Understanding Dispute Resolution Bodies in International Patent Law: A Global Administrative Law Perspective on International Law-Making

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Declarations

The thesis contains no materials accepted for any other degrees in any other institutions. The thesis contains no materials previously written and/or published by another person, except where appropriate acknowledgement is made in the form of bibliographical references.

Signed,

David Tilt.

Acknowledgements

One day in the late mid-eighties, I was in my early late-twenties. I had just been dismissed from university after delivering a brilliant lecture on the aggressive influence of German philosophy on rock 'n' roll entitled 'You, Kant, Always Get What You Want'.

I want to thank both Professor Schmidt-Kessen and Professor Tajti for their feedback that was essential in completing this project. Their efforts in reading, responding to, and challenging the thesis have had a profound impact that I take into all of my writing. Thank you to Ágnes Diós-Tóth who is responsible for me now questioning how 'reader responsive' every single piece of writing I produce is, and your helpful comments on my research proposal. Thank you to Professor Möschel who, from the very first day, has shown the importance of reaching beyond your project and learning from the incredible expertise of those around you.

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Don't dream it, be it.

- David.

Abstract

Patent law, in many ways, reflects the complex state of law and legal research in 2023. While from a narrow perspective it simply provides legal protection for technical innovations, its impact is at once political, societal, and legal in a way that undermines strict divisions in academic work. From this broader perspective, patent law has been understood from a variety of different viewpoints that emphasise its property characteristics, its relationship to human rights, and as a form of international regulation.

The thesis instead approaches the development of international patent law from a Global Administrative Law (GAL) perspective that explores the role of dispute settlement bodies in a European context. Focusing on the role of dispute resolution bodies reflects many themes that emerge in GAL scholarship, highlighting the important function of non-legislative bodies and non-episodic forms of dispute resolution in law and law-making. The thesis brings together values and perspectives from international patent law, administrative law, and GAL to analyse how dispute resolution bodies contribute significantly to the functioning and development of international patent law.

The work is grounded in five main research questions – how are new systems of patent law created? Is there a distinct global space in international patent law? What are the processes through which different systems of patent law interact? What is the role of dispute settlement bodies in facilitating these systemic interactions? To what degree does patent law reflect specific values drawn from GAL scholarship? Adopting a GAL perspective to the development of international patent law emphasises the relationship between dispute settlement bodies and accountability, transparency, and participation in a dynamic context. The thesis, while not comparative in a traditional sense, uses the EU to ground each chapter to support a more thorough exploration of these values in an international patent law setting.

Chapter 1 contextualises the theoretical approach of the thesis, exploring how international patent law can be understood in terms of GAL scholarship and the major concepts in this area. Chapter 2 explores the development of the European Patent with Unitary Effect (EPUE) and the Unified Patent Court (UPC) from a GAL perspective that questions the degree to which the system empowers participation. Chapter 3 shifts towards the relationship between the CJEU and the WTO, emphasising the creative role of the CJEU in modulating EU accountability for WTO obligations. Chapter 4 approaches the more diffuse bilateral trade context in a way that highlights the fundamentally interconnected nature of accountability, transparency, and participation in patent law in the bilateral space.

The thesis provides three general contributions, the first of which is developing the relationship between international patent law and the emerging system of global administration. International patent law has been discussed as regulatory, yet the exercise of delegated administrative power that provides the foundation of patent law means that patent law can also be understood from an administrative perspective.

The second contribution of the thesis is more abstract and connects several contemporary issues in international patent law. By recognising the administrative foundation of patent law, the thesis then deconstructs it through the lens of accountability, transparency, and participation as a form of internal critique. This is in contrast to the approaches found throughout the literature that often involve applying a specific distributive or human rights perspective to issues of patent law that can raise questions of legitimacy.

The third contribution of the thesis is that it provides a more comprehensive and nuanced understanding of the role of dispute resolution bodies in the development of international patent law. Approaching this area from a GAL perspective, the thesis explores how dispute settlement bodies are central institutions for promoting (and also undermining) traditional administrative values like accountability, accessibility, and participation.

Table of Contents

DECLARATIONS ..... **II**
ABSTRACT ..... **IV**
CONNECTING INTERFACES, LEGITIMACY, AND THE FUNDAMENTALS OF PATENT LAW **1**
1. INTRODUCTION **1**
2. CONTEXTUALISING THE RESEARCH **7**
2.1 MAJOR THEMES IN PATENT LAW RESEARCH 7
2.1.1 How intellectual property features in GAL scholarship *7*
2.1.2 Development of a 'European' patent law *8*
2.1.3 The economic framing of international patent law *10*
2.1.4 Critiques of the substantive outcomes in international patent law *12*
2.2 MAJOR THEMES IN GLOBAL ADMINISTRATIVE LAW (GAL) 14
2.2.1 On the existence of global administration *14*
2.2.2 The role of courts and dispute settlement bodies *17*
3. FRAMING THE RESEARCH **20**
3.1 PROBLEM STATEMENT 20
3.2 RESEARCH QUESTIONS 24
3.3 METHODOLOGY 26
4. STRUCTURE OF THE THESIS **27**
4.1 EXPLORING THE BACKGROUND OF GAL SCHOLARSHIP 27
4.2 THE CREATION OF A NEW PATENT INTERFACE IN EUROPE 27
4.3 MANAGING AN EXISTING LEGAL INTERFACE: PERSPECTIVES ON DIRECT EFFECT AND INTERNATIONAL LAW FROM THE CJEU AND WTO 29
4.4 EXPLORING THE DEVELOPMENT AND DYNAMIC OF LEGAL INTERFACES IN EU BILATERAL TRADE AGREEMENTS 30
5. CONCLUSION **32**
EXPLORING THE BACKGROUND OF GLOBAL ADMINISTRATIVE LAW (GAL) **33**
1. INTRODUCTION **33**
2. EXPLORING THE FUNDAMENTALS OF GAL IN THIS PROJECT **36**
2.1 INCORPORATING GAL IN A PATENT CONTEXT 36
2.1.1 Values, patent law, and administrative power *36*
2.1.2 Situating dispute resolution, the WTO, and GAL values *39*
2. EXPLORING THE CONCEPTS OF GLOBAL ADMINISTRATIVE LAW (GAL) **41**
2.1 CONSTRUCTING ADMINISTRATIVE LAW AS A DISCIPLINE 41
2.1.1 The permeable boundaries of administrative law *41*
2.2 PROMINENT VALUES IN GAL SCHOLARSHIP 45
2.2.1 The role of law, democracy, and accountability in administration *45*
2.3 EXPLORING THE NATURE OF GAL AS A SUBDISCIPLINE 47
2.3.1 The interconnected nature of administrative law *47*
3. CRITICAL PERSPECTIVES ON GAL **52**
3.1 THE ROLE OF THE GLOBAL NORTH 52
3.1.1 Harlow's 'double colonization' *52*
3.1.2 Normative and descriptive overlaps in GAL scholarship *57*
3.2 STRUCTURAL REFLECTIONS OF GAL VALUES 60
3.2.1 The structural aspects of transparency and accountability *60*
4. EXPLORING THE RELATIONSHIP BETWEEN GAL SCHOLARSHIP AND THE WTO **64**
4.1 HOW THE WTO IS USED IN GAL WORK 64
4.1.1 The WTO as an element of the international regulatory 'space' *64*
5. CONNECTING THE THESIS CHAPTERS AND CONCEPTS FROM GAL **66**
5.1 CHAPTER 2 66
5.2 CHAPTER 3 67
5.3 CHAPTER 4 69
6. CONCLUSION **70**
A NEW PATENT INTERFACE IN EUROPE: EXPLORING PARTICIPATION **74**
1. INTRODUCTION **74**
2. PATENT LAW IN EUROPE: THE EXISTING INTERFACE(S) **77**
2.1 COEXISTING MECHANISMS OF PATENT PROTECTION 77
2.1.1 The emphasis on territoriality *77*
2.2 THE FAILED COMMUNITY PATENT CONVENTION AS A HISTORICAL PATENT INTERFACE 81
2.2.1 The early development of the Community Patent Convention *81*

2.2.2 EPUE as a successor to the Community Patent Convention *84*
2.3 THE 'EUROPEAN' PATENT SYSTEM 87
2.3.1 The European Patent Convention *87*
3. THE CREATION OF A NEW PATENT INTERFACE IN EUROPE **90**
3.1 PROVISIONS OF THE 'UNITARY PATENT' 90
3.1.1 Establishing the patent *90*
3.1.2 Creating the interface of the EPUE *93*
3.2 LEGAL CHALLENGES 97
3.2.1 Legal basis of enhanced cooperation *98*
3.2.2 The language regime *101*
3.3 EXPLORING THE INSTITUTIONS OF THE INTERFACE: THE UNIFIED PATENT COURT 103
3.3.1 Establishing the court *103*
3.3.2 Developing the institutional identity of the court *107*
3.4 PERMANENTLY SHIFTING THE PROCESS OF INTERFACE CREATION: CONTEXTUALISING THE USE OF ENHANCED COOPERATION 111
3.4.1 Issues with enhanced cooperation in the creation of an interface *111*
3.4.2 Distinguishing the enhanced cooperation process of the EPUE *116*
3.4.3 Fundamental shifts in the law-making interface *119*
4. IDENTIFYING THE FLEXIBILITIES OF THE NEW INTERFACE **122**
4.1 BIOTECHNOLOGY 122
4.1.1 European biotechnology *122*
4.1.2 Exploring biotechnology and the EPUE *127*
4.2 PHARMACEUTICALS 129
4.2.1 Compulsory licensing. *129*
5. CONCLUSION **131**
UNDERSTANDING THE RELATIONSHIP BETWEEN THE EU, THE CJEU, AND THE WTO: ACCOUNTABILITY, DIRECT EFFECT, AND MODULATION **134**
1. INTRODUCTION **134**
2. EU MEMBER STATES AND THE WTO **137**
2.1 THE INTRA-EU DYNAMIC 137
2.1.1 Positioning the EU Institutions and the Member States *137*
2.1.2 Connecting autonomy, accountability, and the European interface *140*
2.2 AUTONOMY IN EUROPE: INTELLECTUAL PROPERTY PERSPECTIVES 143
2.2.1 Formal autonomy emerges *144*
2.3 THE CJEU, AUTONOMY, AND SELF-CREATION 147
2.3.1 The use of general principles and subsequent transformation *147*
2.3.2 Contextualising this process of legal transformation *151*
3. THE EU AND THE WTO **153**
3.1 LEGAL BASIS AND RELATIONSHIP 153
3.1.1 Exploring the early entanglement *153*
3.2 DIRECT EFFECT OF WTO AGREEMENTS 156
3.2.1 Exploring the direct effect decisions *156*
3.2.2 Is direct effect really that significant? *160*
3.3 THE WTO AGREEMENT AS A MIXED AGREEMENT 164
3.3.1 The initial development of responsibility in the WTO Agreements *164*
3.3.2 Further developments in WTO mixity *167*
3.4 NAVIGATING LIABILITY IN THE WTO FRAMEWORK 168
3.4.1 Constructing responsibility in the EU/WTO interface *168*
3.4.2 Exploring EU law and WTO obligations in a dispute context *173*
4. COMMUNICATION BETWEEN DISPUTE RESOLUTION BODIES **177**
4.1 THE LEGAL CONTEXT OF DISPUTE RESOLUTION 177
4.1.1 Constructing the process of judicial communication *177*
4.2 DIRECT EFFECT AND DSB PANEL REPORTS 180
4.2.1 Early cases in the direct effect of DSB Panel Reports *180*
4.2.2 Distinguishing the two threads of jurisprudence in the CJEU *183*
4.3 SUBMITTING TO DISPUTE SETTLEMENT AND THE ISSUE OF COMPETENCE 186
4.3.1 On the expansive jurisdictional scope of the CJEU *186*
4.3.2 Contextualising the major cases in the WTO/EU dispute interface *191*
4.4 THE EU, RESPONSIBILITY, AND ACCOUNTABILITY 193
4.4.1 Broader perspectives on responsibility and liability for WTO violations *193*

5. CONCLUSION **197**
EXPLORING THE VALUES OF EU BILATERAL AGREEMENTS: BRINGING TOGETHER ACCOUNTABILITY, TRANSPARENCY, AND PARTICIPATION **200**
1. INTRODUCTION **200**
2. THE EU AND THE SHIFT TOWARDS BILATERALISM **205**
2.1 EXPLORING THE INCREASED ATTENTION TO BILATERAL NEGOTIATIONS 205
2.1.1 Resurgent bilateralism after the Uruguay Round *205*
2.1.2 Exploring the dynamic of the global ratchet *207*
2.1.3 Contextualising the role of bilateral trade agreements *213*
2.2 FINDING THE SPACE: NATIONAL AUTONOMY AND POLICY SPACE AS FLEXIBILITIES 216
2.2.1 Policy space, autonomy, and developing countries *216*
2.2.2 The global growth of bilateral trade agreements *220*
3. ON THE ENFORCEMENT DIMENSION OF BILATERAL AGREEMENTS **221**
3.1 EUROPE AND THE GLOBAL EUROPE STRATEGY 221
3.1.1 Bilateral trade agreements and 'particular strategic interest' *221*
3.1.2 The potential subversion of the multilateral environment *222*
3.2 EXPANSION IN BILATERAL INTERFACES AND THE POTENTIAL FOR ENTANGLEMENT 224
3.2.1 Expanding the available policy levers and the impact on autonomy *224*
3.2.2 Preferential trade agreements as an additional interface in trade law *227*
3.2.3 Understanding the entangling effect of preferential trade agreements *230*
4. THE EU AND ITS BILATERAL EXPERIENCES **232**
4.1 MOVING BEYOND A NARROW CONSTRUCTION OF TRADE LIBERALISATION 232
4.1.1 The shifting focus of international cooperation *232*
4.2 UNDERSTANDING THE ENFORCEMENT DIMENSION OF BILATERAL AGREEMENTS 238
4.2.1 ACTA and the criminal enforcement of intellectual property infringement *238*
4.2.2 The development of European priorities in bilateral negotiations *242*
4.2.3 Exploring the specific tension of criminal sanctions in intellectual property *246*
4.2.4 Exploring how responsiveness is minimised in the bilateral space *251*
4.3 EU PARTICIPATION IN BILATERAL NEGOTIATIONS 256
4.3.1 Institutional identity, integration, and entanglement *256*
6. CONCLUSION **258**
CONCLUSION **261**
1. INTRODUCTION **261**
2. CONTRIBUTIONS OF THE THESIS **262**
3. CHAPTER 1 ..... **265**
3.1 EXPLORING THE BACKGROUND OF GLOBAL ADMINISTRATIVE LAW (GAL) 265
3.2 REVISITING THE CHAPTER AND FURTHER REFLECTIONS 267
4. CHAPTER 2 ..... **271**
4.1 A NEW PATENT INTERFACE IN EUROPE: EXPLORING PARTICIPATION 271
4.2 BALANCING THE CHAPTER: BETWEEN SPECULATION AND ANALYSIS 274
5. CHAPTER 3 ..... **276**
5.1 UNDERSTANDING THE RELATIONSHIP BETWEEN THE EU, THE CJEU, AND THE WTO: ACCOUNTABILITY, DIRECT EFFECT, AND MODULATION 276
5.2 ACCOUNTABILITY TO WHOM? 279
6. CHAPTER 4 ..... **282**
6.1 EXPLORING THE VALUES OF EU BILATERAL TRADE AGREEMENTS: BRINGING TOGETHER ACCOUNTABILITY, TRANSPARENCY, AND PARTICIPATION 282
6.2 RECONCILING AUTONOMY WITH A GAL CRITIQUE OF BILATERALISM 286
7. CONCLUSION **289**
BIBLIOGRAPHY **292**
LITERATURE 292
Articles *292*
Books *300*
Chapters *306*
DISCUSSION PAPERS/WORKING PAPERS 319
CASES AND LEGISLATION 320
Cases and Decisions *320*
Legislation and Agreements *321*
NEWS AND OTHER MISCELLANEOUS SOURCES 322

Connecting interfaces, legitimacy, and the fundamentals of patent law

1. Introduction

Patent law is an important aspect of both national and international trade policy, though its multifaceted nature in practice means that that there are challenges in reconciling the strong property framing of the patent with the reality of related welfare outcomes. Patent law has increasingly been positioned as an element of economic policy in recent decades,[1] though it also impacts society more generally in a variety of ways. Yet successful patent policy in an economic sense does not necessarily support effective advancements in the non-economic aspects of patent law. This creates tension between the economic framing of patent law and the more abstract values that underpin it, particularly when looking at how accessibility, accountability, and participation function in this context. Crucially, these tensions emerge in both national and international contexts and mean that patent law has been implicated in the exploitation of indigenous communities,[2] exacerbating medicine accessibility in developing countries,[3] and the influential role of major economies in the trajectory of international trade law.[4] While these issues can be identified using human rights language and characterising them as such,[5] patent law is an important element of international trade and can also be analysed in terms of its regulatory character. Patent law is produced from both national and international

[1] Kenneth W Dam, 'The Economic Underpinnings of Patent Law' (1994) 23(1) Journal of Legal Studies 247, 248.
[2] Highlighting how traditional intellectual property systems cannot capture the entire sense of indigenous knowledge and '…allows for the possibility of uncompensated transfers for indigenous knowledge assets.': Peter Drahos, 'Indigenous Developmental Networks and the Non-Developmental State: Making Intellectual Property Work for Indigenous People Without Patents' in Ruth L Okediji and Margo A Bagley (eds), *Patent Law in Global Perspective* (OUP 2014) 287, 295.
[3] Emmanuel Kolawole Ole, *Patents, Human Rights, and Access to Medicine* (CUP 2022) 72, 93.
[4] Though cf. the influence of even hegemonic powers is necessarily limited by the broader framing that the WTO provides. See: Detlev F Vagts, 'Hegemonic International Law' (2001) 95(4) AJIL 843, 845.
[5] Appearing as two major constructions – conflict and coexistence approaches – to human rights and intellectual property: Jennifer Anna Sellin, 'Does One Size Fit All? Patents, the Right to Health and Access to Medicines' (2015) 62 Netherlands International Law Review 445, 448.

sources of law that has a profound impact on the autonomy of a state to grant patents – which aside from a more general regulatory character, produces an interactive system of law that can be analysed from a Global Administrative Law (GAL) perspective. Dispute resolution bodies appear central in managing how these different legal orders interact and the points of contact between legal systems. Throughout the thesis, the role of values that are typically considered in administrative law scholarship are used to deconstruct the processes by which international patent law is developing and how this works to centre the role of central dispute settlement bodies.

In this, international patent law can be constructed as an interface where two or more legal systems are brought into direct contact and is something that features in GAL scholarship.[6] Interactions in this space involve various actors engaging with different sources of law to produce a workable environment, but in a way that necessarily involves a somewhat porous relationship between sovereignty, autonomy, and legal fragmentation. A straightforward interface would be an international trade agreement that provides binding provisions because it brings together different actors that are subject to the obligations of a singular legal text. Even in this simplified example, the importance of the dispute settlement body (and its relationship to accountability and participation) is clear. Yet in practice, there are a variety of tools that an actor can use to modulate the impact of these binding provisions that can be interpreted as an issue of accountability. Dispute settlement bodies are essential in this process, particularly when disputes directly concern these binding international provisions. This is because their interpretative role is an important part of how the relationship between national law and international law is constructed for each particular state. The CJEU is perhaps

[6] Krisch explores the idea of interface norms, norms that govern how entangled (and not integrated) legal spheres interact. Where '[t]heir relations are not predefined but remain to be determined through the social interplay of actors': Nico Krisch, 'Framing Entangled Legalities Beyond the State' in Nico Krisch (ed), *Entangled Legalities Beyond the State* (CUP 2022) 1.

the clearest example of a dispute resolution body performing this function because of the authoritativeness of not only EU law,[7] but how it essentially negotiates or mediates the status of international law *within* the framework of binding EU law.[8] Chapter 4 interrogates the qualities of the legal context that are essential for a dispute resolution body to perform this function. In exploring how international patent law is necessarily broader than dispute resolution bodies, the chapter presents an analysis that highlights the unique characteristics of the 'bilateral space' that analyses intellectual property, law, and dispute resolution in a contextually sensitive way.

The thesis is an application of GAL concepts to the dispute resolution bodies of patent law in three international contexts – the EU Member States, the EU and the WTO, and the bilateral trade agreements of the EU. The thesis centres the role of dispute settlement bodies in managing how these legal systems interact in intellectual property and analyses the extent to which these bodies contribute to GAL values like accountability, participation, and transparency. While these are drawn directly from GAL literature that has typically not focused on patent law, there are parallels with existing patent scholarship that questions the transparency and accountability of international patent law from a human rights or other critical perspective.[9] As such, the thesis represents a different way of understanding how patent law is produced at the international level and the role of dispute resolution bodies in supporting effective accountability and participation. While other bodies are a necessary part of this process, the focus here is on dispute resolution bodies because of their deliberative role. This reinforces the sense, discussed below, that dispute resolution bodies and the space they occupy

[7] Francisco de Abreu Duarte, '"But the Last Word is Ours": The Monopoly of Jurisdiction of the Court of Justice of the European Union in Light of the Investment Court System' (2020) 30(4) EJIL 1188.
[8] See generally: Jan Klabbers, 'The Reception of International Law in the EU Legal Order' in Robert Schütze and Takis Tridimas (eds), *Oxford Principles of European Union Law* (OUP 2018) 1208, 1209.
[9] Particularly from the perspective of 'deep' and 'systematic' transparency: Kali Murray, *A Politics of Patent Law: Crafting the Participatory Patent Bargain* (Routledge 2013) 57.

between legal orders is a creative space that is both interactive and dynamic. Understanding this dynamic character is an important part of chapter 4, where the role of dispute resolution (and legal disputes more generally) becomes less central as the emphasis shifts towards its relationship to the broader 'bilateral space'.

More generally, the thesis develops the idea that beyond just regulation, patent law has a fundamental relationship to administration and aligns with more conventional GAL scholarship. What distinguishes patent law as a form of administration, rather than just an area of regulation, is that the grant of a patent relies on a delegated power of the state. This administrative character of the patent grant can be found explicitly in many civil law jurisdictions where proceedings for validity and infringement can be separated,[10] or more generally in the fact that the patent is a legal instrument is only enforceable within a specific territorial scope. As such, provisions that constrain or otherwise modify the ability to grant a patent can be interpreted as restrictions on the exercise of delegated state power that more conventional administrative law scholarship considers. This approach connects some of the criticisms of patent law, of its complexity and potential for capture by technocrats,[11] and presents these not as patent-specific but as another example of the challenges involved with global administration and international regulation.

Patent law provides a strong foundation for examining how legal orders interact within specific contexts precisely because of the interconnected national and international legal environments. The ongoing trend towards harmonisation in patent law, as well as the relatively

[10] With a specific German influence in China, and a more generalised European influence in Japan: Weinian Hu, *International Patent Rights Harmonisation: The Case of China* (Routledge 2017) 139, 140.

[11] With Thambisetty suggesting that there has been a 'heightening of technocratic decision-making as a response to uncertainty' and more broadly on the 'technocratic disposition of patent law': Siva Thambisetty, 'Improving Access to Patented Medicines: Are Human Rights Getting in the Way?' (LSE Law, Society and Economy Working Papers 3/2018) <https://eprints.lse.ac.uk/87540/1/Thambisetty_Access%20to%20Patented%20Medicines_Author.pdf> 5, 9, 10.

settled nature of patent law over time,[12] means that mechanisms like compulsory licensing or other exceptions appear in similar textual form in both national and international law. The thesis focuses on these connections to emphasise the interactive or creative quality of GAL values within these localised contexts. From this perspective, patent law involves many different legal spaces in which various interests are balanced and reconstructed to create workable relationship between different systems of law. By focusing on the role of dispute settlement bodies, the thesis is an investigation into how administrative values influence or otherwise shape the interactions between different systems of law. Within patent law, compulsory licensing and *l'ordre public* exceptions can be seen as facilitating this type of function as they help to adjust or adapt general principles of patent law in a more locally responsive way.

Exploring how courts manage the points of contact between different legal systems necessarily involves an understanding of both substantive and procedural aspects of patent law. While the substantive content of patent law is valuable, like the application of inventiveness criteria or novelty in a specific concrete case, the thesis focuses on the procedural or abstract aspects of patent law because it highlights the more structural dimensions of international patent law. The thesis not only develops the idea that dispute resolution bodies are central institutions in patent law for managing how legal systems interact, but also investigates the normative dimension of this process and the degree to which it reflects GAL values. As such, the thesis draws on both the interface work developed by Krisch and work within GAL more generally. Though discussed later, the thesis presents patent law as a fundamental, if overlooked, part of the global administrative system that has emerged in recent decades.

[12] Such that the original provisions of the Paris Convention, read today, present no radically different concepts.

A prominent existing example of an interface in patent law would be the global influence of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and the WTO Agreements more generally. The TRIPS Agreement brought together a very diverse set of international actors and essentially provides the basis for modern patent law obligations. For patent law, this diversity in stakeholders meant that the TRIPS Agreement created a space where different values and understandings of patent law were brought together with the aim of producing a single binding instrument. The TRIPS Agreement harmonised the broad contours of patent law at a global level,[13] but the general nature of the obligations it creates are then given practical meaning over time through the consistent interactions of the actors involved. Yet beyond the TRIPS Agreement as an international interface, patent law also provides an important case study in the creation of *new* interfaces. The development (and eventual implementation) of the European Patent with Unitary Effect (EPUE) is a project of patent harmonisation that brings together, substantively and in terms of enforcement,[14] European patent law. This project necessarily brings into contact national interests but in a way that is inherently framed by the EU legal and political context. Particularly from a GAL perspective, the EPUE presents an important opportunity to explore values of accountability and transparency in a patent context that centres on the creation of a new specialised court.

[13] Though it certainly builds on the developments brought by the Paris Convention and Patent Cooperation Treaty, it is clear that multilateral initiatives – and interfaces – in both procedural and substantive patent contexts are not a new development: Randy Campbell, 'Global Patent Law and Harmonization: Benefits and Implementation' (2003) 13(2) Indiana International & Comparative Law Review 609, 610.

[14] The EPC, in centralising patent applications and requirements, alleviated some of the risks or uncertainty with the previous approach to multiple national applications. This provided an important foundation for more substantive harmonisation in the grant of a patent: Douwe de Lange, 'EU Patent Harmonization Policy: Reconsidering the Consequences of the UPCA' (2021) 16(10) JIPLP 1078, 1084.

2. Contextualising the research

2.1 *Major themes in patent law research*

2.1.1 How intellectual property features in GAL scholarship

While intellectual property appears in GAL scholarship, it is generally very limited. Patent law, also, rarely appears in GAL scholarship and even the TRIPS Agreement is often mentioned only in passing. Casini is representative of the how intellectual property is incorporated in GAL scholarship because the TRIPS Agreement is simply presented as an element of the broad normative reach of the WTO.[15] While the TRIPS Agreement is mentioned in Tamanaha's work,[16] the analysis is focused on TRIPS and the WTO as elements of a 'burgeoning multiplicity of transnational legal and regulatory regimes'.[17] Intellectual property is sometimes discussed as a contentious area in GAL scholarship,[18] though the literature does not appear to meaningfully distinguish between the administrative elements of intellectual property generally and patent law more specifically. More attention is given to the interaction of the TRIPS Agreement and the more conventionally administrative dimensions of the SPS or TBT Agreements.[19]

The thesis works to more specifically distinguishes these areas within the more general approach found in GAL scholarship. The research here contributes to exploring an important gap in the GAL literature in the analysis of patent law – a gap that stands out particularly

[15] Lorenzo Casini, 'The Expansion of the Material Scope of Global Law' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 28.
[16] Brian Z Tamanaha, 'A Reconstruction of Transnational Legal Pluralism and Law's Foundations' in Nico Krisch (ed), *Entangled Legalities Beyond the State* (CUP 2022) 452.
[17] *ibid.*
[18] Specifically in the enforcement of intellectual property rights by multinational firms: Benedict Kingsbury, Nico Krisch, and Richard B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3-4) Law and Contemporary Problems 47.
[19] Lorenzo Casini, 'The Expansion of the Material Scope of Global Law' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 28.

because the WTO otherwise features quite prominently in GAL literature.[20] Despite significant work that explores the WTO as an important actor in global regulation and administration,[21] TRIPS and patent law have been overlooked as fundamental elements of the global administrative system. The thesis develops the idea that patent law is a form of administration and has an impact far beyond a technical standards context. International patent law is a fundamental element of the modern trade environment and, because of this importance, should be subject to the same type of scrutiny as more conventional examples of administrative power. Exploring how accountability and transparency function in patent law also contributes to the GAL literature by applying them in a complex and technical area that has generally been shielded from this type of critique.[22]

2.1.2 Development of a 'European' patent law

A long-standing discussion within the literature on European patent law has been on the development of a truly 'European' patent law. This encompasses a variety of work that explores the historical development of the Community Patent Convention (CPC),[23] the considerable progress with the European Patent Convention (EPC),[24] and the more recent

[20] Particularly the dispute resolution system of the WTO: Jan Wouters, 'Government by Regulation' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 209.
[21] Where the WTO shows 'comparable potential' to the EU, where the EU 'transitioned from clearing away a dense web of national regulations inhibiting cross-border trade, to itself creating a dense web of transnational regulation.': Martin Shapiro, '"Deliberative," "Independent" Technocracy v. Democratic Politics: Will the Globe Echo the E.U.?' (2005) 68(3/4) Law and Contemporary Problems 341.
[22] Understanding patent law from a GAL perspective would seem to be generally less controversial than other studies which have investigated areas like foreign relations law and touch on issues of military force, conflict, and human rights. See generally: Angelo Jr Golia, 'Judicial Review, Foreign Relations and Global Administrative Law: The Administrative Function of Courts in Foreign Relations' in Helmut Philipp Aust and Thomas Kleinlein (eds), *Encounters Between Foreign Relations Law and International Law: Bridges and Boundaries* (CUP 2021) 130.
[23] Vilhelm Schröder, 'Reverse Burden of Proof and the Protection of Trade Secrets in European Pharmaceutical Patent Litigation: Part Two' (2017) 4 EIPR 296.
[24] Rochelle C Dreyfuss, 'Resolving Patent Disputes in a Global Economy' in Toshiko Takenaka (ed), *Patent Law and Theory: A Handbook of Contemporary Research* (Edward Elgar 2008) 611.

European Patent with Unitary Effect (EPUE).[25] Common to each of these legal projects is their relationship to the continued fragmentation of patent law in Europe.[26] Focusing more specifically on the EPUE as it represents the creation of a new forum for patent law, several authors have approached it from a more critical perspective. Jaeger has consistently questioned the legal basis for the EPUE and how significantly it disrupts patent law in Europe,[27] while Lamping has also questioned the legitimacy of the enhanced cooperation process that was used to establish EPUE and the Unified Patent Court (UPC).[28]

Yet the work in the literature appears to take a narrow focus on the issues of fragmentation and legitimacy in European patent law. Understanding patent law as related to conventional administrative power instead highlights the more systemic and interconnected nature of current patent developments and the broader EU context. While Lamping and Jaeger both critique the enhanced cooperation process, it was disconnected from the previous uses of enhanced cooperation. So while the EPUE has been critiqued on the basis that it is an EPC patent that is given an expanded territorial scope,[29] this has not been linked to a more substantive shift towards analysing the foundational values of patent law and understanding patent law from an administrative sense. This approach to the territorial scope of the EPUE is specifically designed to avoid the *Meroni* doctrine,[30] which itself emerged from cases that dealt with the improper delegation of power to regulatory agencies and their relationship to the broader EU apparatus. If the grant of a patent is not an exercise of administrative power, then

[25] Winfried Tilmann, 'The UPC Agreement and the Unitary Patent Regulation–Construction and Application' (2016) 11(7) JIPLP 547, 548.
[26] With critique as to the potential of the EPUE in addressing this fragmentation: Aurora Plomer, 'The Unitary Patent and Unified Patent Court: Past, Present, and Future' in Marise Cremona, Anne Thies, and Ramses A Wessel (eds), *The European Union and International Dispute Resolution* (Hart 2017) 276, 277.
[27] Particularly exploring the issue of characterizing the UPC Agreement as a special agreement under Article 142 EPC: Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2017) 48(3) IIC 272, 273.
[28] Matthias Lamping, 'Enhanced Cooperation: A Proper Approach to Market Reintegration in the Field of Unitary Patent Protection?' (2011) 42(8) IIC 25, 26.
[29] Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2017) 48(3) IIC 277.
[30] Discussed more extensively in chapter 2, see generally: C-9/56, C-10/56 *Meroni v High Authority* [1957/1957].

the EPUE could have instead been an actual unitary patent for the participating states in the EU. Understanding patent law in this way connects the fragmentary impact of the EPUE on European patent law, the lack of accountability and responsiveness in the enhanced cooperation process with the EPUE, and the relationship between the EU and its Member States. In doing so, the administrative perspective provides a way of critiquing patent law developments in Europe that emphasises the interconnected nature of patent law and the systemic importance of transparency, accountability, and responsiveness even in technical or more 'economic' areas of law.

2.1.3 The economic framing of international patent law

There is a significant economic aspect of patent law scholarship that appears in two distinct ways. The first is from a methodological perspective, with the rise in the early 2000s of law and economics concepts being applied to patent law. Work from Lemley is fairly typical of this type of approach to patent law in this area[31] – emphasising how patent law relates to efficiency,[32] innovation,[33] incentive.[34] While critical perspectives on patent law have become more mainstream in recent years,[35] this economic focus on patents reflects a broader perception of patent law as a market or economic tool. Constructing patent law in terms of economic objectives or function is the second major theme that can be found in the patent law scholarship. Framing the purposes of patent law in terms of its economic characteristics has extended

[31] Applying an empirical and economic perspective to elements of the patent like patent term: Mark A Lemley, 'An Empirical Study of the Twenty-Year Patent Term' (1994) 22(3–4) AIPLA Quarterly Journal 369, 370.
[32] Particularly on the role of licensing in static and dynamic efficiency: Thomas Cotter, 'Antitrust, Intellectual Property, and Dynamic Efficiency: An Essay in Honor of Herbert Hovenkamp' (2020) 3 Concurrences 6.
[33] Robert D Cooter and Uri Y Hacohen, 'Progress in the Useful Arts: Foundations of Patent Law in Growth Economics' (2020) 22 Yale Journal of Law & Technology 191, 195.
[34] Exploring incentives in a law and economics approach: Richard A Posner, 'The Law & Economics of Intellectual Property' (2002) Dædalus 10.
[35] For an overview of how critical perspectives in intellectual property have continued to impact the discipline: Margaret Chon, 'Intellectual Property and Critical Theories' in Irene Calboli and Maria Lillá Montagnani (eds), *Handbook of Intellectual Property Research: Lenses, Methods, and Perspectives* (OUP 2021) 746, 747.

beyond academic scholarship and has made its way into the innovation policy of many countries.[36] This is considered in chapter 3 more extensively, where the economic framing of patent law is presented as an important element of the relationship between the EU and WTO systems of law (particularly in the attribution of responsibility for violations under the TRIPS Agreement).

Applying an administrative law perspective to patent law is an attempt to address the simplification of patent law that occurs when exclusively focusing on its economic characteristics and function – though administrative law concepts are not necessarily completely detached from the values in economic work on patents. There is a significant practical overlap between the effect of maximising efficiency in the law and economics scholarship and the impact of increased transparency and accountability. Informational transparency appears throughout the literature, appearing as an element of efficiency,[37] while accountability has broad parallels with how rule of law is essential in supporting effective economic activity.[38] Taken together, while the administrative law perspective would at first appear to focus on non-economic concepts, the multifaceted nature of GAL concepts like accountability, transparency, and participation necessarily encompass these economic dimensions. These economic dimensions, however, are integrated by the GAL perspective rather than isolated as in the law and economics scholarship. The result is that the analysis

[36] One example that appears in many jurisdictions is the relationship between university, patents, and national economic growth. The chairman of the Japanese Intellectual Property Strategy Committee has previously commented on the importance of creating and exploiting intellectual property in this context: Hisamitsu Arai, 'Intellectual Property Strategy in Japan' (2005) 1 International Journal of Intellectual Property Law, Economy and Management 6, 7.

[37] Gianna Lotito, Matteo Migheli, and Guido Ortona, 'Transparency, Asymmetric Information and Cooperation' (2020) 50 European Journal of Law and Economics 267, 268.

[38] Specifically discussing the role of risk reduction as 'an important channel through which strong, accountable, transparent and efficient institutions support financial markets': Bogdan Dima, Flavia Barna, and Miruna-Lucia Nachescu, 'Does Rule of Law Support the Capital Market?' (2018) 31(1) Economic Research–Ekonomska Istraživanja 475.

reflects not only an internal critique of patent law, but one that incorporates or reflects the complexity of patent law as an economic, political, and legal area.

2.1.4 Critiques of the substantive outcomes in international patent law

Another of the broad themes in the patent law literature focuses on substantive outcomes. One example would be how the role of patents in restricting access to medicine, particularly in developing countries,[39] is presented as one of the most significant issues in the development of international patent law.[40] Here, the role of patent law in access to medicine has been critiqued from a feminist perspective,[41] work that uses approaches from political science,[42] and more critical work that draws on indigenous or post-colonial perspectives.[43] There are two consistent elements that appear to characterise the literature in this area, the first of which is the emphasis on human rights as a tool of critique. Across the various critical approaches to patent law, the substantive outcomes of patent law are being understood in terms of rights like the right to health,[44] the right to self-determination,[45] and the right to development.[46] This reflects the second consistent element in the literature which is a fairly

[39] Olufemi Soyeju and Joshua Wabwire, 'The WTO-TRIPS Flexibilities on Public Health: A Critical Appraisal of the East African Community Regional Framework' (2017) 17(1) WTR 150, 151.
[40] Dhanay M Cadillo Chandler, 'The Never-Ending Story of Access to Medicines' (2016) 8 WIPOJ 55, 56.
[41] Though it appears prominently as an epistemological critique of patents and copyright: Debora Halbert 'Feminist Interpretations of Intellectual Property' (2006) 14(3) Journal of Gender, Social Policy & the Law 437, 438.
[42] Particularly using social network analysis techniques: Jiaming Jiang and Xingyuan Zhang, 'Essential Patents and Knowledge Position, a Network Analysis on the Basis of Patent Citations' (2021) 1 Standards 90, 91.
[43] Laura A Foster, 'Situating Feminism, Patent Law, and the Public Domain' (2011) 20(1) Columbia Journal of Gender and Law 261.
[44] Where '[p]atent rights have a direct impact on the right to health, especially in developing countries where pharmaceutical products are priced beyond the reach of poor patients.': Emmanuel Kolawole Oke, 'Defining the Right to Health Responsibilities of Patent-Owning Pharmaceutical Companies' (2019) 1 IPQ 45.
[45] Though considered in a Hawaiian context, converting 'the traditional knowledge and cultural heritage of the Native Hawaiian people into definitions of patents, copyrights, trade-marks, personality, and trade secrets… makes a mockery of the Native Hawaiian struggle for freedom and self-determination': Danielle Conway-Jones, 'Safeguarding Hawaiian Traditional Knowledge and Cultural Heritage: Supporting the Right to Self-Determination and Preventing the Commodification of Culture' (2005) 48(2) Howard Law Journal 752.
[46] Ruth L Gana, 'The Myth of Development, The Progress of Rights: Human Rights to Intellectual Property and Development' (1996) 18 Law & Policy 316, 316.

explicit recognition that these tools of critique are *external* to patent law and thereby work to reinforce the economic character of the patent.

Because of these features in the literature, significant work has been dedicated to legitimising or otherwise grounding the critique of the substantive outcomes in patent law. Owoeye, for example, has presented patent law and medicine from the perspective of the right to development and how this should shape the international trajectory of patent law.[47] This reflects a more general theme in the literature of integrating patent law with another discipline to somewhat legitimise the analysis of specific issues within patent law. The thesis seeks to dissolve, rather than resolve,[48] this issue by constructing patent law as a form of administrative power within an emerging system of GAL. In this construction of patent law, the processes by which patent law develops internationally can be legitimately critiqued in terms of accountability, transparency, and participation because they are fundamental related to an exercise of administrative power. Patent law as administration does this without needing to deal with the legitimacy of assessing patent law outcomes using non-patent disciplines as a lens. This perspective also contributes to addressing one of the key issues within the literature which is the distinction between systemic and discrete issues in international patent law. The difficulty of dealing with critiquing access to medicine, even when it is presented as a systemic issue,[49] is that each discrete issue requires its own legitimation. Whether it is the negotiating

[47] Olasupo Owoeye, 'Patents for Drugs and the Right to Development in International Law' (2015) 8(1) Law and Development Review 69, 70.
[48] Referencing Wittgenstein's description of pseudo-problems that 'cannot be solved, but only *dissolved*' and the tension between Wittgenstein's earlier and later work (with a subsequent emphasis on *resolving* problems): Jerry H Gill, 'Wittgenstein and the Function of Philosophy' (1971) 2(2) Metaphilosophy 137.
[49] Where the 'continued demands by developing countries for systemic solutions to address systemic solutions to address structural inequities and the dominance of the market over health rights and socioeconomic justice remain largely ignored.': Gaëlle Krikorian and Els Torreele, 'We Cannot Win the Access to Medicines Struggle Using the Same Thinking That Causes the Chronic Access Crisis' (2021) 23(1) Health and Human Rights Journal 121, 123.

capacity of developing countries,[50] access to medicine,[51] or the treatment of genetic material,[52] work in each of these areas takes on the difficult task of establishing a sufficient link between patent law and the specific issue under consideration. Understanding the administrative law dimensions of patent law removes this tension by emphasising the systemic nature of transparency, accountability, and responsiveness as inherent elements of patent law rather than working to establish a hierarchy of economic and non-economic objectives or rights.

2.2 *Major themes in Global Administrative Law (GAL)*

2.2.1 On the existence of global administration

One of the major themes in the GAL literature is based on exploring whether a global administrative system even exists. Work from Kingsbury, Krisch and Stewart touch on the question of whether a global administrative 'space' truly exists,[53] though Xavier has focused on the potentially contentious relationship between the global administrative space and the character of domestic administrative law.[54] This type of discussion is linked to the issue of defining what GAL is because it has a substantial overlap with international regulation and

[50] Particularly in the information asymmetry between developed and developing countries during the TRIPS negotiation: Coenraad J Visser, 'Making Intellectual Property Laws Work for Traditional Knowledge' in J Michael Finger and Philip Schuler (eds), *Poor People's Knowledge: Promoting Intellectual Property in Developing Countries* (World Bank and OUP 2004) 208.
[51] Olasupo Owoeye, 'International Patent Laws and Health: Resisting the TRIPS Compulsory Licensing Regime and the Doha Paragraph 6 System' (2015) 37(4) EIPR 794, 795.
[52] Prashant Reddy, 'Access to Plant Genetic Resources and Benefit Sharing: Has India Lost the Plot?' (2018) 3 IPQ 181.
[53] Benedict Kingsbury, Nico Krisch, and Richard B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3-4) Law and Contemporary Problems 18.
[54] Deconstructing the sense of an American-inflected global administrative space as a result of 'intellectual influence' rather than a colonisation: Sujith Xavier, 'Top Heavy: Beyond the Global North and the Justification for Global Administrative Law' (2018) 57 Indian Journal of International Law 342, 343.

multilevel governance.[55] Even from a more administrative-focused perspective, the GAL literature generally appears to embrace a more inclusive approach that includes elements from beyond domestic administrative law.[56]

Yet what underlies much of the GAL scholarship (and works to distinguish it from a simpler sense of international regulation) is that it concerns the exercise of public power or the power of the state.[57] Because GAL as an academic discipline is a relatively recent development, identifying the *purpose* of administrative regulation appears to draw on a mix of domestic administrative law traditions. Harlow considers more European approaches to administrative law (and the judiciary that supports this system) as fundamental parts of 'the legislation and regulations set in place by government and administrators for the implementation of policy'.[58] In doing so, values that are central to administrative law analysis like accountability, transparency, and participation have also become fundamental aspects of GAL work. Kingsbury, Krisch, and Stewart in particular have focused on how transparency and accountability function as important points of analysis when looking at the international institutional context from a global administrative perspective.[59]

The work in this thesis connects with and contributes to the existing GAL scholarship in two particular ways. The first is that it provides an analysis of how values like transparency and accountability function in a technical legal context such as patent law. Other work has

[55] Discussing the mutual shaping of administrative law, global governance, and constitutional law post-Cold War: Santiago Montt, *State Liability in Investment Treaty Arbitration: Global Constitutional and Administrative Law in the BIT Generation* (Hart 2009) 131, 132.
[56] Sabino Cassese, 'Global Administrative Law: The State of the Art' (2015) 13(2) ICON 466.
[57] Discussing a paradigm within administrative law, where 'there are two normative remarks, which must be highlighted: first, administrative law is a product of the state, of *each* state; second, it is a product *only* of the state': Giacinto Della Cananea, 'Administrative Law Beyond the State: The Influence of International and Supranational Organizations' in Peter Cane, Herwig Ch Hofmann, Eric C IP, and Peter L Lindseth (eds), *Oxford Handbook of Comparative Administrative Law* (OUP 2021) 358.
[58] Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) 17(1) EJIL 192.
[59] Where Kingsbury, Krisch, and Stewart define GAL as principles, practices and mechanisms that support accountability, standards of transparency, participation, legality, and review: Benedict Kingsbury, Nico Krisch, Richard B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3-4) Law and Contemporary Problems 17.

considered how accountability and transparency are important ways of monitoring state activity in areas of human rights,[60] immigration,[61] and specific aspects of environmental law.[62] Patent law, on the other hand, does not attract the same type of visibility and political attention outside of a few specific issues like access to medicine and the use of genetic materials. Because of this, applying an administrative law perspective to patent law contributes to our understanding of how transparency and accountability function in less visible, but perhaps more technical areas of law. Exploring these values in a patent context also incorporates some of the more implicit issues that are discussed in the GAL literature like the appropriate role of experts in international administration and the risk/potential of technocrats.[63]

The second development of the thesis to GAL scholarship is the idea of patent law as a form of administrative law. So far, an exploration of the administrative character of patent law has been missing from GAL scholarship. Central to the grant of a patent is the exercise of delegated state power which, fundamentally, is the unifying characteristic of more conventional administrative law scholarship. The administrative character of patent law is clear in terms of the grant of the patent and its territorial effect, yet it is also reflected in the international agreements that provide for the general characteristics of the patent. All of these elements, such as the length of the patent or appropriate subject matter,[64] all represent implicit limits to the exercise of state power (in general and also in the delegation to a patent office). As such, international patent law has many similarities with more traditional administrative scholarship that focuses generally either on the control of state power (particularly against

[60] Sanae Fujita, *The World Bank, Asian Development Bank and Human Rights: Developing Standards of Transparency, Participation and Accountability* (Edward Elgar 2013) 7.
[61] Transparency features prominently in this examination of immigration enforcement: Fatma Marouf, 'Regional Immigration Enforcement' (2022) 99 Washington University Law Review 1649, 1651.
[62] Alexander Gillespie, 'Transparency in International Environmental Law: A Case Study of the International Whaling Commission' (2001) 14 Georgetown International Environmental Law Review 333.
[63] The tension in regulation by experts and how experts 'on tap but not on top' does not work in practice: Martin Shapiro, '"Deliberative," "Independent" Technocracy v. Democratic Politics: Will the Globe Echo the E.U.?' (2005) 68(3-4) Law and Contemporary Problems 343, 344.
[64] Article 27 TRIPS Agreement.

individuals) or a sense of facilitating or implementing government objectives.[65] Patent law is particularly interesting to approach from this perspective because it reflects elements from both of these themes. The power to grant (and subsequently enforce) patents relies on state power and approaches that focuses on government objectives have typically emphasised the role of the government in intervening in the market.[66] Patents have an economic quality to them and, as discussed previously, have been incorporated extensively in economic policy to encourage national growth or competitiveness and so reflect many of the important conversations currently happening in GAL scholarship.

2.2.2 The role of courts and dispute settlement bodies

Dispute settlement bodies, specifically courts, appear prominently in GAL literature. Harlow considers the role of courts in developing and applying norms in this context,[67] while Cananea explores how specialised administrative courts affect both the nature of administrative law and how administrative law connects with the broader legal system.[68] The emphasis on courts and dispute resolution is also something that reflects the more general difficulties in actually defining the scope of GAL. For the thesis and its investigation into a more specific patent context, the characteristics of GAL that are highlighted by Stewart, Ratton, and Badin are adopted here.[69] Their approach to identifying dispute resolution bodies appear to be focused more on the functional characteristics of the actor rather than whether it is a true 'court'. As

[65] Alfred C Aman, 'The Limits of Globalization and the Future of Administrative Law: From Government to Governance' (2001) 8(2) Indiana Journal of Global Legal Studies 392.
[66] ibid 393.
[67] Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) 17(1) EJIL 192.
[68] Giacinto Della Cananea, 'Administrative Law Beyond the State: The Influence of International and Supranational Organizations' in Peter Cane, Herwig Ch Hofmann, Eric C IP, and Peter L Lindseth (eds), *Oxford Handbook of Comparative Administrative Law* (OUP 2021) 359, 360.
[69] Stewart, Ratton, and Badin present administration as 'all forms of law other than treaties or other international agreements on the one hand and episodic dispute settlement on the other': Richard B Stewart, Michelle Ratton, and Sanchez Batin, 'The World Trade Organisation: Multiple Dimensions of Global Administrative Law' (2011) 9(3-4) ICON 557.

such, the thesis explores three different institutional contexts within patent law that centre on dispute resolution bodies that exist somewhere on the spectrum between permanent and episodic.

There are some specific courts that appear repeatedly throughout the GAL literature. D'Alterio has discussed the role of the International Court of Justice (ICJ) in creating a 'significant effect on public interests and fundamental rights'.[70] Madsen instead considers the role of international courts more generally and how the proliferation of these institutions (as well as their expansion) happened in parallel to the emergence of GAL.[71] Despite the emphasis on 'legal orders' in the work of Michaels,[72] the actual process of recognition, of mediation, and creation of the legal order is realised through the actions of courts. The emphasis may be on the lack of hierarchy between legal systems and the sense of coexistence that 'brings about the possibility that conflicts… about the place of the border between legal systems… may exist'[73] – yet in which venue are these tensions visibly deconstructed? The court, less frequently but perhaps more importantly, becomes a central environment in which the entanglement of legal regimes is explored.[74] Duval extensively discusses the role of the Court of Arbitration for Sport (CAS) to explore how it functions as an example of hybrid and transnational legal practice.[75] Duval highlights specifically the tension that comes from lacking a single authoritative actor

[70] Elisa D'Alterio, 'Judicial Regulation in the Global Space' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 304.
[71] Mikael Rask Madsen, 'Judicial Globalization: The Proliferation of International Courts' Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 299, 300.
[72] Ralf Michaels, 'Tertiary Rules' in Nico Krisch (ed), *Entangled Legalities Beyond the* State (CUP 2022) 442, 443.
[73] Ralf Michaels, 'Tertiary Rules' in Nico Krisch (ed), *Entangled Legalities Beyond the* State (CUP 2022) 440.
[74] The importance of dispute resolution bodies appears early *Entangled Legalities*, though specifically explores the impact of the 'situatedness' of the court or dispute resolution body on the ability (or will) to act as 'bridge-builders' between legal orders and norms: Nico Krisch, 'Framing Entangled Legalities Beyond the State' in Nico Krisch (ed), *Entangled Legalities Beyond the State* (CUP 2022) 13, 14.
[75] Antoine Duval, 'Seamstress of Transnational Law: How the Court of Arbitration for Sport Weaves the Lex Sportiva' in Nico Krisch (ed), *Entangled Legalities Beyond the State* (CUP 2022) 286.

as leading to creating transnational legal practice through 'strange loops and contextual assemblages'.[76]

While the WTO DSB and Appellate Body appear occasionally in the literature as examples of international dispute resolution bodies,[77] there does not appear to be work that specifically explores the relationship of international dispute resolution with the issues (and values) of international patent law and WTO law more generally. The thesis represents an important step towards investigating this area because it bridges the existing literature that explores how the WTO DSB and Appellate Body could be central in promoting accessibility and transparency in their cases but grounds it in a more intellectual property-specific context that deconstructs the position of WTO law.[78] The thesis is intended as a starting point for understanding how administrative values can be used as a tool of analysis in a less traditional area of law. Though this gap is not surprising given the general lack of attention to patent law within GAL scholarship, TRIPS and the WTO do both feature prominently in the literature. As such, applying this lens to patent law is then not a radical departure from GAL scholarship and can instead be seen as a more measured extension. Exploring the role of dispute settlement bodies in patent law is particularly valuable for understanding transparency and accountability from a GAL perspective because of the continued drive towards substantive harmonisation in patent law. Particularly with the TRIPS Agreement, this means that while the institutional setup and identity is different, the general framework of patent obligations are broadly similar. The analysis in the thesis not only investigates how dispute resolution bodies are fundamental in

[76] ibid 286, 287.
[77] Specifically how the DSB uses interface norms to engage with elements of international environmental law on a 'case-by-case basis… while keeping them formally at bay.': Lucy Lu Reimers, 'International Trade Law: Legal Entanglement on the WTO's Own Terms' in Nico Krisch (ed), *Entangled Legalities Beyond the State* (CUP 2022) 193, 194.
[78] Scholarship has explored how the DSB and the AB could impose GAL norms on the standards agencies that they essentially legitimise in their decisions as a form of judicial review: Richard B Stewart, Michelle Ratton, and Sanchez Badin, 'The World Trade Organisation: Multiple Dimensions of Global Administrative Law' (2011) 9(3-4) ICON 577.

promoting participation or accountability, but which factors are central in supporting or undermining this activity from a more institutional or soft-law perspective.

3. Framing the research

3.1 *Problem statement*

The development of patent law in recent decades has prompted reflection on the degree to which it is representative, transparent, and responsive to the distributive outcomes that it creates.[79] Patent law in the complex global environment is not just the product of legislative power, and instead is the result of interactions between individual countries, agencies, and courts. The result is that the international form of patent law is constructed from the interactions of these disparate actors and is therefore constantly undergoing a process of reconstitution and reinterpretation that centres the role of dispute resolution bodies. This ongoing creative process highlights the flexible potential for specific actors to influence or otherwise direct the development of international patent law, particularly in this multifaceted context that necessarily bridges between law, economics, and politics. The development of international patent law represents a significant constraint on the exercise of state power in the grant of a patent. As such, the issues of accountability and responsiveness in international patent law are systemic problems rather than manifesting uniquely in specific patent issues.

The thesis focuses on the international aspects of this process because, as developed in the GAL literature on international administration,[80] the activities of a national court or national

[79] Shlomit Yanisky-Ravid, 'The Hidden Though Flourishing Justification of Intellectual Property Laws: Distributive Justice, National Versus International Approaches (2017) 21(1) Lewis & Clark Law Review 35, 36.
[80] Benedict Kingsbury, Nico Krisch, and Patrick B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 16.

agency are more directly accountable within their own national legal systems. In contrast, and why the thesis investigates the international element of patent law, administrative power and factors that constrain the exercise of administrative power in the global 'space' are subject to a much more indirect system of accountability. The lack of direct relationship between the exercise of power and constraints that typically characterise domestic administration, work to minimise direct oversight in a similar way to other elements of global administration.[81] The thesis combines both of these perspectives to analyse patent law as being fundamentally connected with the exercise of administrative power and how dispute resolution bodies, in the process of managing how different legal systems interact, promote or undermine traditional administrative values like accountability, participation, and transparency.

There are two major dysfunctions that have been identified and discussed extensively in the patent law literature, related to access to medicine for developing countries and the legal treatment of genetic resources (and benefit sharing more generally). These two issues are problematic because they highlight two important aspects of patent law, the first of which is how the impact of a patent necessarily goes beyond its economic framing.[82] These issues, while they appear throughout patent law scholarship, perform an important role in grounding the context of the thesis in terms of participation, accountability, and transparency. Conventional areas of GAL scholarship are perhaps less reliant on this type of grounding because they demonstrate an obvious (and causal) link between values and consequences.[83] Yet because patent law is not typically connected with administrative law, these examples not only demonstrate that patent law has an administrative character but that there are real, concrete,

[81] ibid 16.
[82] In a general sense that a patent is often considered as an incentive, but extending to scholarly work that more fully integrates patents with economic modelling and innovation policy: Brian D Wright, 'The Economics of Invention Incentives: Patents, Prizes, and Research Contracts' (1983) 73(4) American Economic Review 691.
[83] Tripathi discusses the role of elections as a mechanism within GAL. In a political context, the absence of elections would have clear and significant consequences for accountability that are visible and intuitive. Rajeshwar Tripathi, 'Concept of Global Administrative Law: An Overview' (2011) 67(4) India Quarterly 363.

consequences when administrative values are impaired or undermined. While patent law may be consistently employed as a part of national industrial strategy, the reality is that patent rights – and how these rights function internationally – are inherently connected to health, culture, and heritage. This means that a lack of responsiveness and accountability not only impacts how international patent law functions and how it is produced, but also affects non-legal parts of life. More fundamentally, this issue emerges because of the disconnect between patent policy and a sense of accountability or responsiveness to the needs of specific communities at a more fundamental level.

The second problematic area in international patent law can be identified in areas such as the treatment of genetic materials. Like with access to medicine and *l'ordre public*, this issue has been discussed extensively in the literature but not from a perspective that emphasises the administrative character of the patent as a tool of critique. Here, the continued territorial focus of the patent grant means that dispute resolution bodies have become central in managing the diverging interests of developing countries, patent owners, and developed countries. This is exacerbated by the lack of concrete provisions at the international level. While the exploitation of these communities and their resources would be problematic if it only occurred in terms of plants, the complex interactions between the international interfaces of patent law facilitates an exploitation of Indigenous communities.[84] These problems have generally been constructed as coming from the 'one-size-fits-all' approach of international patent law that benefits developed countries and marginalises developing countries.[85] While access to medicine and

[84] Where the taking of genetic material from Indigenous communities is not always plant genetic material. Instead, it can involve the collection of blood, hair, and saliva in exchange for money: Marie-Claude Strigler, 'Tribal Communities and Genetic Research: Concerns and Expectations' in Susanne Berthier-Foglar, Sheila Collingwood-Whittick, and Sandrine Tolazzi (eds), *Biomapping Indigenous Peoples: Towards an Understanding of the Issues* (Brill 2012) 174.

[85] Arguing that negotiating an international agreement on minimum standards is inherently a 'one size fits all' agreement: Alexander Stack, *International Patent Law: Cooperation, Harmonization and an Institutional Analysis of WIPO and the WTO* (Edward Elgar 2011) 128; more specifically on the reality that substantially deviating from TRIPS obligations is not an option for developing countries though they 'must therefore seek to position their laws and policies strategically to both abide by TRIPS and facilitate economic development':

the treatment of genetic resources are two important issues to investigate in patent law, they are particularly concerning when patent law is explored from this more macro or systemic GAL perspective. In terms of the creation and development of international patent law, these issues demonstrate the failure of international patent law to enable or support meaningful participation and accountability. These issues, and the continued difficulty in resolving them, highlight the disconnect between patent law and direct oversight or accountability that we see in more traditional areas of administrative law scholarship. In this sense, patent policy reflects many of the same issues that are found in GAL that, in practice, are shielded from meaningful oversight.

These two problems in patent law, and particularly the emphasis on the undifferentiated international obligations, also reveal additional problems in a more structural sense of the international patent interface. Particularly when patent law is considered beyond the WTO Agreements, bilateralism and the interpretation of broad multilateral obligations emerge as the creative sites for interpreting or modulating how participation and accountability function in these contexts. Here, the problem has often been cast as a more general one between developing and developed countries.[86] This type of construction emphasises the connection between economic and political asymmetries in producing a patent system in which developing countries experience additional challenges.[87] This more structural issue of balance between parties to international patent law raise questions not only about current relationships between

Bryan Mercurio, 'Intellectual Property Rights, Trade, and Economic Development' in Yong-Shik Lee, Gary N Horlick, Won-Mog Choi, and Tomer Broude (eds), *Law and Development Perspective on International Trade Law* (CUP 2011) 59.

[86] Though this asymmetry is not always the same quality or character as that in the negotiation of the Uruguay Round (a more comprehensive political/technical asymmetry) and could be an opportunity to develop trade initiatives more flexibly through preferential trade agreements (XXIV GATT): Stephen Woolcock, 'The Scope for Asymmetry in the World Trade Organisation (WTO)' in Sanoussi Bilal, Philippe de Lombaerde, and Diana Tussie (eds), *Asymmetric Trade Negotiations* (Routledge 2016) 27, 31, 32.

[87] One example being the complex relationship between campaigning, awareness-raising, and lobbying in the context of patent rights. Explored here specifically in terms of pharmaceuticals and developing countries face specific challenges to address the imbalance in power: Gregory Schaffer and Susan K Sell, 'Transnational Legal Ordering and Access to Medicines' in Ruth L Okediji and Margo A Bagley (eds), *Patent Law in Global Perspective* (OUP 2014) 124, 125.

developing and developed countries, but the *future* responsiveness of these patent law interfaces. In both WTO-centred and bilateral contexts, dispute settlement bodies are the central institutions that interpret and reinterpret the actual substantive impact of patent obligations in these international texts. More fundamentally from a GAL perspective, dispute settlement bodies are a key part of ensuring effective accountability. This type of accountability is not just an accountability for the provisions being disputed, but a part of accountability in a more systemic sense that promotes meaningful participation and accessibility in the future development of these systems and the bilateral space more generally.

Taken together, these two specific problems and the more general sense of structural imbalance reveal that patent law struggles with negotiating a relationship between effective patent policy, responsiveness and accountability in patent law, and the appropriate dynamic between different legal systems. It is important to investigate these issues from a perspective that integrates the more abstract structural dimension with concrete legal provisions. The thesis explores how patent-specific provisions provide flexibility to dispute resolution bodies in how accountability and participation are interpreted. In the thesis, the three central contexts are the Unified Patent Court (UPC), the CJEU, and the bilateral space more generally. This type of approach considers not just the tools with which the court facilitates the interactions of different legal interfaces in patent law, but whether in doing so, they are promoting or undermining accountability, transparency, and participation more fundamentally in international patent law.

3.2 *Research questions*

There are two main themes in the research questions of the thesis that explore both the administrative nature of patent law and how dispute settlement bodies manage the interactions between different legal systems. The thesis investigates how this management function of the

court can contribute to or undermine administrative law values like transparency, accountability, and participation in patent law. The research questions are intended as a response to contemporary criticism of international patent law, where patent law has been presented as unresponsive to local conditions and needs,[88] lacking transparency in its development,[89] and lacking in accountability for negative welfare outcomes.[90] Focusing on the complex and overlapping nature of GAL and patent law emphasises the more systemic nature of issues within patent law.

- *How do dispute settlement bodies facilitate the interactions between different legal systems in patent law?*
- *GAL scholarship speaks of a 'global space': Can a similar distinction in 'space' be found in international patent law?*
- *Which aspects of patent law are used by these bodies to facilitate systemic interactions?*
- *How do dispute settlement bodies contribute to or undermine administrative law values like accountability, transparency, and participation in patent law?*
- *Do the specific characteristics or position of the dispute resolution body change the answers to the previous questions?*

The thesis focuses on dispute settlement bodies and centres the EU as an actor to enable the more comparative and reflective analysis involved in answering question 5. Because the

[88] An issue that is linked explicitly by Singh to the emphasis on harmonisation in patent law: Kshitij Kumar Singh, *Biotechnology and Intellectual Property Rights: Legal and Social Implications* (Springer 2015) 130, 131.
[89] Particularly in the shift to bilateral trade agreements that 'are often struck with developing countries at a time in their development when they cannot resist Northern demands'. This is presented as part of a broader strategy of breaking coalitions and preventing them from participating fully in a more open forum: Rochelle C Dreyfuss, 'Intellectual Property Lawmaking, Global Governance, and Emerging Economies' in Ruth L Okediji and Margo A Bagley (eds), *Patent Law in Global Perspective* (OUP 2014) 80, 81.
[90] One example would be the lack of accountability over the 'promise of liberalisation' for developing countries in terms of agriculture and textiles in the Uruguay Round: Jordana Hunter, 'Broken Promises: Trade, Agriculture and Development in the WTO' (2003) 4(1) Melbourne Journal of International Law 299, 300.

research questions investigate the systemic interactions of patent law, each chapter involves a dispute resolution body and two opposing groups of actors. In chapter 2, it is the patent interface created between the EU Member States and the EU with the EPUE. Chapter 3 looks at how EU law deals with the influence of WTO law and issues of direct effect. Chapter 4 takes a slightly different approach by deemphasising the dispute resolution body and instead contextualising disputes within the relationship between the EU law and the values of an emerging 'bilateral space'.

3.3 Methodology

The methodology of the thesis is primarily doctrinal because it focuses on the use of legislation and other international agreements, as well as the secondary literature on these sources of law. Like with the general focus of the thesis, specific attention is paid to the procedural elements of these primary sources rather than just the substantive provisions. This approach draws on themes in the GAL literature that also considers the distinction between substantive and procedural aspects of law.[91] Specifically for the secondary sources, the thesis draws on doctrinal materials across a variety of legal sub-disciplines. The doctrinal approach starts primarily from an intellectual property and global administrative law perspective, though there is an important influence of EU law literature that is integrated with a patent perspective.

[91] Discussing how a thin, or procedural understanding of GAL values can work to legitimise law (the sense that '…those officials are playing by the rules, and as a result those subject to those rules may be expected to do the same'. Capps specifically highlights Kingsbury's work in identifying this 'thin' conception of procedural fairness: Patrick Capps, 'International Legal Positivism and Modern Natural Law' in Jörg Kammerhofer and Jean D'Aspremont (eds), *International Legal Positivism in a Post-Modern World* (CUP 2014) 227.

4. Structure of the thesis

4.1 *Exploring the background of GAL scholarship*

Chapter 1 explores the development of GAL and the prominent themes and values that emerge in the literature. This chapter is essentially the foundation for the thesis because it frames how the later chapters, focusing on patent law, contribute to the GAL literature by positioning patent law as forming part of the global administrative system itself. The latter half of the chapter considers how GAL scholarship and GAL values are applied to the patent law contexts throughout the thesis. Applying this GAL framing to patent law has two main dimensions that are discussed in this chapter, the first of which centres on how values have developed in GAL scholarship. Work in this area emphasises the role of accountability, transparency, and participation in international administration though it also discusses the challenges of realising these values in a global space without systems of direct oversight. Patent law highlights exactly these tensions and reflects other specific concerns in GAL work such as the normative character of procedure in law-making and potential capture by technocrats. The second dimension of GAL scholarship that is applied in a patent law context is the institutional focus that appears throughout the literature. The GAL scholarship emphasises the role of dispute settlement bodies as a key element of international administration and the thesis incorporates this by centring the role of dispute resolution bodies in patent law.

4.2 *The creation of a new patent interface in Europe*

Chapter 2 considers the development of the EPUE as an example of the creation of a new interface in patent law, bringing together the tensions in harmonisation, codification, and

coherence within an overarching system. This provides a very specific environment for understanding the role of a dispute settlement body because the EPUE was introduced with the very specific purpose of dramatically improving the efficiency of dispute settlement and the overall competitiveness of European patent law.[92] The current form of the EPUE is dramatic from the perspective of a workable interface for patent law because its legal configuration fails to realise the objectives that have underpinned the decades-long project of a European patent right. Chapter 2 is aimed at answering research questions 1, 3, 4, and 5, investigating how an interface in patent law is created and how different values are reflected or undermined within a single framework. The chapter concludes that *l'ordre public* exceptions and compulsory licensing face unique challenges in this new interface that minimise their function as tools to promote responsiveness and participation.

The chapter turns first to the legal foundation of the EPUE and contextualises it with the failure of the CPC in the 1970s because it provides a rare insight into the difficulties involved with establishing the values of a new legal interface. The EPUE is a particularly dramatic example of a patent law interface because while it claims to bring harmonisation and simplify patent law in Europe, it actually exacerbates the existing criticisms of European patent law. The EPUE is significant as a legal interface because it is both the substantive and procedural elements of its creation that are concerning. The latter half of the chapter considers how the enhanced cooperation process risks permanently shifting the dynamic involved in the creation of new legal projects in a way that minimises transparency and accountability. This is because the EPUE, unlike the CPC,[93] is the product of enhanced cooperation that allows a group of EU Member States, as a last resort, to proceed with their own projects when their objectives cannot be agreed upon by the Union as a whole.[94] Using enhanced cooperation to

[92] Klaus Haft, 'The Unitary Patent System from an SME's Perspective' (2017) 52(4) Les Nouvelles 274.
[93] Dennis Thompson, 'The Draft Convention for a European Patent' (1973) 22(1) ICLQ 51, 52.
[94] Article 20(1) TEU.

establish a patent interface distinguishes it from other uses of enhanced cooperation and highlights importance of contextual analysis in international patent law. When considered in light of the previous uses of enhanced cooperation, the EPUE represents a potential turning point in the dynamic of EU law-making in terms of participation.

4.3 *Managing an existing legal interface: Perspectives on direct effect and international law from the CJEU and WTO*

The shift in emphasis from the national, Member State level to the EU institutions leads to the analysis in chapter 3. The chapter is aimed at exploring how the CJEU is central in interpreting, reinterpreting, and reframing the relationship between the EU and external systems of law in a way that minimises EU accountability for WTO obligations. The analysis of chapter 3 considers the development of the TRIPS Agreement and explores the issue of direct effect to analyse how the CJEU manages points of tension or conflict. This chapter is aimed at answering the first, third, and fifth research questions because it looks not only at the function of the CJEU in the relationship between the WTO and EU, but how the specific character of the CJEU impacts the available legal tools for doing so. The chapter considers a particular kind of interface in that it is represents a point of contact between the EU (as a supranational project) and a multilateral trade organisation (the WTO). The conclusions of the chapter suggest that while patent law principles can be identified as effective interface tools that allow actors to modulate the obligations of a framework, the CJEU relies on more general legal principles that are not grounded in a specific text to modulate accountability. With sufficient institutional authority, the lack of specific mechanisms within the legislative text does not prevent an actor from modulating obligations in the same way that specific patent mechanisms can be used to promote accountability.

The CJEU, as the legitimate interpreter of EU law,[95] is a key element in modulating how WTO law is received and the degree to which it impacts EU law. This chapter draws on the transformation of the EU as a constitutional legal order[96] – with its emphasis on EU-level values[97] – and analyses the approach of the CJEU as it impacts the values of accessibility, participation, and transparency. A key conclusion here is that the CJEU has not rejected outright the legal authority of WTO Agreements. Instead, it is engaged in a process of modulation that varies the binding quality of trade obligations in a way that maximises EU autonomy but significantly impairs both transparency and accountability more broadly.

