UDK 061.1(4EU)(05) ISSN 1845-5662

CROATIAN YEARBOOK OF EUROPEAN LAW & POLICY

Vol. 21 [2025]

Zagreb, 2025

CROATIAN YEARBOOK OF EUROPEAN LAW AND POLICY (CYELP)

Publisher
University of Zagreb – Faculty of Law

Editorial Board Address
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Printed by
Sveučilišna tiskara d.o.o.

Printed in 100 copies

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Volume price: €50 for Europe, €60 for other countries. Student price: €25.

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CYELP is financially supported by

- University of Zagreb – Faculty of Law
- Ministry of Science, Education and Youth of the Republic of Croatia

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Editorial note

Ramses A Wessel*

DIGITAL DIPLOMACY: THE EU AS A GLOBAL DIGITAL ACTOR

In the context of rapid technological change and increasing geopolitical instability, the European Union (EU) has sought to redefine its global role through the lens of what has been termed 'digital diplomacy'. Digital diplomacy, as practised by the EU, integrates regulatory influence, cybersecurity initiatives, and artificial intelligence (AI) policy into broader external relations.

Over the past few years, the European Union has emerged as a significant actor in the global digital policy arena, utilising its regulatory power and external relations mechanisms to project values and norms beyond its borders.[1] Although not a State, the EU wields considerable normative power due to its legal personality (Article 47 TEU) and competences in areas such as trade, data protection, and internal market regulation. Articles 3(5) and 21 TEU set out the Union's external objectives: promoting peace, democracy, human rights, and the rule of law. These form the normative backbone of its digital diplomacy,[2] and the 2025 International Digital Strategy for the European Union expressly presents 'Digital as a core element of the EU's external action'.[3]

This editorial note briefly examines how legal frameworks, strategic objectives, and geopolitical shifts shape the EU's external digital engagements. Drawing from EU treaties, institutional strategies, and academic analysis, the aim is to evaluate the coherence and limitations of the

* Professor of European Law, University of Groningen. This editorial note is partly based on a presentation given by the author during the 'Jean Monnet Seminar on Advanced Issues of EU Law: Modern Technologies and EU Law', Dubrovnik, April 2025.

[1] Elaine Fahey, *The EU as a Global Digital Actor: Institutionalising Global Data Protection, Trade, and Cybersecurity* (Hart 2024). In this book, Fahey concludes that the EU has firmly positioned itself as a proactive rule-maker and global norm exporter. Its approach to digital regulation – particularly in data protection – has influenced legal frameworks in many third countries, often prompting them to align with EU standards to facilitate digital trade and data flows.

[2] Uphold and promoting its values and interests and contributing to the protection of its citizens are even formal legal obligations for the EU on the basis of Art 3(5) TEU. In a broader sense, Art 21(1) TEU refers to the principles which inspired the Union's own creation to guide its global actions.

[3] Joint Communication to the European Parliament and the Council, 'An International Digital Strategy for the European Union' JOIN(2025) 140 final.

EU's digital foreign policy. We will also assess its development through brief case studies in cybersecurity and AI governance. Given the EU's self-declared lag in technological innovation,[4] a key question is what the EU's ambitions are in this field. It is not the objective of this short note to provide an extensive overview of this complex field. Rather, it aims to draw attention to a development that is becoming increasingly relevant: the 'externalisation' of the EU's internal regulation of the digital world as part of its 'digital diplomacy'.

While the EU's digital diplomacy is framed as a values-driven, normative project, its effectiveness in translating internal regulatory power into global influence remains contested. The EU's reliance on 'regulatory power' – rather than technological or military power – raises questions about its ability to shape global norms in a multipolar digital landscape. Can a model built on human rights, democracy, and the rule of law compete with the market-driven pragmatism of the US or the State-controlled digital authoritarianism of China? This note argues that the EU's normative ambitions, while laudable, face structural and geopolitical limitations that may ultimately constrain its global leadership.

