constitutional safeguards, and how it affects the balance between protection, access and regulatory autonomy.

2.3 Broader Implications and Controversies

The incorporation of IP provisions in modern FTAs has generated a rich body of academic and policy debate. Many scholars – such as Sell – argue that these provisions extend well beyond the multilateral baseline set by the TRIPS Agreement, establishing so-called "TRIPS-plus" standards that reshape the balance between private rights and public goods in global trade governance[120]. While the economic rationale for stronger IP protection is often presented in terms of innovation, competitiveness and legal certainty, the social and political consequences remain highly contested.

[119] Christophe Geiger, 'The TTIP and Its Investment Protection: Will the EU Still Be Able to Regulate Intellectual Property?' (2018) 49 IIC - International Review of Intellectual Property and Competition Law 631.

[120] Susan K Sell, 'Trips Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TTP' (2011) 18 Journal of Intellectual Property Law 447; Yu (n 84); Peter K Yu, 'TRIPS and Its Contents' (2020) 60 IDEA: The Law Review of the Franklin Pierce Center for Intellectual Property 149.

A first area of debate concerns innovation, competitiveness, and regulatory convergence. Proponents argue that robust IP chapters in FTAs reduce legal uncertainty, harmonize fragmented standards, and thereby facilitate cross-border trade and investment in knowledge-intensive sectors such as pharmaceuticals, biotechnology, and digital industries. An empirical study by the European Centre for International Political Economy (ECIPE) in 2022 concludes that the inclusion of strong IP provisions in EU FTAs "can meaningfully contribute to EU strategic resilience by promoting innovation in the EU, driving the digital transformation, green technology development and R&D into innovative medicines"[121]. From this perspective, FTAs are not merely trade instruments but also vehicles of transnational regulatory cooperation, embedding common enforcement mechanisms that create predictable frameworks for firms to commit resources to research, development, and creative activity.

The second debate centers on public interest and access to essential goods. Critics stress that TRIPS-plus provisions – such as extended patent terms, regulatory data exclusivity, and stringent border enforcement – may delay the entry of generic medicines, raise healthcare costs, and reduce access to treatments in both developed and developing economies. Mohammed El Said emphasizes that such provisions can significantly undermine the use of TRIPS flexibilities, thereby restricting governments' ability to address public health needs and ensure equitable access to medicines and vaccines[122]. Similarly, Abbott and Reichman argue that higher IP standards introduced through TRIPS and subsequent FTAs have imposed significant social costs on developing countries by undermining their capacity to provide "basic public goods as nutrition and agriculture, education, public health, environmental safety, scientific research and industrial policy"[123]. These concerns are echoed more broadly in the literature on global health governance, which highlights how trade rules increasingly intersect with states' obligations to ensure public health and social welfare. Such critiques underscore the tension between incentivizing pharmaceutical innovation and safeguarding equitable access to medicines.

A third line of controversy relates to democratic legitimacy, transparency, and distributional consequences. Civil society organizations and academic commentators pointed out that FTA

[121] Erixon and others (n 9) 10.
[122] Mohammed El Said, 'The Impact of "TRIPS-Plus" Rules on the Use of TRIPS Flexibilities: Dealing with the Implementation Challenges' in Carlos María Correa and Reto M Hilty (eds), *Access to medicines and vaccines: implementing flexibilities under intellectual property law* (Springer International Publishing 2022).
[123] FM Abbott and JH Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 Journal of International Economic Law 921-987, 925.

negotiations often occur with limited parliamentary or public participation, raising concerns about accountability and the privileging of corporate interests. While the EU has introduced reforms to improve transparency in trade negotiations, empirical studies show that significant gaps remain. Marx and Van der Loo find that the EU's transparency practices often emphasize formal disclosure while leaving limited scope for meaningful public participation[124]. Kleine and Huntington similarly argue that transparency initiatives may paradoxically shift sensitive bargaining into informal or confidential venues, thereby undermining substantive accountability[125]. Beyond transparency, Çapar questions the legitimacy of the broader international IP regime, noting that TRIPS-plus commitments in FTAs risk reinforcing structural asymmetries between developed and developing countries[126].

These critiques underscore concerns that FTA negotiations may privilege the interests of large rights-holders, while SMEs and civil-society actors lack the resources or access to shape outcomes. Such legitimacy and distributional challenges remain central to debates on the governance of IP in modern trade agreements.

Overall, the debates reviewed above illustrate the dual character of IP provisions in FTAs. On the one hand, they can function as engines for innovation, competitiveness, and regulatory convergence across borders. On the other hand, they carry the risk of narrowing domestic policy space, limiting access to essential goods, and raising questions of legitimacy and fairness. For policymakers, the central challenge lies in designing trade agreements that achieve an effective balance – strengthening IP protection where it supports innovation and trade, while ensuring that public interest, democratic accountability, and equitable economic development are not undermined in the process.

From an EU-specific perspective, these debates also illuminate the internal ambivalence of the Union's external IP policy. The EU's self-image as a proponent of stringent regulatory standards, fundamental rights, and sustainable development is in stark contrast to its reliance on economic arguments concerning competitiveness and export prospects in IP-intensive sectors to substantiate its extensive TRIPS-plus clauses. This "dual mandate" engenders structural tension: the more robust the protection exported through FTAs, the greater the pressure on the EU's constitutional commitment to public health, cultural diversity, and access

[124] Axel Marx and Guillaume Van Der Loo, 'Transparency in EU Trade Policy: A Comprehensive Assessment of Current Achievements' (2021) 9 Politics and Governance 261.
[125] Mareike Kleine and Samuel Huntington, 'Negotiating with Your Mouth Full: Intergovernmental Negotiations between Transparency and Confidentiality' [2024] The Review of International Organizations.
[126] Gürkan Çapar, '(Il)Legitimacy of International Intellectual Property Regime?' (2023) 36 Leiden Journal of International Law 721.

to knowledge. This tension is analyzed in doctrinal and constitutional terms in Chapters 3-4, respectively. In Chapter 5, the sectoral case studies trace this tension in concrete policy fields.

Finally, these controversies also demonstrate that the IP chapters of modern FTAs cannot be understood in isolation from broader governance concerns, including constitutional constraints specific to the EU context. They raise fundamental questions about how innovation should be incentivized, how access to knowledge and medicines should be safeguarded, and how regulatory authority should be allocated between national, regional, and international institutions. While these debates resonate globally, they are particularly relevant for the EU, which has sought to position itself simultaneously as a global rule-setter in IP and as a leader in negotiating "new generation" trade agreements. The following chapters take up this perspective more directly: Chapter 3 examines how FTA commitments interact with the existing EU IP acquis, Chapter 4 analyses the constitutional constraints that frame this interaction, and Chapter 5 applies the analysis to key sectors of the European economy.

3 Impact of Free Trade Agreements on Intellectual Property Protection in the European Union

The increasing integration of IP provisions into FTAs has tangible implications for the EU legal order. Whereas Chapter 2 traced the evolution of "new generation" IP chapters and outlined the principal features of CETA, the EU–Japan EPA, the EU–Korea FTA and the EU–Singapore FTA, this chapter examines how those external commitments interact with EU law and how they shape the Union's internal framework. Here, the impact is assessed through three connected dimensions – the scope of protection, the intensity of protection, and the design of enforcement – with particular attention to how TRIPS-plus commitments may channel or constrain legislative choices, judicial interpretation and institutional practice. Section 3.1 develops the comparison between treaty disciplines and the EU acquis, while section 3.2 draws out the principal harmonization effects and points of legal friction. In the final analysis, the sector-specific operation of these dynamics is then tested in case studies in Chapter 5.

3.1 Comparison of Agreements with Existing EU Regulations

The impact of modern FTAs on EU IP law can be illustrated by comparing provisions in CETA with the acquis communautaire and the EU's constitutional framework. These can be situated further against the more sector-specific IP chapters of the EU–Japan EPA, the EU–Korea FTA and the EU–Singapore FTA. While some provisions align closely with existing EU legislation, others introduce "TRIPS-plus" elements that challenge the balance struck in EU law between IP protection and public interest objectives.

In the field of patents, CETA's mechanism for patent-term restoration closely parallels the Union's SPC regime for medicinal products, established under Regulation (EC) No 469/2009[127]. The SPC system is designed to offset the time lost in obtaining regulatory authorization, with its duration and calculation parameters refined by the CJEU, most notably in *Seattle Genetics* (Case C-471/14), where the Court clarified the "date of first marketing authorization" as the reference point for SPC duration[128]. While CETA's restoration provisions aim to provide greater uniformity and predictability, they risk constraining the EU legislature's

[127] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1; Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part [2017] OJ L11/23 art 20.27.
[128] *Case C-471/14 Seattle Genetics Inc v Österreichisches Patentamt EU:C:2015:659* (n 74).

ability to recalibrate the SPC framework in response to shifting public health or industrial policy needs. Put it differently, what the CJEU has treated as a matter of Union legislation and political discretion risks becoming partly "locked in" by bilateral treaty commitments. By contrast, the EU–Japan EPA, the EU–Korea FTA and the EU–Singapore FTA rely more heavily on TRIPS-level obligations and domestic law in the pharmaceutical field, thereby exerting less direct pressure on the Union's SPC architecture, even though they still promote a high overall standard of patent and data protection.

In copyright and the digital environment, the EU acquis, centered on the InfoSoc Directive and more recently the DSM Directive, reflects a carefully calibrated balance between exclusive rights and public-interest exceptions, consistent with the Charter of Fundamental Rights. The CJEU has consistently emphasized this balance, holding in *Scarlet Extended* (Case C-70/10) and *SABAM v Netlog* (Case C-360/10) that general monitoring or filtering duties on intermediaries would violate EU law by infringing fundamental rights and contravening the principle of proportionality[129]. These judgments constitute a central internal benchmark for any FTA-driven enhancement of online enforcement.

Against this background, the enforcement and digital trade provisions in the EU–Korea FTA and the EU–Singapore FTA seek to strengthen the fight against online infringement through civil remedies, injunctions and border measures, while remaining formally compatible with the EU's "notice-and-action" approach. The legal tension, therefore, is less about the existence of enforcement obligations and more about the risk that their implementation in partner countries – and their interpretative feedback into the EU legal order – could gradually recalibrate the balance struck by the CJEU in favor of more stringent intermediary liability.

The investment dimension of CETA further illustrates the novelty of FTA provisions in relation to EU law. Through the ICS, certain IPRs are treated as protected "investments", giving investors direct recourse to an international tribunal. In *Opinion 1/17*, the CJEU ultimately upheld the compatibility of the ICS with the autonomy of EU law, but only after confirming safeguards that preserved the Court's interpretative monopoly and regulatory discretion of the Union and its Member States[130]. Read together with *Opinion 2/15* on the EU–Singapore FTA, which clarified the Union's external competences in the field of IP, these rulings delineate the

[129] *Case C-70/10 Scarlet Extended SA v Société belge des auteurs, compositeurs et éditeurs SCRL (SABAM) EU:C:2011:771* (n 15); *Case C-360/10 Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM) v Netlog NV EU:C:2012:85* (n 15).
[130] *Opinion 1/17 CETA EU:C:2019:341* (n 8).

constitutional perimeter within which treaty-based investment protections may operate[131]. The EU–Singapore FTA itself separates trade and investment chapters, with the investment protection and ICS elements contained in a parallel Investment Protection Agreement[132]. Nevertheless, both CETA and the EU–Singapore framework confirms a trend towards treating IP as a protected investment asset in the EU's external economic relations. The concern remains that heightened investor remedies directed at IP-related measures – for instance, reforms to pharmaceutical patenting or copyright exceptions – may generate a "regulatory chill", dissuading legislators from adopting public-interest measures despite the formal compatibility of ICS with EU law.

Doctrinal and scholarly perspectives reinforce these concerns. Geiger cautions that robust investment protections coupled with IP's classification as an "investment" risk compressing the EU's capacity to adjust limitations and exceptions in the public interest, thereby impinging upon freedoms such as expression and access to information[133]. Van Harten's critique of investor – state arbitration as a public law mechanism suggests that its structural asymmetry privileges investor expectations over state sovereignty, creating bargaining advantages for large firms and exacerbating the risk of regulatory chill[134]. Similarly, Titi underscores the broader tension between investment protection and the right to regulate, warning that arbitration frameworks may undermine democratic accountability in socially sensitive sectors. While she focuses primarily on cultural policy, the implications extend to other public-interest domains where regulatory space is essential [135].

Seen through these doctrinal and judicial lenses, the comparative analysis demonstrates that modern FTA IP chapters can both reinforce and destabilize the EU legal order. They extend the reach of EU standards to trading partners, strengthening the outward projection of the acquis. Yet at the same time, they may compress legislative discretion and recalibrate carefully constructed balances between rightsholders and users, with implications for fundamental rights and regulatory autonomy. The challenge for EU policymakers lies in ensuring that such external

[131] *Opinion 2/15 EU–Singapore FTA EU:C:2017:376* (n 115).
[132] Free trade Agreement between the European Union and the Republic of Singapore [2019] OJ L294/3; Council Decision (EU) 2018/ 1676 - of 15 October 2018 - on the signing, on behalf of the European Union, of the Investment Protection Agreement between the European Union and its Member States, of the one part, and the Republic of Singapore, of the other part [2018] OJ L 279/1.
[133] Geiger (n 119).
[134] Gus Van Harten, *Investment Treaty Arbitration and Public Law* (Oxford University Press 2007) ch 7.
[135] Catharine Titi, *The Right to Regulate in International Investment Law* (1st edition, Nomos Verlagsgesellschaft mbH & Co KG 2014) 32–52; 152–160; 216–233.

commitments do not crystallize rules in ways that bypass the Union's internal constitutional safeguards.

3.2 Analysis of Harmonization Effects and Potential Conflicts

One of the central justifications for incorporating IP provisions into FTAs is the pursuit of harmonization. For the EU, which already operates a relatively harmonized IP framework through directives and regulations, such commitments may appear consistent with its broader strategy of exporting legal norms. However, the experience of CETA and other "new generation" FTAs demonstrates that the harmonization envisaged by FTAs is not always congruent with the balances struck in EU law and may generate substantive conflicts.

A prominent example arises in the field of copyright. The EU's acquis, anchored in the InfoSoc Directive [136] and reinforced by the DSM Directive[137], reflects a model that protects authors' rights while also safeguarding users' interests through exceptions and limitations, particularly for education, research, and access for people with disabilities.