4.4 *Exploring the development and dynamic of legal interfaces in EU bilateral trade agreements*

The development of bilateral trade agreements and their relationship to the broader, global trade environment present an important perspective on the creation of legal interfaces and their relationship to administrative values. This is because a primary question that has followed their development in history has been whether bilateral agreements are a supplement to, or replacement for, multilateral instruments.[98] This chapter is aimed at exploring research questions 1, 2, and 4 because it explores the degree to which these bilateral frameworks constitute legal interfaces and how they present unique challenges (and a unique space) for the realisation of administrative values. The issue of accountability between these multilateral

[95] Which more than arising from consensus, is very much a position taken by the CJEU itself: Gareth Davies, 'Does the Court of Justice own the Treaties? Interpretative Pluralism as a Solution to Over-Constitutionalisation' (2018) 24(6) ELJ 360, 361.
[96] Damian Chalmers and Luis Barroso, 'What Van Gend en Loos Stands For' (2014) 12(1) ICON 105, 106.
[97] Though specifically the turning point of the Lisbon Treaty: Yumiko Nakanishi, 'Mechanisms' to Protect Human Rights in the EU's External Relations' in Yumiko Nakanishi (ed), *Contemporary Issues in Human Rights Law*: *Europe and Asia* (Springer 2018) 6, 7.
[98] Knut Brünjes and Milena Weldenfeller, 'Multilateral Trade Policy is Back' in Christoph Herrmann, Bruno Simma, and Rudolf Streinz (eds), *Trade Policy Between Law, Diplomacy and Scholarship* (Springer 2015) 52.

frameworks and bilateral agreements also takes on a specific dynamic because of the accompanying growth of enforcement mechanisms that shifts, in context, how transparency and participation emerge in the bilateral space. As with early GAL work that attempted to establish the idea of a global administrative space that differed from national administration,[99] the chapter is aimed at analysing how these values are produced and challenged within a distinct 'bilateral space' that is separate to (and yet connected with) the dynamics of multilateral initiatives.

Beyond the specific interplay of agreements with developed enforcement models and those which do not, transparency and responsiveness become a problem between these different interfaces that *do* have binding enforcement measures. In terms of enforcing these agreements, it is very much a narrow and developing area because the overlap between WTO dispute settlement and enforcement mechanisms contained in specific agreements has been generally small.[100] Yet it does present a particular challenge in intellectual property because of the fuzzy scope of these rights and how they can be deployed.[101] The difficulty here is the presumption that WTO Panels would be unable to decline these disputes just because the facts may also give rise to an action in a different dispute mechanism.[102] Taken together, it is not only the textual provisions of an agreement that can produce tensions in accountability,

[99] Drawing on perspectives and themes that were prominent in the early development of GAL, where much of the work deals with establishing that there is a 'global space' at all: Elisa D'Alterio, 'Judicial Regulation in the Global Space' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 321.

[100] Peter-Tobias Stoll, 'The WTO Dispute Settlement System and Regional Trade Tribunals: The Potential for Conflict and Solutions' in Alberto do Amaral Júnior, Luciana Maria de Oliveira Sá Pires, and Christiane Lucena Carneiro (eds), *The WTO Dispute Settlement Mechanism: A Developing Country Perspective* (Springer 2019) 235.

[101] One example would be the challenges to Canada's promise doctrine in patent law: Pratyush Nath Upreti, 'Eli Lilly v Government of Canada: The Tale of Promise v Expectation' (2018) 21(3) IntALR 84.

[102] Peter-Tobias Stoll, 'The WTO Dispute Settlement System and Regional Trade Tribunals: The Potential for Conflict and Solutions' in Alberto do Amaral Júnior, Luciana Maria de Oliveira Sá Pires, and Christiane Lucena Carneiro (eds), *The WTO Dispute Settlement Mechanism: A Developing Country Perspective* (Springer 2019) 237.

transparency, and participation, but the interplay of these agreements within a specific legal space.

5. Conclusion

Intellectual property has emerged in recent decades as an important discipline in both national and international contexts, in domestic legislation and multilateral initiatives, and is linked to some of the most profound issues currently facing society. Yet our understanding of how these different spheres of intellectual property are constituted, maintained, and interact remains limited. The thesis represents an initial investigation into how dispute settlement bodies are central to the process of sustaining international patent policy and supporting or undermining valuable administrative law concepts. It explores how, in the process of facilitating the interactions of different legal systems, dispute settlement bodies can contribute to or undermine GAL values like accountability and transparency. To achieve this, the thesis presents patent law as somewhat of an extension of administrative power that can then be legitimately critiqued through the lens of conventional GAL values. International patent law shares many similarities with more conventional GAL scholarship because, at a fundamental level, patent law centres on a delegated exercise of state power in the grant of a patent. Patent law is both regulatory and administrative in character, yet it is the way in which the TRIPS Agreement fundamentally restricts or otherwise alters the state power to issue patents that emphasises its administrative nature. Patent law is an interesting opportunity to explore the current dynamic in global intellectual property because it reflects all of the tensions that can be found in the interactive relationship between different legal systems. The patent system itself has been presented as enabling several controversial areas of policy that include the exploitation of Indigenous communities and restricting the accessibility of critical medicine.

Exploring the background of Global Administrative Law (GAL)

1. Introduction

Patent law is a complex area of law that involves the interaction of national and international systems across a variety of hierarchies. Patent law stands out in the conventional forms of intellectual property as one in which the drive towards harmonisation has yet to produce a truly global system of protection.[103] Instead of developing a single global patent, there has instead been cooperation between legal systems on what the fundamental qualities of a patent are.[104] Enforcement and the actual grant of the patent have, however, remained distinctly national.[105] This means that, in its ordinary functioning, patent law develops from the interactions between actors in a horizontal sense (national systems cooperating on a bilateral basis) and in a vertical sense (direct hierarchies of primacy). This project focuses on these more systemic dynamics that produce patent law rather than the substantive features of the patent in each legal system. The objective is to explore the processes that facilitate interactions between diverse legal systems and produce international patent law. Understanding patent law as fundamentally connected to an exercise of administrative power emphasises the role of values in shaping this dynamic process. The thesis applies concepts from administrative law like transparency and accountability to a patent law context and, more specifically, to the role of dispute resolution bodies in supporting these values.

[103] Randy Campbell, 'Global Patent Law Harmonization: Benefits and Implementation' (2003) 13(2) Indiana International & Comparative Law Review 605. And while Rajec remain unconvinced by the explanatory value of harmonisation within international intellectual property (preferring maximalism instead), it remains that there is no global system that deals with the grant and enforcement of patent rights: Sarah R Wasserman Rajec, 'The Harmonization Myth in International Intellectual Property Law' (2020) 60 Arizona Law Review 735, 740.
[104] Such as the length of a patent and the technological scope of patent law: Adam Isaac Hasson, 'Domestic Implementation of International Obligations: The Quest for World Patent Law Harmonization' (2002) 25 Boston College International & Comparative Law Review 379, 380.
[105] Randy Campbell, 'Global Patent Law Harmonization: Benefits and Implementation' (2003) 13(2) Indiana International & Comparative Law Review 614.

Europe highlights how tensions can emerge from the broad interactions of legal systems in a more general sense, as with the process of EU enlargement,[106] but more specifically in the history of patent harmonisation.[107] Non-intellectual property contexts in Europe provide many examples of the type of mechanisms and values used to moderate how legal systems interact, drawing on the vocabulary of domestic administrative law.[108] Intellectual property has generally not been analysed from a perspective that emphasises its connection to the exercise of delegated public power. Patents (and more specifically, the *grant* of a patent) are produced through state power that is exercised through an administrative agency. International agreements and institutions that produce international patent law can then be considered restrictions or limits on the ability for a state to freely grant patents. From this perspective, international patent law – particularly with its important economic and regulatory character – fits with the more conventional subject matter of GAL scholarship. In this, there is a tension in identifying patent law as administrative rather than simply regulatory in nature. Yet it is because the patent relies on a delegated exercise of public power that means restrictions or rules that govern its use can be interpreted in a similar way to conventional principles of administrative law. So while Ghosh is correct in presenting patent law as an element of international trade regulation,[109] this is *in addition* to a more fundamental administrative character of the patent. Patent law presents an interesting opportunity for this type of investigation because its economic framing has often been used to push for harmonisation on the basis of efficiency, yet what is actually being protected is intensely connected to the

[106] Günter Burghardt, 'The EU/US Transatlantic Relationship: The Indispensable Partnership' in Christoph Hermann, Bruno Simma, and Rudolf Streinz (eds), *Trade Policy Between Law, Diplomacy and Scholarship* (Springer 2015) 197.
[107] Victor Rodriguez, 'Constructing a Unitary Title for the European Patent System' (2011) 6(8) JIPLP 576.
[108] Giacinto Della Cananea, 'Administrative Law Beyond the State: The Influence of International and Supranational Organizations' in Peter Cane, Herwig Ch Hofmann, Eric C IP, and Peter L Lindseth (eds), *Oxford Handbook of Comparative Administrative Law* (OUP 2021) 359, 373.
[109] With patent law proposed as a tool of marketplace regulation, suggesting that the patent bargain theory of patent law is misguided: Shubha Ghosh, 'Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor after Eldred' (2004) 19(4) Berkeley Technology Law Journal 1315, 1318.

autonomy of national legal systems and the exercise of state power. The patent system, though it necessarily produces a legal right that has an economic impact,[110] is informed by many considerations from outside this narrow economic framing. It brings together a mix of national conditions and societal values that distinguishes between what is or is not inventive,[111] which inventions could be contrary to public morals,[112] and the appropriate role of the patent system in national growth.[113]

This chapter first looks into the development of GAL as an academic focus and some of the prominent features of this area of scholarship. Particular attention is given to the role of dispute settlement bodies across a variety of international contexts. Part 3 of the chapter presents how the thesis applies the concepts of GAL to a patent law context. Building on this, the thesis also incorporates the more recent work of Krisch that emphasises the interactive quality of the space between legal orders. In this, there are two elements in bringing together patent law, GAL values, and Krisch's work to analyse dispute resolution bodies in this context. First, applying a GAL lens to these institutions helps to investigate the degree to which patent law can be properly interpreted from the perspective of administrative values. The thesis applies GAL concepts to patent law to explore how dispute settlement bodies in this context maximise, promote, or elaborate traditional administrative values of accountability, participation, and transparency. Secondly, combining a general GAL foundation with the more specific analytical work of Krisch helps to investigate the degree to which these institutions

[110] Discussing the utilitarian perception of patents as 'economic instruments' that should protect only minimum term required to incentivise innovation: Federica Baldan, *Judicial Coherence in the European Patent System: Lessons from the US and Japan* (Edward Elgar 2022) 91.
[111] Such as excluding mathematics from patentability: Hazel V J Moir, *Patent Policy and Innovation: Do Legal Rules Deliver Effective Economic Outcomes?* (Edward Elgar 2013) 64.
[112] The changing approach to 'products manufactured by an atomic transformation' in Japan is one example: Nobuhiro Nakayama, 'The Enforcement of the TRIPS Agreement in Japan' (1995) 38 Japanese Annual of International Law 58.
[113] Like the reforms around universities and patent commercialization that appeared around the world: Hiroyuki Odagiri, Akira Goto, and Atsushi Sunami, 'IPR and the Catch-Up Process in Japan' in Hiroyuki Odagiri, Akira Goto, Atsushi Sunami, Richard R Nelson (eds), *Intellectual Property Rights, Development, and Catch-up: An International Comparative Study* (OUP 2010) 120.

succeed in managing the interfaces between different legal systems. Beyond clarifying how these institutions facilitate the interactions between legal systems and through which mechanisms, the analysis also explores the extent to which this facilitative role of the dispute settlement body is also creative. This creative potential is also discussed in more traditional GAL scholarship in terms of giving meaning to values,[114] and is applied here to centre a more active understanding of dispute resolution bodies as they relate to administrative values.

2. Exploring the fundamentals of GAL in this project

2.1 Incorporating GAL in a patent context

2.1.1 Values, patent law, and administrative power

In terms of academic focus, the project draws on the vocabulary and history of GAL. GAL emerged perhaps more formally as a field in the early 2000s as a response to increasing globalisation and the impact of international regulation and governance,[115] focusing on the relationship between these international modes of governance and values like accountability and transparency in the exercise of administrative power.[116] GAL has been presented essentially as a response to the

[114] Discussing the central (and fundamentally creative) role of courts in developing and applying norms: Li-Ann Thio, 'Courts and Judicial Review' in Peter Cane, Herwig Ch Hofmann, Eric C IP, and Peter L Lindseth (eds), *Oxford Handbook of Comparative Administrative Law* (OUP 2021) 721, 722.
[115] Benedict Kingsbury, Nico Krisch, and Patrick B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 15; though Aman presents the beginning of 'the global era of administrative law' as being in the 1980s: Alfred C Aman, 'Administrative Law in the United States: Present and Future' (1991) 16 Queen's Law Journal 179.
[116] Rajeshwar Tripathi, 'Concept of Global Administrative Law: An Overview' (2011) 67(4) India Law Quarterly 356.

> '*vast increase in the reach and forms of transgovernmental regulation and administration signed to address the consequences of globalized interdependence in such fields as security… environmental protection… intellectual property... and cross-border movements of populations, including refugees.*'[117]

GAL scholarship is important for understanding the trajectory and dynamic of international patent law because of the type of institutional focus and legal values that appears throughout this area of work. By focusing on sources of law that are outside of legislation or international treaties, dispute settlement bodies become central institutions in studying how values develop in regulatory practice.[118] Dispute settlement bodies are crucial for giving actual meaning or force to these concepts precisely because they work directly with the type of general language that provides the space for interpretation. Yet this type of framing has not been applied directly to patent law despite the considerable regulatory character of patent law and how the WTO has emerged as an important international actor for global administration. When patent or intellectual property elements appear in GAL work, they are often covered briefly and work has tended to focus on relationship between the TRIPS Agreement and technical standard-setting.[119] The thesis represents an early attempt at integrating patent law within the more traditional subject matter of GAL scholarship and reinforcing the conceptual understanding of patent law as resulting from an administrative exercise of public power.

Patent law provides an interesting opportunity to explore administrative and regulatory perspectives because of the complex role of the WTO as an international trade organisation. The WTO appears prominently in GAL scholarship as an important forum in managing

[117] Benedict Kingsbury, Nico Krisch, and Patrick B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 16.
[118] Mikael Rask Madsen, 'Judicial Globalization: The Proliferation of International Courts' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 282.
[119] Lorenzo Casini, 'The Expansion of the Material Scope of Global Law' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 28.

international regulation,[120] applying administrative law principles,[121] and how increasing harmonisation or uniformity can be more critically approached.[122] The lack of work that seeks to apply a GAL perspective to patent law is even more stark when considering the context of the creation of the WTO. This moment also represented the conclusion of the TRIPS Agreement and yet the administrative character of TRIPS remains overlooked in the literature. The TRIPS Agreement regulates the fundamental aspects of patent law, yet it was produced from negotiations that were shaped by a dissonance between developing and developed countries.[123] Though the TRIPS Agreement was important because it pushed international patent law further and bound it with a system of dispute resolution,[124] the general contours of patent law have been generally settled since the Paris Convention in 1883. From an administrative perspective, this dissonance that emerged with the TRIPS Agreement is particularly significant. This is because the provisions in TRIPS not only regulate the ability for a state to grant patents in the same way as the Paris Convention, but precisely because it ties these obligations to an effective system of dispute resolution. It establishes the type of invention that may be patented,[125] the length of the protection to be granted,[126] and the mechanisms through which patent protection can be limited or otherwise minimised.[127] All of these regulate an exercise of state power and yet have not been investigated as such in the literature. Even when the provision appears to be permissive and not a restriction on state power

[120] Martin Shapiro, '"Deliberative," "Independent" Technocracy v. Democratic Politics: Will the Globe Echo the E.U.?' (2005) 68(3/4) Law and Contemporary Problems 341, 342.
[121] Giacinto Della Cananea, 'Administrative Law Beyond the State: The Influence of International and Supranational Organizations' in Peter Cane, Herwig Ch Hofmann, Eric C IP, and Peter L Lindseth (eds), *Oxford Handbook of Comparative Administrative Law* (OUP 2021) 373.
[122] René Fernando Urueña Hernandez, 'Global Administrative Law and the Global South' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 395, 396, 397.
[123] Jörg Reinbothe and Anthony Howard, 'The State of Play in the Negotiations on TRIPS (GATT/Uruguay Round)' (1991) 13(5) EIPR 157.
[124] Srividhya Ragavan, *Patent and Trade Disparities in Developing Countries* (OUP 2012) 74.
[125] Patentable subject matter: Article 27(1), TRIPS Agreement.
[126] Term of protection: Article 33, TRIPS Agreement.
[127] *L'ordre public*: Article 27(2), TRIPS Agreement.

per se, the reality is that these flexibilities or policy space only exist as they are provided for by the TRIPS Agreement. One example would be patentable subject matter because it provides that patents must be granted for all areas of technology and therefore does not immediately read as a restriction of state power. In practice however, it means that this freedom is constructed *through* the operation of the TRIPS Agreement and necessarily frames the legitimate scope of autonomy of participants within that system.

2.1.2 Situating dispute resolution, the WTO, and GAL values

The WTO has, even beyond the specific issues that have emerged in patent law,[128] been discussed critically in terms of administrative principles like accountability and transparency.[129] In this, there is a significant parallel between the way in which the language of democratic deficit has been applied to both the WTO and the EU.[130] Though despite this overlap, the GAL perspective and GAL values have not been specifically applied in the context of international patent law. The role of dispute settlement bodies appears throughout GAL scholarship in a variety of different legal contexts[131] – though it is important to recognise that they are only one element of a broader institutional scope that can be found in the literature.[132] The institutional focus here is more closely on dispute settlement bodies because, particularly

[128] Noah Benjamin Novogrodsky, 'Beyond TRIPS: The Role of Non-State Actors and Access to Essential Medicines' in Thomas Pogge, Matthew Rimmer, and Kim Rubenstein (eds), *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (CUP 2010) 346, 347.
[129] Sarah Joseph, 'Democratic Deficit, Participation and the WTO' in Sarah Joseph, David Kinley, and Jeff Waincymer (eds), *The World Trade Organization and Human Rights: Interdisciplinary Perspectives* (Edward Elgar 2009) 313, 314.
[130] Kevin Featherstone, 'Jean Monnet and the "Democratic Deficit" in the European Union' (1994) 32(2) JComMarSt 149, 150.
[131] Particularly in the European context: Giulio Vesperini, 'Europe and Global Law' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 386, 387.
[132] Such as the role of private and hybrid institutional arrangements in the creation of regulation, such as the Codex Alimentarius Commission or International Organization for Standardization: Stefano Battini, 'The Proliferation of Global Regulatory Regimes' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 52; 59.

with patent law and the mirrored institutional setups across different hierarchies, the ability for an institution to produce a binding decision as to the precise state of law provides a strong common basis of analysis.

Rather than just exploring how transparency and accountability can be realised through court structures in intellectual property, the project interprets the vocabularies of prominent GAL scholars that emphasise the interactions of legal systems. In this context, the focus has been on interfaces – the points of contact between different legal regimes and the tools and mechanisms that are necessary to realise a workable system of law.[133] As with GAL more generally, patent law provides an interesting environment to investigate interfaces because of its multilevel nature. Patent law is constructed from national and international instruments, standards of protection that are required by these international instruments but still rely on the grant of patents by national bodies, and an enforcement environment that involves decisions from both national and international actors. This means that international patent law is made up of a mosaic of the Paris Convention, the TRIPS Agreement, and national patent laws that establish the foundations of the international patent system. This foundation is then built on by legal instruments with more specific disciplinary objectives (like the Biotechnology Directive) and addressing areas of additional cooperation (like the European Patent Convention). Rather than just exploring the role of a dispute settlement body in promoting or realising these general GAL values, framing it within the language of legal interfaces instead highlights the powerful role of the dispute settlement body in creating regulation, managing these hierarchical interactions, and exploring which tools are used by courts to achieve this balance between values. Beyond identifying how the dispute settlement body fulfils this role, the thesis links this interface perspective with the more conventional administrative law concepts of

[133] Predominantly through the concept of interface norms and the interface itself as developed by Nico Krisch: Nico Krisch, 'Framing Entangled Legalities Beyond the State' in Nico Krisch (ed), *Entangled Legalities Beyond the State* (CUP 2022) 1, 2.

accountability and transparency to analyse the more normative dimensions of this process in international patent law.

2. Exploring the concepts of Global Administrative Law (GAL)

2.1 Constructing administrative law as a discipline

2.1.1 The permeable boundaries of administrative law

It is clear that, throughout the literature, there is a variety in how administrative law (even without considering the complicating 'global' dimension of this area) can be constructed. There appears a diversity in understanding the precise nature of administrative power, and the boundaries of what exactly should be considered 'administrative' law. The indistinct boundaries between what is administrative and what is not are also reflected internally, where Ziller highlights that there is often a distinction made between general administrative law and special administrative law.[134] Ziller suggests that this distinction between general and special emerges from the difficulty in cleanly separating the law 'applying to the substance of policies… and the law applying to policy-making'.[135] This is further complicated by the diversity of national perspectives on what is typically considered administrative. Ziller focuses on the specific examples of French, German, and Italian administrative law, which can incorporate elements of contract law and liability in the French context and a narrower construction with elements of adjudication by public agencies in Italy and Germany through

[134] Jacques Ziller, 'Comparison Within Multi-Level Polities and Governance Regimes' in Peter Cane, Herwig Ch Hofmann, Eric C IP, and Peter L Lindseth (eds), *Oxford Handbook of Comparative Administrative Law* (OUP 2021) 139.
[135] ibid.

the twentieth century.[136] While the US has a distinct history of administrative law, a prominent aspect remains the role of courts in restraining or otherwise checking the exercise of power by administrative agencies.[137]

Along with the variety of approaches to administrative law, there is also a spectrum in terms of the functioning (and expectations) of administrative law itself. The literature appears to frequently explore the extremes of this spectrum, with work that focuses on thin or more procedurally focused understandings of the administrative. Harlow argues that this thin version of administrative law, with its emphasis on procedural guarantees of the rule of law, aligns with the perspective of economic liberals.[138] In this economic framing, the institutions that are central to entrenching the procedural form of administrative law are the institutions of international trade law like the WTO, World Bank (WB) and the International Monetary Fund (IMF).[139] The presence of developed dispute resolution mechanisms within these institutions is also central to the attempts to 'juridify' the values of thin administrative law principles and authoritatively frame them.[140] Given the attention to the impact of binding dispute resolution systems in patent law through the TRIPS Agreement,[141] it is clear that the multifaceted nature of the WTO and intellectual property reflect some similar tensions. Here, there is no simple way of disentangling the development of the WTO, the central role of dispute resolution bodies in a patent context, and the degree to which the system itself represents an attempt to juridify or otherwise legitimise a more thin conception of administrative values.

[136] Jacques Ziller, 'Comparison Within Multi-Level Polities and Governance Regimes' in Peter Cane, Herwig Ch Hofmann, Eric C IP, and Peter L Lindseth (eds), *Oxford Handbook of Comparative Administrative Law* (OUP 2021) 139.
[137] Alfred C Aman, 'Administrative Law in the United States: Present and Future' (1991) 16 Queen's Law Journal 184.
[138] Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) 17(1) EJIL187, 208.
[139] ibid.
[140] In using these dispute mechanisms to gain authority, if not always legitimacy: ibid 187, 208.
[141] Srividhya Ragavan, *Patent and Trade Disparities in Developing Countries* (OUP 2012) 74.

For some academics, the role or purpose of administrative law in the global space is connected to its institutional context. Here, the focus is on the institutional arrangement that emerges when regulation occurs at the global level, challenging the ability to draw a clear connection between domestic, administrative work within a single state and parallel activities of a similar nature at the international or global level.[142] Indeed, it is this institutional arrangement that highlights the issues in constructing a sufficient, in both descriptive and a functional sense, definition of what administration *is.* A definition presented in some of the academic work is functionally very broad, incorporating all modes of law and law-making except international treaties, formal international agreements, and episodic dispute resolution bodies.[143] One of the limitations that has been identified in using the vocabulary of domestic regulatory administration is that it may not fit the bodies that have emerged and operate at the global level.[144] Even at the national level, the bureaucratic understanding of administration is being challenged in other approaches to constructing regulatory activity like in those of 'new governance' regulation.[145]

Within administrative law, there is also a significant question as to the purpose or primary function of administrative law. Harlow emphasises how, in Europe, these legal systems have administrative law framed predominantly as a tool for restraining or otherwise controlling the exercise of public power.[146] From this, Harlow considers that this general emphasis on the potential for administrative to control or contain then influences the definition

[142] Richard B Stewart, Michelle Ratton, and Sanchez Badin, 'The World Trade Organisation: Multiple Dimensions of Global Administrative Law' (2011) 9(3-4) ICON 556, 583.
[143] ibid.
[144] ibid.
[145] Specifically considered from the perspective of democratic accountability: Adrienne Héritier and Dirk Lehmkuhl, 'New Modes of Governance and Democratic Accountability' (2011) 46(1) Government and Opposition 126, 127; though see also the discussion on new governance paradigms and 'instances of "new governance" regulation' in political science: Neli Frost, 'Out with the "Old", in With the "New": Challenging Dominant Regulatory Approaches in the Field of Human Rights' (2021) 32(2) EJIL 507, 515.
[146] Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) 17(1) EJIL191.

of what is administrative law within these systems.[147] The French perspective, and its perhaps more expansive construction of administrative law,[148] reflects a broader understanding of administrative law that is beyond this type of procedural control based in the courts.[149] Instead, administrative law takes on a much broader scope when its internal perspective is considered. One example that is raised in the literature is the approach of French judges, where administrative judges work from *inside* the framework to develop its norms.[150] Harlow argues that this facilitates an understanding, or an alternative definition, of administrative law that considers all rules and laws that apply to the administration.[151]

Applying these perspectives on the function and role of administrative power to patent law highlights the administrative foundation of patent law and the patent grant itself. Turning first to the breakdown between a clear (or effective) distinction between national and international administration because of globalisation, patent law highlights the tense relationship between international systems of regulation and state sovereignty. Patents are granted by the state and rely on the power of the state to enforce these property rights. Yet international agreements, like the TRIPS Agreement, prescribe limits to the ability for states to grant patents.[152] As such, the administrative exercise of power involved in the grant of a patent is tempered by international sources of law. This also reflects Harlow's discussion of how the *function* of administrative law in a European context emerged as a controlling of the power of the state.[153] From this perspective, it is then clear that international patent law not only elevates patent law as an element of international trade but fundamentally prevents state power from

[147] Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) 17(1) EJIL191.
[148] Jacques Ziller, 'Comparison Within Multi-Level Polities and Governance Regimes' in Peter Cane, Herwig Ch Hofmann, Eric C IP, and Peter L Lindseth (eds), *Oxford Handbook of Comparative Administrative Law* (OUP 2021) 139.
[149] Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) 17(1) EJIL192.
[150] ibid.
[151] ibid.
[152] Article 27, TRIPS Agreement.
[153] Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) 17(1) EJIL 191.

freely exercising the power to grant patents. It is from this understanding that the role of typical GAL values become more important because they can used to question the extent to which state sovereignty in this area is constrained, the actual processes by which international patent law is created, and whether the participants have mechanisms to enforce accountability.

2.2 Prominent values in GAL scholarship

2.2.1 The role of law, democracy, and accountability in administration

Two values of GAL that emerge in the literature are rule of law and democracy, considered in some parts of the literature as the 'legitimating principles' in Western administrative legal systems.[154] Indeed, a strong theme within the literature is the importance of a contextualist analysis that takes into consideration not just the functioning of administrative law in states, but the specific legal features of these states more broadly. In this, the potential of the values that are developed through GAL literature must be understood in the context of a global environment in which the 'functions, governance arrangements, and the ability of different players to use GAL tools are all relevant'.[155] Accountability also appears throughout administrative law, though there appears to be some flexibility as to whether it is framed solidly as a general aspect of democratic order or represents values that are essentially derived from administrative law.[156] Taggart's work represents this third approach, where

[154] Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) 17(1) EJIL 190.
[155] Richard B Stewart, Michelle Ratton, and Sanchez Badin, 'The World Trade Organisation: Multiple Dimensions of Global Administrative Law' (2011) 9(3-4) ICON 556, 586.
[156] 'While liberal democratic orders are committed to democratic values such as transparency, accountability, and participation, whether judicial review of executive rule or policy-making is robust or minimal turns on contextual factors…': Li-Ann Thio, 'Courts and Judicial Review' in Peter Cane, Herwig Ch Hofmann, Eric C IP, and Peter L Lindseth (eds), *Oxford Handbook of Comparative Administrative Law* (OUP 2021) 727; with Krisch arguing that the purpose of GAL is '…whether and to what extent ideas from domestic administrative law can help us solve accountability problems in global governance.': Nico Krisch, 'The Pluralism of Global Administrative Law' (2006) 17(1) EJIL 247, 248.

accountability appears alongside other conventional rule of law principles (but notably for the thesis, with participation and openness) but in a way that characterises them as elements of public law that are derived predominantly from the development of administrative law.[157]

Beyond the classification of accountability as an administrative law value, a more specific construction of legal accountability has been presented as a way of helping to protect less powerful members within a legal framework.[158] Despite the important function of accountability in presenting a path toward decisional review, an important distinction appears in the literature between accountability and legitimacy.[159] The emphasis appears to land on *where* this accountability is directed. If accountability leads to 'powerful states or organized economic interests',[160] then accountability is especially limited in its connection to legitimacy and can be no guarantee of normatively just or fair outcomes.[161] Some of the literature focuses on how institutions relate to the values that are developed by GAL, particularly in how legitimacy is connected with effectiveness. From this perspective, organisations have an interest in promoting inclusiveness in terms of participation as a way of increasing their legitimacy and how representative they are.[162] Yet the shift away from the domestic administrative space and into a new global paradigm also affects the construction of these values in GAL. Central to this, particularly for the work in the thesis, is how legitimacy and accountability are incorporated through legal mechanisms. Cassese argues that, unlike the domestic space, legitimacy and accountability mechanism operate in a horizontal manner rather

[157] Michael Taggart, 'The Province of Administrative Law Determined' in Michael Taggart (ed), *The Province of Administrative Law* (Hart 1997) 3; though these principles are further analysed through a public law and governance framing in Megan Donaldson and Benedict Kingsbury, 'The Global Governance of Public Law' in Cormac Mac Amhlaigh, Claudio Michelon, and Neil Walker (eds), *After Public Law* (OUP 2013) 271.
[158] Richard B Stewart, Michelle Ratton, and Sanchez Badin, 'The World Trade Organisation: Multiple Dimensions of Global Administrative Law' (2011) 9(3-4) ICON 556, 584.
[159] ibid.
[160] ibid.
[161] ibid.
[162] Laurence Boisson de Chazournes, 'Changing Roles of International Organizations: Global Administrative Law and the Interplay of Legitimacies' (2009) 6(2) International Organizations Law Review 655, 657.

than being introduced through vertical hierarchies.[163] Because of this, Cassese suggests that it is a mistake to bring the same paradigm and understanding of the state into GAL and focus on identifying a sufficiently legitimate relation between the institutions and the demos.[164] Applying this perspective to patent law, it highlights the importance of a legitimate connection between the institutions that are shaping patent law and democratic accountability. This emphasises the relationship between institution and public rather than reproducing a national understanding of patent law (and its institutions) in an international context. Intellectual property has been discussed by McKenna, in rebuttal to Rose's previous article questioning the contribution of these rights to democratisation,[165] exploring specifically the relationship between intellectual property, stability, and power-spreading as promoting political engagement.[166] While there are many institutions in international patent law that are involved in this process, dispute settlement bodies are important precisely because they more easily transcend this national/international paradigm and are actively involved with how patent is shaped in response to binding international obligations.

2.3 Exploring the nature of GAL as a subdiscipline

2.3.1 The interconnected nature of administrative law

The type of 'internal' difficulty in defining what exactly constitutes administrative law is also mirrored at the international and global levels. Harlow argues that this results from the very nature of the global space – where 'economic globalization, liberalization and

[163] Sabino Cassese, 'Global Administrative Law: The State of the Art' (2015) 13(2) ICON 465, 467.
[164] ibid.
[165] Carol M Rose, 'Privatization: The Road to Democracy?' (2006) 50 Saint Louis University Law Journal 691, 693.
[166] Mark P McKenna, 'Intellectual Property, Privatization, and Democracy: A Response to Professor Rose' (2006) 50 Saint Louis University Law Journal 839.

privatization are so closely linked to be indistinguishable…',[167] emphasising the internal role of administrative law as both the subject of regulation *and* contributing to the norms of this regulation. Aman characterises law as the tool by which, in this new 'global era', an institutional framework that is essential for democracy can be created.[168] Here though, Aman argues that this role of law in promoting democracy through institutional frameworks extends beyond governmental institutions and into the private sector.[169] Patent law remains a technical area with a strong economic focus, yet it cannot be divorced from either its broader institutional context or the process by which international patent law was (and is) constituted. The functioning of the TRIPS Agreement, despite its technical subject matter, is necessarily a part of the contentious relationship between developing and developed countries. It represents a coming together of related issues like the role and function of representation and autonomy in international law,[170] as well as the enforcement of binding provisions in international agreements.[171] All of these reflect aspects of how democratic accountability and transparency function in the context of international or global actors and the difficulty of meaningfully incorporating them in technical legal contexts.

And yet despite the amount of academic scholarship on the impact of this global shift, the definition of GAL remains contested. Beyond the definitional difficulties in establishing the boundaries of GAL,[172] there is also ongoing work to explore how GAL relates to other areas of law. Cassese highlights the lack of settled status in GAL that extends from a general

[167] Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) 17(1) EJIL 208.
[168] Alfred C Aman, 'Globalization, Democracy, and the Need for a New Administrative Law' (2003) 10(1) Indiana Journal of Global Legal Studies 125, 126.
[169] ibid.
[170] On the flexible quality of autonomy available to developing countries in the WTO (though also specifically discussing this in the context of the TRIPS Agreement): Alvaro Santos, 'Carving out Policy Autonomy for Developing Countries in the World Trade Organisation: The Experience of Brazil and Mexico' (2012) 52(3) Virginia Journal of International Law 570, 588.
[171] Peter K Yu, 'TRIPS Enforcement and Developing Countries' (2011) 26(3) American University International Law Review 728, 729.
[172] Sabino Cassese, 'Global Administrative Law: The State of the Art' (2015) 13(2) ICON 465.

lack of a singular understanding of the field to more specific interactions between GAL and international law or constitutional law.[173] At this general level, Cassese highlights work that has shifted away from GAL vocabulary and instead towards an 'exercise of international public authority' or a 'law of global governance'.[174] The work of scholars such as Teubner is highlighted by Cassese as contributing to this blurring between constitutional and administrative law.[175] But it is the clearly interconnected nature of what is being studied by GAL that challenges a strict focus on a traditional or typical understanding of administration. In some areas, considered here as patent law and intellectual property, the object and institutions of study share significant overlaps with conventional regulation or governance scholarship. Patent law is interesting because it reflects this type of intersectional position and embodies elements of regulation, administration, and governance. This type of indistinct boundary has been discussed as affecting the 'global' of 'global administrative law' because what is being explored by GAL is not just global, not just administration, and not just law.[176]

From a more institutional perspective, there are two main approaches that have been discussed in the literature as they relate to the unique challenges of the global space. These can broadly be divided between approaches that emphasise the creation of new institutions and those which propose amendments to existing international institutions.[177] It is commonly highlighted in GAL literature that global challenges require the introduction of global

[173] Sabino Cassese, 'Global Administrative Law: The State of the Art' (2015) 13(2) ICON 465.
[174] Armin von Bogdandy, Matthias Goldmann, and Ingo Venzke, 'From Public International to International Public Law: Translating World Public Opinion into International Public Authority' (2017) 28(1) EJIL 116, 117; Eyal Benvenisti, *The Law of Global Governance* (Hague Academy of International Law 2014) 25.
[175] Sabino Cassese, 'Global Administrative Law: The State of the Art' (2015) 13(2) ICON 465.
[176] 'It is now clear that global administrative law is not only global, not only administrative, and not only law. It is not only global because it includes many supranational regional or local agreements and authorities. It is not only administrative, because it includes many private and constitutional elements… Global administrative law is not only law, because it also includes many types of "soft law" and standards': ibid 466.
[177] Laurence Boisson de Chazournes, 'Changing Roles of International Organizations: Global Administrative Law and the Interplay of Legitimacies' (2009) International Organizations Law Review 655, 656; on the complex relationship between new institutions in a global governance framework from a critical perspective: Yakub Halabi, 'The Expansion of Global Governance into the Third World: Altruism, Realism, or Constructivism?' (2004) 6(1) International Studies Review 21, 35, 36.

institutions to sufficiently deal with the unique character of the space.[178] Yet it is precisely these global challenges that have raised questions about the capacity of these organisations to meet these challenges and whether their mandate is sufficient.[179] Though the responses to this question of sufficient mandate have varied over time,[180] an alternative to adjusting existing institutions has been to simply create a new organisation (like with the rise of field organisations) that is more closely aligned with specific issues.[181]

One of the complicating factors of translating governance and administration, particularly from a national level to a global level,[182] is that much of the administrative framework and decision-making is characterised by a less formalised normative output and a non-hierarchical institutional structure that centres the work of administrative committees.[183] There is a recurring emphasis on the institutional elements of GAL systems that fundamentally affects the contours and dynamics of the field. A prominent feature of the literature has been devoted to exploring what exactly distinguishes GAL and its 'peculiarities'.[184] Institutionally, the global space is particularly interesting from this administrative perspective because it enables the production of law without legislatures and the legal implementation of these

[178] Sabino Cassese, 'Global Administrative Law: The State of the Art' (2015) 13(2) ICON 465, 466.
[179] Laurence Boisson de Chazournes, 'Changing Roles of International Organizations: Global Administrative Law and the Interplay of Legitimacies' (2009) 6(2) International Organizations Law Review 655, 656.
[180] ibid.
[181] ibid.
[182] Though the relationship between regulation and administration was discussed earlier in the chapter, governance appears throughout GAL scholarship. With the WTO, it has been examined as an 'important example of the many dimensions of global administrative law (GAL) in multilevel global regulatory governance' and how '[m]uch of this global regulatory governance–especially in fields such as trade and investment, financial and economic regulation– can now be understood as administration'. Beyond this, the references to governance appear to emphasise the institutional elements of GAL systems: Richard B Stewart, Michelle Ratton, and Sanchez Badin, 'The World Trade Organisation: Multiple Dimensions of Global Administrative Law' (2011) 9(3-4) ICON 556, 557.
[183] 'It is more challenging, however, to successfully apply GAL requirements to "horizontal" decision making processes, like those within regulatory committees composed of member representatives… or regulatory networks of diverse actors that are not hierarchically organized and whose normative output is often much less formalized.': Richard B Stewart, Michelle Ratton, and Sanchez Badin, 'The World Trade Organisation: Multiple Dimensions of Global Administrative Law' (2011) 9(3-4) ICON 582, 583.
[184] Sabino Cassese, 'Global Administrative Law: The State of the Art' (2015) 13(2) ICON 466.

instruments without an executive.[185] All of this is then monitored and enforced through a very limited number of dispute resolution bodies where the emphasis is shifted towards a complex network of reviewing bodies that perform what is essentially a quasi-judicial function.[186]

International patent law reflects many of these same tensions but is not usually characterised as an element of GAL. Taking this institutional focus and applying it to international patent law reveals a difficult relationship between the dysfunctional WTO dispute settlement system and the mandate of the WTO as an organisation.[187] Even with a functional Appellate Body, it remained a dispute settlement body disconnected from democratic oversight that nevertheless decided on issues of law that restrict or otherwise constrain the state power involved with a patent grant. One illustrative example would be *Eli Lilly* that questioned the clarity and underlying principles of Canada's promise doctrine.[188] While this case is obviously framed in terms of an expropriation claim and the economic features of patent law,[189] it nevertheless is an international dispute settlement body of a trade organisation issuing binding recommendations as to how patents should and should not be granted. It does so from a trade perspective and there would appear to be no conflict in terms of the mandate of the WTO that were discussed above, yet I would argue that it is this economic focus that disguises the complex nature of the patent grant and obscures the administrative power which provides the foundation of patent law.

[185] Sabino Cassese, 'Global Administrative Law: The State of the Art' (2015) 13(2) ICON 466.
[186] ibid.
[187] On the paralysis of the Appellate Body: Georgie Juszczyk, 'Legitimacy Crisis in the World Trade Organisation Appellate Body: Other Ways than the MPIA?' in Jelena Bäumler, Christina Binder, Marc Bungenberg, Markus Krajewski, Giesela Rühl, Christian J Tams, Jörg Philipp Terhechte, and Andreas R Ziegler (eds), *European Yearbook of International Economic Law* (Springer 2022) 90.
[188] *Eli Lilly and Company v The Government of Canada* UNCT/14/2.
[189] See generally Pratyush Nath Upreti, 'Eli Lilly v Government of Canada: The Tale of Promise v Expectation' (2018) 21(3) IntALR 84, 85.

3. Critical perspectives on GAL

3.1 The role of the Global North

3.1.1 Harlow's 'double colonization'

Yet despite the significant potential of the values developed through GAL scholarship to analyse several of the challenges involved in global administration and regulation, the exact status and content of these values is not necessarily settled within the discipline. This is particularly important for understanding GAL as a field of scholarship because these values are central to this area.[190] Harlow argues that, in the development and dissemination of GAL, there has been something of a 'double colonization'.[191] This development is presented as a result of the general bias in GAL concepts and principles towards Anglo-American understandings of administrative law more generally.[192] The first of these colonisations is suggested to occur when administrative law (and the administrative law system) 'absorbs' the values which underpin global governance or human rights,[193] but specifically in the way it incorporates democracy, participation, transparency, and accountability.[194] In doing so, the form of administrative law itself reflects a set of normative values which are themselves contextually specific. While Harlow frames this evocatively through the language of a 'colonisation', from a more abstract or consequentialist perspective, there is no inherent problem with administrative law embodying values like accountability and transparency.

[190] Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) 17(1) EJIL 193.
[191] ibid 209
[192] ibid.
[193] ibid.
[194] ibid.

The second 'colonisation' occurs through the legal processes of cross-fertilisation or more explicitly through legal transplants.[195] Though Harlow recognises that this type of diffusion of legal norms, institutions, or principles can happen spontaneously,[196] specific emphasis is given to the role of the 'powerful transnational juristocracy' that operates in human rights courts and across European legal systems to eventually form an abstract common European standard.[197] Underlying Harlow's approach to legal transplants, however, is the suggestion that there are no inherent characteristics of either the source of the principle or the principle itself that necessarily characterise this process negatively.[198] Yet this highlights a tension that emerges in both intellectual property and GAL scholarship. In a GAL context, this can be found where developed countries attempt to impose external standards (and thus, normative values in the law) on less-developed countries while either remaining unwilling to give proper effect to these standards (or actually practically unable to).[199] For patent law, there is considerable scholarship that explores the double standard of developed countries encouraging high standards of protection when their own industrialisation benefited from lax intellectual property enforcement.[200]

Even when the focus is precisely on this 'thin' understanding of GAL, with an emphasis on the use of procedural safeguards rather than substantive objectives, academic commentary has warned against an uncritical acceptance of these elements of GAL as being value-neutral

[195] Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) 17(1) EJIL 209.
[196] ibid.
[197] ibid.
[198] 'There is, of course, no particular reason why administrative law norms borrowed from Western systems should not be successfully diffused throughout the world': ibid.
[199] ibid 211.
[200] Where 'the patent law policies of European countries during their early years of industrialization reveal a clear instrumentalist policy of appropriating the ideas and technologies of other states.': Ikechi Mgbeoji, *Biopiracy: Patents, Plants, and Indigenous Knowledge* (UBC Press 2006) 34; though this sense of a double standard in patent law also extends to biological materials and how non-Western contributions to plant development 'systematically relegated to an inferior status for appropriation through the patent system': ibid 14; and also in discussions around how the use of fossil fuels in developing countries is condemned by Western governments (despite their own industrialisation benefiting from fossil fuels): Augustine Sadiq Okoh, *Oil Mortality in Post-Fossil Fuel Era Nigeria: Beyond the Oil Age* (Springer 2021) 66.

in practice. Chimni argues that, by focusing on the procedural elements,[201] GAL principles in the procedural dimension work to legitimise the types of unjust or unfair outcomes that GAL principles are intended to combat.[202] Here, global regulation is presented as proceeding not in a 'value-free manner', but in a way that is necessarily informed by the market dynamics between developed and developing countries that focus on the important role of 'fair competition' through regulation.[203]

This is also an important element of the broader academic treatment of the TRIPS Agreement, where the process – created and agreed upon by WTO Members – works to legitimise or stabilise any negative welfare outcomes and current paradigms within intellectual property.[204] The concerns over stability and legitimacy stand out here particularly because of the emphasis on the WTO as being led by its members.[205] As such, the worth of procedural transparency and accountability has to be interpreted in light of the fact that the TRIPS Agreement was created by its members and voluntarily accepted. This type of tension is also mirrored in patent exceptions and flexibilities. The presence of these flexibilities, as procedural flexibilities in the administration and regulation of patent law, works to legitimise the welfare outcomes and the international patent system more generally. This procedural legitimation

[201] Though Chimni also argues that the reality of our current international law necessarily requires a broad definition of GAL that does not try to maintain a distinction between substantive law and administrative law. Where '[a] broader definition of GAL does not, in the face of the democracy deficit that characterizes international institutions and bodies, accept the strict separation between substantive law and administrative law': B S Chimni, 'Co-Option and Resistance: Two Faces of Global Administrative Law' (2005) 37 NYU Journal of International Law and Politics 799, 804, 805, 827

[202] ibid 805.

[203] Yakub Halabi, 'The Expansion of Global Governance into the Third World: Altruism, Realism, or Constructivism?' (2004) 6(1) International Studies 33, 34.

[204] Using a similar vocabulary found in GAL scholarship more broadly, Cloatre suggests that even with progress in medicine accessibility, '…certain patterns of inequality and exclusion seem to persist… TRIPS, by inscribing them into law, has stabilized some of the patterns of dominance that allowed it emerge': Emilie Cloatre, *Pills for the Poorest: An Exploration of TRIPS and Access to Medication in Sub-Saharan Africa* (Palgrave 2013) 175, 176.

[205] 'The WTO is run by its member governments' and '[i]n this respect, the WTO is different from some other international organizations such as the World Bank and the International Monetary Fund. In the WTO, power is not delegated to a board of directors or the organization's head': WTO, 'Understanding the WTO: The Organization' (*WTO*) <https://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm>.

frames the perception of the TRIPS Agreement and can work to somewhat disguise the difficulty with which countries have had in actually making use of these mechanisms.[206]

Indeed, legitimacy appears throughout a lot of GAL scholarship and how an emphasis on procedural transparency or narrow accountability can be deployed to legitimise or stabilise specific institutions or relationships between particular actors.[207] Kingsbury, Krisch, and Stewart in particular argue that this is an issue with the fundamental contours of GAL as an academic focus. This is because accepting that there is a global administrative space, in which global regulation becomes cast in the language of administration,[208] has the potential to legitimise or stabilise the current powerholders.[209] Understood from this perspective of legitimacy, the GAL vocabulary has the potential to reinforce Global North and Western understandings of what governance – and the principles that underly it – should be.[210] This is particularly the case when GAL concepts are predominantly applied in their 'thin' construction, prioritising procedural aspects of regulation and administration without connecting them with their substantive frameworks and contexts.

This connects more broadly to the critique within the literature that administrative law itself can be considered as a 'Western' construct.[211] Though there are significant contributions in the literature that explore the positive impact of typical GAL principles on the domestic administrative context – China is an example which appears repeatedly[212] – the critical

[206] On the bureaucratic burden involved in the use of TRIPS flexibilities (specifically for medicine and licensing): Roy Love, 'Corporate Wealth or Public Health? WTO/TRIPS Flexibilities and Access to HIV/AIDS Antiretroviral Drugs by Developing Countries' (2007) 17(2**)** Development in Practice 211, 212.
[207] Benedict Kingsbury, Nico Krisch, and Patrick B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 15, 27.
[208] ibid.
[209] Benedict Kingsbury, Nico Krisch, and Patrick B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 15, 27.
[210] ibid.
[211] Richard B Stewart, Michelle Ratton, and Sanchez Badin, 'The World Trade Organisation: Multiple Dimensions of Global Administrative Law' (2011) 9(3-4) ICON 573.
[212] Sarah Biddulph, 'Administrative Power' in Peter Cane, Herwig Ch Hofmann, Eric C IP, and Peter L Lindseth (eds), *Oxford Handbook of Comparative Administrative Law* (OUP 2021) 381.

discussions around the fundamental nature of administrative law emphasise the potential for 'structural biases'.[213] This understanding is essentially a contextualist view of administrative law, with scholars arguing that because administrative law emerged in a particular time and space that it would reflect an inherent bias towards certain values or interests. It is precisely the type of discussion that focuses on the contextualist features of a legal development's *origin* that have formed an important part of critical work in intellectual property. Indeed, this type of structural critique is highlighted in GAL literature as being paralleled in the academic treatment of the TRIPS Agreement.[214]

This type of approach emphasises not only the structural nature of these tensions, in intellectual property and GAL more generally, but the *interconnected* nature of these structures. Patent law demonstrates this, though it was also highlighted earlier in the discussion of domestic administrative law, because it presents structural tensions not just as affecting a singular, global legal framework but an interconnected network of frameworks. Just as GAL is necessarily constructed from elements that challenge distinctions between global and national, or administrative and non-administrative, the structural tensions in patent law operate at a variety of different scales that incorporate international, regional, and global legal forms. Rather than a rejection of administrative law values like democratic accountability or legitimacy in the thesis on the basis of their 'Western' character, the discussion here is to simply recognise that their status within GAL is not uncontested. The sense of administrative values being 'Western' takes on a distinctive character when considering the functioning of the TRIPS Agreement that is not necessarily found in other contexts (like when analysing the UPC in a European context). Here, the thesis recognises that there are broad parallels between the colonialist critique of GAL and how patent law has been variously 'imposed' on developing

[213] Richard B Stewart, Michelle Ratton, and Sanchez Badin, 'The World Trade Organisation: Multiple Dimensions of Global Administrative Law' (2011) 9(3-4) ICON 573.
[214] ibid 574.

countries,[215] yet the analysis is not centred on this critical perspective. The EU does stand out in this context for its high-profile commitments to typical GAL values,[216] though critical colonial or postcolonial dimensions of GAL are not necessarily as relevant when analysing the development of European patent law as it concerns the Member States.

3.1.2 Normative and descriptive overlaps in GAL scholarship

One of the fundamental discussions that appears throughout the academic literature is around the nature of GAL scholarship itself and the degree to which it represents a normative project. More accurately, given the acceptance by their authors that many of these projects are normative,[217] the question that emerges implicitly in the literature is the *degree* to which these projects are normative. Kingsbury, Krisch, and Stewart argue that that is well accepted amongst those who are involved in the study or the continued construction of GAL as an academic field that these projects go beyond establishing a taxonomy or a technocratic advocacy of technical solutions to regulatory problems.[218] Approaching patent law from a normative perspective, whether it starts from a conventional patent analysis or from the more explicitly values of GAL, challenges the conventional understanding of patents as economic tools. Patents occupy a unique space normatively because they are forms of intellectual property and therefore

[215] David Lea, *Property Rights, Indigenous People and the Developing World: Issues from Aboriginal Entitlement to Intellectual Ownership Rights* (Martinus Nijhoff 2008) 194, 195.
[216] EU Parliament, 'Transparency and Ethics' (*Europarl*) <https://www.europarl.europa.eu/at-your-service/en/transparency>; though perhaps more explicitly declared through Article 15 TFEU, where the EU bodies and institutions 'conduct their work as openly as possible in order to ensure the participation of civil society and thus promote good governance'.
[217] 'Participants in either the study or the construction of a global administrative law recognise that these are normative projects, and not simply a taxonomical exercise or the promulgation of practical technical solutions to well-defined and accepted problems posed by global regulatory administration. But the potential normative foundations are as varied as their practical administrative counterparts.': Benedict Kingsbury, Nico Krisch, and Patrick B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 42.
[218] ibid.

intangible.[219] From this, Peukert's work emphasises that the form, function, and the values that animate patent law are all produced by the participants of a legal system rather than occurring as a natural fact.[220] Taking this perspective and applying it to a GAL-focused project like this thesis highlights that there is no inherent tension or contradiction when critiquing patent law from a normative perspective. Emphasising that patent law is produced essentially as a form of community acceptance mirrors Michaels' perception of legal interfaces as creative spaces.[221] Patent law, and the values that it reflects and promotes, are created through the interaction of its participants and the recognition of patent law's administrative foundation cast this analysis as internal critique rather than external.

Turning to more specific normative concerns within GAL, Kingsbury, Krisch and Stewart identify three potential normative foundations for GAL scholarship. These range from the least normatively demanding with international administrative accountability, through the protection of private rights or the rights of states, and finally, the promotion of democracy.[222] Given that the project here focuses on the treatment of intellectual property, it is the second strand that relates most closely with the current subject matter. Kingsbury, Krisch, and Stewart argue that an emphasis on private rights as the normative foundation presupposes a legal order

[219] Alexander Peukert, *A Critique of the Ontology of Intellectual Property Law* (CUP 2021) 1.
[220] Describing debates as to the ontological character of intellectual property, where the 'relationship between "is" and "ought" is particularly unstable…'. Patents are presented as paradigmatic of these ontological concerns because it 'generates its object from itself–namely from highly formalised patent documents.': ibid 7, 8; Yet this analysis of normative value also appears in a GAL context, where 'the GAL approach claims to retain a soft normative value, aiming to bridge a relatively little gap between an "Is" and "Ought" at a global level, by expanding guarantees in administrative action, in fields where they have not been established yet': Angelo Jr Golia, 'Judicial Review, Foreign Relations and Global Administrative Law: The Administrative Function of Courts in Foreign Relations' in Helmut Philipp Aust and Thomas Kleinlein (eds), *Encounters Between Foreign Relations Law and International Law: Bridges and Boundaries* (CUP 2021) 139.
[221] Where legal systems, and the tertiary rules that Michaels focuses on, are part of the creation of the legal order itself. 'Tertiary rules thus do not only respond to, and organize, a world of separated legal systems, they are themselves involved in the creation of such a system', and from a broader perspective, '[w]hile the law at large is autopoietic, individual legal systems are not; they constitute each other through mutual recognition.': Ralf Michaels, 'Tertiary Rules' in Nico Krisch (ed), *Entangled Legalities Beyond the State* (CUP 2022) 426, 427.
[222] Benedict Kingsbury, Nico Krisch, and Patrick B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 46.

that prioritises liberal values in a global context,[223] yet they highlight the development of human rights as evidence of how this is possible even in a non-cosmopolitanist setting.[224] Fundamentally, the tension in the development of GAL is found in managing these different legal interfaces. Though they are contextualised here in the struggles of international patent law in the thesis and focus on how national institutions are minimised, this type of tension would appear to be inherent to regulatory functions more generally when they take on a global character. Kingsbury, Krisch, and Stewart argue that this type of relational interaction between societies becomes central when the regulation of governmental functions is elevated beyond the national context.[225] They suggest that because no one society can insist on the values to govern (or even establish) global institutions,[226] the development of these institutions then represents a generalised threat to *all* participants and their national values, ethics, and societal orders.[227] Yet this type of critical perspective, if taken in isolation, could serve to overlook or otherwise minimise the very different degrees of threat to national values. While it is true that, within TRIPS, the EU cannot solely insist on the values and governance of the relevant global institutions, the degree to which these institutions then represent a threat to or divergence from EU values is more contextual. The principles and values of the WTO, the functioning of the TRIPS Agreement, and the values underpinning the patent system all find clear parallels in EU legal systems in a way that would not necessarily be the case for other countries. The development of global institutions, as a result of the global space that they are created in, may indeed represent a threat to the value systems of all participants (but perhaps some more than others).

[223] Benedict Kingsbury, Nico Krisch, and Patrick B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 46.
[224] ibid.
[225] ibid.
[226] 'Since none of the participating states can demand that its own ideas should exclusively govern global institutions, these institutions appear to threaten every state's own way of organizing the state and society': ibid.
[227] ibid.

3.2 Structural reflections of GAL values

3.2.1 The structural aspects of transparency and accountability

There is also a substantive dimension to these global institutions and their relationship to democracy, legitimacy, and accountability, as well as the legal content of their output. In this, Kingsbury, Krisch, and Stewart highlight the development of arbitral remedies in investment treaties where there have been successful expropriation claims under NAFTA in relation to environmental legislation and the cancellation of a water service franchise.[228] They also highlight the enforcement of intellectual property rights under TRIPS by multinational firms that resulted in similar controversies.[229] And yet even if the results of the arbitral mechanisms of dispute resolution functioned well in both a substantive and procedural sense, there are still issues about how these bodies – as well as the regulatory institutions that are implicated in the establishment of these arrangements – are sufficiently connected to the public and values of democracy.[230] Kingsbury, Krisch, and Stewart argue that this type of technocratic deliberation may indeed result in positive results,[231] but the fact that global regulatory administration is increasingly creating important distributional concerns means that it requires a greater connection with principles of democracy and accountability.[232]

Patent law represents an important context to explore through this lens of accountability because, as a discipline, is particularly vulnerable to capture by technocrats because it is a fairly

[228] Benedict Kingsbury, Nico Krisch, and Patrick B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 47.
[229] ibid.
[230] ibid 49.
[231] ibid.
[232] ibid.

narrow and specialised field,[233] the barriers to entry can be high,[234] and it necessarily considers a technically complex subject of study.[235] Values from administrative law like transparency and accountability in a general sense do not often appear in discussions of patent law. They appear in work that considers specific, substantive outcomes like access to medicine and the role of the WTO,[236] but not always in a generalised sense. Applying this type of framing to patent law has two functions as discussed in the introduction, to both explore patent law as fundamentally connected to administrative law and to also analyse how more traditional administrative values function in a dispute settlement context to shape how different legal systems interact.

It is also important to recognise in the development of GAL as an academic subdiscipline that it remains only one of many potential ways of constructing the institutions and relations in a system of global regulation. Part of the appeal of alternative conceptions is that, within GAL, the mechanisms and tools for promoting accountability or democracy within global regulation are essentially drawn from the legal systems of the Global North and thus raise questions about *who* is shaping the development of GAL.[237] One alternative that is explored within the literature is the idea to maintain an international environment without strict hierarchical structures.[238] By keeping the relationships between institutions and legal orders in a more flexible state, there is the potential for an actor to challenge others within the system on the basis of 'their own normative principles and standards'.[239] This type of arrangement

[233] Kara W Swanson, 'The Emergence of the Professional Patent Practitioner' (2009) 50(3) Technology and Culture 521.
[234] ibid 523, 524.
[235] Banks Miller and Brett Curry, 'Expertise, Experience, and Ideology on Specialized Courts: The Case of the Court of Appeals for the Federal Circuit' (2009) 43(4) Law & Society Review 841.
[236] Devi Sridhar, 'Improving Access to Essential Medicines: How Health Concerns can be Prioritised in the Global Governance System' (2008) 1(2) Public Health Ethics 83, 84.
[237] Benedict Kingsbury, Nico Krisch, and Patrick B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 51.
[238] ibid 49.
[239] ibid 47.

emphasises a variable geometry approach as to the degree of participation of each actor, the relationship between the actors, and the potential for mutual reinforcement and challenges within the system.[240] Yet patent law, in contextualising the interactions of national and global legal arrangements, provides a way of highlighting how these soft hierarchies still privilege specific actors and institutions. Not only are specific actors able to reinterpret or otherwise instrumentalise these interactions, but this process also (particularly as the thesis focuses on the role of dispute resolution bodies) correspondingly reinterprets and reshapes the values that underpin these interactions like transparency and accountability. Krisch highlights, while grounding the analysis in the investigation of interface norms, the role of dispute resolution bodies in reaching between different legal orders and different systems of norms.[241] Though it is not made particularly explicit in that work, I would argue that it is not just the initial entanglement that results from this type of norm borrowing that is important, but that the ongoing practice of entanglement produces a unique legal space. In such a context, the norms, practices, and values take on a distinctive character that is reinforced or reshaped by their use within that specific context by progressive episodes of dispute resolution. The emphasis in Krisch's work is on the role of norms in this context, though patent law exceptions represent a similar creative space because of their standardised text that is then strategically developed through the statement and restatement of its participants. In this way, the emphasis on the actors stating and restating the content of a patent provision takes on a similar character to that which Krisch applies to the development of norms that progressively revisit the normative impact of transparency, participation, and accountability.[242]

[240] Benedict Kingsbury, Nico Krisch, and Patrick B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 47.
[241] Where '[a]ctors – litigants, judges, dispute settlers, observers, addressees – make claims about the relation of norms from different backgrounds, and they thus define and redefine the relative weights and interconnection between the norms at play': Nico Krisch, 'Framing Entangled Legalities Beyond the State' in Nico Krisch (ed), *Entangled Legalities Beyond the State* (CUP 2022) 5.
[242] ibid.

This type of more structural critique – and one that invites a more radical reconstruction of the system rather than reform of the institutions – appears throughout the literature. This can be found particularly in work that adopts a TWAIL perspective or emphasises post-colonial approaches to international law. From these perspectives, simply identifying the presence of administrative principles in international institutions does not resolve the fundamental inequalities that are part of the structural fabric of global governance.[243] Xavier essentially argues that designing approaches that incorporate GAL principles does nothing to address how the tribunals and institutions are created, their dominant rationale, and the politics involved in their functioning and creation.[244] Xavier develops this, though specifically in terms of procedural aspects,[245] to suggest that the presence of administrative law principles does not bring a greater legitimacy to the practice and constitution of international institutions.[246] Instead, Xavier characterises these principles as functioning to camouflage a universalist approach to Western values that is 'embedded within the global infrastructure and creates a sense of false hope for the people of the Global South'.[247]

In emphasising the important role of context in understanding international institutions, Xavier argues that 'top heavy theory from the Global North' may not be sufficient to properly understand the nature of political compromises that are involved in the creation and operation of international institutions.[248] Instead, analysis must seek to move beyond the general legal frameworks that create the system of international regulation and into the internal dynamics that characterise each institution.[249] This emphasis on internal dynamics and the more

[243] 'Ultimately, the presence of procedural administrative law does not usher in greater legitimacy to the various international institutions. Rather, this argument camouflages the Western universalism embedded within the global infrastructure…': Sujith Xavier, 'Top Heavy: Beyond the Global North and the Justification for Global Administrative Law' (2018) 57 Indian Journal of International Law 353.
[244] ibid.
[245] ibid.
[246] ibid.
[247] ibid.
[248] ibid 355.
[249] ibid.

interactional analysis of legal frameworks is a very prominent part of the thesis. It is precisely in this global administrative space that lacks an authoritative legislator that these interactions between legal interfaces take on a central importance (as well as the facilitative role of the associated dispute settlement bodies). Beyond just investigating the character of the interactions between legal systems, this type of approach highlights the importance of analysing how they interact, the precise scope of the actor managing these interactions, and the values that are (explicitly or implicitly) used to shape this process.

4. Exploring the relationship between GAL scholarship and the WTO

4.1 How the WTO is used in GAL work

4.1.1 The WTO as an element of the international regulatory 'space'

The WTO is an important institution through which to view GAL and GAL principles because it signifies, perhaps more clearly than other international organisations, something that has been described as a 'pervasive shift of authority from domestic governments to global regulatory bodies' that emerged as a result of increased economic integration and general interdependence.[250] Here, there is a prominent overlap between the construction of administrative bodies or administrative 'space' and specialised global regulatory bodies that operate in a 'multifaceted global regulatory and administrative space'.[251] While the broad definition of this sense of 'space' can be found in GAL scholarship, and even in a narrower context like that of analysing the WTO through GAL principles, strict definitions remain

[250] Richard B Stewart, Michelle Ratton, and Sanchez Badin, 'The World Trade Organisation: Multiple Dimensions of Global Administrative Law' (2011) 9(3-4) ICON 557.
[251] ibid.

difficult. Some academic work proceeds from an understanding that trade, investment, and economic regulation can be considered a form of administration.[252] As such, their definitions of 'administrative' are necessarily expansive and include 'all forms of law-making other than treaties or other international agreements and episodic dispute settlement'.[253]

What is interesting in this emphasis on the regulatory nature of administration, or perhaps the fundamentally administrative nature of regulation in an economic context, is that GAL values appear throughout. The value of accountability, for example, is strongly emphasised in work considering the WTO and highlights the need for new mechanisms outside traditional national and international approaches to ensure that global regulatory decision-makers are accountable.[254] Yet beyond this, and very relevant for applying these principles in the context of intellectual property, it is the linking between accountability and responsiveness in the work of Stewart, Ratton, and Badin.[255] Intellectual property law, particularly at the international level and especially so in the context of the TRIPS Agreement, has been criticised as being unresponsive to the needs of diverse populations and instead promoting a homogenised legal approach that entrenches the legal and economic interests of developed countries.[256]

While the GAL literature certainly considers the role of the WTO as an important institution in the development of global administration, there remains a lack of material that specifically explores how it impacts the development of intellectual property and patent law more specifically. While TRIPS appears occasionally in the literature, it is usually explored

[252] Richard B Stewart, Michelle Ratton, and Sanchez Badin, 'The World Trade Organisation: Multiple Dimensions of Global Administrative Law' (2011) 9(3-4) ICON 557.
[253] ibid.
[254] ibid.
[255] ibid.
[256] Highlighting the importance of patent law being 'responsive' to diverse global needs (but specifically in a pharmaceutical context): Shayana Kadidal, 'Plants, Poverty, and Pharmaceutical Patents' (1993) 103(1) Yale Law Journal 226.

briefly in comments that suggest there are controversies in its application. References generally highlight the relationship between WTO Agreements, private administrative bodies (such as the Codex Alimentarius), and a general sense of restrictiveness from TBT or SPS.[257] For Kingsbury, Krisch, and Stewart, the Codex Alimentarius is indicative of a specific type of regulatory regime – a hybrid intergovernmental-private administration[258] – that is given 'quasi-mandatory' effect through the SPS Agreement.[259] There is a distinction made in the literature between the hybrid initiatives (like the Codex Alimentarius) and the more complex dynamic of private administrative bodies like the ISO where their output has a major economic impact and is also incorporated in regulatory decisions in organisations like the WTO.[260]

5. Connecting the thesis chapters and concepts from GAL

5.1 Chapter 2

Chapter 2 explores the development of the new European Patent with Unitary Effect (EPUE) because it represents a development in European patent law, the creation of a new legal interface, and a new dispute resolution body. The EPUE demonstrates the complex dynamics of patent law, though its development necessarily reflects the process of negotiation between national and international, political and legal, and European and non-European. Central to this analysis is the development of the Unified Patent Court (UPC) and interpreting its position through the values of transparency and accountability found in GAL scholarship.

[257] Benedict Kingsbury, Nico Krisch, and Patrick B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 22.
[258] ibid.
[259] ibid.
[260] ibid 23.

While the chapter involves an investigation into the more legislative elements that establish the EPUE, the focus is very much on the more procedural aspects of the EPUE implementation and the UPC court structure rather than the legislative process more generally. Institutionally, the focus centres on the role of courts in the implementation of the EPUE. Understanding the EPUE legislative progression from the perspective of GAL values presents a more critical way of interpreting the enhanced cooperation mechanism that was used to create the EPUE. This chapter develops a more expanded use of traditional GAL principles, particularly in terms of accountability and transparency, to question the legitimacy of the EPUE and its potential implications for EU law-making more generally. GAL presents an important lens for this investigation because, particularly in more critical constructions, it provides a vocabulary for deconstructing the presumptions of validity and legitimacy in law. The EPUE provides an important context for this type of investigation because it has been repeatedly endorsed in terms of its legal validity by the CJEU and yet the potential broader impact of the project – specifically for participation and accountability as legal values – presents serious system risks for the future of EU law-making.

5.2 Chapter 3

Chapter 3 considers the relationship between the CJEU and the WTO, focusing specifically on legal status of the TRIPS Agreement in terms of direct effect. The CJEU has been central in managing the position of the TRIPS Agreement and its relationship to direct effect. In this sense, the way that the CJEU has positioned the TRIPS Agreement as an element of the WTO legal order is part of the broader way in which non-EU sources of law are treated. Central to this chapter are the values of transparency, participation, and accountability as with conventional GAL scholarship. The chapter aims to move beyond the thin conception of

transparency discussed by some scholars into a more developed sense of reason-giving.[261] Reason-giving and participation appear in GAL scholarship but this chapter applies these perspectives in the context of the TRIPS Agreement.[262] These values provide a different way of critiquing the jurisprudence of direct effect discourse in the CJEU about the TRIPS Agreement beyond the fact that it has been inconsistent. Fundamentally, it demonstrates the more abstract value of direct effect and reflects the powerful symbolic effect of transparency that is described in GAL scholarship.[263] For the TRIPS Agreement, however, it suggests that the failure of the CJEU to engage more explicitly with the WTO legal regime can be more properly characterised as a failure to promote transparency, accountability, and reason-giving.

Considering the issue from the perspective of legal interfaces and the norms that govern their interactions, the activities of the CJEU (specifically in direct effect) demonstrate how central courts are in managing systemic interactions. The CJEU also demonstrates the framing role of legitimacy in the context of legal interfaces because the mechanisms for managing the interface rely on a mixture of general and specific legal principles. The CJEU, both generally and considering the WTO legal regime, relies on the general power of legitimate interpretation to transform or otherwise operationalise general legal principles and ensure a workable interaction. This contrasts with the analysis developed in chapter 2 that focused on the UPC and the facilitative role of patent-specific legal mechanisms.

[261] On the 'thin conception of procedural fairness in law-creation and application' related to Kingsbury's work: Patrick Capps, 'International Legal Positivism and Modern Natural Law' in Jörg Kammerhofer and Jean D'Aspremont (eds), *International Legal Positivism in a Post-Modern World* (CUP 2014) 227.
[262] Where 'reason giving' appears alongside transparency, participation, and review: Richard B Stewart, 'Global Standards for National Societies' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 175, 176.
[263] 'In contrast to opaqueness, transparency has a symbolic dimension': Laurence Boisson de Chazournes, 'Changing Roles of International Organizations: Global Administrative Law and the Interplay of Legitimacies' (2009) 6(2) International Organizations Law Review 659.

5.3 Chapter 4

Chapter 4 represents an application of GAL principles and Krisch's concept of an interface as an interactive and creative space in a less conventional context. The institutional and legal environment explored in chapter 4 stretches the understanding of 'court' and 'dispute settlement body' as it used in GAL scholarship. Part of this comes from presenting bilateral trade agreements as a legal interface and, for the promotion of GAL principles, how the particular role of dispute resolution bodies is constructed within these trade agreements.