Conceptualising EU digital diplomacy

Digital diplomacy has not clearly been defined by the EU. Any conceptualisation therefore needs to be done on the basis of descriptions provided by policy documents and by the relevant literature. It is fair to say that, in general, digital diplomacy refers to the strategic use of digital tools and policies in diplomatic practice. For the EU, this includes the promotion of a rules-based international digital order, the export of normative standards (eg, the GDPR, the AI Act), and partnerships with global actors to counter digital authoritarianism. As articulated by the European External Action Service (EEAS), the EU's digital diplomacy involves engagement with States, international organisations, and private sector stakeholders to shape global digital norms.[5]

On 6 June 2025, the European Commission adopted a Joint Communication on an International Digital Strategy for the European Union, setting out a joint vision for the EU's external action for digital.[6] This Strategy aims to enhance tech competitiveness through cooperation, re-

[4] See in particular the Draghi Report on EU Competitiveness <https://commission.europa.eu/topics/competitiveness/draghi-report_en> accessed ? One of the responses of the EU was the adoption in 2025 of the EU's 'Competitiveness Compass', Communication on a Competitiveness Compass for the EU, COM(2025) 30 final.

[5] European External Action Service, *Digital Diplomacy for an Inclusive and Sustainable Digital Future* <www.eeas.europa.eu/eeas/digital-diplomacy_en> accessed 14 December 2025.

[6] An International Digital Strategy for the European Union (n 3).

search, and digital trade agreements. It focuses on strengthening cybersecurity, tackling cybercrime, and securing ICT supply chains. The strategy promotes a values-based approach to global digital governance, emphasising human rights and responsible technological advancement.

Reference is made to the 2023 Council Conclusions on Digital Diplomacy.[7] The conclusions mark an evolution towards a holistic, value-driven, and proactive digital foreign policy. While grounded in human rights and democratic values, the strategy balances these with concrete actions on security, technological leadership, and effective international engagement – positioning the EU as both a global standard-setter and a pragmatic international player. The Council conclusions phrase this as follows:

> The Council […] underlines the need for a stronger, more strategic, coherent and effective EU policy and action in global digital affairs to confirm EU engagement and leadership. This is essential to strengthen the EU's strategic autonomy, while preserving an open economy. It requires the EU and its Member States to further develop cooperation with partners around the world, bringing together and leveraging all diplomatic and policy tools, and ensuring complementarity and coherence between internal and external policies.[8]

It is interesting to see that the aims of digital diplomacy combine a need for EU global engagement and leadership, a strengthening of the EU's strategic autonomy,[9] and at the same time an emphasis on multilateralism. The latter element is also strengthened by the EEAS:

> [t]he EU approach to the digital transition is firmly anchored in its commitment to multilateralism and the promotion of universal human rights and fundamental freedoms, the rule of law and democratic principles. The EU, with the full involvement of the Member States, is developing tailored approaches to strengthen cooperation in and with the UN system, the G7, the G20, the OSCE, the OECD, the WTO, NATO, the Council of Europe and other multilateral fora, including multi-stakeholder organisations, and particularly in standardisation bodies, in which coherent and harmonised European standards play an influential role.[10]

Key aspects of digital diplomacy include: *Global Digital Governance* (the EU actively participates in international forums (eg, UN, G7, G20, WTO) to advocate for a rules-based digital order); *Regulatory Influence*

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[7] Council conclusions on EU Digital Diplomacy – Council conclusions approved by the Council at its meeting on 26 June 2023.

[8] Council conclusions on EU Digital Diplomacy (n 7).

[9] See, for instance, for a legal appraisal of strategic autonomy, Eva Kassoti and Ramses A Wessel (eds), 'Strategic Autonomy: The Legal Contours of a Security Policy Construct' (2023) 28 European Foreign Affairs Review, special issue.

[10] EEAS (n 5).