The CJEU has consistently underlined that these provisions must be interpreted considering the Charter of Fundamental Rights, ensuring proportionality between exclusive rights and freedoms such as expression and information. In *Deckmyn* (Case C-201/13), for instance, the Court emphasized that exceptions like parody must be interpreted and applied in a manner that respects fundamental rights, including freedom of expression and the principle of non-discrimination, thereby ensuring a fair balance between the interests of copyright holders and users[138]. In contrast, the EU–Japan EPA's primary contribution has been to align copyright term in Japan with the EU standard (70 years post mortem auctoris), thereby reducing divergence without directly altering the internal balance of exceptions and limitations. Similarly, enhanced enforcement provisions in the EU–Korea and EU–Singapore agreements must be implemented in a manner that respects the CJEU's prohibition of general monitoring obligations (see *Scarlet Extended* and *SABAM v Netlog* discussed in §3.1).

[136] Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the Harmonisation of Certain Aspects of Copyright and Related Rights in the Information Society [2001] OJ L167/10.

[137] Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC [2019] OJ L130/92.

[138] *Case C-201/13 Johan Deckmyn and Vrijheidsfonds VZW v Helena Vandersteen and Others EU:C:2014:2132* (n 42).

Furthermore, conflicts are evident in the domain of GIs. EU law provides robust protection for GIs under Regulation (EU) 2024/1143 (repealing Regulation (EU) No 1151/2012), underscoring the EU's commitment to both economic development and cultural heritage by formally linking product identity to geographical origin[139]. While CETA extended protection to over 170 EU GIs, it simultaneously permitted coexistence with certain pre-existing Canadian trade marks and generic uses. This compromise, while politically pragmatic, diluted the level of exclusivity typically afforded to GIs within the EU's internal market. A similar pattern can be observed, though with different product coverage, in the EU–Japan and EU–Singapore agreements, which also combine strong TRIPS-plus protection with negotiated coexistence solutions.

Scholars such as Deere have noted that such negotiated outcomes often expose the limits of harmonization in FTAs. Rather than entrenching the EU model wholesale, these agreements tend to involve strategic concessions that generate inconsistencies between external commitments and the internal regulatory regime. Although Deere's analysis focuses primarily on developing countries, her examination of bilateral trade pressures – including those exerted by the EU – illustrates how TRIPS-plus obligations are selectively applied, reinforcing the broader critique of fragmented regulatory exportation[140]. The distributive and doctrinal consequences of these compromises are further examined in more detail in the GI case study in Chapter 5.

The broader challenge lies in reconciling harmonization with regulatory autonomy. The EU has long sought to balance high standards of IP protection with public-interest considerations such as access to medicines, educational resources, and cultural participation. Yet the TRIPS-plus obligations often embedded in FTAs can narrow the discretion of EU institutions and Member States to recalibrate these balances in response to evolving social or economic needs. For example, patent-term restoration under CETA may constrain the Union's capacity to modify its SPC regime, even though the CJEU has treated the precise calculation of SPC duration as a question of legislative design, as seen in *Seattle Genetics* (Case C-471/14)[141].

[139] Regulation (EU) 2024/1143 of the European Parliament and of the Council of 11 April 2024 on geographical indications for wine, spirit drinks and agricultural products, as well as traditional specialities guaranteed and optional quality terms for agricultural products, amending Regulations (EU) No 1308/2013, (EU) 2019/787 and (EU) 2019/1753 and repealing Regulation (EU) No 1151/2012 [2024] OJ L 2024/1143.
[140] Carolyn Deere-Birkbeck, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford University Press 2008) ch 5.
[141] *Case C-471/14 Seattle Genetics Inc v Österreichisches Patentamt EU:C:2015:659* (n 74).

From a constitutional perspective, the potential conflicts raised by FTA harmonization are not merely technical but structural. They touch upon the allocation of regulatory authority between the EU and its trading partners, the autonomy of EU law as safeguarded by the CJEU, and the Union's capacity to preserve its fundamental-rights framework in the face of external commitments. Academic commentators such as Geiger have expressed concerns that FTAs may incorporate external norms which, in the absence of adequate safeguards, prioritize the interests of rightsholders over democratic accountability and proportionality within the framework of EU law[142].

In general, while harmonization through FTAs promises economic efficiency and legal certainty, it also generates tensions with the EU's carefully constructed internal IP architecture. These tensions demonstrate the difficulty of reconciling external commitments with internal constitutional balances, a theme that runs throughout the EU's trade policy and is particularly pronounced in the field of intellectual property.

[142] Geiger (n 119).

4 Legal Challenges and Conflicts

Besides the critical points discussed earlier in this thesis, the inclusion of IP Chapters in FTAs presents complex legal challenges for the EU. While FTAs are intended to complement the internal market and promote legal certainty for rights holders, they may also conflict with existing EU legislation, the division of competences between the Union and Member States, and the constitutional principles safeguarded by the CJEU. The present chapter undertakes an examination of three interrelated legal challenges: (i) the compatibility of FTA provisions with existing EU legislation, (ii) competence and institutional balance in the negotiation and implementation of FTAs, and (iii) constitutional safeguards (autonomy of EU law and the Charter). It analyses these dimensions through the lenses of norm-conflict management, competence demarcation and the limits imposed by the CJEU's case law, thereby delineating how far "TRIPS-plus" commitments in FTAs can be integrated into the EU legal order without destabilizing the internal balance between market integration, fundamental rights and regulatory autonomy.

4.1 Compatibility with EU Intellectual Property Law

A primary challenge posed by FTAs is methodological rather than sector-specific. It lies in managing the interface between detailed FTA IP clauses and an acquis that the CJEU treats as the outcome of legislative calibration. Under Article 216(2) TFEU, international "agreements concluded by the Union are binding upon the institutions of the Union and on its Member States"[143]. Although such agreements form part of the EU legal order, the CJEU has consistently – for instance in case C-149/96 – held that they cannot permit the circumvention of explicit legislative choices in secondary law, nor to introduce obligations that the Union legislature has not adopted[144].

The technique of consistent interpretation – used to construe EU legal acts in conformity with international obligations – has long been recognized in Union law, but the SPC case law illustrates its limits. In *Seattle Genetics* (C-471/14) and *Santen* (C-673/18), the CJEU interpreted SPC duration and eligibility within the framework of Regulation (EC) No 469/2009, insisting that the scope and parameters of protection reflect legislative policy decisions [145].

[143] Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/1.
[144] *Case C-149/96 Portuguese Republic v Council of the European Union EU:C:1999:574*.
[145] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1; *Case C-471/14 Seattle*

Given this case law, treaty-fixed patent-term restoration formulas risk narrowing the legislature's future space to recalibrate SPC policy in response to public health or industrial priorities. In other words, where the Court has treated the scope of protection as a matter for Union legislation, FTA commitments may "freeze" a particular configuration at treaty level. Similar concerns arise in the field of GIs, where Regulation (EU) No 1151/2012 together with the Court's evocation doctrine have established a significant level of protection that cannot simply be read down based on more flexible coexistence solutions negotiated with third countries (see Chapter 3 and §5.4).

A second dimension of compatibility management involves ex-post interpretative practices, notably through joint interpretative instruments and committee decisions adopted under FTAs. Such instruments can legitimately record or clarify the parties' shared understanding of treaty provisions and, where the parties so intend, may inform the legal interpretation of those provisions[146]. They cannot, however, rewrite the treaty, override the ordinary meaning of its terms, or displace Charter-conforming readings of EU secondary legislation. Therefore, these instruments function as coordination mechanisms rather than substitutes for formal amendment procedures, especially when TRIPS-plus obligations affect Charter-sensitive domains such as online enforcement, data protection, and access to information. Where interpretative frictions arise, the primary response remains Charter-consistent interpretation of the relevant EU implementing measures, with joint declarations or committee practice used, at most, to channel discretion or specify technical modalities. The Joint Interpretative Instrument on CETA illustrates this approach. It records shared understandings of contested provisions without altering the agreement's legal effects or relaxing the Union's constitutional safeguards[147]. Comparable constraints apply to decisions of FTA committees. While they may update annexes or settle technical details (e.g., by adding or removing individual GIs), they are not permitted to amend the essential elements of EU legislation or lower the level of protection required by the Charter.

A third avenue of compatibility management lies in ex ante design, notably through review (or "rendez-vous") clauses and explicit safeguard provisions that preserve regulatory flexibility. Public health-oriented recitals, drafted in line with the Doha Declaration on the TRIPS

Genetics Inc v Österreichisches Patentamt EU:C:2015:659 (n 74); *Case C-673/18 Santen SAS v Directeur général de l'INPI EU:C:2020:531* (n 74).

[146] Vienna Convention on the Law of Treaties (1969) 1155 UNTS 331 act 31.

[147] Joint Interpretative Instrument on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union and its Member States [2017] OJ L 11/3 2017.

Agreement and Public Health, can inform proportionality assessments where patent-term restoration or data exclusivity regimes intersect with the public-health objectives articulated under Article 168 TFEU[148]. Equally important are explicit fundamental rights safeguards, such as prohibitions on general monitoring obligations and guarantees of effective remedies, to ensure that platform-liability measures remain within the limits constitutionalized by the CJEU. In the context of copyright law, for instance, the acquis (InfoSoc Directive and DSM Directive) and the Court's case law in *Scarlet Extended* (C-70/10) and *SABAM v Netlog* (C-360/10) preclude general monitoring and require the establishment of robust safeguards [149]. Consequently, any FTA-driven move toward a "notice-and-takedown" model must be designed and implemented in a manner that satisfies the Charter's requirements, particularly the necessity and proportionality tests applicable to restrictions on fundamental rights. The same principle applies to GIs. CETA's Annex 20-A contains a comprehensive list of EU GIs, accompanied by provisions for the coexistence of pre-existing trade marks and generic terms[150]. As discussed in Section 3.2 and further illustrated in the agri-food case study in Chapter 5, such external commitments must be implemented consistently with the Union's evocation doctrine and Regulation (EU) 2024/1143 (repealing Regulation (EU) No 1151/2012).

Viewed systematically, these three techniques – consistent interpretation, ex-post coordination through joint instruments, and ex ante safeguard clauses – operate together as a "compatibility toolkit" rather than as a single test. Their shared purpose is to preserve the policy balances embedded in EU secondary law and the Charter, so that even where FTAs incorporate TRIPS-plus standards the Union's internal allocations and fundamental-rights protections remain intact.

In areas where competence is sensitive, such as investment, reservation practice and non-direct-effect formulations help to preserve the autonomy of EU law, in line with *Opinion 2/15* (EU–Singapore) and *Opinion 1/17* (CETA/ICS). Finally, Article 207(1) and (3) TFEU require the common commercial policy (CCP) to operate within the Union's external-action principles and to remain "compatible with internal Union policies and rules", reinforcing a Charter-conscious implementation of IP chapters. In this sense, compatibility is not a static condition but an ongoing process of interpretative, institutional and textual adjustment through which the Union

[148] Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/1.
[149] *Case C-70/10 Scarlet Extended SA v Société belge des auteurs, compositeurs et éditeurs SCRL (SABAM) EU:C:2011:771* (n 15); *Case C-360/10 Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM) v Netlog NV EU:C:2012:85* (n 15).
[150] Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part [2017] OJ L11/23 ch 20.

accommodates external commitments without eroding its internal constitutional balance. A recent briefing by the European Parliament Research Service stresses that any EU FTA, including CETA, must remain consistent with internal rules and fundamental rights such as the protection of personal data under Article 8 of the Charter of Fundamental Rights, as well as with Article 207(3) TFEU, which requires alignment with the Union's internal policies[151].

4.2 Competence between EU and Member States

Beyond substantive conflicts, FTAs generate institutional challenges in the Union's distribution of competences. Article 207 TFEU designates the CCP to the EU and specifies that it covers the "commercial aspects of intellectual property", thereby bringing much of IP-related trade policy within exclusive EU competence[152]. Yet, *opinion 2/15* on the EU–Singapore agreements elucidated that while most provisions, including commercial aspects of IP, fall under the EU's exclusive competence, certain investment components – notably portfolio investment and investor–state dispute settlement – require mixed ratification involving Member States[153]. The Court, thus, refined the scope of Article 207 TFEU, holding that provisions "specifically relating to international trade" fall within the CCP, whereas elements whose primary object is the protection of investors or capital movements extend beyond it and trigger shared or Member State competences. This division complicates the ratification and implementation of FTAs, as seen with CETA, where several national and regional parliaments (e.g., Wallonia in Belgium) initially resisted approval and where political assurances and interpretative instruments were needed to secure consent[154].

A further consequence of *Opinion 2/15* has been a gradual shift in treaty practice. Negotiators have been increasingly seeking to isolate an "EU-only" trade component that the Union can sign and provisionally apply, while placing investment or other Member-State competences in separate instruments – an approach illustrated by the EU–Singapore FTA and the accompanying Investment Protection Agreement[155]. This technique can reduce the procedural and political uncertainty associated with mixed ratification and facilitate provisional application, but it does

[151] European Parliamentary Research Service, 'The EU's Digital Trade Policy' (European Parliament 2024) 5–6.
[152] Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/1 art 207.
[153] *Opinion 2/15 EU–Singapore FTA EU:C:2017:376* (n 115).
[154] Kurt Hübner, Anne-Sophie Deman and Tugce Balik, 'EU and Trade Policy-Making: The Contentious Case of CETA' (2017) 39 Journal of European Integration 843, 854–855.
[155] Free trade Agreement between the European Union and the Republic of Singapore [2019] OJ L294/3; Council Decision (EU) 2018/ 1676 - of 15 October 2018 - on the signing, on behalf of the European Union, of the Investment Protection Agreement between the European Union and its Member States, of the one part, and the Republic of Singapore, of the other part [2018] OJ L 279/1.

not eliminate national-level scrutiny entirely and may narrow the formal opportunities for national parliaments to vote on IP-related trade provisions that have significant domestic effects.

Conflicts also arise where FTA provisions intersect with sensitive areas of national policy. Member States with strong traditions of educational exceptions or cultural support schemes may encounter greater adjustment pressure where FTAs promote more intensive copyright-enforcement expectations. Likewise, FTA-driven extensions of trade secret protections can sit uneasily alongside domestic transparency regimes, particularly in health and technology regulation. For instance, the EU's Trade Secrets Directive already sets out a harmonized baseline – including civil remedies and procedural confidentiality measures – which, if extended by external commitments without commensurate public-interest exceptions, may limit regulators' ability to disclose information necessary for oversight and public health protection[156].