Turning first to the application of GAL values and principles in the context of bilateral trade agreements, the focus remains on the EU and extends to the trade agreements which it has concluded. This provides a continuity in terms of actor throughout the thesis because chapter 2 considers the development of the UPC, chapter 3 analyses the functioning of the CJEU as a central dispute settlement body, and chapter 4 looks at how the EU is developing similar systems in the bilateral context. Particularly for analysing how these environments relate to GAL principles, it is the EU's express commitment to values like transparency and accountability that presents an important opportunity to explore how far these commitments produce tangible outcomes in patent law. Bilateral agreements have been criticised for the way in which they minimise the role of national parliaments and the degree of secrecy that surrounds their negotiations more generally, but interpreting these legal developments through the prism of GAL provides a more integrated or grounded critique of transparency and accountability. GAL principles provide a more systemic perspective as to the issues with bilateral trade agreements in a way that joins together the validity and importance of values like transparency, participation, and accountability. The lack of transparency, and the resulting issues in accountability and participation in the European context, are then not individual critiques of bilateral trade agreements and instead a more systematic failure to implement specific values from a GAL perspective in patent law. From this, the chapter tries to draw a parallel between

the discussions in GAL literature as the existence of distinct 'global space' and explore the specific challenges and character of the 'bilateral space'.

The bilateral trade context also provides an environment to both apply and expand the theoretical understanding of dispute resolution bodies in GAL studies. This relates to the fundamental scope of dispute settlement bodies within GAL scholarship, where the emphasis has typically been on arrangements that are not ad hoc or episodic.[264] The enforcement dimension of intellectual property provisions in bilateral trade agreements has been criticised in the literature for the dynamic it produces between developed and developing countries,[265] but this has not been connected with the GAL principles from this more systemic perspective. In doing so, dispute resolution is contextualised alongside the more structural aspects of the bilateral space in a way that shifts away from a sole focus on dispute. This chapter provides an important exploration into how GAL principles can guide conduct in the bilateral space because, as highlighted through the broad principles and undefined concepts in many agreements, these arrangements vest considerable interpretative power in fairly opaque dispute settlement bodies and present a fairly open-textured legal space.

6. Conclusion

Patent law is an area of law that operates across national and international spheres of regulation. Increasingly, patent law has become a prominent aspect of industrial policy in many different countries that emphasises the economic function of patents and patent law.[266] This

[264] Richard B Stewart, 'Global Standards for National Societies' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 177.
[265] Kajal Bhardwaj, 'India's Free Trade Agreements: Implications for Access to Medicines in India and the Global South' in Hans Löfgren (ed), *The Politics of the Pharmaceutical Industry and Access to Medicines: World Pharmacy and India* (Routledge 2018) 155.
[266] Brad Sherman, 'Towards a History of Patent Law' in Toshiko Takenaka (ed), *Intellectual Property in Common Law and Civil Law* (Edward Elgar 2013) 3.

type of economic framing of the patent disguises the fundamentally administrative character of the patent grant. While the procedural aspects of patent law have been a feature of international agreements since the late 19th century and resulted in a solid foundation of global patent law,[267] many features of the patent system (like opposition) remain generally national.[268] The emphasis of the investigation throughout the thesis is not just on the values that produce these systems of law, but the dynamics of how these systems interact to produce workable systems of law. Drawing on the exercise of state power that underpins patent law, the thesis interprets the legal framework, how actors interact, and the role of dispute resolution bodies in facilitating systemic interactions through the lens of GAL values and concepts.

The institutional focus of the thesis has been informed by GAL scholarship because the substantive chapters of the thesis all incorporate dispute settlement perspectives. This reflects some of the most prominent approaches in GAL scholarship and highlights the role of the dispute settlement bodies in developing the principles that shape the substantive content of general provisions.[269] The focus on dispute settlement bodies is particularly useful in intellectual property and patent law because courts (or similar structures) with broadly comparable features appear throughout international patent law.[270]

The WTO appears throughout GAL scholarship as an important actor in the development of values and principles in international regulation,[271] how harmonisation can be

[267] Dongwook Chun, 'Patent Law Harmonization in the Age of Globalization: The Necessity and Strategy for a Pragmatic Outcome' (2011) 93(2) Journal of the Patent & Trademark Office Society 129.
[268] Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 234.
[269] Mikael Rask Madsen, 'Judicial Globalization: The Proliferation of International Courts' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 285, 286.
[270] With Romano providing a six-part criteria for identifying a true international court (as distinct from other international bodies involved in administrative activities): Cesare Romano, Karen J Alter, and Yuval Shany, 'Mapping International Adjudicative Bodies, the Issues and Players' in Cesare Romano, Karen J Alter, and Yubal Shany (eds), *The Oxford Handbook of International Adjudication* (OUP 2015) 1, 6.
[271] Elisa D'Alterio, 'Judicial Regulation in the Global Space' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 304.

interpreted from a more critical perspective,[272] and how administrative law principles (like accountability) can be translated to the global space.[273] While the TRIPS Agreement is mentioned sporadically in the literature, it is usually discussed in relation to how technical standards function as a form of regulation and how the WTO necessarily privileges specific bodies with administrative power.[274] The lack of scholarship directly considering the regulatory dimensions of patent law and the TRIPS Agreement from a more administrative perspective stands out because the creation of the WTO – and the transformation of the international trade system into a full administrative network[275] – coincided with the signing of the TRIPS Agreement at the conclusion of the Uruguay Round.[276] The lack of scholarly work exploring how dispute settlement bodies contribute to traditional GAL values in the context of intellectual property is also notable because of the central role of courts in GAL scholarship.

Though the project investigates how GAL principles appear throughout the activities of dispute settlement bodies, the analysis is framed more broadly by the work of Krisch as a more specific strand of GAL.[277] Here, the emphasis is on the more interactional dimensions of legal systems and characterises them as interfaces,[278] while at the same time thereby shifting the focus towards the mechanisms and principles which are used to manage how these

[272] On the tensions around universalizing standards and the movement from values, to human rights, to universal constitutional values: Carol Harlow, 'Global Administrative law: The Quest for Principles and Values' (2006) 17(1) EJIL 206, 207.
[273] Mariana Mota Prado, 'Diffusion, Reception and Transplantation' in Peter Cane, Herwig Ch Hofmann, Eric C IP, and Peter C Lindseth (eds), *The Oxford Handbook of Comparative Administrative Law* (OUP 2021) 265, 266.
[274] Stefano Battini, 'The Proliferation of Global Regulatory Regimes' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 60.
[275] Particularly in the transformation from the dispute settlement system under the GATT and then under the WTO: Barbara Marchetti, 'The Enforcement of Global Decisions' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 248, 249.
[276] Roger Kampf, 'Does Intellectual Property Belong to the Trade Family?' in Christoph Herrmann, Bruno Simma, and Rudolf Streinz (eds), *Trade Policy Between Law, Diplomacy and Scholarship* (Springer 2015) 92, 93.
[277] In both sole-authored and co-authored works: Benedict Kingsbury, Nico Krisch, and Richard B Stewart, 'The Emergence of Global Administrative Law' (2005) 68(3/4) Law and Contemporary Problems 15, 16.
[278] Nico Krisch, 'Framing Entangled Legalities Beyond the State' in Nico Krisch (ed), *Entangled Legalities Beyond the State* (CUP 2022) 21, 22.

interfaces interact.[279] This shift from broad values explored in GAL literature towards a more specific investigation into how they emerge at the interfaces of patent law highlights the important creative function of dispute settlement bodies (both generally and in patent law more specifically).

[279] Nico Krisch, 'Framing Entangled Legalities Beyond the State' in Nico Krisch (ed), *Entangled Legalities Beyond the State* (CUP 2022) 21, 22.

A new patent interface in Europe: Exploring participation

1. Introduction

The development and implementation of the European Patent with Unitary Effect (EPUE) is an important step for European patent law because it represents significant progress towards a more complete patent harmonisation in Europe.[280] While European patent law can be described as fragmented,[281] this is more of a fragmentation in substance rather than in procedure. This is primarily because of the European Patent Convention (EPC) and other Directives on specific areas of patent law.[282] The grant of a single patent that would be valid and enforceable throughout the EU would represent a simplification for inventors and businesses over the existing administrative centralisation and systems of national enforcement. Yet despite this potential, the EPUE falls significantly short of creating a harmonised patent interface. It is important to analyse the development and implementation of the EPUE because it is a rare opportunity to explore the creation of a new, contemporary, patent interface. The EPUE can be used to explore the processes by which international patent law is produced, but within a fairly specific European context before considering more complex environments. Beyond the creation of a new patent interface, the EPUE represents a way of analysing how transparency, accountability, and participation work to not only influence this initial moment of creation but how they can permanently shift the dynamic of law-making more fundamentally.

[280] With the objective of creating a specialised patent jurisdiction and promote research, development and investment in innovation: EU Commission, 'Internal Market, Industry, Entrepreneurship, and SMEs: Unitary Patent' (*EU Commission*) <https://ec.europa.eu/growth/industry/strategy/intellectual-property/patent-protection-eu/unitary-patent_en>.

[281] Specifically in terms of patent validation but also more generally: Amanda Odell-West, 'Exclusions in Patent Law as an Indirect Form of Regulation for New Health Technologies in Europe' in Mark L Flear, Anne-Maree Farrell, Tamara K Hervey, and Thérèse Murphy (eds), *European Law and New Health* Technologies (OUP 2013) 152.

[282] On the complex role of the EPC in bringing together standards in patent law: Alexander Stack, *International Patent Law: Cooperation, Harmonization and an Institutional Analysis of WIPO and the WTO* (Edward Elgar 2011) 94.

Particularly for developing a GAL approach to patent law, the EPUE is actually only one aspect of the patent interface that is being created. The Unified Patent Court (UPC) Agreement creates an associated court structure to deal with the enforcement of the EPUE.[283] As such, the UPC is a particularly central consideration when analysing the values of European patent law because of its important role in dispute resolution within this new patent framework. The UPC also represents both the development of a specialised patent court in Europe and a broader, more global trend towards specialisation in intellectual property dispute resolution.[284] It is in this capacity as a specialised court that it will necessarily shape the trajectory of patent law in Europe as a network of courts and judges deal with the interpretation and application of EPUE (and EPUE-adjacent) sources of law.[285] The focus of the chapter is investigating a modern example of how legal interfaces are formed and sustained, the mechanisms that are used to facilitate interactions between different systems of law, and the extent to which these processes support or undermine the typical GAL values of transparency, accountability, and participation.

While the analysis of the chapter remains firmly grounded in the textual provisions of the UPC Agreement (UPCA) because it is yet to be implemented, the text of the agreement provides an initial starting point for the capability of the courts and its judges. The text considered here covers elements of both substantive patent law and more procedural mechanisms like compulsory licensing and *l'ordre public*. Precisely because the EPUE represents a step beyond the more limited centralisation of previous patent cooperation in Europe, the EPUE necessarily interacts with aspects of patent law that facilitate responsiveness like compulsory licensing and *l'ordre public* exceptions. Patent exceptions work to flexibly

[283] Agreement on a Unified Patent Court ("UPC Agreement").
[284] On the increasing global attention that specialised intellectual property courts have attracted: Olga Gurgula, Maciej Padamczyk, and Noam Shemtov, 'Specialised IP Judiciary: What are the Key Elements to Consider when Establishing or Reforming an Effective IP Court?' (2022) 71(3) GRUR International 206, 207.
[285] Such as the interpretation of the EPC and national law.

adapt patent law in a more responsive way, and so are necessarily part of a normative process of adaptation and reconstruction that occurs in a dispute resolution body. As such, the chapter investigates how the construction and application of these mechanisms work to impair or otherwise empower a European patent law that reflects accountability, participation, and transparency.

In this, the mechanisms of compulsory licensing and *l'ordre public* are discussed here primarily in terms of their capacity to be understood as tools to flexibly interpret binding obligations in patent law, as well as their impact within the EPUE system in specific technological contexts. The two disciplines that are considered here are pharmaceuticals and biotechnology, providing two additional complicating factors for understanding patent law as an interface because they are themselves subject to a broader set of legal provisions.[286] So while the discussion in this area is necessarily connected to the substantive treatment of these technologies within the patent system, the procedural emphasis here is presented as primarily in terms of how they provide further clarification as to their flexible quality within the EPUE.

Patent law provides an interesting context for understanding how dispute resolution bodies work to support or undermine certain values because, as with the classic critique of patent fragmentation in Europe,[287] the EPUE will actually coexist with several, already functioning, legal interfaces in European patent law. The result is that the EPUE, as an interface, not only involves negotiating the values and objectives of the Member States involved but the relationship *between* patent interfaces like the EPC and national patent systems through the UPC. This additional fracturing of patent law and its foundational elements in Europe

[286] One example would be the overlap in terms of subject matter for biotechnology inventions that the EPC provisions are specifically an element of: Estelle Derclaye and Matthias Leistner, *Intellectual Property Overlaps: A European Perspective* (Hart 2011) 98.
[287] On the costs of the fragmented patent enforcement system in Europe: Bruno van Pottelsberghe de la Potterie and Malwina Mejer, 'On the Consequences of a Highly Fragmented European Patent System' in Vivek Ghosal (ed), *Reforming Rules and Regulations: Laws, Institutions, and Implementation* (MIT Press 2011) 60.

necessarily impacts transparency and accountability. These two values in particular are implicated here because it is not only the creation of the EPUE interface that becomes somewhat disconnected from ordinary political control and the users of the patent system, but the evolution of this interface and its relational interactions become obscured by an unconventional legal form and general complexity.

This chapter is aimed primarily at investigating research questions 1 and 3 of the thesis, specifically looking at how interfaces in patent law are created and how elements of patent law can be used as tools to facilitate the interactions of different systems of law. Part 1 of the chapter considers the existing parallel interfaces in European patent law, while part 2 analyses the development and implementation of the EPUE. Part 2 specifically explores the legal impact of both the EPUE and the UPC in constituting a new legal interface for patent law and how the role of a specialised dispute settlement body is particularly important. Part 3 considers the interactions between the EPUE and specific technological contexts, focusing primarily on the relationship of *l'ordre public* exceptions and compulsory licensing to the values of participation and accountability.

2. Patent law in Europe: The existing interface(s)

2.1 *Coexisting mechanisms of patent protection*

2.1.1 The emphasis on territoriality

The enduring role of territoriality in patent law is a key aspect of the potential in harmonised initiatives, particularly in Europe, where the validity of a patent is tied to the

jurisdiction in which it was granted.[288] The tensions in territoriality are particularly pronounced in Europe because of the internal market, where patent law stands out against a market environment that prioritises integration and rejects the splitting or isolation of markets. The attempts at resolving this tension in patent law have consistently encountered political difficulty,[289] resulting in less ambitious projects that emphasise a sense of administrative centralisation over true substantive harmonisation that would incorporate enforcement. The EPUE, at least a theoretical level, is a way of addressing the negative aspects of a strictly territorial approach in Europe and meaningfully advancing the harmonisation of patent law. Though this is not to understate the significance of the administrative and broad harmonisation brought by the EPC. The ability for applicants to file a single application, despite how this then leads to a suite of national applications, was a major development for European patent law.[290]

Yet the impact of territoriality extends beyond the grant of a patent right and into its enforcement, where the judgment of the validity of a patent (rather than its validity alone) are strictly connected to the jurisdiction in which the decision was rendered. While this raises issues even at a global level, it is in a European context that it contrasts so sharply with the freedom of establishment and the internal market. Companies and goods flow easily, yet the patent protection of any products (and the licences held by assignees) is still very much nationally focused. The territorial emphasis takes on a particular character in Europe though because it reflects issues that are common to systems that deal with complex decentralised or federalist structures. The distinguishing factor between the EU and somewhere like the US is

[288] Volker Michael Jänich, 'The Territorial Dimension of Intellectual Property Law' in Karl M Meessen (ed), *Economic Law as an Economic Good: Its Rule Function and its Tool Function in the Competition of Systems* (Sellier 2009) 216, 217.

[289] Even with the more technical aspects of jurisdiction under the CPC, where a number of national courts would serve as courts of first instance, several members 'designated all their courts – obviously for political and federalist reasons – to have jurisdiction at the national level': Stefan Luginbuehl, *European Patent Law: Towards a Uniform Interpretation* (Edward Elgar 2011) 20.

[290] Tony Howard, 'The Legal Framework Surrounding Patents for Living Materials' in Johanna Gibson (ed), *Patenting Lives: Life Patents, Culture and Development* (Routledge 2008) 9.

that, in practice, the EU lacks a unifying forum for these disputes.[291] The creation of the Court of Appeals for the Federal Circuit (CAFC), in joining together the Court of Customs and Patent Appeals and the appellate division of the Court of Claims,[292] was specifically aimed at remedying the diverging approaches of different Circuit courts that were damaging the user experience of the patent system.[293] The lack of a unifying forum in the European context, specifically in enforcement, is an important part of what hampers any attempt at minimising the impact of territoriality and why the UPC is such an important development.

2.1.2 *National systems of patent protection*

Though Member States are broadly bound by the provisions of the TRIPS Agreement, they are generally free to develop their own approaches to elements of substantive patent law with 'considerable national autonomy over how to comply with the minimum standards'.[294] The emphasis on these national perspectives to patent law contrasts more generally with the strong trend towards harmonisation in Europe. Three primary outcomes of this national emphasis are considered here. These are the cost of applying to several jurisdictions for patent protection, the risk of divergent judgments in the event of a dispute, and how this positions the EU as a competitive patent jurisdiction in a global context. Turning first to the cost of applying to multiple jurisdictions within the EU, it is common practice for businesses to apply for patent

[291] Though the role of the CJEU and its involvement may increase with the introduction of the UPC as there will be a more direct patent basis for considering referred questions (though this is a complement to more traditional avenues such as competition law elements and the Biotech Directive): Clement Salung Petersen and Jens Schovsbo, 'Decision-making in the Unified Patent Court: Ensuring a Balanced Approach' in Christophe Geiger, Craig Allen Nard, and Xavier Seuba (eds), *Intellectual Property and the Judiciary* (Edward Elgar 2018) 231, 238.
[292] Through the Federal Courts Improvement Act 1982.
[293] On the conflicting interpretations of patent principles and the eventual introduction of the CAFC: Srividhya Ragavan, *Patent and Trade Disparities in Developing Countries* (OUP 2012) 22.
[294] Susy Frankel, 'The TRIPS Agreement and Cross-Retaliation' in Susy Frankel and Meredith Kolsky Lewis (eds), *Trade Agreements at the Crossroads* (Routledge 2014) 210.

protection in only a handful of jurisdictions rather than in *all* Member States.[295] Applicants are free to apply for patents with national patent offices, in a process that is more integrated with the national context and provides an important option for SMEs.[296] Because this type of application can be more appropriate for small businesses, this process will remain a significant part of patent law in Europe even as patent cooperation initiatives continue.[297]

Despite the economic sense of this for applicants, it results in a patent climate in which specific Member States (particularly Western European ones) are disproportionately influential in the overall trajectory of European patent law. While to an extent Europe still relies on these national systems of protection, there is a certain asymmetry as to which European jurisdictions are truly for the development of patent law in practice. Though this is discussed later in terms of the enhanced cooperation process, this type of asymmetry raises issues about the accountability and transparency of patent law in Europe. It is at this broader level that the lack of European harmonisation highlights how influential individual Member States will be in defining the values of a harmonised patent system. This necessarily frames the creation of a new patent interface because it raises questions around the degree to which this new framework will privilege or otherwise reflect the high patent activity jurisdictions and their legal systems. In a related sense, it questions the extent to which any patent harmonisation will be responsive to the needs of smaller jurisdictions, if at all. All of these elements raise important challenges

[295] Typically Germany, France, the UK, and the Netherlands: Dan L Burk, 'Patents and Related Rights: A Global Kaleidoscope' in Rochelle C Dreyfuss and Justine Pila (eds), *The Oxford Handbook of Intellectual Property Law* (OUP 2018) 462.

[296] One concern that emerged in McDonagh's interview work investigating the perception of the EPUE in the UK was that, because SMEs typically only patent in a small number of jurisdictions, the cost of renewal for an EPUE may be still too high: Luke McDonagh, 'Exploring Perspectives of the Unified Patent Court and Unitary Patent Within the Business and Legal Communities' (2014) UKIPO 32, 33 <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/328035/UPC_Study.pdf>.

[297] 'Patent applicants should remain free to obtain either a national patent, a European patent with unitary effect, a European patent taking effect in one or more of the Contracting States to the EPC, or a European patent with unitary effect validated in addition in one or more other Contracting States to the EPC which are not among the participating Member States': paragraph 26, Regulation 1257/2012.

about how responsive and accountable the EPUE will be in terms of patent stakeholders in Europe. Particularly in terms of accountability, the development of the EPUE and UPC practice presents a tension in where this accountability leads – something that is complicated by the fact that this project was led by the Member States themselves rather than a unified EU.

2.2 *The failed Community Patent Convention as a historical patent interface*

2.2.1 The early development of the Community Patent Convention

The Community Patent Convention (CPC) and the corresponding Community patent have a long history in Europe, emerging in discussions as far back as the 1950s.[298] Although it would have provided many of the benefits that the EPUE is intended to realise, the CPC provides an insight into the patent dynamic and broader institutional concerns involved in patent harmonisation. Exploring the process of negotiating a harmonised patent instrument is useful because it provides a historical example of how tension between different interfaces can emerge. This is because, for a long time, the development of the CPC was in parallel to that of the EPC.[299] The CPC would have created a singular patent right that would have, particularly in the European context of the 1970s, represented a significant improvement over the grant of individual national rights. The issue of language was a significant part of the CPC's development process, though it was a combination of a lack of political will and the complex issues of adjudicating these new Community-wide patent rights that ultimately led to its

[298] Discussing the early work of the Council of Europe's Committee of Experts on Patents in 1950 in exploring patent harmonization in Europe: Margaret Llewelyn and Mike Adcock, *European Plant Intellectual Property* (Hart 2006) 146.

[299] With the CPC intended to restore '…the territorial unity lost following the grant of a European patent…' Stefan Luginbuehl and Teodora Kandeva, 'The Role of the European Court of Justice in the European Patent Court System' in Christophe Geiger, Craig Allen Nard, and Xavier Seuba (eds), *Intellectual Property and the Judiciary* (Edward Elgar 2018) 208.

failure.[300] The CPC initially incorporated the same five-language regime that the EUIPO uses and placed a strong emphasis on the role of national courts.[301]

The CPC project eventually failed in the 1970s when only nine Member States signed it,[302] but it remains an important part in the history of European patent law because a draft text was actually produced and remains one of the only truly European attempts at patent harmonisation. Yet it is this completed draft that presents a particularly clear vision of participation and accountability in the design of patent law. The CPC, through its grounding in difficult negotiations and disagreements between Member States, provided at least in theory a more transparent sense of how patent law was developing in Europe. The CPC text presents a less obscured sense of accountability because it was produced through the broadest possible (at the time) political engagement between European members. The development and negotiation of the CPC very much occurred in the shadow of the EPC, from which the relationship between EU and non-EU sources of patent law has been characterised as a sort of 'rivalry.'[303] This kind of dynamic meant that the successful introduction of the EPC, both legally and in from the perspective of patent users in Europe, has been presented as having a

[300] Specifically, the cost involved with the language regime of the CPC was a prominent issue for patent users: Jan Willems, 'The EPLA Project and the Forthcoming Community Patent System – A Model for IP in General?' in Josef Drexl and Annette Kur (eds), *Intellectual Property and Private International Law: Heading for the Future* (Hart 2005) 91.

[301] Though political discussions eventually led to a regime incorporating 9 languages that was clearly unworkable: Vincenzo Scordamaglia, 'The Legal Framework of Legislative Activity Concerning Intellectual Property Rights at European Regional Level' in Christophe Geiger (ed), *Constructing European Intellectual Property: Achievements and New Perspectives* (Edward Elgar 2013) 66; Community Patent Convention 76/76/EEC, Article 14(1); Article 36(1)

[302] Following the signing of the 1975 of the Convention after the Luxembourg Conference by 9 Member States, constitutional challenges by Ireland and Denmark (specifically on the legal basis for conferring additional competences to the CJEU without reference to the EEC Treaty) led essentially to the failure of the project: Vincenzo Scordamaglia, 'The Legal Framework of the Legislative Activity Concerning Intellectual Property Rights at European Regional Level' in Christophe Geiger (ed), *Constructing European Intellectual Property: Achievements and New Perspectives* (2013) 65, 66.

[303] Catherine Seville, 'EU Intellectual Property: Exercises in Harmonization' in Anthony Arnull and Damian Chalmers (eds), *The Oxford Handbook of European Union Law* (OUP 2015) 691, 713.

negative impact on the likelihood of an EU-originated patent instrument.[304] The success of the EPC can be partially attributed to the fact it represents a more modest attempt at patent cooperation than the CPC, focusing on important elements of patent harmonisation but without dealing with the enforcement apparatus (though this produces the current system of individual, national patents).[305] Even in the CPC, the issue of litigation and patent enforcement was controversial and the EPC manages to avoid the enforcement tension while minimising the political significance of language choice within the EPO.

The 'rivalry' between EU and non-EU sources of law was apparent in the dynamic between the CPC and the EPC, though it actually frames much of the development in this area up until the creation of the EPUE. A distinct feature of this relationship is a continued effort at minimising the influence or direct oversight of EU law in patent disputes, which also appeared in the European Patent Litigation Agreement (EPLA). The EPLA proposed a supranational court that would deal with cross-border disputes,[306] though in what appears to be a foreshadowing of the disputes that emerged in the context of the EPUE and the UPC, the EPLA failed on two principal grounds that were related to the legitimacy of the court applying EU law and the language regime of the initiative.[307] The first concern was related to a specific aspect of EU law and a strict reading of Article 19 and Article 267 TFEU,[308] barring the court proposed in the EPLA from applying EU law directly.[309] Yet even this raises tensions for the accountability and responsiveness of patent law. As discussed previously in the context of GAL,

[304] Antonina Bakardjieva Engelbrekt, 'Dilemmas of Governance in Multilevel European Patent System' in Hans Henrik Lidgard (ed), *National Developments at the Intersection of IPR and Competition Law* (Bloomsbury 2011) 44.
[305] Arnaud Nuyts, *International Litigation in Intellectual Property and Information Technology* (Kluwer 2008) 15.
[306] The EPLA proposed an 'integrated judicial system' and common appeal court in 1998, though by 2003 the Working Part on Litigation had established that the EPLA would have a European Patent Court. Considered in paragraph 8, Opinion 1/09.
[307] Massimiliano Granieri, Andrea Renda, *Innovation Law and Policy in the European Union* (Springer 2012) 131.
[308] Article 19 TEU; Article 267 TFEU; paragraph 83, Opinion 1/09.
[309] Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2017) 48(3) IIC 257.

accountability to *whom* is an important consideration. If patent law is isolated from other areas of law and beyond generalist courts, does this result in a patent law that is responsive only to the concerns of technocrats? While patent stakeholders have their own concerns about the role of the CJEU in patent law that are discussed later, the alternative presents an equally concerning vision of a European patent system that becomes increasingly insular and emphasises the participatory value of a small number of high value patent jurisdictions.

2.2.2 EPUE as a successor to the Community Patent Convention

The legal difficulties of the CPC and the non-EU patent initiatives provide some solid examples as to where difficulties have emerged with the development of the EPUE. Two specific areas would be the emphasis on language and the difficulty in establishing a legitimate legal foundation that can operate within the EU legal system for adjudication and enforcement. The issue of language would appear to take on a less controversial tone in other (non-EU) international negotiation contexts,[310] and so represents one of the distinct challenges of legal cooperation in Europe. The difficulty with the EPUE as the next attempt at harmonising European patent law is that these older examples demonstrate that language and adjudication are complex core elements that have political, cultural, and legal dimensions to them that need to be addressed for effective patent harmonisation. The EPUE represents a less substantive engagement with these issues than could have been possible because of the use of enhanced cooperation. While the number of jurisdictions involved does include the majority of EU Member States, the reality is that these negotiations as to the design of the EPUE took place

[310] On the growth of English as a lingua franca (specifically in business contexts)– though considered here in a narrow Japanese example where interviewees distinguished between Japanese and non-Japanese business participants: Miyuki Takino, 'Bridging the Language Barrier in International Business: BELF and Multilingual Practices' in Mayu Konakahara and Keiko Tsuchiya (eds), *English as a Lingua Franca in Japan: Towards Multilingual Practices* (Palgrave 2020) 233, 234, 247.

outside the ordinary EU legislative process. As a result, the responsiveness of patent law in Europe to both its Member States and patent stakeholders remains impaired because they the participants were engaged in a negotiating context that does little to remedy asymmetries between them. The EPUE lacks the broad engagement and discussion that were found so visibly in the development of the CPC.

The CPC actually provides an important example for the EPUE because it demonstrates that, while these interfaces are essentially a form of narrow and technical cooperation, they are necessarily inflected by the unique political, political, and legal context of the EU. Even though the CPC failed, its legal foundation was clear and it would have provided a legally solid basis for harmonisation in patent law in Europe. For the CPC, the sources of law would be European, the negotiating process would have been difficult but thorough, and as a project, it would represent a commitment to the EU-wide legal progression. These elements all reflect a trajectory of European patent law that is transparent and responsive to the diversity of the EU Member States. The CPC also demonstrates the importance of political will in patent harmonisation, which considered in the context of the EPUE, has already turned out to be a significant challenge. This appeared not only in a patent specific sense as with the CPC and dealing with the issues of adjudication, but the current state of political relationships between EU Member States. Patent harmonisation remains a niche area, and yet the increasingly polarised relationships between Member States are central in the success of these niche technical projects.[311] Ensuring appropriate levels of participation and accountability in patent law and patent interfaces is not the result of a singular event. Instead, a truly responsive patent law that is transparent and accountable requires not only the political will to establish it, but

[311] One example would be the relationship between Hungary and the EU which is becoming increasingly fractured: Ramona Coman, *The Politics of the Rule of Law in the EU Polity: Actors, Tools and Challenges* (Palgrave 2022) 119, 272.

sufficient motivation to sustain and adjust it as it evolves in tandem with a sufficiently developed dispute resolution body.

Brexit was perhaps the clearest example of these tensions around political will, with the unprecedented move of an EU Member State leaving the EU.[312] Even during the transition period, the UK appeared to be politically committed to the EPUE project and hosting one part of the Central Division of the UPC (even though it would then subject British businesses with EPUEs to the jurisdiction of the CJEU).[313] The CPC demonstrated that even when the legislation originates within the formal EU legislative process, the negotiations take an extended period of time and a difficult process of reconciliation between the national and international spheres of autonomy. Yet it is precisely these commitments to difficult negotiations and complex compromise that highlight a sense of accountability and transparency that is not found in the EPUE. The capacity for Member States to either devote that level of political attention to an issue of patent law, or to even consider this additional layer of integration would be a difficult proposal in the current climate of the EU as it deals with several concurrent crises.[314] Yet this should not mean that these issues should be simply sidestepped. The CPC failed but it represented an EU that is united in dialogue and is committed to comprehensive integration for all Member States in patent law. The EPUE fails at both addressing the discrete issues that were critical in the failure of the CPC and the EPLA, whilst *also* failing at a more systemic level as a European patent interface that prioritises participation and accountability.

[312] At least an unprecedented modern example, cf. Algeria and Greenland in the 1960s and 1980s: Kiran Klaus Patel, 'Something New Under the Sun?: The Lessons of Algeria and Greenland' in Benjamin Martill and Uta Staiger (eds), *Brexit and Beyond: Rethinking the Futures of Europe* (UCL Press 2018) 120; Piet Eeckhout, 'The Emperor has no Clothes: Brexit and the UK Constitution' in Benjamin Martill and Uta Staiger (eds), *Brexit and Beyond: Rethinking the Futures of Europe* (UCL Press 2018) 166.
[313] UK Government, 'UK Ratifies the Unified Patent Court Agreement' (26 April 2018, *Gov.uk*) <https://www.gov.uk/government/news/uk-ratifies-the-unified-patent-court-agreement>.
[314] COVID-19 is one such example, though the invasion of Ukraine is interconnected with issues of security, energy, and refugees: European Council, 'EU Response to Russia's Invasion of Ukraine' (European Council 2022) <https://www.consilium.europa.eu/en/policies/eu-response-ukraine-invasion/>.

2.3 *The 'European' patent system*

2.3.1 The European Patent Convention

The European Patent Convention (EPC) is an important element of patent law in Europe because, despite not being an EU instrument, it essentially provides an international framework that provides for a substantial administrative and substantive harmonisation.[315] It is precisely because of this bringing together in standards that the actual impact of the EPUE would at first appear to be much more subtle. This is primarily because the EPC provides for both procedural and more substantive elements of a patent.[316] The EPC is an international convention that allows actors to submit a singular patent application to the EPO for any number of EPC signatories and provides a route towards patent protection that simplifies applications covering multiple jurisdictions.[317] Yet this process does not lead to the grant of a singular patent right, and here, the fundamental administrative character of patent law can be found. Instead, the grant of a European patent results in a patent that 'shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State…'.[318] So while the administrative centralisation of the initial filing of patent applications in Europe does meaningfully facilitate applications that cover multiple

[315] Alfredo Ilardi, *The New European Patent* (Hart 2015) 10; though the EPO itself states that 'the EPC has established a single European patent procedure for the grant of patents on the basis of a single application and created a uniform body of substantive patent law designed to provide easier, cheaper and stronger protection for inventios in the contracting states.': EPO, 'European Patent Guide: 2.2' (*EPO*) <https://www.epo.org/applying/european/Guide-for-applicants/html/e/ga_c2_2.html>.

[316] Like the subject matter exclusions of Article 52, EPC

[317] On discussion of the cost-saving of an EPO application (in some studies, more affordable when applying for more than 4 member countries) but also that the idea of international competition is skewed – more affordable costs in Japan or the US are not directly relevant because they cannot grant patents in Europe: Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (CUP 2010) 127, 128.

[318] Article 2, EPC.

jurisdictions, it also highlights the importance of how these substantive requirements of patent law can be interpreted in practice.

These mechanisms are essential in modulating the generalised nature of provisions in the overarching framework in a way that makes them more responsive to local needs. The EPC is interesting because the mechanisms that it provides operate in a different manner to either compulsory licensing or *l'ordre public* exceptions. The subject-matter exclusions of Article 52 can be seen as an interface mechanism that facilitates this type of interactive process, a static provision that has been extensively developed through interpretation and dispute. Though as a non-EU provision, this process of interpretation and development takes on a distinctive character to those produced in an ordinary legislative context. The development of Article 52 as flexibility comes from how the jurisprudence on Article 52 has predominantly developed through the Enlarged Board of Appeal (EBA) rather than through ordinary national courts.[319] Unlike compulsory licensing that provides a space for autonomous action by the parties, empowering the signatories to act, the subject-matter exclusions allow a specific type of actor to negotiate the meaning and impact of a binding obligation within international patent law. This necessarily raises issues about the accountability and transparency of the provisions themselves and their subsequent evolution when this process is divorced from conventional systems of accountability. This approach to flexibilities within a legal presents a context in which specialised administrative bodies, broadly shielded from general oversight, interpret and advance areas of international patent law. In this context, what options are there for stakeholders to challenge this type of progressive interpretation of patent provisions? From a more practical sense, this type of deep involvement by patent actors could perhaps reflect a

[319] The complex development of Article 52(3) through the Technical Board of Appeal and the Enlarged Board of Appeal in the context of computer programs: Sigrid Sterckx and Julian Cockbain, *Exclusions from Patentability: How Far Has the European Patent Office Eroded Boundaries?* (CUP 2012) 70.

development of a patent law that is more responsive to novel issues that users face because they directly observe how legal problems emerge.

The central role of the EBA also emphasises the influence of the European Patent Office (EPO) in the development of patent law at this broader level and how the provisions of the EPC are interpreted over time. Because the patent rights that are granted through this process are then subject to challenge in their own jurisdictions, the jurisprudence about patent law is still very much grounded in the national law environment. There is then a tension in the interface that the EPC creates. This is because while the general contours of the patent as a legal instrument are fairly settled, the actual adjudication of the patent takes place in a dispute settlement context that is more responsive to priorities in the embedded national legal context. Decisions taken by the national dispute settlement body lack the more general or foundational impact to patent law that can be found in decisions that are rendered by the EBA. The Patent Cooperation Treaty (PCT) is an important complement to the EPC, though it focuses entirely on simplifying the administrative burden of applying for patent protection in multiple jurisdictions.[320] The PCT essentially represents a more elaborate version of the administrative centralisation of the initial application in the EPC because the agreement provides for a standard form of patent application that still results in the grant of individual national patents.[321] After filing an application with a Receiving Office, the application is then assessed by competent International Authorities and communicated through WIPO then to the Designated Offices (which can national or regional patent offices).[322]

[320] Highlighted very explicitly in the preamble to the PCT as a project to '…perfect the legal protection of inventions' and '…simplify and render more economical the obtaining of protection for inventions where protection is sought in several countries': page 6, Patent Cooperation Treaty <https://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct.pdf>.
[321] Article 4, PCT.
[322] Article 16 (International Searching Authority); Article 20 (Communication to the Designated offices); Article 4(3) (that without contrary indication, the 'desired protection consists of the grant of a patent by or for the designated State').

The PCT creates what is essentially a weak or simple interface because it does not deal with any enforceable or actionable parts of substantive patent law and, perhaps as a result, does not provide for any tools to modulate the binding quality of its provisions. The provisions of the PCT rely on national authorities and national actors to such an extent that there is no need for explicit tools to modulate the PCT provisions because it happens as an inevitable part of the process anyway. This relates to one of the most significant weaknesses of the PCT system. While a singular application is convenient, it restricts applicants from providing tailored applications to each jurisdiction in a way that reflects customs or practice in each patent office.[323] The lack of more substantive harmonisation or integration in terms of the grant of the patent then undermines the administrative centralisation when it occurs at a global level because the output is still, and remains, framed by and *responsive to* national practice and interests.

3. The creation of a new patent interface in Europe

3.1 *Provisions of the 'Unitary Patent'*

3.1.1 Establishing the patent

The EPUE and the UPC are constituted by a set of three agreements that deal with the structure of the court, the creation of unitary patent protection, and an agreement that

[323] There is a critique of the PCT in respect of seeking national protection in certain jurisdictions. Because the PCT procedure requires a single specification that generally conforms with the administrative requirements, the '…PCT specification that has been homogenized in this manner does not necessarily ensure that the applicant can maximize patent protection in any particular country': Hideo Kodama and Jeffrey D Tekanic, 'Reducing the Costs of Obtaining and Maintaining Japanese Patents' (1999) 81 Journal of the Patent and Trademark Office Society 117, 125.

specifically deals with the translation arrangements. Regulation 1257/2012 establishes the EPUE as a legal instrument and highlights the important objectives in promoting harmonisation in European patent law.[324] Early in the text, the EPUE is presented as an important development in fostering scientific development and a way of improving the functioning of the internal market.[325] The EPUE is explicitly aimed at eliminating 'costs and complexity for undertakings throughout the Union' yet there is a tension between these broad objectives and the fundamentally compromised nature of the EPUE.[326] The compromised nature of the EPUE appears prominently in two contexts. The first is a more specific or narrow legal perspective as to the actual qualities of the patent and the second is how it relates to the proposed benefits of harmonising European patent law. While the Regulation highlights the role of the EPO in granting 'European' patents,[327] the EPUE Regulation does not actually deal with the grant of a unitary patent. Instead, it deals with an expansion of the territorial scope of a granted patent whereby the patent can only be limited, revoked, or transferred in all the participating states.[328] Licensing, however, retains a national focus and allows the patent to be licensed with regard to part of or entire territory of a participating Member State.[329] Compulsory licensing also retains this national focus and is governed by the provisions applicable in each Member State.[330] Taken together, this structure emphasises the administrative law character of the patent grant process by avoiding the direct grant of a unitary patent. Without the appropriate delegation of this power from the Member States themselves, the grant of a patent remains a national function that is exercised by specific agencies of the state.

[324] Paragraph 4, Regulation 1257/2012.
[325] Paragraph 4, Regulation 1257/2012.
[326] Paragraph 4, Regulation 1257/2012.
[327] Paragraph 5, Regulation 1257/2012.
[328] Article 3(2), Regulation 1257/2012.
[329] Paragraph 7, Regulation 1257/2012.
[330] Paragraph 10, Regulation 1257/2012.

One of the broader tensions in the development of the EPUE's objectives of harmonisation and the reality of the EPUE comes from the fact that the EPUE is intended, at least through a lengthy transition period,[331] to coexist with other forms of patent protection in Europe.[332] The text itself of the Regulation highlights four possible options for patent applicants – obtaining a national patent, an EPUE, a patent that results from the EPC, and an EPUE in addition to patents from signatories to the EPC who are not part of the EPUE.[333] Exhaustion, and particularly the role of the CJEU in the jurisprudence of this area,[334] is considered explicitly in the Regulation and ensures that despite these varying options for patent applicants, at least exhaustion remains harmonised. All of this raises issues of transparency and participation in patent law in Europe for stakeholders. Just in terms of the complexity of options for obtaining patent protection, these different systems remain isolated from any systemic challenges to patent law provisions. The overlapping nature of patent protection in Europe obscures accountability and weakens the link between stakeholder participation and effective challenges to the development of patent law because the system, in practice, is so diffuse.

The Regulation itself recognises the shifting scope of the EPUE territory in Article 17, establishing that the uniform protection of the EPUE shall only extend to those participating Member States that have implemented the UPC as the court with exclusive jurisdiction over EPUEs.[335] This shifting nature of the EPUE territory also affects the more administrative aspects of patent harmonisation like the development of an EPUE register established by Rule 16 of the Rules relating to Unitary Patent Protection.[336] In addition to the more ordinary aspects of patent ownership that must be entered into the register like the date of filing for unitary effect

[331] Article 6, Regulation 1260/2012.
[332] Paragraph 26, Regulation 1257/2012.
[333] Paragraph 26, Regulation 1257/2012.
[334] Paragraph 12, Regulation 1257/2012.
[335] Article 18 2 EPUE Regulation.
[336] Formally *Rules Relating to Regulation 1257/2012 and 1260/2012*, but EPO refers to it as 'rules relating to Unitary Patent protection'.

or the date of publication of the European patent,[337] the register should have both the date of effect of the unitary protection *and* the participating Member States in which the patent has unitary effect.[338] While this type of arrangement is a necessary consequence of developing a patent regime with lengthy transition periods, it reflect a system that fails to simplify the process of identifying both the scope and existence of patent rights in Europe. In complicating the European patent system and creating obstacles to quickly establishing the status of a patent, the EPUE creates significant challenges to accessibility. The lack of simplicity has the potential to impair stakeholders – patent holders and more generally – from being able to clearly and effectively understand the legal state of patent protection in their areas.

3.1.2 Creating the interface of the EPUE

The agreements that establish the EPUE are interesting because they rely extensively on existing sources of law, described as a 'hollow' piece of legislation because the EPUE is defined essentially in reference to other established legal sources like the EPC.[339] The use of enhanced cooperation instead of the ordinary legislative procedure of the EU is directly connected to one of the major controversies with the legal status of the EPUE because of its reliance on secondary, non-EU law. One result of this is that where the effect of the EPUE agreements centre on the acceptance of the 'transformation fiction' to explain how the EPUE functions.[340] The transformation fiction is intended to address existing EU principles of law and necessarily highlights the administrative foundation of patent law. The use of the transformation fiction is related to concerns over the *Meroni* doctrine that deals with improper

[337] Rule 16 (1)(a) and (c), Rules relating to Regulation 1257/2012 and 1260/2012.
[338] Rule 16 (1) (f) and (g), Rules relating to Regulation 1257/2012 and 1260/2012.
[339] Winfried Tilmann, 'Recitals' in Winfried Tilmann and Clemens Plassmann (eds) *Unified Patent Protection in Europe: A Commentary* (OUP 2018) 83.
[340] Angelos Dimopoulos, 'An Institutional Perspective II: The Role of the CJEU in the Unitary (EU) Patent System' in Justine Pila and Christopher Wadlow (eds) *The Unitary EU Patent System* (Bloomsbury 2015) 58.

delegation of administrative or regulatory powers.[341] As a result, the legal framework characterises the EPUE as a patent granted according to the existing EPC procedure that, through the sole and exclusive operation of EU law, is then given territorially unitary effect.[342] In avoiding the *Meroni* doctrine, the EPUE confirms that the grant of a patent is an administrative function and relies fundamentally on an exercise state power. While the process may not lead to direct judicial review in the classic administrative sense, provisions that restrict patentable subject matter or the patent term are necessarily constraints on the exercise of a delegated state power. The legal character of the EPUE seems almost minimised or side-lined when referred to as just a 'unitary patent' because it is distinctly *not* the grant of a unitary patent. The EPUE simply involves expanding the applicable territory of an EPC patent rather than establishing a new right in itself to specifically avoid the grant of an EU patent.

The Regulation also provides a degree of institutional entanglement that extends beyond the legislative provisions and into the substantive content of the patent. Article 14, in particular, establishes a strong relationship between the Commission and the EPO on the EPUE.[343] While Article 14 highlights the importance of cooperation on how the agreement functions, there is an economic focus to the text that presents the issue of renewal fees for the EPUE and how this impacts the budget of the EPO.[344] This type of coordinating function of the Commission extends to Article 16 because it provides for periodic reporting about the functioning of the Regulation to the European Parliament and Council.[345] Interestingly, renewal fees appear also in Article 16 with a particular emphasis on compliance with Article 12,[346] suggesting that the issue of fees will be a prominent part of the regular reporting to the

[341] C-9/56, C-10/56 *Meroni v High Authority* [1957/1957].
[342] Regulation (EU) No. 1257/2012 of the European Parliament and of the Council (2012) 1(7).
[343] Article 14, Regulation 1257/2012.
[344] Article 14, Regulation 1257/2012.
[345] Article 16, Regulation 1257/2012.
[346] Article 16(2), Regulation 1257/2012.

European Parliament. These elements do promote a degree of transparency and accountability in the EPUE system, though the economic focus could suggest that the system will only be particularly responsive to a narrow set of issues or concerns from stakeholders.

Chapter V of the UPC Agreement establishes the sources of law for the adjudication of the EPUE and forms a central part of the new patent interface.[347] The outlining of the applicable sources of substantive law are necessarily framed by the sections that immediately precede it, which emphasise the primacy of EU law and establish a system in which the Contracting Member States are jointly and severally liable for damages that result from breaches of EU law by the Court of Appeal.[348] Article 24 presents a clear set of legal sources that starts with EU law (but specifically highlighting Regulations 1257/2012 and 1260/2012), the UPC Agreement, the EPC, other international agreements applicable to patent law, and finally, national law.[349] Subsection (2) of Article 24 explores more substantially the role of national law and again establishes what could essentially be seen as a hierarchy of applicable law.[350] The extent to which national law shall form the basis of decisions of the UPC can be decided from a set of related sources: the directly applicable EU rules on private international law;[351] international provisions that have international law rules;[352] and in the absence of either of those, the national provisions on private international law as decided by the UPC.[353] None of these provisions provide either a strong transparency as to the precise relationship between the different sources of law, nor the basis for challenging how these relationships are applied in specific disputes.

[347] Chapter V (Articles 24–30), UPC Agreement.
[348] Specifically grounding the non-contractual liability of Member States for damage caused by national courts that breach Union law: Article 22, UPC Agreement.
[349] Article 24 (1) (a)-(e), UPC Agreement.
[350] Article 24 (2), UPC Agreement.
[351] 24 (2) (a), UPC Agreement.
[352] 24 (2) (b), UPC Agreement.
[353] 24(2) (c), UPC Agreement.

So while the EPUE does not necessarily provide the harmonised application of patent law that was imagined under the failed CPC, it succeeds as a basic interface for European patent law. It succeeds in bringing together these different sources of law with at least some periodic reporting to the European Parliament, and establishes a hierarchy of applicable law that, while not providing complete detail, does present a basic or fundamental understanding. Crucially for the EPUE as an interface, the bringing together of these different sources of law is backed by a court system and means that the interactions will be shaped (and enforced) at the international level rather than the national level. One area of tension that emerges in what is clearly a hierarchy of sources in the UPC provisions is between the strong international emphasis (of EU law and primacy) and the more contextual mechanisms within patent law that make binding obligations more responsive to local (here, national) conditions.

The transition period that is provided for in the UPC Agreement impacts not only the development of the EPUE and its patent harmonisation in Europe, but meaningfully shapes how successful the EPUE is in bringing together this diverse set of legal sources in an organised and transparent way. The transition period has two main elements, a combination of a general seven-year transition period of the UPC's exclusive jurisdiction and the ability for patent owners to opt-out their patents from UPC jurisdiction.[354] The seven-year transition period is provided for in Article 83(1) and allow owners of a European patent to bring their actions for revocation or infringement before national courts or other competent national bodies.[355] The opt-out provisions covered in subsection 3 of the same Article provide for the general ability of patent owners to opt-out from the exclusive jurisdiction of the UPC,[356] as long as the patent

[354] Article 83, UPC Agreement.
[355] Article 83 (1), UPC Agreement.
[356] Article 83(3), UPC Agreement.

or supplementary certificate was applied for before the end of the transition period and an action has not already been brought before the UPC.[357]

The emphasis on autonomy for patent owners and the transition period more broadly means that the EPUE, in bringing together these sources of law within the same interface, will involve a very long-term project of gradual harmonisation. The objectives of the EPUE were explicitly to deal with the harmonisation of European patent law and reduce fragmentation, yet it will be a considerable time before this will be realised even if the EPUE and UPC are successfully introduced. Article 83 provides for a 'broad consultation' by the Administrative Committee of the users of the patent system, as well as investigating the number of patents or supplementary certificates that are still processed by national authorities.[358] The transition period can, based on the results of this consultation, be extended a further seven years and represents an important element of responsiveness in the EPUE system.[359] The interface that the EPUE creates, particularly with the UPC as a crucial element in ensuring the interface is workable, provides some unique challenges to participation and transparency because the results are not immediate. While the relevant provisions establish hierarchies of law and the jurisdiction of the court, the reality is that the true impact of bringing together patent law at this more truly European level will be developed more completely through the long-term interactions of the UPC, Member States, and the CJEU.

3.2 *Legal challenges*

[357] Article 83 (3), UPC Agreement.
[358] Article 84(5), UPC Agreement.
[359] Article 84)5), UPC Agreement.

3.2.1 Legal basis of enhanced cooperation

Understanding how enhanced cooperation functions and how it was used to produce the EPUE is important from the perspective of administrative values because it challenges, quite profoundly, the degree to which participation and accountability are meaningfully represented. The use of enhanced cooperation was the subject of several legal challenges, where the first major developments occurred in the joined cases of Spain and Italy that suggested the legal basis for enhanced cooperation were not satisfied.[360] Beyond the actual substance of the decision that authorised enhanced cooperation, the gap of only 8 months between the language proposals put forward by the Commission and the authorisation of enhanced cooperation attracted particular attention given that enhanced cooperation is explicitly constructed as a 'last resort'.[361] In fairness, while there was only a short period between these two events, it is not perhaps as radical as it would first appear. The similarities between the EPUE and the CPC, specifically on the issue of language and how controversial it is, at least gives some context as to how this negotiating impasse could be perceived as critical enough to allow for enhanced cooperation. Yet this short period between the proposals and the enhanced cooperation authorisation foreclosed the ability for the Member States to negotiate the issues more comprehensively. As suggested earlier, language is a complex issue that involves culture, law, and politics while patent law has become increasingly considered in terms of its narrow economic potential. Both of these factors suggest that negotiations would obviously be extended and difficult but would correspondingly reflect a more engaged, reflective, and accountable construction of European patent law.

Beyond the specific criticism that focuses on the degree to which the EPUE meets the criteria for enhanced cooperation, there has been some opposition to the use of enhanced

[360] 2011/167/EU Council Decision of 10 March 2011.
[361] Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2017) 48(3) IIC 259.

cooperation more generally.[362] The relationship of enhanced cooperation to Article 118 TFEU has also resulted in specific criticism, connecting intellectual property policy and the creation of centralised Union intellectual property rights with the internal market.[363] The CJEU in *Joined Cases C-274/11 and C-295/11* ruled that the authorisation of enhanced cooperation in pursuit of a patent right is legitimate because Article 118 empowers the creation of a system of uniform protection.[364] From this, and with the EPUE being created through enhanced cooperation, it creates a system of uniform protection in the participating states and binds only the participating states.[365] Italy had argued that because Article 118 refers to EU institutions establishing European intellectual property rights and the setting up of centralised 'Union-wide' initiatives in supervision and coordination,[366] the Council had actually authorised the creation of a right which is not valid throughout the Union.[367] The parties also argued more generally under Article 326 that the internal market and social cohesion would be damaged by the creation of the EPUE through enhanced cooperation.[368]

The approach of the court has been criticised as overly formalistic and narrow,[369] but it demonstrates that there is clearly a priority on the progress of harmonisation in European patent law. Specifically on the relationship between Treaties, AG Villalón produced an opinion in Case C-414/11 that dealt with a specific understanding of intellectual property competence post-Lisbon.[370] The Member States in that case argued that Lisbon did not in fact change the legal status of intellectual property rights in Europe as a shared competence.[371] These

[362] David Medina, 'How the Unitary Patent Will Fragment European Patent Law' (2015) 47 Arizona State Law Journal 342.
[363] Article 118, TEU.
[364] Paragraphs 66–68, Joined Cases C-274/11 and C-295/11.
[365] ibid.
[366] Paragraph 64, ibid.
[367] ibid.
[368] Paragraphs 70–74, 75–78, ibid.
[369] Joseph Kenneth Yarsky, 'Hastening Harmonisation in EU Patent Law Through a Preliminary Reference Power' (2017) 40(1) Boston College International and Comparative Law Review 176.
[370] Paragraph 44, C414/11 Opinion of Advocate General Cruz Villalón.
[371] ibid.

arguments centred on an understanding that intellectual property rights form part of the internal market under Article 4(2)(a), the more or less harmonised nature of intellectual property under Article 114, and the broader reach of Article 118.[372] Considering patent law from this more contextual perspective highlights that the difficulties within the EPUE regime of clearly establishing the interplay of different legal sources are much broader than they would first appear. In the legal challenges to the EPUE, the arguments that were raised by the parties involved reflect a deep tension in European law-making around the relationship between the Member States and EU. Given the increasingly economic framing of patent law, it is perhaps not surprising that the discussions – particularly on competence – are framed by the central importance of the internal market. The challenge to effective participation raised by the parties in the context of patent law can then be seen as reflections of more fundamental questions around competence and the evolving relationship between the EU and Member States.

The Commission in that case disagreed because it argued that, through the operation of the TRIPS Agreement and the similar wording between EU and WTO texts, that intellectual property formed a substantial part of the common commercial policy and therefore formed an exclusive competence of the Union.[373] AG Villalón suggests that both the Member States *and* the Commission are correct regarding the status of intellectual property in Europe,[374] but specifically that the Commission is correct in the necessity for consistency in the commercial aspects of intellectual property and also that intellectual property is a shared competence and must remain so.[375] Though this issue is complex and understanding it necessarily has to go beyond one-sided conclusions, the practical impact of these opinions undermine effective clarity and transparency. Suggesting that both the Commission and the Member States were

[372] Paragraph 44, C414/11 Opinion of Advocate General Cruz Villalón.
[373] Paragraph 43 (outlining the argument of the European Commission as to the validity of case-law relevant to establishing exclusive or shared competence), C414/11.
[374] Paragraph 55, C414/11 Opinion of Advocate General Cruz Villalón.
[375] Paragraph 59, ibid.

correct in their construction of patent law may reflect the nuances of the discussion, it does little to address the concerns of how European patent law will develop in the future.

3.2.2 The language regime

The second set of issues that were raised in the legal challenges to the EPUE by Italy and Spain were focused on the use of three official languages.[376] Here, they argued that the use of English, German, and French in the EPUE was discriminatory.[377] In these proceedings, Spain and Italy put forward the five language regime that is used by the EUIPO.[378] The return of a five-language regime reflects the early proposals of the CPC and highlights the complex process of reconciling the cultural and legal diversity of Europe with the type of linguistic diversity that is costly and unwieldy for patent users. The disputes around the language regime speak to the complex nature of patent law as an interdisciplinary subject, where the economic function of the patent needs to be balanced against a more nuanced construction of responsiveness. This appears prominently here because of the general use of five languages in European intellectual property. While it would have been only a small modification to the provisions to more proactively incorporate two important patent jurisdictions in the EPUE, it would have presented an image of European patent law as responsive to both economic and non-economic elements of patent law.

With the CJEU endorsing this language regime and the fact that this is occurring within the framing of an enhanced cooperation project, it communicates something about the priorities

[376] C-274/11 *Kingdom of Spain v Council of the European Union*; C-295/11 *Italy v Council of the European Union*.
[377] Regulation 1260/2012 clarifies that language regime should build on that of the EPO as the body responsible for the grant of the patent (paragraphs 5 and 6) and therefore the official languages of the EPO are the official languages of the EPUE: Article 14(1) EPC; C-274/11 *Kingdom of Spain v Council of the European Union*; C-295/11 *Italy v Council of the European Union*.
[378] paragraphs 10–15, ibid.

of the institutions involved. Rather than a project of patent harmonisation that presents measured and sustainable development at an EU-wide level, the EPUE demonstrates clearly that the interests of major patent jurisdictions in Western Europe were crucial drivers of the project. This raises significant issues in terms of participation and accountability in the development of patent law. While these jurisdictions may be the most active areas and logically should drive (and benefit) from harmonisation, it still takes place within the EU and some weight should be given to the active incorporation of all Member States. The timing of the EPUE and the intensely political nature of language disputes are particularly interesting when seen in the context of Brexit.[379] While it is not to suggest that the CJEU would have arrived at a different conclusion if the intended language regime was to exclude English, there is certainly something different about the character of the dispute when it permits the exclusion of languages that are clearly perceived to be less economically central to patent law.

The impact of permitting a language regime that proceeds with three choices presents an implied hierarchy of languages in European patent law. It is important to recognise, however, that language regimes are not always this contentious. The language regime of the EPO has been German, French, and English since its inception and has generally avoided any controversy for this structure. The fact that these issues have emerged in the context of the EPUE then suggest that there is something materially different in how the relationship between Member States, the EU, and patent law is now constructed. If the objective was to provide a competitive patent framework from an international perspective, academics have suggested that choosing English as the sole language would have been altogether less controversial.[380]

[379] Arguing that the language disputes could have been raised in relation to any EU Member State, Steve Peers, 'The Constitutional Implications of the EU Patent' (2011) 9(1) ECLR 251; arguing that only English should be used in the EPUE to minimise any potential discrimination: Ceyhun Necati Pehlivan, 'The Creation of a Single European Patent System: From Dream to (Almost) Reality' (2012) 34(7) EIPR 458.

[380] 'In a globalized world and a highly-integrated Union, in light of the increasing intermingling of languages, in spite of the legitimate interests of protecting Europe's individual regions and cultures, the time has come in which at least the economic and commercial sector should be run in a single language: English.' Christoph M

There is something about the exclusion of Italian and Spanish that stands out as something that would not happen to English or French. The EPUE regime could have been designed around French and German and legitimately, like with Spanish and Italian, excluded English. Yet there is clearly something – politically, legally – that suggests that the CJEU would not have endorsed a regime that excluded English. Taken together, the tensions here demonstrate that responsiveness and participation in patent law, particularly in a European context, is complex and extends far beyond narrow (economic) perspectives.

3.3 *Exploring the institutions of the interface: The Unified Patent Court*

3.3.1 Establishing the court

The precise structure of the UPC changed throughout its drafting history, with the UPC as currently understood representing a more moderate proposal for a specialised court that is firmly within the EU court system and subject to oversight by the CJEU.[381] The early drafts of the UPC was more radical in that it was intended to form its own closed system that was an attempt at removing the CJEU jurisdiction in patent issues.[382] Given that one of the explicit motives for introducing a specialised court for patent law was increased efficiency,[383] concerns over CJEU jurisdiction were understandable. Concerns over the CJEU's timeline for cases and case backlog appeared as motivation for trying to exclude or minimising its oversight.[384] The

Sielmann, *Governing Difference: Internal and External Differentiation in European Union Law* (Nomos 2019) 91.

[381] Agreement on Unified Patent Court (2013/C 175/01).

[382] Alfredo Ilardi, *The New European Patent* (Bloomsbury 2015) 80.

[383] Luke McDonagh, European Patent Litigation in the Shadow of the Unified Patent Court (Edward Elgar 2016) 167.

[384] Though noting that this is no longer the case, with EU courts making serious progress with the backlog and that expansions between 2015-19 should permanently address this: Nigel Foster, *EU Law Directions* (OUP 2018) 67.

court structure and its functioning are core elements in realising the more efficient patent climate that the EPUE was intended to create,[385] specifically connected to the current difficulties that characterise European cross-border patent litigation with the delays from torpedo litigation and *lis pendens*.[386]

The UPC Agreement was modified after *Opinion 1/09* to include the CJEU as the terminal court of appeal for matters arising under the EPUE.[387] The extensive reliance on non-EU law in the EPUE agreements did, however, raise concerns about the role (and legitimacy) of the CJEU as a final court of appeal.[388] This was reflected specifically in the issue of how the CJEU would interpret the primacy of EU law,[389] especially as the EU is a party to the EPC which is then incorporated through the EPUE agreements.[390] The UPC, for the patents that it has jurisdiction over,[391] will decide on the validity and infringement of EPUEs in respect of the entire territory covered by the enhanced cooperation participants.[392] There are two issues with the jurisdiction of the UPC, though both are related to the boundaries of the UPC and how this positions the court moving forward. The issue of jurisdiction is important because the EPUE includes a transition period of seven years,[393] with an option to extend this for an

[385] Luke McDonagh, European Patent Litigation in the Shadow of the Unified Patent Court (Edward Elgar 2016) 167.
[386] Defining *lis pendens* and the impact: Stefan Luginbuehl, *European Patent Law: Towards a Uniform Interpretation* (Edward Elgar 2011) 48; defining torpedo litigation and its broader impact: Marketa Trimble, *Global Patents: Limits of Transnational Enforcement* (OUP 2012) 55.
[387] Paragraph 66, Opinion 1/09.
[388] Joseph Kenneth Yarsky, 'Hastening Harmonisation in EU Patent Law Through a Preliminary Reference Power' (2017) 40(1) Boston College International and Comparative Law Review 180.
[389] Though concerns about the CJEU and primacy of EU law are present outside of intellectual property, Diana-Urania Galetta, *Procedural Autonomy of EU Member States: Paradise Lost? A Study on the "Functionalised Procedural Competence" of EU Member States* (Springer 2010) 75.
[390] Winfried Tilmann, 'Article 21' in Winfried Tilmann and Clemens Plassmann (eds) *Unified Patent Protection in Europe: A Commentary* (OUP 2018) 455.
[391] While the jurisdiction will eventually be expansive, the opt-out potential and the transition period impacts this: Article 3 (scope of application) and Article 83 (transitional regime) UPC Agreement.
[392] 'Consequently, a European patent with unitary effect should only be limited, transferred or revoked, or lapse, in respect of all the participating Member States.' Regulation No. 1257/2012.
[393] Transitional period for up to seven years, with potential extension of additional seven. Article 83, Agreement on Unified Patent Court (2013/C 175/01).

additional seven,[394] and has raised concerns about potentially relegating the UPC to the periphery as an optional court with shared jurisdiction throughout this (potentially extensive) transition period.[395]

The transition period is an important opportunity to strengthen the standing and legitimacy of the UPC in the long-term. This is because it can demonstrate the competence and effectiveness of the decentralised structure and build precedent, but also in more concrete legal terms through the preliminary reference system and further promote harmonisation in EU patent law.[396] For harmonisation specifically, the transition period is an opportunity for the UPC to present itself as a stable forum to ensure its success post-transition period and to generate user trust in its (almost) pan-EU jurisdiction. Yet this question of legitimacy, effectiveness, or responsiveness to users of the patent system is not necessarily an issue unique to the UPC – these are problems that would seem common to any newly introduced court, specialised or otherwise.

There are some limitations to the use of preliminary references to promote harmonisation through the UPC, though again, these are also not exclusive to the UPC and appear in other intellectual property contexts.[397] Some examples of these concerns are that the clarification and certainty in law is essentially random,[398] the clarifications are limited to specific and narrow areas,[399] and that preliminary references involve a lengthy process.[400]

[394] Article 83, Agreement on Unified Patent Court (2013/C 175/01).
[395] Nicholas Fox, 'Brevets Sans Frontières: How Much Litigation Will Actually Take Place in the Unified Patent Court?' (2018) 40(2) EIPR 86.
[396] On the general use of the preliminary reference procedure to gradually clarify specific areas of law, Folkert G Wilman, 'A Decade of Private Enforcement of Intellectual Property Rights under IPR Enforcement Directive 2004/48: Where Do We Stand? (And Where Might We Go?) 42(4) ELR 530.
[397] Morten P Broberg and Niels Fenger, *Preliminary References to the European Court of Justice* (OUP 2010) 185.
[398] Fabrizio Vismara, 'The Role of the Court of Justice of the European Communities in the Interpretation of Multilingual Texts' in Barbara Pozzo and Valentina Jacometti (eds) *Multilingualism and the Harmonisation of European Law* (Kluwer 2006) 63.
[399] ibid.
[400] Interviews with Italian practitioners highlighted the broad concerns around speed: Stefania Bariatti, Ilaria Viarengo, Francesca C Villata, Sara Bernasconi, Filippo Marchetti, 'Cross-Border Litigation Pattern - Empirical

Specific to the UPC, however, is that the preliminary reference system would necessarily be informed by the more technology-specific dimensions of the EPUE (and the transition period more broadly). Here, the receptiveness of industry (or lack of receptiveness) to the untested patent environment would mean that preliminary references would likely only appear well outside this transition period and could not form part of the early competence/legitimacy building of the UPC.[401] This also informs how much litigation the UPC system will actually see in this transition period. At least initially, the actual amount of litigation in UPC has been questioned in academic work.[402] This has generally been linked with how responsive it is to both industry-specific factors and the fact that national patents will initially not form part of the UPC jurisdiction.[403]

So at least during the transition period, the apparently broad jurisdiction of the UPC will, in practice, be quite limited.[404] The limited activities of the UPC, particularly with the coexisting national and international methods of patent protection, mean that the UPC has an important period of reflection during which any issues can be addressed. Though issues would remain about which stakeholders would be central in this process of reflection and how this impacts effective participation, the transition period does provide a space for developing an emerging institutional identity. From this, the UPC has time to further develop its relationships to other institutions and sources of law in a patent context. The scale of the EPUE means that while the transition period is an important opportunity for establishing legitimacy and effective participation, there are several elements of the UPC and EPUE structure that suggest the

Data and Analysis' in Paul Beaumont, Mihail Danov, Katarina Trimmings, and Burcu Yüksel (eds) *Cross-Border Litigation in Europe* (Bloomsbury 2017) 182.

[401] Nicholas Fox, 'Brevets Sans Frontières: How Much Litigation Will Actually Take Place in the Unified Patent Court?' (2018) 40(2) EIPR 85.

[402] ibid.

[403] ibid.

[404] Nicholas Fox, 'Brevets Sans Frontières: How Much Litigation Will Actually Take Place in the Unified Patent Court?' (2018) 40(2) EIPR 85.

potential for review during the transition period will be severely limited and may be primarily related to the permeable territorial scope of the EPUE.

3.3.2 Developing the institutional identity of the court

One of the major shortcomings in the UPC system is the role of ambitious timeframes for decisions, translations, and appeals – though they do, on the surface, appear to be an important part in trying to address the delays and inefficiencies that have typically characterised European patent litigation. The guidelines are generally considered to be roughly equivalent with existing systems in the EU,[405] though there are some unique institutional features of the UPC that mean these timescales take on a particular character within the soft law dimension of the specialised court. These time limits are important because they will shape the early litigation challenges, and subsequently, the identity of the UPC in demonstrating both the efficiency and effectiveness in their decisions. Though this, again, will also take on a disciplinary-specific dimension and provide an opportunity to create a broadly effective (and European) response to the threat of non-practicing entities and convincing other industries that the court can competently deal with high-value patent issues.[406] The development of a robust institutional identity is also related to the legal foundation of the UPC, where Jaeger argues that the stability could be further advanced by either modifying Article 257 TFEU to explicitly include international courts or by introducing a new subsection to the same effect.[407] This would have the immediate effect of legitimising the legal foundation of the court,[408] but it would also recast the harmonisation that the UPC brings. This consolidates the foundation of

[405] Nicholas Fox, 'Brevets Sans Frontières: How Much Litigation Will Actually Take Place in the Unified Patent Court?' (2018) 40(2) EIPR 89.
[406] Specifically on the potential issue of non-practicing entities (NPEs): Daniel Krauspenhaar, *Liability Rules in Patent Law: A Legal and Economic Analysis* (Springer 2014) 84.
[407] Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2017) 48(3) IIC 280.
[408] ibid.

the court in a way that reflects positively on its decisions – and specifically the precedent it generates – by rejecting the legal fiction of transformation,[409] and instead founding the UPC on a legitimate basis of EU law.

There has also been an attempt to construct the UPC as a more conventional European court in the style of the Benelux courts, as a common court with a joint court of appeals that could be considered to have sufficient national ties to establish it as a legitimate court structure.[410] Equating the UPC with the Benelux court, despite their significant differences discussed in academic commentary,[411] then appears as an attempt to rescue the legitimacy of the court. As it stands, the UPC seems to highlight the priority in establishing a European patent court and presenting the image of a harmonised patent over ensuring a robust and thorough legal process and foundation.

One of the more abstract shortcomings of the UPC comes from the tensions in its institutional structure and the difficulties of harmonising substantive patent law within Europe. This becomes particularly evident as it involves the negotiation of the relationship between this new interface and the more general push towards harmonisation. While there are provisions to ensure that there are a variety of judges that hear cases throughout the UPC structure,[412] this necessarily entails a variable set of perspectives on issues of patent law on an essentially ad hoc basis. The judges hearing cases within the UPC are expected to apply, somehow consistently across the effective territory of the EPUE, a mixture of national and international law with no transparent indications as to how this would be achieved. Perhaps more concerning is that this precise mix of national and international law could not be known to the users of the

[409] Paragraph 66, Opinion 1/09.
[410] Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2017) 48(3) IIC 281.
[411] 'The legal construction of the UPC according to the UPCA in its final form follows the legal construction of the Benelux Court': Andreas von Falck and Stephan Dorn, 'Article 34' in Clemens Plassman and Winfried Tilmann (eds), *Unified Patent Protection in Europe: A Commentary* (OUP 2018) 677.
[412] Article 15, UPC Agreement.

patent system before the legal proceedings take place. Relying extensively on sources of law outside of an agreement is not a significant problem per se, but it does appear more contentious when this extensive referencing is combined with the unusual legal foundation of the EPUE, the difficulties in ensuring consistency throughout a changing territory,[413] and the inevitable difficulties that will face the CJEU in appeals. A primary law basis, despite how difficult this would have been in negotiations, would have at least addressed these questions of legal certainty even they would have delayed the implementation of a true EU patent even further. The CJEU will eventually be called upon to interpret the Agreement (both the UPC and the EPUE), raising difficult questions about the priority (and however this is eventually reflected in actual UPC practice) of sources of law within the Agreement and the need to preserve the primacy of EU law.[414] Underlying this complexity are serious concerns about the consistency of UPC jurisprudence and the transparency of how each court will construct the specific relationship between different spheres of law.