(the EU's digital regulations, such as the GDPR and the AI Act, serve as global benchmarks); *Cybersecurity & Resilience* (strengthening global cybersecurity cooperation, combating cybercrime, and promoting digital rights); *Technology & Trade Agreements* (engaging in digital trade policies and partnerships with key allies like the US, Japan, and India);[11] *Countering Digital Authoritarianism* (promoting an open, secure, and free internet while countering disinformation and digital repression);[12] and *Capacity Building* (supporting digital development in emerging economies through initiatives like Global Gateway).[13]

All of this is to be done on the basis of what Anu Bradford has famously described as a 'Rights-Driven Regulatory Model', which focuses on safeguarding individual rights, data privacy, and claims a human-centric, and a fair digital marketplace through strong regulatory frameworks (like the GDPR and the Digital Markets Act).[14] Guided by its own values (compare Article 21 TEU), the EU thus attempts to set global standards for tech regulation, emphasising democratic values and protection against both corporations and the State. Bradford contrasted this model with both the American and the Chinese models. The American 'Market-Driven Model' prioritises economic growth, innovation, and free speech. Regulation is minimal, allowing tech companies significant freedom and influence. The Chinese 'State-Driven Model' positions the State at the centre of digital governance, using technology for political and social control. The government heavily monitors and guides the tech sector, prioritising State interests and surveillance, often at the expense of individual freedoms and data privacy.

It has to be kept in mind, however, that while the EU's 'Rights-Driven Regulatory Model' is often celebrated for its emphasis on human rights, data privacy, and democratic oversight, this model also has evident flaws. First, the EU's regulatory approach risks overburdening innovation with compliance costs, potentially stifling the very technological leadership it seeks to foster. Second, the model's effectiveness depends on the willingness of third countries to adopt EU standards – a process that is far from

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[11] See also on the sensitive link between trade and technology Charlotte Beaucillon and Sara Poli (eds), 'Special Focus on EU Strategic Autonomy and Technological Sovereignty' (2023) 8(2) European Papers.

[12] As part of its digital diplomacy efforts, the EU itself has also become much more active with regard to the use of social media. As argued by Zaiotti, 'The EU has recognized that digital platforms are an essential tool in contemporary world affairs for the purpose of communicating and engaging with the outside world, particularly foreign audiences'. See Ruben Zaiotti, 'The European Union and Digital Diplomacy: Projecting Global Europe in the Social Media Era' in Corneliu Bjola and Ilan Manor (eds), *The Oxford Handbook of Digital Diplomacy* (OUP 2024) 457.

[13] See '2025 International Digital Strategy for the European Union' (n 3).

[14] Anu Bradford, *Digital Empires: The Global Battle to Regulate Technology* (OUP 2023).

automatic and often contingent on economic or political leverage. Finally, the EU's normative framework may struggle to address the asymmetrical power dynamics of the digital economy, where a handful of non-European tech giants dominate the market. The EU's ability to 'export' its values is thus not just a question of legal design, but of geopolitical clout.

All these elements together allow us to loosely define EU digital diplomacy as: *The strategic use of digital technologies – including the internet and social media – to strengthen the EU's global role, protect its strategic interests, advance its regulatory values (such as human rights, rule of law, and democracy), and shape international digital policy and governance, both by conducting diplomatic activities online and by addressing digital issues (like cybersecurity, internet governance, and AI) as key topics in foreign policy.*[15]

Cybersecurity as a diplomatic priority

One key element of digital diplomacy concerns cybersecurity. The EU lacks an explicit treaty basis for cybersecurity, necessitating a piecemeal legal approach.[16] At the same time, the EU has recognised cybersecurity as a strategic priority since the 2013 Cybersecurity Strategy.[17] Subsequent documents, including the 2016 Global Strategy and the 2020 EU Security Union Strategy, emphasise resilience, cooperation, and the integration of cyber elements into the Common Security and Defence Policy (CSDP). Other recent instruments also reveal the ongoing attention the EU pays to this topic: the *2016 NIS Directive*, updated in 2020 as NIS2 (concerning measures for a high common level of security of network and information systems across the Union);[18] the *2019/2025 Cybersecurity Act* (strengthening the role of the European Union Agency for Cybersecurity – ENISA, and providing for a European Cybersecurity Certification Framework – ECCF); the *2024 Cyber Resilience Act* (establishing common standards for products with digital elements, including hardware and software); and the *2024 Cyber Solidarity Act* (improving the prepared-