These frictions show that FTAs do not merely test the outer limits of EU competences but also can recalibrate the internal balance between Union law and Member State autonomy in policy fields that remain only partially harmonized. FTA provisions and other external commitments intersect with the pre-emption doctrine developed in the Court's external-relations case law: once the Union has exercised its competences externally in a given field, Member States' ability to conclude divergent international agreements or to maintain conflicting internal rules is significantly reduced[157]. Accordingly, once external commitments are undertaken under the Union's CCP, implementation may further narrow the scope for divergent national measures[158]. In the area of IP, this may affect national room for manoeuvre in fields where the Union has not fully harmonized substantive law but has nonetheless concluded detailed FTA chapters, such as copyright exceptions, cultural policy or aspects of access to medicines.
The debates surrounding the implementation of CETA's pharmaceutical and GI provisions, and the digital enforcement clauses in the EU–Korea and EU–Singapore agreements, illustrate how such pre-emption concerns can rapidly acquire political salience (see Chapter 5). National constitutional courts and parliaments have responded by intensifying scrutiny of mixed

[156] Directive (EU) 2016/943 of the European Parliament and of the Council - of 8 June 2016 - on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure [2016] OJ L 157/1.
[157] *Opinion 2/15 EU–Singapore FTA EU:C:2017:376* (n 115); Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/1 arts 2 and 3(1)(e).
[158] Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/1 art 207.

agreements, sometimes invoking constitutional identity or democratic oversight as counterweights to competence centralization. The German Federal Constitutional Court's jurisprudence on external economic agreements and the Belgian constitutional debate around CETA exemplify this interaction between EU-level competence allocation and domestic constitutional safeguards[159].

From a normative perspective, the competence allocation in EU FTAs has clear constitutional and democratic prominence. It shapes which institutions authorize IP-related trade commitments, who can be held politically accountable for those choices, and which parliamentary arenas can scrutinize their distributive effects. Where ambitious standards on patents, digital enforcement or GIs are concluded largely within the CCP framework as an "EU-only" instrument, national legislatures may be left primarily with implementation-stage debate, even when the commitments have tangible implications for health budgets, cultural support schemes or rural development. Future treaty practice must, therefore, balance the coherence and credibility gains of a unified external policy with procedures that secure meaningful parliamentary engagement (at Union and national level) and preserve space for constitutional review in Charter-sensitive fields.

4.3 Constitutional Safeguards: Autonomy of EU Law and Fundamental Rights

The most fundamental legal challenge is constitutional: ensuring that FTA commitments do not undermine the autonomy of EU law or the Charter-based rights architecture. Whereas the earlier sections of this chapter addressed techniques for accommodating treaty obligations and questions of competence, this section focuses on autonomy in the strict sense developed by the CJEU – namely, limits on external adjudication and the Charter-based ceiling on implementation. In *Opinion 1/17*, the CJEU upheld the compatibility of CETA's ICS on the basis that the Union's interpretative monopoly and regulatory space are preserved by design[160]. Crucially, however, the Court's reasoning indicates that external adjudication is acceptable only within strict limits that protect the Court's exclusive jurisdiction and the Union's right to regulate – constraints that are especially essential where IP exceptions, data protection, or public health are implicated. In particular, ICS tribunals may not interpret or apply EU primary

[159] Hübner, Deman and Balik (n 154) 854–855; *Bundesverfassungsgericht, Judgment of 6 December 2022 (2 BvR 547/21; 2 BvR 798/21)* (Bundesverfassungsgericht (Federal Constitutional Court, Germany)).
[160] *Opinion 1/17 CETA EU:C:2019:341* (n 8).

or secondary law as such, but only the provisions of the agreement, and they must respect the level of public-interest protection chosen by the Union legislature .

Read alongside *Achmea (C-284/16)* and *Komstroy (C-741/19)*, which reject intra-EU investor–state arbitration as incompatible with EU autonomy, *Opinion 1/17* delineates the outer boundary of permissible external adjudication[161]. In *Achmea* and *Komstroy*, the Court held that arbitral tribunals created by intra-EU investment treaties cannot guarantee the full effectiveness and uniform interpretation of EU law, precisely because they operate outside the Union judicial system. By contrast, the ICS accepted in *Opinion 1/17* is confined to reviewing compliance with the agreement and is structurally prevented from substituting its own understanding of EU law for that of the CJEU. At this institutional level, autonomy, thus, operates as a hard limit: no external body may give binding interpretations of EU primary or secondary law or call into question the final authority of the Union courts.

This constitutional line dovetails with a substantial scholarly critique of investor–state adjudication. Van Harten argues that investor remedies may generate "regulatory chill" by discouraging governments from adopting legitimate public-interest measures due to the risk and cost of arbitration, even where those measures pursue public-interest objectives[162]. Similarly, Titi underscores the structural imbalance between investor expectations and the state's right to regulate, particularly in fields with strong public interest dimensions such as pharmaceuticals or access to knowledge[163]. These perspectives suggest that even if mechanisms like ICS satisfy the formal autonomy test, they may still reshape the substantive policy space available to the EU and its Member States. Accordingly, autonomy operates on two levels: institutionally, as a prohibition on external bodies giving binding interpretations of EU law; and substantively, as a requirement that sufficient regulatory space remains to pursue Charter-consistent policies.

However, meeting the institutional safeguards does not end the analysis. A more fundamental concern persists regarding the prevention of FTAs from re-allocating adjudicatory authority away from the CJEU and constraining democratic space for policy reform. Geiger warns that such external commitments of far-reaching investment protections "would considerably limit

[161] *Case C-284/16 Slovak Republic v Achmea BV EU:C:2018:158* (n 8); *Case C-741/19 Republic of Moldova v Komstroy LLC EU:C:2021:655*; *Opinion 1/17 CETA EU:C:2019:341* (n 8) paras 153–156.
[162] Van Harten (n 134) 166–167.
[163] Titi (n 135) 32–52; 152–160; 216–233.

the future room to manoeuvre of the European institutions and their power to regulate in order to implement a balanced and effective legislative framework for intellectual property", raising concerns about democratic legitimacy and fundamental rights protection[164]. Applied to IP policy, these concerns become visible where reforms – such as reducing effective exclusivity for certain medicines, broadening exceptions for text and data mining, or recalibrating GI protection – could be framed by investors as indirect expropriation or unfair treatment. Even if such measures remain compatible with the Charter, the prospect of costly disputes may exert ex ante pressure on legislators, echoing the dynamics identified in the pharmaceutical and digital case studies (§5.1–5.2).

At the same time, the justiciability of external commitments within the EU legal order remains limited. For instance, the CJEU has consistently held that WTO-type obligations lack direct effect within the EU legal order (*Portugal v Council*, C-149/96) and, moreover, that breaches of such obligations cannot in themselves ground non-contractual liability for counter-measures (*FIAMM*, Joined Cases C-120/06 P and C-121/06 P)[165]. This reinforces the importance of careful implementation strategies, non-direct-effect clauses and robust rights-preserving language at the drafting stage. In practice, these techniques enable the Union to honor its international commitments while preventing individuals from directly invoking FTA provisions to challenge legislative choices anchored in the Charter and the Treaties.

Finally, the Charter of Fundamental Rights provides an additional safeguard. Measures affecting copyright enforcement or data protection must be consistent with Article 11 "freedom of expression and information" and Article 8 "Protection of personal data"[166]. Their reconciliation also engages Article 16 "freedom to conduct a business" and Article 17(2) "protection of intellectual property", requiring a structured proportionality assessment rather than automatic prioritization of exclusivity or enforcement[167]. In its IP case law, the CJEU has operationalized this requirement through multi-step analyses that examine the suitability, necessity and proportionality stricto sensu of enforcement measures, as illustrated by *Scarlet*

[164] Geiger (n 119) 632.
[165] *Case C-149/96 Portuguese Republic v Council of the European Union EU:C:1999:574* (n 144) paras 46–47; 49; *Joined Cases C-120/06 P and C-121/06 P FIAMM and Fedon v Council and Commission EU:C:2008:476* [110–111;174-176;184].
[166] Charter of Fundamental Rights of the European Union [2012] OJ C326/391 art 11;8.
[167] ibid 16;17(2).

Extended, *SABAM and Poland v Parliament and Council* in the context of online platforms, and by *Deckmyn* in the context of copyright exceptions[168].

Moreover, Article 207(1) TFEU stipulates that "the common commercial policy shall be conducted in the context of the principles and objectives of the Union's external action". Article 207(3), further, requires that negotiated agreements be "compatible with internal Union policies and rules"[169]. Anchoring this Charter-conscious approach at the level of treaty-making reinforces the need for alignment between IP chapters in FTAs and the Union's internal rights framework. Articles 3(5) and 21 TEU complement this picture by requiring the Union to promote its values in its external action, thereby linking the design of FTA IP chapters to broader objectives such as human rights, sustainable development and high levels of health protection[170].

Viewed as a whole, these constitutional safeguards cut across sectors and instruments. Pharmaceutical patent-term restoration and data exclusivity must be read in the light of public-health obligations and the limits of SPC recalibration (§ 3.1; § 5.1). Digital enforcement provisions in FTAs interact with the CJEU's prohibition of general monitoring and the Charter-based requirements for platform liability (§ 3.1; § 5.2). GI protection in CETA, the EU–Japan EPA and the EU–Singapore FTA must be implemented consistently with the Union's evocation doctrine and the case law on coexistence and consumer protection (§ 3.2; § 5.4).

As a result, this chapter demonstrates that the principal legal challenges of integrating FTA IP provisions into the EU framework lie not in the simple duplication of standards, but in the risk of constitutional friction. The constitutional techniques and safeguards identified here provide the backdrop against which the sectoral case studies in Chapter 5 must be read and explain why apparently technical IP clauses can trigger far-reaching debates on autonomy, competences and fundamental rights.

[168] *Case C-70/10 Scarlet Extended SA v Société belge des auteurs, compositeurs et éditeurs SCRL (SABAM) EU:C:2011:771* (n 15); *Case C-360/10 Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM) v Netlog NV EU:C:2012:85* (n 15); *Case C-401/19 Republic of Poland v European Parliament and Council ECLI:EU:C:2022:297*; *Case C-201/13 Johan Deckmyn and Vrijheidsfonds VZW v Helena Vandersteen and Others EU:C:2014:2132* (n 42).

[169] Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/1 art 207(1) and (3).

[170] Consolidated version of the Treaty on European Union [2012] OJ C326/13 art 3(5), 21.

5 Case Studies

Case studies provide a structured way to examine the practical implications of FTAs on IP protection in the EU. By focusing on concrete sectors, this chapter highlights how FTA commitments translate into legal, economic and social consequences, and how they interact with the doctrinal and constitutional framework analyzed in Chapters 3 and 4.

The chapter concentrates on four IP-intensive areas – pharmaceuticals, digital technologies, creative industries and the agri-food sector (GIs) – and draws on examples from selected Member States and key trading partners to illustrate empirical trends. Methodologically, each case study follows a common analytical template: it (i) reconstructs the EU baseline (relevant directives, regulations and CJEU case law), (ii) identifies the pertinent FTA commitments and explains the direction and channel of impact on that baseline, (iii) analyses empirical and political responses in the Union and in partner countries, and (iv) examines the resulting normative and constitutional tensions, with particular attention to fundamental rights, regulatory autonomy and distributive effects. This common structure permits systematic comparison across sectors and agreements and clarifies how specific FTA provisions operate within the broader EU legal order.

5.1 Pharmaceuticals, Patent-Term Restoration and Access to Medicines

EU baseline

Within the EU, pharmaceutical exclusivity is structured primarily through patents and SPCs. SPCs, based on Regulation (EC) No 469/2009 and amended by Regulation (EU) 2019/933 introducing a manufacturing waiver, were introduced to compensate patent holders for the time lost in obtaining regulatory approval for medicinal products, thereby extending effective market exclusivity beyond the normal 20-year patent term[171]. The waiver, codified in Article 5(2) of the amended Regulation, permits Union-based manufacturers of generics and biosimilars to produce for export to third-country markets and, under certain conditions, to stockpile for EU market entry immediately upon SPC expiry, partially re-balancing incentives for originators and follow-on producers[172]. The CJEU has progressively narrowed the scope of SPC protection

[171] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1 art 13; Regulation (EU) 2019/933 of the European Parliament and of the Council - of 20 May 2019 - amending Regulation (EC) No 469 / 2009 concerning the supplementary protection certificate for medicinal products [2019] OJ L153/1.

[172] Regulation (EU) 2019/933 of the European Parliament and of the Council - of 20 May 2019 - amending Regulation (EC) No 469 / 2009 concerning the supplementary protection certificate for medicinal products [2019] OJ L153/1 art 5(2).

in cases such as *Seattle Genetics* (C-471/14), *Teva v Gilead* (C-121/17) and *Santen* (C-673/18), clarifying both the triggering event for SPC duration and the eligibility of follow-on uses[173]. This jurisprudence underscores that SPCs are a matter of fine legislative calibration, balancing innovation incentives against the Union's broader regulatory, public health objectives and the commitments laid down in Article 168 TFEU and Article 35 of the Charter of Fundamental Rights of the European Union[174].

FTA commitments and direction of impact

CETA contains a dedicated pharmaceutical annex that goes beyond TRIPS by requiring each party to provide a sui generis period of protection to compensate for regulatory delay (often labelled "patent-term restoration") [175]. This mechanism runs parallel to the Union's existing system of SPCs under Regulation (EC) No 469/2009, which has been interpreted by the Court of Justice in cases such as *Seattle Genetics* (Case C-471/14) and *Teva v Gilead* (Case C-121/17). While the CJEU has treated the calculation of SPC duration as a matter of Union law and legislative discretion, CETA's binding provisions introduce a uniform restoration method that may restrict the EU's ability to recalibrate SPC policy in response to evolving public health needs (see §3.1 and §3.2).

In contrast to SPCs, which remain subject to recalibration by the legislature and interpretation by the CJEU, patent-term restoration under CETA fixes both calculation methods and duration ceilings within a treaty framework. Comparative scholarships on mega-regional and EU bilateral agreements support this reading. As Cottier observes, the IP chapters of mega-regional FTAs introduce TRIPS-plus standards that constrain domestic regulatory flexibility, with pharmaceutical patents and data exclusivity provisions being particularly significant [176]. Complementing this perspective, El Said highlights that provisions such as extended patent terms and data exclusivity can significantly restrict the use of TRIPS flexibilities, undermining governments' ability to address urgent health priorities [177]. In doctrinal terms, the pharmaceutical sector, therefore, exemplifies how FTA commitments affect the protection of

[173] *Case C-471/14 Seattle Genetics Inc v Österreichisches Patentamt EU:C:2015:659* (n 74); *Case C-121/17 Teva UK Ltd and Others v Gilead Sciences Inc EU:C:2018:585* (n 74); *Case C-673/18 Santen SAS v Directeur général de l'INPI EU:C:2020:531* (n 74).
[174] Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/1 art 168; Charter of Fundamental Rights of the European Union [2012] OJ C326/391 art 35.
[175] Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part [2017] OJ L11/23 art 20.27;20.29.
[176] Cottier (n 94) 163–164.
[177] El Said (n 122) 312–315.