The tension here is that either outcome – whether the judges succeed in applying a specific mix of patent law appropriately and create a functioning harmonised enforcement process or fail and thus further fragment patent law in Europe – has a negative aspect to it. The impact of further fragmentation, specifically within a forum intended to address fragmentation, would have a clearly negative impact. Yet there is also the 'flattening' effect of a successful harmonisation that is perhaps just as concerning. Imagining a successful harmonisation of law through the EPUE and the UPC could suggest a concretisation of patent norms at the international level that becomes unresponsive to the diversity of EU Member States and their patent environments. This dynamic mirrors the discussions that emerged around international human rights law where accepted treaties have the potential to solidify norms and reduce the

[413] Highlighted specifically in the definitions provided in the text that the coverage is those Participating Member States that have ratified the agreements at the time of grant: Article 2(a), Regulation 1257/2012
[414] Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2017) 48(3) IIC 261.

flexibility of states.[415] A further distinction between this settling of norms in human rights at the international level and patent law also appears in terms of legal status.

The concern here is that the more resources that are put into addressing any potential fragmentation with the EPUE and the UPC, the resulting patent system moves further away from what could have been a true successor to the Community patent. Europe could have developed a system that would not have been founded on a process that marginalises Member States and privileges a handful, to instead encourage a more responsive and long-term development of European patent law rather than an 'emergency patchwork'.[416] This type of tension in the long-term development of European patent law reflects some more conventional discussions around the capture of courts by repeat players.[417] There needs to be a balance between the accessibility of the court and the risk that it becomes used predominantly by a specific type of patent actor located in specific Member States. Yet the retained element of national law in the EPUE presents a more complex dimension to this dynamic. Because the national law of the patent is an essential part of EPUE adjudication, the actors that make use of the UPC will be an important factor in how the jurisprudence of the UPC develops and will incorporate many of the same problematic elements inherent to the preliminary reference system.

This creates something of a dissonance between the objectives of the EPUE in harmonising and simplifying European patent law with a system that encourages broad participation. This is because it would enable distinctions in the applicable national law based

[415] Laurence R Helfer, 'Intellectual Property and Human Rights: Mapping an Evolving and Contested Relationship' in Rochelle C Dreyfuss and Justine Pila (eds) *The Oxford Handbook of Intellectual Property Law* (OUP 2018) 142.
[416] Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2017) 48(3) IIC 284.
[417] That in patent law 'repeat players and larger firms have certain advantages in managing IP enforcement costs' that are related to portfolio size and even their *reputation* as repeat players: Ben Depoorter, 'Intellectual Property Enforcement Costs' in Ben Depoorter and Peter S Menell (eds), *Research Handbook on the Economics of Intellectual Property Law* (Vol 1, Edward Elgar 2019) 412.

on the nationality of the actor, presenting a small risk that only the largest jurisdictions (with repeat players) will drive the understanding of national law in the EPUE through their participation in the UPC. More generally, participation by actors from specific jurisdictions will necessarily contribute to how national law should feature in the UPC. This happens because the practical relationship between different sources of law is left essentially unclear in the UPC Agreement.[418] Just as the provisions of the EPUE appear to be more responsive to the needs of the largest patent jurisdictions, relying on adjudication to provide actual meaning as to the role of national law will necessarily result in an approach that contextually reflects the interests of specific EU Member States.

3.4 *Permanently shifting the process of interface creation: Contextualising the use of enhanced cooperation*

3.4.1 Issues with enhanced cooperation in the creation of an interface

As discussed previously, the process of enhanced cooperation is outlined in Article 2 TEU and allows a minimum of nine Member States to proceed together with their own legislative projects as a last resort to overcome a complete stalling in negotiations.[419] These projects must not prejudice the rights of non-participating states.[420] The EPUE is a particular example of how enhanced cooperation projects can impact or undermine values like accountability and responsiveness. In a related sense, enhanced cooperation can be approached from the perspective of its participants and the degree to which smaller Member States have

[418] Article 24 of the UPC Agreement provides the applicable sources of law, but provides no real indications as to how these can be used to make decisions. The text states that the Court will 'base its decisions on' these sources but this would appear to invite a flexible understanding of the proper role of, for example, national law.
[419] Article 20, TEU.
[420] ibid.

the ability to effectively articulate their concerns within that process. The expansion of applicable territory as a way of producing the EPUE effect stands out as a very particular use of enhanced cooperation given that its previous uses have been in managing the complications of international divorces and the proposed financial transaction tax.[421] The EPUE, in contrast, results in essentially an approximation of a property right that is specifically designed to avoid the unlawful delegation of administrative or regulatory power.

Rather than a niche area of cooperation that requires technical or specialist cooperation between a small number of Member States, the development of the unitary patent presents a much more exclusionary model of law-making that centres the interests of the largest economic stakeholders. It is significant in this context that the UK leaving the EU was considered a fundamental threat to the project because of its market size and innovation output.[422] On the other hand, EU Member States that had actually challenged the working of the agreement had little leverage to meaningfully change parts of the EPUE. This lack of capacity to amend the legal structure of the EPUE means that their participation or non-participation was irrelevant as long as the largest patent jurisdictions supported it. This is magnified when considering how significantly the unitary patent enhanced cooperation diverges from its early examples. This is not the minimum nine states required by Article 20 and nor is the 15 states involved in the divorce cooperation. The unitary patent is all but two Member States, creating a legal regime that necessarily affects the internal market and thereby influences all Member States regardless of whether they participate or not.

[421] On divorce: Jan-Jaap Kuipers, 'The Law Applicable to Divorce as Test Ground for Enhanced Cooperation' (2012) 18(2) ELJ 202; on the proposed financial transactions tax: Joachim Englisch, John Vella, Anzhela Yevgenyeva, 'The Financial Transaction Tax Proposal Under the Enhanced Cooperation Procedure: Legal and Practical Considerations' (2013) 2 British Tax Review 224.
[422] Aisling McMahon, 'Brexit and the Unitary Patent Package: A Further Compromised Future?' (2018) 15(2) Scripted 181.

It is important to recognise that, from an institutional perspective, the structure of the UPC can be seen as an attempt at integrating the interests of all the participating Member States. It does this by establishing specialist divisions and regional divisions in a geographically distributed way.[423] Brexit, and the UK leaving the EU, fundamentally impacted the implementation of the EPUE because London was to be the host of a technical division.[424] This was further undermined by significant concerns that were raised about the legal basis on which the UK could participate in the process of enhanced cooperation given that they were no longer a Member State.[425] But even in this attempt at a distributed approach, the Central Divisions are located in – as they should be – the states that are most connected to these industries. But this does demonstrate clearly who the key stakeholders are in European patent law and who is important for the trajectory of European patents.[426] Here, the tension between a patent system that maximises the economic potential of industry and one which is both accountable and responsive to the needs of all participants is clear.

The cultural dimensions of the legal challenges around languages have been criticised as irrelevant,[427] though patent law has a particular relationship to text and textual documents and this highlights the distinct importance of machine translations within the EPUE system.[428] The patent specification in particular is the primary way in which the protected innovation is demarcated and so the modes and uses of language are connected to their cultural

[423] Annex II, Agreement on a Unified Patent Court. Available at <https://www.unified-patent-court.org/sites/default/files/upc-agreement.pdf>.
[424] ibid; though discussed briefly in the context of patent litigation volume: Jorge L Contreras, Fabian Gaessler, Christian Helmers, and Brian J Love, 'Litigation of Standards-Essential Patents in Europe' (2017) 32(4) Berkeley Technology Law Journal 1467.
[425] Edwin Parks, 'The European Unified Patent Court and UK Assumptions on its Post-Brexit Patent Litigation' in Prinz von Sachsen Gessaphe, Karl August, Juan J Garcia Blesa, and Nils Szuka (eds), *Legal Implications of Brexit* (MV Wissenschaft 2018) 257.
[426] Paragraphs 28 and 29, C-147/13 *Spain v Council* 2015.
[427] The suggestion has been made that the argument that a narrower language regime is discriminatory could equally be applied to any EU language *outside* of Spain and Italy's proposed five languages: Steve Peers, 'The Constitutional Implications of the EU Patent' (2011) 9(1) ECLR 255.
[428] See generally: Siva Thambisetty, 'The Construction of Legitimacy in European Patent Law' (2017) 3 IPQ 221, 222.

background.[429] Writing patent specifications is difficult enough in a native language,[430] particularly in certain industries like software development,[431] in a way that accurately and concisely describes what exactly the invention is. By relying on machine translations and only producing human translations when infringement is alleged,[432] smaller states (and particularly SMEs) within those territories are disadvantaged because they have additional barriers in establishing a clear image of the state of the art. This is exacerbated by the concerns around exploitative litigation as seen in the US,[433] and in the context of the EU could lead to companies in smaller states receiving notifications of infringement and pressure to licence. With only a machine translation as to the actual scope of the patent in their language, the business or individual would have to commence legal proceedings to then have access to a true, human translated version of the patent unless they proactively pay for a translation themselves.

The efficiency of a single application to cover the majority of the territory is certainly challenged if the result is a much more convoluted enforcement system that opens itself to the type of aggressive patent litigation that has characterised the US market for some time.[434] The concern here is not simply that the reliance on machine translation merely defers cost to a later

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[429] On the central importance of the patent specification (as well as its limits in specific industries such as software): Julie E Cohen and Mark A Lemley, 'Patent Scope and Innovation in the Software Industry' (2001) 89(1) California Law Review 24, 25.

[430] Hanns Ullrich, 'National, European and Community Patent Protection: Time for Reconsideration' (2006) EUI Working Papers, No 2006/41. 36. < https://ideas.repec.org/p/erp/euilaw/p0070.html>.

[431] Notorious for difficulties in enablement and disclosure: Andrew Chin, 'Computational Complexity and the Scope of Software Patents' (1998) 39(1) Jurimetrics 26.

[432] Emphasising that after a transition period, machine translations are expected to be of sufficient quality to be used generally: Aline A Larroyed, 'Machine Translation and Disclosure of Patent Information' (2018) 49 IIC 763, 777; with reimbursements for limited classes of applicants for translations produced in the registering of a patent: Article 5, Council Regulation No. 1260/2012; and provisions for either the court or the defendant to request a translation of the patent into either the language of the place of alleged infringement or the domicile of the defendant: Article 4.1, 4.2 Council Regulation No. 1260/2012.

[433] Jiaqing Lu, 'The Myths and Facts of Patent Troll and Excessive Payment: Have Nonpracticing Entities (NPEs) Been Overcompensated?' (2012) 47(4) Business Economics 234.

[434] The issue was highlighted as a potential in the report commissioned by the UK Intellectual Property Office: Luke McDonagh, 'Exploring Perspectives of the Unified Patent Court and the Unitary Patent Within the Business and Legal Communities' (2014) UKIPO 5, 26. <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/328035/UPC_Study.pdf>; the different 'styles' of patent drafting internationally can also influence the ease with which it can be translated accurately by machines: Aline A Larroyed, 'Machine Translation and Disclosure of Patent Information' (2018) 49 IIC 763, 780.

stage of the patent lifecycle, but that it specifically disadvantages smaller EU Member States. In these spaces, innovators must rely on machine translations when investing and producing a product in an area of law that is so specifically reliant on the actual text (and associated culture of specification) of a document.[435] There is also the issue of the machine translations themselves. Despite an understanding that they will be fully operational in time for the implementation of the EPUE, the quality remains extremely variable.[436] The issue is that patent law requires comprehensive understanding and accurate translation because it is the foundation of a property claim. Even in English, if a reader only understood 90% of the terms found in the specification (much higher than the three out of ten rating the Hungarian translation was given by some researchers),[437] the full disclosure of the working of the invention is impaired at best and, at worst, the understanding of what the invention is at all could become impossible.

This sense of marginalisation and how the process itself by which the EPUE is legally constituted centres the interests of specific Member States and requires a more critical investigation into the EPUE as a legal interface. More than this, the EPUE and UPC can be seen as an unfortunate turning point in European law and very clearly marks a break in the character of legal projects undertaken through the enhanced cooperation mechanism and what this could mean for the EU in the long term. The resulting patent law is then, in the course of its development, at once less accountable to all of its members and produces a framework that is less responsive to the needs of those very same members.

[435] Siva Thambisetty, 'The Construction of Legitimacy in European Patent Law' (2017) 3 IPQ 223.
[436] Specifically on the low quality of translation from Czech and Finnish: Kluwer Patent Blog, 'Translating the Unitary Patent I: "Laminated Jealous Glass"' (*Wolters Kluwer*, 18 December 2014) <http://patentblog.kluweriplaw.com/2014/12/18/translating-the-unitary-patent-i-laminated-jealous-glass/>
[437] Kluwer Patent Blog, 'Translating the Unitary Patent I: "Laminated Jealous Glass"' (*Wolters Kluwer*, 18 December 2014) <http://patentblog.kluweriplaw.com/2014/12/18/translating-the-unitary-patent-i-laminated-jealous-glass/>.

3.4.2 Distinguishing the enhanced cooperation process of the EPUE

What is particularly concerning about how the EPUE minimises the ability for smaller states to have meaningful input in the substantive design of the patent is that this is embodied in the procedural aspects of its creation through enhanced cooperation. It is important to recognise that participation is an issue in many systems of law, and even the ordinary legislative procedure in the EU does not require unanimous voting.[438] Yet enhanced cooperation presents a slightly different dynamic. The use of enhanced cooperation to address a negotiating impasse has been used a handful of times including the EPUE,[439] though it is this emphasis on this mechanism as a last resort that distinguishes these participation concerns to the more general ordinary legislative process. In this context, enhanced cooperation is intended to produce a specific cooperation between participating states without prejudicing the interest of non-participating states. Yet with the EPUE, the impact to patent law more fundamentally will necessarily extend beyond the participating states. The expectations in the ordinary legislative process are more clearly communicated, where it simply requires a 2/3 majority and inevitably Member States who are not part of this majority will still be affected. Yet enhanced cooperation is explicitly presented as a mechanism that must not prejudice the interests of non-participating states – which is not an expectation in the ordinary EU law-making.

Enhanced cooperation was first used in the context of divorce, a cooperation of states to facilitate the treatment of international divorces in 2010 that responds to the specific legal dimensions of marriages and property that have an international character.[440] The focus here is the individual and minimising the difficulties of resolving cross-border issues between

[438] On the qualified majority required in the European Parliament (though specifically in the context of environmental issues): Christian Zuidema, *Decentralization in Environmental Governance: A Post-Contingency Approach* (Routledge 2017) 167.
[439] Bernd Martenczuk, 'Enhanced Cooperation: The Practice of Ad Hoc Differentiation in the EU Since the Lisbon Treaty' (2013) 66(3) Studia Diplomatica 86.
[440] Katharina Boele-Woelki, 'To Be, or Not to Be: Enhanced Cooperation in International Divorce Law Within the European Union' (2008) 39 Victoria University of Wellington Law Review 779, 782.

individuals. The legal impact of the enhanced cooperation in the context of divorce is, therefore, from a broader perspective, relatively contained within very defined boundaries and generally limited in its structural impact to the EU legal environment it operates within. While there is a great diversity in the states as to their approach to divorce,[441] it is not an issue that touches the internal market and its functioning, nor is an issue of national economic scale.

The proposed financial transaction tax is another of the enhanced cooperation projects, specifically aimed at ensuring the proper taxation of financial services across the EU.[442] The lack of a harmonised approach to a financial transaction tax, at both an economic and conceptual level,[443] highlights the benefits of a novel cooperation between a small number of states to facilitate experimentation. This is reinforced by the diversity in terms of exactly how the proposed financial transaction tax would function amongst EU Member States.[444] The structural impact of the enhanced cooperation is fairly limited in this context, though it does provide a model of how a closer (and more experimental) cooperation between states could serve as a foundation for later EU-level implementation that involves all EU Member States.

In contrast, the EPUE is both wider in its structural impact on the broader EU environment and its focus is decidedly beyond the relationship between private actors and extends to the relationship between industry and the state. The financial transaction tax certainly demonstrates the potential of greater cooperation and a more harmonised approach, yet the EPUE differs somewhat here too. The EPUE appears to skip this testing or experimentation of cooperation on a smaller scale and instead moves straight towards structural

[441] Specifically on the more accessible or more restrictive approaches found between different countries: Daniela A Kroll and Dirk Leuffen, 'Enhanced Cooperation in Practice: An Analysis of Differentiated Integration in EU Secondary Law' (2015) 22(3) Journal of European Public Policy 359.
[442] For a broad overview of the progress of enhanced cooperation in this context: Caroline Heber, *Enhanced Cooperation and European Tax Law* (OUP 2021) 63.
[443] Specifically discussing Macron postponing discussions regarding the financial transaction tax until after Brexit to prevent a huge move of businesses to London: ibid.
[444] Robert Böttner, *The Constitutional Framework for Enhanced Cooperation in EU Law* (Brill 2021) 56.

changes in the functioning of patent law in the EU. It represents a successful example of law-making in which the interests of small dissenting states can be overlooked as long as the states with the largest economic interest agree. As such, at a structural and procedural level, the development of the EPUE is distinctly unresponsive to the needs of EU Member States beyond a small group of economically important, Western European, countries.

The key to the enhanced cooperation process is that the legal projects arising from it should not prejudice the rights and interests of non-participating states and remain open for participation from the non-participating states.[445] While there is an ongoing debate and a variety of opinions regarding the prejudicing of non-participating states,[446] the significance of the EPUE project must carry with it a higher standard when assessing whether it prejudices the rights of non-participating states. The EPUE moves beyond the scope of the other enhanced cooperation projects and fundamentally impacts the internal market itself, in a way that there is a clear tension between larger and smaller states in terms of their ability to meaningfully influence its provisions. It is therefore appropriate to assess the impact to non-participating states more critically than that which would be employed with more niche or individual cooperations between states (though it is apparent that the CJEU does not agree with such a differentiated standard as discussed in the context of the Spanish and Italian legal challenges).

Allowing Member States to cooperate in areas that touch competences of the EU and shape the internal market finds clear parallels in the international multilateral context.[447] One example would be in the description of 'country club' multilateralism that refers to like-minded

[445] Alfredo Ilardi, *The New European Patent* (Hart 2015) 30.
[446] The CJEU concluded that enhanced cooperation did not breach Article. 326 TFEU that requires that enhanced cooperation does not undermine the internal market or economic, social, and political cohesion between Member States: C-274/11 *Spain & Italy v Council*.
[447] Peers, concluding that the CJEU was appropriately placed to authorise enhanced cooperation because intellectual property is an internal market area (and is therefore a shared competence) that also falls outside the exclusive scope of the Common Commercial Policy: Steve Peers, 'The Constitutional Implications of the EU Patent' (2011) 9(1) ECLR 251.

states who cooperate internationally.[448] While this is presented as states with similar interests cooperating, the impact on smaller countries becomes clear as they are increasingly pressured to accept higher standards and the approaches of larger economies to make gains in international trade.[449] Endorsing an approach to enhanced cooperation that similarly emphasises the will of the economic larger states reflects some of the distortions that bilateral agreements have brought internationally.[450] The impact of enhanced cooperation works to reshape the dynamic of patent law in Europe to fit the interests of the largest economic actors of the EU without requiring, or encouraging, the participation of smaller states.

3.4.3 Fundamental shifts in the law-making interface

The issue with constructing the requirement that enhanced cooperation be a 'last resort' is that it presents an example of law-making that undermines the fundamental mission of the EU that has distinguished it from other multilateral projects.[451] By constructing enhanced cooperation as a process that can be used to overcome negotiating difficulties in the ordinary course of legislative development instead of an exceptional response to a complete breakdown in communication, the functioning of the enhanced cooperation mechanism is distorted. It sets an example for future negotiations that objections, particularly those by smaller states, can be overlooked as enhanced cooperation provides a ready alternative. The very existence of this

[448] On the development of a 'country club' approach in multilateralism though specifically in the context of intellectual property: Peter K Yu, 'ACTA and Its Complex Politics' (2011) 3 WIPOJ 1.
[449] One understanding of small states through realism theory is that they are best functioning essentially as satellite states to larger states: Abelraouf Mostafa Galal, 'External Behavior of Small States in Light of Theories of International Relations' (2019) 5(1) Review of Economics and Political Science 38, 39.
[450] For example, in intellectual property more broadly, the bilateral trade environment encourages developing countries to adopt intellectual property standards that do not meet national objectives or reflect their national industries' needs: Kenneth C Shadlen, 'Intellectual Property, Trade, and Development: Can Foes Be Friends?' (2007) 13(2) Global Governance 171.
[451] On the enduring role of consensus in European legislation (as well as the increasing conflicts that provoke a more majoritarian dimension): Stéphanie Novak, Olivier Rozenberg, and Selma Bendjaballah 'Enduring the Consensus: Why the EU Legislative Process Stays the Same' (2020) 43 Journal of European Integration 475.

alternative and its use in the EPUE has been presented as potentially impacting the character of EU legal development,[452] and could affect the readiness with which the smaller Member States try to articulate their concerns within these processes.

Particularly with projects that involve larger Member States, the departure of the EPUE from the previous enhanced cooperation projects (even just in terms of the number of parties involved) means that the EPUE's design continued relatively unimpaired despite these initial legal challenges. It is important to recognise that the impact of the EPUE in enhanced cooperation can be seen not just from a volume perspective in the number of parties, but from a disciplinary perspective as well. Future EU legislation and the ways in which smaller Member States participate will necessarily be conducted in the shadow of the expansive disciplinary approach that has been signalled with the EPUE. The EU institutions, in endorsing the EPUE package, have expanded the scope of projects that can be implemented using enhanced cooperation and legitimised projects that have a more complex relationship to the functioning of the internal market.

This expansive approach to enhanced cooperation also does not clearly distinguish between participating and non-participating states in the practical impact of the EPUE. This means that the issue of participation is so one-sided that the non-participating states are impacted anyway. This is not a small number of states creating a specialised solution to a specific legal problem but, instead, a majority of states that are legitimised by their economic size in a way to establish what is essentially a new property right. Poland's innovation environment will necessarily be impacted by the development of the EPUE in a variety of direct and indirect ways.[453] Not participating in the EPUE (though joining the EPUE, Poland has not

[452] That the use of enhanced cooperation in this coercive manner 'tilts the EU away from solidaristic norms and practices': Matthias Lamping, 'Enhanced Cooperation: A Proper Approach to Market Reintegration in the Field of Unitary Patent Protection?' (2011) 42(8) IIC 28.

[453] As far back as the 1970s, the economic risk for smaller states from the unitary patent driving out innovative activity has been discussed (notably both Czechia and Poland): Aurora Plomer, 'The Unified Patent Court and

ratified the court structure and therefore the means to enforce these patents) does little to meaningfully shape or help create a more responsive EPUE. Likewise, joining the EPUE leaves little scope for shaping its functioning because the objectives have already been clearly defined by the largest patent jurisdictions in Europe.

The difficulties in articulating the interests of smaller states are not simply occurring in the context of intellectual property and the tensions in the EPUE instead reflect the broader climate of the EU in 2023. This involves sustained criticism specifically about the relationship between the EU institutions and smaller states,[454] but also a threat to the EU itself that is represented (though not totally captured) by Brexit.[455] There is a legal tension between what is seen as a Western European bias in the EU from the smaller Central or Eastern states that has resulted in a variety of conflicts.[456] In the context of intellectual property and the EPUE, what is significant is that the tension is not being played out in the more open forum of the ordinary EU legislative process. Instead, these issues have been transplanted to a more convoluted process that minimises the capacity for the smaller countries to meaningfully participate.

Hungary and Poland are two particularly clear examples of this broader tension with the value of participation in international patent law. While Poland is not participating in the EPUE, Hungary was the host to the training program for the judges of the UPC.[457] Both of these countries have a complex relationship with the EU that involves a financial dimension

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the Transformation of the European Patent System' (2020) 51 IIC 794, 795; though also specifically Poland's political climate is not conducive to the unitary patent project (with 'protection of Polish economy, strong Euroscepticism'): Bird&Bird, 'The Unitary Patent and the Unified Patent Court – Poland' (*Bird&Bird*) <https://www.twobirds.com/en/in-focus/unitary-patents-and-the-unified-patent-court/up-and-upc-interactive-map/poland>.

[454] Specifically Hungary, though discussing more broadly Central European states and constitutionalism: Michel Rosenfeld, Wojciech Sadurski, and Roberto Toniatti, 'Central and Eastern European Constitutionalism a Quarter Century After the Fall of the Berlin Wall: Introduction to the Symposium' (2015) 13(1) ICON 119, 121.

[455] On the broader challenges of sustaining the EU project: Leonardo Scuira, 'Brexit Beyond Borders: Beginning of the EU Collapse and Return to Nationalism' (2017) 70(2) Journal of International Affairs 115.

[456] Tomáš Valášek, 'Why Can't the EU's West and East Work as One?' Carnegie Europe 1–2. <https://carnegieendowment.org/files/10-8-19_Valasek_EU_East_West.pdf>.

[457] Edward Nodder, 'Training Centre for UPC Judges Opens in Budapest' (*Bristows*) <https://www.bristowsupc.com/latest-news/Training-Centre-for-UPC-judges-opens-in-Budapest/>.

and has generally centred on challenges to the social, rather than economic, objectives of the EU.[458] The geographically distributed nature of the UPC is one way of trying to address this more political aspect of intellectual property harmonisation, particularly with the capacity for regional divisions. Yet the reality is that certain regional divisions (if they are even established) will be significantly underused compared with those in Western Europe and will necessarily occupy a different role in the overall development of EPUE jurisprudence. As a result, the EPUE will remain resistant to interests from outside the major patent jurisdictions and minimise the opportunities for participation from smaller EU Member States.

4. Identifying the flexibilities of the new interface

4.1 *Biotechnology*

4.1.1 European biotechnology

While the legal foundation and the structure of the UPC have an impact on the responsiveness and accountability of patent law more generally in Europe, the EPUE and UPC also have a more technologically specific dimension in terms of the nature of the legal interface. Just as patent law is technologically specific in its enforcement,[459] the way in which the provisions of the EPUE and UPC interact suggests that the functioning of the interface itself may also be technology specific. The Legal Protection of Biotechnological Inventions Directive (Biotechnology Directive) was an important part in augmenting or otherwise building

[458] One particular example being the EU negotiations over asylum seekers: John Chalmers and Gabriela Baczynska 'Hungary's Orban Rejects Criticism Over Rule of Law, Says He is a "Freedom Fighter"' (*Reuters*, 25 September 2020) <https://www.reuters.com/article/us-hungary-orban-interview-idUSKCN26G26Q>.
[459] Dan L Burk and Mark A Lemley, 'Is Patent Law Technology-Specific?' (2002) 17(4) Berkeley Technology Law Journal 1156.

on the more general patent law interface in a way that is responsive more specifically to the issues of inventions in biotechnology.[460] Interestingly for the Biotechnology Directive, academic commentary has focused on the use of concepts like 'integrity' and 'dignity' in the recitals.[461] While it has been brought together with how 'naturalness' is understood in biotechnological inventions,[462] the references to the morality or ethics of patent law highlights the tension in translating these highly contextual concepts to the EPUE precisely because it involves an enforcement dimension that extends outside the national environment. The Biotechnology Directive, grounded in Article 114 TFEU and in pursuit of safeguarding the integrity of the internal market,[463] is explicitly framed as a tool for encouraging investment. It essentially insulates biotechnological inventions from a diverse set of national biotechnology responses in patent law.[464] The Biotechnology Directive has an interesting relationship to the broader patent context because of this explicit market-oriented framing that seeks to minimise nationally grounded legal concepts like public morality in order to promote commercialisation. It is the economic framing that minimises the opportunities for the accountability or responsiveness of patent law on the basis of non-economic concerns.

At a more abstract level, the Biotechnology Directive also highlights that patent law can often be more properly constructed as a series of overlapping interfaces rather than a single one. This multilevel understanding of patent law seeks to highlight that, while in practice patent law functions as a whole, the way in which participation or accountability are realised within European patent law is the result of complex interactions in a variety of political, economic,

[460] Directive 98/44/EC.
[461] Aurélie Mahalatschimy, Pin Lean Lau, Phoebe Li, and Mark L Flear, 'Framing and Legitimating EU Legal Regulation of Human Gene-Editing Technologies: Key Facets and Functions of an Imaginary' (2021) 8(2) Journal of Law and the Biosciences 7.
[462] ibid.
[463] On the scope and major cases that considered Article 114 TFEU: Kathleen Gutman, *The Constitutional Foundations of European Contract Law: A Comparative Analysis* (OUP 2014) 330.
[464] On the arguments about the negative impact of fragmentation at the Member State level as to the legal status of biotechnology inventions: Mark L Flear, 'Regulating New Technologies: EU Internal Market Law, Risk, and Socio-Technical Order' in Marise Cremona (ed), *New Technologies and EU Law* (OUP 2017) 99.

and legal contexts. The 'market-oriented rationale' of the Biotechnology Directive has been highlighted as significant from a patent law perspective because of how it centres the commercial exploitation of inventions and conditions the legal construction of naturalness.[465] Yet it also highlights a more fundamental tension with *l'ordre public* or public morality exceptions more broadly in the EU. These exceptions not only bring these concepts into contact with economic justifications, but it elevates these mechanisms beyond their national operating context through reference to the internal market. For exceptions to patentability on these moral or ethical grounds, this elevation is problematic because the contents of these exceptions are necessarily tied to national consideration but can only subsequently be operationalised at the international level. Participation in the direction of patent law is then subject to a complex negotiation between national and international interpretations of binding patent obligations.

While the Biotechnology Directive is an important example of the interactions between different patent instruments that can work to create a more responsive application of patent law, the academic discussion around the public morality in the context of the Biotechnology Directive is very specifically grounded in the Article 6 text. Article 6 provides a framework for identifying an invention where the commercial exploitation would be contrary to *l'ordre public*.[466] The text of Article 6 is interesting for exploring how different patent regimes interact and the patent environment becomes essentially co-constituted because, as Beyleveld and Brownsword have discussed extensively,[467] the morality clause of Article 53 in the EPC was revised to match the text of Article 6 in the Biotechnology Directive. The specific elements of the subject matter highlighted in Article 6, though non-exhaustive,[468] necessarily provide a

[465] Aurélie Mahalatschimy, Pin Lean Lau, Phoebe Li, and Mark L Flear, 'Framing and Legitimating EU Legal Regulation of Human Gene-Editing Technologies: Key Facets and Functions of an Imaginary' (2021) 8(2) Journal of Law and the Biosciences 9.
[466] Article 6, Biotechnology Directive.
[467] See generally: Deryck Beyleveld and Roger Brownsword, *Human Dignity in Bioethics and Biolaw* (OUP 2002).
[468] Paragraph 38, Biotechnology Directive.

narrow framing of public morality exceptions because they predominantly relate to very specific types of use around human genetic material.[469]

Again, at this more abstract level, the Biotechnology Directive highlights the important institutional role of dispute settlement bodies in this area. Dispute settlement bodies are not just central in adjudicating the provisions of the text but have a significant role in actually developing the substantive moral content of these provisions in a way that promotes a more responsive patent law. The CJEU itself has been central in elaborating how the Article 6 provisions could function in practice and thereby shaped how the morality provisions respond to these complex tensions.[470] The CJEU produced an indicative list of how 'human embryo' should be legally understood in *Brüstle v Greenpeace*, but a tension in the Court's reasoning has been highlighted in academic discussion of the decision. Major themes in this area are that it represents an attempt to balance between the sensitive and contextually-specific nature of 'human embryo' and the need for an autonomous interpretation of the term for the EU territory.[471]

While the role of the CJEU in developing the substantive content of these provisions is important, it raises some questions as to how these provisions will further develop with the EPUE. Biotechnology, in particular, highlights these tensions because of the rapid progress in the field that will continue to challenge societal understandings of human life and how these are interpreted in a legal, intellectual property, context. Here, the role of participation becomes particularly clear. Given the tensions between national and international frames of reference

[469] Aurélie Mahalatschimy, Pin Lean Lau, Phoebe Li, and Mark L Flear, 'Framing and Legitimating EU Legal Regulation of Human Gene-Editing Technologies: Key Facets and Functions of an Imaginary' (2021) 8(2) Journal of Law and the Biosciences 13.
[470] Reaffirming the discussion in Recital 38 that the list of exceptions is illustrative and not exhaustive: paragraph 33, C-34/10 *Brüstle v Greenpeace*.
[471] Discussing the fact that the Directive does not rely on national law to define specific concepts like 'embryo', the CJEU argues that this means it must be considered an autonomous concept and is supported by the fact that Recitals 3–6 demonstrate that the intention of the Directive was to 'remove obstacles to trade and to the smooth functioning of the internal market…' Paragraphs 26, 27, ibid.

for applying and enforcing the EPUE provisions, it raises the question of how participating Member States can articulate their own responses to any challenging developments in technology. In particular, the CJEU has highlighted that the role of the reference procedure in EU law and of its role in legal interpretation rather than ethical interpretation of the provisions.[472] This also necessarily raises questions about how the UPC will respond to these challenges in technological development and how it will reflect the inevitable diversity in Member State response. The CJEU, by revising the definition of 'human embryo' in a later case and from the broader legal impact of the EU Charter,[473] has been described as embedding a moral stance in patent law that functions as a 'legitimating support for EU involvement and a restrictive approach in all patenting relating to the human embryo'.[474] This can certainly be linked to the UPC and its emerging institutional identity, in terms of whether it takes a similar approach in response to technologically and socially difficult questions of patent law (or if it even has the institutional legitimacy to 'embed' specific value perspectives at all).

Yet there is a fundamental asymmetry between the preliminary references that the CJEU used to ground its indicative list (in trying to respect the distinct national responses to the status of a human embryo) and the geographical scope of the UPC which is necessarily more malleable. There can only be preliminary references on issues around the EPUE from Member States that successfully implement the corresponding court system. As such, it will skew which jurisdictions end up using preliminary references in a way that, again, privileges

[472] Where the CJEU states that while the social and legal status of an embryo is a sensitive issue in many Member States, the questions referred to the CJEU are legal questions and not medical or ethical ones: Paragraph 30, C-34/10 *Brüstle v Greenpeace*.
[473] Aurélie Mahalatschimy, Pin Lean Lau, Phoebe Li, and Mark L Flear, 'Framing and Legitimating EU Legal Regulation of Human Gene-Editing Technologies: Key Facets and Functions of an Imaginary' (2021) 8(2) Journal of Law and the Biosciences 14; on the interactions between the CJEU, the Biotechnology Directive and the impact of respect for human dignity: S Millns, 'Consolidating Bio-Rights in Europe' in Francesco Francioni (ed), *Biotechnologies and International Human Rights* (Hart 2007) 80, 81.
[474] Aurélie Mahalatschimy, Pin Lean Lau, Phoebe Li, and Mark L Flear, 'Framing and Legitimating EU Legal Regulation of Human Gene-Editing Technologies: Key Facets and Functions of an Imaginary' (2021) 8(2) Journal of Law and the Biosciences 15.

the most active patent jurisdictions. The jurisprudence around how public morality exceptions respond to new technological development (and the unclear role of national law) will therefore reflect a narrower stakeholder perspective rather than even the EU autonomous interpretation created through the CJEU's interactions with the Biotechnology Directive.

4.1.2 Exploring biotechnology and the EPUE

A key feature of the international patent law interface is the role of *l'ordre public* or public morality exceptions in providing a way of excluding an area of technology from patent protection that would otherwise be eligible. The exception can be used to prevent the patenting of an invention that the exploitation of which would be considered contrary to public morality and can be found in both the TRIPS Agreement and the EPC.[475] While *l'ordre public* cases have mostly been considered in the context of the TRIPS Agreement and controversial genetic inventions, there is also a distinct institutional dynamic to this discussion that centres on the role of patent offices.[476] The EPUE represents a new development in this context, specifically for inventions in biotechnology, because it questions the degree to which *l'ordre public* exceptions can function within the harmonising influence of the UPC. Tensions have been identified between *l'ordre public* and the EU Member States because this type of exception has a strong connection to national autonomy and the diverse national histories within Europe.[477] The suggestion is that because it will be a single court system interpreting the scope and substantive content of *l'ordre public*, the EPUE essentially limits the national autonomy of EU

[475] Article 27(2), TRIPS Agreement; Article 53, EPC.
[476] On the reluctance of the EPO to apply a strict interpretation of the public morality provisions: Benjamin D Enerson, 'Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine' (2004) 89(3) Cornell Law Review 704, 709.
[477] Aisling McMahon, 'An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: A Fragmented Future Too Far?' (2017) 48(1) IIC 42, 46.

Member States in terms of their ability to exclude specific areas from patent eligibility.[478] This raises a tension between accountability and the responsiveness of these exceptions in the UPC because it abstracts the issue from local patent conditions and actors.

One of the important features of biotechnology as realised through the EPUE is the relationship to the broader patent context, particularly in terms of shifting attitudes to patent law. Other jurisdictions have developed legislation that specifically deals with the more distributional aspects of patent law (and subject matter eligibility in particular) that significantly alter the framing of patent law.[479] While legislative developments on this type of scale are perhaps unlikely in Europe, a more explicit emphasis on the distributional impact of biotechnology inventions could become an important aspect of the biotechnology patent law interface when they rely on specific forms of genetic material or natural resources. The difficulty with expanding the application of both general exceptions and more specific, national developments is that they would operate within the same court system. The UPC would then be central in navigating between harmonisation and additional fragmentation, between standardising common constructions or national approaches, and either applying them more broadly or creating a differential regime that really incorporates a more reflective and responsive construction of national law within the EPUE. The interface of European patent law is then, as it emerges from the interaction of the EPUE and the UPC, undergoing a process of transformation and instability that specifically questions what effective participation actually means in the development of international patent law. The EPUE is important for the study of legal interfaces not only because it represents contemporary example of an interface being

[478] Aisling McMahon, 'An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: A Fragmented Future Too Far?' (2017) 48(1) IIC 42, 46.
[479] One example would be legislative provisions in Costa Rica, China, and Ghana: James O Odek, 'Bio-Piracy: Creating Proprietary Rights in Plant Genetic Resources' in Nikos Passas (ed), *International Crimes* (Routledge 2017) 385; Leslie Roberts, 'Chemical Prospecting: Hope for Vanishing Ecosystems?' (1992) 256(5060) Science 1142.

created, but because it signals a period of significant porousness and indeterminacy about the future of patent law in Europe. Seen from this perspective, the process of interface creation necessarily involves a negotiation (and constant renegotiation) of how participation and responsiveness empower or inhibit the subjects of a legal framework.

4.2 *Pharmaceuticals*

4.2.1 Compulsory licensing.

The characterisation that the EPUE represents an emergency patchwork also extends to its interactions with other established mechanisms within patent law like compulsory licensing. This involves both the national dimension (the participating Member States) and also how it relates to the international functioning of compulsory licensing. One of the fundamental issues with the EPUE and compulsory licensing is that the process is very much envisaged as an issue left to the national courts.[480] The role of national courts was highlighted specifically in Recital 10 and endorsed a national framing to compulsory licensing.[481] Even within the European framing of patent law and licensing, it is somewhat more broadly framed by the existing *Parke-Davis* jurisprudence that presents intellectual property rights as national rights and therefore not automatically subject to EU competition law.[482] The balancing in terms of patent owners, the rights, and the public shifts with the EPUE given its expanded territory. As such, a refusal to licence – as an abuse of dominant position[483] – would take on a correspondingly greater role.

[480] Hugh Dunlop, 'Compulsory Licensing Under A Unitary Patent' (2017) 39(7) EIPR 393.
[481] Recital 10, Regulation (EU) No. 1257/2012.
[482] C 24/67: *Parke, Davis & Co v Probel, Reese, Beintema-Interpharm and Centrafarm* (1968).
[483] Where the refusal to licence undermines the entry of an innovative product with consumer demand, cannot be objectively justified, and has an anticompetitive effect in secondary markets: Applying and developing criteria from *Magill*: paragraph 37, C-418/01 *IMS Health GmbH and NDC Health GmbH*; more completely discussed here: Jonathan Berger, 'Advancing Public Health by Other Means: Using Competition Policy' in

Compulsory licensing that tries to integrate a national licensing approach with an otherwise international system of protection could have two additional consequences, both of which are fundamentally linked to technology-specific applications of patent law. The first is that there are already concerns around the degree to which pharmaceutical patents, particularly on their vulnerability to central attack in validity for revocation,[484] will adopt the EPUE in the transition period.[485] Any concerns around compulsory licensing (specifically in terms of licensing) are likely to unsettle patent owners of pharmaceutical or pharmaceutical-related technologies even further during the transition period. This is linked to the second potential consequence of how the EPUE disjoints licensing from the other (if not harmonised) firmly international aspects of the EPUE – a technology-specific impact. Pharmaceuticals are particularly interesting because they occupy a difficult position (legally, politically, and socially) in terms of compulsory licensing. Here, discussions of compulsory licensing have become increasingly tied to issues of access to medicine and a distinctly different character to historical examples of compulsory licensing.[486] Though issues around access to medicine have typically not been raised in a European context, the disruptive COVID-19 pandemic prompted a renewed interest in the issue. These discussions involved more general subjects (such as the role of national funding and what this means for accessibility),[487] but also resulted in EU

Pedro Roffe, Geoff Tansey, and David Vivas-Eugui (eds), *Negotiating Health: Intellectual Property and Access to Medicines* (Earthscan 2006) 191, 192.

[484] Luke McDonagh, 'Exploring Perspectives of the Unified Patent Court and Unitary Patent Within the Business and Legal Communities' (2014) UKIPO 4.

[485] Kluwer Patent Blog, 'Initiatives to Include SPCs in the Unitary Patent System' (21 November 2015) <http://patentblog.kluweriplaw.com/2015/11/21/initiatives-to-include-spcs-in-unitary-patent-system/>.

[486] One global example would be the Trading with the Enemy Act in the US. Compulsory licensing has an obvious competition framing but the actual social and political subject it deals can be very specific and impact the character of the jurisprudence that emerges. Discussing the Trading with the Enemy Act: Petra Moser and Alessandra Voena, 'Compulsory Licensing: Evidence from the Trading with the Enemy Act' (2012) 102(1) The American Economic Review 396.

[487] With the EU providing 350 million euros towards COVID vaccine development: EU Commission, 'EU Support for Vaccines' (*EU Commission*, 4 May 2021) <https://research-and-innovation.ec.europa.eu/research-area/health/coronavirus/vaccines_en>.

Member States issuing controversial licences for specific medications.[488] In creating a harmonised patent right and then allowing compulsory licensing to operate at such a national level, the EPUE specifically disincentivises adoption of the EPUE on a technology-specific basis and fragments the practical benefits of the EPUE for European innovation. Rather than simply introducing a new legal interface that is better or worse than the EPC approach that currently exists, the issue is that it introduces an additional dimension of fragmentation and uncertainty. It creates uncertainty as to the type of decisions the court will render in a more abstract sense, and uncertainty as to the approach of the national court in how strictly these TRIPS concerns (domestic market obligation) and abuse of dominant position will be interpreted with only limited capacity for input by stakeholders.

5. Conclusion

The EPUE is an important development for Europe because it represents the next level of patent cooperation and harmonisation, intended to essentially bring patents within the same functional scope as trademarks and copyright. Patent rights and intellectual property more generally have been highlighted by the EU as an important element in the future economic growth of the region[489] – particularly in light of the negative economic consequences of the COVID-19 pandemic.[490] A significant part of the EPUE, as well as the earlier CPC and the

[488] One prominent example being Hungary's use of a special legal order to facilitate compulsory licensing (specifically in relation to Remdesivir, currently under patent by Gilead): WIPO, 'Hungary: Government Decree No. 212/2020 on Public Health Compulsory Licenses for Exploitation Within Hungary' (*WIPO*, 17 May 2020) <https://wipolex.wipo.int/en/legislation/details/19883>.
[489] EPO, 'Unitary Patent Expected to Boost Trade and Investment in the EU, New Study Shows' (14 November 2017, *EPO*) <https://www.epo.org/news-events/news/2017/20171114_fr.html>.
[490] Carolina Arias Burgos and Nathan Wajsman, 'Economic Impact of COVID-19 Crisis in IPR-Intensive Industries' (May 2021, EUIPO Discussion Paper) <https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/2021_Economic_Impact_COVID19/2021_Economic_impact_of_COVID19_crisis_in_IPR_intensive_industries_study_FullR_en.pdf>.

developed harmonisation of the EPC, has been improving the competitiveness of both the European patent system and the position of SMEs specifically.[491] Fragmentation within the European patent system and the difficulty of substantively harmonising the enforcement of national patent rights has consistently distinguished the European approach to patents from that of other major jurisdictions like the US and Japan.[492]

Yet the EPUE also has a broader importance beyond what it provides in the discussion of harmonisation in European patent law. The legal structure of the EPUE reinforces the administrative nature of patent law by being specifically designed to avoid the *Meroni* doctrine. From a perspective that emphasises the administrative foundation of patent law, the chapter has developed an analysis that draws on values that typically appear in administrative law scholarship. Specifically for the development of the EPUE, the chapter focused on how participation – and how the system supports or impairs – features in European patent law. These values manifest in the development of patent law, the structure and capacity of the specialised court, and in the construction of specific patent law mechanisms. The EPUE represents the creation of a new interface in patent law, bringing together various national interests and actors in the pursuit of a harmonised legal framework.

The broader legal context also highlights the usefulness of considering the EPUE from a perspective that emphasises the interactive nature of legal frameworks. This is because, particularly in the European context, European patent law is constituted from several overlapping interfaces. The creation of a new interface within this overlapping environment highlights the importance of these contextual interactions, particularly because the existing

[491] EU Commission, 'Internal Market, Industry, Entrepreneurship and SMEs: Unitary Patent' (*EU Commission*) <https://ec.europa.eu/growth/industry/strategy/intellectual-property/patent-protection-eu/unitary-patent_en>.
[492] Specifically highlighting the cost of patent protection in the US and Japan compared to the proposed EPUE fees: Thierry Breton, 'Intellectual Property: Statement by EU Internal Market Commissioner Thierry Breton Welcoming the Provisional Application of the Unitary Patent' (19 January 2022, *EU Commission*) <https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_22_426>.

interfaces are a mix of national and international, European and global. It is in this overlap that values like participation and accountability become particularly important. The significance of the national elements of the EPUE on the broader legal context is particularly unusual because of the way that the EPUE was developed. The development of the EPUE has been driven by the Member States and has been implemented through the enhanced cooperation procedure rather than the ordinary legislative process of the EU institutions. There is a specific relationship between the use of the enhanced cooperation mechanism and the more political aspects of legislative cooperation, interesting because it was precisely due to the political difficulty of harmonisation that led to enhanced cooperation. As a result, the EPUE provides a unique example of a patent project that is framed by, but not necessarily constrained by, the EU legislative apparatus and centres the value of participation in European patent law. It provides a very visible, contemporary, example of actors coming together from different patent histories and traditions with the aim of advancing the substantive harmonisation of patent law – though the chapter interprets these developments through the lens of administrative values, and for the EPUE specifically, in terms of effective participation.

Understanding the relationship between the EU, the CJEU, and the WTO: Accountability, direct effect, and modulation

1. Introduction

Building from the work in Chapter 2 that considers the relationship between the Member States and the EU through the UPC, the focus in this chapter shifts to the borders of the EU legal order and the WTO. As with the thesis more generally, the focus here is on the more procedural aspects of WTO law rather than issues of substantive patent obligations. Intellectual property is a particularly interesting context to examine the relationship between WTO law and the CJEU because there is somewhat of a clear hierarchy between the actors involved that *should* present a clear or linear construction of accountability. This context represents a specific type of hierarchical organisation because it has not necessarily been imposed by some external force and instead came about from multilateral negotiations in trade liberalisation. Yet despite the fundamentally voluntary character of multilateral obligations, the development of the WTO dispute resolution system distinguishes it from previous trade regimes.[493] This sense of hierarchy was explicitly considered in the emergence of the modern EU legal order when the generally binding quality of international law was presented alongside a stressing of the unique constitutional arrangement of the EU.[494]

The relationship between the WTO and the EU is considered in two specific contexts here, the first of which highlights the complex legal position of the EU Member States in terms of WTO obligations. While responsibility and accountability have been raised in these contexts

[493] John F Murphy, *The United States and the Rule of Law in International Affairs* (CUP 2004) 50.
[494] Discussing briefly that the 'EU represents a unique departure in international law': Raymond J Friel, 'Providing a Constitutional Framework for Withdrawal from the EU: Article 59 of the Draft European Constitution' 53 ICLQ 407.

in academic literature, they have not been approached from a perspective that grounds them in a patent law context. An important aspect of GAL scholarship that was highlighted in chapter 1 was about what exactly accountability means in this complex global space.[495] Here, the emphasis is not necessarily on the strict sense of accountability that involves direct review by an institution that is above the implementing body in a hierarchy. Instead, the relationship between the CJEU and the WTO is considered here in terms of a more abstract accountability – when the CJEU makes decisions as to the status of WTO law, who can meaningfully question this? How does the CJEU modify the EU's accountability for binding WTO obligations? How can the CJEU be held responsible when it develops or reinterprets elements of intellectual property and their relationship to non-EU sources of law? This type of accountability actually mirrors a lot of the priorities in GAL scholarship, where the emphasis has often been on the impact of unclear or non-existent hierarchies in the international space.[496] Here, this sense of accountability is developed in a more interactive way that presents accountability as being quite fluid and subject to interpretation. The EU is in an interesting position in the WTO because it is a full member despite being a customs union,[497] yet the Member States also retained their WTO membership even as the formal institutions of the EU took over external competences in commercial policy.[498] So while this relationship appears to be simple in that it brings together the EU and the WTO, the EU position in terms of responsibility for WTO obligations is actually much more nuanced.

[495] Where 'in deploying procedural tools to promote accountability and responsiveness, GAL must confront the question of accountability and responsiveness "to whom"?': Richard B Stewart, Michelle Ratton, and Sanchez Badin, 'The World Trade Organization and Global Administrative Law' (IILJ Working Paper 2009/7) 29.
[496] Discussing the 'features of the global space, which is non-hierarchical, diffused and definable as a "fluid or liquid order": Elisa D'Alterio, 'Judicial Regulation in the Global Space' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 321.
[497] ibid 185.
[498] Rafael Leal-Arcas, 'Exclusive or Shared Competence in the Common Commercial Policy: From Amsterdam to Nice' (2003) 30(1) Legal Issues of Economic Integration 3, 4.

The second element that meaningfully shapes accountability in the relationship between the EU and the WTO is the CJEU and its approach to the legal status of WTO agreements and reports from its dispute settlement bodies. The CJEU is fundamental in producing and interpreting accountability because it has a great scope of legal autonomy and represents an example of very specific institutional interaction at the interface of EU law and non-EU law. Part of this importance derives from the interpretative monopoly that the CJEU possesses as to the precise interpretation of EU law,[499] providing a singular institution with the power to definitively construct the precise nature of EU law.[500] This scope for interpretative autonomy necessarily extends to obligations that stem from the WTO Agreements when they have been transposed into EU law, and also at a more general level when considering the relationship between WTO law and direct effect.[501] Direct effect is important for accountability and a dominant theme in the literature appears to centre on whether the CJEU considers WTO materials to have direct effect.[502] Yet in deciding on whether these sources of law have direct effect, the CJEU is essentially making a decision to either endorse the authority and legitimacy of the WTO (or of specific WTO Agreements) or reject them. This chapter suggests that, in line with a more flexible construction of accountability, what is happening is actually a contextually specific modulation of their binding quality. In this, the chapter suggests that the CJEU neither accepts or rejects outright the legal importance of WTO law and instead takes a dynamic approach that renders EU obligations as more or less binding depending on the discipline, actors involved, and specific obligation.

[499] Though argued here that it relies 'on no more than the Court's own assertion': Gareth Davies, 'Does the Court of Justice Own the Treaties? Interpretative Pluralism as a Solution to Over-Constitutionalisation' (2018) 24(6) ELJ 358, 359.
[500] Nial Fennelly, 'Legal Interpretation at the European Court of Justice' (1996) 30(3) Fordham International Law Journal 656, 673.
[501] Francesca Martines, 'Direct Effect of International Agreements of the European Union' (2014) 25(1) EJIL 129, 130.
[502] With direct effect of TRIPS 'expressly rejected' by European courts: Francis Snyder, *The EU, the WTO and China: Legal Pluralism and International Trade Regulation* (Hart 2010) 167.

Direct effect, though it would appear as only somewhat related to a technical aspect of the interface between these two spheres, is actually a fundamental element in understanding accountability as a value. The analysis here demonstrates the flexible character of accountability in practice, produced and maintained through a set of contextual interactions that create a variety of accountabilities. Binding obligations, from this contextual perspective on accountability, then exist along a spectrum from less binding to more binding. The chapter is divided into three parts, with the first focused on exploring how the relationship between EU law and WTO law is impacted by the Member States. Part 2 considers more explicitly the legal foundations of the legal relationship between the EU and the WTO, specifically on the role of direct effect and how this necessarily impacts accountability. The final part narrows the focus to the CJEU to explore how the accountability for violations of binding WTO obligations is, in practice, modulated. The chapter is aimed primarily at answering research questions 3 and 4, exploring how dispute settlement bodies facilitate the interactions of different legal systems and whether the institutional identity of the dispute settlement body meaningfully influences this process.

2. EU Member States and the WTO

2.1 *The intra-EU dynamic*

2.1.1 Positioning the EU Institutions and the Member States

When considering the legal relationship between the EU and the Member States in intellectual property, it is important to recognise the more fundamental shift towards European

centralisation more generally.[503] More recently, and perhaps as a direct result of the unsuccessful Comprehensive Economic and Trade Agreement (CETA) negotiations and the general political climate of the Europe,[504] there have been efforts to more consciously include the perspectives of Member States in the development of international agreements. Doing so, however, also raises concerns around individual EU Member States being able to undermine the EU political process more generally.[505] However, especially for provisions that deal with intellectual property, this type of stakeholder engagement is essential in ensuring that the output is considered legitimate and connects with more conventional administrative law values.[506] Yet focusing on the accountability of the output is fundamentally limited because it does not capture fully the role of the CJEU in managing the relationship between different systems of law. The CJEU is essentially engaged in a distinct process of modulation in terms of accountability for binding obligations that fundamentally impacts the relationship between EU and non-EU sources of law. This appears in both an internal and external sense that preserves autonomy at the EU level, managing the pressure or perspectives of both the Member States (internal) and the broader international community (external).

The EU responses to issues of competency and accountability shape the relationship between the EU and the WTO particularly in matters of intellectual property law. The balance between autonomy and the binding nature of international obligations is a central factor in

[503] Though the EU and the degree of centralisation is dynamic and can change over time, centralisation at the level of the EU may be difficult to reverse: Sjef Ederveen, George Gelauff, and Jacques Pelkmans, 'Assessing Subsidiarity' in George Gelauff, Isabel Grilo, and Arjan Lejour (eds), *Subsidiarity and Economic Reform in Europe* (Springer 2008) 38.
[504] 'The European Union (EU) is currently facing one of the rockiest periods in its sixty years existence. Not often in its history has the country bloc looked so economically fragile, so insecure about how to protect its borders, so divided over how to tackle the crisis of legitimacy facing its institutions, and so under assault by Eurosceptic political entrepreneurs.': Catherine E De Vries, *Euroscepticism and the Future of European Integration* (OUP 2018) 3.
[505] The Walloon Parliament's rejection of the CETA trade agreement is one particular example of this: Antonio Morelli, *Withdrawal from Multilateral Treaties* (Brill 2021) 56.
[506] Discussed prominently in the context of BITs, exploring input, output, and exit legitimacy: Santiago Montt, *State Liability in Investment Treaty Arbitration: Global Constitutional and Administrative Law in the BIT Generation* (Hart 2009) 144, 145.

navigating the traditionally strong emphasis on territoriality in patent law and the policy space that remains for countries in a post-TRIPS context.[507] Even just from a European perspective, this relationship between autonomy and international obligations is a complex legal area that significantly affects not only how the EU and the WTO institutions interact, but also the Member States themselves relate to the EU. In this relationship between the EU and the WTO, the chapter suggests that there is a 'bunching' of autonomy that enables the CJEU modulation of binding international obligations. Here, there is an increasing degree of autonomy that is preserved and a corresponding restrictiveness for both the Member States and the broader system of WTO law. While the EU reduces the autonomy of the Member States to act in many contexts, it has generally taken responsibility for WTO violations by Member States.[508] In doing so, the CJEU and its decisions on issues of WTO law work to effectively modulate how binding the provisions of WTO Agreements are on the EU and Member States. This happens because the CJEU, as a dispute settlement body and protector of EU autonomy,[509] is central in determining how exactly the legal status of a non-EU obligation is interpreted and whether it meets the criteria for direct effect. It is this process of interpretation, occurring through the necessarily narrow dispute settlement context, that enables a case-by-case consideration of each agreement.

[507] As well as whether increased policy space would even be beneficial, specifically for developing countries: Olivier Cattaneo, 'Has the WTO Gone Too Far or Not Far Enough? Some Reflections on the Concept of "Policy Space"' in Andrew D Mitchell (ed), *Challenges and Prospects for the WTO* (Cameron May 2005) 69.
[508] Pavel Šturma, 'The Responsibility of International Organizations and Their Member States' in Maurizio Ragazzi (ed), *Responsibility of International Organizations* (Brill 2013) 319.
[509] Pamela Finckenberg-Broman, *Weaponizing EU State Aid Law to Impact the Future of EU Investment Policy in the Global Context* (Springer 2022) 197.

2.1.2 Connecting autonomy, accountability, and the European interface

Policy space and its relation to autonomy also highlights the unique position that the EU occupies within the WTO framework. This is because, as an economically powerful trading bloc, it can approach these relationships in a way that it seems unlikely to be available to smaller WTO Members.[510] While autonomy does not appear as distinctly as the other values in the GAL scholarship, exploring autonomy in a European context helps illustrate how autonomy is fundamentally connected to (and perhaps enables) effective accountability, participation, and transparency. As will be discussed in terms of responsibility for trade violations, a prominent element in these discussions is the distinction between principal and agent and of which actors have the potential to correct or otherwise adjust the state of affairs that led to the violation. The way that these different understandings of autonomy are used, particularly by the CJEU, are informative for understanding how autonomy provides the scope for a flexible construction of accountability that appears in a more TRIPS-specific legal context. The CJEU, constructed in this chapter as involved in a process of modulation, is positioned in a way that its broader institutional framework provides multiple opportunities to modulate the accountability of the EU for binding legal obligations. This kind of policy space and balancing is fundamentally linked to legal concepts of autonomy, a key aspect of EU policy across multiple disciplines and time periods that appears in landmark cases that have shaped the direction of EU constitutional law.[511]

Despite this consistent presence in the development of EU law, the exact parameters of the European legal order's 'autonomy' are hard to define and Klamert has proposed three

[510] On the benefits of greater regional integration of developing countries and institutionalization to offset negotiating imbalances: Carolyn Deere Birkbeck, 'Systemic Issues for the Commonwealth Small States in the Functioning of the World Trade Organization: Options and Proposals' in Teddy Y Soobramanien and Laura Gosset (eds), *Small States in the Multilateral Trading System: Overcoming Barriers to Participation* (Commonwealth Secretariat 2015) 57.

[511] Marcus Klamert, 'The Autonomy of the EU (and of EU Law): Through the Kaleidoscope' (2017) 42(6) ELR 815; Diana-Urania Galetta, *Procedural Autonomy of EU Member States: Paradise Lost? A Study on the 'Functionalised Procedural Competence' of EU Member States* (Springer 2010) 3.

dimensions of European autonomy.[512] There are three related claims that Klamert makes about the use of autonomy by the CJEU.[513] Firstly, it is argued that autonomy refers to the substantive and institutional independence of EU actors and the EU's legislative provisions; while the second is related to the 'integrity' of the European legal order at a systemic level.[514] The third sense of autonomy is related to the way that standards and norms in the European constitutional order are developed and upheld.[515] This more developed construction of 'autonomy' takes the concept from being a simpler understanding of capability and into something more nuanced.[516] The more straightforward construction focuses on the ability of the EU or its Member States to act freely within a broader framework and protection from submitting to other legal regimes. Instead, autonomy in this more developed sense presents it as a more multi-faceted construction that can be realised to a greater or lesser degree and incorporates multiple legal and political functions.[517]

This reflects both the international law dynamic and the WTO as a potential rival legal regime as elements that contribute to the plurality of intellectual property law. Autonomy is not expressed as a binary value, and instead is found in the compromises between WTO law, international law, the EU, and the Member States that all come together to produce a workable system of accountability and responsibility. This flexible quality of autonomy also extends to accountability for obligations produced in these international contexts. These can be specific

[512] Marcus Klamert, 'The Autonomy of the EU (and of EU Law): Through the Kaleidoscope' (2017) 42(6) ELR 815.
[513] ibid.
[514] ibid.
[515] ibid.
[516] '…where paradoxically, the autonomy of EU law does not prevent its openness to incorporating binding international norms within the EU legal order': Ramses A Wessel and Steven Blockmans, 'Introduction' in Ramses A Wessel and Steven Blockmans (eds), *Between Autonomy and Dependence: The EU Legal Order Under the Influence of International Organisations* (Springer 2012) 3.
[517] 'What makes the Commission rather peculiar in the universe of both national and international bureaucracies is that it finds itself in a nexus of multiple political overseers with overlapping authority to control it. In combination with the broad range of functions the Commission is asked to perform and the important input it gets to have in the policy-making process, the multicephalous nature of the EU institutional architecture gives the Commission considerable scope for bureaucratic autonomy*'*: Antonis A Ellinas and Ezra Suleiman, *The European Commission and Bureaucratic Autonomy: Europe's Custodians* (CUP 2012) 25.

provisions of binding international agreements, the interpretation of these provisions, or even the actors that are involved. All of these elements impact just how binding these binding provisions are in practice when they are constructed (and reconstructed) in the context of dispute settlement. This type of dynamic can be observed in the development of WTO exceptions and flexibilities,[518] but also in how the relationship between the EU and Member States (particularly the CJEU) has evolved.

A typical distinction that appears in the context of European autonomy is that of internal autonomy and external autonomy.[519] This distinction presents EU law as independent from the law of the Member States in internal autonomy, and the broader independence of the EU legal regime from the frameworks of public international law as a representation of external autonomy.[520] As the development of the EU constitutional order has advanced, the distinctions between internal and external autonomy appear to have become much more permeable. This has grown to the point that some authors have rejected the relevance of this distinction at all because of the more nuanced qualities that European 'autonomy' has taken on.[521] Membership of the WTO is one of the key elements that have contributed to this breakdown between a strict internal and external autonomy if there ever was such a strict distinction between the two. This is important for understanding accountability for binding provisions of international patent law because instruments like the TRIPS Agreement highlight the flexible relationship between binding obligation, offending legislation, and dispute resolution body that together construct accountability. One visible aspect of this is that the EU and the Member States both have full

[518] Thailand is one prominent example – even with no violation of TRIPS alleged by the US, they were listed on the Special 301 Report after Thailand's compulsory licensing: Cynthia M Ho, 'Current Controversies Concerning Patent Rights and Public Health in a World of International Norms' in Toshiko Takenaka (ed), *Patent Law and Theory: A Handbook of Contemporary Research* (Edward Elgar 2008) 694, 695.
[519] Fisnik Korenica, *The EU Accession to the ECHR: Between Luxembourg's Search for Autonomy and Strasbourg's Credibility on Human Rights Protection* (Springer 2015) 83.
[520] ibid.
[521] Marcus Klamert, 'The Autonomy of the EU (and of EU Law): Through the Kaleidoscope' (2017) 42(6) ELR 816.

membership of the WTO and are therefore both bound by trade obligations. It is from this perspective that the minimising of intra-EU internal/external distinctions in autonomy has influenced the development of WTO law. In this regard, it is difficult to identify whether it is internal or external autonomy being exercised when the EU takes active responsibility for trade violations committed by the Member States. Accountability of the EU for Member State violations emerges not just from the binding provisions of an international agreement (external facing) but of a tactical assumption of accountability that necessarily subsumes the autonomy of the Member State involved with the violation (internal). Scholarship has highlighted the tension in the EU as a WTO member and responsibility,[522] yet it is this voluntary assumption of responsibility that give a much more nuanced sense of how accountability actually functions. Here, accountability is not simply a descriptive concept that establishes the relationship between two actors, but instead takes on a normative dimension that can be deployed to support specific objectives that may be more political, legal, or economic in nature. Autonomy and accountability in this context are then linked, specifically in the ability to voluntarily assume responsibility for violations of international obligations. This relationship suggests that, for accountability in its less value-neutral understanding, autonomy takes on a particularly generative quality for dispute settlement bodies.

2.2 *Autonomy in Europe: Intellectual property perspectives*

[522] Plarent Ruka, *The International Legal Responsibility of the European Union in the Context of the World Trade Organization in Areas of Non-Conferred Competences* (Springer 2017) 20.

2.2.1 Formal autonomy emerges

Three of the major cases in EU constitutional law represent manifestations of the three aspects of Klamert's autonomy and begin to sketch the qualities of the autonomy that the EU enjoys in the WTO interface.[523] The first, and foundational case, in terms of the legal autonomy in the EU is *Van Gend en Loos*.[524] Here, the EU's nature as a unique legal order distinct from an ordinary system of public international law was highlighted.[525] While *Van Gend en Loos* transformed the European legal order into one that is *sui generis* and autonomous, various international law principles were retained. Crucially, however, they were transformed through their adoption into the EU legal framework.[526] In this, the EU legal order is defined by its transformational power that contributes to the European 'identity' of these general legal concepts in the context of international law. The transformative power, and the space that enables it, is itself a process of modulation that is fundamentally similar to the more trade-specific context discussed later in the chapter.

The introduction of a patent that functions at a European, rather than national level, brings intellectual property within the transformative remit of the CJEU. While the risk of courts has raised previously in the context of EPUE and the moral exceptions to patentability,[527] it has a much broader impact than these narrow examples because it enables a more profound quality or scale of transformation. By raising patent law to this EU level, it essentially decontextualises an area of law that is connected to its domestic legal environment. In doing so, patent principles (and precedent, eventually) become distinctly European and can form the foundation of an international patent norm. In this environment, patent law undergoes

[523] Marcus Klamert, 'The Autonomy of the EU (and of EU Law): Through the Kaleidoscope' (2017) 42(6) ELR 816.
[524] Case 26/62 *Van Gend en Loos v Nederlandse Administratie der Belastingen* (1963) ECR 1.
[525] Mathieu Isenbaert, *EC Law and the Sovereignty of the Member States in Direct Taxation* (IBFD 2010) 128.
[526] Beatrice I Bonafé, 'International Law in Domestic and Supranational Settings' in Jörg Kammerhofer and Jean D'Aspremont (eds), *International Legal Positivism in a Post-Modern World* (CUP 2014) 392.
[527] Clement Salung Petersen and Jens Schovsbo, 'Decision-Making in the Unified Patent Court: Ensuring a Balanced Approach' in Christophe Geiger, Craig Allen Nard, and Xavier Seuba (eds), *Intellectual Property and the Judiciary* (Edward Elgar 2018) 233.

a similar change to the legal principles of international law in the creation of the EU in that they are reshaped, operationalised as tools to manage the relationship between EU law and non-EU law. An important caveat here, however, is that obviously the shift that patent law undergoes is of a completely different scale to the creation of the EU legal order. Even within a more patent-specific context, the EPC means that the scope of what is being considered is not particularly radical. Yet the core of what is happening, of a progressive interpretation and recreation, is similar. Though the emphasis here is on exploring the consequences of a Europeanised patent law framework, it is important to consider first how this process of Europeanisation has functioned in regard to general legal principles. Across both generalised and specialised contexts, autonomy (in its more ordinary sense) appears to 'gather' at the EU level. At the same time, this reshaping and redeployment of legal principles has a clear impact on how binding obligations can be modulated or otherwise reinterpreted. The transformation of the EU legal order specifically considered the binding quality of international law,[528] demonstrating that the autonomy and capacity to develop EU-inflected legal principles does shape how binding obligations function in practice.

In this, the process of transformation contributes to the decontextualising of these legal principles from any specific national environment and reshaping them in a way that provides an additional way of managing the influence of external sources of law. The development of autonomous concepts of law by the CJEU represents a particularly interesting example of this elevation. While the CJEU draws on the legal traditions of various Member States in producing these autonomous concepts, it necessarily represents a compromise-driven and edited perception of these practices. Major discussions within the literature specifically focus on the uneasy relationship between the CJEU, the Member States, and autonomous concepts precisely

[528] Damian Chalmers and Luis Barroso, 'What Van Gend en Loos Standards For' (2014) 12 ICON 117, 118.

because it cannot (because of the scale of the EU) ever be completely representative of European legal diversity.[529] The decisions made by the UPC, and eventually the CJEU, are necessarily engaged in establishing a functional hierarchy in terms of legal sources considered in the EPUE and present a similar opportunity to reframe or reinterpret established legal relationships and concepts. In this context, the issue is that the more structural elements of patent law are being generated through an insular system in which the CJEU will eventually be called to interpret the arrangement of international patent law sources. As Shapiro highlights in the context of technocratic legitimacy,[530] the analysis here suggests that there is only a weak sense of accountability for the development of European patent law because there appears to be no real effective response to the CJEU's interpretative developments.

The risk is that the development of 'autonomous' legal interpretations of patent principles risks detaching these from their distinctly national origins, something that patent law is particularly vulnerable to because of the continued national emphasis in both enforcement and patent grant. In international law, legal principles have been subsequently transformed further through the interpretation of the CJEU. This process centres the CJEU, as an authoritative dispute settlement body, in the transformational interpretative process.[531] This can be observed through the cases of *Francovich* and *Brasserie du Pecheur*,[532] whereby the CJEU took general principles and fashioned them in a way that suited the objectives of the European legal order. In this, direct effect and supremacy are two core principles that were

[529] While more general critique has been raised as to how representative of Member State practice an autonomous concept can be, it has also appeared in more patent-specific contexts. Walsh questions how appropriate it is for the CJEU to elevate specific terms as autonomous concepts particularly in the context of patents, morality, and embryos: Karen Walsh, *Fragmentation and the European Patent System* (Hart 2022) 153.
[530] Martin Shapiro, '"Deliberative," "Independent" Technocracy v. Democratic Politics: Will the Globe Echo the E.U.?' (2005) 68(3-4) Law and Contemporary Problems 347.
[531] One example would be the doctrinal development of *pacta sunt servanda*, where loyalty (both 'versions of the same root concept') became effective internally (to establish primacy and state liability) and externally (in restricting the unilateral capacity of Member States): Daniel Davison-Vecchione, 'Beyond the Forms of Faith: Pacta Sunt Servanda and Loyalty' (2015) 16(5) German Law Journal 1163, 1165.
[532] Joined Cases C-6/90 and C-9/90 *Andrea Francovich and Danila Bonifaci and others v Italian Republic* (1991) ECR I-5357; C-46/93 *Brasserie du Pêcheur SA v Germany* (1996) ECR I-1029.

transformed in their adoption to the EU legal framework,[533] though it is important to note that the important change with these cases is that the decisions come from the CJEU itself.[534] While this process of transformation by the CJEU can be understood in a fairly neutral way, there are significant decisions that have been criticised as presenting the CJEU as an institution that is particularly concerned with protecting its own autonomy.[535] The CJEU, in this sense, establishes its own legitimate range of action in a way that brings together concerns around legitimacy, accountability, and autonomy. This autonomy enables a flexible approach to accountability for its own actions, actions of members states, and the binding quality of national or international law in a way that undermines any sense of accountability that goes beyond a more formal construction.

2.3 *The CJEU, autonomy, and self-creation*

2.3.1 The use of general principles and subsequent transformation

The use of general principles to develop the EU legal order by the CJEU has not always been a smooth process in terms of the consistency in the legal reasoning. The effect of this approach is that the CJEU's decisions have been criticised as increasingly detached from the Treaty text which provides the foundations of the legal order.[536] For Klamert, this is not an argument that the reasoning of EU law is simply becoming increasingly detached from the

[533] Marcus Klamert, 'The Autonomy of the EU (and of EU Law): Through the Kaleidoscope' (2017) 42(6) ELR 821.
[534] Rachel A Cichowski and Alec Stone Sweet, 'Participation, Representative Democracy, and the Courts' in Bruce E Cain, Russell J Dalton, and Susan E Scarrow (eds), *Democracies Transformed? Expanding Political Opportunities in Advanced Industrial Democracies* (OUP 2006) 203.
[535] Particularly with *Opinion 2/13*, where the decision has been criticised as demonstrating a self-interested CJEU that was acting to safeguard its position within the EU legal order: Steve Peers, 'The CJEU and the EU's Accession to the ECHR: A Clear and Present Danger to Human Rights Protection' (EU Law Analysis, 18 December 2014) <http://eulawanalysis.blogspot.com/2014/12/the-cjeu-and-eus-accession-to-echr.html>.
[536] Lifted to a '*fundamental level of systemic debate*': Marcus Klamert, 'The Autonomy of the EU (and of EU Law): Through the Kaleidoscope' (2017) 42(6) ELR 818.

Treaty text but instead, it is a claim that this approach now has a systemic impact on the EU legal order.[537] Crucially though, this is a process of blurring the boundaries of Treaty text and *not* necessarily a rejection of the textual foundation. The CJEU, through its expansive or restrictive reading of obligations is modulating the EU's real-world accountability of those provisions rather than supporting an accept/reject or applicable/non-applicable binary. From this perspective, accountability (and the process by which responsibility is established) is dynamic and contextually responsive.

Klamert has referred to this as a process of self-creation,[538] which can be found throughout chapter 2 and the creation of the EPUE. The CJEU's flexible reasoning around the nature of the European legal order,[539] the legitimacy of creating property rights in the context of intellectual property and enhanced cooperation,[540] and the legitimacy in the enhanced cooperation authorisation all show that the CJEU is involved in a creative process that goes beyond simple interpretation.[541] This has also been observed in the broader context of EU constitutional law. A particularly liberal approach to general principles has meant that the CJEU appears to have adopted the approach of using one general principle to create another, subsequently applying these two principles as if they were completely distinct.[542] This is what happened in the context of *Francovich* liability (or state liability).[543] Klamert argues that the CJEU created this type of liability by using the meaning that effectiveness had come to acquire

[537] Marcus Klamert, 'The Autonomy of the EU (and of EU Law): Through the Kaleidoscope' (2017) 42(6) ELR 818.
[538] ibid 816.
[539] On the inconsistency of drawing parallels between the UPC and the Benelux Court of Justice: Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2017) 48(3) IIC 254, 270.
[540] Discussing how the *Meroni* doctrine was inapplicable and Spain's challenge was rejected: Tuomas Mylly, 'A Constitutional Perspective' in Justine Pila and Christopher Wadlow (eds), *The Unitary EU Patent System* (Bloomsbury 2015) 98.
[541] This process can also be observed in the context of the ECHR: Ondrej Hamul'ák, *National Sovereignty in the European Union: View from the Czech Perspective* (Springer 2016) 40.
[542] Marcus Klamert, 'The Autonomy of the EU (and of EU Law): Through the Kaleidoscope' (2017) 42(6) ELR 819.
[543] Joined Cases C-6/90 and C-9/90 *Andrea Francovich and Danila Bonifaci and others v Italian Republic* (1991) ECR I-5357.

(a meaning of its own, as opposed to its origin as what was effectively an application of the principle of loyalty) and appeared to be disconnected from Treaty references to legitimise its function.[544] Yet where is the accountability for the development of these principles? Specifically because *Francovich* deals with the liability of states, and therefore accountability in a more fundamental sense, there is limited potential to actually challenge how these principles work in practice. This disconnect from accountability is particularly interesting here because they are not simply radical or unusual interpretations of a textual provision, and instead extend to a new, yet equally binding, legal principle.

Intellectual property creates its own risk of this detachment and accountability because it relies on nationally grounded interpretations that have developed in distinctly national contexts. Much will depend on the eventual relationship between the UPC and the CJEU, and this will necessarily influence the broader relationship to WTO obligations. It is in this dimension that the ordinary legislative process of a pan-EU instrument would have addressed the major concerns of the UPC and the interpretative autonomy of the CJEU. It could have contributed through extensive negotiations and considerations, where at least the Treaty text would present a clear starting point in interpretation. This strong legal foundation could guide, at least somewhat, how the international representation of these provisions would interact with the WTO law and more properly construct the legal foundation to be interpreted.

Brasserie du Pecheur represented a similar type of process, though the reasoning of the CJEU was even more stark because effectiveness and loyalty were considered to be equal

[544] Marcus Klamert, 'The Autonomy of the EU (and of EU Law): Through the Kaleidoscope' (2017) 42(6) ELR 817.

elements of state liability,[545] which then created the principle of state liability itself. [546] The CJEU is clearly central in this process of transforming general principles of law into European law, and through such a process, shaping the development of the Union legal order. Even though loyalty has been constructed in the literature as a variation of *Bundestreue* and *pacta sunt servanda*,[547] these are both examples whereby principles of international law take on a modulating character.[548] Rather than being discarded by the newly autonomous legal order, they are instead transformed through adoption and used to modulate how the CJEU constructs its own role and that of other sources of law. This contributes to the breakdown in a distinction between internal and external autonomy, as well as the central role of the CJEU in managing these competing norms and systems. Though in doing so, the CJEU occupies a position in which there is only minimal accountability for how these competing norms and system are eventually arranged in practice. While international law was formally separated from EU law, what happened in reality was more of a negotiated transition that balances between competing systems. Understood from this perspective, it involved a process of adjustment (rather than the creation of entirely new principles). This is then mirrored when the EU legal order encounters other legal regimes such as the WTO, whereby the binding nature of these principles or legal concepts is modulated rather than rejected. [549] This process, relying on the strong legal

[545] Reflecting principles 'inherent in the Community legal order which form the basis for State liability' that include 'the full effectiveness of Community rules and the effective protection of the rights which they confer and, second, the obligation to cooperate imposed on Member States by Article 5 of the Treaty': Paragraph 39, C-46/93 *Brasserie du Pêcheur SA v Germany* (1996) ECR I-1029; Marcus Klamert, *The Principle of Loyalty in EU Law* (OUP 2014) 271.
[546] ibid.
[547] Marcus Klamert, 'The Autonomy of the EU (and of EU Law): Through the Kaleidoscope' (2017) 42(6) ELR 821.
[548] Specifically in the context of *Bundestreue*, Lanceiro presents it as not establishing a new relationship but instead a legal principle with the capacity to 'support, modify or limit the respective powers and duties within the existing legal relationship': Rui Tavares Lanceiro, 'The Implementation of EU Law by National Administrations: Executive Federalism and the Principle of Sincere Cooperation' (2018) 10(1) Perspectives on Federalism 90.
[549] '…a brief consideration of concrete situations shows that beyond clear-cut positions in favour of or against the direct effect of WTO obligations, it is possible to detect some nuances and a grey area where things move softly from a total lack of direct effect to indirect effect or limited exceptions to the denial of direct effect.':

autonomy of the CJEU, insulates the EU institutions from provisions that would otherwise be clearly binding. In doing so, understanding accountability from this more dynamic perspective highlights how responsibility takes on a flexible character through the exercise of autonomy.

2.3.2 Contextualising this process of legal transformation

Autonomy, more broadly, then has went through several transformations, from the *Van Gend en Loos* justification for the development of an independent legal order to the *Opinion 2/13* construction.[550] This process has preserved less an idea of strict legal autonomy, and instead something more abstract around the protection of the EU's institutional integrity.[551] The worrying trend in the development of autonomy and its increased prominence places it squarely in the territory of the principles of effectiveness and loyalty.[552] By relying on these general principles on law and allowing the CJEU to effectively create and re-create interpretations and permutations of these principles, the accountability for their actual content becomes obscured. In intellectual property contexts, there would be particular concerns around any legal challenges that are the result of technological development – precisely because they emphasise a process of adaptation and creation that centres the role of the dispute settlement body. The autonomy and scope of action that is available to the dispute settlement body, though particularly when considering the CJEU, seems to lack any effective accountability for the way in which European patent law develops (other than legislative initiatives, which the EPUE has already demonstrated to be particularly difficult). There is no easy response or mechanism that

Hélène Ruiz Fabri, 'Is There a Case – Legally and Politically – for Direct Effect of WTO Obligations?' (2014) 25 EJIL 151, 153.

[550] Koen Lenaerts and José A Gutiérrez-Fons 'A Constitutional Perspective' in Robert Schütze and Takis Tridimas (eds*), Oxford Principles of European Union Law* (OUP 2017) 106.

[551] ibid.

[552] Marcus Klamert, 'The Autonomy of the EU (and of EU Law): Through the Kaleidoscope' (2017) 42(6) ELR 829.

would remedy this lack of accountability – especially given the importance of judicial independence in Europe and as a practical element of the separation of powers.[553] Yet there is a tension here because the CJEU has demonstrated, discussed throughout this section, a particularly active approach to a more creative or generative process of interpretation that lacks any real oversight. Accountability does not necessarily mean introducing a system of review for CJEU decisions, but instead could be realised through a more transparent system of dialogues with stakeholders in European law and beyond.

Yet it is far from clear that this expansive and disruptive role of the CJEU is an inevitable development in European patent law. The reality is that the CJEU has, so far, taken a generally minimal role in the development of substantive patent law in the EU and this gradual harmonisation has been driven by a mixture of instruments and institutions.[554] The EPC is perhaps the most obvious here, significant because of its complex relationship with EU-based instruments while it was being developed,[555] though the EPO has also been prominent in driving harmonisation because of its central nature in dealing with European patent filings.[556] The expertise within the EPO is also interesting because the practice and interpretations that emerge from its Board of Appeal are considered by national courts and patent offices.[557] The potential for the CJEU to meaningfully shape the development of patent law in Europe requires

[553] The importance of judicial independence and the separation of powers more broadly was recently raised in the C-192/18 *Commission v Poland*, specifically concerning the function of Article 19(1) TEU on the rule of law.

[554] Though the CJEU has been involved significantly with the jurisprudence around biotechnology: Luke McDonagh, 'UK Patent Law and Copyright Law after Brexit: Potential Consequences' in Oonagh E Fitzgerald and Eva Lein (eds), *Complexity's Embrace: The International Law Implications of Brexit* (Centre for International Governance Innovation 2018) 181.

[555] Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2017) 48(3) IIC 254.

[556] The EPO have highlighted in their own materials how they contribute to simplifying patent applications and how cooperation between national patent offices (though specifically the IP5) is an important project: EPO, 'Driving Harmonisation for the Benefit of Applicants' (2013) <https://www.epo.org/about-us/annual-reports-statistics/annual-report/2013/global-harmonisation.html>.

[557] While there is certainly an important relationship between the EPO expertise and national patent offices, there appears to be a diversity in how this relationship is perceived. Drahos writes that there is a wide spectrum of opinions – ranging from a broad distrust of the EPO (the UK) to an understanding that sees the EPO as a form of competition (with offices designated as ISAs under the PCT): Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (CUP 2010) 132.

both the enabling space (the broad autonomy of the CJEU in EU law) *and* an institutional dynamic that provides the opportunity for this type of active engagement. We have established that CJEU may have the theoretical space to take a particularly creative approach to law and legal principles, but to what degree does the relationship between the WTO and the CJEU provide opportunities for the *exercise* of this autonomy and how does it affect binding WTO obligations?

3. The EU And the WTO

3.1 *Legal basis and relationship*

3.1.1 Exploring the early entanglement

Institutions can exert an influence on one another even without explicit coordinated action, meaning that when specific institutions are reformed, the impact on surrounding infrastructure and the processes through which they interact are important considerations.[558] The EU and the WTO are both involved in a sort of de facto process of dialogue as prominent organisations in the international intellectual property environment, where it is this sense of perception and authority that shape some contextual challenges to accountability. Intellectual property is a particularly complex subject from an institutional perspective, incorporating economic, legal, political, and social elements into the structure of property across multiple independent institutions.[559] Within the broader context of the EU, the system of checks and

[558] Nari Lee and Liguo Zhang, 'Specialized IP Courts in China – Judicial Governance of Intellectual Property Rights' (2017) 48(1) IIC 901, 902.
[559] Hanoch Dagan, 'Judges and Property' in Shyamkrishna Balganesh (ed), *Intellectual Property and the Common Law* (CUP 2013) 28.

balances can be seen as an attempt to mitigate the negative impact of such institutional dynamics.[560] The EU represents a prominent example of this as an '*integrated yet incomplete governance project*',[561] though it is perhaps in this incomplete nature that enable such a flexible quality in accountability and responsibility that centres the role of dispute settlement bodies.

The EU, despite its impressive reach now, has its origin firmly in the development of trade.[562] From this, it has become the most successful project of regional integration that relies on a legal framework with an essentially federalist structure.[563] The EU provides a clear example of the type of legal developments that can flow from the establishment of cooperation on the issue of trade, and represent de facto influences on other frameworks of economic or trade cooperation. This is tempered somewhat with discussions around whether the EU is actually model of international integration or whether its development has been so historically and economically unique that it could not be repeated.[564] For the EU, the approach to ensuring compliance with the WTO trade framework has been constructed as a method of extending or 'projecting' its norms into the international legal context.[565] Rather than an additional or incidental aspect in how the WTO legal regime has developed, the positioning of the EU to be

[560] Alison L Young, *Democratic Dialogue and the Constitution* (OUP 2017) 179.
[561] The problem of checks and balances is perhaps more evident in the EU as an integrated yet incomplete governance project: Nari Lee and Liguo Zhang, 'Specialized IP Courts in China – Judicial Governance of Intellectual Property Rights' (2017) 48(1) IIC 901, 903; Ernst-Ulrich Petersmann, 'Multilevel Judicial Protection of "Rule of Law" in Transnational Regulation Requires "Struggles for Justice"' in Fabrizio Cafaggi (ed), *Enforcement of Transnational Regulation: Ensuring Compliance in a Global World* (Edward Elgar 2012) 182.
[562] Dora Borbély, *Trade Specialisation in the Enlarged European Union* (Springer 2006) 5.
[563] Institutional features of EU federalism: Bojan Kovacevic, *Europe's Hidden Federalism: Federal Experiences of European Integration* (Taylor & Francis 2017) 143; Piet Eeckhout, 'The EU and its Member States in the WTO: Issues of Responsibility' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006).
[564] Piet Eeckhout, 'The EU and its Member States in the WTO: Issues of Responsibility' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 449.
[565] Alasdair R Young, 'Effective Multilateralism on Trial: EU Compliance with WTO Law' in Spyros Blavoukos and Dimitris Bourantonis (eds), *The EU Presence in International Organisations* (Routledge 2010) 124).

able to export its norms appears to be a clear and conscious decision that sometimes operates to the detriment of its immediate economic interests.[566]

The shifts of recent decades in the US undermining the functioning of the WTO also demonstrates the reciprocal nature of EU/WTO participation and support. The WTO, with its participants and not 'Member States' and limited autonomy of the Secretariat,[567] relies on the participation of prominent global trade actors for its effectiveness and this impacts the dynamic between the WTO and its Participating Members. Accountability in the context of the WTO therefore takes on a distinct quality which appears quite specific to this institutional and legal environment. Though not to the same degree as under the GATT pre-WTO,[568] the accountability for trade violations in the WTO system is fundamentally premised on a voluntary consent to being held accountable. The evolving nature of the COVID-19 pandemic has highlighted that the true danger for the WTO, far beyond the periods of criticism that both the US and the EU have been involved with,[569] is inconsistency. Without a national population, the changing tides of support for the WTO (and the ease with which it can be undermined) demonstrate the fundamental instability of these international initiatives. These organisations are reliant on consistent political support, even when they are trade-focused and avoid more controversial areas of law such as immigration or human rights. Accountability and responsibility in this type of institutional dynamic then reflect the complexity of these values more fundamentally. While a sense of formal accountability and responsibility are created in

[566] Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 42.
[567] 'Thus, the emphasis is on the WTO being a "member-driven" organization.': Richard Blackhurst, 'The Capacity of the WTO to Fulfil Its Mandate' in Anne O Krueger (ed), *The WTO as an International Organization* (University of Chicago Press 1998) 41.
[568] For academic contextualization of the importance of the GATT being a 'member-driven organization' (and specifically the impact of the US): Ernst-Ulrich Petersmann, 'Multilevel Judicial Governance of International Trade Requires a Common Conception of Rule of Law and Justice' in William J Davey and John Jackson (eds), *The Future of International Economic Law* (OUP 2008) 93.
[569] The US is a particularly clear example, even with its historically contentious relationship with some international agencies (like UNESCO), with its rapidly changing position on the WHO: Cosmas Emeziem, 'COVID-19 Pandemic, the World Health Organization, and Global Health Policy' (2021) 33(2) Pace International Law Review 192, 197, 198.

the adoption of binding WTO obligations, *actual* accountability for these provisions relies on something more sustained. The EU, and more specifically the CJEU, provides an example of this flexible distinction between formal and practical accountability through the legal status of the WTO Agreements.

3.2 *Direct effect of WTO Agreements*

3.2.1 Exploring the direct effect decisions

The *Kupferberg* approach of the 1980s continues to define the EU's approach to direct effect,[570] and it is in this that the EU's protectionist approach to the integrity of the EU legal order and the internal market can be seen most clearly. While the issue of direct effect has been discussed extensively in terms of the protection of the internal market and the integrity of the EU legal order,[571] the thesis approaches this area of jurisprudence from the perspective of accountability and dynamic modulation. This type of approach presents the direct effect jurisprudence as a way of modulating the binding quality of international law (or at least non-EU sources of law) rather than simply a way of protecting the integrity of the EU legal system. From this perspective, decisions on direct effect function to make the EU more or less accountable in a way that depends on the discipline, the actors involved, and the sources of law concerned. The tension here is that many international agreements have direct effect, and yet this is not the case when they originate from within the WTO system. An important

[570] Case 104/81 *Hauptzollamt Mainz v C.A. Kupferberg* [1982] ECR-3641; Eleftheria Neframi, 'Mixed Agreements as a Source of European Union Law' in Enzo Cannizzaro, Paolo Palchetti, and Ramses A Wessel (eds), *International Law as Law of the European Union* (Martinus Nijhoff 2011) 338.
[571] On the tensions that have emerged in academic discourse around direct effect as an expression of uniformity (specifically in terms of a legal order's integrity and coherence): Pavlos Eleftheriadis, *A Union of Peoples* (OUP 2020) 140.

qualification however, particularly given the diversity of EU Member States,[572] is that an assumption of direct effect also relies on an monist legal structure.[573] This is complicated further by the role of each state's approach to procedural rules on standing (particularly for individuals) and mean that issues of direct effect are not uniform internationally.[574] The CJEU has shown that it will generally accept that international agreements that have been negotiated and implemented through the EU structure have direct effect in the Union legal order.[575] This was the general approach that came from the *Kupferberg* jurisprudence and continues to set the tone for determining direct effect in this context. In fact, the CJEU has shown itself to be very willing to grant direct effect to other international agreements,[576] which makes the refusal in the context of the WTO (and its predecessor, the GATT), much more striking.

Though importantly, the disputes that have emerged on direct effect (or direct application) outside of a WTO or GATT context have generally been agreements that establish close ties (such as developmental cooperation or association).[577] As such, these were framed specifically as private individuals aiming to enforce some right provided for in an agreement (rather than an abstract or more general claim).[578] Greece,[579] Turkey,[580] and Morocco are all

[572] With both monist and dualist systems: Andrea Ott, 'Multilevel Regulations Reviewed by Multilevel Jurisdictions: The ECJ, the National Courts and the ECtHR' in Andrea Follesdal, Ramses A Wessel, and Jan Wouters (eds), *Multilevel Regulation and the EU: The Interplay Between Global, European and National Normative Processes* (Brill 2008) 346.
[573] Such as France: Eva Steiner, *French Law: A Comparative Approach* (2nd edn, OUP 2018) 6, 7; and Switzerland: Thomas Fleiner, Alexander Misic, and Nicole Töpperwien, *Swiss Constitutional Law* (Kluwer 2005) 43.
[574] Fernando Pastor-Merchante, 'The Private Enforcement of State Aid Law' in Leigh Hancher and Juan Jorge Piernas López (eds), *Research Handbook on European State Aid* Law (2nd edn, Edward Elgar 2021) 238.
[575] Marc Maresceau, 'The Court of Justice and Bilateral Agreements' in Allan Rosas, Egils Levit and Yves Bot (eds), *The Court of Justice and the Construction of Europe: Analyses and Perspectives on Sixty Years of Case-Law / La Cour de Justice et la Construction de l'Europe: Analyses et Perspectives de Soixante Ans de Jurisprudence* (Springer 2012) 716.
[576] Michelle Q Zhang, 'Shall We Talk? Judicial Communication Between the CJEU and WTO Dispute Settlement' (2017) 28(1) EJIL 273, 276.
[577] Francesca Martines, 'Direct Effect of International Agreements of the European Union' (2014) 25(1) EJIL 138.
[578] ibid 138, 139.
[579] Case 17/81 *Pabst & Richarz* (1982) ECR 1331
[580] Case 12/86 *Demirel v Stadt Schwäbish Gmünd* (1987) ECR 3719.

examples of parties to Association Agreements where the CJEU has supported direct effect.[581] The CJEU in *Kupferberg* established what was essentially a presumption in favour of direct effect in international agreements that are being incorporated into the EU legal order, where it would take a specific deficiencies provisions to be excluded from direct effect.[582] So when the *Kupferberg* decision was made, it was not necessarily the introduction of a revolutionary change to the construction of direct effect. Instead, the GATT was the single exception to direct effect of EU international agreements.[583]

One of the landmark cases in terms of the GATT and the justification of the CJEU refusing direct effect was *International Fruit*.[584] This case would later be criticised extensively for the apparent deficiencies in the Court's reasoning,[585] and it developed further the principles that first appeared in *Kupferberg*.[586] In this case, the CJEU found that the GATT was considered to be too flexible to be afforded direct effect in the EU framework.[587] The denial of direct effect in *International Fruit* extended to the WTO, where again, flexibility was seen as the root that prevented these agreements from having direct effect in the European context.[588] The criticism that emerged from this decision to deny direct effect focused on both the legal reasoning that was used,[589] but also in the lack of attention that was paid to the differences

[581] Case C-18/90 *Kziber* (1991) ECR I 99; though see more generally on the practical opposition of granting direct effect to WTO Agreements because of the distinct nature of multilateral agreements: Francis Snyder, 'Constructing Multi-Site Governance: WTO Law in the European Courts' in Sonja Puntscher Riekmann, Monika Mokre, and Michael Latzer (eds), *The State of Europe: Transformations of Statehood from a European Perspective* (Campus 2004) 313.
[582] Case 104/81 *Hauptzollamt Mainz v C.A. Kupferberg* (1982) ECR-3641.
[583] Robert Schütze, *European Constitutional Law* (CUP 2015) 110.
[584] Joined Cases 41 to 44-70 *NV International Fruit Company and others v Commission of the European Communities* (1971) ECR 411.
[585] Mario Mendez, *The Legal Effects of EU Agreements* (OUP 2013) 178.
[586] ibid.
[587] Servaas van Thiel and Armin Steinbach, 'The Effect of WTO Law in the Legal Order of the European Community: A Judicial Protection Deficit or Real-Political Solution, or Both?' in Michael Lang, Judith Herdin, and Ines Hofbauer (eds), *WTO and Direct Taxation* (Kluwer 2005) 59.
[588] Thomas Cottier, *The Challenge of WTO Law: Collected Essays* (Cameron May 2007) 292.
[589] William Phelan, *Great Judgments of the European Court of Justice: Rethinking the Landmark Decisions of the Foundational Period* (CUP 2019) 131.

between the WTO framework and the GATT framework (specifically in the significant judicialisation that the system underwent in its transition).[590]

The GATT 1947 has been criticised for its numerous exceptions and the approach to grandfathered trading exceptions,[591] creating (and endorsing) a framework that provides multiple constellations of obligations for existing GATT members and prospective new members moving forward.[592] It is clear therefore that in managing the plurality of the international framework – in both intellectual property and in law generally – that the CJEU has a central role in managing these competing influences, choosing which to legitimise and which to try and minimise the disruptive impact of. In isolation, this is not a particularly controversial or important decision by the CJEU as it is entitled to take notice of these criticisms.[593] Yet even with the transformation of the WTO and the creation of the DSB,[594] the CJEU still avoided the issue of direct effect (criticising the lower court in failing to distinguish between direct effect of the WTO Agreements and the Panel reports) in *Biret* and decisively rejecting it in *FIAMM*.[595] Here, there is clearly something that distinguishes the WTO Agreements and the extent of those obligations from other, non-EU sources of law. By refusing to give these sources of law direct effect, the CJEU establishes a space in which the binding obligations of the WTO Agreements are subject to interpretation and casts the EU's accountability for these obligations in a flexible way. The WTO provisions are then at once binding and non-binding in a way that can be adjusted and interpreted. This undermines even

[590] Piet Eeckhout, *A Panorama of Two Decades of EU External Relations Law* (OUP 2008) 330.
[591] John H Jackson, *Sovereignty, the WTO, and Changing Fundamentals of International Law* (CUP 2006) 96.
[592] ibid.
[593] While specifically in the context of GATT and national security exception, considered a 'catch-all clause' and an easily exploited flexibility to justify violations: Krzysztof J Pelc, *Making and Bending International Rules: The Design of Exceptions and Escape Clauses in Trade Law* (CUP 2016) 3.
[594] John Errico, 'The WTO in the EU: Unwinding the Knot' (2011) 44 Cornell International Law Journal 187.
[595] Case C-94/02 *Établissements Biret et Cie SA v Council* (2003) ECR 10565; Joined Cases C-120/06P and C-121/06P *Fabbrica Italiana Accumulatori Motocarri Montecchio SpA v Council* (2008) ECR 6513; though see generally for a discussion on AG Alber, *Biret*, and FIAMM: ibid 188, 189.

the symbolic dimensions of accountability that would be supported with a more straightforward approach to direct effect.

3.2.2 Is direct effect really that significant?

Regarding the broader context of these decisions, there have been suggestions in the literature that focusing too much on the issue of direct effect (and its denial for the WTO and GATT) can unnecessarily narrow the understanding of the status of WTO norms in the EU.[596] While the WTO obviously has a wider impact than the issue of direct effect, it perhaps more important because it provides the space in which a generalised interpretative tool can be used to create distance between binding obligations and EU accountability. While the focus on how the CJEU has restricted direct effect in the WTO context and should not obscure the normative potential of WTO law and decisions, the issue of direct effect is entirely central to understanding how the CJEU manages its interactions with other legal regimes. The distancing in this sense is a modulation, rather than a simple rejection or acceptance, of the legitimacy or authority of the legal system under consideration. The significance of denial of direct effect is apparent in several circumstances, most of which pertain to the enforcement of EU obligations. There also appears to be an element of direct effect scholarship that reflects the type of discussions of legitimacy and transparency that emerged in a GAL context.[597] The EU and the CJEU rejecting the inconsistencies in the jurisprudence and giving the WTO Agreements direct effect would present a symbolic restatement of the binding quality of these provisions (and of the accountability of the EU to these obligations).

[596] Sungjoon Cho, *The Social Foundations of World Trade* (CUP 2014) 191.
[597] On the 'symbolic' dimension of specific GAL values: Laurence Boisson de Chazournes, 'Changing Roles of International Organizations: Global Administrative Law and the Interplay of Legitimacies' (2009) 6(2) International Organizations Law Review 659.

The CJEU rejects the idea that WTO law can be used as a basis to question validity or legality of norms in the context of EU law.[598] At this foundational level, this essentially insulates the EU from accountability for obligations that it has voluntarily adopted. However, where EU legal provisions can be read in conformity with WTO law, the court is expected to do so and therefore there is no explicit conflict between the legal regimes.[599] *Commission v Germany* considered this issue specifically in the context of EU secondary law, deciding that they must be interpreted in a manner that is consistent with international law obligations.[600] In this manner, the EU's approach to incorporating WTO law when already in conformity with (or at least when not in conflict) EU law reflects other legislative approaches to interpretative activities.[601] This method of managing competing regimes of principles and norms through the interpretative space means that they do not come into actual conflict. By doing so, they avoid ever being placed into a direct hierarchical structure where one system is placed above the other. This preserves the autonomy to modify or otherwise change the approach if it becomes appropriate, but actually protects a degree of autonomy for both parties involved to construct a more flexible approach to accountability and responsibility. This is then not an outright rejection of the accountability of the EU for WTO obligations, but a modulation that comes from the specific contextual elements involved and the central role of the dispute settlement body involved.

The CJEU refused to address the issue of direct effect in the case of *Hermès*, where the emphasis was shifted back to the role of the national courts.[602] Here, the CJEU decided that

[598] Plarent Ruka, *The International Legal Responsibility of the European Union in the Context of the World Trade Organization in Areas of Non-Conferred Competences* (Springer 2017) 127.
[599] Jan Klabbers, 'Straddling the Fence: The EU and International Law' in Anthony Arnull and Damian Chalmers (eds), *The Oxford Handbook of European Union Law* (OUP 2015) 66.
[600] C-195/95 *Commission v Germany* (1998) ECR I-5449.
[601] Helen Fenwick, Roger Masterman, and Gavin Phillipson, 'The Human Rights Act in Contemporary Context' in Helen Fenwick, Gavin Phillipson, and Roger Masterman (eds), *Judicial Reasoning under the UK Human Rights Act* (CUP 2007) 15.
[602] Case C-53/96 *Hermés v FHT* [1998] ECR I-3603.

they were to interpret the procedural rules in a way that complies with Article 50 of the TRIPS Agreement.[603] *Dior* took the same approach as *Hermès*,[604] though the CJEU were much more explicit in their reasoning as to the relationship between international law, direct effect, and the central role of national courts in giving effect to the interpretative obligation.[605] The CJEU in *Dior* distinguished between the Member States interpreting their national legislation in a manner that is consistent with international obligations[606] – which is an EU obligation and therefore originates within the EU legal order[607] – and WTO law provisions having direct effect.[608] The obligation for consistent interpretation is one of the clearer examples of modulation, rather than outright rejection or acceptance, in this context. Some authors, however, have contended that it would have made more sense to simply grant the TRIPS Agreement direct effect because without it, consistent interpretation does nothing to remedy a piece of national legislation that violates the TRIPS provisions.[609]

The reference to national legislation is important because it highlights that the impact of direct effect would have on the autonomy, and therefore accountability, at the EU level. By ensuring Member State compliance with provisions outside of the EU system, it reduces the

[603] Alan Dashwood, 'Preliminary Rulings on the Interpretation of Mixed Agreements' in David O'Keeffe (ed), *Judicial Review in European Union Law: Essays in Honour of Lord Slynn* (Kluwer 2000) 172.
[604] Joined Cases C-300/98 and C-392/98 *Parfums Christian Dior SA v Tuk Consultancy BV* [2000] ECR I-11307.
[605] 'Indeed, there appears to be no justification at all for requiring the national courts or even national administrative authorities – when applying the provisions of agreements to which essentially only the Member State, and not the Community, is party – to apply the Court's interpretation rather than their own or, possibly, that of a WTO body.': paragraph 42, Joined Cases C-300/98 and C-392/98 *Parfums Christian Dior SA v Tuk Consultancy BV* (2000) ECR I-11307.
[606] Paragraph 25, ibid.
[607] Michelle Q Zhang, 'Shall We Talk? Judicial Communication Between the CJEU and WTO Dispute Settlement' (2017) 28(1) EJIL 273, 285.
[608] Tobias Lock, *The European Court of Justice and International Courts* (OUP 2015) 108.
[609] 'If a provision of national law is incompatible with a directly effective provision of TRIPS, the national provision does no longer display effects. However, if a TRIPs provision does not have direct effect, the principle of consistent interpretation does not expunge the effects of a provision of national law incompatible with that TRIPS provision. Thus, granting direct effect would have been the better option than the principle of consistent interpretation if expressing primacy of TRIPS over national legislation was intended.': Sabina Nüesch, *Voluntary Export Restraints in WTO and EU Law: Consumers, Trade Regulation and Competition Policy* (Peter Lang 2010) 130.

autonomy of the CJEU to interpret the bounds of these provisions and minimise them. The denial of direct effect, even when it would have been an obvious choice in *Dior*, is a preservation of the legal space that enables interpretation to modulate the impact of external sources of law and accountability for these obligations. Viewed from this perspective, the inconsistencies in the legal position as to the status of international law (and the WTO Agreements more specifically) function as a flexibility that enables a more contextual approach to EU accountability. This allows, depending on the objective, the interactions with the EU legal order to alternatively be framed as an issue of international law or a national issue (like with *Hermès*). This emphasis on context allows the same obligation to be interpreted differently in a way that then influences the binding quality of these provisions. Accountability and responsibility are then not general values or qualities of a legal framework but are instead produced by (and in) contextually specific interactions between actor, legislation, and dispute settlement body. The EPUE is very important in terms of exploring the flexible approach to responsibility and liability (as well as direct effect) precisely because it came from the Member States themselves and challenges the clarity of the decision in *Dior*. It also underscores the dramatic nature of using enhanced cooperation to attempt the creation a property right, particularly as it blurs the relationship between national and international so profoundly. In doing so, it provides a degree of uncertainty as to the question of responsibility and a correspondingly large space for the interpretative autonomy of dispute settlement bodies. Yet coexisting systems in European intellectual property (particularly with trademark and design rights) are not a new development and have hardly resulted in dramatic legal uncertainty.[610] What distinguishes the current state of patent law, however, is the development of the EPUE.

[610] And the harmonisation of design rights and trademark actually facilitates, specifically in terms of cross-border enforcement, the empowerment of rights-holders across the EU: Olivier Vrins and Marius Schneider, 'Cross-Border Enforcement of Intellectual Property: The European Union' in Paul Torremans (ed), *Research Handbook on Cross-Border Enforcement of Intellectual Property* (Edward Elgar 2014) 167, 168.

In exposing the artificial nature of the distinction presented in *Dior* and how this reasoning can be essentially deployed to reach opposing conclusions, the EPUE highlights just how influential the role of the dispute settlement body is for constructing accountability.

3.3 *The WTO Agreement as a mixed agreement*

3.3.1 The initial development of responsibility in the WTO Agreements

The WTO Agreement is a mixed agreement in that both the Member States and the EU itself are both parties, confirmed by the CJEU in *Opinion 1/94*.[611] While this legal arrangement of membership for the EU and the Member States appears to be highly irregular, the ordinary functioning of the WTO seems to obscure any (if there are any to be obscured) of the differences resulting from this mixed membership.[612] Exploring the tensions in mixed agreements is important because it so closely related to the issue of accountability and responsibility. Part of what obscures the mixed nature of the agreement is that action by individual Member States in the EU is very uncommon,[613] with the EU participating in a variety of international organisations either as a full participant or with observer status (though full participation remains uncommon).[614] The EU generally participates in the WTO like a single state where the Commission takes over the role of negotiator and Council of Ministers

[611] Eleftheria Neframi, 'Mixed Agreements as a Source of European Union Law' in Enzo Cannizzaro, Paolo Palchetti, and Ramses A Wessel (eds) *International Law as Law of the European Union* (Martinus Nijhoff 2011) 351.
[612] Specifically, in reference to the Common Commercial Policy and the competence required for the agreement to not be mixed: Henri de Waele, *Legal Dynamics of EU External Relations: Dissecting a Layered Global Player* (Springer 2017) 86.
[613] Piet Eeckhout, 'The EU and its Member States in the WTO: Issues of Responsibility' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 450.
[614] Simon Duke, 'Form and Substance in the EU's Multilateral Diplomacy' in Knud Erik Jørgensen and Katie Verlin Laatikainen (eds), *Routledge Handbook on the European Union and International Institutions: Performance, Policy, Power* (Routledge 2013) 19.

represent political interests.[615] What we see here is the adoption of ordinary national roles by EU institutions, while minimising the space in which national actors can participate. The WTO system for dispute settlement is one of the more important elements that the WTO introduced, where the obligations agreed in the international agreements can (and regularly are) enforced.[616] This becomes of increasing importance when considering the broad scope and general expansion of WTO law, where the disputes clearly go beyond mere trading obligations and work to establish the WTO as an important international legal forum for disputes.[617] The unique position of the EU as a Member of the WTO (along with the EU Member States) also raises issues for liability in terms of WTO obligations in the absence of a clear division of responsibility.[618] This is concerning because it would have been clear at the point of accepting the independent membership of the EU and the Member States that the apportionment of responsibility would be an issue that needs to be addressed, though it remains an issue today as COVID-19 continues to challenge the functioning of patent law and relationship between the EU and Member States.[619] So even at this general level, without considering the CJEU jurisprudence, there appears to be a significant lack of clarity regarding how responsibility for WTO violations is assigned.

In the absence of guidance as to who would be responsibility for the WTO violations and the increasingly contentious behaviour of EU Member States such as Hungary and

[615] 'In negotiations the Commission is the only member of the EU delegation to speak, although national officials from member governments are present in formal negotiations. This is the case for topics on which the EU has competence, as well as in trade negotiations in which there is mixed or member-state competence.': Stephen Woolcock, 'Trade Policy: A Further Shift Towards Brussels' in Helen S Wallace, Mark A Pollack, and Alasdair R Young (eds), *Policy-Making in the European Union*, (OUP 2010) 388.
[616] '[about the dispute resolution mechanisms] …this mechanism has improved and become one of the most successful conflict resolution systems in the international community.': Sherzod Shadikhodjaev, *Retaliation in the WTO Dispute Settlement System* (Kluwer 2009) 2.
[617] ibid.
[618] Plarent Ruka, *The International Legal Responsibility of the European Union in the Context of World Trade Organisation in Areas of Non-Conferred Competences* (Springer 2017) 108.
[619] One prominent example of a potential TRIPS dispute would be Hungary's use of a special legal order to facilitate compulsory licensing (specifically in relation to Remdesivir, currently under patent by Gilead): WIPO, 'Hungary: Government Decree No. 212/2020 on Public Health Compulsory Licenses for Exploitation Within Hungary' (*WIPO*, 17 May 2020) <https://wipolex.wipo.int/en/legislation/details/19883>.

Poland,[620] the present environment provides a great deal of uncertainty as to what limits the EU would accept on Member State responsibility for WTO violations. Accountability in this environment becomes particularly dynamic and politically responsive, highlighting the potentially fragile construction of responsibility and how it is assigned. Yet without an expansive approach to responsibility, the EU loses one of the main ways that it participates in the international trade environment and performs its internal modulation of WTO law. The issue of responsibility was eventually addressed the CJEU itself in respect of the WTO Agreement, where it was split along its annexes in terms of exclusive and shared competencies.[621] Agreements pertaining to trade in goods were considered to be an exclusive competence of the EU,[622] while both GATS and TRIPs were considered to be a shared competence and therefore within the scope of Member State and EU action.[623] While this could have been remedied from the outset with a more comprehensive agreement regarding the obligations and expectations of the EU and the Member States, it presents a space where the CJEU can develop its own approach as to the how the WTO and EU can interact. Certainly, this provides a degree of clarity on the issue of responsibility. Yet it also reveals a clearer sense of what substantive accountability actually is. The chapter suggest that accountability, just as it was discussed in the context of the WTO earlier, is essentially co-constructed by the CJEU, the WTO, and the Member States and emerges in practice from these interactions.

[620] Like that of Hungary and CEU: Andrew Ryder, *The Challenge to Academic Freedom in Hungary: A Case Study in Authoritarianism, Culture War and Resistance* (de Gruyter 2022) 53; also Poland's rule of law crisis in the judiciary: Aleksandra Kustra-Rogatka, 'An Illiberal Turn or a Counter-Constitutional Revolution? About the Polish Constitutional Tribunal Before and After 2015' in Martin Belov (ed), *Courts and Judicial Activism Under Crisis Conditions: Policymaking in a Time of Illiberalism and Emergency Constitutionalism* (Routledge 2021) 100, 101.

[621] Joni Heliskoski, 'The "Duty of Cooperation" Between the European Community and its Member States within the World Trade Organisation' in *The Finnish Yearbook of International Law* (Martinus Nijhoff 1997) 67.

[622] *Opinion 1/94* 52, 85.

[623] Only cross-frontier supplies were covered by Article 113 (international transport agreements are excluded) and 'it follows that competence to conclude GATS is shared between the Community and the Member States': ibid 53, 74, 75 98; and TRIPS: ibid 105.

3.3.2 Further developments in WTO mixity

Parliament v Council centred on the dimensions of the Lomé IV Convention, highlighting that unless the international agreement directly points to the contrary, liability under a mixed agreement is held by both the Member States and the EU.[624] This is an important starting point because it provides an explicit basis for understanding responsibility and liability. The majority of literature adopts the same approach as *Parliament v Council*, whereby the Member States and the EU are considered to be jointly liable for obligations under a mixed agreement unless there are explicit contraindications in the agreement itself.[625] There still remains a sizeable minority opinion that follows Mischo AG from *Commission v Ireland* though.[626] This position was confirmed in *Hermès*,[627] restating that the WTO Agreement was indeed signed by the Member States and the EU without distinguishing the degree of obligation and liability between them.[628] *Hermès* represents the end of the consistent jurisprudence of the CJEU and there does not appear to be a consensus as to how liability should be considered in the context of mixed agreements.[629] The Attorney General in a dispute around the EEA

[624] *European Parliament v Council of the European Union* C-316/91 15.
[625] 'The most convenient conclusion is that the EC and the Member States in principle assume joint obligations, the performance of which they all are required to assure. This view is consistent with the Court's emphasis on the 'requirement of unity'. This solution is supported in the Community's declaration to the UNCLOS…': Lena Granvik, 'Incomplete Mixed Environmental Agreements of the Community and the Principle of Bindingness' in Martti Koskenniemi (ed), *International Law Aspects of the European Union* (Martinus Nijhoff 1998) 265.
[626] Highlighting the dissenting view of the Advocate Generals in two other cases (and adopting a broadly similar approach to Mischo AG from *Commission v Ireland*): AG Jacobs, *European Parliament v Council of the European Union* C-316/91; and AG Tesauro, *Hermès* - C-53/96; For broader academic dissent see: Philippe Ruttley and Marc Weisberger, 'The WTO Agreement in European Community Law: Status, Effect and Enforcement' in Arthur E Appleton and Michael G Plummer (eds), *The World Trade Organisation: Legal, Economic, and Political Analysis* (Springer 2007) 1480.
[627] Case C-53/96 *Hermés v FHT* [1998] ECR I-3603.
[628] Armin von Bogdandy and Tilman Makatsch, 'Collision, Coexistence or Cooperation?' in Joanna Copestick (ed), *The EU and the WTO: Legal and Constitutional Issues* (Hart 2001) 148.
[629] Piet Eeckhout, 'The EU and its Member States in the WTO: Issues of Responsibility' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 452.

Agreement had disagreed with the previous jurisprudence and unsettled the approach to joint or separate liability.[630]

In the context of dispute resolution outside the EU, however, the EU does take a clear approach to the liability of the Member States for international obligations.[631] While individual complaints have been addressed to specific Member States for violations of WTO obligations, the EU has taken over in all cases that led eventually to a panel.[632] This is particularly interesting because no Member State has tried to become an active party in the WTO dispute settlement process after this.[633] This type of dynamic highlights the dissonance between a more abstract sense of accountability as an administrative value and how it emerges in practice through this process of co-creation. It seems that accountability, particularly though not exclusively in the context of the EU and the Member States, become politically inflected through the interactive nature of dispute settlement. This development of an instrumentalised version of accountability takes on more significance in this context because there is a lack of clarity regarding the exact division of responsibility and liability for the WTO Agreements.

3.4 *Navigating liability in the WTO framework*

3.4.1 Constructing responsibility in the EU/WTO interface

The key starting point to investigation in this area is the theory of the relationship between the EU and its Member States, with a very early case that has been presented in the

[630] C- 249/81 *Commission of the European Communities v Ireland*; Inge Govaere, 'A Tale of the (Un)expected: Backlash for all Mixed Agreements of the 'External' Harmonisation of Intellectual Property' in Josef Drexl (ed), *Technologie et Concurrence - Technology and Competition (*Armando Editore 2009) 704.
[631] Roy H Ginsberg, *Demystifying the European Union: The Enduring Logic of Regional Integration* (Rowman & Littlefield 2007) 298.
[632] Piet Eeckhout, 'The EU and its Member States in the WTO: Issues of Responsibility' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 453.
[633] ibid.

literature as characterising the EU's willingness to assume responsibility for violations occurring within the WTO framework.[634] In this case, *EC - Computer Equipment*,[635] the US had complained about the conduct of Ireland and the UK, as well as the EC.[636] The EU argued that the customs authorities and agencies of Ireland and the UK (as members of the EU) were acting under the authority of the EU as agents in a field that is subject to the EU's exclusive competence.[637] In emphasising the dynamic of EU authority to establish the Member States as agents, the EU also demonstrated its eagerness to take responsibility for Member State conduct in the context of the WTO dispute settlement system.[638] Key to this decision was that the discipline was one of the EU's exclusive competences and that a clear link could be drawn between the implementing agents of the Member States and the applicable law. The fact that it concerned customs agents is not insignificant. Given the number of borders to the EU and the integrity of the internal market, it makes sense that the EU would be particularly eager to take responsibility for the dispute.

The Panel in *EC - Trademarks and Geographical Indications* accepted the 'domestic constitutional arrangements' of the EU,[639] along with the European submission that EU law is not executed through EU institutions and instead is executed through the national institutions of each Member State.[640] Thus, it was accepted by the panel that the Member States were – in the context of the TRIPs Agreement implementation considered in *EC - Trademarks and*

[634] James Flett, 'WTO and the EU' in André Nollkaemper, Ilias Plakokefalos, Jessica Schedinger, and Jann K Kleffner (eds), *The Practice of Shared Responsibility in International Law* (CUP 2017) 891.
[635] DS375: *European Communities and its Member States – Tariff Treatment of Certain Information Technology Products* (*EC – IT Products*).
[636] James Flett, 'WTO and the EU' in André Nollkaemper, Ilias Plakokefalos, Jessica Schedinger, and Jann K Kleffner (eds), *The Practice of Shared Responsibility in International Law* (CUP 2017) 891.
[637] DS62 *European Communities – Customs Classification of Certain Computer Equipment*. *EC - Computer Equipment*.
[638] Paragraph 8.2, *EC - IT Products*.
[639] DS290: *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* (EC Trademarks and Geographical Indications).
[640] '...of what amount to its sui generis domestic constitutional arrangements that Community laws are generally not executed through authorities at the Community level but rather through recourse to the authorities of its member States…': Pavel Šturma, 'The Responsibility of International Organisations and Their Member States' in Maurizio Ragazzi (ed), *Responsibility of International Organisations* (Martinus Nijhoff 2013) 319.

Geographical Indications – acting as de facto organs of the EU.[641] The construction of the Member States as de facto executory organs of the EU is an important one when considered in the broader context of the autonomy of the EU to take responsibility for Member State action. It explicitly casts the Member States as executors, and not creators, and creates a situation by which the EU would almost always have recourse to take responsibility for the trade violation. This presents a more formalist understanding of accountability that emphasises a linear relationship between the EU, the trade violation, and the Member State. Yet this would then appear to be in tension with the CJEU's jurisprudence on direct effect, highlighting how the lack of clarity enables a flexible approach to responsibility. Here, the relationship between different actors and the EU can always be, when strategically appropriate, interpreted to extend EU responsibility for Member State action.

Two features of the relationship between the EU and WTO in the context of assigning liability and obligations can be identified,[642] the first being that the EU appears to be very eager to assume responsibility for Member State violations.[643] This has been described as being a counterintuitive conclusion,[644] given that the WTO Agreement is formally a mixed agreement and there are certainly areas where the EU has not legislated that would challenge the federal-style arguments put forward by the EU in WTO panels.[645] Specifically for intellectual property and the framework of the EPUE, the legitimacy of the EU acting on behalf of Member States

[641] Pavel Šturma, 'The Responsibility of International Organisations and Their Member States' in Maurizio Ragazzi (ed), *Responsibility of International Organisations* (Martinus Nijhoff 2013) 319.
[642] Of both the eagerness of the EU to participate and the apparent acceptance of federal-style arguments accepted by the WTO: Piet Eeckhout, 'The EU and its Member States in the WTO: Issues of Responsibility' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 456.
[643] Plarent Ruka, *The International Legal Responsibility of the European Union in the Context of the World Trade Organisation in Areas of Non-Conferred Competences* (Springer 2017) 61.
[644] Piet Eeckhout, 'The EU and its Member States in the WTO: Issues of Responsibility' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 456.
[645] 'At least in the case of mixed agreements, in which there is no ex-ante declaration of competence, the assumption of full responsibility by the Union renders the remaining competences of Member States under EU law, in terms of international responsibility, meaningless.': Graham Coop, *Energy Dispute Resolution: Investment Protection, Transit and the Energy Charter Treaty* (Juris Publishing 2011) 147.

in a trade violation would be questionable when it is not the result of an EU treaty and was introduced specifically because a consensus could not be reached at the EU level. The justification for the EU's willingness to take what appears to be sole responsibility in these disputes seems to centre on the promotion of further integration and concentrated EU presence in international policymaking.[646]

This is reinforced by the unwillingness of WTO Panels to interfere on this issue and to simply accept the justifications put forward by the EU.[647] More broadly, however, the degree to which that this is even desirable is questionable.[648] Why would a WTO Panel, as part of the WTO institutional framework, be engaged in either the legitimacy of the EU representing the violations of the Member States or even presenting an analysis as to the balance of liability of the EU and Member States in trade violations of a mixed agreement?[649] The EU pushing for increased responsibility in the context of WTO disputes is indeed counterintuitive because of the additional burden it brings. The relationship between the EU and its Member States, perhaps now more than ever, is profoundly troubled in a variety of different contexts.[650] Carrying on with the practice of taking responsibility for alleged trade violations by Member States will be challenged by the increasingly contentious relationship between the Member States, the EU, and the direction of the European project. But rather than the Commission's

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[646] Debra Johnson and Colin Turner, *European Business: Policy Challenges for the New Commercial Environment* (Psychology Press 2000) 317.
[647] Marise Cremona, 'Who Can Make Treaties? The European Union' in Duncan B Hollis (ed), *The Oxford Guide to Treaties* (OUP 2012) 121.
[648] With suggestions that EU guidelines for responsibility in cases of mixed liability could be one way of addressing this issue: ibid 122.
[649] Arguing that the burden falls on the EU to demarcate liability and responsibility: ibid.
[650] 'Europe is in crisis. Dissatisfaction with the general state of affairs in Europe seems quite widespread today, from the populist turn in a number of member states of the European Union to the outburst of social unrest in countries like Greece and Spain. neither is it the first existential crisis in the history of European integration… seemingly unrelated events have profoundly disturbed national and European elites in recent times, and have used the elite-driven process of European integration grinding to a halt. From the riots in the suburbs of big French cities, through the traumatic and prolonged institutional crisis after the French and Dutch referenda in 2005, to the recent upsurge of Euroscepticism, xenophobia and right-wing populism, all these developments point at Europe's profound impasse.': Otto Holman, 'Lisbon Agenda, New Structural Policy and Social Cohesion in Times of Economic Crisis' in Ipek Eren Vural (ed), *Converging Europe: Transformation of Social Policy in the Enlarged European Union and in Turkey* (Ashgate 2011) 76.

objective of further integration, the sole representation by the EU in WTO disputes presents an additional avenue for advancing the EU's normative identity internationally. By taking a broad approach to Member State liability in terms of WTO obligations and violations, the EU has at least some control over how the norms of the dispute process develop. This provides another indirect way of modulating of accountability for WTO obligations that operates through (and relies on) the dynamic process of dispute resolution. It not only shapes the immediate legal status of the WTO obligation, but also impacts the normative context of these obligations and specifically how they develop through dispute settlement.

The issue of sole responsibility is linked with two specific contexts in which this is likely to become more problematic in the coming years. The first is related to the state of the EU as a whole, where Member States are becoming increasingly critical about the objectives of the EU and the way that there are perceived to be disconnected from the national identities and objectives of the Member States.[651] This has led to certain Member States that were highlighted earlier engaging in controversial policy choices in areas like immigration and human rights.[652] The EU would need to be particularly cautious in the next ten years about maintaining the strong federalist argumentation that it has advanced in Panel complaints previously because if Member States start to be particularly disruptive in areas that affect WTO obligations, the EU may find itself assuming responsibility for these violations. Given the strength with which the EU has advocated this de facto agent nature of the Member States, it

[651] Particularly in regard to its legitimacy: 'At a time when Europe faces some of its biggest economic, political, and social challenges since the Second World War, the integration project itself has become highly contested among the public. As a result, the EU finds itself faced with an existential challenge: the unprecedented development in supranational governance in recent years has led to greater public contestation, yet at the same time the Union is more reliant on public support for its continued legitimacy than ever before.': Catherine E De Vries, *Euroscepticism and the Future of European Integration* (OUP 2018) 4.

[652] Hungary, in the face of being outvoted on the issue of the migrant crisis (along with Czech Republic, Slovakia, and Romania) in 2015, constructed a fence along its border with Serbia and Croatia; Greece in 2012 built a fence along its border with Turkey; Calais was fortified; and Germany, Sweden, and France in 2015 had temporarily reinstated border checks: Andrew Geddes and Peter Scholten, *The Politics of Migration and Immigration in Europe* (SAGE 2016) 2.

would be difficult for them to – in the face of such disruptive behaviour – to completely reverse their argumentation and instead present the Member States as beyond EU control and *not* as de facto organs of the EU.

The second, we can already observe with the challenging behaviour currently going on in some Member States and is essentially around the effectiveness, or ineffectiveness,[653] or sanctions within the EU.[654] A system where the EU could internally deal with Member States that deliberately implement policy that is incompatible with WTO trade obligations, and then carry on representing the Member States in WTO Panels could be a solution. Yet more fundamentally however, the EU mechanisms that currently exist for sanctioning Member States involve lengthy processes and even the threat of the sanctions appears to have minimal effect on Member State conduct.[655] Not only would the entire approach to sanctions in the EU need to be revisited, for this to work as a counterbalance for the EU assuming responsibility for WTO violations would require an effective system of coordination. Beyond this, the resources required to implement a sanctioning system that would respond quickly enough to WTO-specific violations by Member States would be unworkable.

3.4.2 Exploring EU law and WTO obligations in a dispute context

Implementing a more EU law-involved process in the WTO Panel disputes would be equally unworkable, given that they are complex enough without incorporating unsettled EU law. This would also involve asking that a WTO Panel resolve an issue that would more

[653] Even in relation to the acquis and EU enlargement, the Commission appeared to be predominantly concerned with the political threat of delaying accession: ibid.
[654] Monitoring member state compliance appears to be very much more informal: John O'Brennan, *The Eastern Enlargement of the European Union* (Routledge 2006) 91.
[655] Sanctions have remained very much a last resort, and monetary penalties are not intended to be punishment-oriented (rather, forward-looking, persuasive or a deterrent): Stine Andersen, *The Enforcement of EU Law: The Role of the European Commission* (OUP 2012) 135.

appropriately considered by the EU institutions (given that it has a more significant effect on the legal dynamic between the EU and the Member States).[656] Shifting the issue of the correct role of EU law in a WTO Panel dispute is not an option because it would be the product of an isolated decision – rather than a dialogue between actors – that would be narrow and not necessarily applicable more generally. Taking the *EC - Computer Equipment* case even further, the Common Commercial Policy (CCP) was a key aspect of the decision that the Member States are clearly acting as agents of the EU in an of exclusive competence.[657] But taxation raises an interesting issue, which forms part of the CCP but is not yet harmonised at the EU level (except rules establishing the minimum rates of VAT and capital income tax).[658] The issue of taxation has been specifically highlighted by Eeckhout in terms of competence and responsibility because it also still subject to the GATT and thereby an exclusive competence of the EU.[659] Again, this process of dialogue and interpretation presents an accountability that does not flow singularly or directly from a trade violation and the actor involved. Instead, accountability emerges from a multi-stage *interactive* process where responsibility for binding trade obligations takes on a flexible quality that, in practice, can become more or less binding. The role of the WTO Panels and their reports necessarily highlight the tensions of determining accountability in a decisive way because it is not an issue that can be resolved by either regime acting independently.[660]

[656] Especially with the already-existing complexity of WTO disputes, an EU law dimension would exacerbate this further: Piet Eeckhout, 'The EU and its Member States in the WTO: Issues of Responsibility' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 459.
[657] Marina Foltea, *International Organisations in WTO Dispute Settlement: How Much Institutional Sensitivity?* (CUP 2012) 112.
[658] *Parent-Subsidiary Directive*, *Interest and Royalties Directive*, *VAT* as part of the acquis.
[659] Especially with the already-existing complexity of WTO disputes, an EU law dimension would exacerbate this further: Piet Eeckhout, 'The EU and its Member States in the WTO: Issues of Responsibility' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 461.
[660] Which actually parallels the discussions around *Opinion 1/94* and the broader relationship between the EU and its Member States. As a shared competence, however contested by the Commission at the time, implementation of the TRIPS Agreement requires the cooperation of the Member States and the EU: Michael Hahn and Livia Danieli, 'You'll Never Walk Alone: The European Union and Its Member States in the WTO' in Marc Bungenberg and Christoph Herrmann (eds), *Common Commercial Policy after Lisbon* (Springer 2013) 55, 56.

A WTO Panel that addresses the status of EU law would be limited because this would essentially amount to an interpretation of EU law. This would be the case whether the interpretations were on issues of EU law that were settled or not, and whether or not they related to general questions of law or were constructed specifically in reference to competence. The CJEU would be fully entitled to disregard or otherwise modify any conclusion that was reached by a Panel on interpretations of EU law. Yet by avoiding these questions, the WTO prevents the foundational principles of the WTO framework and EU law coming into conflict and creating an explicit hierarchy in practice. Like with the interpretative obligation discussed previously and the space that denial of direct effect creates, the WTO refusing to engage with questions of EU law means that both organisations retain a degree of flexibility and autonomy that facilitates their legal relationship to accountability.

The TRIPS Agreement is actually a key example of the difficulties in apportioning liability or responsibility for WTO breaches in the context of the EU and the Member States, and specifically for patent law. The EU, at the point of conclusion of the WTO Agreement, was not considered to have had exclusive competence in this area.[661] This means that the EU could not have assumed the responsibility of the Member States in terms of patent obligations in the TRIPs Agreement.[662] This raises the prospect that a WTO Panel could find that a Member State violated their TRIPS obligations and that this conduct cannot be attributable to the EU. Such a decision would, however, be undermined by the continued lack of declaration in terms of the competencies and responsibilities shared between the EU and Member States and could therefore result in the EU being considered jointly liable anyway.

TRIPS represents a particular tension between Member States and the EU, though perhaps more clearly in the context of *l'ordre public* exceptions and national policy, because

[661] Piet Eeckhout, 'The EU and its Member States in the WTO: Issues of Responsibility' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 463.
[662] ibid.

intellectual property appears to be more vulnerable to complex questions of responsibility than other areas. Member States as agents of the EU would be much clearer with a harmonised patent law convention, though these nationally responsive patent exceptions could undermine this. Member States could take their own perspectives on the *l'ordre public* exceptions to justify national practice and would sever the direct link between the EU and the Member States' conduct. Additionally, and more specifically in the context of patent law, the EPUE provisions do nothing to address this and actually expose how responsibility between the EU and Member States is an unstable cocreation. Patent law stands out in the EU because it (perhaps uniquely) challenges the assumptions about accountability between the Member States and the EU. The lack of a completely harmonised patent law in Europe highlights the tension in focusing on formal accountability, stressing the limitations of understanding accountability as automatically flowing from national trade violation to EU responsibility.

However, even with a completely harmonised patent framework at the EU level, the scope of autonomy that the Member States have in relation to *l'ordre public* means that, as long as neither the WTO Panels nor the EU take responsibility for the issue of assigning liability, patent law will remain a challenge in this area. The completely harmonised patent framework in this context actually represents the ideal situation because the fragmentation that the EPUE brings is sure to raise further difficulties. This is particularly relevant as the active membership of the EPUE expands, the uncertain role of national law, and the important role of inter-institutional dynamics all develop through EPUE practice. All of these elements highlight the importance of legal certainty in this context and, again, how the EPUE works to undermine a clear and consistent link between Member State and EU in terms of accountability. As the EPUE expands and the UPC becomes operational, it is unclear how responsibility would be assigned if the EPUE provisions (particularly on the role of national law or the interpretation of the EPC) were challenged in the context of WTO dispute settlement.

4. Communication between dispute resolution bodies

4.1 *The legal context of dispute resolution*

4.1.1 Constructing the process of judicial communication

The WTO Agreements are not the only point of contact extending from the WTO framework, and direct effect has taken on a slightly different character in terms of the WTO Panel reports and their appropriate legal impact is constructed. The relationship and 'judicial communication' between the WTO Panels and the CJEU has been very much shaped by the international law context in which it operates, and has been presented as an important way in which international law is perceived and enforced within the EU.[663] Like the discussion of direct effect and WTO Agreements, the decision to avoid bringing the two legal systems into conflict (and therefore, hierarchy) through their dispute settlement bodies can also be observed in the legal treatment of their judgments. This relationship and dialogue between the dispute bodies of each legal regime is fundamentally linked to the (lack of) direct effect of the WTO Agreements. This is because while the issue of direct effect is reasonably settled in respect of the actual Agreements, the legal status of Panel reports and the DSB appear to be still evolving. Like with direct effect of the WTO Agreements, it is this flexibility that provides an opportunity to modulate the binding quality of these Panel reports and therefore the underlying obligations. Understanding the complex relationship between the DSB, direct effect, and the CJEU presents perhaps a more nuanced institutional context than when just considering the EU, WTO

[663] Michelle Q Zhang, 'Judicial Interaction of International Trade Courts and Tribunals' in Robert Howse, Hélène Ruiz-Fabri, Geir Ulfstein, and Michelle Q Zhang (eds), *The Legitimacy of International Trade Courts and Tribunals* (CUP 2018) 433.

Agreements, and the CJEU. This is because the form of communication takes on a different character as it centres on the relationship between two dispute resolution bodies that are responding to specific issues, rather than the general reception of an international agreement.

Going back to the GATT, it was the *International Fruit* decision and Germany that pointed towards the CJEU's early position on the direct effect issue.[664] But this decision was also important in terms of the other uses for the WTO Agreements within the EU legal order, starting a line of jurisprudence that established that the CJEU would not allow provisions of EU law to be reviewed against the GATT.[665] This approach would later be applied again to WTO provisions.[666] From a perspective that focuses on EU autonomy, the focus in the early strands of jurisprudence was not necessarily about the direct effect treatment of a judgment or report, but rather, can be seen as the CJEU avoiding the establishment of an explicit hierarchy between the WTO and the EU. It is this absence of a strict hierarchy, as with GAL more generally, that enables a more flexible approach to responsibility for violations of binding obligations. Rather than an explicit rejection of the legal importance or status of the WTO Panel Reports, it is a modulated response that casts their legal impact somewhere below direct effect but above outright rejection. An issue that is unique to the EU is that the Member States, at the signing of Treaty of Rome, could have existing international trade obligations.[667] Schütze argues that this created a complex system of trade agreements and obligations that could exist before or after the conclusion of the Treaty of Rome.[668] *International Fruit* gave a two-part test that addressed the issue of when exactly the EU would become bound by these, potentially pre-

[664] Michelle Q Zhang, 'Shall We Talk? Judicial Communication Between the CJEU and WTO Dispute Settlement' (2017) 28(1) EJIL 273, 276.
[665] Mario Mendez, *The Legal Effects of EU Agreements* (OUP 2013) 174.
[666] ibid.
[667] Hannah Woolaver, 'Withdrawal from the International Criminal Court: International and Domestic Implications' in Gerhard Werle and Andreas Zimmermann (eds), *The International Criminal Court in Turbulent Times* (Springer 2019) 28.
[668] Robert Schütze, *European Constitutional Law* (CUP 2012) 339.

existing, trade obligations.[669] This type of complex transition in EU law highlights the fractured nature of accountability when looking at international systems of law – rather than a binary or formal value, it instead emerges from the contextually specific interactions between different actors across time that presents a multiplicity of varying accountabilities. This process of establishing accountability, itself, involves the complex interplay of dispute resolution bodies, international agencies, and states that together influence how binding international provisions are in practice.

Article 351(1) TFEU states that these pre-existing trade obligations or agreements between Member States and third countries shall not be affected by the provisions of the Treaty,[670] though this was clearly not the determining factor for the CJEU in *International Fruit* because otherwise that would have been the end of this case.[671] The first part of the test is looking at whether the EU is bound by an international agreement.[672] Mendez argues that if Article 351(1) was the key provision, this would present an immediate conclusion that the EU would be bound by the GATT.[673] The second part of the test is that with the EU being bound by the international agreement, the provisions in question must be capable of conferring rights.[674] Agius has discussed how, remarkably, the CJEU in *International Fruit* provided no justification of this requirement.[675] As discussed previously, the GATT was considered to be

[669] Robert Schütze, *European Constitutional Law* (CUP 2012) 339.
[670] Article 351(1) TFEU.
[671] Mario Mendez, *The Legal Effects of EU Agreements* (OUP 2013) 179.
[672] Jan Willem Van Rossem, 'The EU at Crossroads: A Constitutional Inquiry into the Way International Law is Received within the EU Legal Order' in Enzo Cannizzaro, Paolo Palchetti and Ramses A Wessel (eds), *International Law as Law of the European Union* (Martinus Nijhoff 2011) 74.
[673] Instead of emphasizing the gradual transfer of competencies process: Mario Mendez, *The Legal Effects of EU Agreements* (OUP 2013) 179.
[674] Maria Fogdestam Agius, *Interaction and Delimitation of International Legal Orders* (Martinus Nijhoff 2014) 70.
[675] ibid 71.

extremely flexible and this seemed to be the main element that was under inspection rather than providing an analysis of any specific GATT provision.[676]

Immediate criticism of this decision focused on the fact the CJEU appeared to be relying on some caricature of the GATT in finding it incapable of conferring rights.[677] The CJEU, finding the GATT to be incapable of conferring rights, protected the EU legal order from a source of unfiltered external influence. By choosing to deny direct effect and then to limit the circumstances in which WTO obligations can either be enforced or used as a standard for review, the CJEU is presenting a system where there are multiple opportunities to exclude or otherwise modify rules that do not fit within EU objectives. At the same time, it essentially immunises the EU and EU law from challenge on the basis of those very trade obligations and standards. At a fundamental level, what is happening is that the EU legal order has established a legitimate environment in which binding provisions of international law are subject to a process of interpretation. This interpretation does not just shape the substantive content of these obligations, but the binding quality of the agreement itself in a way that creates a flexible construction of accountability.

4.2 *Direct effect and DSB Panel Reports*

4.2.1 Early cases in the direct effect of DSB Panel Reports

In terms of the Panel Reports themselves and their legal treatment, the starting point is the *Chiquita* line of jurisprudence.[678] This provides an important framing for accountability

[676] Joel P Trachtman, *The International Economic Law Revolution and the Right to Regulate* (Cameron May 2006) 524.
[677] On the focus on flexibility - 'all legal rules are flexible and conditional: the correct question to ask relates to the degree to which they are flexible and conditional*.':* ibid.
[678] Michelle Q Zhang, 'Shall We Talk? Judicial Communication Between the CJEU and WTO Dispute Settlement' (2017) 28(1) EJIL 273, 278.

because it considers the issues that emerge when considering how binding these decisions are on EU law. The cases of *Van Parys* and *Chiquita v Commission* centred on the issue of whether direct effect should be considered differently when it is in the context of WTO Panel decisions instead of WTO obligations more generally.[679] But they are also key decisions in the CJEU maintaining the autonomy of the EU legal order and represent an example of how accountability is modulated through the interactive process of dispute resolution.

Because it was argued that a WTO Panel decision does not include 'special obligations',[680] any amendments taken by the EU in bringing the law into compliance with WTO obligations are not to be considered within the meaning of the *Nakajima* doctrine (which has been constructed as a particularly narrow exception and generally only used in anti-dumping complaints).[681] The *Nakajima* doctrine is an exception as to the use of WTO law in challenging the legality of an EU law provision,[682] applicable only when the EU legislature had intended to implement an obligation stemming from the WTO Agreements.[683] The *Nakajima* doctrine has remained a narrow exception that has been interpreted by the CJEU in a particularly restrictive way.[684] The later *Biret* case in 2003 raised the question of the legal status of WTO Panel decisions,[685] dealing with the WTO compliance of trade measures to restrict the import of beef that had been treated with hormones.[686] While the CJEU criticised the lower court for ignoring the complainant's argument about the role of WTO Panel

[679] Case C-377/02 *Léon Van Parys NV v Belgisch Interventie-en Restitutiebureau (BIRB)* (2005); Case C-469/93 *Amministrazione delle Finanze dello Stato v Chiquita Italia SpA* (1995) ER I-4533;'Since *Van Parys*, differentiation has been made between rulings of the DSB '…on the basis of WTO rules to which the ECJ has exceptionally allowed private challenges, i.e. antidumping and countervailing duty rules and other rulings.': Anne Thies, *International Trade Disputes and EU Liability* (CUP 2013) 28.
[680] Rass Holdgaard, *External Relations Law of the European Community: Legal Reasoning and Legal Discourses* (Kluwer 2008) 317.
[681] ibid.
[682] Case C-69/89 *Nakajima v Council* EU:C:1991:186.
[683] Kristiyan Stoyanov, 'Three Decades of the Nakajima Doctrine in EU Law: Where are We Now?' (2021) 24 JIEL 724, 725.
[684] ibid 726, 727.
[685] Case C-94/02 *Établissements Biret et Cie SA v Council* (2003) ECR I-10565.
[686] ibid paragraphs 3-6.

decisions,[687] this appeared to be essentially an aside as Eeckhout highlights that the reasonable period of implementation had already ended and left the CJEU to affirm the Court of First Instance's decision.[688]

More broadly, AG Léger, in respect of the *Ikea - Wholesale* case,[689] has argued that DSB findings cannot be binding because this would threaten the autonomy of the EU legal order.[690] The fact that autonomy was raised in the context of the legal effect of WTO Panel decisions is important because they are the result of an international process and are effectively judgments regarding specific trade measures that have been adopted by their signatories. Instead of preserving the autonomy of the EU legal order, it can instead be read as a way of insulating the EU and EU law provisions from the impact of external dispute settlement mechanisms (while not denying their legal impact or importance entirely). This works to adjust how accountable the EU is for violations of these binding provisions, but in a way that is dynamic and responsive to the broader political and legal context of the international trade environment.