IP in the EU less by altering the substance of exclusivity rights than by narrowing the discretion of Union institutions to adjust the temporal and material scope of those rights in response to public health or industrial policy objectives.

Empirical and political responses

Against that background, debates around CETA-style patent-term restoration can be read less as a binary dispute about whether exclusivity should exist than as a contest over how far the EU retains room to adjust the duration and modalities of that exclusivity once treaty obligations are in place. The Union's response to patent-term restoration commitments has not been confined to treaty implementation, it has also played out through internal recalibration of the SPC regime. In 2019, the EU amended the SPC framework for medicinal products through Regulation (EU) 2019/933, introducing the so-called SPC manufacturing waiver as a targeted exception to the exclusivity effects of an SPC[178]. By permitting, under defined conditions, manufacture for export to third-country markets and limited stockpiling ahead of expiry, the waiver reflects a deliberate effort to reduce the competitive disadvantage claimed by EU-based generic and biosimilar producers in markets where equivalent protection does not apply, without abandoning the core logic of SPC-based extension. A European Commission-commissioned study by Copenhagen Economics provides empirical grounding for this policy logic. The report shows how longer effective protection periods are associated with delayed generic and biosimilar entry and with postponed post-entry price reductions, findings that help explain the Commission's interest in narrowly circumscribed mitigation measures[179].

Therefore, the political contestation around CETA-type restoration provisions is symptomatic of a broader distributive trade-off. A substantial empirical and doctrinal literature links extensions of effective exclusivity – whether through SPC-type restoration or other TRIPS-plus devices – to delayed generic/biosimilar entry and corresponding upward pressure on pharmaceutical expenditure, although the magnitude and timing of these effects vary across therapeutic areas, markets and regulatory regimes[180].

[178] Regulation (EU) 2019/933 of the European Parliament and of the Council - of 20 May 2019 - amending Regulation (EC) No 469 / 2009 concerning the supplementary protection certificate for medicinal products [2019] OJ L153/1.
[179] European Commission. Directorate General for Internal Market, Industry, Entrepreneurship and SMEs., *Study on the Economic Impact of Supplementary Protection Certificates, Pharmaceutical Incentives and Rewards in Europe: Final Report.* (Publications Office 2018) 13–15.
[180] Brigitte Tenni and others, 'What Is the Impact of Intellectual Property Rules on Access to Medicines? A Systematic Review' (2022) 18 Globalization and Health 40.

Under those circumstances, CETA's "additional period of protection" operates as a commitment device that strengthens expectations of continuity in exclusivity settings and, in doing so, can raise the political and legal cost of later recalibration (as analyzed doctrinally in §3.1 and constitutionally in §4.1). Further doctrinal analysis by Xavier Seuba of CETA shows how such treaty commitments can constrain regulatory discretion and increase the risk or cost of legal challenge, even where Member States retain formal competence to act[181].

This interaction helps explain why debates about pharmaceutical IP commitments increasingly track internal policy agendas rather than remaining "external trade" questions. The Commission's Pharmaceutical Strategy for Europe explicitly couples industrial and innovation objectives with the need to ensure safe, effective and affordable medicines, and to strengthen supply-chain resilience and EU strategic autonomy[182]. Yet stronger or more rigid exclusivity settings can shift adjustment burdens onto downstream payer-side processes – especially national pricing and reimbursement negotiations and related procurement dynamics – rather than addressing affordability effects at the level of the exclusivity rule itself. The Commission's evaluation of the SPC regime underlines this mechanism[183]. After marketing authorization, access and timing are strongly shaped by national pricing and reimbursement negotiations, while extended exclusivity delays generic entry and carries costs for health budgets through monopoly pricing[184]. Moreover, where exclusivity is reinforced through external commitments (including SPC-related provisions in bilateral trade agreements), the evaluation points to knock-on issues of transparency deficits and administrative burden within the fragmented SPC system, with implications for availability and accessibility of medicines[185].

Accordingly, the central point is not simply that CETA-style restoration may extend exclusivity, but that it can re-structure the governance of adjustment. These findings illustrate the core tension within CETA's pharmaceutical IP chapter. While the European Commission frames patent-term restoration as a necessary incentive for innovation and R&D investment, critics highlight the risk of higher healthcare expenditure and reduced access to medicines. The issue is particularly acute in Member States with publicly funded healthcare systems, where extended

[181] Xavier Seuba, 'The Export and Stockpiling Waivers: New Exceptions for Supplementary Protection Certificates' (2019) 14 Journal of Intellectual Property Law & Practice 876, 880–881.
[182] European Commission, 'Pharmaceutical Strategy for Europe' COM(2020) 761 Final, 25 November 2020' s 1,3-4.
[183] European Commission, 'Commission Staff Working Document – Evaluation of the SPC Regulations' (2020) SWD(2020) 292 final s 5.2.1.
[184] ibid 5.2.1, 4.4.
[185] ibid 5.1.3.2, 5.2.2.

exclusivity may undermine commitments to equitable access. The case demonstrates how FTAs can crystallize IP protection standards in ways that interact directly with EU law, case law of the CJEU, and national health policy, raising questions about the balance between international obligations and the Union's constitutional commitment to public health under Article 168 TFEU and the Charter (see §4.1 and §4.3).

Normative and constitutional tensions

At the normative level, the controversy is less about whether pharmaceutical exclusivity is legitimate per se and more about constitutional control of its calibration once exclusivity settings are embedded in treaty commitments. CETA is instructive because it simultaneously entrenches a restoration obligation and builds an internal "public health" interpretive safeguard. Specifically, article 20.3 requires interpretation and implementation of the IP chapter consistently with the Doha Declaration on TRIPS and Public Health, while Article 20.4 preserves each Party's freedom on exhaustion[186]. This drafting choice supports a reading of CETA's restoration mechanism that remains permeable to TRIPS flexibilities (including compulsory licensing and parallel trade/exhaustion choices). However, it does not remove the structural effect identified earlier that treaty-level restoration can still raise the political and legal cost of later EU recalibration of effective protection periods (see §3.1; §4.1).

Member-State constitutional discourse can amplify this tension. In Germany, the Federal Constitutional Court has recognized an enforceable guarantee to a dignified subsistence minimum under Article 1(1) GG read together with the "social-state" principle in Article 20(1) GG[187]. While that doctrine is not an "access to medicines" ruling as such, it provides a doctrinal vocabulary through which exclusivity-driven affordability effects can be framed as questions of social-rights protection and legislative proportionality, thereby increasing the salience of fundamental-rights scrutiny at implementation stage rather than treating patent-term restoration as a purely external trade commitment[188].

[186] Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part [2017] OJ L11/23 art 20.3-20.4.
[187] *Bundesverfassungsgericht, Judgment of 9 February 2010, 1 BvL 1/09 (and joined cases)* (Federal Constitutional Court (Bundesverfassungsgericht)).
[188] Claudia Bittner, 'Casenote — Human Dignity as a Matter of Legislative Consistency in an Ideal World: The Fundamental Right to Guarantee a Subsistence Minimum in the German Federal Constitutional Court's Judgment of 9 February 2010' (2011) 12 German Law Journal 1941, 1941–1944, 1948–1951.

Comparable constraints arise at Union level, albeit through a different architecture. Article 35 of the Charter, read with Article 168 TFEU's requirement to ensure a high level of human health protection, guides Union policy direction but does not mandate specific pricing outcomes[189]. Operationally, the Charter frames the balancing exercise. Article 17(2) of the Charter protects intellectual property but does not allow it to trump health protection automatically[190]. Thus, any restriction or rebalancing of IPRs must satisfy the conditions of Article 52(1) and should be read in light of Article 35 of the Charter as well as Article 168 TFEU, which mainstream health considerations into Union policy-making[191]. CETA's reference to the Doha Declaration reinforces this interpretive stance by confirming, at treaty level, that IP obligations should not be read to prevent public-health measures supported by TRIPS flexibilities.

Accordingly, the constitutional pressure point is not "more protection versus less protection" but whether restoration commitments are drafted and applied in a way that preserves meaningful regulatory space for public-health safeguards, including TRIPS-consistent flexibilities explicitly acknowledged in the agreement. Where restoration is treated as a quasi-immutable entitlement insulated from such correctives, the risk is a de facto re-weighting of the Charter balance (Article 17(2) versus Articles 35 and 52(1)) and an implementation dynamic that shifts distributive adjustment onto national health budgets rather than the exclusivity rule itself.

5.2 Digital and Technology Sectors, Online Enforcement and Intermediary Liability

EU baseline

The technology and digital sectors are shaped by IP rules, above all through copyright enforcement and the liability of online intermediaries. The EU's framework – built around the InfoSoc Directive, the E-Commerce Directive and the DSM Directive – aims to mediate between rightsholders' protection interests, platform governance, and users' fundamental rights[192]. Since 2022, that baseline is further conditioned by the Digital Services Act (DSA),

[189] Tobias Lock, 'Article 35 CFR' in Manuel Kellerbauer, Marcus Klamert and Jonathan Tomkin (eds), *The EU Treaties and the Charter of Fundamental Rights: A Commentary* (1st edn, Oxford University Press, Incorporated 2019).
[190] Charter of Fundamental Rights of the European Union [2012] OJ C326/391 art 17(2).
[191] ibid 52(1), 35; Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/1 168.
[192] Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the Harmonisation of Certain Aspects of Copyright and Related Rights in the Information Society [2001] OJ L167/10,; Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain

which preserves the core "no general monitoring" principle while layering horizontal due-diligence duties.

The E-Commerce Directive 2000/31/EC establishes conditional liability exemptions for "mere conduit" (Art 12), "caching" (Art 13) and "hosting" (Art 14) and, crucially, prohibits Member States from imposing a general obligation to monitor information transmitted or stored by intermediaries (Art 15) [193]. The DSA retains this architecture (including the "no general monitoring" rule) but adds procedural and transparency obligations – most visibly a harmonized notice-and-action mechanism – without converting intermediaries into general-purpose enforcers[194].

Against this background, the DSM Directive creates a sector-specific carve-out in Article 17 for online content-sharing service providers (OCSSPs). Such providers must obtain authorization or make best efforts regarding the unavailability of notified works, but only within a safeguard package (proportionality, complaint and redress, transparency, and protection of lawful uses) [195]. The CJEU constitutionalized the limits of intermediary-based enforcement in *Scarlet Extended* (C-70/10) and *SABAM v Netlog* (C-360/10), rejecting general and indiscriminate filtering/monitoring duties as disproportionate interferences with Articles 11 and 8 of the Charter[196]. At the same time, the Court accepts targeted, proportionate intermediary injunctions as a legitimate enforcement channel (e.g. *L'Oréal v eBay* (C-324/09); *UPC Telekabel Wien* (C-314/12)), which clarifies that the constitutional constraint is not "no intermediary duties", but "no generalized surveillance"[197].

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legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') [2000] OJ L 178/1 acts 12–15; Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC [2019] OJ L130/92 act 17.

[193] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') [2000] OJ L 178/1 arts 12–15.

[194] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) OJ L 277/1 act 8,16.

[195] Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC [2019] OJ L130/92 art 17.

[196] *Case C-70/10 Scarlet Extended SA v Société belge des auteurs, compositeurs et éditeurs SCRL (SABAM) EU:C:2011:771* (n 15); *Case C-360/10 Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM) v Netlog NV EU:C:2012:85* (n 15).

[197] *Case C-324/09 L'Oréal SA and Others v eBay International AG and Others EU:C:2011:474*; *Case C-314/12 UPC Telekabel Wien GmbH v Constantin Film Verleih GmbH and Wega Filmproduktionsgesellschaft mbH ECLI:EU:C:2014:192*.

More recently, in Poland v Parliament and *Council* (Case C-401/19), the CJEU upheld Article 17 DSM only on the basis that it must be implemented with effective safeguards against over-blocking (including user redress and a strict reading of "manifestly infringing" content)[198]. In doctrinal terms, this case fixes a rights-sensitive interpretative frame. That is to say, external commitments on online enforcement can be accommodated only insofar as implementing measures remain compatible with the Charter-based proportionality structure developed in the Court's intermediary case law.

FTA commitments and direction of impact

The digital case study illustrates a distinctively indirect influence channel. Modern FTAs rarely "rewrite" EU intermediary law, but by stabilizing external enforcement architectures and embedding procedural and dispute mechanisms they can raise the political and legal costs of internal deviation, producing harmonizing or chilling effects on domestic policy choices.

In the EU–Korea FTA, the intermediary section closely tracks the EU safe-harbor model. It provides limitations of liability for mere conduit, caching and hosting, preserves the possibility of targeted injunctions, and includes an explicit "no general obligation to monitor" clause[199]. This matters for two reasons. First, it exports a rights-conscious template that is broadly compatible with the CJEU's constitutional ceiling (*Scarlet Extended*; *SABAM v Netlog*). Second, because the FTA is a treaty commitment, it can operate as an external "anchor". This means that proposals to shift EU policy towards systematic "stay-down" or general monitoring can be framed not only as Charter-sensitive, but also as externally inconsistent with the model the EU has promoted in its bilateral practice[200].

Likewise, the EU–Singapore FTA contains a dedicated provision on liability of intermediary service providers. This provision combines conditional liability limitations with a prohibition on general monitoring and an orientation toward notice-and-action procedures[201]. Hence, the influence is not best characterized as the EU importing a US-style DMCA model (i.e. conditional safe harbors tied to notice-and-takedown and a counter-notification procedure under the US Copyright Act). Rather, the risk is a subtler governance effect: treaty language

[198] *Case C-401/19 Republic of Poland v European Parliament and Council ECLI:EU:C:2022:297* (n 168).
[199] Free trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part [2011] OJ L127/6 art 10.63-10.66.
[200] ibid.
[201] Free trade Agreement between the European Union and the Republic of Singapore [2019] OJ L294/3 art 10.47.

that prioritizes "expeditious" disabling of access upon notice can, depending on implementation practices, tilt private enforcement toward rapid removal and automated moderation, with predictable pressure on lawful uses and due-process guarantees – precisely the concerns that drove the Court's insistence on safeguards in Poland v Parliament and Council[202].