The fact that the CJEU in *Biret* highlighted the importance of the reasonable period of implementation has been criticised extensively in academic work.[691] This criticism (and the argument that the WTO Panel reports are not binding on the EU legal order more broadly) has centred on the fact that these Panel reports are prospective and involve a clear obligation to

[687] Sabina Nüesch, *Voluntary Export Restraints in WTO and EU Law: Consumers, Trade Regulation and Competition Policy* (Peter Lang 2010) 132.
[688] Piet Eeckhout, *A Panorama of Two Decades of EU External Relations Law* (OUP 2008) 334; Case C-94/02 *Établissements Biret et Cie SA v Council* (2003*)* ECR I-10565 paragraph 72.
[689] Case C-351/04 *Ikea Wholesale Ltd v Commissioners of Customs and Excise* (2007) ECR I-7723; 'Furthermore, the Court of First Instance took the view that the DSU did not establish a mechanism for the judicial resolution of international disputes by means of decisions with binding effects comparable with those of a court decisions in the internal legal systems of the Member States.': Christian Koenig and Jens-Daniel Braun, 'The International Regulatory Framework of EC Telecommunications Law: The Law of the WTO and the ITU as a Yardstick for EU Law' in Christian Koenig, Andreas Bartosch, Jens-Daniel Braun, and Marion Romes (eds), *EC Competition and Telecommunications Law* (Kluwer 2009) 32.
[690] Case C-351/04 *Ikea Wholesale Ltd v Commissioners of Customs and Excise* (2007) ECR I-7723, Opinion of AG Léger, paragraph 79.
[691] Piet Eeckhout, *A Panorama of Two Decades of EU External Relations Law* (OUP 2008) 335.

bring the law into compliance with the WTO obligations and should not be conditional upon the reasonable period of implementation.[692] Eeckhout suggests that the fact that there is a reasonable period of implementation does nothing to affect the nature of this international obligation – neither while the period of implementation is still active, nor when it expires.[693] The obligation to bring the law into compliance remains and it is from this perspective that the filtering of external influence through EU law principles is perhaps most clear. This is why the transformation of the GATT and the constitution of the WTO did nothing to change the EU's position on direct effect. By creating a more complete legal regime with its own dispute resolution system that issues binding reports, the WTO put direct effect of the Agreements and the Panel reports even further away because the threat to autonomy of the EU became much more explicit. There is something of a tension in this drive towards more formal and structured legal arrangements in the international context. As the WTO system becomes more explicitly legal, there should have been a corresponding increase in accountability as the institutional relationships between the actors involved became more visible and defined. Yet what has happened in practice, particularly with the Panel Reports, is that these formal institutional hierarchies and the provisions they enforce remain flexible and dynamic in a process of contextual accountability.

4.2.2 Distinguishing the two threads of jurisprudence in the CJEU

There is a clear distinction (or perhaps even contradiction) between the two lines of jurisprudence in the CJEU about the status of WTO Panel reports. While *Kadi* and *Yusuf* demonstrate a significant degree of openness towards the WTO Panel reports, this approach

[692] Piet Eeckhout, *A Panorama of Two Decades of EU External Relations Law* (OUP 2008) 335.
[693] ibid.

seems to be entirely reversed through the lines of *Chiquita* and *van Parys* which amount to an almost complete rejection.[694] As mentioned previously in the context of the political sensitivity that is key to the WTO's existence, this type of variation in approach by the CJEU (across a relatively small period of time) does not speak to a settled approach as to the status of WTO Panel reports. This is interesting because the actual nature of a WTO Panel dispute is not particularly complex. It considers an issue of law and its relationship to an alleged trade violation, rather than a more conceptually difficult (and sensitive) human rights dispute. For accountability, it demonstrates the dynamic process(es) through which it is constructed and how it is fundamentally realised through dispute settlement bodies. The jurisprudence in this area has been criticised as inconsistent,[695] but this inconsistency can instead be read as a reflection of the contextual processes through which accountability is being produced. Accountability, both as a substantive value *and* the processes by which accountability is assigned, is a flexible and dynamic construct that is contextually responsive rather than systemically or objectively represented.

Eeckhout highlights that the way international law is interpreted and incorporated appears to be increasingly distributed between different international institutions and courts and,[696] from this perspective, can be understood as emphasising the necessarily interactive process of international law that takes place between the CJEU, the WTO Panels, and EU Member States. This reflects themes that appear prominently in the GAL literature, in particular in discussions that emphasise the diversity of the international legal system (though particularly in this sense of 'multiplicity of publics').[697] The relationship between intellectual

[694] Piet Eeckhout, *A Panorama of Two Decades of EU External Relations Law* (OUP 2008) 336.
[695] On the critique that this jurisprudence is inconsistent, and also what can be interpreted as a 'silent continuation' of *Kupferberg* reasoning in later cases: Nadine Zipperle, *EU International Agreements: An Analysis of Direct Effect and Judicial Review Pre- and Post-Lisbon* (Springer 2017) 38, 39.
[696] Piet Eeckhout, *A Panorama of Two Decades of EU External Relations Law* (OUP 2008) 336.
[697] Though particularly in the diversity of applicable principles that are shaped by context Paul Craig, *UK, EU and Global Administrative Law: Foundations and Challenges* (CUP 2015) 658; Nico Krisch, 'The Pluralism of

property and the WTO is a particularly clear example of this, where managing the regime interactions of the EU and WTO (with all of the associated enforcement framework and institutions) demonstrate a plurality in the actors involved. This variety shapes not only the enforcement of international intellectual property obligations but how accountability takes on a different character depending on the institutional and legal context.

The CJEU is obviously central to this contextual inflection of accountability: it is the key institution in developing the way that the interface between WTO law and EU law functions.[698] If the Panel reports had direct effect or they were more willing to actively engage with questions of EU competence, conflicts would emerge, and a more distinct hierarchy would come into focus. This type of hierarchical force could emphasise compliance with international obligations and, in removing the most obvious avenues of interpretation for the CJEU, create a more direct flow of accountability for violations. This gives the CJEU a great deal of autonomy because the existing legal framework often does not give clear direction or instruction.[699] Beyond the more immediate European context, however, the CJEU is significant as one of the first institutions dealing with this type of issue at this scale in the global context.[700] This has the effect of presenting the EU as *the* model of how to manage the impact of external legal regimes and so specific attention will be paid to the CJEU precisely because of its potential value for future policy development in other contexts.[701] Yet it is this central role that highlights why accountability should be considered an important concern in this area. While we can critique the lack of accountability for international obligations and the way in which

Global Administrative Law' (2006) 17 EJIL 247; additional discussion of this multiplicity in the international legal order: Devika Hovell, *The Power of Process: The Value of Due Process in Security Council Sanctions Decision-Making* (OUP 2016) 116.

[698] Marise Cremona and Anne Thies, *The European Court of Justice and External Relations Law: Constitutional Challenges* (Hart 2014) 3.

[699] Highlighting the expansive readings of common market principles and narrowing the interpretation of Treaty provisions preserving the sovereignty of Member States: Gerard Conway, *The Limits of Legal Reasoning and the European Court of Justice* (CUP 2012) 1.

[700] Piet Eeckhout, *A Panorama of Two Decades of EU External Relations Law* (OUP 2008) 337.

[701] ibid.

the CJEU modulates their binding character, the reality is that this entire legal environment is actually fairly unique. The EU has often been described in terms of its unique development and unprecedented success (in both a political and economic sense),[702] but as has the WTO.[703] From this perspective, then, it is understandable that accountability would take on a fluid and evolving character. The reality is that the EU and the WTO are involved in a novel system of international trade, filtered through large systems of stakeholders and participants, with no direct historical model for guidance. Effective global accountability is important and suffers from several issues that have been discussed throughout, though it should still be recognised that there are least positive elements that have emerged.

4.3 *Submitting to dispute settlement and the issue of competence*

4.3.1 On the expansive jurisdictional scope of the CJEU

The judicial monopoly of the CJEU in the EU has been discussed as presenting no significant 'jurisdictional overlap' with the WTO Panels and the EU system of adjudication.[704] Again, we see the impact of Article 344 TFEU in preventing the Member States from submitting disputes to other forums of dispute settlement.[705] In terms of incorporating the institutions of dispute settlement, the preliminary reference procedure is key in the discussions

[702] Even from the early integration in the mid-20th century and the EU emerging as a 'unique and unprecedented success story of peace, stability and economic development among its Member States': Julien Berger, *International Investment Protection Within Europe: The EU's Assertion of Control* (Routledge 2021) 2.
[703] Yet despite its 'manifest success' in supporting rules-based trading that is essentially globally accepted, it is more recent tensions around the Doha Round (and post-Doha) that are significant issues for the future of the WTO: Richard Baldwin, 'The World Trade Organization and the Future of Multilateralism' (2016) 30(1) Journal of Economic Perspectives 95, 96.
[704] Ernst-Ulrich Petersmann, 'The Establishment of a GATT Office of Legal Affairs and the Limits of 'Public Reason' in the GATT/WTO Dispute Settlement System' in Gabrielle Marceau (ed), *A History of Law and Lawyers in the GATT/WTO: The Development of the Rule of Law in the Multilateral Trading System* (CUP 2015) 206.
[705] Article 344 TFEU; Tobias Lock, *The European Court of Justice and International Courts* (OUP 2015) 151.

around direct effect because it indicates the degree to which a court (or other dispute resolution body) has become integrated in the EU legal order. Incorporating a court in this manner also necessarily involves an extension of accountability because it frames questions of interpretation, as preliminary references, in a binding manner within a closed system of dispute resolution bodies. International institutional frameworks cannot have direct effect within the EU unless they also incorporate the preliminary reference system and the *MOX Plant* case developed the understanding of Article 344 TFEU in the dimension of exclusive competences.[706] The CJEU decided in *MOX Plant* that in the context of dispute settlement mechanisms, Member States cannot submit disputes to the settlement mechanisms of international conventions when the international agreement comes under an EU competence.[707]

The argument essentially rested on the fact that if the EU was party to the international agreement and falls within an EU competence,[708] then the provisions would fall within the scope of Article 216(2) TFEU (which should include their interpretation and application) and therefore within the jurisdictional monopoly of the CJEU.[709] This has been presented as embodying an expansive approach because it not only includes the provisions themselves, but the interpretation and validity of them.[710] This creates a situation where, at least in the intra-EU context, it would be difficult to imagine the CJEU allowing Member States to bring

[706] Case C-459/03 (*MOX Plant) Commission of the European Communities v Ireland* (2006) ECR I-4635; Article 292 EC and its relation to strict jurisdictional monopoly: Pierre-Marie Dupuy, 'Competition Among International Tribunals and the Authority of the International Court of Justice' in Bruno Simma, Rudolf Geiger, Daniel-Erasmus Khan and Sabine von Schorlemer (eds), *From Bilateralism to Community Interest: Essays in Honour of Judge Bruno Simma* (OUP 2011) 865.
[707] Veronica Frank, *The European Community and Marine Environmental Protection in the International Law of the Sea: Implementing Global Obligations at the Regional Level* (Martinus Nijhoff 2007) 141.
[708] ibid.
[709] Article 216(2) TFEU; Nicholas Tsagourias, 'Conceptualising the Autonomy of the European Union' in Richard Collins and Nigel D White (eds), *International Organisations and the Idea of Autonomy: Institutional Independence in the International Legal Order* (Routledge 2011) 343.
[710] *MOX Plant*; Nicholas Tsagourias, 'Conceptualising the Autonomy of the European Union' in Richard Collins and Nigel D White (eds), *International Organisations and the Idea of Autonomy: Institutional Independence in the International Legal Order* (Routledge 2011) 343.

disputes with each other under the WTO dispute framework.[711] The Lisbon Treaty reinforces this position and the EU's exclusive competence in the context of WTO law,[712] though academic scholarship has highlighted how the EU neglected to actually describe the scope of Article 344 TFEU other than saying it was incompatible with the Article 8 BIT dispute settlement mechanisms under consideration in the *Achmea* judgment.[713] *Achmea* is significant not only because it essentially explored autonomy in relation to inter-EU bilateral investment agreements,[714] but because it provided the foundation for how Investor-State Dispute Settlement (ISDS) systems disputes must be reconciled with the autonomy of the EU legal order.[715] ISDS has been further discussed specifically in the context of intellectual property (and even patent law more narrowly),[716] and again presents accountability for international trade violations as a multifaceted concept. Accountability for violation of the same trade provision is constructed from the same elements (actor, violation, legal provision) but arranged differently by each dispute settlement body in a way that creates a dynamic (or perhaps unstable) sense of accountability.

It is important to recognize how significant the opportunity that the CJEU had in the *Achmea* judgment to specifically consider this aspect of capacity to submit to a dispute settlement body was, though it does reflect how the exercise of autonomy is linked to areas that are absent of specific jurisprudential interpretations. The jurisdictional monopoly and the

[711] Michelle Q Zhang, 'Shall We Talk? Judicial Communication Between the CJEU and WTO Dispute Settlement' (2017) 28(1) EJIL 273, 281.
[712] ibid.
[713] Zdenėk Novy and Barbara Warwas, 'The Recent Developments in Arbitration and the European Regulatory Space' in Lucia de Almeida, Marta Cantero Gamito, Mateja Durovic, and Kai P Purnhagen (eds), *The Transformation of Economic Law* (Bloomsbury 2019) 257.
[714] Case C-284/16 *Achmea* EU:C:2018:158.
[715] Such as Opinion 1/17 on the legality of the CETA investor-state dispute mechanisms: *Opinion 1/17* ECLI:EU:C:2019:341.
[716] Valbona Muzaka, 'Making Global Public Policy: Business and Global Patent Protection Standards' in Aynsley Kellow, Tony Porter, and Kartsten Ronit (eds), *Handbook of Business and Public Policy* (Edward Elgar 2019) 136.

presence of the CCP have all, unlike in other Regional Trade Agreements,[717] almost eliminated the issues that typically associated with assigning jurisdiction and competence.[718] By extension, this also created a much stronger link between legal provision and substantive accountability for violations. The relationship between the CJEU corpus and WTO Panel decisions go far beyond just considering the enforceability of the outcome, and instead, the institutions have been described as engaged in process of 'muted dialogue' across a variety of legal materials.[719] This has been constructed as a two-way process that informs both the decisions of the WTO Panel and the CJEU in a mutual way.[720] Dialogue, in itself, is a process of managing differences through mutual exchange without necessarily invoking a strict hierarchal structure and creating clashes between rival legal regimes. The CJEU occupies a unique position in the context of this dialogue because it is considered a form of domestic court (as the court of a customs union that has full and distinct membership of the WTO),[721] *and* an international court.[722] On the other side, the WTO Panels have been known to reference external practice and norms when incorporating resources from outside the WTO framework.[723] This relationship between the WTO Panels and the CJEU has been described as specifically as a form of 'muted' communication because even if the underlying judicial principle or approach is considered and

[717] On the difficulty of balancing jurisdiction within RTAs against biased self-interest of the institution: page Julia Molestina, *Regional Competition Law Enforcement in Developing Countries* (Springer 2019) 282.
[718] Though a 2012 Council Regulation was adopted to cover transitional arrangements for bilateral agreements conducted with third countries, the Common Commercial Policy has made clear the EU's exclusive competence in specific fields: Peter Van Elsuwege, 'The Legal Framework of EU-Russia Relations: Quo Vadis?' in Inge Govaere, Erwan Lannon, Peter van Elsuwege, and Stanislas Adam (eds), *The European Union in the World: Essays in Honour of Marc Maresceau* (Martinus Nijhoff 2013) 451.
[719] For an overview of the 'muted dialogue' phenomenon: Maria Fogdestam Agius, *Interaction and Delimitation of International Legal Orders* (Martinus Nijhoff 2014) 363.
[720] Michelle Q Zhang, 'Shall We Talk? Judicial Communication Between the CJEU and WTO Dispute Settlement' (2017) 28(1) EJIL 273, 282.
[721] André Nollkaemper, *National Courts and the International Rule of Law* (OUP 2012) 33.
[722] ibid 34.
[723] Michelle Q Zhang, 'Shall We Talk? Judicial Communication Between the CJEU and WTO Dispute Settlement' (2017) 28(1) EJIL 273, 282.

influences the decision, the Panel and Court will not make explicit reference to the resources from the other framework.[724]

There is the suggestion in the broader analysis of the WTO decisions and the CJEU that this process of muted dialogue is a way of implicitly preventing significant inconsistencies between the two systems.[725] While it would accurately describe what is going on (and also is in line with the general propositions of this chapter), Zhang has suggested that this operates with zero endorsement from the CJEU and WTO.[726] Yet there must be some recognition within the CJEU of the risks, specifically in accountability and enforcement, in taking extreme action regarding the legal status of WTO Panel Reports. By engaging in muted dialogue, the CJEU can develop the law of the EU in harmony with that of the WTO *without* formally legitimising it in the context of trade violations/dispute resolution and drawing from elements that are compatible with the trajectory of EU law. This approach allows the EU and the CJEU to emphasise the development of EU law in conformity with the general tone of international trade but in a way that prevents a direct and enforceable line of accountability being drawn between them. Explicit references between the CJEU and the WTO, still, remain uncommon. One notable example though is the *Anheuser-Busch* decision that implemented the principle of consistent interpretation and took the explicit approach of the Appellate Body.[727] Similarly, the

[724] Marco Bronckers, 'From 'Direct Effect' to 'Muted Dialogue'- Recent Developments in the European Courts' Case Law on the WTO and Beyond' (2008) 11 JIEL 885.
[725] 'However, the CJ has seldom referred explicitly to a report of the AB in order, for instance, to follow its interpretation of EU obligation under the WTO agreements… By contrast, the General Court has very explicitly dealt with the AB's report on zeroing in the Bed Linen case and has in the end distinguished the case before it from that case and deviated from it, but this was at least done in full transparency and with clear, although perhaps misguided, reasoning.': Pieter Jan Kuijper, 'The Court and the Appellate Body: Between Constitutionalism and Dispute Settlement' in Sanford E Gaines, Birgitte Egelund Olsen, and Karsten Engsig Sørensen (eds*), Liberalising Trade in the EU and the WTO: A Legal Comparison* (CUP 2012) 134.
[726] Michelle Q Zhang, 'Shall We Talk? Judicial Communication Between the CJEU and WTO Dispute Settlement' (2017) 28(1) EJIL 273, 285.
[727] C-245/02 *Anheuser-Busch Inc v Budejovicky, národní podnik*; Court quoted two rulings from the appellate court; though still in the broader context that the WTO Agreements do not have direct effect and therefore reports of WTO Panels cannot suddenly create direct effect (also on the basis that many of these panel reports have been framed in terms of their direct effect): Pieter Jan Kuijper, '"It Shall Contribute to… the Strict Observance and Development of International Law…": The Role of the Court of Justice' in Allan Rosas, Egils Levit, and Yves Bot (eds), *The Court of Justice and the Construction of Europe: Analyses and Perspectives on*

CJEU appears to have made only one reference to WTO jurisprudence and so the relationship has subsequently remained defined by the 'muted dialogue' dynamic.[728]

4.3.2 Contextualising the major cases in the WTO/EU dispute interface

There are three cases that have been submitted as evidence in the context of WTO dispute settlement, though in each instance the decision of the CJEU was dismissed (in terms of relevance) in respect of its applicability. These cases were *WTO - Korea Alcoholic Beverages*; *EC - Computer Equipment*; and *EC - Chicken Cuts*.[729] In each of these cases where the CJEU judgment was submitted as evidence, Zhang has explored how they were not approved as legitimate evidence by the WTO Panel.[730] *EC - Computer Equipment* is particularly important in these three because the decision reached by the Panel differed substantially from that of the CJEU.[731] Here, we see the same type of incentive with the treatment of WTO Panels by the CJEU. By avoiding an explicit confrontation between these two regimes (avoiding direct effect and direct references) and allowing the EU institutions to carry out this process of modulation, the WTO Panels have the freedom to rule against the EU without fundamentally alienating it. This is because, inevitably, the relationship between the two (even with a negative Panel Report) is not simply linearly or hierarchical. Considering this reverse situation more broadly, there is uncertainty around the legal status or usage of WTO

Sixty Years of Case-Law - La Cour de Justice et la Construction de l'Europe: Analyses et Perspectives de Soixante Ans de Jurisprudence (Springer 2012) 609.

[728] A Skordas, 'Völkerrechtsfreundlichkeit as Comity and the Disquiet of Neoformalism: A Response to Jan Klabbers' in Panos Koutrakos (ed), *European Foreign Policy: Legal and Political Perspectives* (Edward Elgar 2011) 129.

[729] DS75 *Korea – Taxes on Alcoholic Beverages*; DS62 *European Communities – Customs Classification of Certain Computer Equipment*; DS269 *European Communities – Customs Classification of Frozen Boneless Chicken Cuts*.

[730] Michelle Q Zhang, 'Shall We Talk? Judicial Communication Between the CJEU and WTO Dispute Settlement' (2017) 28(1) EJIL 273, 289.

[731] Isabelle Van Damme, *Treaty Interpretation by the WTO Appellate Body* (OUP 2009) 108.

decisions in deciding CJEU cases.[732] Here, without an explicit statement from the WTO or through a WTO Panel, Zhang argues that the legitimate expectations of the parties could be undermined when there are no guidelines as to when decisions of the CJEU would be incorporated as significant or decisive points of evidence.[733]

The approach of the CJEU and the WTO as to the legal impact and influence of each other's materials clearly indicate that both are cautious of maintaining autonomy in these interactions.[734] Given the increasing role (and variety) of international actors, courts, and tribunals, the development from 'muted dialogue' to an open exercise in communication has been discussed as a desirable evolution.[735] This more open sense of communication would increase legal certainty in the proceedings and explicitly address the issues of concrete scope and dimension of such communication.[736] Unfortunately, as long as the CJEU maintains a strict emphasis on autonomy and direct effect, specifically in relation to the WTO Agreements and obligations, any communication that outlines the official role of WTO and CJEU decisions in disputes will remain unlikely. This is further compounded by the fact that the CJEU and the WTO struggle to even explicitly recognise each other's decisions in their own legal reasoning, so it would be remarkable for them not only recognise such a usage and then go on to clarify the specific dimensions and conditions under which they can be legitimately incorporated. This indeterminate legal status, subject to flexible and repeated interpretation, thereby adjusts the accountability of the actors involved for violations of binding provisions and produces a workable system of international law.

[732] Michelle Q. Zhang, 'Shall We Talk? Judicial Communication Between the CJEU and WTO Dispute Settlement' (2017) 28(1) EJIL 273, 292.
[733] ibid.
[734] ibid 292.
[735] Kati Kulovesi, *The WTO Dispute Settlement System: Challenges of the Environment, Legitimacy and Fragmentation* (Kluwer 2011) 12.
[736] Joris Larik, *Foreign Policy Objectives in European Constitutional Law* (OUP 2016) 107.

4.4 *The EU, responsibility, and accountability*

4.4.1 Broader perspectives on responsibility and liability for WTO violations

There are more radical approaches to the WTO/EU apportionment of liability and responsibility in the context of WTO trade violations. One suggestion is that while the EU's exclusive responsibility for such Member State breaches may have been accepted by other WTO members and the WTO Panels themselves, this is not grounded in post-Lisbon WTO dispute practice or WTO dispute jurisprudence more generally.[737] Duran, in particular, has argued that what is happening in the process of ascribing international responsibility for WTO breaches in the EU is not a purely external process.[738] Rather than the division of treaty-making competences between the EU and Member States, it is actually a division along an infringement/performance alignment. [739] In this infringement/performance context, this distinction no longer describes the external treaty-making capability between the EU and the Member States and instead describes an internal process of assigning responsibility and exercising autonomy.[740]

[737] Gracia Marin Duran, 'Untangling the International Responsibility of the European Union and its Member States in the World Trade Organisation post-Lisbon: A Competence/Remedy Model' (2017) 28(3) EJIL 697.
[738] ibid; though also discussions around the argument that the EU should be considered in a restricted manner when negotiating international agreements that involve mixed competencies or shared responsibility, on the basis that the EU is a 'derivative subject of international law that derives its existence and powers from the will and constituting acts of its members, flowing from the principle of conferral of powers in Article 5 TEU. Thus, under EU law, the international legal personality of the EU and its capacity to conclude such treaties run along its treaty-making competences.': Philipp Theodor Stegmann, *Responsibility of the EU and the Member States under EU International Investment Protection Agreements: Between Traditional Rules, Proceduralisation and Federalisation* (Springer 2019) 31.
[739] Gracia Marin Duran, 'Untangling the International Responsibility of the European Union and its Member States in the World Trade Organisation post-Lisbon: A Competence/Remedy Model' (2017) 28(3) EJIL 697.
[740] ibid; appearing to reflect the decisions of the CJEU in the 1970s whereby the conferral of an internal competence necessarily involves a corresponding external, treaty-making, power: J H H Weiler, 'The Transformation of Europe' in Miguel Poiares Maduro and Marlene Wind (eds*), The Transformation of Europe: Twenty-Five Years On* (CUP 2017) 14.

The EU, while capable of participating in the WTO dispute settlement process as a full and independent member, is necessarily framed by its strong trade presence.[741] From 1995, the EU has participated in over 300 of the 525 disputes that have been brought within the WTO framework.[742] As discussed previously, the EU has been noted for its eagerness in participating in the international settlement disputes and demonstrating leadership,[743] with the EU's participation in the WTO dispute resolution system being generally very successful.[744] This has not, however, led to the EU always being compliant with WTO obligations.[745] A key principle in the WTO Panels has been the consideration about which institution or body had the power to amend or remove the offending provision.[746] While the EU is clearly responsible in some areas, like where the EU is the body with the power to amend or remove infringing provisions, this cannot be said for all areas of law.[747] Critique about the appropriateness of a WTO Panel transforming, through practice, the WTO Agreement into one that operates as one conferring exclusive responsibility upon the EU for WTO violations has also emerged.[748] In areas of law that are harmonised at the EU level, the EU is obviously the actor with the power to amend or remove provisions that are alleged to have violated WTO law.[749] Areas such as

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[741] Luca Pantaleo, *The Participation of the EU in International Dispute Settlement: Lessons from EU Investment Agreements* (Springer 2018) 15.
[742] Gracia Marin Duran, 'Untangling the International Responsibility of the European Union andits Member States in the World Trade Organisation post-Lisbon: A Competence/Remedy Model' (2017) 28(3) EJIL 698.
[743] Petros C Mavroidis and André Sapir, 'Dial PTAs for Peace: The Influence of Preferential Trade Agreements on Litigation between Trading Partners' in Jagdish N Bhagwati, Pravin Krishna, and Arvind Panagariya (eds), *The World Trade System: Trends and Challenges* (MIT Press 2016) 92.
[744] Antonis Antoniadis, 'The Participation of the EC in the WTO' in Takis Tridimas and Paolisa Nebbia (eds), *European Union Law for the Twenty-First Century: Rethinking the New Legal Order* (Hart 2004) 339.
[745] Gracia Marin Duran, 'Untangling the International Responsibility of the European Union and its Member States in the World Trade Organisation post-Lisbon: A Competence/Remedy Model' (2017) 28(3) EJIL 727.
[746] Cedric Ryngaert, 'The Responsibility of the Member States of International Organisations' in Ana Sofia Barros, Cedric Ryngaert, and Jan Wouters (eds), *International Organisations and Member States Responsibility: Critical Perspectives* (Brill 2016) 217.
[747] Richard H Steinberg, 'The Transformation of European Trading States' in Jonah D Levy (ed),*The State after Statism: New State Activities in the Age of Liberalization* (Harvard University Press 2006) 348.
[748] Gracia Marin Duran, 'Untangling the International Responsibility of the European Union and its Member States in the World Trade Organisation post-Lisbon: A Competence/Remedy Model' (2017) 28(3) EJIL 728.
[749] Philipp Theodor Stegmann, *Responsibility of the EU and the Member States under EU International Investment Protection Agreements: Between Traditional Rules, Proceduralisation and Federalisation* (Springer 2019) 92.

tariffs and customs issues are a clear example of this where there is only minimal autonomy for the Member States because they operate within a European legislative framework.[750] Accountability, in these contexts, highlight precisely the type of linear accountability that is obscured or less clear in patent law.

One of the ways suggested in the literature that other WTO Members could challenge the EU's position would be to keep challenging the provisions of Member States and keeping the EU and the Member States joined in joint complaints.[751] This would continue to challenge the EU's eagerness to assume responsibility for Member State violations and threaten continued EU unity at the international level.[752] This would be particularly unfortunate if it were to occur while the EU is in its current state, though it is unclear what other WTO Members would gain from challenging the EU's strong influence in the WTO. Very few of the other WTO Members are large enough to recreate the EU's effect on international dispute resolution and generate their own legal norms in the way that the EU does. Beyond this, the consistent presence of a prominent international actor in WTO dispute settlement could actually be an especially positive force for the integrity of the system at a more fundamental level. This type of consistent challenge may serve to highlight the fractured process of assigning accountability for WTO violations between the EU and the Member States, yet how would this contribute to a more effective sense of accountability? Challenges from other WTO members may draw attention to the issue but solving the issue of accountability and responsibility rests on the

[750] Philipp Theodor Stegmann, *Responsibility of the EU and the Member States under EU International Investment Protection Agreements: Between Traditional Rules, Proceduralisation and Federalisation* (Springer 2019) 92.
[751] Gracia Marin Duran, 'Untangling the International Responsibility of the European Union and its Member States in the World Trade Organisation post-Lisbon: A Competence/Remedy Model' (2017) 28(3) EJIL 729.
[752] Regarding the actual potential for members to challenge EU unity: 'None of the least-developed country Members have brought a complaint. There are many reasons for this - an important one may be the desire not to offend the EU and the United States and risk losing aid and GSP benefits.': Christine Schuchhardt, 'Consultations' in Patrick F J Macrory, Arthur E Appleton, and Michael G Plummer (eds), *The World Trade Organisation: Legal Economic and Political Analysis* (Springer 2007) 1230.

willingness of EU actors to engage productively with it. Particularly with other major global challenges in 2022/2023, it is unlikely that this would be a priority for the EU.

The fact that joint complaints against the EU and Member States in a post-Lisbon EU context means that the issue of who exactly is responsible for international trade violations has clearly not been settled.[753] The argument that the EU's role as sole representative for the Member State violations has been accepted by other WTO members is undermined by the fact that there is no extensive WTO jurisprudence on this issue.[754] The EPUE and the UPC represent an area in which the impetus and conclusion of the provisions can be distinctly traced to the Member States themselves in that, although they were endorsed and supported by the EU apparatus, the roots of these provisions are not of the same kind as an ordinary EU Treaty. Yet, as highlighted in chapter 2, it is important to recognise that the UPC Agreement is *not* the product of enhanced cooperation. This presents a complexity in patent law accountability that suggests a split between the power to amend provisions and the power to enforce, where the type of linear accountability discussed above is obscured even further. For responsibility and the power to amend the provisions, this could be considered as a distinction for the EPUE in that the emphasis is more on the participating Member States (rather than the EU institutions because not of all of the Member States are participating in the enhanced cooperation process).

The EPUE and (patent law more generally) highlights that while the capacity for autonomy on the part of the Member States is minimised, there is still some form of autonomy retained. This is particularly relevant for considering the issue of responsibility because it was a project that was created by the Member States themselves. It highlights how, specifically in the compromised fragmentation that the EPUE brings, the current approach to the liability or

[753] Gracia Marin Duran, 'Untangling the International Responsibility of the European Union and its Member States in the World Trade Organisation post-Lisbon: A Competence/Remedy Model' (2017) 28(3) EJIL 699.
[754] Joni Heliskoski, 'Joint Competence of the European Community and its Member States and the Dispute Settlement Practice of the World Trade Organisation' in Alan Dashwood and Angela Ward (eds), *The Cambridge Yearbook of European Legal Studies* (Hart 2000) 76.

responsibility for violations is more of a workable response to complex arrangements rather than a consistent legal approach. Crucially, the position of the EU as underscoring Member State liability relies not on legal interpretation or provisions, but on the fact that it resolves a complex issue in a simple manner and has been accepted by other international actors. The EPUE highlights that this relationship of responsibility between the Member States and the EU is, particularly for the development of patent law violations, essentially a legal fiction that is co-created by the EU, the Member States, and other WTO Members.

5. Conclusion

This chapter builds on the work of chapter 2 by shifting the focus the relationship between the EU and other sources of international law. The chapter focused on the impact of the WTO and the WTO Agreements in the EU to explore how accountability for these provisions is supported, reinforced, and undermined. The analysis here is necessarily framed by the fact that this context represents only a single example of the how the EU interacts with non-EU sources of law.

The chapter has been focused specifically at the first and third research questions of the thesis in that it is intended to explore how the legal relationship between the EU and the WTO can be interpreted from an administrative law perspective, and specifically how accountability is realised in this context. The major theme of the chapter has been the interactions between the CJEU and the WTO which present an a more flexible construction of accountability. The analysis in the chapter emphasised that accountability takes on a flexible and context-specific character for WTO obligations in the EU, predominantly through the CJEU as the central dispute resolution body. Through a process of interpretation, the CJEU flexibly interprets the legal status of binding international obligations in a way that modulates EU responsibility for

alleged violations or incompatibilities with international trade obligations. While the discussions in the chapter highlighted how this has generally been cast as a rejection of WTO authority, a closer look from the perspective of accountability instead suggests that it is a process of modulation rather than rejection. This emphasis on a contextually inflected accountability means that binding obligations, in practice, can essentially be rendered more or less binding depending on the specific circumstances involved.

The chapter considered the interactions between the WTO and the EU in two particular contexts. The first is the complex way that responsibility has been constructed in the EU in terms of WTO violations and the liability of EU Member States. The EU has exclusive competence in terms of WTO obligations as an aspect of the CCP and is complicated by the fact that the EU (as a customs union) is also a full member of the WTO. Responsibility for violations, and the process of establishing responsibility, takes on a specific character because the EU Member States retained their WTO membership even after the CCP rendered trade an exclusive competence. The interface that is created here would first appear to be a simple bringing together of the WTO and the EU, though what emerges in the analysis is that this arrangement results from an interactive process of co-creation that takes place within the EU and is accepted by the international community.

The second aspect of the legal interface between the EU and the WTO is the CJEU and the analysis explored how dispute settlement bodies work to produce (and adjust) accountability. The CJEU has a great scope for autonomy in that it has the power to interpret EU law, and this necessarily shapes how international law (or other sources of law generally) is filtered through the CJEU interpretative lens. The CJEU is then central in shaping the dynamic of the interface between the EU and the WTO because it represents a very specific institutional actor that has the power to meaningfully influence accountability and responsibility for violations of binding obligations. Direct effect of WTO agreements would

appear to only be a small element of this relationship, but it is precisely through the denial of direct effect that empowers this interpretative ability of the CJEU to flexibly adapt accountability. This chapter has demonstrated how a dispute settlement body works within a specific institutional and legal context to flexibly produce accountability, yet it necessarily reflects a fairly stable and identifiable group of actors because of the central role of the CJEU. But how does accountability function when both the legal interfaces and dispute resolution bodies take on a more diffuse character? Chapter 4 explores the processes through which legal interfaces are produced and how accountability, when unlinked from a consistent dispute resolution body like the CJEU, evolves.

Exploring the values of EU bilateral agreements: Bringing together accountability, transparency, and participation

1. Introduction

Bilateral agreements have become an increasingly prominent aspect of the international trade environment and contribute significantly to the trade relationship between countries on a global scale.[755] Particularly with the criticisms around both the multilateral process more generally and the speed at which these projects can be concluded,[756] bilateral trade agreements have been an important element of continuing increases in trade and cooperation between countries. Bilateralism of recent decades – particularly that which preceded the conclusion of the Uruguay Round and the crisis in multilateralism post-Cancún[757] – may have resulted in significant developments in international trade but remain a small part in a long history of bilateral agreements.[758]

Bilateral trade agreements produce a legal context that in which disputes are necessarily diffuse, emerging from context-specific legal arrangements that reflect more localised characteristics of these agreements. As such, approaching the development of modern

[755] On the sharp growth of trade agreements since the 1990s: Silvia Sopranzetti, 'Overlapping Free Trade Agreements and International Trade: A Network Approach' (2018) 41(6) The World Economy 1549.
[756] 'The institutional machinery of the GATT/WTO system is cumbersome and slow. Multilateral rounds take many years to negotiate, and tend to address issues agreed upon by the parties at the inception of each round.': Thomas R Howell, 'The Multilateral Trading System and Transnational Competition in Advanced Technologies: The Limits of Existing Disciplines' in Göran Marklund, Nicholas S Vonortas, and Charles W Wessner (eds), *The Innovation Imperative: National Innovation Strategies in the Global Economy* (Edward Elgar 2009) 52.
[757] On the subversive impact of preferential trade agreements on the GATT obligations before Uruguay: Marcelo de Paiva Abreu, 'Developing Countries and the Uruguay Round of Trade Negotiations' (1990) Proceedings of the World Bank Annual Conference on Development Economics 1989 28.
[758] On the long history of bilateral agreements (as well as the more general trends of liberalism and protectionism over time): Olivier Cattaneo, 'The Political Economy of PTAs' in Simon Lester, Bryan Mercurio, and Lorand Bartels (eds), *Bilateral and Regional Trade Agreements: Commentary and Analysis* (CUP 2015) 31.

bilateralism, and the challenges of dispute settlement, helps explore the nuances of GAL values and the degree to which the 'bilateral space' is a distinct legal context. What appears when analysing bilateral trade agreements from the perspective of transparency, participation, and accountability is a sense that not only are these values fundamentally interconnected, but they remain somewhat distinct from the same values when they appear in a multilateral context. Turning first to the interconnected nature of these values, the approach of the thesis was to artificially separate out these values to explore how they function. Yet here, in the bilateral space, the agreements are so grounded in their own specific legal and political context that the overlaps between the values are much more prominent. Taking transparency as an example, weaknesses of transparency in a bilateral trade agreement are at once enabled by, and also produce, deficiencies in participation and accountability. The diffuse character of dispute resolution bodies in this unsettled bilateral space means that their role in bringing substantive meaning to these values is both pervasive and yet fundamentally isolated in its reach. As such, the chapter emphasises how these administrative values function in the construction of a 'bilateral space' – drawing on the GAL scholarship that works to explore (and construct) the 'global space'.[759] In doing so, the role of dispute resolution bodies (and how legal disputes feature in international patent law) is necessarily minimised as they are contextualised alongside the more amorphous processes that produce the bilateral space itself. This sense of contextual responsiveness also connects the bilateral space with the distinction that appears between values in a bilateral agreement and a multilateral agreement. When transparency or accountability is advanced at the more systemic or multilateral level, this has a clear and more generalisable impact on how patent law functions in a broad sense. Yet as will be discussed in this chapter, advancements (or more commonly, the challenges) in the bilateral context are

[759] Elisa D'Alterio, 'Judicial Regulation in the Global Space' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 321.

limited in their impact to the specific legal space between trade partners. In this, administrative values appear to fit well within the dominant narratives of the increasing atomisation of international trade law,[760] contributing to a trade environment that is driven by contextual and individualised relationships between state actors.

For a significant period of time, bilateral trade agreements considered intellectual property in a relatively general way that emphasised references to major agreements over the adoption of specific legal standards.[761] This lack of attention to intellectual property and patent law in bilateral trade mirrors the more general sense pre-TRIPS to these areas as the 'domain of specialists'.[762] The rapid shift from general disinterest even in legal circles to the public protests about the provisions of specific agreements like ACTA signal that intellectual property has become an increasingly visible point of tension. This increase in attention has occurred in a context in which major trade actors like the EU increasingly conclude bilateral agreements that contrast with the earlier approach to bilateralism by devoting elaborate chapters to the treatment of intellectual property and providing very specific obligations.

This also relates to the development of 'TRIPS-Plus' and 'WTO-Plus' disciplines and their incorporation within bilateral trade agreements.[763] The WTO Agreements, while they

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[760] Though in reference to international investment law, Hamdani specifically discusses the negative impact of a patchwork of individual treaties between trade partners: Khalil Hamdani, 'Panel: Process and Value of Uniform Commercial Law: Proceedings of the Congress of the United Nations Commission on International Trade Law Held on the Occasion of the Fortieth Session of the Commission' (2007) 25 <https://uncitral.un.org/sites/uncitral.un.org/files/media-documents/uncitral/en/09-83930_ebook.pdf>.

[761] One more recent example would be the agreement between the Central American Association Agreement where Article 78(g) refers simply to a commitment to 'the adequate and effective protection of intellectual property rights, in accordance with international obligations in force between the parties…': Article 78(g) Agreement Establishing an Association between the European Union and its Member States, On the One Hand, and Central America on the Other; while Title VI of the same agreement (that deals with intellectual property) simply reaffirms the binding nature of the TRIPS Agreement in Article 229.

[762] Arguing that prior to the introduction of the TRIPS Agreement, intellectual property had 'was still the domain of specialists and intellectual property right producers': Wenwei Guan, 'Diversified FRAND Enforcement and TRIPS Integrity' (2018) 17(1) WTR 111.

[763] Though WTO-plus provisions, because of the standards in the application of Article XXIV GATT and Article V GATS, necessarily have somewhat of a unclear or flexible nature and makes it more difficult to concretely define: Gary Clyde Hufbauer and Sherry Stephenson, 'The Free Trade Area of the Americas: How Deep an Integration in the Western Hemisphere?' in Hadi Soesastro and Christopher Findlay (eds), *Reshaping the Asia Pacific Economic Order* (Routledge 2006) 130, 148.

certainly frame these agreements at a more fundamental level,[764] are still limited in the subject matter that they cover. The tension in the bilateral space is that it involves the creation of multiple, discipline-specific interfaces that have a varying relationship to the broader framing provided by the multilateral instrument. This presents a challenge to transparency in a more abstract sense than that which appeared in chapter 2 and 3. Rather than the formalist transparency of precisely which provisions are binding in practice and the concerns of legal predictability, the type of transparency that is undermined in bilateral trade agreements is more closely linked to the *trajectory* of development. Bilateral trade agreements emerge from complex legal and political relationships where, in practice, it is not clear which provisions have been the result of strategic trading.[765] Bilateral agreements now represent a large number of trade agreements and have been an important part of justifying global consensus for higher standards in intellectual property.[766] Because of the lack of transparency in bilateral trade agreements,[767] this means that the values and principles that drive the process by which global consensus is legitimised become fundamentally obscured.

The precise nature of these relationships at the bilateral level still remains connected to that of the multilateral environment however, particularly as it concerns the 'global ratchet' and the impact of more developed obligations on the precise character of any future multilateral

[764] On the growth of preferential trade agreements that are explicitly formed from the provisions of the WTO and GATT (though specifically highlighting goods with Article XXIV): Pravin Krishna, 'The Economics of PTAs' in Simon Lester, Bryan Mercurio, and Lorand Bartels (eds), *Bilateral and Regional Trade Agreements: Commentary and Analysis* (2nd edn, CUP 2015) 11.

[765] One multilateral example of this type of strategic trading of standards can be found in the Uruguay Round, with the dynamic between increased intellectual property standards and the possibility of greater market access in textiles and agriculture for developing countries: J H Reichman, 'The TRIPS Component of the GATT's Uruguay Round: Competitive Prospects for Intellectual Property Owners in an Integrated World Market' (1993) 4 Fordham Intellectual Property, Media & Entertainment Law Journal 178.

[766] Or less than *justifying* a global consensus, and just in practice producing the minimum standards applicable to intellectual property: Rohan Kariyawasam, *International Economic Law and the Digital Divide: A New Silk Road?* (Edward Elgar 2007) 239.

[767] Though with more effective presumptions of transparency after *Council v Sophie In't Veld* EU:C:2014:2039: Chris Kimura and Fernanda G Nicola, 'The Negotiating Capital of Trade Experts: Transparency in EU-Asian Free Trade Agreements' in Emilia Korekea-Ago and Päivi Leino-Sandberg (eds), *Law, Legal Expertise and EU Policy-Making* (CUP 2022) 176, 177.

consensus.[768] While the dysfunctional relationship between the multilateral and bilateral is significant, it is through this continuous ratcheting of standards that bilateral agreements have become increasingly implicated in contemporary patent issues like access to medicine.[769] These developments can be identified as dysfunctions because, even from the GAL perspective here, these increased standards are detached from any meaningful sense of broader engagement or participation. This lack of participation appears at two levels, the first of which is perhaps the more obvious sense of democratic engagement that is explored through GAL scholarship.[770] The second is narrower and concerns the participation of state actors – though is just as concerning from a GAL perspective. This is because, as exemplified particularly through bilateral trade agreements, even state participation is limited to a specific group of actors within those territories that results in significant challenges to broader accountability, transparency, and participation.

Part 1 considers how the EU strategy towards bilateral trade agreements has shifted, transitioning from an emphasis on general provisions in intellectual property towards one that requires the implementation of specific standards. Part 2 explores the issue of enforcement in these bilateral trade agreements, analysing how the process of dispute resolution can be a more generalised mechanism for modulating accountability and how this relates to other administrative values. Part 3 looks at problematic areas within bilateral relationships and

[768] With the three factors identified by Drahos: forum-shifting, coordinating bilateral and regional adaptations to this forum-shift, and entrenchment of these standards in future agreements: Peter Drahos, 'Expanding Intellectual Property's Empire: The Role of FTAs' (2003) 8 <https://www.researchgate.net/publication/268001027_Expanding_Intellectual_Property%27s_Empire_The_Role_of_FTAs>; discussion and further context: Anke Dahrendorf, 'Global Proliferation of Bilateral and Regional Trade Agreements: A Threat for the World Trade Organization and/or for Developing Countries?' in Jana Hertwig, Sylvia Maus, Almut Meyer zu Schwabedissen, and Matthias Schuler (eds), *Global Risks: Constructing World Order Through Law, Politics, and Economics* (Peter Lang 2010) 39, 50.

[769] Kyung-Bok Son, 'Understanding the Trends in International Agreements on Pricing and Reimbursement for Newly Marketed Medicines and their Implications for Access to Medicines: A Computational Text Analysis' (2020) 16 Globalization and Health 10, 11.

[770] Martin Shapiro, '"Deliberative," "Independent" Technocracy v. Democratic Politics: Will the Globe Echo the E.U.?' (2005) 68(3/4) Law and Contemporary Problems 343.

focuses on the potential for overlap as a challenge to transparency in patent law. It also considers the tensions in transparency and participation that emerge from an increasingly inclusive understanding of trade liberalisation.

2. The EU and the shift towards bilateralism

2.1 *Exploring the increased attention to bilateral negotiations*

2.1.1 Resurgent bilateralism after the Uruguay Round

Intellectual property at the international level has clear cyclical elements that contribute to increasing standards,[771] of a repeating process of multilateral consensus, with bilateral or regional agreements that introduce higher standards which are then consolidated in subsequent multilateral instruments as the new consensus.[772] These bilateral interfaces can be interpreted as allowing new approaches to emerge as experimental smaller-scale projects that, if successful enough, are then consolidated at the multilateral level. Unlike the previous rounds of multilateral and bilateral development, the concerning progression of policy in this area amounts much more explicitly to a substitution of the process of multilateral consensus building rather than a complement. For the broader realisation of administrative values, this type of shift can be particularly concerning because it localises or atomises the relationships between actors. In these more specific contexts, values like transparency or accountability take

[771] Peter Drahos, 'Doing Deals with Al Capone: Paying Protection Money for Intellectual Property in the Global Knowledge Economy' in Peter K Yu (ed), *Intellectual Property and Information Wealth: Issues and Practices in the Digital Age* (Greenwood 2007) 50; Anke Dahrendorf, 'Global Proliferation of Bilateral and Regional Trade Agreements: A Threat for the World Trade Organisation and/or for Developing Countries?' in Jana Hertwig and Sylvia Maus (eds), *Global Risks: Constructing World Order Through Law, Politics and Economics* (Peter Lang 2010) 50.

[772] Bryan Mercurio, 'TRIPS-Plus Provisions in FTAs: Recent Trends' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 235.

on a local character that is subject to contextual interpretation rather than general or widely developed norms.

As the Doha Development Round stalled,[773] the EU shifted towards bilateral and regional free trade agreements to pursue the same agricultural aspects of the Doha Round but in a bilateral setting.[774] The Doha Round and its troubled progress are the start of the modern dynamic of the global ratchet in intellectual property, though it is also what distinguishes the current arrangement from that of previous multilateral consolidations. While the WTO had been involved in controversy previously, Seattle and Cancún in particular,[775] the cycle of the global ratchet has never occurred in a political and trade context in which major international trade actors have so forcefully denied the legitimacy of multilateral institutions as we experience now. COVID-19 has certainly contributed to this in a more general sense with the WHO,[776] but it is the issues of vaccine accessibility and intellectual property that have brought engagement with the WTO into more ordinary public life. The diversity of responses to COVID-19 found in WTO discussions (as well as the perceived lack of progress) highlight the lack of speed or, perhaps more critically, lack of political responsiveness in the multilateral apparatus.

[773] Tesh W Dagne, 'The Narrowing Transatlantic Divide: Geographical Indications in Canada's Trade Agreements (2016) 10 EIPR 598.
[774] Chad E Hart and John C Beghin, 'Rethinking Agricultural Domestic Support under the World Trade Organization' in Kym Anderson and Will Martin (eds), *Agricultural Trade Reform and the Doha Development Agenda* (World Bank Publications 2005) 238.
[775] On the negative result of Cancún: Olivier Cattaneo, 'The Political Economy of PTAs' in Simon Lester and Bryan Mercurio, *Bilateral and Regional Trade Agreements; Commentary and Issues* (CUP 2009) 37; Patricia Garcia-Duran, Montserrat Millet, and Jan Orbie, 'EU Trade Policy Reaction to the BIC: From Accommodation to Entrenchment' in Esther Barbé, Oriol Costa, and Robert Kissack (eds), *EU Policy Responses to a Shifting Multilateral System* (Macmillan 2016) 93.
[776] Gonca Oguz Gok and Radiye Funda Karadeniz, 'The UN's Legitimacy in Global Governance and the COVID-19 Pandemic' in Gonca Oguz Gok and Hakan Mehmetcik (eds), *The Crises of Legitimacy in Global Governance* (Routledge 2022) 78.

2.1.2 Exploring the dynamic of the global ratchet

The global ratchet provides an interesting perspective for understanding how a distinct bilateral space is created between trade partners because the emphasis has typically been on the distributional outcomes of these higher standards.[777] The critique is generally founded on a perceived mismatch between the intellectual property standards and the trade partner's economic development or how these elaborated standards create some negative distributional outcomes.[778] Yet from a more systemic perspective, the global ratchet highlights the important role of administrative values as a way of interpreting how international patent law is developing. Increasing standards of protection through the global ratchet can be interpreted from a variety of perspectives: as collaboration towards more specific objectives within intellectual property,[779] as a critical marginalising of developing countries,[780] or as a problem of political bargaining power between global actors.[781] Yet an approach that centres GAL values in these interactions of bilateral and multilateral patent law connects and integrates each of these perspectives. This is because it recognises the importance of participation in the development of these increased standards (as participation) but balances this critique of international patent

[777] That this upward ratcheting is particularly acute in the pharmaceuticals and its relationship to incremental innovation: Mario Cimoli, Giovanni Dosi, Roberto Mazzoleni, Bhaven N Sampat, 'Innovation, Technical Change, and Patents in the Development Process: A Long-Term View' in Mario Cimoli, Giovanni Dosi, Keith E Maskus, Ruth L Okediji, Jerome H Reichman, and Joseph E Stiglitz (eds), *Intellectual Property Rights: Legal and Economic Challenges for Development* (OUP 2014) 81.

[778] That this upward ratcheting is particularly acute in the pharmaceuticals and its relationship to incremental innovation: ibid.

[779] Australian bilateral trade agreements with TRIPs-Plus provisions have been discussed in promoting the ratification of the WIPO internet treaties, Madrid Protocol and the Singapore Treaty related to trademarks: Christoph Antons and Reto M Hilty, 'Introduction: IP and the Asia-Pacific "Spaghetti Bowl" of Free Trade Agreements' in Christoph Antons and Reto M Hilty (eds), *Intellectual Property and Free Trade Agreements in the Asia-Pacific Region* (Springer 2015) 20.

[780] Where '[j]ust when these emerging economies started to benefit from TRIPS Standards and just when other smaller developing countries were contemplating similar strategies, developed countries once again pushed for higher intellectual property standards': Peter K Yu, 'Development Bridge Over Troubled Intellectual Property Water' in Carlos Correa and Xavier Seuba (eds), *Intellectual Property and Development: Understanding the Interfaces* (Springer 2019) 98.

[781] 'Even if developing countries possess the relevant intellectual property expertise they have little real bargaining power in a negotiation I which they are seeking access to the U.S. or European markets (especially if they wish to become members of the European Community or NAFTA. Almost certainly, developing country negotiators are acquiescing to the intellectual property norms in BIPs as part of the "standard deal" they have to accept as the price for gaining access to the entry to the lucrative markets of Europe and the United States': Peter Drahos, 'BITS and BIPS: Bilateralism in Intellectual Property' (2001) 4 JWIP 805.

law by suggesting that in practice these binding provisions are not always completely binding (accountability and transparency). Integrating more critical perspectives, the GAL focus on accountability, transparency, and participation demonstrates how context-dependent these values are in practice. The thesis has focused on European dispute resolution bodies from this administrative perspective, but implicit throughout the thesis is an exploration of the role of context – it is difficult to imagine which other global actors would be able to successfully interpret binding obligations in the way that the EU has. From this perspective, there is a dissonance or unsettling asymmetry between the way the EU experiences international patent law (and international law more generally) and the way developing countries do. The EU experience of the bilateral space in intellectual property is actually representative of a more fundamental warping of administrative values that reaches far beyond patent law.

Exceptions and flexibilities in patent law then take on a particular importance in this bilateral space because, as discussed in chapter 2 and 3, they represent an opportunity to flexibly modulate the binding quality of a trade obligation. In combination with transparency and participation, the GAL perspective provides a more nuanced understanding of how international patent law is developing. It presents the interaction of bilateral and multilateral legal initiatives in patent law as producing a flexible system in which accountability, transparency, and participation are modulated in a way that shapes legal provisions, their binding quality, and frames the role of dispute settlement bodies.

From a more abstract perspective, there is certainly no inherent problem with countries coming together to pursue specific trade interests or develop higher standards of intellectual property protection.[782] This 'country club' approach to bilateral agreements is an optimistic

[782] The TRIPS Agreement does not mirror the Paris or Berne Conventions in their guidance as to the relationship with subsequent agreements, though the relationship with 'special agreements' and essentially an endorsement by the Appellate Body as to the priority of these specific provisions over general Vienna Convention principles as a *lex specialis*: Henning Grosse Ruse-Khan, 'From TRIPS to FTAS and Back: Re-

view of what is happening in international trade, but it certainly does describe some specific examples of bilateral agenda setting. Deals involving Australia,[783] for example, typically incorporate more stringent intellectual property enforcement mechanisms, while both South Korea and Japan have favoured strong enforcement mechanisms in agreements with other industrialised countries.[784] Tension arises when there is a prominent asymmetry between trade partners in terms of market, economy, or resources and particularly between agreements of developed and developing countries. It is in this context that the use of bilateral agreements to increase standards in intellectual property is perhaps most problematic and demonstrates how the bilateral space takes a specific character distinct from multilateralism.

Transparency emerges as a central concern in the global ratchet, though given the complex nature of bilateral legal development, it does also incorporate some elements from accountability and participation. The global ratchet fundamentally obscures the values that drive legal development in a way that does not occur in either national or global contexts. Decentralised and atomised negotiations between partners have become an essential part in producing an accepted international standard.[785] Yet in doing so, the actual formation of this

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Conceptualising the Role of a Multilateral IP Framework in a TRIPS-Plus World' (2018) Netherlands Yearbook of International Law 39.

[783] While Australia is a developed country with a robust intellectual property framework, in the AUSFTA, both copyright and enforcement standards were raised – a benefit to the US as Australia is a net importer of intellectual property: Andrew D Mitchell and Tania Voon, 'Australia-United States Free Trade Agreement' in Simon Lester and Bryan Mercurio (eds), *Bilateral and Regional Trade Agreements: Case Studies* (CUP 2009) 31.

[784] From the late 1980s, South Korea saw a domestic strengthening of intellectual property standards: Alan Gutterman and Bentley J Anderson, *Intellectual Property in Global Markets* (Springer 1997) 299; also on the important regional position that Japan and South Korea occupy (and more recently, China) in the beneficiaries of increased intellectual property standards in the context of ASEAN and the Regional Comprehensive Economic Partnership Agreement: Anupam Chander and Madhavi Sunder, 'The Battle to Define Asia's Intellectual Property Law: From TPP to RCEP' (2018) 8 UC Irvine Law Review 331, 337.

[785] Sarah R Wasserman Rajec, 'The Harmonization Myth in International Intellectual Property Law' (2020) 62 Arizona Law Review 762; though see also the discussion on the role of non-multilateral agreements as templates and providing a 'specific vision of economic ordering' (also raised by Rajec, 763): Rochelle C Dreyfuss, 'Harmonization: Top Down, Bottom Up–and Now Sideways?: The Impact of the IP Provisions of Megaregional Agreements on Third Party States' in Benedict Kingsbury, David M Malone, Paul Mertenskötter, Richard B Stewart, Thomas Streinz, and Atsushi Sunami (eds), *Megaregulation Contested: Global Economic Ordering After TPP* (OUP 2019) 345, 346.

accepted international standard is hidden. The bilateral space lacks the type of clear and identifiable legal processes that a national piece of legislation would be subject to, while it also facilitates an obscuring of which actors are actually producing the global standards in international patent law (and perhaps more importantly, their normative objectives and values). This is not to say that we cannot identify the major actors that drive international consensus in the context of the global ratchet, it is very clear that the EU (and the US) have been important in this process.[786] Rather, from the perspective of a substantive sense of transparency and accountability over narrow formalism, this way of producing international consensus cannot be more sharply or cleanly separated out into distinct legal processes in a way that national law can. The signing of trade agreements is perhaps the only part of this bilateral consensus building process that provides a clear or marked point in its development, but it necessarily represents only one (limited) indication of formal agreement on legal provisions and cannot provide the negotiation context or priorities that produced it.

The first step of the global ratchet as put forward by Drahos is that the standard-setting objectives need to be shifted away from a forum in which there are negotiating difficulties and into a forum that is more open to realising the trade objectives.[787] One of the clearest examples of forum shifting in this style was, at least in the context of intellectual property, the move away from WIPO towards the WTO.[788] The second step takes this multilateral foundation and uses bilateral or regional trade agreements to coordinate intellectual property interests, driving

[786] Where the EU and the US regularly appear as central actors in the upward trajectory of standards in intellectual property protection: Susan Sell, 'The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play' (2010) PIJIP Research Paper 15, 4, 5 <https://digitalcommons.wcl.american.edu/research/15/>.
[787] Peter Drahos, 'BITs and BIPs: Bilateralism in Intellectual Property' (2001) 4 JWIP 798.
[788] Though complaints remain as to the effectiveness of WIPO for developing countries, an important element of the WTO-WIPO interface is the 1995 agreement that covered the provision of technical assistance to developing countries in their TRIPS implementation: Carolyn Deere Birkbeck, 'WIPO's Assistance to Developing Countries: The Evolution of Debate and Current Challenges' in Xavier Seuba and Carlos Correa (eds), *Intellectual Property and Development: Understanding the Interfaces* (Springer 2019) 142.

standards above the established international minimums.[789] The final step of the ratchet is where these higher international standards are then consolidated in a multilateral instrument and form the new international minimum.[790]

While a lot of emphasis has been placed on how bilateral and regional trade agreements have developed, the broader multilateral context has an important relationship to how these bilateral standards are actually consolidated.[791] The use of bilateral agreements as a tool for developing countries to achieve specific objectives has been highlighted as an important element in the bilateral dynamic.[792] The consensus that these agreements help to produce necessarily reflects these complex drivers of cooperation, but the trade agreement text (outside of extreme examples) resists a disentangling of the exact source of its provisions.[793] The consensus proper comes into existence at the point of multilateral recognition and consolidation, but there is a degree of obscuring the origins (and producers) of this consensus because it emerges from the diffuse bilateral space. The consolidation stage has been where the Global North/South divide can be most clearly identified because it necessarily produces a singular, authoritative, framing of international trade that privileges certain interests.[794] Despite the critiques as to the quality or character of the multilateral consolidation,[795] the multilateral space

[789] Peter Drahos, 'BITs and BIPs: Bilateralism in Intellectual Property' (2001) 4 JWIP 798.
[790] ibid.
[791] Bryan Mercurio, 'TRIPS-Plus Provisions in FTAs: Recent Trends' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 236.
[792] Jan Wouters, Sanderign Duquet, and Nicolas Hachez, 'International Investment Law: The Perpetual Search for Consensus' in Olivier de Schutter, Johan F M Swinnen, and Jan Wouters (eds), *Foreign Direct Investment and Human Development: The Law and Economics of International Investment Agreements* (Routledge 2013) 26.
[793] One such example would be where the text of specific provisions is directly taken from one of the trade partners.
[794] The tension between the Global North and South in a multilateral context is not new, nor is it reserved for intellectual property. Of particular importance is the idea of the G20 as a 'bridge' between these groups but questions regarding how representative the G20 actually is, continue: Amitav Acharya, 'Global Governance in a Multiplex World' (2017) RSCAS Working Paper 2017/29 5.
[795] The reality is that the participation in the Uruguay Round was enabled through state autonomy and sovereignty. Though there are tensions as to the precise balance between 'the imperative of trade liberalization and respect for state sovereignty' in the WTO Agreements: Anne Orford, 'Theorizing Free Trade' in Anne Orford and Florian Hoffmann (eds), *The Oxford Handbook of the Theory of International Law* (OUP 2016) 733.

it is still procedurally inflected by very visible elements of participation and transparency that encourage compromise, negotiation, and moderation.

But when considered from the perspective of the major economies of the world (and the EU in particular), what does the EU gain from submitting to the multilateral process? What objectives cannot be realised through the use of bilateral agreements? It is from this uncertainty around the eventual consolidation stage, with the struggles of multilateral organisations and cooperation, that these bilateral agreements become a central driver of international patent law. From this perspective, bilateral agreements and the dispute settlement systems they create facilitate the type of localised modulation of accountability discussed in chapter 3. Yet the bilateral space joins this flexible accountability with a more limited or impaired sense of transparency and participation. The EU, though also applicable to other major economies,[796] has the market size and international presence that enables a relative freedom in designing these bilateral interfaces. It is this scale, and global presence, which empowers the contextual flexibility of accountability and transparency in the bilateral space. Yet, perhaps more optimistically, it also reflects the potential of the EU to support the reform and strengthening of these values in international patent law. Rather than increasing the substantive protection of patent law in these agreements, they could be used to entrench standards and expectations around transparency and participation. From this perspective, bilateral trade agreements can be experimental spaces that provide the foundational elements of a global consensus around GAL values in intellectual property more broadly.

[796] The trade agreements pursued by the EU and US are not uniform and respond to the capacity of their trading partners: Jayashree Watal, 'Is TRIPS a Balanced Agreement from the Perspective of Recent Free Trade Agreements?' in Josef Drexl, Henning Grosse Ruse-Khan, and Souheir Nadde-Phlix (eds), *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* (Springer 2014) 48.

2.1.3 Contextualising the role of bilateral trade agreements

The structure that encourages this type of differential treatment stems from the precursor to the TRIPS Agreement, the GATT, where tariff-based trade liberalisation and broad welfare gains were central priorities.[797] Not only was the focus very much on barriers to trade, but it was also couched in neoliberal discussions of 'unmitigated welfare gains' that helped establish a system in which commitments to tariff reductions were a major tool of liberalisation.[798] This emphasis on barriers to trade is also reflected in the relatively simple design of flexibilities and exceptions because the disciplinary focus was narrow and easily defined. Yet applying a GAL perspective to these more conventional trade disciplines can also provide a more nuanced understanding of how trade liberalisation has developed. Here, what is being negotiated and the consequences of accepting such binding provisions can be more strictly delineated. This certainty in scope promotes a type of transparency that has a more substantive character. In this, the entangling of legal and economic systems could be pursued effectively because there was a clear correspondence between the provisions, the objectives of the trade partners, and the relevant instruments to manage any conflicting expectations regarding those provisions. The difficulty in balancing the broader integrity of a system that encourages more specific agreements but within a framework of minimum obligations is that, because of the early economic framing and rationale around liberalisation, it is difficult to sufficiently justify going below these standards for non-economic reasons.[799]

In such a system, members are entirely free to go beyond the minimum obligations but, as we see in the context of TRIPS flexibilities,[800] become extremely risk-averse with provisions

[797] Rochelle C Dreyfuss, 'TRIPS-Round II: Should Users Strike Back?' (2004) 71 University of Chicago Law Review 21.
[798] ibid; that a minimum framework flows from the 'unmitigated welfare gains' Laurence R Helfer and Graeme W Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (CUP 2011) 34.
[799] Raj Bhala, *Modern GATT Law: A Treatise on the General Agreement on Tariffs and Trade* (Sweet & Maxwell 2005) 619.
[800] Particularly in the context of African states, the lack of usage of the compulsory licensing mechanism is not because there is an absence of epidemics rather the fear of economic repercussions: Olufemi Soyeju and Joshua

that could *suggest* their legal treatment of intellectual property falls below this minimum standard.[801] Particularly concerning in this type of arrangement is that the process of dispute resolution is increasingly detached from that of the WTO and instead filters into an arbitration process. This raises many concerns around transparency,[802] but it is also framed by the fact that these dispute resolution mechanisms are constructed on a per agreement basis and further contribute to the atomisation of dispute resolution. Here, the focus on dispute resolution bodies identified in earlier chapters (and in GAL scholarship more broadly) shifts into something more hazy and indistinct, where the dispute resolution bodies themselves take on a different character to those typically identified in GAL literature.[803] It is perhaps the very contextual construction of dispute resolution bodies emerging from bilateral agreements that contribute to the complex (and often unclear) relationship between GAL values, organisational structure, and distinctions between the substantive and procedural. These dispute settlement bodies are produced from these agreements and dissolve the distinction between substantive and procedural values. The dispute settlement bodies are then both the subject and the object of these trade agreements, produced from a legal framework that reflects specific values which are then judged by that very dispute settlement body.

While bilateral and regional agreements develop rules that apply to specific regions or specific countries, they are an essential part in the process of developing international

Wabwire, 'The WTO-TRIPS Flexibilities on Public Health: A Critical Appraisal of the East African Community Regional Framework' (2018) WTR 166.

[801] Laurence R Helfer and Graeme W Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (CUP 2011) 34; that members who go below these standards are subject to dispute settlement: Rochelle C Dreyfuss, 'TRIPS-Round II: Should Users Strike Back?' (2004) 71 University of Chicago Law Review 21.

[802] With the increasing complexity of choice of forum and law for dispute resolution: Frederick M Abbott, 'A New Dominant Trade Species: Is Bilateralism a Threat?' (2007) 10(3) JIEL 571, 577.

[803] GAL scholarship features prominent international dispute resolution bodies (like the ICJ) throughout: Jan Wouters, 'Government by Negotiation' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 208; though see also Alberto do Amaral Júnior and Cynthia Kramer, 'WTO as a Self-Limited Regime: The Case of Article XX GATT' in Alberto do Amaral Júnior, Luciana Maria de Oliveira Sá Pires, and Cristiane Lucena Carneiro (eds), *The WTO Dispute Settlement Mechanisms: A Developing Country Perspective* (Springer 2019) 70.

consensus.[804] When enough of these more specific trade agreements have been negotiated and implemented, they form a strong basis for recognising certain principles or practices as forming part of the multilateral consensus.[805] The development of intellectual property rights in this context must be understood in the broader history of intellectual property. Patent law has maintained a strong foundation of territoriality but intellectual property as a distinct policy area involves the balancing of different legal, regulatory, and economic factors more generally. This national emphasis presents a tension when these disciplines are incorporated in bilateral agreements because it broadens the relevant factors for balancing. Instead of industrial policy being balanced against a domestic set of factors, intellectual property in a bilateral context becomes one of many legal elements up for negotiation. As opposed to the single undertaking in the WTO that reduces the scope for substantial asymmetries,[806] the bilateral context allows (and even facilitates) the trading of intellectual property standards for trade gains in other areas. The result is that while the bilateral space broadens the scope of relevant disciplines for trade gains, the mechanisms and flexibilities within specific disciplines like intellectual property are restricted in return for market access or other economic incentives. The result is a system of law in which the origins of its values, principles, and objectives can never be reliably identified. Though some cases may present obvious indications about what exactly was 'traded',[807] the absence of more developed mechanisms that enable transparency (and thus broader participation) mean that patent law produced in these environments lacks transparency of a more fundamental character.

[804] Bob Reinalda, *Routledge History of International Organisations: From 1815 to the Present Day* (Routledge 2009) 636.
[805] Bryan Mercurio, 'TRIPS-Plus Provisions in FTAs: Recent Trends' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 236.
[806] Though Wolfe concludes that the single undertaking, rather than producing an outcome in negotiation, instead shapes the possibility of an outcome: Robert Wolfe, 'The WTO Single Undertaking as Negotiating Technique and Constitutive Metaphor' (2009) 12(4) JIEL 835, 836.
[807] As in the Uruguay Round in areas like textiles and agriculture: J H Reichman, 'The TRIPS Component of the GATT's Uruguay Round: Competitive Prospects for Intellectual Property Owners in an Integrated World Market' (1993) 4 Fordham Intellectual Property, Media & Entertainment Law Journal 178.

2.2 *Finding the space: national autonomy and policy space as flexibilities*

2.2.1 Policy space, autonomy, and developing countries

The use of bilateral agreements in pursuit of trade liberalisation is not inherently problematic, but it further distinguishes the current generation of as yet unconsolidated bilateral standards from the global ratchet of previous decades. It is important to recognise that the EU is not the only jurisdiction using bilateral agreements in a way that restricts TRIPS flexibilities, with the US also promoting similar agreements.[808] Developing countries occupy a specific position in this environment because they necessarily have to balance between maximising national autonomy (and a nationally responsive intellectual property policy) and market access.[809]

An important element of the TRIPS Agreement is that it preserved a degree of policy space for WTO Members that can be used to moderate the relationship between the multilateral and national spheres to empower actors.[810] The TRIPS Agreement has a complex relationship to policy space because, by reserving some space for national autonomy, it enables both the freedom to trade away this autonomy for strategic trade gains *and* the flexibility to interpret TRIPS obligations from a specific perspective. Within this global framework, the WTO Members are not only using the remaining policy space to work towards their national

[808] Alvaro Santos, 'Carving Out Policy Autonomy for Developing Countries in the World Trade Organisation: The Experience of Brazil and Mexico' in David M Trubek, Helena Alviar Garcia, Diogo R Coutinho, and Alvaro Santos (eds), *Law and the New Developmental State: The Brazilian Experience in Latin American Context* (CUP 2013) 204.

[809] where '…resistance to demands for higher levels of protection might be based on concepts of good governance and political responsibility towards citizens': Frederick M Abbott, 'The Future of IPRs in the Multilateral Trading System' in Christophe Bellmann and Ricardo Melendez-Ortiz (eds), *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (Routledge 2013).

[810] The TRIPS Agreement preserved a degree of national autonomy, this policy space can be used to implement standards that are still fully consistent with TRIPS: Keith E Maskus, 'Policy Space in Intellectual Property Rights and Technology Transfer: A New Economic Research Agenda' in Xavier Seuba and Carlos Correa (eds), *Intellectual Property and Development: Understanding the Interfaces* (Springer 2019) 13.

objectives, but they are also using this lateral movement to create new interfaces between trade partners that may either build on the TRIPS Agreement (TRIPS-Plus) or entangle other, non-WTO disciplines (WTO-Plus).[811] The scope of national policy space is then tied to the national intellectual property environment and highlights how, in the bilateral space, the interfaces that are created are very context-specific and how they function may not be generalisable. The values that drive these cooperations, and thus the resulting legal relationship, may indeed reflect GAL principles and priorities. Yet they are produced from specific interactions that suggest a more contextual transparency, a more contextual accountability, that may be different to how transparency functions in multilateral legal arrangements. Considerations like industry size, industry type, and export market size all impact what exactly can be traded to secure greater protection for intellectual property and create a unique profile for each country and prospective trading partner.[812]

The push towards bilateralism, and the space that enables this type of legal development, comes from the inherent character of multilateral initiatives. While the gains from multilateral consensus-building are impressive from a political perspective, they necessarily represent the absolute minimum of commonality and are very rarely radical developments.[813] This process of consensus building is particularly complex in the WTO because of its expansive membership. Yet this broad membership also brings with it a greater transparency and participation in terms of what is proposed, negotiated, and accepted – though there are obviously issues with how

[811] On WTO-Plus provisions: Knut Brünjes and Milena Weldenfeller, 'Multilateral Trade Policy is Back' in Christoph Herrmann, Bruno Simma, and Rudolf Streinz (eds), *Trade Policy Between Law, Diplomacy and Scholarship* (Springer 2015) 51; on TRIPS-Plus provisions: 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 2014) 52, 63.

[812] Despite the linguistic isolation of Japanese and Korean, both of these markets have significant cultural exports. Anime, for example, in the US is worth around $2.7 billion in 2009: Nissim Kadosh Otmazgin, *Regionalizing Culture; The Political Economy of Japanese Popular Culture in Asia* (University of Hawaii Press 2013) 74.

[813] Alex F McCalla and John D Nash, *Reforming Agricultural Trade for Developing Countries: Quantifying the Impact of Multilateral Trade Reform* (World Bank Publications 2007) 29.

non-official activities and relationships between actors within the WTO framework affect the *process* of negotiation.[814] The impact of relationships between different actors and the broader sense of institutional dynamics are, however, not unique to the WTO.[815] Yet the procedural safeguards and emphasis on participation embedded in the WTO system also impact not only the speed of negotiations but their viability more generally. Speed has been presented as one of the benefits of bilateral agreements over multilateral rounds of negotiation (as well as potentially more freedom in subject matter),[816] but a shift in tone in recent years has undermined this idea of bilateral agreements as the quicker route to trade liberalisation. In the European context, the development of CETA and ACTA were not only protracted negotiations simply due to the complexity of the provisions themselves,[817] but because of the growing political opposition that contributed to the drawn-out process and eventual failure.[818]

The extensive use of exceptions and options in multilateral agreements also highlighted the potential of the bilateral space where trade gains can be more directly responsive to the specific trading relationship between countries.[819] This quality of multilateral agreements to

[814] See generally the work of Tommaso Soave, *The Everyday Makers of International Law: From Great Halls to Back Rooms* (CUP 2022).
[815] Jeffrey J Rachlinski and Andrew J Wistrich, 'Judging the Judiciary by the Numbers: Empirical Research on Judges' (2017) 13 Annual Review of Law and Social Science 203, 204.
[816] One particular example would be the rapid pace of negotiation and conclusion for the US and Korea trade agreement, though important counterexamples of the AUSFTA and ACTA that experienced much longer timelines but due primarily to the extensive criticism rather than the bilateral mode: Andrew D Mitchell and Tania Voon, 'Australia-United States Free Trade Agreement' in Simon Lester and Bryan Mercurio (eds), *Bilateral and Regional Trade Agreements: Case Studies* (CUP 2009) 11.
[817] The economic significance and degree of rulemaking contrast markedly with the absolute lack of transparency in developing the CETA text: Panagiotis Delimatsis, 'TTIP, CETA, TISA Behind Closed Doors: Transparency in the EU Trade Policy' (2016) TILEC Discussion Paper 2016-020 12.
[818] The opposition to ACTA and CETA appeared in both civil and governmental contexts. On the widespread online coverage and in-person protests at the leaked texts: Peter K Yu, 'Development Bridge Over Troubled Intellectual Property Water' in Xavier Seuba and Carlos Correa (eds), *Intellectual Property and Development: Understanding the Interfaces* (Springer 2019) 112. The withdrawal of US support from TPP is perhaps another example of a failure to conclude inspiring the remaining members to form a different agreement with similar provisions (Comprehensive and Progressive Agreement for Trans-Pacific Partnership): Peter K Yu, 'Development Bridge Over Troubled Intellectual Property Water' in Xavier Seuba and Carlos Correa (eds), *Intellectual Property and Development: Understanding the Interfaces* (Springer 2019) 108.
[819] Pierre Latrille, 'Services Rules in Regional Trade Agreements: How Diverse or Creative are they Compared to the Multilateral Rules?' in Rohini Acharya (ed), *Regional Trade Agreements and the Multilateral Trading System* (CUP 2016) 460.

provide space for exceptions demonstrates that a strong focus on participation, and by extension transparency, does not necessarily prevent or remove flexibility. Instead, it provides a space for essentially a more transparent exercise of flexibilities. In this, flexibilities are essential not just in the development of intellectual property but in how they shape the dynamic of bilateral agreements more generally. Intellectual property standards are still often bound up with other areas of trade in bilateral agreements in a way that works to minimise flexibilities and incentivise the adoption of higher standards in exchange for gains elsewhere.[820] Multilateral agreements almost require exceptions and opt-out clauses because of the political nature of the process and implicitly recognise the importance of these mechanisms in workable legal regimes. Without allowing for some member autonomy, the risk would be that a country that disagrees with a specifically onerous provision would entirely withdraw from an agreement that they would otherwise stand to benefit from. By providing space for these tensions and divergences, the increased flexibility has the potential to simultaneously undermine accountability through opt-outs while at the same time promoting a much more visible representation of transparency. In doing so, these divergent values and expectations are recognised, brought within the multilateral system, and legitimised. Rather than the modulation occurring through interpretation as in chapter 3, the flexible quality of accountability is instead realised much earlier and outside the interpretative context of dispute resolution. The bilateral space itself exists in the shadow of multilateral, compromise-driven, decision-making that is in a process of constant balance between progress and flexibility.

[820] On the single undertaking approach in FTAs that joins together trade and intellectual property to incentivise partners, particularly developing countries, to accede to agreements with TRIPs-Plus provisions: 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 2014) 24.

2.2.2 The global growth of bilateral trade agreements

The use of bilateral agreements as a way of supplementing (rather than as an alternative to) multilateral standards is not unique to the post-TRIPS legal environment. Both the US and the EU had used bilateral agreements to further their trade interests in the period even leading up to the Uruguay Round.[821] Though what is significant about the shift of the Global Europe strategy in 2006 is not that it was a return to bilateralism, but as Araujo argues, that it destabilised the distinction between internal EU intellectual property policy and recast it as a generalised policy.[822] This porous quality of intellectual property policy necessarily impacts the values used in the production of bilateral agreements because they provide a forum that can be used to export EU intellectual property policy. The Global Europe strategy presents a transformation from an EU that had been engaged in bilateralism into an EU that actively *uses* bilateralism and the bilateral space. It can be interpreted as an instrumentalist transformation that reflects and reproduces domestic standards and domestic arrangements within the bilateral context. It is here that the inherent quality of bilateral negotiation becomes relevant again. The EU has strong commitments to transparency and so,[823] in theory, the more conscious usage of bilateral agreements could be a positive shift for GAL values in patent law. The reality is that, whatever current criticism of the EU and its bilateral trade agreements, the EU is free to go beyond the legal minimums provided for by the WTO. In doing so, the EU could give actual meaning to its commitments on transparency and accountability whilst essentially enshrining these values in the evolving international patent law space (though this would necessarily impact the norms of international trade law more generally). This shift in perspective is distinct from the previous cycles of multilateral and bilateral development precisely because of the political climate that led to the Global Europe initiative to begin with. It combines the use of

[821] Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 141.
[822] ibid 142.
[823] EU Commission, 'Transparency in EU Trade Negotiations' <https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/transparency-eu-trade-negotiations_en>.

bilateralism as an instrument and a political landscape that persistently questions the value of multilateral institutions in a way that presents the bilateral space as the best tool for promoting trade gains.

3. On the enforcement dimension of bilateral agreements

3.1 *Europe and the Global Europe strategy*

3.1.1 Bilateral trade agreements and 'particular strategic interest'

The EU has followed the direction of the US in negotiating trade agreements after adopting the Global Europe Strategy,[824] incorporating comprehensive chapters on patent term extension, genetic resources, and most interestingly as of recently, enforcement.[825] Two specific areas of intellectual property have been particularly important for the EU, highlighted as instances of 'particular strategic interest' and define the current trajectory of EU identity in bilateral negotiations.[826] The Global Europe shift saw this emphasis on enforcement of intellectual property rights and Geographical Indications (GIs) increase, with GIs in particular becoming the de facto way of protecting specific cultural products in many countries due to the strict insistence of the EU in negotiations.[827]

Understood in the context of the global ratchet, this presents another dimension to the process of forum-shifting. The EU has obtained most of its gains in terms of the substantive requirements of patents and is now, in line with their post-2006 'deep trade integration'

[824] Richard Schaffer, Filiberto Agusti, Lucien J Dhooge, *International Business Law and Its Environment* (Cengage 2017) 575.
[825] One example being the EU-South Korea trade agreement that covers all of these issues: Article 10.40 (genetic resources), Section C (enforcement), and Article 10.35 (patent term extension) KOREU FTA.
[826] Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 143.
[827] That the EU's traditional focus has been on making protection for GIs more robust internationally: Jayashree Watal, 'Is TRIPS a Balanced Agreement from the Perspective of Recent Free Trade Agreements?' in Josef Drexl, Henning Grosse Ruse-Khan, and Souheir Nadde-Phlix (eds), *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* (Springer 2014) 42.

direction,[828] using bilateral agreements or preferential trade agreements to regulate areas that had been rejected from inclusion at the WTO level. These bilateral interfaces are then a subversion of the WTO, both in terms of the legal impact of the agreements and the implicit restrictions to autonomy that are occurring through the adoption of specific forms of legal protection like GIs. Yet despite the enthusiasm with which the EU has focused on the use of bilateral agreements to develop intellectual property standards, it is unclear in a post-Global Europe context whether the EU perceives these agreements as policy alternatives to multilateralism or if it is merely preparation for an eventual consolidatory multilateral instrument.[829] This perhaps raises some fundamental questions about how transparency and accountability take on a specific character in a multilateral space – would a successful multilateral trade round in patent law remedy the impaired transparency and participation that has been central in how bilateral agreements have been produced in recent years? Or does it simply legitimise, as is discussed in the GAL literature,[830] the output of an impaired system with little shift in status quo?

3.1.2 The potential subversion of the multilateral environment

What is important in understanding this subversion of the multilateral environment is that, rather than addressing the concerns around the expansion of trade disciplines and sustainably committing to progress at the multilateral level,[831] the EU bilateral agreements are themselves an expansion. They incorporate additional regulatory areas, promote the EU legal

[828] Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 13.
[829] Tesh W Dagne, 'The Narrowing Transatlantic Divide: Geographical Indications in Canada's Trade Agreements' (2016) 10 EIPR 598, 603; Klaus Meyer and Mike W Peng, *International Business* (Cengage 2016) 265.
[830] Sujith Xavier, 'Top Heavy: Beyond the Global North and the Justification for Global Administrative Law' (2018) 57 Indian Journal of International Law 353.
[831] Something that is particularly apparent in the EU's environmental approach in the absence of a multilateral consensus, by building on from the bottom up through a more decentralised approach: Elisa Morgera, 'The EU and Environmental Multilateralism: The Case of Access and Benefit-Sharing and the Need for a Good-Faith Test' (2014) 16 Cambridge Yearbook of European Legal Studies 8.

construction of these fields, and thereby contribute to the type of breakdown between internal and external (as well as substantive and procedural) that was identified in chapter 3. What is occurring here is not, as others have argued,[832] that the bilateral context is a direct precursor to a multilateral consensus – in which bilateral agreements are used to pressure the inclusion of similar trade provisions multilaterally.[833] Instead, the position of bilateral agreements relative to the multilateral space is much more contextually sensitive. The process of compromise in terms of intellectual property protection in a multilateral context is highlighted in the literature and explores how lengthy negotiations lead, inevitably, to a final text that represents significant compromises between the parties.[834] But here the thesis suggests that the modern political environment of 2023 means that large trade actors can simply choose not to interact with this process of compromise or reduce its scope dramatically by using bilateral agreements. The EU no longer has to pressure the inclusion of new trade disciplines at the multilateral level because of the systemic weakness of the WTO and the lack of tangible benefits in accepting a slower or more compromise-driven negotiation strategy. Rather than an entanglement that comes from the adoption of common obligations in a multilateral sense, this process of entanglement in the bilateral space is inherently framed by EU interests and centres them in how the provisions function. For transparency, and GAL values in bilateral agreements more generally, this enables a space in which there is a progressive loosening between the corresponding values of the bilateral and multilateral frameworks.

[832] Kent Jones, *Reconstructing the World Trade Organisation for the 21st Century: An Institutional Approach* (OUP 2015) 186.
[833] That regional trade agreements do not automatically lead to a global consensus that can be used for multilateral reinforcement, instead requiring a concerted effort to broaden the membership of these regional agreements and to raise these issues at the level of the WTO for it to be truly consolidated: Kent Jones, *Reconstructing the World Trade Organisation for the 21st Century: An Institutional Approach* (OUP 2015) 186.
[834] Sam Ricketson, 'Implementing Treaty Obligations at the National Level' in Niklas Bruun, Graeme B Dinwoodie, Marianne Levin, and Ansgar Ohly (eds), *Transition and Coherence in Intellectual Property Law* (CUP 2021) 108.

The subversive impact of bilateral interfaces in this context is magnified when the trade agreements being negotiated cover wide areas of trade between the partners.[835] As discussed previously, these agreements position intellectual property alongside other disciplines and risk the adoption of specific modes of intellectual property protection in exchange for trade access.[836] While the multilateral trade environment also allows countries to strategically offer access to specific markets in order to secure concessions from the other trade partners, the bilateral context makes this approach much more effective because it atomises the relationship and allows for more differentiated negotiations. From this perspective, transparency takes on a localised character and is impaired or promoted within these atomised legal relationships. This is concerning in terms of the agreements themselves, but also because these represent additional tensions in fragmentation of international patent law that undermine a more consistent transparency in future multilateral initiatives.

3.2 *Expansion in bilateral interfaces and the potential for entanglement*

3.2.1 Expanding the available policy levers and the impact on autonomy

Specifically for intellectual property, the interactions between potentially competing frames of reference (like in the context of pharmaceuticals and human rights) can be difficult enough to manage at a national level because they involve many different policy levers. These policy levers can be understood as broader interface flexibilities because they modulate the impact of obligations and mitigate conflicts that emerge in the interactions of different legal regimes. Like with the process of bilateral cooperation discussed previously, this presents a significant concern for transparency. This is because it obscures the precise way in which

[835] Thomas Cottier, Dannie Jost, and Michelle Schupp, 'The Prospects of TRIPS-Plus Protection in Future Mega-Regionals' in Thilo Rensmann (ed), *Mega-Regional Trade Agreements* (Springer 2017) 193.
[836] ibid 191.

competing objectives are balanced, how dominant actors approach areas of priority, and how compromise is negotiated around important issues. The bilateral context opens this balancing exercise up to a greater number of factors, externalising – from a disciplinary perspective – the assessment of trade-offs to be made. A trading partner must weigh entirely distinct regulatory approaches within intellectual property against areas such as agricultural access, state subsidies, and FDI.[837] Patent law and intellectual property policy that flow from this type of exercise are somewhat disconnected in that they represent the product of a very contextually specific interaction, creating a legal space that differs in character from either national or multilateral interfaces.

Returning to the distinction between TRIPS-Plus and WTO-Plus provisions, there is a tension in the EU strategy of 'deep trade integration' because it is not clear that the potential for overlapping spheres of regulation is a prominent concern.[838] Part of this shift towards deep trade integration has been moving beyond border measures or import tariffs and into more complex forms of regulation,[839] where issues like technical standards and internal regulatory policies are considered. One of the difficulties with this area is defining what exactly constitutes 'deep' integration, but it has been approached flexibly as going beyond import tariff measures and often into competition policy, sanitary and phyto-sanitary standards (SPS), government procurement, and transport standards.[840] One example of this transition towards

[837] On the tense relationship between bilateral agreements and their practical (and symbolic) relationship to agricultural developments in the WTO: Ellis S Krauss, 'The United States in APEC's EVSL Negotiations' in Ellis S Krauss and T J Pempel (eds), *Beyond Bilateralism: US-Japan Relations in the New Asia-Pacific* (Stanford University Press 2004) 287.

[838] On the process and substance of deep trade integration: Bernard Hoekman and Denise Eby Konan, 'Deep Integration, Discrimination, and Euro-Mediterranean Free Trade' in Jürgen von Hagen and Mika Widgren (eds), *Regionalism in Europe: Geometries and Strategies After 2000* (Springer 2012) 171; James H Mathis, 'Regional Trade Agreements and Domestic Regulation; What Reach for "Other Restrictive Regulations of Commerce"?' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 100.

[839] Bregt Natens, *Regulatory Autonomy and International Trade in Services: The EU under GATS and RTAS* (Edward Elgar 2016) 147.

[840] Michael Emerson, T Huw Edwards, Ildar Gazizullin, Matthias Lücke, Daniel Müller-Jentsch, Vira Nanivska, Valeriy Pyatnytskiy, Andreas Schneider, Rainer Schweickert, Olexandr Shevtsov, and Olga Shumylo, *The Prospect of Deep Free Trade Between the European Union and Ukraine* (CEPS 2006) 8, 9.

deeper integration can be seen with the work on the Partnership and Cooperation Agreement with Ukraine from 1994 and the 2014 Cooperation Agreement, where academic analysis has explored the different routes of cooperation between deep and simple.[841] From a more conventional GAL perspective, these are areas that are more firmly within the sphere of administrative power and have their own complex relationships to accountability, transparency, and participation.

Yet the move toward more explicit regulatory processes and away from simpler border provisions emphasises the importance of flexibilities because they provide some way of mitigating the tensions in multiple, potentially overlapping, regulatory obligations created by different bilateral agreements. From a more systemic perspective, this type of overlapping regulation can be understood an issue of transparency because it presents an obscuring of precisely which obligations are binding and in which contexts. It is only in dispute that these overlapping obligations begin to be disentangled, where their binding quality is interpreted to produce a workable system of law in practice. The potential for dramatically incoherent policy stemming directly from tariff measures is limited because tariffs represent only minimal cooperation with a legal actor and involve a relatively manageable resource burden (particularly relevant for developing countries).[842] Explicit regulation in this deep trade integration sense raises the same type of issues but with a dramatically increased risk for conflict between regulatory regimes. Managing this type of regulatory integration also requires a much greater degree of administrative support and, again, centres the role of contextually

[841] Michael Emerson, T Huw Edwards, Ildar Gazizullin, Matthias Lücke, Daniel Müller-Jentsch, Vira Nanivska, Valeriy Pyatnytskiy, Andreas Schneider, Rainer Schweickert, Olexandr Shevtsov, and Olga Shumylo, *The Prospect of Deep Free Trade Between the European Union and Ukraine* (CEPS 2006) 7, 8.

[842] Even in the context of ACTA, the provisions concerned border seizures which while expansive in their reach (applying even if the destination of the goods was one in which no intellectual property rights were violated), were not particularly legally disruptive. On the impact of ACTA and border measures: Olasupo Owoeye, 'Access to Medicines and Parallel Trade in Patented Pharmaceuticals' (2015) 37(6) EPIR 359, 366.

positioned dispute resolution bodies in producing a workable understanding of complex trade obligations.

The tensions between different regulatory approaches, specifically in intellectual property, are directly relevant to the EU's more recent focus on enforcement because it they have the greatest potential for (actual or perceived) grievances regarding compliance. As the regulatory dimensions of trade in these agreements become more widespread, the emphasis will shift to the ever-increasing mechanisms for dispute resolution in these agreements.[843] All of these issues are magnified for developing countries that the EU concludes trade agreements with because, in a bilateral space, the EU is only one of many potential trade partners. It is unlikely that a country would seek to only conclude a trade agreement with the EU and not seek out similar agreements with China or the US (though this also does not take into account geographic drivers of cooperation and integration, as with the ASEAN countries or close neighbours). Because of this, countries must invest the resources necessary to actively manage these potentially competing (or at the very least, different) regimes or face dispute proceedings for breaching the terms of the trade agreement. The continued attention to regulatory systems highlights the difficulty of managing the relationship between different bilateral interfaces, which, depending on the agreement, intersect differently in terms of discipline, scope of the obligations, and impact on transparency in regulation.

3.2.2 Preferential trade agreements as an additional interface in trade law

Preferential Trade Agreements (PTAs) are another aspect of legal interfaces that operate within the multilateral framework but are distinct from bilateral trade agreements.

[843] On the problematic trajectory of ever-stronger dispute resolution mechanisms that could lead to trade restrictiveness: James H Mathis, 'Regional Trade Agreements and Domestic Regulation; What Reach for "Other Restrictive Regulations of Commerce"?' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 108.

PTAs have the potential to meaningfully shape the relationship between an overarching multilateral legal framework and the collection of bilateral and unilateral agreements. PTAs are expressions of unilateral preferences as opposed to the free trade agreements that involve reciprocal parties and have become a fundamental aspect of the international trade context.[844] PTAs have been used in a similar way to bilateral agreements and were used extensively in the pre-Uruguay Round.[845] Like with the global ratchet and bilateral trade agreements, PTAs represent an additional way in which multilateral consensus can be undermined from *within* the WTO system. The US, in particular, was active with PTAs to secure trade liberalisation in the period leading up to the Uruguay Round.[846] The use of PTAs can also be seen as a further example of forum-shifting, and has been highlighted in discussions on both the US and the EU as a way to open foreign markets and achieve the types of legal reform that would be difficult to do so through the multilateral framework.[847] Because it represents a form of forum-shifting, PTAs also contribute to a more general undermining of transparency and participation in the creation of international or multilateral consensus. This is because PTAs, like bilateral trade agreements, can be used as evidence of international consensus and support a specific type of multilateral consolidation. Yet unlike bilateral trade agreements, this lack of transparency as to the origin of this consensus is more dramatic because it is produced through unilateral action and reflects something closer to self-creation than cooperation.

[844] On the differences between PTAs and FTAs: Thomas Cottier and Christophe Germann, 'The WTO and EU Distributive Policy' in Joanna Copestick (ed), *The EU and the WTO: Legal and Constitutional Issues* (Hart 2001) 187; on the rise of PTAs in International trade: Meredith Kolsky Lewis, 'The Embedded Liberalism Compromise in the Making of the GATT and Uruguay Round Agreements' in Gillian Moon and Lisa Toohey (eds), *The Future of International Economic Integration: The Embedded Liberalism Compromise Revisited* (CUP 2018) 30.

[845] The prominent role that PTAs had in the US pursuing trade liberalisation pre-Uruguay Round: Jagdish Bhagwati, *Termites in the Trading System: How Preferential Trading Agreements Undermine Free Trade* (OUP 2008) 71.

[846] Jagdish Bhagwati, *Termites in the Trading System: How Preferential Trading Agreements Undermine Free Trade* (OUP 2008) 71.

[847] Joseph W Glauber, *Negotiating Agricultural Trade in a New Policy Environment* (International Food Policy Research Institute 2019) 15.

The EU's pursuit of deep trade integration disciplines through the use of PTAs are particular in that they generally incorporate the same type (or more extreme in some circumstances) of coverage or disciplines that were previously rejected at the multilateral level.[848] Because deep trade integration involves much more specific and sensitive intrusions into the regulatory regimes of developing countries (and is coupled with a rigorous dispute settlement regime), the risk of negative outcomes is much greater than with bilateral provisions on intellectual property. This type of emphasis on dispute resolution also highlights the more fundamental issue with PTAs in the development of international trade policy. These initiatives that promote deep trade integration lack the institutional framework of the WTO that guarantee at least a degree of transparency and facilitate broad participation. These systems of trade regulation produced by PTAs are highly localised and contextually sensitive and, as such, become somewhat disconnected. While individual agreements could promote transparency in obligations or accountability, these values cannot take on the same type of systemic impact that transparency has in the multilateral context. The negative impact of these interfaces on the broader multilateral framework could be mitigated with a stringent application of Article XXIV of the GATT and would help to recentre the process of compromise and negotiation of multilateral initiatives. And even though Article XXIV of the GATT is,[849] by its nature, a restrictive mechanism because PTAs are exceptions to the non-discrimination principle, there are concerns with its actual functioning.[850] Taken together, these agreements represent a unique

[848] The irony of explicitly rejecting this deeper integration at the multilateral level to then accept it through PTAs: Billy A M Araujo, *The EU Deep Trade Agenda: Law and Policy* (OUP 2016) 23.
[849] GATT 1947, Article XXIV, Ad Art XXIV 1994.
[850] Rizwanul Islam, 'Promoting Intra-Regional Trade in South Asia through Trade Facilitation Measures under the Auspices of the South Asian Association for Regional Cooperation' in Jiaxiang Hu and Matthias Vanhullebusch (eds), *Regional Cooperation and Free Trade Agreements in Asia* (Martinus Nijhoff 2004) 294; focusing specifically on PTAs as an exception to non-discrimination and Article XXIV GATT as a legal restriction rather than an enabling provision: Kyle Bagwell and Robert W Staiger, *The Economies of the World Trading System* (MIT Press 2004) *112.*

challenge to international cooperation and GAL values that is distinct to those found in the bilateral space – predominantly because of the unique dynamic of unilateral trade preferences.

3.2.3 Understanding the entangling effect of preferential trade agreements

But beyond the impact of these agreements on trade diversion and regulatory overlap, the sheer number of PTAs that have been concluded suggests that the WTO mechanisms for evaluating whether an agreement was correctly concluded in terms of the Article XXIV provisions are in need of revisiting.[851] One of the reasons for the ineffectiveness of the WTO test for legality in PTAs, and therefore how it functions as a flexibility, is that it focuses on the issue of trade diversion.[852] Focusing on the issue of trade diversion does not meaningfully address the potential for overlapping regulatory approaches in a single territory, how this works to reduce transparency, or how it complicates questions of accountability. This is because the increased regulatory integration produces a reduction in discriminatory behaviour and therefore satisfies Article XXIV.[853] An approach that focuses on the use of trade diversion as the singular lens of interpretation for whether PTAs have been legally concluded ignores the impact of these agreements on both the broader multilateral framework and the specific context of developing countries seeking to trade with multiple partners. In the narrowest sense, PTAs represent a legal configuration that brings together regulation, integration, and trade in a way that does not necessarily threaten future multilateral initiatives.[854] But from the perspective of transparency

[851] The disconnect between the legal restrictiveness of the provisions and the number of PTAs concluded is some type of issue in their functioning: Kateryna Holzer, *Carbon-Related Border Adjustment and WTO Law* (Edward Elgar 2014) 286.
[852] That 'deep' PTAs do not result in trade diversion: Michael Trebilcock, Robert Howse, and Antonia Eliason, *The Regulation of International Trade* (4th edn, Routledge 2013) 95.
[853] On the inverse relationship of behind-the-border regulation and discrimination: Mustapha Rouis and Steven R Tabor, *Regional Economic Integration in the Middle East and North Africa* (World Bank 2012) 80.
[854] Because they do not incentivise discrimination, PTAs do not necessarily threaten future multilateral negotiation and action: Stephen Woolcock, 'Making Multi-Level Rules Work' in Philippe de Lombaerde (ed), *Multilateralism, Regionalism, and Bilateralism in Trade and Investment: 2006 World Report on Regional Integration* (Springer 2007) 55; though cf. the still unsettled debate as to the role of PTAs in supporting multilateral action: William J Davey, 'A Model Article XXIV: Are There Realistic Possibilities to Improve It?'

in how these interfaces relate to each other, the development of multiple, potentially incompatible regulatory approaches that entail domestic legal reform (predominantly for developing countries) presents PTAs as something of a destabilising force. These agreements, like bilateral agreements more generally, shift attention away from the more systemic multilateral level and towards a more intensely localised space between the trade partners.

The risk in a more extensive system of regulatory 'deep' PTAs is that it can create (and subsequently, entrench) asymmetric power dynamics at the international level, producing systems that operate as regulatory blocs and further minimise the availability of any flexibilities.[855] This type of entrenchment minimises not only how impactful substantive understandings of transparency or accountability are, but further marginalises them in the development of future legal agreements. Mavroidis argues that this entrenchment would create rival regulatory trading blocs and reinforce any diverging approaches toward regulation[856] – something that would present a meaningful obstacle to future multilateral-based negotiation as parties already increasingly insist on their own regulatory standards when developing international trade instruments.[857] Because these agreements are fundamentally linked to the issue of market access, there is a clear power dynamic between the parties who negotiate such agreements. The fact that the EU negotiates trade agreements on behalf of the Member States and therefore controls access to the largest trading bloc in the world has significant consequences for developing countries. During the process of establishing a trade relationship, developing countries would have very little capacity to reject aggressive negotiations if they want access to the EU market – regardless of whether the agreement itself promotes or produces

in Kyle W Bagwell and Petros C Mavroidis (eds), *Preferential Trade Agreements: A Law and Economics Analysis* (CUP 2011) 246.

[855] On the potential for PTAs to push the development of rival regulatory blocs: Petros C Mavroidis, *The Regulation of International Trade* (MIT Press 2015) 297.

[856] Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 25.

[857] ibid.

transparency, accountability, and participation. As discussed previously, however, these agreements represent such contextual interactions that the systemic impact of high transparency or a specific emphasis on equitable participation would also be limited. The shift away from multilateral institutions and safeguards facilitates an environment in which these values can be flexibly adjusted on a per-agreement basis without inviting the type of burden that more systemic interpretations of these values would bring.

4. The EU and its bilateral experiences

4.1 *Moving beyond a narrow construction of trade liberalisation*

4.1.1 The shifting focus of international cooperation

Trade liberalisation and the removal of barriers to trade has been the main method of integration for the Members of the WTO, representing the primary method by which markets are opened and trade relations between countries are improved.[858] Bilateral agreements and PTAs are, compared with the more substantially impactful method of multilateral instruments, considered the 'second-best' option for trade policy.[859] Multilateralism as a way of promoting trade liberalisation has also been shaped by the shifting priorities of the international trade environment.[860] It is a trade context that, in recent decades, has moved from simpler issues of cross-border trade and towards more contentious deep trade disciplines with noticeable

[858] Ernst-Ulrich Petersmann, 'The WTO and Regional Trade Agreements as Competing Fora for Constitutional Reforms: Trade and Human Rights' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 282.

[859] On trade liberalisation as primarily the elimination of trade discrimination, regional agreements as a second-best policy: Ernst-Ulrich Petersmann, 'The WTO and Regional Trade Agreements as Competing Fora for Constitutional Reforms: Trade and Human Rights' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 282.

[860] 'Moreover, deeper integration is always much easier at the regional level than it is at the multilateral level. As we know from previous experience, multilateral negotiations take a very long time and are very complex, whereas RTAs move much faster.': Rafael Leal-Arcas, *Climate Change and International Trade (*Edward Elgar 2013) 371.

opposition.[861] The increase in complexity in how legal regimes are connected highlights the need for an appropriately developed understanding of not only how these connections are formed, but the values and mechanisms that are used to facilitate them. Yet it is this shift towards more complex representations of international trade that the importance of, if not GAL values, but guiding values more generally becomes clear. Tariff-based trade liberalisation presents clear and delineated factors within international trade that, in terms of binding obligations, appear to inherently reflect a more substantive sense of transparency. Like with bilateral trade agreements discussed previously, however, this obviously does not necessarily speak to the actual empowerment of participation or transparency in the *process* of producing tariff-based liberalisation.[862] Yet at least in terms of what the binding obligation entails, the resulting provisions are clear in the legal effect that they produce.

While there are more and more regional trade agreements being negotiated and implemented, the fact is that they are increasingly moving from trade liberalisation to a more explicit approach of *coordination* in terms of domestic policy and foreign policy.[863] One example of this shift would be the EU, though this has been suggested to be a feature of customs unions rather than the EU per se.[864] Customs unions involve explicit coordination between the members that constitute the union, though there are some features that are particular to the EU. What separates the EU from the nascent customs unions around the world,[865] currently

[861] That the shift from regulating cross-border trade in goods to more integrated regulation is so difficult that it has successfully happened at the multilateral level: Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 22.

[862] On the political economy dimensions of tariff-based trade liberalization and environmental protection: Per G Fredriksson, 'The Political Economy of Trade Liberalization and Environmental Policy' (1999) 65(3) Southern Economic Journal 513, 514.

[863] The shift towards domestic policy coordination and foreign policy coordination away from simple trade liberalisation is particularly pronounced for customs unions like the EU: Ernst-Ulrich Petersmann, 'The WTO and Regional Trade Agreements as Competing Fora for Constitutional Reforms: Trade and Human Rights' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 282.

[864] ibid.

[865] The rise of customs unions is a global phenomenon that promotes greater integration and trade at a regional and subregional level, with the aspirational development of the African Union, the successful customs unions of the East African Community (EAC), the West African Economic and Monetary Union (UEMOA), Central

emerging in a variety of institutional and political contexts, is that the EU has a developed apparatus that manages its international representation. Considered in its broader context, it is clear from chapter 2 and 3 that the EU is not necessarily a manifestation of 'coordination' between its constituting members in domestic and foreign policy but rather a breaking down of the distinction between internal and external, national and international, substantive and procedural. Yet what distinguishes this from earlier periods in international history is that all of this is occurring in a trade context in which the viability of multilateral consolidation is fundamentally in question.

The EU's position regarding the externalisation of its regulatory environment and eagerness to participate in the international trade environment can be seen to emanate from the central position that the internal market holds in Europe. Externalisation of at least some regulatory principles is required to not subject European producers to different regulatory schemes in foreign markets.[866] In embracing deeper trade integration through these bilateral and regional interfaces, the EU is preserving its own policy space (by not being subject to multilateral compromise) and progressively reshaping the bilateral space in a way that reflects its own priorities and the regulatory needs of European producers.[867] There is also a more neutral understanding of the spread of European regulatory approaches, specifically in new and emerging disciplines, where it is the quality, robustness, or prestige that leads other countries

African Economic and Monetary Union (CEMAC), and the Southern African Customs Union (SACU) all prominent examples just within the African continent: Anna-Luise Chané and Magnus Killander, 'The EU and Africa' in Ramses A Wessel and Jed Odermatt (eds), *Research Handbook on the European Union and International Organisations* (Edward Elgar 2019) 594; though cf. the analysis that customs unions are actually a second-best policy option if the objective is free trade, that membership rules and other factors mean that customs union stop short of a complete trade liberalisation: Karl Farmer and Matthias Schelnast, *Growth and International Trade: An Introduction to the Overlapping Generations Approach* (Springer 2013) 297.

[866] That regulatory externalisation is required to not disadvantage European producers in a global marketplace: Sangeeta Khorana and W Gregory Voss, 'The Digital Single Market: Move from Traditional to Digital?' In Sangeeta Khorana and Maria Garcia (eds), *Handbook on the EU and International Trade* (Edward Elgar 2018) 389.

[867] Integration inevitably leads to a loss of policy space and regulatory autonomy: Brendan Vickers, 'Sub-Regions First: The Role and Evolution of Regional Economic Communities in Africa' in Giovanni Carbone (ed), *A Vision for Africa's Future: Mapping Change, Transformation and Trajectories Towards 2030* (Ledizioni 2018) 80.

to adopt.[868] This appears prominently in the development of data protection regimes and extends even to other developed countries,[869] yet the distinction here is that the regulatory convergence is being promoted through trade agreements rather than an independent adoption of the standards. While the outcome is the same, there is something in the dynamic between the EU and developing countries, in the asymmetry, that suggests a less neutral process or a more explicit exporting of standards. All of this highlights the complex and interconnected nature of GAL values, where transparency, participation, and accountability are necessarily joined in practice. This normative power of the EU, whether expressed in a bilateral or more unilateral context, minimises in practice the ability for smaller trade actors to participate as equals. This is not to say that all agreements from the EU are inherent threats to standards of transparency and participation, but rather that even high procedural standards for these values within trade agreements cannot necessarily address the practical, more political, relationship between the actors involved.

This emphasis on participation was previously identified in the context of dispute resolution and WTO Panel decisions in chapter 3, which serves to further distinguish the EU from the US. The creation of bilateral interfaces by the EU occurs firmly from an internal perspective as an active member of the WTO and this necessarily presents the relationship between the EU, its pursuit of regulatory integration, and the multilateral framework as interconnected even at this more abstract level. This contrasts with the US that, as evidenced

[868] On the diffusion of competition law models in Asia from Europe (though crucially these transplants were modified slightly to meet local expectations, like creating a competition authority that is not independent from the government): Tony Prosser, 'Competition Law and the Role of the State in East Asia' in Michael W Dowdle, John Gillespie, and Imelda Maher (eds), *Asian Capitalism and the Regulation of Competition: Towards a Regulatory Geography of Global Competition Law* (CUP 2013) 253.

[869] Even before the GDPR, the Data Protection Directive has been highlighted as a prominent influence in the data protection laws of Asian countries from the 1990s onwards: Graham Greenleaf, *Asian Data Privacy Laws: Trade and Human Rights Perspectives* (OUP 2014) 12.

through some prominent critiques of multilateral initiatives and the DSB more specifically,[870] would appear more willing to position itself somewhat more distantly or external to the WTO.

The rate with which these regional agreements are being negotiated – particularly post-2003 Seattle Ministerial[871] – has been put forward as evidence that the Members of the WTO do not perceive such agreements to be supplementing the WTO framework and are rather intended to supplant it.[872] These agreements also have a significant element in terms of the issue of enforcement in relation to these regulatory issues, specifically in terms of which disputes can be submitted to the enforcement apparatus created by the trade agreement. The EU is particularly interesting in the context of dispute resolution in such RTAs, where they have tended to focus on implementing exclusive mechanisms of dispute resolution.[873] As briefly mentioned previously, the diversion of disputes away from the transparent dispute settlement of the WTO and into specialised and exclusive mechanisms established by the agreement introduces a significant element of differential treatment into the international environment. The tension here is that, as mentioned above, the paralysis of the WTO DSB has severely impacted the functioning of the multilateral trading system.[874] Yet exclusive dispute

[870] On the broader 'unease' of the US with multilateralism: Stewart Patrick, 'Multilateralism and Its Discontents: The Causes and Consequences of U.S. Ambivalence' in Stewart Patrick and Shepard Forman (eds), *Multilateralism and U.S. Foreign Policy: Ambivalent Engagement* (Lynne Reinner 2002) 2, 3; referencing the paralysis of the Appellate Body: 'Recent practice by the USA also shows a remarkable departure from the WTO framework, in terms of its acceptance of multilateral adjudication, of prohibition of counterretaliation, the regulation of remedies and norms enforcement.': Chiari Giorgetti, 'International Courts and Tribunals in the USA and in Europe: The Increasingly Divided West' in Chiari Giorgetti and Guglielmo Verdirame (eds), *Whither the West? International Law in Europe and the United States* (CUP 2021) 191.

[871] The surge in regional agreements after the failed Ministerial: Tubagus Feridhanusetyawan, 'Preferential Trade Agreements in the Asia-Pacific Region' (2005) (IMF Working Paper) 13.

[872] With a number of around 60, WTO Members clearly see bilateralism or regionalism at least somewhat as a replacement for multilateralism: ibid.

[873] On the emphasis on (exclusive) dispute settlement mechanisms in the EU regional trade agreements and excluding substantive topics from ordinary WTO dispute settlement process: Claude Chase, Alan Yanovich, Jo-Ann Crawford, and Pamela Ugaz, 'Mapping of Dispute Settlement Mechanisms in Regional Trade Agreements: Innovative or Variations on a Theme?' in Rohini Acharya (ed), *Regional Trade Agreements and the Multilateral Trading System* (CUP 2016) 636.

[874] Imogen Saunders, 'Populism, Backlash and the Ongoing Use of the World Trade Organization Dispute Settlement System: State Responses to the Appellate Body Crisis' (2021) 35(1) Maryland Journal of International Law 172, 173.

settlement mechanisms in these agreements are not the only option for dealing with this dysfunction, with the Multi-Party Interim Appeal Arbitration Arrangement (MPIA) demonstrating that there is still at least some vitality in multilateral dispute settlement. This shift in dispute settlement context also presents its own challenges to the use of flexibilities and exceptions because their operation is then individualised and their exercise is constructed relatively within each trade agreement.

Specifically for understanding the impact on transparency and participation in the international patent system, the shift towards exclusive dispute settlement would be minimal if it were contained to technically ambitious or complex agreements. This type of response would mirror the development of other specialised dispute mechanisms,[875] yet the rate and scope of agreements concluded provide what is essentially a parallel system of dispute resolution. In this context, it renders the WTO dispute settlement system as an exception but also has the potential to impact the future trajectory of the WTO more generally. The disruption to the DSB Appellate Body has been significant and the MPIA does represent at least some positive response to these challenges. Yet the continued proliferation of agreements with their own dispute settlement mechanisms gives no positive indication that major economies like the EU will want to (or now, need to) engage with the work necessary to address the DSB Appellate Body problem. The entanglement that occurs here between actors in the bilateral space is taking place *within* the WTO framework and yet operates in a way that emphasises these more discrete points of contact contained in the specific agreements between countries. Such an inversion

[875] The rise of specialisation across intellectual property and at a global level: intellectual property courts in Japan, South Korea, and China: Kyle Pietari, 'An Overview and Comparison of US and Japanese Patent Litigation' (2016) 98 Journal of the Patent and Trademark Office Society 540, 542; Duncan Matthews, 'Intellectual Property Courts in China' in Spyros Maniatis, Ioannis Kokkoris, and Wang Xiaoye (eds), *Competition Law and Intellectual Property in China and the ASEAN* (OUP 2019) 76; increased specialisation within Portugal for family and juvenile courts: *OECD Economic Surveys: Portugal 2019* (OECD 2019) 121; and the efficiency of court specialisation of the Tel Aviv District Court: Yifat Aran and Moran Ofir, 'The Effects of Specialised Courts over Time' in Sofia Ranchordás and Yaniv Roznai (eds), *Time, Law, and Change: An Interdisciplinary Study* (Bloomsbury 2020) 186.

has been identified in the evolution of the MFN principle whereby the WTO framework has instead become representative of the 'least-favoured nation'.[876] And so too with dispute settlement – the WTO apparatus and institutions become not only the baseline, but the very bare minimum which is afforded to parties. This sense of a minimum or baseline applicable standard also impacts how transparency and accountability function in this context. The relegation of multilateral values as a minimum standard undermines any attempt at developing more responsive or nuanced understandings of transparency and participation at the systemic multilateral level. Instead, values are advanced (or undermined) in the more limited and isolated contexts of discrete dispute resolution bodies. Even if a specific dispute body was to provide a strong interpretation of these values,[877] there is only a limited impact on the generalised role of transparency or accountability because it comes from such a contextually inflected environment.

4.2 *Understanding the enforcement dimension of bilateral agreements*

4.2.1 ACTA and the criminal enforcement of intellectual property infringement

ACTA was one of the most controversial examples of the EU trying to negotiate increasingly stringent intellectual property protection,[878] significant in that it brought

[876] Least favoured nation as it relates to discriminatory international trade as a subversion of MFN tariffs: Jagdish Bhagwati, *Termites in the Trading System: How Preferential Trading Agreements Undermine Free Trade* (OUP 2008) 14.

[877] Such as a broader construction of participation in WTO disputes: Richard B Stewart, Michelle Ratton, and Sanchez Badin, 'The World Trade Organisation: Multiple Dimensions of Global Administrative Law' (2011) 9(3-4) ICON 564.

[878] Some have sought to frame ACTA as a response to low levels of protection in developing countries: Vincenzo di Cataldo, 'Goods in Transit and Trademark Law (and Intellectual Property Law?)' (2018) 49 IIC 441; though other commentators have stressed the political dimension of ACTA: 'An alternative account of ACTA is that it is the product of densely networked global political actors responding not to the threat of growing infringement but rather… the most salient manifestation of an agenda manufactured for political reasons.': Andrew Rens, 'Lessons to be Drawn from the ACTA Process: An African Perspective' in Pedro Roffe and Xavier Seuba (eds), *The ACTA and the Plurilateral Enforcement Agenda: Genesis and Aftermath* (CUP 2014) 220.

intellectual property to public awareness and resulted in such broad political pushback.[879] The dissonance between the provisions of ACTA and the feedback from national and international actors across Europe highlight some sense of disconnect between the EU institutions, the Member States, and European citizens that was also part of chapter 3. Yet here, the dissonance between legal and non-legal actors presents the complexity of accountability as an administrative value. Accountability, and one of the issues specifically highlighted with the WTO,[880] has generally been understood as accountability of the elected to the electorate.[881] From this perspective, ACTA demonstrates a form of accountability that is not reliant on specialised or explicit legal mechanisms that specifically make space for stakeholder perspectives. This is particularly relevant for more technical areas that are outside the traditional administrative law scope because it demonstrates that these areas, with sufficient engagement, can produce the type of direct accountability that is generally not provided for within a regulatory framework. The draft provisions of ACTA were important because they represented the start of a shift towards an emphasis on enforcement (as opposed to the contours of the intellectual property rights themselves),[882] and strikingly included criminal sanctions for (wilful) infringement.[883] Moving into the regulation of infringement, rather than the outline of what constitutes infringement itself, presents a development in terms of how these trade

[879] On the unprecedented lobbying by ordinary citizens and NGOs in response to ACTA, see generally: Benjamin Farrand, 'The Digital Agenda for Europe, the Economy and its Impact upon the Development of EU Copyright Policy' in Irini Stamatoudi and Paul Torremans (eds), *EU Copyright Law: A Commentary* (Edward Elgar 2014) 988.
[880] Where Joseph suggests, from a human rights perspective, that the right of participation has been overlooked by States 'acting within and through the WTO': Sarah Joseph, *Blame it on the WTO? A Human Rights Critique* (OUP 2011) 73.
[881] Where 'democratic rights are not only about elections and the free choice of government by the majority; they entail individual rights to have a meaningful opportunity to take part in the political process': ibid 72.
[882] 'From a substantive perspective, both ACTA and the TPP were conceived with the aim of strengthening enforcement.': Dana Beldiman, 'Introduction' in Dana Beldiman (ed), *Access to Information and Knowledge: 21st Century Challenges in Intellectual Property and Knowledge Governance* (Edward Elgar 2013) 19.
[883] On the significance of the criminal enforcement sanctions: Christophe Geiger, 'The Rise of Criminal Enforcement in Intellectual Property Rights… and its Failure in the Context of Copyright Infringements on the Internet' in Susy Frankel and Daniel Gervais (eds), *The Evolution and Equilibrium of Copyright in the Digital Age* (CUP 2014) 123.

agreements are approaching greater integration. Sanctions for intellectual property infringement (and criminal sanctions in particular) are closely related to national perceptions of wrongful action and domestic constructions of what is suitably within the ambit of criminal activity. Particularly as accountability as a form of direct relationship to the electorate was discussed previously, there is something especially jarring about the development of criminal sanctions for intellectual property infringement. The lack of participation from national lawmakers as representatives of the people stands out here and produces international legal provisions that are both lacking in accountability and effective participation.[884]

High standards of intellectual property protection and strengthened enforcement mechanisms have been highlighted as key elements of competitiveness, where the EU and US use of bilateral agreements have been specifically linked to the greater control it provides for their own producers.[885] It has become a necessary fact that developing countries should expect to be faced with extensive intellectual property chapters when negotiating bilateral agreements with developed countries,[886] presenting a challenge for policy that prioritises domestic needs when these intellectual property chapters have tended to replicate national law frameworks.[887] The Global Europe initiative had an impact beyond the instrumentalising of bilateralism in that it directly affected the types of provisions that were typically included in intellectual property

[884] Which is particularly notable in the context of the WTO or international trade, where 'there is no "legislator" that is capable of regulating the relations between legal systems at the global level': Elisa D'Alterio, 'Judicial Regulation in the Global Space' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 320. The disproportionate role of interpretative dispute resolution bodies, rather than an accountable legislator, is particularly concerning when applied to sensitive provisions like criminal sanctions for intellectual property infringement.

[885] Josef Drexl, 'The Political Foundations of TRIPS Revisited' in Hanns Ullrich, Reto M Hilty, Mathias Lamping, and Josef Drexl (eds), *TRIPS Plus 20: From Trade Rules to Market Principles* (Springer 2016) 73; though specifically on the key relationship between high standards of enforcement and competitiveness: Julio Faundez, 'International Economic Law and Development: Before and After Neo-Liberalism' in Julio Faundez and Celine Tan (eds), *International Economic Law, Globalisation and Developing Countries* (Edward Elgar 2010) 31.

[886] Anke Moerland, 'Do Developing Countries Have a Say? Bilateral and Regional Intellectual Property Negotiations with the EU' (2017) 48 IIC 760, 761.

[887] Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 143.

chapters of bilateral trade agreements,[888] bringing the EU into much closer alignment (in terms of negotiating style and agreement structure) with the US.[889] Effective participation appears as an immediate concern here as, again, the issue of asymmetry between the trade partners and their economies would undermine GAL commitments even if they were legally provided for.

The US, as the world's largest economy,[890] is particularly important in terms of this shift in negotiating style because it has generally experienced a great success and only minor challenges to the export of its intellectual property principles in bilateral agreements.[891] One perspective in the literature is that the EU has followed the approach of the US so that it could realise the same type of trade gains internationally.[892] While the EU strategy has certainly evolved in terms of what is being negotiated and appears closer to similar US trade priorities, the broader political context that was identified earlier provides an important contextualisation to this shift. Whatever is being negotiated in international patent law, the EU has demonstrated a commitment to the WTO in a way that the US has not and suggests at least an implicit relationship between the WTO Agreements and these new texts. Like with dispute resolution discussed earlier, part of the EU development in trade objectives and style could be from the fact that there is no real alternative. The Doha Round stalled for over a decade before finally producing something,[893] and the lack of progress regarding intellectual property at the WTO

[888] Geoff Tansey and Tasmin Rajotte, *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security* (Earthscan 2008) 142.
[889] Anke Moerland, 'Do Developing Countries Have a Say? Bilateral and Regional Intellectual Property Negotiations with the EU' (2017) 48 IIC 760, 761.
[890] The significance not only of the economic size of the US, but the economic contribution of intellectual property-related goods: Andro Linklater, *Owning the Earth: The Transforming History of Land Ownership* (A&C Black 2014) 383.
[891] That the 'institutionalised bargaining' that took place in the post-war setting allowed the incorporation of important exceptions from the GATT, starting a '…process of bilateral and mini lateral negotiations in the 1950s and 1960s in which the agreements were subsequently extended to other participants.': Friedrich Kratochwil, 'Norms Versus Numbers: Multilateralism and the Rationalist and Reflexivist Approaches to Institutions - A Unilateral Plea for Communicative Rationality' in John G Ruggie (ed), *Multilateralism Matters: The Theory and Praxis of an Institutional Form* (Columbia University Press 1993) 468.
[892] Anke Moerland, 'Do Developing Countries Have a Say? Bilateral and Regional Intellectual Property Negotiations with the EU' (2017) 48 IIC 760, 763.
[893] Fasih Uddin, 'Multilateral Trade Negotiations: Doha to Bali and Beyond' (2015) 12(1) Policy Perspectives 81.

presents a multilateral system that is slow, unresponsive, and ultimately limited in what can be currently achieved.[894] Yet it is precisely this long and drawn-out process that provides a good space for participation and mirrors many of the tensions in chapter 2 with the negotiation process of the EPUE. From the narrow perspective of maximising participation in the development of international trade, the less rapid multilateral environment should not be abandoned just because there are practical challenges. Intellectual property, but patent law specifically, actually presents a good opportunity for promoting GAL values in a multilateral context because of its inherent complexity as a subject matter. Patent law is representative of the difficulties of advancing trade liberalisation beyond tariffs and provides a way of exploring how transparency, accountability, and participation could look in the promotion of more 'fuzzy' liberalisation.

4.2.2 The development of European priorities in bilateral negotiations

The main focus of the EU in its bilateral agreements before the implementation of the Global Europe Strategy had typically been the protection of GIs and generally did not consider intellectual property as a discrete discipline.[895] The emphasis on GIs was an early priority for the EU for two main reasons, the first of which is that as a geographically and culturally diverse region, the EU (more than most international actors) had the most to gain from ensuring the products of its producers were protected in a manner that reflected the standard of protection domestically.[896] Ensuring the protection of GIs – even by using the language of GIs – was

[894] On the variety of different positions as to the COVID intellectual property waiver: 'Thus, those expecting quick agreement on the waiver will be disappointed': Bryan Mercurio, 'The IP Waiver for COVID-19: Bad Policy, Bad Precedent' (2021) 52(8) IIC 983, 984.
[895] David Vivas Eugui and Christoph Spennemann, 'The Treatment of Geographical Indications in Recent Regional and Bilateral Free Trade Agreements' in Meir Perez Pugatch (ed), *The Intellectual Property Debate: Perspectives from Law, Economics, and Political Economy* (Edward Elgar 2006) 317.
[896] With an estimated sales value of over 77 billion Euros in 2017: EU Commission, 'Study on Economic Value of EU Quality Schemes, Geographical Indications (GIs) and Traditional Specialities Guaranteed (TSGs)' (2021) <https://op.europa.eu/en/publication-detail/-/publication/a7281794-7ebe-11ea-aea8-01aa75ed71a1>.

important because TRIPS requires countries to ensure the protection of these assets but not necessarily to incorporate the GI system as it emerged in Europe. The bilateral context became a central forum in exporting this mechanism of protection for GIs, though the majority of this 'exporting' was done in the context of developing countries that either lacked a robust enough existing system or were willing to adopt the EU standard to secure market access.[897] It is particularly striking in its homogenising impact on developing countries because two of the largest economies – the US and Japan – do not protect GIs in the same manner as the EU. Both have distinct histories of cultural heritage and in products that are typically protected by GIs, but neither of them have adopted the vocabulary of the EU.[898] The legislative provisions in both jurisdictions result in very similar levels of protection in practice to that provided under the GI system in Europe, and the unwillingness to harmonise the language of GIs suggests that there is a certain degree of conscious distancing going on.

In terms of how these different systems of protection coexist, the cultural and economic significance of the subject matter has the potential to meaningfully subvert future multilateral consensus. While the threat of multiple regulatory blocs has been raised in the context of broader trade regulation, GIs are politically and culturally sensitive enough that it would be a remarkable development for a major market actor such as the US or Japan to abandon their existing domestic principles and adopt the EU framework in a multilateral forum. As stated

[897] The majority of the EU-Colombia-Peru FTA as it concerns the protection of GIs is essentially a set of demands from the EU side, covering an expanded scope of protection for instances that do not confuse a customer and terms that are considered generic or semi-generic in many other countries: Keith E Maskus, 'Assessing the Development Promise of IP Provisions in EU Economic Partnership Agreements' in Josef Drexl, Henning Grosse Ruse-Khan, and Souheir Nadde-Phlix (eds), *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* (Springer 2014) 179.

[898] Despite lacking a geographical indications system, discussing the active involvement of the US government in promoting competition through a system of certification marks: Yogesh Pai and Tania Singla, '"Vanity GIs": India's Legislation on Geographical Indications and the Missing Regulatory Framework' in Irene Calboli and Ng-Loy Wee Loon (eds), *Geographical Indications at the Crossroads of Trade, Development, and Culture* (CUP 2017) 343; on the transition in Japan from regional collective trademarks to the current GI system: Greg de St Maurice, 'Savoring the Kyoto Brand' in Nancy K Stalker (ed), *Devouring Japan*: *Global Perspectives on Japanese Culinary Identity* (OUP 2018) 155.

previously, the protection in each of these jurisdictions is very similar in practice but the language and precise structures are distinct to each.

In a process that would also come to define the development of the EPUE, the bilateral agreements that were concluded before 2006 would typically incorporate international agreements by reference.[899] This meant that these agreements would typically not outline distinct provisions that would bind the parties and instead include an obligation to respect specific international agreements.[900] Incorporation by reference reflects the tension between the substantive and formal understandings of GAL values, where transparency has the potential to legitimise a lack of participatory impact. In this context, there is a transparency as to where the provisions come from and their legal effect, yet because of their mode of incorporation, trade partners have no real way of challenging these provisions or adapting them to their own needs.

This emphasis on broad principles and general themes changed with the Global Europe strategy in 2006. From this point, bilateral agreements now include extensive intellectual property chapters and provisions to bind the parties involved to specific, generally more stringent, standards.[901] These chapters that govern intellectual property are also more specialised in the sense that they consider each intellectual property right separately[902] – something that has been highlighted as contributing significantly to the increasing length, scope, and specificity of these intellectual property sections.[903] The negotiation of each intellectual

[899] Tilman Krüger, 'Shaping the WTO's Institutional Evolution: The EU as a Strategic Litigant in the WTO' in Dimitry Kochenov and Fabian Amtenbrink (eds), *The European Union's Shaping of the International Order* (CUP 2014) 174.
[900] ibid.
[901] Thitapha Wattanapruttipaisan, 'The Topology of ASEAN FTAs, with Special Reference to IP-Related Provisions' in Christoph Antons and Reto M Hilty (eds), *Intellectual Property and Free Trade Agreements in the Asia-Pacific Region* (Springer 2014) 137, 138.
[902] Anke Moerland, 'Do Developing Countries Have a Say? Bilateral and Regional Intellectual Property Negotiations with the EU' (2017) 48 IIC 760, 763.
[903] Michael Handler and Bryan Mercurio, 'Intellectual Property' in Simon Lester, Bryan Mercurio, and Lorand Bartels (eds), *Bilateral and Regional Trade Agreements: Commentary and Analysis* (CUP 2015) 363.

property right as a distinct regulatory sphere has a distinct impact on the character of the resulting agreement, primarily from a domestic perspective and particularly in the case of developing countries. It represents an additional layer of complexity in the balancing of intellectual property rights for trade partners, criticised earlier for widening the scope of relevant factors when balancing an appropriate intellectual property policy to considerations not just outside of intellectual property, but to the macroeconomic features of another international actor. This type of shift in strategy also raises the same type of issues discussed previously, where this more diffuse and individualised approach to trade agreements works to obscure the values and principles driving the development of international trade law.

The individualised intellectual property provisions of the EU's intellectual property chapters push this further, with trade partners assessing trade-offs and compromises to their autonomy to set their own intellectual property policy on an industry-specific basis. This allows the EU to extract specific concessions in terms of intellectual property standards that maximise the benefits to its domestic producers, while also presenting an increasingly disciplinary-specific relationship between actors. This type of arrangement also highlights the multilevel impact of atomisation that is going on in international trade agreements. Rather than presenting a generalised lack of transparency (though this is also a concern),[904] the deficiencies themselves become localised and discipline specific. One example would be in Chapter 10 of the KOREU Agreement that deals with intellectual property broadly, but it is the comprehensive scope of the agreement that is perhaps indicative of the general developments in bilateral trade agreements. While it deals with substantive elements of patent law – even the controversial introduction of criminal sanctions for infringement[905] – it also regulates more specific or niche

[904] 'After all, trade negotiations under the multilateral trading system are more open and transparent than in any bilateral or plurilateral trade agreements': Michelle Limenta, 'Open Trade Negotiations as Opposed to Secret Trade Negotiations: From Transparency to Public Participation' (2012) 10 New Zealand Yearbook of International Law 84.
[905] Subsection B, Chapter 10 – Criminal Enforcement: KOREU Agreement.

considerations like the publication of judicial decisions,[906] legal costs and who bears the cost of proceedings,[907] and the protection of data submitted for plant protection products.[908] Together, KOREU is interesting because it represents the conclusion of a text which could easily be a standalone agreement in terms of scope. The agreement reflects the expansiveness of the bilateral agreements being concluded and the challenge of balancing between trade gains, autonomy, and increased standards in intellectual property in a way that empowers participants and promotes transparency.

4.2.3 Exploring the specific tension of criminal sanctions in intellectual property

In terms of criminal sanctions for the infringement of intellectual property, TRIPS requires members to provide for criminal sanctions. This provides signatories with a great deal of autonomy in deciding on an appropriate regime for addressing criminal infringement, centring on wilful infringement that is conducted at a commercial scale.[909] The issue with these provisions is that TRIPS provides no further guidance as to what 'commercial scale' actually means in Article 6 and therefore provides WTO Members with a considerable margin in which to legally act.[910] It is this scope for interpretation that enables actors to reconstruct the space in a way that reflects specific objectives or priorities through the use of bilateral agreements. The example of 'commercial scale' is a particularly important example of the transformation that policy space undergoes in the bilateral context, presenting a reconstruction or reconfiguration rather than an outright removal. The legitimate scope of action is reduced not in an arbitrary

[906] Article 10.52, KOREU.
[907] Article 10.51, ibid.
[908] Article 10.37, ibid.
[909] 'Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale.*':* Article 61, TRIPS Agreement.
[910] In the reference to 'commercial scale' in TRIPS but without an elaboration of what this means: Christophe Geiger, 'Towards a Balanced International Legal Framework for Criminal Enforcement of Intellectual Property Rights' in Hanns Ullrich, Reto M Hilty, Matthias Lamping, and Josef Drexl (eds), *TRIPS Plus 20: From Trade Rules to Market Principles* (Springer 2016) 651.

fashion but reconstructed to reflect a specific perspective and specific interests. Yet at the same time, this process of reconstruction is fundamentally limited in terms of transparency and participation. As appears as a concern in the GAL literature,[911] the lack of an ordinary legislator in this process means that the process is not subject to the usual constraints of domestic legislation. Here, not only is there a lack of broad participation in the procedural sense but this is compounded by a general lack of transparency as to the precise values, principles, and objectives interact to produce the textual agreement. The provisions of the trade agreement provide a legal basis, yet the negotiating dynamic and strategy that produced those provisions remain obscured. As the EU's approach to intellectual property in trade agreements has shifted from merely referencing external agreements and into the realm of enforcement, there have been general developments in three areas that cover civil actions, rules pertaining to border control, and ISP liability.[912]

The provisions in these agreements that relate to those issues are typically taken directly from EU law, representing a more explicit form of legal entanglement and again raising the question of effective participation in a bilateral trade context.[913] The entanglement of these interfaces is an explicit form of legal entanglement because it represents an integration through provisions of an agreement rather than a more neutral form of adoption. The entangling effect is legal in both the sense that it is the bringing together of two legal regimes and is legal in character, but also because the entanglement itself is produced through explicit provisions that have a textual grounding rather than a more abstract process. ACTA, despite the fact it is

[911] The lack of a single 'centre of power' in the European context is also discussed from an administrative perspective (where the EU has many centres): Sabino Cassese, 'The Administrative State in Europe' in Armin Von Bogdandy, Peter M Huber, and Sabino Cassese (eds), *The Max Planck Handbooks in European Public Law: The Administrative State* (Vol 1, OUP 2017) 78.
[912] The three areas of civil proceedings, border measures, and online service providers: Billy A M Araujo,*The EU Deep Trade Agenda* (OUP 2016) 166.
[913] ibid.

considered a failed agreement,[914] has remained a powerful source of inspiration for the EU in developing the provisions in their trade agreements and often take provisions directly from ACTA.[915]

It is in the most recent trade agreements that we see the extent to which the EU is prioritising the enforcement of intellectual property rights in these agreements, as well as a somewhat tense relationship between the EU and its Member States. The KOREU agreement is one such example, where its provisions regarding criminal enforcement had been directly inspired from the text of ACTA.[916] While taking the provisions from another EU trade agreement is not in itself that controversial, the fact that the criminal enforcement provisions contained in ACTA are an area of law that is not regulated at the EU level presents the KOREU Agreement as a profound development in the EU approach to trade agreements.[917] Because KOREU is the first agreement to consider criminal enforcement in such detail, it has set an important precedent for future trade agreements in two distinct ways. It not only presents criminal enforcement as within the legitimate remit of a bilateral trade agreement, but also provides an example of the type of trade priorities the EU could pursue in future negotiations. As highlighted previously, bilateral trade agreements can be used by trading partners to improve their trading relationship and pursue common objectives together by providing rules that more specifically address the specificities of their geographic and economic relationship.

[914] Xavier Seuba, *The Global Regime for the Enforcement of Intellectual Property Rights* (CUP 2017) 196.
[915] Susan K Sell, 'GATT and the WTO' in Ralph Pettman (ed), *Handbook on International Political Economy* (World Scientific 2012) 156.
[916] Chapter 10 covers intellectual property in the agreement, though it is subsection B (Articles 10.55–10.60) that deal with the criminal enforcement of intellectual property. This corresponds with section 4 of ACTA, where Articles 23-26 also deal with criminal enforcement. A crucial example of the connection between ACTA and KOREU provisions is that both consider aiding and abetting in intellectual property from this criminal enforcement perspective (Article 10.57 in KOREU, and Article 23.4 of ACTA).
[917] The peculiarity of KOREU is that criminal sanctions are not regulated at Union level: Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 166; that KOREU remains the only global FTA that considers the issue of criminal enforcement in such detail: Justyna Lasik and Colin Brown, 'The EU-Korea FTA: The Legal and Policy Framework in the European Union' in James Harrison (ed), *European Union and South Korea* (Edinburgh University Press 2014) 38.

In this context, the KOREU agreement represents the opposite of this, whereby the criminal enforcement provisions do not represent a cooperation in policy of two trading partners because it is not, in fact, EU policy. However, the KOREU agreement is not simply an exporting of EU norms and principles either (or the inverse, an adoption of South Korean standards), but instead represents the development of *new* norms and principles that originate at the EU level but have not been developed through the Union legislative or political apparatus.[918] This disconnect with the Member States is concerning not simply because of the autonomy that the EU institutions appear to exercise in the conclusion of bilateral agreements (here, the Commission), but that this exercise of autonomy is not subject to any direct oversight by the Member States.[919] This type of situation demonstrates the fundamentally interconnected nature of participation, accountability, and transparency that appears in more conventional administrative areas.[920] Though the thesis has attempted to artificially separate these values out to explore how they are individually constituted, the bilateral agreements of the EU and their legal implementation demonstrate that rarely can this be achieved in practice.

This process of implementing legal provisions through bilateral trade agreements that have previously been rejected at the EU level has been referred to as 'policy laundering' in that it involves using a different forum to introduce binding provisions and avoid the difficulties of the EU legislative process.[921] The consolidation of norms in this context is dangerous for the autonomy of Member States because these agreements enable an expansive trade mandate that

[918] Justyna Lasik and Colin Brown, 'The EU-Korea FTA: The Legal and Policy Framework in the European Union' in James Harrison (ed), *European Union and South Korea* (Edinburgh University Press 2014) 40.
[919] Parliamentary control in the process of bilateral deals is relegated to an ex-post one, presenting an accept/reject decision: Panagiotis Delimatsis, 'TTIP, CETA, TISA Behind Closed Doors: Transparency in the EU Trade Policy' (2017) TILEC Discussion Paper DP 2016-020 14.
[920] With Boisson de Chazournes highlighting the interactions and enabling quality of the relationship between accountability, participation, and transparency: Laurence Boisson de Chazournes, 'Changing Roles of International Organizations: Global Administrative Law and the Interplay of Legitimacies' (2009) 6 International Organizations Law Review 660, 661.
[921] Specifically as an example of using this forum as a way of passing provisions already rejected at the EU level: Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 166; though describing the process of 'policy laundering' more broadly: Kim Rygiel, *Globalising Citizenship* (UBC Press 2011) 61.

can incorporate areas of law that are not yet settled at EU level without any significant oversight. This further minimises the role of Member States and highlights how participation and accountability have a broad impact. Earlier, the issue of participation was presented in the asymmetric relationships of the EU and developing countries, yet the experience of the EU Member States demonstrate that this is not something inherent or exclusive to relationships with a significant developmental asymmetry. This is particularly striking given that the Member States have already been side-lined in both the negotiation and ratification stages of these bilateral agreements.[922] Taken together, the lack of meaningful participation in this type of trade agreement appears to reinforce the deficiencies in transparency and accountability at the EU level between the EU and the Member States.

The concerns around policy laundering must be contextualised in its relationship to the broader constitutional structure of the EU, whereby the agreements that have emerged recently are mixed agreements and therefore require the ratification of both the Member States and the EU.[923] While on the face of it this appears to be an important counterbalance to a more disconnected bilateral space, the development of mixity in international agreements has its own politicised development that has essentially dispensed with facultative mixity and produced a remarkably inconsistent approach to the factors that trigger a presumption of mixity.[924] Mixity

[922] Panagiotis Delimatsis, 'TTIP, CETA, TISA Behind Closed Doors: Transparency in the EU Trade Policy' (2017) TILEC Discussion Paper DP 2016-020 14.
[923] Mixity tempers the process of policy laundering by requiring Member State approval: Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 166.
[924] Mixity as a tool for not only interfacing between the Member State interests in a trade agreement but the very legal foundation – as to the competence being shared or accrued to the EU – of the EU conclusion of an agreement. *Opinion 2/15* suggested a shared competence must result in a mixed agreement because it could not be established without the Member States' consent (itself a response to the political context around the investment provisions of the Singapore FTA), though this was disrupted by the later decision of *Germany v Council* that demonstrated the EU could conclude a trade agreement alone even if it related to a shared competence: Eleftheria Neframi and Mauro Gatti, 'Autonomy and EU Competences in the Context of Free Trade and Investment Agreements' in Isabelle Bosse-Platière and Cécile Rapoport (eds), *The Conclusion and Implementation of EU Free Trade Agreements: Constitutional Challenges* (Edward Elgar 2019) 56; *Opinion 2/15 Free Trade Agreement between the European Union and the Republic of Singapore* ECLI:EU:C:2017:376; Case C-600/14 *Germany v Council* ECLI/EU:EU:C:2017:935.

has been analysed in terms of its impact on the binding obligations of international law,[925] though from an administrative perspective it also represents an important force for promoting transparency, accountability, and participation. It primarily centres the participation of the Member States, though in doing so, it necessarily impacts how transparency and accountability shape the process of negotiating a bilateral trade agreement. With this background of the inconsistent EU approach, the cases of KOREU, ACTA, and CETA are important examples of how the EU responded to the pushback at the national level by incorporating mixity as a way of addressing those concerns.[926] The EU did not construct these agreements as mixed agreements from their inception and without the vocal interventions of civil society and governmental bodies across the EU, it is unlikely that the Member States would have had even the limited scope of action that currently exists. In this context, the dynamic between the EU and the Member States reflects many of the conventional tensions in GAL scholarship around a formal sense of participation being used to legitimise the output of a flawed system.