Counterfactual comparator (TTIP): Although the TTIP negotiations were never concluded, drafts and transparency releases made intermediary enforcement a politically salient issue and sharpened the contrast between EU constitutional constraints (no general monitoring; proportionality) and more enforcement-maximalist approaches discussed in transatlantic debates[203]. This makes TTIP useful not as binding law, but as a stress-test for how far the EU could have moved in treaty form without colliding with the Charter framework analyzed in Chapter 4.

Empirical and political responses

Beyond doctrinal debates, empirical evidence underscores the sector's economic importance. However, the principal empirical signal in this sector is not simply "more infringement" or "more enforcement", but implementation divergence and risk-shifting. Enforcement duties are increasingly operationalized through platform processes (terms of service, automated detection, notice workflows), while the costs of error (over-removal, chilling effects, compliance burdens) fall unevenly on users, SMEs, and smaller rightsholders.

Internally, Article 17 DSM has been a focal point of contestation. The Commission's Article-17 Guidance underscores that Member States must implement Article 17 in a manner that protects lawful uses and avoids general monitoring, effectively translating the CJEU's requirements in Poland v Parliament and Council into administrative expectations[204]. National implementation choices then become constitutionally loaded. Germany's implementation statute (UrhDaG) is illustrative. It hard-codes complaint/redress and user-protection mechanisms intended to reduce over-blocking, while still enabling rightsholders to pursue rapid

[202] *Case C-401/19 Republic of Poland v European Parliament and Council ECLI:EU:C:2022:297* (n 168).
[203] European Commission, 'Transatlantic Trade and Investment Partnership (TTIP) – Intellectual Property EU Position Paper' (European Commission 2015) <https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/countries-and-regions/united-states/eu-negotiating-texts-ttip_en> accessed 30 June 2025.
[204] Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC [2019] OJ L130/92 art 17.

action against clearly infringing uploads[205]. This confirms the broader thesis claim (see §4.1): where exclusivity rules and enforcement expectations harden, the "adjustment" often reappears downstream as procedural design – complaints, redress, transparency, and accountability – rather than as a simple recalibration of the underlying right.

Externally, the EU's FTA practice adds a further political layer. When the EU requests its partners to adopt safe-harbor/no-monitoring structures (EU–Korea; EU–Singapore), it strengthens the Union's claim to be exporting a balanced governance model. However, it also increases scrutiny of whether EU internal reforms remain coherent with that exported template. This coherence pressure is likely to intensify as the EU's wider digital rulebook expands (DSA-style proceduralizing; AI governance) and as enforcement increasingly relies on platform-based moderation systems.

Normative and constitutional tensions

The normative tension in this case study can be conceptualized in a triangular structure: (i) effective enforcement, (ii) regulatory autonomy in digital governance, and (iii) Charter-protected freedoms – notably Articles 11 (freedom of expression) and 8 (privacy), with Article 17(2) of the Charter operating as a countervailing constitutional interest rather than an automatic trump.

First, fundamental rights operate as a ceiling. The CJEU in *Scarlet Extended* and *Netlog* rejected generalized filtering because it substitutes ex-ante surveillance for adjudication and predictably captures lawful speech[206]. Then, Poland v Parliament and Council confirms that even Article 17's distinctive platform regime is acceptable only under a safeguards reading that protects lawful uses and meaningful redress[207]. In the FTA context, this implies a disciplined interpretative approach: treaty provisions on intermediary enforcement must be read through the Charter-consistent proportionality logic developed by the Court, rather than treated as mandates for maximal removal.

[205] Germany, Urheberrechts-Diensteanbieter-Gesetz (UrhDaG) (Act on the Copyright Liability of Online Content Sharing Service Providers) 2021.
[206] *Case C-70/10 Scarlet Extended SA v Société belge des auteurs, compositeurs et éditeurs SCRL (SABAM) EU:C:2011:771* (n 15); *Case C-360/10 Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM) v Netlog NV EU:C:2012:85* (n 15).
[207] *Case C-401/19 Republic of Poland v European Parliament and Council ECLI:EU:C:2022:297* (n 168).

Second, regulatory autonomy is tested through "path dependence" rather than direct conflict. By embedding safe-harbor/no-monitoring language in FTAs, the EU projects a governance model that is broadly compatible with its constitutional identity in digital regulation. Yet the same practice can constrain future legislative bargaining space. Once a model is treaty-stabilized externally, internal moves toward more intrusive monitoring architectures become harder to justify, even before Charter review is reached (see §4.3).

Finally, the distributional stakes are structural. Stronger intermediary enforcement tends to privilege actors with scale (large platforms and large rightsholders) and to burden smaller market participants with compliance costs and heightened legal uncertainty. The literature on intermediary injunctions and platform enforcement stresses that the design choice is not "enforcement or no enforcement", but where the system places error-costs, oversight, and accountability – a question that sits at the heart of the Union's "fair balance" approach.

Overall, the digital case study shows how FTAs can consolidate an enforcement-capable template (i.e. safe harbors + no general monitoring) while simultaneously enhancing the significance of Charter safeguards as the condition of legitimacy for any shift toward accelerated, more automated enforcement. This phenomenon makes intermediary liability an archetypal site where external trade commitments intersect with constitutional limits on enforcement design (see §§3.1-3.2; §4.3).

5.3 Creative Industries , Copyright and Cultural Policy

EU baseline

The creative industries – encompassing film, music, publishing, and audiovisual services – are structurally dependent on copyright and neighboring rights. The EU has long regarded cultural diversity and the protection of authors' rights as core policy objectives, enshrined both in its internal legislation (notably Article 167 TFEU) and in international commitments such as the UNESCO Convention on the Protection and Promotion of the Diversity of Cultural Expressions (2005)[208]. At the same time, the CJEU has underlined the constitutive role of limitations and exceptions in maintaining a "fair balance". In *Deckmyn and Vrijheidsfonds VZW v Vandersteen*

[208] Convention on the Protection and Promotion of the Diversity of Cultural Expressions (UNESCO) 2005.

(Case C-201/13), it emphasized that exceptions such as parody can give effect to freedom of expression and must be interpreted in a manner that respects fundamental rights[209].

More broadly, the InfoSoc Directive and the DSM Directive establish a catalogue of exceptions and limitations for education, research and certain transformative uses, leaving Member States a degree of discretion to tailor implementation choices that interact with cultural and educational policy. This combination of strong exclusive rights and structured flexibilities constitutes the baseline against which external copyright commitments must be assessed.

FTA commitments and direction of impact

Modern FTAs increasingly include copyright disciplines and digital-enforcement clauses that shape the legal environment for cultural goods and services. In the EU–Japan EPA, the IP package consolidates convergence on long copyright duration (life + 70) and related rights, and clarifies expectations on enforcement as well as technological protection measures and rights-management information[210]. However, the practical point for EU-law analysis is less a "change" in EU law than a stabilization dynamic. The EU externalizes the acquis as a bilateral benchmark, which can complicate the later political reopening of term length and enforcement calibration as a matter of regulatory credibility. A comparable logic operates in the EU–Singapore FTA, whose IP chapter imposes obligations on technological protection measures and rights-management information and requires effective civil enforcement, thereby reinforcing a high-protection template in a major distribution and services hub[211].

From a structural EU-law perspective, these commitments matter because they can convert contested internal parameters (term length; enforcement intensity; the practical effectiveness of exceptions) into default settings in the EU's external economic constitution. The effect is indirect because the treaties do not amend EU directives. However, they may raise the justificatory threshold for reforms that would shorten term, broaden user-oriented flexibilities, or recalibrate enforcement tools.

Furthermore, FTAs raise a special regulatory-autonomy issue in the cultural field. To preserve space for cultural policy and media support, the EU has historically employed reservations and

[209] *Case C-201/13 Johan Deckmyn and Vrijheidsfonds VZW v Helena Vandersteen and Others EU:C:2014:2132* (n 42).
[210] Economic Partnership Agreement between the European Union and Japan [2018] OJ L330/3 ch 14.
[211] Free trade Agreement between the European Union and the Republic of Singapore [2019] OJ L294/3 ch 10.

exclusions for audiovisual services as a means of allocating resources for cultural policy and media support. This approach, often described by Burri as "*cultural exception"*[212], has gained significant political prominence during the TTIP debates and continues to influence the treaty design[213]. As a result, the constitutional tension manifests at two levels. On the one hand, the EU seeks to keep market-access disciplines away from audiovisual policy, while simultaneously exporting strong copyright/enforcement disciplines that can still affect the conditions under which cultural works circulate, are licensed, and are reused.

The same logic extends beyond term length. Even where the EU preserves an audiovisual carve-out ("cultural exception") in services/e-commerce chapters, digitization makes that protection structurally porous. Digital trade disciplines and copyright-enforcement baselines can still shape cultural circulation and platform distribution even when audiovisual services are formally excluded. Burri's work frames this as a trade-and-culture tension that is intensified in the online environment, where the line between "cultural policy" and "digital trade governance" is increasingly difficult to police in practice [214].

Empirical and political responses

Economically, the cultural and creative sectors are significant, but the distributive effects of stronger copyright disciplines are uneven across actors. Eurostat's latest Culture Statistics report that cultural employment in the EU reached 7.9 million people in 2024 (3.8% of total employment), and that nearly one-third of cultural workers (31.7%) were self-employed – well above the EU economy-wide average[215]. This labor-market profile matters for FTA-linked copyright disciplines because compliance costs and enforcement frictions are not borne evenly. Self-employed creators and micro-enterprises often face higher transaction costs in licensing, clearance, and dispute management than large catalogues and major distributors.

Enterprise data point in the same direction. In 2023, 2.1 million cultural enterprises generated around €202 billion in value added and approximately €524 billion in net turnover, with SMEs

[212] Mira Burri, 'The European Union, the World Trade Organization and Cultural Diversity' in Evangelia Psychogiopoulou (ed), *Cultural Governance and the European Union* (Palgrave Macmillan 2015) 200–207.
[213] Maria Chochorelou, 'The European Identity Rationale in the EU Free Trade Agreements: Economic Rather than Cultural Objectives?' [2019] Cuadernos Europeos de Deusto 227 <https://ced.revistas.deusto.es/article/view/1557> accessed 25 October 2025.
[214] Burri (n 212) 200–207.
[215] Eurostat, 'Culture Statistics – Cultural Employment' (European Commission) <https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Culture_statistics_-_cultural_employment> accessed 18 November 2025.

generating most of the sector's value added[216]. This phenomenon provides a contextual framework for understanding the propensity of large rightsholders and collecting societies to advocate for extended protection durations and robust enforcement mechanisms, especially where FTAs reduce friction in key export markets. In contrast, entities such as libraries, archives, educational institutions, and smaller creators underscore the importance of ensuring the practical accessibility of exceptions as well as the viability of licensing and collective management schemes.

Politically, these distributive patterns map onto the core controversy in this case study. Eurostat notes cultural goods exports outside the EU valued at €31.5 billion (headline figure in its 2025 sector briefing), which reinforces the trade-policy rationale for high external protection standards[217]. Yet the same enforcement and technological-measure commitments that facilitate cross-border commercial exploitation can increase the risk that reuse, digitization projects and educational access depend on costly, fragmented permissions, unless exceptions and public-interest safeguards remain practically effective.

This sectoral structure helps explain why the political controversy focuses on how copyright duration and enforcement techniques allocate costs and benefits across market actors. Term-length debates illustrate this distributive structure. Policy reviews of EU term extension in neighboring rights show that benefits are concentrated and that the public-cost/availability side requires careful justification, rather than being assumed[218]. In the digital cultural economy, concerns also focus on enforcement techniques (blocking, de-indexing, accelerated takedown dynamics) that can have a chilling effect on lawful quotation, parody, and remix unless procedural safeguards are strong and effective in practice[219].

Normative and constitutional tensions

[216] Eurostat, 'Culture Statistics - Cultural Enterprises' (European Commission) <https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Culture_statistics_-_cultural_enterprises> accessed 18 November 2025.

[217] Eurostat, 'Culture Statistics - International Trade in Cultural Goods' (European Commission) <https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Culture_statistics_-_international_trade_in_cultural_goods> accessed 18 November 2025.

[218] Ana Ramalho and Aurelio Lopez-Tarruella, 'Implementation of the Directive 2011/77/EU: Copyright Term of Protection' (European Parliament, Policy Department for Citizens' Rights and Constitutional Affairs (Directorate-General for Internal Policies of the Union) 2018) PE 604.957 16–17.

[219] Christophe Geiger and Elena Izyumenko, 'The Role of Human Rights in Copyright Enforcement Online: Elaborating a Legal Framework for Website Blocking' (2016) 32 American University International Law Review 43, 57–63.

At Union level, the key constitutional point is that exceptions and limitations are not peripheral "loopholes" but part of the copyright settlement, and CJEU case law treats freedom of expression as an internal constraint on enforcement design[220]. That constraint has been reaffirmed in the Court's "freedom of expression" line of copyright judgments, which treats the Charter balance as an internal limit on both the scope of exclusive rights and the design of remedies (including in sampling/quotation contexts)[221]. Scholarship on "constitutionalized" EU copyright similarly stresses that users' interests and access rationales must remain operational, not merely formal, framing exceptions as user-facing entitlements whose effectiveness can require procedural and access-facilitating duties, rather than purely formal statutory permissions [222].

For the EU–Japan EPA and the EU–Singapore FTA, the interpretative task is thus to read external commitments through the Charter-sensitive limits already developed in EU law. Treaty commitments on technological measures and enforcement cannot be implemented (or used as interpretative leverage) in a way that renders exceptions practically ineffective, or that pushes enforcement into overbroad restrictions on lawful cultural speech. A recurring pressure point is the interaction between anti-circumvention rules and exceptions. Where technological protection measures (TPMs) are robustly protected, lawful uses risk becoming "rights on paper" unless the EU's own correction mechanisms – notably Article 6(4) InfoSoc – operate effectively in practice[223]. The CJEU's insistence on the effectiveness of exceptions in institutional contexts, including for libraries and cultural heritage functions, reinforces that point. That is reflected in its ruling – case C-117/13 – that libraries may digitize works for access via dedicated on-site terminals while respecting the limits of the exception[224].

As shown above, the creative-industries case study illustrates the double-edged character of copyright provisions in FTAs. They can strengthen EU rightsholders' position abroad and reduce transaction frictions in key export markets, but they also risk "hardening" term length

[220] *Case C-201/13 Johan Deckmyn and Vrijheidsfonds VZW v Helena Vandersteen and Others EU:C:2014:2132* (n 42); *Case C-314/12 UPC Telekabel Wien GmbH v Constantin Film Verleih GmbH and Wega Filmproduktionsgesellschaft mbH ECLI:EU:C:2014:192* (n 197).
[221] *Case C-476/17 Pelham GmbH and Others v Ralf Hütter and Florian Schneider-Esleben ECLI:EU:C:2019:624*.
[222] Christophe Geiger and Bernd Justin Jütte, 'Copyright as an Access Right: Concretizing Positive Obligations for Rightholders to Ensure the Exercise of User Rights' (2024) 73 GRUR International 1019, 1019–1026, 1030–1035.
[223] ibid 1023–1026; Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the Harmonisation of Certain Aspects of Copyright and Related Rights in the Information Society [2001] OJ L167/10, art 6(4).
[224] *Case C-117/13 Technische Universität Darmstadt v Eugen Ulmer KG ECLI:EU:C:2014:2196*.

and enforcement expectations in ways that compress cultural-policy flexibility and intensify pressure on the public domain and user freedoms (see §§3.2 and 4.3).

5.4 Agri-Food Sector and Geographical Indications (GIs)

EU baseline

Within the EU's legal framework, the protection of GIs is notably robust. This protection is now consolidated in Regulation (EU) 2024/1143 (repealing Regulation (EU) No 1151/2012), while largely carrying forward the "high exclusivity" logic of the earlier regime[225]. It extends beyond direct misuse to capture evocation, translation and comparable practices that exploit the protected name's reputation, even where consumers are not misled in the classical trade mark sense[226].

The CJEU has delineated the operational contours of that "high protection" through a line of GI judgments that treat evocation as a distinct infringement pathway. In *Scotch Whisky Association v Klotz* (C-44/17), the Court clarified that evocation could arise even without consumer confusion, focusing on whether the contested sign triggers a sufficiently direct association with the protected indication[227]. In *Budějovický Budvar* (C-478/07), the Court addressed the interface between protected geographical designations – including those protected under international/bilateral arrangements – and national rules on signs/trade marks, illustrating that GI-type protection may coexist with (and constrain) trade mark strategies under EU-law conditions[228]. Finally, in *Consorzio del Prosciutto di Parma* (Joined Cases C-108/01 and C-109/01), the Court reinforced the centrality of product specifications and control mechanisms for ensuring that GI functions as a credible quality signal rather than a mere marketing device [229].

From a doctrinal perspective, this baseline matters for the thesis because it shows that EU GI law is not "just another IP right". It is also an instrument of consumer information, fair returns for producers, and rural-development policy, which explains why the EU is willing to spend

[225] Regulation (EU) 2024/1143 of the European Parliament and of the Council of 11 April 2024 on geographical indications for wine, spirit drinks and agricultural products, as well as traditional specialities guaranteed and optional quality terms for agricultural products, amending Regulations (EU) No 1308/2013, (EU) 2019/787 and (EU) 2019/1753 and repealing Regulation (EU) No 1151/2012 [2024] OJ L 2024/1143.
[226] ibid 3.
[227] *Case C-44/17 Scotch Whisky Association v Michael Klotz EU:C:2018:415*.
[228] *Case C-478/07 Budějovický Budvar, národní podnik v Rudolf Ammersin GmbH ECLI:EU:C:2009:521*.
[229] *Joined Cases C-108/01 and C-109/01 Consorzio del Prosciutto di Parma and Salumificio S Rita SpA v Asda Stores Ltd and Hygrade Foods Ltd EU:C:2003:296*.

negotiating capital on GI recognition abroad and why external compromises can be constitutionally sensitive when they appear to dilute internal protection[230].

FTA commitments and direction of impact

CETA offers a clear example of how FTAs extend EU-style GI protection beyond European borders. CETA offers protection for a listed set of EU names (173 in the EU text as signed/published), coupled with a mechanism to update lists through the frame work of treaty governance[231]. The EU–Japan EPA and the EU–Singapore FTA employ a comparable "list + enforcement + updating" template, extending EU-style GI protection into major Asian markets (with over 200 EU GIs protected in Japan and a defined list protected in Singapore)[232].

For EU producers, these frameworks strengthen legal certainty, reduce misappropriation risk and support premium-price strategies in export markets. For example, the Commission's GI value study in 2020 estimates GI product sales in the EU at around €74.8 billion with €16.9 billion in exports (reference year 2017), underscoring why GI protection features prominently in external commercial strategy[233].

The legally significant point for this thesis, however, is the direction and channel of impact. Modern FTAs raise protection abroad above the minimum standards of TRIPS (Arts 22–24) by extending strong-form protection beyond wines/spirits and by adopting EU-style concepts (including evocation-type protection), while simultaneously tempering export through coexistence and "grandfathering" clauses for certain prior uses/trade marks and (in some partner states) terms treated as generic in local practice[234]. This produces an asymmetric effect: it strengthens EU producers' exclusivity abroad, but it does so through negotiated exceptions that would be difficult to replicate inside the internal market without colliding with the Court's evocation case law and the policy functions embedded in the EU GI regime[235].

[230] Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [2012] OJ 343/1 art 4, rec. 1–4.
[231] Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part [2017] OJ L11/23 chs 20, Annex 20-A.
[232] Economic Partnership Agreement between the European Union and Japan [2018] OJ L330/3 Annex 14-B; Free trade Agreement between the European Union and the Republic of Singapore [2019] OJ L294/3 Annex 14-B.
[233] European Commission, 'Geographical Indications–a European Treasure Worth €75 Billion' (*Press release*) <https://ec.europa.eu/commission/presscorner/detail/en/ip_20_683> accessed 19 November 2025.
[234] TRIPS Agreement.
[235] *Case C-44/17 Scotch Whisky Association v Michael Klotz EU:C:2018:415* (n 227).

Equally important is the governance shift. GI protection in these FTAs entails more than merely implementation of substantive rules and domestic enforcement. It also involves management by committees, enabling technical updates (e.g. additions to GI lists) through treaty bodies rather than ordinary EU legislation. In constitutional terms, this matters because it relocates parts of the "calibration work" to Article 218 TFEU decision-making and committee practice, increasing the premium on ensuring that updates remain compatible with the internal baseline and do not become a vehicle for lowering protection standards by interpretative drift[236].

Empirical and political responses

The distributive effects of GI export are most visible in contexts where a partner's established market practice treats certain European names as generic. Canada's implementation of CETA exemplifies this adjustment dynamic. The treaty design protects listed EU GIs, while providing carve-outs and qualifiers for certain pre-existing uses, requiring relabeling and re-positioning strategies in affected product segments. Empirical work on the Canadian dairy market finds that GI protection combined with such transitional/coexistence arrangements can reshape competitive conditions and consumer perceptions, with heterogeneous welfare effects across producer groups and product categories[237].

The counterfactual comparator (TTIP) helps explain why the EU relies on "list-based" GI export and why GI chapters are recurrent flashpoints in transatlantic trade politics. In TTIP debates, the EU's insistence on recognition of key names encountered sustained US resistance grounded in a trade mark/consumer-protection framing and in the claim that many disputed terms are generic in US commerce[238]. The practical implications for EU treaty practice are evident in CETA-style compromise architecture, which secures strong protection for a defined list of EU GIs combined with specified coexistence or transitional arrangements for certain prior users, rather than the "maximalist" internal model projected without adjustment[239].

Normative and constitutional tensions

[236] Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/1 art 218.
[237] Peter Slade, Jeffrey D Michler and Anna Josephson, 'Foreign Geographical Indications, Consumer Preferences, and the Domestic Market for Cheese' (2019) 41 Applied Economic Perspectives and Policy 370.
[238] Carmen-Cristina Cîrlig, 'Overcoming Transatlantic Differences on Intellectual Property' (European Parliamentary Research Service (European Parliament) 2014) 29–30 <https://www.europarl.europa.eu/RegData/bibliotheque/briefing/2014/140760/LDM_BRI%282014%29140760_REV1_EN.pdf> accessed 19 November 2025.
[239] Martijn Huysmans, 'Exporting Protection: EU Trade Agreements, Geographical Indications, and Gastronationalism' (2022) 29 Review of International Political Economy 979, 990–992.

From an EU-constitutional perspective, the primary tension does not lie in the legitimacy of GI protection (as it is firmly embedded in EU law). Rather, the central question is whether external compromises and committee-based updates can be reconciled with the internal GI settlement and the Court's insistence on an autonomous, high-protection interpretation. The case law's logic – as illustrated in Scotch Whisky on evocation and Parma Ham on specification/control – suggests that GI protection is meaningful only if the sign retains its capacity to act as a credible quality-and-origin signal. Consequently, overly permissive coexistence can, from a doctrinal perspective, be regarded as a partial functional downgrade of the GI right[240].

The academic literature captures this as an export-versus-integrity problem. Gangjee's account of GI law emphasizes that strong-form protection is closely tied to the EU's quality-policy narrative and that trade-agreement coexistence solutions can generate normative friction by normalizing weaker protection abroad for names that are strongly protected at home[241]. Similarly, Huysmans' empirical-institutionalist work shows that the EU's export of GIs protection relies on politically sustainable compromise designs, which can entrench distributive asymmetries and provoke continued contestation where genericness or prior-use claims persist[242].

Accordingly, the GI case study illustrates a distinctive constitutional limit relevant to the research question. FTA-driven expansion of GI protection is a prominent channel for exporting EU regulatory preferences, but it also externalizes and stabilizes contested boundary choices (genericness, coexistence, evocation) in treaty form, shifting parts of the adjustment burden to governance mechanisms (committees, domestic implementing authorities, and litigation in partner states) rather than to EU legislative recalibration. This makes GIs a paradigmatic site where modern FTAs both extend IP protection and generate legal-constitutional friction around regulatory autonomy, coherence, and distributive legitimacy (see §3.2; §4.1; §4.3).

Across the four case studies, the legal effect of modern FTAs is best captured as selective entrenchment rather than wholesale transformation of the acquis. Pharmaceutical exclusivity (patent-term restoration alongside SPCs), intermediary-centered enforcement templates, copyright duration and TPM/enforcement expectations, and GI evocation-style protection with

[240] *Joined Cases C-108/01 and C-109/01 Consorzio del Prosciutto di Parma and Salumificio S. Rita SpA v Asda Stores Ltd and Hygrade Foods Ltd EU:C:2003:296* (n 229); *Case C-44/17 Scotch Whisky Association v Michael Klotz EU:C:2018:415* (n 227).
[241] Dev Gangjee, *Relocating the Law of Geographical Indications* (Cambridge University Press 2012) ch 7.
[242] ibid 983–986, 989–992.

coexistence carve-outs illustrate how treaty commitments can stabilize regulatory baselines and shift adjustment to implementation and governance form (committees, guidance, litigation), thereby raising the political and legal cost of later recalibration. The distribution of benefits and burdens also varies systematically by sector, mapping onto the institutional "pressure points" identified in Chapter 4. In health and agri-food, friction is primarily distributive and budgetary. In digital and cultural sectors, it concentrates on the operability of exceptions, procedural safeguards and speech-sensitive enforcement design. These sector-specific mechanisms provide the evidentiary basis for the evaluative and reform-oriented analysis in Chapter 6.

6 Critical Evaluation and Reform Directions

The intersection of FTAs and IP protection within the EU raises a recurrent EU-law problem. External "TRIPS-plus" commitments can reinforce protection and enforcement abroad while narrowing the Union's room to recalibrate its internal balances. FTAs have contributed to regulatory convergence and enforcement cooperation, but they have also intensified debates about regulatory autonomy, distributive effects, and Charter-sensitive enforcement design. Building on the doctrinal and case-study analysis in Chapters 1-5, this chapter (i) synthesizes the principal strengths and vulnerabilities of the current EU "acquis + FTA" configuration, (ii) identifies reform levers that remain constitutionally and politically available, and (iii) outlines plausible trajectories for future FTA practice and internal IP adjustment.

6.1 Strengths and Weaknesses of Current Regulations and Agreements

The incorporation of IP provisions into modern FTAs, and their interaction with the EU's internal framework, presents both considerable strengths and significant vulnerabilities. Given that the research question pertains to both "legal effects" and "constitutional limits", the relevant inquiry is not the abstract question whether FTAs "raise" protection, but rather, which parts of the EU baseline they (a) export, (b) harden through treaty form, and (c) expose to rights-based or competence-based challenges. The following analysis synthesizes the findings of Chapters 2-5 without presenting new empirical material.

Strengths

A first major advantage lies in the EU's capacity to reduce regulatory divergence in key partner markets by exporting a recognizable IP template. By embedding common rules in FTAs and pursuing alignment through secondary legislation and regulatory cooperation, the Union has reduced fragmentation for EU operators when commercializing protected subject matter cross-border. Internally, unitary titles (notably EU trade marks and designs) and centralized filing/grant routes (especially under the EPC and EUIPO) lower transaction costs. Externally, FTAs extend comparable standards on enforcement, border measures and – where relevant – lists of protected subject matter (such as GIs), thereby reducing clearance and misappropriation risks in export markets. As stated in Chapter 1, joint EPO–EUIPO studies show that IP-intensive industries account for a substantial share of EU GDP and employment, underscoring the link between legal predictability and economic performance[243].

[243] European Patent Office and European Union Intellectual Property Office (n 1).

A second strength is the existence of relatively robust enforcement mechanisms at both the EU and FTA levels. Regulation (EU) No 608/2013 empowers customs authorities to detain and destroy counterfeit goods, while the CJEU has developed clear standards for the enforcement of IPRs that respect proportionality and fundamental rights[244]. In *Huawei v ZTE (Case C-170/13)*, the Court articulated a framework for balancing the enforcement of standard-essential patents (SEPs) with competition-law constraints, illustrating the Union's capacity to manage frictions between exclusivity and other public interests[245].

In FTAs such as CETA, the inclusion of detailed civil enforcement disciplines reinforces deterrence and cross-border cooperation, providing rightsholders with greater confidence in enforcement abroad[246]. The case studies in Chapter 5 confirm that these tools are perceived as valuable by IP-intensive sectors, notably pharmaceuticals, technology and agri-food.

Third, FTAs and EU internal measures together contribute to the promotion of innovation and investment by stabilizing expectations about protection and enforcement in partner markets. By ensuring extended protection in certain configurations – most visibly through treaty-level "restoration" commitments in the pharmaceutical field – policymakers aim to compensate firms for protracted regulatory approval processes and thereby encourage further R&D. This "credibility" function is a strength for investment planning, but it is also the channel through which treaties can harden time-bound exclusivities and complicate later recalibration.

In principle, such measures align with the EU's ambition to build a "knowledge-based economy" and with Article 17(2) of the Charter, which recognizes the protection of IP as a fundamental right[247]. The case-law and empirical material discussed in Chapters 3 and 5 show, however, that these benefits are unevenly distributed across sectors and actors, raising questions of distributive justice.