4.2.4 Exploring how responsiveness is minimised in the bilateral space

One of the major features of EU trade agreements with developing countries is that rather than providing for specific exceptions to the enhanced intellectual property standards, there are typically only general statements about the trade partner's retained access to the flexibilities offered under TRIPs.[927] One example can be found in the KOREU Agreement which demonstrates the typically asymmetric approach. While all of Chapter 10 of the KOREU Agreement deals with intellectual property, there are essentially two explicit references to

[925] Michael De Boeck, *EU Law and International Investment Arbitration: The Compatibility of ISDS in Bilateral Investment Treaties (BITs) and the Energy Charter Treaty (ECT) with the Autonomy of EU Law* (Brill 2022) 153.
[926] Eleftheria Neframi and Mauro Gatti, 'Autonomy and EU Competences in the Context of Free Trade and Investment Agreements' in Isabelle Bosse-Platière and Cécile Rapoport (eds), *The Conclusion and Implementation of EU Free Trade Agreements: Constitutional Challenges* (Edward Elgar 2019) 56.
[927] Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 167.

flexibilities in this sense. Before considering these references to potential flexibilities in the text, it is important to recognise just how uneven the attention is in the agreement for issues of intellectual property. Flexibilities that deal with public health can be found in Article 10.34 – and yet there are entire subsections to the agreement that deal with different intellectual property rights.[928] The agreement is also indicative of how bilateral agreements are advancing in terms of scope because the KOREU Agreement, in subsection D of chapter 10, deals with the protection of design rights. The agreements are not just targeted cooperation in high value areas like patent law or trademark, and instead are really quite comprehensive intellectual property agreements on their own. Article 10.34 purports to deal with the relationship between patents and public health, and yet it consists of two paragraphs. One of these paragraphs appears to merely outline the fact the Doha Round produced the paragraph 6 system and parties should respect that,[929] and the other requires that the parties should recognise the importance of the TRIPS Agreement and Doha Declaration.[930]

Given the difficulties with which developing countries have had in successfully using the Doha Declaration or TRIPS flexibilities,[931] these agreements clearly demonstrate the fundamental asymmetry in legal obligation for trade partners.[932] While the developing country adopts higher standards (specifically in enforcement) that generally reflect the legal approach of the EU, there is no corresponding increase or advance in flexibilities or options for lawfully

[928] Subsection C of Chapter 10 would be one example which deals with how liability for ISPs should be constructed.
[929] Article 10.34(1), KOREU.
[930] Article 10.34(1) ibid.
[931] '…the difficulties that may exist for developing countries to establish and maintain the political conditions which they can make a concrete use of TRIPS flexibilities.': Gaëlle Krikorian, 'The Politics of Patents: Conditions of Implementation of Public Health Policy in Thailand' in Sebastian Haunss and Kenneth C Shadlen (eds), *Politics of Intellectual Property: Contestation Over the Ownership, Use and Control of Knowledge and Information* (Edward Elgar 2009) 49.
[932] On the difficulties of developing countries making use of the flexibilities in TRIPS: Ernias Tekeste Biadgleng, 'The Development-Balance of the TRIPS Agreement and Enforcement of Intellectual Property Rights' in Justin Malbon and Charles Lawson (eds), *Interpreting and Implementing the TRIPS Agreement: Is it Fair?* (Edward Elgar 2008) 110.

derogating the obligations of the trade agreement in specific circumstances. In these agreements, what is lost is not just the overall structure of negotiations in a multilateral context, but the institutional mechanisms and values that mitigate obvious imbalances between WTO members. One example would be the role of third parties in WTO procedures,[933] falling short of the type of formal amicus system in other legal arrangements but still enabling a wider scope of participation and minimising information asymmetries. This emphasis on participation is essential to reducing great asymmetries and more generally contributing to the legitimacy of an initiative, and yet cannot be easily transplanted to the bilateral space. More generally however, these concerns around participation and transparency are taking place in an environment where there have been persistent calls to allow for NGOs or other civil society contributions to EU and WTO Agreements.[934]

References to specific flexibilities also appear when the EU is negotiating on the implementation of enforcement obligations, though this has typically taken the form of provisions lifted almost identically from the Enforcement Directive in the EU that permit some manoeuvrability in the process of domestic implementation.[935] Rather than suggesting an EU that is focused on mitigating the negative impact of its trade rules, these inconsistencies speak to a bilateral trade policy that is constituted from discrete and somewhat disconnected legal interfaces. The KOREU agreement in particular represents an experimentalist approach to trade agreements that will set the foundation for future trade agreements. In the context of these references to flexibilities in trade agreements, even a particularly generous reading of those

[933] For academic commentary: Marc L Busch and Eric Reinhardt, 'Three's a Crowd: Third Parties and WTO Dispute Settlement' (2006) 58(3) World Politics 446.
[934] On the contested perspectives on NGO involvement (or 'global civil society' more generally) in the WTO: Matthew D Stephen, 'Contestation Overshoot: Rising Powers, NGOs, and the Failure of the WTO Doha Round' in Matthew D Stephen and Michael Zürn (eds), *Contested World Orders: Rising Powers, Non-Governmental Organizations, and the Politics of Authority Beyond the Nation-State* (OUP 2019) 43.
[935] Thomas Jaeger, 'IP Enforcement Provisions in EU Economic Partnership Agreements' in Josef Drexl, Henning Grosse Ruse-Khan, and Souheir Nadde-Phlix (eds), *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* (Springer 2014) 192.

interpretations into the trade agreements cannot overcome the fact that these are agreements that have been negotiated outside of the multilateral trade environment and are, by their nature, TRIPs-Plus and implement more restrictive obligations. These provisions do not modify the underlying multilateral framework and therefore without the explicit and concerted development of flexibilities within these agreements, there is little hope that these trading partners could rely securely on a provision that merely references an aspirational objective of food security or research.[936] Developing countries in particular have struggled in making use of the explicit flexibilities of the TRIPS Agreement – for a variety of legal and political reasons[937] – which would also question the value of the legal status of a side document or underdeveloped provision in a bilateral trade agreement.[938]

The KOREU Agreement, in Article 10.34, provides something similar in terms of an aspirational mechanism. In contrast to the elaborate subchapters devoted to each specific type of intellectual property, Article 10.34 merely states that the parties are entitled to rely on the Doha Declaration. A fundamental element of this agreement, however, is that it is an agreement between two industrialised countries and this necessarily impacts the scope of provisions that are included (or not included). Yet the KOREU Agreement is significant even just in how clearly it demonstrates what is essentially non-content in the part that deals with public health. The KOREU Agreement reflects a more general trend that, within these broader trade

[936] One notable example is the side letters the US included in its FTA with Peru, Colombia, and Panama that state the importance of the trade agreement signatories to protect public health, though the legal status of these letters is concerning not least because they do not form part of the actual trade agreement text and provide difficulties in the terminology they use (such as 'TRIPS health solution'): Michael Handler and Bryan Mercurio, 'Intellectual Property' in Simon Lester and Bryan Mercurio (eds), *Bilateral and Regional Trade Agreements: Commentary and Issues* (CUP 2009) 337.

[937] On the political elements of bilateral agreements that balance the economic sense of an agreement: Olivier Cattaneo, 'The Political Economy of PTAs' in Simon Lester and Bryan Mercurio (eds), *Bilateral and Regional Trade Agreements: Commentary and Issues* (CUP 2009) 30.

[938] Michael Handler and Bryan Mercurio, 'Intellectual Property' in Simon Lester and Bryan Mercurio (eds), *Bilateral and Regional Trade Agreements: Commentary and Issues* (CUP 2009) 337.

agreements, there is a comprehensive, standalone intellectual property agreement being concluded as well.

KOREU, as controversial as it is in the development of criminal enforcement, can also be read as the first step into a cautious new stage of policy development at the level of bilateral agreements and an increasingly comprehensive approach these initiatives. Beyond the criticisms of policy laundering and the expansive Commission mandate, its significance extends far beyond this because it highlights the importance of interpretation in constructing legal meaning. By failing to provide an appropriate sense of transparency as to how policy and provisions were produced, accountability as to how those provisions are then interpreted is also impacted. As a result, a limited set of actors who are empowered to interpret or create meaning from broad trade provisions benefit from the combined failings in transparency, accountability, and participation in the bilateral space. Though its rules on criminal enforcement may be extensive, the KOREU text does not, in fact, define what is to be considered 'commercial scale' infringement and therefore retains the relatively open definition in TRIPS and provides scope for interpretative development.[939] Crucially, the interpretation of what constitutes 'commercial scale', if it emerged from a dispute over KOREU provisions, would reflect the process of increasingly specific frames of reference for these interfaces and essentially produce a definition of 'commercial scale' applicable only to the unique context of the KOREU relationship. This is perhaps not, as Araujo argues, evidence that the parties were not willing to incorporate controversial TRIPs-Plus language into the KOREU agreement,[940] and instead should be read more as an exercise in caution. The KOREU agreement is controversial enough because it covers criminal enforcement at all. To then include a specific (and presumably,

[939] Xavier Seuba, *The Global Regime for the Enforcement of Intellectual Property Rights* (CUP 2017) 391.
[940] Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 174.

expansive) definition of what commercial scale is, even though TRIPS fails to provide one, is unlikely to have fundamentally hindered the conclusion of the agreement.

The accusations of policy laundering stand out when one considers the development of enforcement provisions within the EU framework and do suggest a subversion of the legislative process by the Commission.[941] When criminal enforcement measures were proposed in the EU, there were important human rights considerations that were raised by the EU Parliament to balance the expansiveness of the provisions.[942] These safeguards are not incorporated into the EU-CA and KOREU trade agreements and therefore rely on the general TRIPS exceptions to protect non-trade human rights concerns.[943] This is the defining characteristic of the EU's strategy in new trade agreements – a post-Global Europe strategy of minimising the internal and external boundaries of law that creates increasingly contextualised legal arrangements that minimise transparency, accountability, and participation. In this, the lack of correspondingly developed flexibilities to the expanded obligations is not simply a minimising of flexibilities but a symptom of a broader approach that prioritises expansion over balanced development.

4.3 *EU participation in bilateral negotiations*

4.3.1 Institutional identity, integration, and entanglement

The role of bilateral trade agreements in shaping the transparency and accountability of international patent law is underscored by the mechanism by which trade agreements are incorporated into the EU legal order, with parliaments essentially accepting or rejecting the

[941] On the Commission forcing internal regulatory reform by stealth: ibid.
[942] George Cumming, Mirjam Freudenthal, and Ruth Janal, *Enforcement of Intellectual Property Rights in Dutch, English, and German Civil Procedure* (Kluwer 2008) 57.
[943] Peter K Yu, 'EU Economic Partnership Agreements and International Human Rights' in Josef Drexl, Henning Grosse Ruse-Khan, and Souheir Nadde-Phlix (eds), *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* (Springer 2014) 126.

trade agreement in its entirety.[944] The role that this constructs for the parliaments is therefore much more restricted than under an ordinary legislative process and envisions a fairly minimal degree of participation.[945] Even when mixity is incorporated as a response to significant public backlash, the ordinary function of parliamentary scrutiny is a central element in how flexibilities are constructed because they provide a potentially much greater scope of interpretations or perspectives on the provisions.

This minimal participation has meant that trade agreements that do not require an amendment to EU law have typically passed unnoticed,[946] of which the KOREU agreement and the criminal enforcement procedures are prominent examples because they did not require an amendment to national law.[947] More broadly, this is a symptom of the degree of substantive harmonisation in the international environment. As we enter an international context that increasingly pursues specific aspects of enforcement, the EU benefits from two specific legal developments. The first is that the development of the EU and the internal market required such a degree of legal reform and cooperation that the legal direction of the Member States becomes essentially interconnected.[948] The EU has a foundation of legitimate authority in acting in the interest of the Member States and the EU as a whole, both explicitly in the principle of subsidiarity and more implicitly in the fact that a consolidated EU presents a much stronger negotiation position for trade.[949]

[944] HL Session 2013-14 179, *The Transatlantic Trade and Investment Partnership: House of Lords* (2014) 54.
[945] Billy A M Araujo, *The EU Deep Trade Agenda* (OUP 2016) 174.
[946] Michaela D Platzer, *Pending US and EU Free Trade Agreements with South Korea: Possible Implications for Automobile and Other Manufacturing Industries* (DIANE 2010) 2.
[947] ibid.
[948] On the origin of the Cohesion policy, the Member States have undergone significant intrusive economic integration that was a high initial hurdle: John Bachtier and Carlos Mendez, *EU Cohesion Policy and European Integration: The Dynamics of EU Budget and Regional Policy Reform* (Routledge 2016) 13.
[949] On the significance of the internal market as it relates to negotiations with countries outside of Europe: Stephen Woolcock, 'The Effectiveness of EU External Economic Policies' in Knud Erik Jørgensen and Katie Verlin Laatikainen (eds), *Routledge Handbook on the European Union and International Institutions* (Routledge 2013) 328.

The second factor was the implementation of TRIPS, bringing a significant degree of harmonisation that required extensive legal reform to ensure compliance (particularly for developing countries). The EU has undergone so much legal reform that broadly consolidated the intellectual property interests of a large group of developed countries that it presents a strong foundation for not only complying with the international baselines of protection, but in gradually developing them in more specialised or stringent ways. This results in a situation in which, considered specifically from the perspective of resources and resulting burden in implementing legal reform, developments in the international context through either multilateral rounds or bilateral agreements will only ever be minimally disruptive to the EU. This degree of consolidation and cooperation throughout the history of the EU (such as the CPC) also speaks to the direction of future intellectual property objectives in bilateral agreements. The substantive characteristics of a patent are relatively settled and so attention has first shifted to patent-adjacent disciplines – like the protection of test data – and then into the development of more specific standards around enforcement and remedies.

6. Conclusion

Bilateral and free trade agreements have emerged as some of the most important elements in the trade relationship between international actors and have contributed significantly to the growth of global trade. Bilateral agreements promote cooperation between partners across a variety of disciplines in a way that provides tangible trade gains at a (potentially, and not always) quicker pace than when negotiating in the multilateral environment. They also provide a unique perspective for exploring how GAL values like accountability, participation, and accountability function in a more contextually sensitive and localised trade environment. While there are periods in recent decades where multilateralism would appear to falter and bilateralism emerges in response, the more recent proliferation of

bilateral agreements (particularly with the EU) reflects a much broader history of alternating cycles of multilateralism and bilateralism.

The creation of these new relationships is then a fundamental part of the development of 'TRIPS-Plus' and 'WTO-Plus' provisions that have emerged as a significant discussion in bilateral agreements in recent decades. Though the WTO Agreements necessarily provide a broad framing for legal interfaces that deal with trade because of their expansive nature, there are still disciplines outside the scope of the WTO. The tension in the bilateral context comes from the fact that it does not involve the creation of a singular legal interface. Instead, the bilateral space involves the creation of multiple, increasingly specific, legal interfaces that produce their own relationship to transparency and accountability. The chapter emphasised not only how the GAL values function in this context but the existence of a distinct bilateral space more fundamentally (drawing on early themes in GAL scholarship that tried to justify the existence of a 'global space').[950] At this level, each IP chapter that is developed in each, specific, trade relationship provides a localised interpretation of the values that drive legal developments in intellectual property. This presents these bilateral trade agreements as being both disciplinary-specific and specific to the trade partners in a way that is not necessarily generalisable. This also extends to the use of mechanisms such as exceptions or flexibilities to navigate these interfaces, highlighting that both the interface itself and the tools it provides are context specific. Evidence of transparency or accountability in specific bilateral trade agreements is not necessarily identical in quality or character, even when similar provisions exist in other bilateral agreements that cover similar subject matter.

Beyond this, the more general dynamic of these bilateral interfaces to the broader instrument will necessarily be influenced by whether or not they are elaborating on existing

[950] Elisa D'Alterio, 'Judicial Regulation in the Global Space' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 321.

obligations (TRIPS-Plus) or are incorporating disciplines that are not currently regulated in a multilateral instrument (WTO-Plus). The 'global ratchet' of ever-increasing standards in intellectual property highlight the tensions in the relationship between the multilateral and bilateral modes of law-making because it has a restrictive effect on how multilateral consensus forms and negotiations function. These higher standards and elaborated constructions of TRIPS provisions have become a central part of the debate around contemporary issues in patent law like access to medicine. The concerns around the global ratchet have been explored throughout this chapter from the perspective of transparency as to the development of intellectual property.

The issue for transparency here is not only the lack of transparency as to the binding quality of provisions discussed in chapter 3, but the transparency around the trajectory of international intellectual property law itself. Bilateral trade agreements have been used as evidence for global consensus and advancing higher global standards, yet it emerges from the increasing atomisation of modern trade agreements in the bilateral space. These concerns are compounded because of the lack of transparency and participation that frame bilateral trade agreements, where the role of state actors appears to be minimised. For participation, it is a narrow class of actors that are responsible for the negotiation and development of bilateral agreements in a way that does not seem to invite general oversight. Taken together, there is a dissonance between the clear textual provisions and its contextual development process. The values and principles that informed the negotiations, as well as the political process of 'trading' standards in areas of strategic interest, are obscured and produce a concerning lack of transparency as to the future development of international patent law.

Conclusion

1. Introduction

Patent law, in many ways, reflects the complex state of law and legal research in 2023. While from a narrow perspective it simply provides legal protection for technical innovations, its impact is at once political, societal, and legal in a way that undermines strict divisions in academic work. From this broader perspective, patent law has been understood from a variety of different viewpoints – emphasising its property characteristics,[951] presenting it as a form of international regulation,[952] and this thesis that centred on the state power that is the foundation of patent law.

The research in this thesis had focused on the five main research questions that were intended to explore how new patent frameworks are created, a sense of global space in international patent law, the processes by which different systems of patent law interact, the role of dispute settlement bodies in enabling these systemic interactions, and the degree to which patent law reflects specific values drawn from administrative law scholarship. The research questions were intended to guide the analysis in a way that questions how international patent law actually develops and how important dispute settlement bodies are beyond their role in specific or contained disputes. The literature approaches the broader trajectory of international patent law in a way that emphasises the economic qualities of the patent but, in doing so, minimises the dynamic process by which patent law is interpreted, reshaped, and developed. Adopting a GAL perspective that emphasises the role of dispute settlement bodies

[951] Though Travis argues that the US has actually departed from the private property model: Hannibal Travis, 'Patents, the Private Property Ideal, and the Public Interest in a Seamless Global Public Health System' (2022) 31(1) Federal Circuit Bar Journal 24, 25.
[952] Henning Grosse Ruse-Khan, 'Intellectual Property and International Law: A Research Framework' in Irene Calboli and Maria Lillà Montagnani (eds), *Handbook of Intellectual Property Research: Lenses, Methods, and Perspectives* (OUP 2021) 15, 16.

and the values of accountability, transparency, and participation highlights the interactive nature of international patent law development. The thesis focused specifically on the role of dispute settlement bodies and how they facilitate the interactions of different systems of law. Through the chapters, the thesis presented dispute settlement as a creative environment that is central in minimising or otherwise mitigating tensions in international patent law in a way that is distinct to legislative power. Applying a GAL perspective to international patent law provides a more accurate understanding of the institutional dynamics involved and the processes by which international patent law actually develops. The thesis, while not comparative in a traditional sense, used the EU as a unifying context for the dispute settlement bodies discussed throughout to more thoroughly understand how transparency, accountability, and participation function in these environments.

The conclusion is split into five parts, with the first four exploring the material covered in each chapter of the thesis. The second part of each section is a more reflective consideration of the limitations and strengths of the chapter, particularly in terms of how the work could be improved and of future work that would be beyond the current scope of the thesis. The chapter ends with a brief conclusion.

2. Contributions of the thesis

The thesis provides three general contributions, the first of which involves positioning international patent law alongside the emerging system of global administration. As patent law has already been discussed extensively as a form of global regulation and an element of global trade regulation, the thesis instead focuses on the role of dispute resolution bodies and the administrative foundation of patent law to understand how international patent law is developing. International patent law is indeed regulatory, but the administrative foundation of

patent law means that legislation that modifies the ability of a state to freely grant patents can instead be considered in a similar way to more conventional administrative law scholarship. The thesis not only provides a more nuanced understanding of international patent law as a part of global regulation, but connects it with the emerging discussions of GAL. In doing so, it provides a novel way of approaching international patent law that recasts tensions in patent law in the language of administrative law. The thesis provided analysis of complex legal problems within patent law, though the GAL framing was intended to encourage dialogue with areas of law that have typically been disconnected from patent law. Framing these issues in the language of administrative values highlights that they are not unique problems of patent law and are, instead, reflective of the general difficulties of international regulation and law-making.

The second contribution of the thesis is a more abstract development that connects several contemporary issues in international patent law. By constructing patent law as fundamentally related to administrative power and control, the thesis deconstructs it from the perspective of accountability, participation, and transparency in a way that can then be considered an *internal* critique of patent law. This also relates to the previous contribution of the thesis in integrating patent law with other areas of law because the economic impact of patent law still appears the central concern in a global context.[953] Critical approaches, specifically on issues of access to medicine,[954] have analysed patent law from perspectives that emphasise human rights or specific values but have done so in a way that puts them in contrast to the economic foundation of the patent. Instead, the thesis recognises that the economic qualities of the patent represent only a single aspect of a more complex whole. The thesis is

[953] US Chamber of Commerce, 'Intellectual Property Key to Economic Recovery and Defeating Coronavirus, New Report Shows' (*US Chamber of Commerce*, 24 March 2021) <https://www.uschamber.com/intellectual-property/intellectual-property-key-economic-recovery-and-defeating-coronavirus-new-report-shows>.
[954] Anjali Vats and Deidré A Keller, 'Critical Race Theory as Intellectual Property Methodology' in Irene Calboli and Maria Lillà Montagnani (eds), *Handbook of Intellectual Property Research: Lenses, Methods, and Perspectives* (OUP 2021) 789, 790.

not an application of a non-patent approach or framework of values to the development of international patent law – instead, it highlights the administrative foundation of patent law and analyses the resulting developments in patent law from that perspective. The GAL perspective minimises the theoretical dissonance with legitimacy that appears with more conventional work in international patent law.

The third contribution of the thesis is a more nuanced and complete understanding of how dispute resolution bodies function in international patent law, beyond their narrow and immediate role as a venue for legal disputes. Framing dispute settlement bodies from a GAL perspective also helped to highlight how these institutions are central in promoting (or undermining) the values of accountability, transparency, and participation. In doing so, the thesis also provides a more comprehensive understanding of what these values can mean in the context of international patent law and also more generally as values in law. The thesis, though particularly in the introduction and in chapter 1, recognises that these three values are fundamentally joined and cannot be easily separated. Yet in choosing to interpret dispute settlement bodies and their broader legal space through the lens of specific values, the analysis in the thesis provides a much more rounded understanding of how these values function within patent law and as a way of promoting dialogue with other areas of law. This is reflected perhaps most clearly in chapter 3 in the context of the CJEU and WTO sources of law because, in artificially isolating the role and function of accountability, the analysis enables a clearer understanding (and a unifying narrative) of what is happening in the jurisprudence of the CJEU.

3. Chapter 1

3.1 Exploring the background of Global Administrative Law (GAL)

Chapter 1 explored the development of GAL as an academic project, contextualising its major features and discussions with the fundamentals of international patent law that is the focus of the thesis. An important aspect of this chapter is establishing the relationship between patent law, GAL scholarship, and administrative power more generally. Within intellectual property, patent law stands out as an area in which the push towards increased international harmonisation has not yet resulted in a singular, global patent system.[955] Enforcement, in particular, has retained a distinctly national characteristic and provides a forum in which national, international, and global forces come into contact on issues of patent law.[956] The thesis focuses on the more systemic interactions that produce international patent law, as well as the values of this process, rather than the substantive patent provisions. Here, applying an administrative law lens to these patent law interactions highlights the importance of values in shaping the interactive creation of international patent law. The thesis applied concepts from GAL work to international patent law to critique the way in which international patent law develops. The values drawn from GAL scholarship that are applied throughout the thesis were transparency, participation, and accountability.

Though the administrative perspective is applied to patent law, the thesis focuses specifically on the role of Europe as a particularly influential actor in this process of

[955] Randy Campbell, 'Global Patent Law Harmonization: Benefits and Implementation' (2003) 13(2) Indiana International & Comparative Law Review 605. And while Rajec remain unconvinced by the explanatory value of harmonisation within international intellectual property (preferring maximalism instead), it remains that there is no global system that deals with the grant and enforcement of patent rights: Sarah R Wasserman Rajec, 'The Harmonization Myth in International Intellectual Property Law' (2020) 60 Arizona Law Review 735, 740.
[956] Randy Campbell, 'Global Patent Law Harmonization: Benefits and Implementation' (2003) 13(2) Indiana International & Comparative Law Review 614.

development. Beyond the importance of the EU in international patent law that was discussed throughout the thesis, this grounding also provides an important example of how tensions emerge (and are managed) when legal systems interact at that particularly systemic level.[957] Europe has many non-intellectual property examples of mechanisms that are used to modulate or otherwise adjust how legal systems interact, discussed prominently in the literature through the vocabulary of domestic administrative law.[958] Intellectual property, and particularly patent law, has not typically been discussed as a form of administrative law despite the fundamental role of administrative power in granting the patent. Patents (and the process of granting a patent) are the result of an exercise of delegated state power. Patent systems and the retained national scope of patent law mean that international agreements, like the TRIPS Agreement, can then be interpreted as restricting or otherwise altering the autonomy of a state in patent law. This can be constructed as a regulation of international patent law or the patent grant process,[959] yet because it relies fundamentally on an exercise of delegated state power, the rules and systems that affect national patent law are actually administrative rather than just regulatory. Ghosh has discussed patent law as an element of international trade regulation but,[960] in recognising the administrative power involved in a patent grant, this regulatory effect is secondary to the more fundamental administrative character of patent law.

Patent law presents a particularly interesting opportunity for applying an administrative lens to the process of policy development in patent law precisely because international patent

[957] Günter Burghardt, 'The EU/US Transatlantic Relationship: The Indispensable Partnership' in Christoph Hermann, Bruno Simma, and Rudolf Streinz (eds), *Trade Policy Between Law, Diplomacy and Scholarship* (Springer 2015) 197; Victor Rodriguez, 'Constructing a Unitary Title for the European Patent System' (2011) 6(8) JIPLP 576.
[958] Giacinto Della Cananea, 'Administrative Law Beyond the State: The Influence of International and Supranational Organizations' in Peter Cane, Herwig Ch Hofmann, Eric C IP, and Peter L Lindseth (eds), *Oxford Handbook of Comparative Administrative Law* (OUP 2021) 359, 373.
[959] P Sean Morris, 'Private Intellectual Property Regulation in Public International Law' (2020) 26(1) UC Davis Journal of International Law and Policy 148, 149.
[960] With patent law proposed as a tool of marketplace regulation, suggesting that the patent bargain theory of patent law is misguided: Shubha Ghosh, 'Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor after Eldred' (2004) 19(4) Berkeley Technology Law Journal 1315, 1318.

law (and also national patent law) has often been framed in terms of its economic potential.[961] This type of economic framing in patent law has been used to drive discussions on the harmonisation of patent law,[962] of the role of efficiency,[963] and the stability of property rights.[964] Yet the reality of patent law is much more complex. Though the system does produce a legal right that necessarily has an economic impact,[965] patent law itself is the result of a much broader set of considerations. Patent law, within a single framework, brings together a diverse and interactive set of factors that distinguish what is and what is not inventive,[966] relevant constructions of public morality,[967] and the appropriate role of the patent system in driving economic growth.[968]

3.2 Revisiting the chapter and further reflections

One of the major aspects of chapter 1 was an attempt to contextualise the development of GAL, patent law, and the broader emergence of global systems of regulation. An essential part of this was highlighting that patent law, specifically through the grant of a patent, was

[961] Albert G Z Hu and I P L Png, 'Patent Rights and Economic Growth: Evidence from Cross-Country Panels of Manufacturing Industries' (2013) 65(3) Oxford Economic Papers 675, 676.
[962] Jerome H Reichman and Rochelle C Dreyfuss, 'Harmonization without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty' (2007) 57(1) Duke Law Journal 87.
[963] Vincent Chiappetta, 'Working Toward International Harmony on Intellectual Property Exhaustion (And Substantive Law)' in Irene Calboli and Edward Lee (eds), *Research Handbook on Intellectual Property Exhaustion and Parallel Imports* (Edward Elgar 2016) 139.
[964] Amina Ahmed Lahsen and Alan T Piper, 'Property Rights and Intellectual Property Protection, GDP Growth and Individual Well-Being in Latin America' (2019) 28 Latin American Economic Review 2, 5.
[965] Discussing the utilitarian perception of patents as 'economic instruments' that should protect only minimum term required to incentivise innovation: Federica Baldan, *Judicial Coherence in the European Patent System: Lessons from the US and Japan* (Edward Elgar 2022) 91.
[966] Such as excluding mathematics from patentability: Hazel V J Moir, *Patent Policy and Innovation: Do Legal Rules Deliver Effective Economic Outcomes?* (Edward Elgar 2013) 64.
[967] The changing approach to 'products manufactured by an atomic transformation' in Japan is one example: Nobuhiro Nakayama, 'The Enforcement of the TRIPS Agreement in Japan' (1995) 38 Japanese Annual of International Law 58.
[968] Like the reforms around universities and patent commercialization that appeared around the world: Hiroyuki Odagiri, Akira Goto, and Atsushi Sunami, 'IPR and the Catch-Up Process in Japan' in Hiroyuki Odagiri, Akira Goto, Atsushi Sunami, Richard R Nelson (eds), *Intellectual Property Rights, Development, and Catch-up: An International Comparative Study* (OUP 2010) 120.

fundamentally built on an exercise of delegated state power and can therefore be analysed from an administrative law perspective. Even within national administrative law, a lot of the discussions in the literature are about legal mechanisms and tools that control the exercise of state power and particularly when this power is used by administrative agencies.[969] Yet one of the limitations of the chapter, and perhaps of the thesis more generally, is that properly exploring the administrative foundations of patent law would be beyond the scope of the thesis. Though earlier versions of the work questioned the ontological elements of patent law, the emphasis on the theoretical aspects of the patent moved the thesis towards legal theory rather than a contextual critique of how international patent law develops. This also reflects a broader shortcoming of chapter 1 and the thesis more generally, which is that patent law as administrative in nature is not a conventional perspective in the literature. Other authors have produced excellent scholarship on how patent law develops from perspectives that focus on economics,[970] human rights,[971] and property law.[972] I believe that the administrative law perspective here helps to deconstruct patent law in a way that more accurately reflects the legal foundation of the patent grant which has not been properly explored. Yet it would be fairly uncontroversial to suggest that patent law is part of international trade regulation and appears to be implicitly accepted throughout the literature. From this, the thesis is simply a more nuanced understanding of the power that produces the legal impact of the patent – shifting the perception of patent law away from just regulation, and towards regulation with an administrative foundation. Patent law is regulatory – but it is also administrative.

[969] Where even edited volumes highlight, beyond the 'necessary control function and the significant role played by courts' in administrative law, the importance of interpreting 'the concept of control more inclusively': Carol Harlow, Päivi Leino, and Giacinto della Cananea, 'Introduction: European Administrative Law – A Thematic Approach' in Carol Harlow, Päivi Leino, and Giacinto della Cananea (eds), *Research Handbook on EU Administrative Law* (Edward Elgar 2017) 7.
[970] Duncan Matthews, 'Patents in the Global Economy' (2010) UKIPO Report 1.
[971] Hans Morten Haugen, 'Patent Rights and Human Rights: Exploring their Relationships' (2007) 10(2) WIPOJ 97, 98.
[972] Adam Mossoff, 'Patents as Constitutional Private Property: The Historical Protection of Patents under the Takings Clause' (2007) 87 Boston University Law Review 689.

The administrative perspective also provides an important internal critique of patent law that is aimed at challenging the dominant economic narrative of patent law. As discussed in the introduction and chapter 1, a major theme within the literature – specifically work that critiques the distributive impact of patent law[973] – is the use of a non-patent perspective to analyse an issue of patent law. In this, there is a significant level of dialogue that appears to be aimed at legitimising this approach, of reconciling two different disciplines. Patent law as fundamentally realised through the exercise of administrative power dissolves this issue by producing a critique that is internal to patent law and draws on conventional values of administrative law as tools of analysis. Despite this, it is clear that this tension in the legitimacy of applying different perspectives to issues of patent law is not necessarily a pressing issue in the literature. The administrative perspective that enables an internal critique of patent law is a novel approach, though the practical value of it for scholars engaged in specific issues (like access to medicine, the right to health) may be limited. This also highlights one of the reasons why the thesis moved away from the more theoretical ontological analysis of patent law. With an approach that was more focused on the legal theory of patent law, the thesis would be even more detached from the real-world issues of international patent law.

Patent law as a form of administrative law (or at least fundamentally related to it) can be seen in two specific elements, the first of which is comes from the scope and means of execution in patent law. Patent law, and the enforcement of a patent, relies on state power for its authority and this explains why patent law has retained such an emphasis on national borders for patent validity. A key part of a patent is that it is a negative right – a right to exclude all others[974] – and cannot be replicated through ordinary contract law or commercial law tools

[973] Philippe Cullet, 'Patents and Medicines: The Relationship Between TRIPS and the Human Right to Health' (2003) 79(1) International Affairs 139, 140.
[974] Adam Mossoff, 'Exclusion and Exclusive Use in Patent Law' (2009) 22(2) Harvard Journal of Law & Technology 2.

precisely because it affects all actors in that legal system with no prior arrangement. From this perspective, provisions in international trade law that control how this delegated power may be exercised (the type of patent that can be issued, the length of a patent) can be approached in a similar way to conventional tools of administrative law.

The second element that highlights the administrative nature of patent law is the way in which the existence of a patent is challenged. This is reflected in many European legal systems, as well as some East Asian jurisdictions,[975] where the validity of the patent is challenged separately to the infringement of the patent.[976] Yet it remains that the patent office, as the office exercising the delegated power to grant the patent, is involved in legal proceedings for validity and revocation. This is particularly the case for the UPC and the EPUE discussed in chapter 2. Though it was discussed more extensively in chapter 2, the very structure of the EPUE reflects the patent grant as an administrative act. Together, this also centres the role of dispute resolution bodies in GAL scholarship specifically and also more generally in patent law. Dispute contexts feature throughout the thesis and in conventional administrative scholarship because of the way that dispute resolution bodies produce, interpret, and give meaning to legal principles and administrative values to facilitate workable systems of law.

[975] Toshiko Takenaka, 'The Best Practice for Patent Judiciary: Lessons from Another Experiment on Specialized Adjudication for Patent Cases in Japan' in Christophe Geiger, Craig Allen Nard, and Xavier Seuba (eds), *Intellectual Property and the Judiciary* (Edward Elgar 2018) 420.
[976] Karen Walsh, *Fragmentation and the European Patent System* (Hart 2022) 27.

4. Chapter 2

4.1 A new patent interface in Europe: Exploring participation

Chapter 2 explored the development and implementation of the European Patent with Unitary Effect (EPUE). Though it is specifically explored through the lens of administrative values, the EPUE is a fundamental evolution of patent law in Europe that significantly addresses the ongoing fragmentation of European patent law.[977] The fragmentation of patent law in this context has been discussed throughout the literature,[978] though it is important to recognise that the lack of harmonisation has typically resulted from a mix of substantive and procedural issues. Significant progress was made with the EPC and other specific Directives that helped to promote a more unified European approach to patents (though specifically in patent application).[979] Particularly for users, a European patent system that presents a single enforceable right effective throughout the EU would be a significant simplification over the multiple national approaches to application and enforcement generally required in Europe. And yet despite this significant potential, the EPUE as currently constructed falls short of producing an effective and harmonised system for patent protection in Europe. The EPUE also represents a unique opportunity within patent law to observe the creation of a new interface and, from an administrative perspective, to explore how specific values shape or otherwise influence the process from a contemporary perspective. The chapter specifically emphasised the role of

[977] With the objective of creating a specialised patent jurisdiction and promote research, development and investment in innovation: EU Commission, 'Internal Market, Industry, Entrepreneurship, and SMEs: Unitary Patent' (*EU Commission*) <https://ec.europa.eu/growth/industry/strategy/intellectual-property/patent-protection-eu/unitary-patent_en>.

[978] Specifically in terms of patent validation but also more generally: Amanda Odell-West, 'Exclusions in Patent Law as an Indirect Form of Regulation for New Health Technologies in Europe' in Mark L Flear, Anne-Maree Farrell, Tamara K Hervey, and Thérèse Murphy (eds), *European Law and New Health* Technologies (OUP 2013) 152.

[979] On the complex role of the EPC in bringing together standards in patent law: Alexander Stack, *International Patent Law: Cooperation, Harmonization and an Institutional Analysis of WIPO and the WTO* (Edward Elgar 2011) 94.

transparency and participation in the development of the EPUE. The challenges of promoting participation were particularly visible in the EPUE context because it was the result of enhanced cooperation rather than the ordinary legislative process of the EU.

Chapter 2 focused on how transparency, accountability, and participation not only influenced the creation of a new legal framework in patent law but explored how these values could continue to shape the functioning of a new and harmonised European patent law. Yet the EPUE is only one aspect of this development though, and the chapter brought together both the EPUE and the UPC in this administrative analytical context.[980] The UPC, particularly because it will be the court structure that deals with both the administration and enforcement of EPUEs, is therefore central in understanding how administrative values function within this system. The UPC also represents an important development for patent law in the EU because it is a specialised court, though it is line with a more general trend towards the specialisation of intellectual property courts globally.[981] The chapter centred the role of the UPC in understanding administrative values in patent law because it is not only the legislative provisions that can embody or reflect specific values, but also the interpretation and enforcement of those provisions in practice by dispute settlement bodies.

The UPC is an ongoing development and so the chapter grounded much of the analysis in the textual provisions of the UPC Agreement (UPCA). Though the court is yet to hear cases, the UPCA at least provides a strong starting point for analysing the position and legal capacity of the court and its judges. Though the chapter emphasised the procedural elements of patent law from an administrative perspective, specifically the development of interface mechanisms, it necessarily involved consideration of more substantive elements. Chapter 1 specifically

[980] Agreement on a Unified Patent Court ("UPC Agreement").
[981] On the increasing global attention that specialised intellectual property courts have attracted: Olga Gurgula, Maciej Padamczyk, and Noam Shemtov, 'Specialised IP Judiciary: What are the Key Elements to Consider when Establishing or Reforming an Effective IP Court?' (2022) 71(3) GRUR International 206, 207.

focused on how compulsory licensing and *l'ordre public* exceptions have a particular connection to the administrative values considered throughout the thesis. Understanding how these two mechanisms are constructed within the EPUE system represents an important analytical objective, though they are central from an administrative perspective because they provide ways for otherwise binding provisions to be modulated. These exceptions were presented throughout chapter 2 as fundamentally connected to transparency and accountability because they are deployed, particularly in a dispute settlement context, to flexibly adapt or adjust binding obligations within patent law. Here, these mechanisms were considered in terms of their ability to promote or undermine a more responsive and reflective (from an administrative perspective) patent law in Europe.

To ground the analysis more concretely in the European patent context, the chapter considered compulsory licensing and *l'ordre public* in specific technological contexts. Pharmaceuticals and biotechnology both provide unique challenges and opportunities within patent law and, for administrative values particularly, reflect the increasing complexity of this area as they are both subject to additional legal regulation.[982] This was also reflected throughout the chapter in the contextualisation of previous patent harmonisation projects. This type of grounding and contextualisation was important to the analysis in the chapter because the EPUE is intended to coexist, rather than replace, existing systems of patent protection. Though the discussion in the chapter was necessarily informed by the substantive provisions of patent law that deal with these two technologies, the objective within the chapter was to use their unique technological features to highlight the discrete functioning *in practice* of these patent exceptions within the EPUE and how we understand responsiveness in patent law more generally.

[982] One example would be the overlap in terms of subject matter for biotechnology inventions that the EPC provisions are specifically an element of: Estelle Derclaye and Matthias Leistner, *Intellectual Property Overlaps: A European Perspective* (Hart 2011) 98.

4.2 Balancing the chapter: Between speculation and analysis

A strength of the chapter is that it investigates a new and emerging legal development in patent law from a perspective that stresses the interconnected nature of law. As an emerging area, the chapter provides valuable analysis of the EPUE and UPC even from a narrow patent law perspective. Yet it is in exploring these specific aspects of patent law that a novel understanding of patent law and its connection to administrative law emerges. Analysis that contextualises the legal challenges to the EPUE may be valuable by itself, but the thesis suggests that it is precisely these challenges that support an administrative reading of patent law. The design of the EPUE is in direct response to establish EU doctrine concerning the improper delegation of regulatory power to administrative agencies.[983] From this perspective, reflecting many discussions on the role of international patent law as an element of global trade regulation,[984] patent law clearly has a regulatory character in that it provides for specific boundaries of the patent but is fundamentally premised on an exercise of delegated state power. Chapter 2 is important because it not only explores the EPUE from the perspective of GAL values, but because it also supports a broader argument on the abstract nature of patent law as deeply connected to administrative law.

Participation was the central value in this chapter and unifies many different themes that appear in more implicit or isolated ways in the literature. This is particularly the case for the EPUE and enhanced cooperation because the focus on participation casts this as a systemic issue rather than one that is unique to the EPUE. The contextual analysis of other uses of

[983] To avoid the *Meroni* doctrine from C-9/56, C-10/56 *Meroni v High Authority* [1957/1957].
[984] Frederick M Abbott, 'Intellectual Property Rights in World Trade' in A Guzman and A Sykes (eds), *Research Handbook in International Economic Law* (Edward Elgar 2007) 444, 445.

enhanced cooperation in the chapter also supports this and works to distinguish the EPUE in a way that has generally not been explored in the literature.

The GAL perspective that was used to guide the analysis throughout the thesis is particularly useful in chapter 2 because the emerging literature has generally focused on a relatively narrow patent law approach. There are some exceptions to this that were discussed in the chapter, particularly with the work of Lamping on the undermining of enhanced cooperation requirements and McMahon on the difficult process of balancing in the context of *l'ordre public* exceptions.[985] But by using participation as a lens through which to view patent law, the chapter effectively explores not only the EPUE as a legal development but the broader dynamics of how international patent law is developing. Throughout the chapter, this was developed alongside a questioning of *who* was important in this process. The GAL perspective helps the chapter join the patent-specific disputes in the EPUE (in particular, the language challenges) with a broader critique of how EU Member States interact with each other in law-making. As developed in the chapter, the precise contours of the EPUE system were essentially beyond any serious threat of redesign because it was only the major patent jurisdictions that were necessary for the project to succeed. As long as the major patent jurisdictions were participating, there was very little room for smaller Member States to modify the EPUE framework and even non-participation would not shield their national innovation contexts from the impact of the EPUE system.

One of the fundamental limitations of the chapter is that the analysis, of both the EPUE and the UPC, is necessarily quite speculative. There are many variables that could affect the eventual usage of the EPUE by industry and how the UPC approaches difficult questions of

[985] Matthias Lamping, 'Enhanced Cooperation: A Proper Approach to Market Reintegration in the Field of Unitary Patent Protection?' (2011) 42(8) IIC 25, 26; Aisling McMahon, 'An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: A Fragmented Future Too Far?' (2017) 48(1) IIC 42, 46.

patent law. Particularly for chapter 2, the speculative quality of the analysis is very pronounced because the focus was on the *values* of an international patent system that is not yet functional. It is important to recognise that this is not something unique to the thesis and GAL approach, where all other scholarship on the EPUE is also speculative. Yet this emphasis on participation and administrative values in the EPUE is important because, as with the thesis more generally, it explores international patent law from a perspective that has often been overlooked. Patent law is an area of law like any other and should be subject to high standards of accountability and participation. This is particularly the case in Europe because of the frequency with which these values specifically appear in official EU materials,[986] and patent law should be no exception. The chapter contextualises these values, the development of international patent law, and EU law-making to highlight how risks to participation in the EPUE may have a systemic impact on Europe more broadly.

5. Chapter 3

5.1 Understanding the relationship between the EU, the CJEU, and the WTO: Accountability, direct effect, and modulation

Chapter 3 built on the work of chapter 2 in considering how different actors interact in the development of patent law. While chapter 2 focused on how the relationship between the Member States and the EU was negotiated through the development of the UPC, chapter 3 shifted the emphasis towards a relationship with more external considerations with the WTO

[986] EU Parliament, 'Transparency and Ethics' (*Europarl*) <https://www.europarl.europa.eu/at-your-service/en/transparency>; though perhaps more explicitly declared through Article 15 TFEU, where the EU bodies and institutions 'conduct their work as openly as possible in order to ensure the participation of civil society and thus promote good governance'.

and the EU. The emphasis, like with the approach more generally in the thesis, was on the procedural elements of this relationship in the context of dispute resolution rather than specific substantive provisions. Intellectual property presents an interesting subject to deconstruct the values and principles that are involved in managing the relationship between the WTO and EU legal systems. The fact that this legal arrangement, as a hierarchy of legal sources, was brought about through trade liberalisation and the voluntary involvement of the EU and the Member States provides an important foundation. Yet it is precisely this prominence of trade liberalisation that distinguishes the relationship (particularly in dispute resolution) between the EU and the WTO from dispute settlement in previous rounds of conventional multilateral trade liberalisation.[987] The emergence of a hierarchy of international law has been a prominent part of the development of the EU, where the binding quality of international law was positioned *alongside* the unique character of the EU's constitutional structure.[988]

The chapter considered the relationship between the WTO and the EU in two specific contexts. The first was the complex construction of responsibility for binding international obligations but specifically as it concerns the Member States. Accountability has certainly appeared in academic discussion on this issue,[989] but the chapter grounds the fundamental character of accountability and responsibility as elements of administrative law and the exercise of state power. Though the EU is a customs union, it is also a full member of the WTO.[990] This complicates the issue of responsibility for trade violations because the Member States retained their membership in the WTO even while the EU had taken over external

[987] John F Murphy, *The United States and the Rule of Law in International Affairs* (CUP 2004) 50.
[988] Discussing briefly that the 'EU represents a unique departure in international law…': Raymond J Friel, 'Providing a Constitutional Framework for Withdrawal from the EU: Article 59 of the Draft European Constitution' 53 ICLQ 407.
[989] Ernst-Ulrich Petersmann, 'Transatlantic Free Trade Agreements: Lack of EU Leadership for Reforming Trade and Investment Law?' (2016) 4 Revue Internationale de Droit Économique 473, 474.
[990] Raymond J Friel, 'Providing a Constitutional Framework for Withdrawal from the EU: Article 59 of the Draft European Constitution' 53 ICLQ 407.

competence for commercial policy.[991] The chapter explored the tensions in this area from an administrative perspective that emphasises the modulation of accountability, but in doing so, it presented a more comprehensive understanding of what is happening. The relationship between the WTO and the EU appears to be relatively straightforward in terms of responsibility, yet in practice, accountability for binding obligations is produced by an ongoing process of modulation that is co-created by the Member States, the EU, and the WTO membership more broadly.

The other element of accountability that the chapter explored was analysed through the role of the CJEU and how it has been central in establishing (and modulating) the legal status of both DSB Panel Reports and the WTO Agreements more fundamentally. The CJEU is a central institution within the EU for realising accountability for international obligations because it has a particularly broad scope of autonomy and represents a specific point of contact between EU law and non-EU law. The interpretative monopoly of the CJEU is particularly relevant for understanding responsibility because it is the sole legitimate institution for producing binding interpretations of EU law.[992] This ability to precisely and authoritatively interpret the nature of EU law necessarily extends to the WTO Agreements. Yet this chapter suggested that, by recognising accountability as a flexible administrative value that exists along a spectrum, what is actually happening is that the CJEU is producing a contextually sensitive modulation of otherwise binding international obligations. From this perspective, the CJEU has not outright rejected the authority of the WTO and its obligations – and yet nor has it endorsed them entirely. Rather, the CJEU has produced a more dynamic process in which

[991] Rafael Leal-Arcas, 'Exclusive or Shared Competence in the Common Commercial Policy: From Amsterdam to Nice' (2003) 30(1) Legal Issues of Economic Integration 3, 4.
[992] Though argued here that it relies 'on no more than the Court's own assertion': Gareth Davies, 'Does the Court of Justice Own the Treaties? Interpretative Pluralism as a Solution to Over-Constitutionalisation' (2018) 24(6) ELJ 358, 359; Nial Fennelly, 'Legal Interpretation at the European Court of Justice' (1996) 30(3) Fordham International Law Journal 656, 673.

binding obligations – and thus the legal impact of the provisions that outline them – can be dynamically adjusted depending on the discipline, relevant actors, and the specific obligation under consideration.

5.2 Accountability to whom?

One of the strengths of the chapter is that it provides a way of understanding a confusing area of CJEU jurisprudence. As discussed in the chapter, scholarship in this area appears to conclude that the CJEU approach to the WTO Agreements and Panel Reports has been inconsistent and responsibility for violations remains an unsettled area of law.[993] The chapter instead approached this area from the perspective of accountability for binding obligations and the interactive process by which this binding quality is modulated. Focusing on how EU accountability for binding WTO provisions is interpreted by the CJEU provides a unifying narrative that, instead of describing inconsistency and isolated incidents, provides a more integrative or unifying narrative of what is happening in this area. Though the chapter may not represent the most radical understanding of how CJEU jurisprudence has developed in this area, it does at least provide a way of contextualising and explaining why the inconsistency discussed in the literature is actually reflective of a dynamic approach to accountability that the CJEU is engaged in.

This emphasis on administrative values, and specifically accountability, highlights two of the limitations of the chapter. The first is that the scholarship exploring the relationship between the CJEU and the WTO adopts a variety of perspectives that emphasise politics,

[993] Inge Govaere, 'A Tale of the (Un)expected: Backlash for all Mixed Agreements of the "External" Harmonisation of Intellectual Property' in Josef Drexl (ed), *Technologie et Concurrence - Technology and Competition (*Armando Editore 2009) 704.

economics, and other legal approaches. A necessary limitation of the chapter is then that it focuses on a single value in a legal context that is interpreted from a GAL perspective. Yet accountability provides an interesting perspective that, in many ways, integrates the majority of the discussions that appeared in the context of integrity of the EU internal market. Accountability in the chapter was deployed to analyse the way in which the CJEU minimises or otherwise modifies the binding quality of international obligations that the EU had taken on. From this perspective, the CJEU is indeed shielding the internal market from outside influence and maintaining the autonomy of the EU legal order but the focus on accountability contextualises this and presents it as a more complex process that goes beyond simple integrity. So while the administrative perspective is necessarily limited in scope, the way in which accountability is developed through chapter 3 actually frames a lot of the academic analysis of the EU-WTO relationship – but in a way that integrates these perspectives within the overarching narrative of a flexible accountability.

But it is this sense of accountability as produced through a dynamic and interactive process that highlights the second limitation of the chapter. Focusing on accountability necessarily raises the question of accountability to whom? How can accountability be enforced? These questions take on a different character depending on their context, and within the chapter the answers differ whether it is the CJEU under consideration or the EU more generally. Turning first to the CJEU, the chapter raised the issue of the CJEU developing legal principles with seemingly no way for stakeholders to meaningfully challenge these developments. *Francovich* liability is one example with its reshaping of general values,[994] but more generally the CJEU has sometimes developed legal principles with a much more tenuous

[994] Joined Cases C-6/90 and C-9/90 *Andrea Francovich and Danila Bonifaci and others v Italian Republic* (1991) ECR I-5357; C-46/93 *Brasserie du Pêcheur SA v Germany* (1996) ECR I-1029.

link to the actual treaty text.[995] In this context, accountability remains limited because it would require legislative intervention. These discussions are of course framed by the separation of powers and, particularly given the current climate in Europe,[996] the fundamental importance of an independent judiciary. But the chapter did highlight that there is some tension in the CJEU's essentially unlimited scope for developing legal principles. Given the complexity of the issue and the importance of judicial independence, there is no simple solution that would adequately balance the role of the court with effective systems of oversight or challenge. And it is this lack of simple solution that highlights one of the broader objectives of the thesis in promoting dialogue and a sense of consciousness raising in international patent law that goes beyond the typical issue of access to medicine.

Moving beyond the role of the CJEU and to the accountability of the EU more generally, the question of accountability becomes much simpler – the EU and its Member States have implemented international agreements and so should be accountable to its trading partners for those obligations. Yet the CJEU, as developed through the chapter, is central in taking those international obligations and producing an accountability that is flexible depending on the context. This manifests most clearly in the treatment of direct effect in the chapter but can also be seen more generally in how the process of interpretation by the CJEU enables a flexibility to obligations that would otherwise be binding. This is framed by the broader sense that responsibility for trade violations highlights the complexity of the EU-Member State relationship, and the expansive approach to EU responsibility provides a ready solution. The issue here, and of accountability in this narrower sense, is one of political will. The chapter highlighted specific contexts in which accountability in the current understanding will be

[995] Marcus Klamert, 'The Autonomy of the EU (and of EU Law): Through the Kaleidoscope' (2017) 42(6) ELR 818.
[996] Specifically in Poland and Hungary: Martin Sunnqvist, 'The Changing Role of Nordic Courts' in Laura Ervo, Pia Letto-Vanamo, and Anna Nylund (eds), *Rethinking Nordic Courts* (Springer 2021) 174.

challenged and will have to be dealt with, particularly with the COVID-19 pandemic. Patent law appears to be particularly well placed to challenge the way accountability has been used in the context of WTO violations and raises fundamental questions about the sustainability of the EU's current approach. The thesis was aimed at making explicit these tensions in international patent law and promoting critical dialogue, precisely because none of these problems have straightforward solutions.

6. Chapter 4

6.1 Exploring the values of EU bilateral trade agreements: Bringing together accountability, transparency, and participation

Particularly in recent years, bilateral and regional trade agreements have become an increasingly prominent part of the global system of trade.[997] These agreements contribute significantly to the trade relationship between global trading partners and represent, particularly in contrast to the perceived (lack of) speed of multilateralism, a more efficient alternative.[998] The increased attention to the impact of bilateral trade agreements, within trade specifically and beyond, is a more recent trend though their use has a much longer history.[999] The contentious events of the Cancún Ministerial Meeting and the conclusion of the Uruguay

[997] On the sharp growth of trade agreements since the 1990s: Silvia Sopranzetti, 'Overlapping Free Trade Agreements and International Trade: A Network Approach' (2018) 41(6) The World Economy 1549.
[998] 'The institutional machinery of the GATT/WTO system is cumbersome and slow. Multilateral rounds take many years to negotiate, and tend to address issues agreed upon by the parties at the inception of each round.': Thomas R Howell, 'The Multilateral Trading System and Transnational Competition in Advanced Technologies: The Limits of Existing Disciplines' in Göran Marklund, Nicholas S Vonortas, and Charles W Wessner (eds), *The Innovation Imperative: National Innovation Strategies in the Global Economy* (Edward Elgar 2009) 52.
[999] On the long history of bilateral agreements (as well as the more general trends of liberalism and protectionism over time): Olivier Cattaneo, 'The Political Economy of PTAs' in Simon Lester, Bryan Mercurio, and Lorand Bartels (eds), *Bilateral and Regional Trade Agreements: Commentary and Analysis* (CUP 2015) 31.

Round have emerged as significant drivers of the more central role that bilateral agreements have taken on in recent years.[1000] As such, the chapter tried to explore both how administrative values had been impaired in the context of bilateral trade agreements and also to suggest that this was happening in a space that was distinct from either national or global environments.[1001]

Bilateral trade agreements, as individualised agreements between trading partners, produce a legal context in which disputes take on a specific character that is different to those found in multilateral frameworks. Disputes between trade partners are necessarily diffuse and reflect the more localised elements of their trade relationship, the agreement concerned, and how dispute resolution bodies are constructed within that agreement. Because of this, bilateral trade agreements and their relationship to localised dispute resolution and settlement provide an interesting context for exploring GAL values. Analysing bilateral trade agreements from this GAL perspective highlight specific characteristics of GAL values, the first of which is their interconnected nature. This supports the conclusions of more conventional GAL work that works to illustrate the mutually reinforcing effect of transparency, accountability, and participation.[1002] Yet despite this interconnected quality, the bilateral trade environment context demonstrates that these localised values remain somewhat isolated from their multilateral counterparts. This type of breakdown between each value considered throughout the chapter challenged the approach taken in the thesis of artificially separating out transparency, accountability, and participation. Bilateral trade agreements highlight how, in

[1000] On the subversive impact of preferential trade agreements on the GATT obligations before Uruguay: Marcelo de Paiva Abreu, 'Developing Countries and the Uruguay Round of Trade Negotiations' (1990) Proceedings of the World Bank Annual Conference on Development Economics 1989 28.

[1001] Drawing on perspectives and themes that were prominent in the early development of GAL, where much of the work deals with establishing that there is a 'global space' at all: Elisa D'Alterio, 'Judicial Regulation in the Global Space' in Sabino Cassese (ed), *Research Handbook on Global Administrative Law* (Edward Elgar 2016) 321.

[1002] Indeed, in the introduction to a symposium issue, Krisch and Kingsbury discuss administrative values and often group together accountability, participation, and transparency: Nico Krisch and Benedict Kingsbury, 'Introduction: Global Governance and Global Administrative Law in the International Legal Order' (2006) 17(1) EJIL 4, 5.

practice, this distinction between impairments to each value are fundamentally connected and overlap in practice. This overlapping quality presents a dissonance between the very contextually sensitive bilateral environment and the ways in which values are supported or undermined in the multilateral context. As such, this approach that centres the importance of administrative values would seem to be in accordance with other perspectives in the trade law literature that discusses the increased atomisation of international trade law.[1003]

Turning to the treatment of intellectual property within bilateral trade agreements, the general approach had been to reference standards of intellectual property protection in major multilateral agreements rather than requiring the adoption of specific legal standards.[1004] Guan has discussed the perception of intellectual property around this period, but specifically around the development of the Uruguay Round, as being the 'domain of specialists'.[1005] Yet this sense of intellectual property as a specialist subject even within legal or trade circles represents a very different perception of intellectual property in recent years. The public protests in response to the leaked ACTA negotiations highlight that intellectual property, even in this more localised sense, has become a visible point of contention for society. ACTA may have failed, but the engagement with these issues by the public is an important development for intellectual property more generally. This shift has also developed in tandem with an approach by major trade actors, like the EU and the US specifically, that depart from the earlier and more general

[1003] Though in reference to international investment law, Hamdani specifically discusses the negative impact of a patchwork of individual treaties between trade partners: Khalil Hamdani, 'Panel: Process and Value of Uniform Commercial Law: Proceedings of the Congress of the United Nations Commission on International Trade Law Held on the Occasion of the Fortieth Session of the Commission' (2007) 25.

[1004] One more recent example would be the agreement between the Central American Association Agreement where Article 78(g) refers simply to a commitment to 'the adequate and effective protection of intellectual property rights, in accordance with international obligations in force between the parties…': Article 78(g) Agreement Establishing an Association between the European Union and its Member States, On the One Hand, and Central America on the Other; while Title VI of the same agreement (that deals with intellectual property) simply reaffirms the binding nature of the TRIPS Agreement in Article 229.

[1005] Arguing that prior to the introduction of the TRIPS Agreement, intellectual property had 'was still the domain of specialists and intellectual property right producers': Wenwei Guan, 'Diversified FRAND Enforcement and TRIPS Integrity' (2018) 17(1) WTR 111.

approaches.[1006] Instead of references to the broad standards of intellectual property in multilateral agreements, intellectual property in more recent bilateralism is subject to elaborate chapters that establish much more specific obligations.[1007]

This type of approach has contributed to the distinction between provisions that are considered 'WTO-Plus' and those that are just 'TRIPS-Plus'.[1008] This distinction emerges because while the WTO Agreements ground the provisions of most bilateral trade agreements, they do still remain fundamentally limited by the legitimate disciplinary scope of the WTO. The interplay of disciplines, regulation, and trade provisions mean that each individual trade agreement has a specific type of relationship with the grounding multilateral instrument (TRIPS). This localisation of the scope of international trade law (and intellectual property more specifically) presents a more abstract challenge to transparency that was considered in a more grounded context in chapters 2 and 3. Transparency in this context is threatened not by the failings of formalist transparency provisions that undermine legal predictability, but rather by an obscuring of the trajectory of international intellectual property law. With successfully concluded bilateral trade agreements, it is not clear to observers or society more generally which provisions were the result of strategic trading.[1009] As such, the values and principles that propel the development of international intellectual property through bilateral trade agreements are fundamentally obscured.

[1006] Chenguo Zhang, *Balance and Limitation of Intellectual Property Protection in China: The Latest Law Amendments and Judicial Developments Under Micro-Comparative Perspectives* (Springer 2022) 129.
[1007] ibid.
[1008] Though WTO-plus provisions, because of the standards in the application of Article XXIV GATT and Article V GATS, necessarily have somewhat of a unclear or flexible nature and makes it more difficult to concretely define: Gary Clyde Hufbauer and Sherry Stephenson, 'The Free Trade Area of the Americas: How Deep an Integration in the Western Hemisphere?' in Hadi Soesastro and Christopher Findlay (eds), *Reshaping the Asia Pacific Economic Order* (Routledge 2006) 130, 148.
[1009] One multilateral example of this type of strategic trading of standards can be found in the Uruguay Round, with the dynamic between increased intellectual property standards and the possibility of greater market access in textiles and agriculture for developing countries: J H Reichman, 'The TRIPS Component of the GATT's Uruguay Round: Competitive Prospects for Intellectual Property Owners in an Integrated World Market' (1993) 4 Fordham Intellectual Property, Media & Entertainment Law Journal 178.

Here, the lack of transparency also undermines a more practical sense of participation in two specific ways. The first impairment to participation is reflected in the more conventional explorations of democratic accountability that appears in many areas of GAL scholarship.[1010] Yet there is a second, more narrow, way in which participation is minimised and centres on the role of state actors in the development of bilateral trade agreements. Even within the specific context of bilateral trade agreements, state participation (and the bodies that would usually provide at least some administrative counterbalance) is restricted to a number of specialised actors that, together, results in a system that minimises accountability, transparency, and participation.

6.2 Reconciling autonomy with a GAL critique of bilateralism

Perhaps one of the fundamental limitations to chapter 4 relates to both GAL as an area of research and the legal arrangement of bilateral trade agreements. Turning first to GAL, chapter 4 reflects some of the tensions identified in chapter 1 around the precise scope of GAL. As was discussed, international regulation is so complex that GAL necessarily incorporates elements that are not just administrative, not just law, and not just global.[1011] Bilateral trade agreements push this hazy construction of GAL the furthest of any of the thesis chapters because while it produces agreements with legal effect, it has a more contextual and nuanced relationship to GAL. The thesis has focused on patent law, though future work could instead centre the bilateral context and analyse how this interacts with principles of GAL and administrative law more generally.

[1010] Martin Shapiro, '"Deliberative," "Independent" Technocracy v. Democratic Politics: Will the Globe Echo the E.U.?' (2005) 68(3/4) Law and Contemporary Problems 343.
[1011] Sabino Cassese, 'Global Administrative Law: The State of the Art' (2015) 13(2) ICON 465.

In a related sense, one of the fundamental critiques of the chapter would be that bilateral trade agreements necessarily involve an exercise of autonomy. This is particularly relevant when discussing the negative dimensions of these trade agreements because developing countries often actively engage with these trade relationships with larger economies.[1012] From this perspective, bilateral trade agreements are a reflection of empowered national governments and a success of trade liberalisation. Yet this is perhaps tempered in the context of the thesis for two specific reasons. The thesis has focused on how accountability, participation and transparency are present in a patent context and at least in these bilateral trade agreements, the chapter discussed several examples where the ability to grant a patent or exercise flexibilities is significantly impacted. Accountability for the binding obligations of the Paragraph 6 system and the TRIPS Agreement more generally are, in practice, being modulated by provisions in bilateral trade agreements that minimise their use. Looking at debates in access to medicine, GIs, and test data exclusivity, it would not be controversial to suggest that these agreements not only affect one partner more than the other but that they function more generally to undermine the binding commitments in the TRIPS Agreement.

The second aspect that questions whether autonomy of trading partners can be used as a critique of the thesis is the scholarship around the political economy of trade agreements. This manifests in trade agreements that work to facilitate some broader geopolitical objective (US-Oman trade agreement is one clear example),[1013] and also in more conventional contexts in intellectual property where higher standards are traded for market access in another area.[1014]

[1012] And not always for the economic gains – Gallagher discusses how Latin America's engagement with the US in trade agreements actually produces fewer economic gains than under global trade liberalisation efforts, instead emphasising the economic diplomacy dimension of these engagements: Kevin P Gallagher, 'Trading Away the Ladder? Trade Politics and Economic Development in the Americas' (2008) 13(1) New Political Economy 37.
[1013] Lucia M Rafanelli, *Promoting Justice Across Borders: The Ethics of Reform Intervention* (OUP 2021) 34.
[1014] Where the bilateral trade negotiation context itself 'easily enables trade deals that trade IP standards against concessions in other areas of trade that are perceived to be more important': Anke Moerland, 'Do Developing Countries Have a Say? Bilateral and Regional Intellectual Property Negotiations with the EU' (2017) 48 IIC 781.

This trading of standards has been discussed extensively in the context of multilateral trade rounds and also can be seen in the bilateral context as well.[1015] From this perspective, the autonomy of the parties involved – though particularly developing countries – is then fundamentally tied to the economic potential of the agreement. The smallest of developing countries, in reality, have little capacity to negotiate the terms of an agreement with the EU and may indeed not want to challenge specific provisions (like patents) because the economic value of the agreement in terms of market access outweighs all other concerns. Trade partners, specifically in agreements with the EU, are then clearly exercising their autonomy in entering these agreements but it reflects a somewhat compromised or qualified autonomy that is subject to a variety of external (to the trade agreement) pressures.

This also links with a further limitation of the chapter which is connected to how the issues within bilateral agreements are constructed. Here, the thesis has characterised the development of international patent law in terms of accountability, transparency, and participation. Yet particularly with problems emerging from bilateral trade agreements, there is already a great deal of literature that focuses more concretely on the discrete issues themselves from a rights perspective. Access to medicine and limitations on the exercise of flexibility is one example,[1016] though GIs and the clawback provisions are another reflection of a more contextualised discussion.[1017] The administrative perspective in chapter 4 is, particularly because it draws more GAL literature, only one way of approaching these issues and is not intended to a definitive understanding. The chapter does however, present the interconnected nature of these issues by emphasising the relationship between the bilateral and

[1015] J H Reichman, 'The TRIPS Component of the GATT's Uruguay Round: Competitive Prospects for Intellectual Property Owners in an Integrated World Market' (1993) 4 Fordham Intellectual Property, Media & Entertainment Law Journal 178.
[1016] Emmanuel Kolawole Oke, *Patents, Human Rights, and Access to Medicine* (CUP 2022) 93, 94.
[1017] Anselm Kamperman Sanders, 'Geographical Indications as Property: European Union Association Agreements and Investor-State Provisions' in Irene Calboli and Ng-Loy Wee Loon (eds), *Geographical Indications at the Crossroads of Trade, Development, and Culture: Focus on Asia-Pacific* (CUP 2017) 179.

multilateral spaces and the way deficiencies in GAL values necessarily enable these more specific legal problems. Approaches in the literature, by focusing on discrete issues, isolate those provisions to a degree because they are contextualised so specifically by the trade relationship of the partners. The thesis incorporates the GAL perspective as a way to instead highlight the systemic and overlapping dynamics of international patent law by unifying its development through the values of accountability, participation, and transparency.

This also links more generally with the way the thesis connects abstract GAL values with the legal frameworks of international patent law. Chapter 4 questioned both the accountability of bilateral trade agreements and the transparency of how international patent law is developing through this diffuse (and relatively opaque) system of trade agreements. The chapter concluded that there is a significant impairment of transparency in how provisions of patent law are being developed that will have a long-term impact, and yet a similar question emerges as in chapter 2 – who can solve this transparency issue? The reality is that patent law is one small area of these large trade agreements and effective oversight, or the effective empowerment of accountability and transparency, would require a significant degree of political will. Addressing the issue of opaque development in this area will not come from a simple or linear system of oversight. Instead, academic commentary that critically highlights the dysfunctional elements of bilateral trade agreements *in combination with* the work that focuses on discrete issues will at least provide a different, non-economic perspective on these agreements.

7. Conclusion

Patent law is a particularly complex area of law that is a fundamental part of global trade and regulation. From this narrower perspective, patent law is an important part of national

innovation strategies that encourages technological development and economic growth. And yet the impact of patent law has also emerged in more critical contexts that involve access to medicine, the treatment of genetic materials, and the exploitation of Indigenous communities. The thesis has approached patent law from a perspective that emphasises the exercise of administrative power and explored the development of international patent law through the lens of values used in GAL scholarship. In doing so, the thesis has been an attempt at presenting international patent law not only as an element of global trade regulation, but also to establishing it in dialogue with different areas of law that have typically remained separate in the literature and highlighting the administrative foundations of international patent law.

The five research questions in the thesis reflected this objective of encouraging communication and dialogue through patent law. The research questions focused on how systems of international patent law develop, the distinctions of global space, how these systems interact, the role of dispute settlement bodies in facilitating these interactions, and how successfully these frameworks support or undermine typical GAL values. In investigating the way in which international patent law is developing, values like accountability, transparency, and participation were positioned as central values to guide the analysis. Taken together, the thesis reveals not only that dispute resolution bodies are essential in establishing the broad contours of international patent law, but that they work to constitute the 'global' space more generally. This is explored more comprehensively in chapter 4, where the lack of singular dispute resolution body to focus on instead highlights the diffuse character of how international intellectual property law is developing. The bilateral space, and the position that dispute resolution bodies occupy in that context, contribute to a broader process of increased specialisation, atomisation, and isolation. From this perspective, accountability, transparency, and participation become intensely localised values. Dispute resolution bodies, patent-specific and beyond, meaningfully shape the substantive content of these values in a way that is

contextually responsive and flexible. The choice of values was informed by the approaches used specifically in GAL scholarship, but also drew from more conventional administrative law work. The research questions were intended to question international patent law in a way that emphasised the interactive nature of this area and promotes a flexible understanding of these administrative values. As with other work within GAL, the role of dispute settlement bodies is important in shaping or guiding this interactive development of law beyond the specific disputes they are involved with. The chapters considered dispute settlement bodies in a variety of international legal contexts to investigate how these institutions facilitate the interactions of different systems of law and how successfully they reflect the administrative values of the thesis. The thesis, in analysing patent law from a GAL perspective rather than efficiency or other economic value, provides a unique perspective on the important institutional dynamics that shape the development of international patent law.

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