Weaknesses

Despite these advantages, the current mix of FTAs and EU rules also exhibits structural weaknesses. The most prominent concern relates to how treaty "hardening" interacts with

[244] Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003 [2013] OJ L 181/15.

[245] *Case C-170/13 Huawei Technologies Co Ltd v ZTE Corp and ZTE Deutschland GmbH ECLI:EU:C:2015:477*.

[246] Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part [2017] OJ L11/23 ch 20.

[247] Charter of Fundamental Rights of the European Union [2012] OJ C326/391 art 17(2).

access-sensitive policy fields, above all pharmaceuticals. Patent-term restoration and related exclusivity mechanisms, while supporting investment in drug development, may delay generic or biosimilar entry and thereby increase expenditure for payers in publicly funded systems. Importantly, the best-documented immediate budgetary effects of CETA-style provisions have been observed (and modelled) in partner systems, notably Canada. Lexchin provides empirical estimates of increased drug spending resulting from extended data protection for biologics, including "lost savings" from delayed generic entry[248].

Within the EU, the central vulnerability is the constraint such treaty commitments may impose on future legislative recalibration of the internal incentives' framework. The Commission's Pharmaceutical Strategy for Europe reflects this tension by coupling competitiveness goals with access and affordability objectives, thereby foregrounding the need for adjustment tools that remain available even when external commitments exist[249].

A second weakness concerns the potential restriction of fundamental rights through expansive enforcement mechanisms, especially in the digital environment. Stricter enforcement measures – such as website blocking, extended copyright terms or stringent obligations on intermediaries – risk interfering with freedom of expression, access to information and the freedom of the arts and sciences (Articles 11 and 13 of the Charter)[250]. In this context, FTAs can function as "expectation setters". Since even in instances where they do not alter EU intermediary-liability rules, they can increase pressure for faster and more automated enforcement that must remain below the Charter ceiling articulated by the CJEU.

Draft TTIP proposals were criticized for potentially undermining the balance struck by InfoSoc Directive between creators' rights and public interests. Civil society organizations expressed concerns that such obligations may disproportionately favor large platforms and rightsholders while placing burdensome compliance obligations on SMEs, thereby impeding entry and experimentation[251]. Similar concerns inform the interpretation of digital-enforcement clauses in in-force agreements such as the EU–Korea and EU–Singapore FTAs (see §§3.1–3.2; §5.2).

[248] Joel Lexchin, 'Increase in Drug Spending in Canada Due to Extension of Data Protection for Biologics: A Descriptive Study' (2019) 14 Healthcare Policy | Politiques de Santé 10.
[249] European Commission, 'Pharmaceutical Strategy' (n 182).
[250] Charter of Fundamental Rights of the European Union [2012] OJ C326/391 art 11,13.
[251] Oliver Mallett, Robert Wapshott and Tim Vorley, 'How Do Regulations Affect SMEs? A Review of the Qualitative Evidence and a Research Agenda' (2019) 21 International Journal of Management Reviews 294, 309–310.

The post-E-Commerce-Directive framework, now consolidated in the DSA, further underscores that enforcement acceleration cannot come at the price of a general monitoring duty[252].

Finally, the lack of flexibility in harmonization presents a structural weakness. While harmonized IP standards promote legal certainty, they can also constrain Member States' capacity to tailor policy choices to specific social, economic, or cultural needs. This issue is particularly relevant in relation to TRIPS-plus provisions in FTAs, which often export stringent models to partners with different institutional capacities and developmental conditions.
In this respect, "upward" harmonization is not merely technical alignment of rules, but it reallocates decision-making away from ordinary domestic recalibration toward treaty management and committee practice, raising democratic-legitimacy and policy-space concerns. Abbott and Reichman, for example, highlight how tightening IP disciplines can erode room for manoeuvre in public-interest domains – especially public health – unless flexibilities remain operational in practice[253].
Within the EU itself, rigid standards can also reduce room for experimentation in areas such as access to digital learning resources or incentives for green innovation. The GI and pharmaceutical case studies in Chapter 5 illustrate how these limits materialize both for EU partners (e.g. adjustment costs in partner agri-food markets) and within the Union (e.g. payer-side budget pressure and the politics of recalibration).

6.2 Potential Reforms and Improvement Suggestions

The weaknesses identified in §6.1 demonstrate the need for reforms that keep IP protection constitutionally sustainable – i.e. compatible with public-interest objectives, fundamental rights, and regulatory autonomy – while preserving credible incentives for innovation and cross-border trade. The following proposals do not introduce new case studies. Instead, they distil reform design techniques intended to guide future EU FTA practice and internal legislative calibration, in accordance with the conflicts mapped in Chapters 3-5.

Balancing IP Protection with Public Interest Objectives

A central reform priority is to reduce treaty "lock-in" where exclusivity settings interact with public health. As noted in §6.1 and illustrated by the CETA/SPC interface (§5.1), provisions on

[252] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) OJ L 277/1 art 8.
[253] Abbott and Reichman (n 4).

patent-term restoration and regulatory data protection can postpone generic/biosimilar entry and shift affordability pressure onto national reimbursement systems. The Doha Declaration on the TRIPS Agreement and Public Health offers an important interpretative anchor here. It affirms that TRIPS "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"[254].

In practical drafting terms, the EU could systematically add operational public-health safeguards – for example (a) an explicit "without prejudice" clause confirming the availability of TRIPS flexibilities (including compulsory licensing under TRIPS Arts 31/31bis), (b) review/Rendez-vous clauses for pharmaceutical exclusivities that allow adjustment in light of evidence on access and expenditure, and (c) emergency modalities for cross-border supply during health crises. This would align external commitments with the EU's own policy framing in the Pharmaceutical Strategy for Europe, which explicitly couples innovation with affordability and security of supply[255].

The COVID-19 experience also showed that formal flexibilities may be insufficient without coordination and workable domestic pathways. In that sense, the reform aim is not to weaken incentives as such, but to ensure that treaty commitments do not function as a rigidity multiplier when EU institutions later recalibrate internal rules (e.g. SPC design) to meet Article 168 TFEU/Charter health-protection demands[256].

Enhancing Transparency and Public Participation

A second priority concerns the procedural legitimacy of negotiating IP rules with distributive consequences. Critiques surrounding TTIP and, to a lesser extent, CETA illustrate that opacity and uneven stakeholder access can undermine political sustainability and amplify "regulatory chill" anxieties even where formal autonomy safeguards exist. The European Ombudsman's work on TTIP transparency and public participation is often cited as a benchmark for the proposition that proactive disclosure and structured participation are not merely "good governance" add-ons, but conditions for trust in EU trade policy[257].

[254] Declaration on the TRIPS Agreement and Public Health 2001 (WT/MIN(01)/DEC/2) para 4.
[255] European Commission, 'Pharmaceutical Strategy' (n 182).
[256] European Commission, 'SPC Evaluation' (n 183).
[257] European Ombudsman, 'TTIP – Transparency and Public Participation: Report on the European Ombudsman's Public Consultation' (2015); Emily O'Reilly, 'Preface of the European Ombudsman:

To address this, the EU could institutionalize a minimum transparency and participation package for IP chapters. This includes the publication of consolidated negotiating texts at defined milestones, structured multi-stakeholder hearings (including SMEs, libraries/education actors, patient organizations, and digital-rights groups), and a Charter-focused impact assessment for enforcement provisions that plausibly affect Articles 8 and 11 of the Charter[258]. This reform vector also serves a constitutional function. Since it helps ensure that rights-sensitive trade-offs are identified early, rather than being litigated later through strained proportionality review.

Strengthening Dispute Resolution Mechanisms

Dispute settlement remains a constitutional pressure point whenever IP is treated as a protected investment asset. The core lesson from *Opinion 1/17* (CETA/ICS) is that compatibility depends on strict safeguards for EU-law autonomy and the legislature's chosen level of public-interest protection[259]. Consequently, future treaty design should translate these autonomy safeguards into operative procedural and interpretative constraints. Procedurally, this entails transparency by default (public access to pleadings, hearings and awards) and structured participation for third parties where disputes implicate public health, cultural policy or digital rights. Substantively, it requires binding interpretative clauses that instruct tribunals to apply "right to regulate" language as a genuine limit on liability and to avoid expansive readings of investor protections that would elevate regulatory expectations above Charter-compatible legislative choices[260].

Consistent with the competence constraints articulated in *Opinion 2/15*, the EU should continue to pursue a treaty architecture that separates competence-sensitive investment protection from EU-only trade and IP chapters where appropriate. Any accompanying investment instrument should then include narrowly drafted carve-outs for bona fide public-interest IP measures (e.g. compulsory licensing, public-health pricing and reimbursement measures, and EU-mandated copyright exceptions), together with interpretative statements and non-direct-effect drafting

Transparency and Participation in the Face of Scientific Uncertainty' (2023) 14 European Journal of Risk Regulation 231.

[258] Charter of Fundamental Rights of the European Union [2012] OJ C326/391.

[259] *Opinion 1/17 CETA EU:C:2019:341* (n 8) paras 118–120.

[260] Van Harten (n 134) chs 6–7; Joint Interpretative Instrument on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union and its Member States [2017] OJ L 11/3.

designed to minimize the risk that Charter-consistent regulatory choices are re-litigated through investment proceedings[261].

Promoting Flexibility and Sector-Specific Approaches

Finally, the EU should consider mitigating "one-size-fits-all" export of high-protection templates by adopting sector-sensitive drafting techniques. The case studies show that the intensity and risk-profile of IP differ across pharmaceuticals (high fixed-cost R&D), digital enforcement (fast-moving markets, intermediary leverage, speech and data-rights externalities), and cultural industries (public-domain and user-right dependencies). In other words, stringent patent protection may be defensible in pharmaceuticals to reward high-risk R&D, whereas digital copyright, education and cultural policy require greater flexibility to safeguard user interests and freedom of expression. Thus, an effective approach does not reside in pursuing maximal harmonization, but rather in fostering calibrated convergence. This entails designing treaty obligations that establish baseline standards of protection and ensure the availability of effective remedies, while simultaneously preserving internal constitutional balances on exceptions, limitations, and proportionality.

Concretely, this could mean (a) embedding explicit "no general monitoring" and due-process guardrails for online enforcement consistent with the CJEU's Charter case law, (b) safeguarding the practical effectiveness of copyright exceptions (education, research, quotation/parody) against technological-measures overreach, and (c) using review clauses and committee powers for technical updates without shifting core value choices away from EU legislative processes[262]. The existing scholarship on the constitutionalization of EU copyright and the treatment of exceptions as user-relevant constraints supports this direction. That is to say, flexibility must be operational, not merely rhetorical[263].

On the TTIP counterfactual, the reform lesson is also comparative: where draft disciplines would have pulled EU practice towards more rigid notice-and-takedown expectations or investor-facing enforcement leverage, the EU's subsequent treaty practice should be explicit that Charter ceilings are part of the bargain, not an external afterthought (see §§3.1–3.2; §4.3).

[261] Van Harten (n 134); *Opinion 2/15 EU–Singapore FTA EU:C:2017:376* (n 115).
[262] Jonathan Griffiths, Tatiana Synodinou and Raquel Xalabarder, 'Comment of the European Copyright Society Addressing Selected Aspects of the Implementation of Articles 3 to 7 of Directive (EU) 2019/790 on Copyright in the Digital Single Market' (2023) 72 GRUR International 22.
[263] Geiger and Jütte (n 222).

6.3 Perspectives on the Future Development of Intellectual Property Protection

The future trajectory of IP law in the EU cannot be separated from broader economic, technological and social transformations. Emerging technologies, sustainability objectives and the changing architecture of global trade all challenge traditional paradigms of IP protection. In EU-law terms, the central challenge is to maintain incentives and legal certainty while preserving the Union's capacity to recalibrate sector-specific balances in response to Charter-sensitive harms and changing innovation models. This section outlines three forward-looking pressure points that are likely to shape that evolution: (i) integration of emerging technologies, (ii) alignment of IP with sustainability and other global challenges, and (iii) strengthening international cooperation. In each area, particular attention is given to implications for future EU FTAs and their IP chapters.

6.3.1 Integration of emerging technologies

Technological change is the most immediate driver of reform in IP. Artificial intelligence (AI), blockchain, additive manufacturing (3D printing) and advanced biotechnology all expose limits of existing doctrines and enforcement mechanisms.

Artificial Intelligence and IP Ownership

The rise of AI has prompted fundamental questions about authorship and inventorship. Under current EU law, copyright subsists only where the protected subject matter is the expression of human intellectual creation – captured in the Court's formula that a work must be "the author's own intellectual creation"[264]. Yet AI-generated content complicates this requirement, because output may be produced with limited (or no) human creative choices that would satisfy the EU originality test. Rather than entrenching a premature settlement in trade agreements, the legally safer approach for future FTAs is technology-neutral drafting that preserves regulatory space, coupled with review clauses that allow adaptation as the internal EU framework develops (including alongside the AI Act's governance rules)[265].

[264] *Case C-5/08 Infopaq International A/S v Danske Dagblades Forening ECLI:EU:C:2009:465*.
[265] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance) 2024.

In patent law, the European Patent Convention requires the designation of an inventor and presupposes a natural person (EPC Art 81; Rule 19 EPC)[266]. The "DABUS" litigation before the EPO illustrates the current institutional position, as the Legal Board of Appeal confirmed that an AI system cannot be designated as inventor (J 8/20 and J 9/20, 21 December 2021)[267]. For FTA design, the implication is not that AI questions are irrelevant, but that "innovation" chapters should avoid locking in definitions of inventorship/authorship that would constrain future EU doctrinal development or generate tension with personality rights and data governance.

Blockchain and IP Enforcement

Blockchain technology offers potential tools for rights management and anti-counterfeiting, including traceability and automated licensing workflows. At the same time, blockchain's immutability features can sit uneasily with EU data-protection requirements – most visibly the right to erasure (GDPR Art. 17) – where personal data are recorded on-chain or rendered practically irreversible[268]. The EUIPO's enforcement-oriented "tech watch" work – including discussion of blockchain applications in IP enforcement contexts – confirms both the attraction of such tools and the need for legally constrained deployment[269]. Accordingly, references in future FTAs to cooperation on "enforcement technologies" should be framed as optional, rights-compatible cooperation (e.g. pilot projects and best practices) rather than as commitments that could be used to justify intrusive monitoring or data practices incompatible with the Charter and EU secondary law (see §4.3).

3D Printing and Industrial Design

Additive manufacturing blurs the line between digital files and physical objects. The unauthorized reproduction and circulation of CAD files can implicate copyright, designs and patents, while decentralized production complicates attribution and enforcement. In work prepared for WIPO, Mendis argues that conventional liability and enforcement frameworks are poorly adapted to distributed 3D-printing ecosystems and that regulatory attention must cover

[266] Convention on the Grant of European Patents (European Patent Convention) art 81, r 19.
[267] *Designation of inventor / DABUS* [2021] EPO Legal Board of Appeal J 8/20; *Designation of inventor / DABUS II* [2021] EPO Legal Board of Appeal J 9/20.
[268] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance) OJ L119/1 2016 (OJ L) art 17.
[269] European Union Intellectual Property Office (EUIPO) Observatory, 'Intellectual Property Infringement and Enforcement: Tech Watch Discussion Paper 2023' (EUIPO Observatory 2023).

both digital design files and downstream production [270]. For future FTAs, the more constitutionally robust approach is regulatory dialogue and cooperation rather than detailed TRIPS-plus commitments in a rapidly evolving field, precisely because premature hardening could obstruct later experimentation with exceptions, liability allocation, and competition-sensitive access models.

Collectively, these developments suggest that future EU IP policy must become more technology-sensitive while remaining Charter-consistent. For FTAs, the safest design move is to prefer high-level principles, interoperability/cooperation mechanisms, and review clauses over rigid obligations that could "freeze" contested issues as technologies (and internal EU regulation) evolve[271].

6.3.2 Focus on Sustainability and Global Challenges

A second perspective concerns aligning IP protection with sustainability and the EU's broader global objectives. The European Green Deal and the Digital Decade program illustrate the Union's ambition to integrate environmental and digital transformation across policy domains; IP settings increasingly operate as enabling conditions for that transition[272].

Green Technologies and IP Incentives

Patents remain important for incentivizing climate-related innovation, but exclusive rights can also slow diffusion in areas where rapid deployment is socially valuable. The relevant policy question is, thus, how to complement patent incentives with dissemination mechanisms – voluntary licensing, patent pools and collaborative R&D – without undermining investment. Reichman et al. argue that, for complex green technologies, dissemination-oriented tools (patent pools, licensing platforms, prizes and liability-based mechanisms) can be more practicable than wholesale de-protection, because they better reconcile incentives for

[270] Dinusha Mendis, 'The 3D Printing Revolution and Its Implications for IPRs: New Opportunities and New Challenges for SMEs' (World Intellectual Property Organization (WIPO) 2019) ch 3,5.
[271] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance).
[272] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions The European Green Deal COM(2019) 640 final 2019; Decision (EU) 2022/2481 of the European Parliament and of the Council of 14 December 2022 establishing the Digital Decade Policy Programme 2030 (Text with EEA relevance) [2022] OJ L 323/4.

innovation with the need for broad diffusion of environmentally critical technologies[273]. In FTA terms, the implication is not to entrench sector-specific patentability rules, but to couple high baseline protection with facilitative clauses on voluntary licensing, patent pools and technology transfer – while keeping public-interest safeguards available where diffusion is blocked.

Public Health and Access to Medicines

The period of the global pandemic "COVID-19" saw a marked intensification of debates surrounding the flexibilities of the TRIPS agreement and proposals for waivers. The EU's official position in the WTO process emphasized improving the operability of compulsory licensing rather than broad suspension of IP rules, and the Union supported the 2022 WTO ministerial outcome on the TRIPS Agreement within a broader pandemic response package [274]. For future FTAs, the lesson is design-oriented. IP chapters should include emergency modalities and explicit "without prejudice" safeguards that preserve the practical availability of TRIPS flexibilities in circumstances of extreme urgency, thereby reducing lock-in effects in access-sensitive fields (see §6.2; §5.1). This approach aligns more closely with the Charter's health protection (Charter Art. 35) and consumer protection (Charter Art. 38) mainstreaming logic than an enforcement-maximalist template[275].

Cultural and Educational Access

Sustainability also has cultural and social dimensions. EU copyright reform increasingly treats education, research and cultural heritage institutions as structural users of protected works. Where enforcement obligations or technological measures are strengthened (including in external commitments), the constitutional risk is that exceptions remain formally available but practically ineffective. Accordingly, future EU FTA practice should avoid prescriptive "closed lists" of exceptions and should preserve interpretative space for education- and heritage-oriented limitations compatible with Charter-based balancing (see Case C-201/13; §5.3)[276].

[273] Jerome . Reichman and others, 'Intellectual Property and Alternatives: Strategies for Green Innovation' in Mario Cimoli and others, *Intellectual property rights : legal and economic challenges for development* (First edition, Oxford University Press 2014) 371–384.
[274] Council Decision (EU) 2022/1293 of 17 June 2022 on the position to be taken on behalf of the European Union within the 12th Ministerial Conference of the World Trade Organization [2022] OJ L196/121.
[275] Charter of Fundamental Rights of the European Union [2012] OJ C326/391 arts 35, 38.
[276] *Case C-201/13 Johan Deckmyn and Vrijheidsfonds VZW v Helena Vandersteen and Others EU:C:2014:2132* (n 42).

6.3.3 Strengthening International Cooperation

The global nature of IP protection requires the EU to pursue enhanced international cooperation. WIPO and the WTO remain central fora, but regional and bilateral arrangements increasingly shape the practical operation of IP rules.

EU as a Global Standard-Setter

The EU's practice of embedding comprehensive IP chapters in FTAs reflects its role as a norm exporter. Bradford's "Brussels Effect" thesis captures the wider dynamic. EU regulatory models can become de facto global standards when market size and regulatory capacity induce adoption beyond EU borders[277]. In IP, this is visible in the export of GI protection and enforcement templates. Yet the thesis' earlier analysis implies a constitutional corollary. The more the EU exports high-protection templates, the more important it becomes to design FTAs that do not export rigidity and that preserve internal recalibration capacity (see §§3.1-3.2; §4.3).

South–North Cooperation and Developmental Concerns

Developing countries have long argued that high IP standards can restrict policy space for education, health and agriculture. These concerns mirror the "public goods" critique discussed above (§6.1). A future-oriented EU approach could respond by differentiating commitments (including transition periods and sectoral tailoring), pairing obligations with capacity-building and technical assistance, and ensuring that public-interest safeguards are drafted as operative limits rather than as preambular aspirations.

Global Challenges and Multilateralism

Climate change, pandemics and digital transformation require collective solutions that go beyond bilateral bargaining. The WHO's COVID-19 Technology Access Pool (C-TAP) exemplifies a multilateral mechanism designed to facilitate voluntary, non-exclusive licensing and technology transfer for health products[278]. For EU policy, the implication is to treat bilateral FTAs as complements, not substitutes, for multilateral problem-solving: FTAs can pilot innovations (e.g. GI governance, cooperation on green-tech licensing) but should remain compatible with WTO/WIPO initiatives and avoid entrenching asymmetries that weaken global legitimacy.

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[277] Bradford (n 5) ch 2,5-6.

[278] World Health Organization, 'COVID-19 Technology Access Pool (C-TAP)' (*WHO*) <https://www.who.int/initiatives/covid-19-technology-access-pool> accessed 22 November 2025.

Finally, looking ahead, the EU's approach to IP protection will have to navigate a balance between innovation and access, exclusivity and openness, and regulatory autonomy and international cooperation. Across the three forward-looking pressure points discussed above, a common design lesson emerges for modern FTAs: export standards without exporting rigidity. This requires (i) technology-neutral drafting and review clauses where doctrine is unsettled (AI, 3D printing), (ii) operational public-interest safeguards where diffusion and access are structurally important (health, education, green innovation), and (iii) dispute-settlement and governance mechanisms that remain anchored in EU constitutional limits and transparent public-law safeguards (see Chapter 4). In this sense, the "future development" agenda is not an add-on to EU trade and IP policy: it is the next iteration of the core problem this thesis addresses—how modern FTAs shape IP protection in the EU, and which legal challenges and constitutional constraints they activate.

7 Conclusions

This thesis has examined how FTAs influence the protection of IP in the EU. Against the backdrop of the EU's dual role as a regional regulator and a global standard-setter, the central research question has been how FTA-based IP commitments affect the EU acquis through identifiable legal channels (export, entrenchment, and governance), and which constitutional constraints those channels trigger. Methodologically, the thesis combined doctrinal analysis of treaty texts, EU legislation and case law with a critical reading of academic literature, institutional reports and sector-specific case studies. Situated within EU constitutional and international trade law, the analysis has addressed both the content of FTA IP provisions and their systemic implications for regulatory autonomy, democratic legitimacy and Charter-sensitive balancing (Chapters 3-6).

The findings point to several interlinked conclusions about the promise and limits of FTAs as instruments of IP governance. First, FTAs operate as a double-edged instrument for IP protection. They can harmonize standards, reduce legal uncertainty and enhance the competitiveness of EU industries in global markets. The EU has successfully used FTAs to project its regulatory model in areas such as GIs, where agreements like CETA and the EU–Japan EPA institutionalize a high level of protection. At the same time, TRIPS-plus or "TRIPS-plus-adjacent" commitments can harden selected baselines (notably pharmaceutical exclusivities and enforcement templates) in treaty form, thereby increasing the political and legal cost of later recalibration in access-sensitive fields. The doctrinal analysis in Chapter 3 and the sectoral case studies in Chapter 5 demonstrate that this tension between convergence and constraint produces sector-specific distributive and governance effects (e.g. payer-side budget pressure in pharmaceuticals; over-removal risks in digital enforcement; genericness/coexistence contestation in GI export).

Second, these substantive dynamics are mediated by the EU's constitutional framework, which functions as a safeguard against external overreach. CJEU jurisprudence including Seattle *Genetics* (SPCs), *Deckmyn* (copyright exceptions) and Poland v Parliament and Council (Article 17 DSM) – confirms that external commitments cannot displace internal requirements of proportionality, fundamental rights and legal certainty[279]. *Opinion 1/17* on CETA's ICS

[279] *Case C-471/14 Seattle Genetics Inc v Österreichisches Patentamt EU:C:2015:659* (n 74); *Case C-201/13 Johan Deckmyn and Vrijheidsfonds VZW v Helena Vandersteen and Others EU:C:2014:2132* (n 42); *Case C-401/19 Republic of Poland v European Parliament and Council ECLI:EU:C:2022:297* (n 168).

likewise underlines that dispute-settlement mechanisms are acceptable only if they respect the autonomy of EU law and the legislature's chosen level of public-interest protection[280]. Chapter 4 shows that these safeguards operate on two levels. Institutionally, by preserving the CJEU's interpretative monopoly and substantively, by protecting regulatory space in Charter-sensitive domains such as public health, data protection and access to culture.

Third, the practical effects of FTA IP chapters differ markedly across sectors. The pharmaceutical sector is exposed to reinforced exclusivity and extended effective protection, with potential consequences for health budgets and access to medicines. Technology and digital sectors confront enforcement templates that may increase pressure for rapid and automated removal, which must nonetheless remain below the Charter ceiling articulated by the CJEU. By contrast, agri-food producers benefit from external recognition of geographical indications, even though coexistence with prior trade marks and generic terms in partner jurisdictions remain contentious. These sectoral differences confirm that uniform drafting choices can misfire and support the case for calibrated and context-sensitive approaches to external IP commitments (see Chapter 5; §6.2).

On this basis, the thesis offers both theoretical and practical contributions. At the theoretical level, it conceptualizes FTAs as instruments of regulatory export and constitutional testing. Instead of treating FTAs solely as vehicles of trade liberalization, it shows how they operate as sites where external commitments interact with internal constitutional constraints and, in turn, influence the conditions of internal reform. At the practical level, the thesis maps how SPC disputes, copyright-enforcement litigation, and GI recognition controversies translate treaty obligations into day-to-day legal practice. It identifies points where investment and enforcement mechanisms risk generating regulatory chill and where judicial review can function as a corrective. In doing so, it proposes an analytical template – applied in Chapters 3-5 – through which future FTA negotiations and implementation choices can be assessed.

The analysis also yields concrete policy implications for the EU, its Member States and partner countries. For the EU, future FTAs should incorporate explicit public-interest safeguards, particularly in health and digital enforcement. Provisions on patent-term adjustments ought to be coupled with clear emergency and flexibility safeguards, while online enforcement disciplines must be framed and applied in conformity with Charter guarantees (notably Articles

[280] *Opinion 1/17 CETA EU:C:2019:341* (n 8).

8 and 11 CFR) and the CJEU's proportionality case law. Enhanced transparency in negotiation processes remains essential to strengthen democratic legitimacy and public trust. For Member States, the findings underscore the importance of constitutional and parliamentary scrutiny at signature, provisional application, and ratification stages, as illustrated by litigation surrounding CETA before national constitutional bodies. For partner countries, especially in lower-income contexts, uniform TRIPS-plus templates risk overlooking institutional and developmental asymmetries. Differentiated commitments, capacity-building and cooperative implementation mechanisms can mitigate distributive imbalances that FTAs may otherwise reinforce.

Looking forward, three forces are likely to shape the trajectory of IP protection in the EU. Emerging technologies such as AI, blockchain and 3D printing challenge traditional categories of authorship, inventorship and enforcement. Sustainability imperatives call for an IP system that encourages green innovation while facilitating diffusion of climate-relevant technologies, potentially through patent pools, open licensing and expedited "green" channels. Finally, global governance remains a central axis. The EU must navigate between bilateral export of standards through FTAs and multilateral cooperation in fora such as WIPO and the WTO. As argued in §6.3, the legitimacy of the international IP system depends on avoiding rigid commitments that impede adaptive responses to crises such as pandemics or climate change.

In conclusion, the thesis argues that FTAs are neither unequivocal engines of progress nor simple threats to sovereignty, but hybrid instruments that crystallize the structural tensions of IP law. They condense, in treaty form, recurrent dilemmas: between rewarding innovation and enabling access, between convergence and flexibility, and between economic objectives and constitutional constraint. The EU's distinctive constitutional contribution lies in insisting that external commitments remain filtered through the autonomy of Union law and the Charter's proportionality architecture. The enduring challenge is whether this equilibrium can be maintained as technological disruption and global crises accelerate. If it is maintained, the EU can continue to shape international IP governance with constitutional dept. If it is not, treaty-level hardening risks deepening distributive conflict and eroding trust in trade-based IP governance. The analysis developed here suggests that the relevant legal tools already exist within the EU order. What remains is their consistent deployment in the negotiation, interpretation and implementation of the next generation of IP-intensive FTAs.

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7.2. National law / courts

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7.3. EPO

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