[15] In their *Oxford Handbook of Digital Diplomacy* (n 12) 3, Bjola and Manor define digital diplomacy in a general, non-EU related, context as: 'the use of digital technologies, such as social media and other online platforms, including virtual communication channels and the metaverse, by ministries of foreign affairs (MFAs) and international organizations (IOs) to communicate with each other and the general public, conduct diplomacy, and advance their foreign policy goals'. Here, much more than in the case of the EU, the emphasis is on communication.

[16] cf Helena Carrapico and André Barrinha, 'The EU as a Coherent (Cyber)Security Actor?' (2018) 56 Journal of Common Market Studies 1259; as well as Ramses A Wessel, 'European Law and Cyberspace' in Nicholas Tsagourias and Russell Buchan (eds), *Research Handbook on International Law and Cyberspace* (Edward Elgar Publishing 2021) 490.

[17] European Commission Joint Communication, 'Cybersecurity Strategy of the European Union: An Open, Safe and Secure Cyberspace' JOIN(2013) 01 final.

[18] See in general on the NIS and its implementation: Theodoros Karathanasis, *Cybersecurity and EU Law: Adopting the Network and Information Security Directive* (Routledge 2024).

ness, detection, and response to cybersecurity incidents across the EU).[19] Furthermore, the EU Cyber Diplomacy Toolbox, adopted in 2017, aims for the 'further development and implementation of a common and comprehensive EU approach for cyber diplomacy at global level'.[20] This toolbox enables joint diplomatic responses to cyber threats, including the use of targeted sanctions. This latter aspect led, *inter alia*, to the adoption of a Council Decision on restrictive measures against cyber-attacks threatening the Union or its Member States.[21] In 2025, further steps were taken to clarify what a cyber crisis is, what triggers a cyber crisis mechanism at Union level, and how relevant actors should interact and make the best use of available mechanisms in terms of crisis management.[22]

Other publications deal with these instruments in much more detail.[23] For this editorial note, it is particularly important to highlight that, based on various instruments, the growing ambition of the EU as a global cyber actor necessitates a shift from an inward-looking approach to cyber incidents towards a more outward-looking perspective. This signifies a transition from the traditional focus on network defence and resilience-building within the EU to one that promotes and enforces norms beyond its borders. Consequently, it can be noted that, with regard to cybersecurity, the EU's internal rule-making has proven to be inseparable from its external rule-making. While the EU and its Member States[24] are

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[19] See respectively Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) [2019] OJ L151/15; Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) [2024] OJ L2024/2847; Regulation (EU) 2025/38 of the European Parliament and of the Council of 19 December 2024 laying down measures to strengthen solidarity and capacities in the Union to detect, prepare for and respond to cyber threats and incidents and amending Regulation (EU) 2021/694 (Cyber Solidarity Act) [2025] OJ L2025/38.

[20] Council Conclusions on Cyber Diplomacy (2015) 6122/1511.

[21] Council Decision 2019/797 of 17 May 2019, concerning restrictive measures against cyber-attacks threatening the Union or its Member States; and Council Regulation (EU) 2019/796 of 17 May 2019 concerning restrictive measures against cyber-attacks threatening the Union or its Member States.

[22] Commission, 'Proposal for a Council Recommendation for an EU Blueprint on cybersecurity crisis management' COM (2025) 66 final.

[23] See, more extensively, Yuliya Miadzvetskaya and Ramses A Wessel, 'The Externalisation of the EU's Cybersecurity Regime: The Cyber Diplomacy Toolbox' (2021) 7 European Papers 413; Wessel (n 16).

[24] In the UN framework in particular, it is above all some Member States that participate in discussions of the UN Group of Governmental Experts (UNGGE) on non-binding normative agreements for cyberspace, or in the Open-Ended Working Group (OEWG) open to all UN members. In addition, discussions continue to take place in the Council of Europe in the framework of the Budapest Convention on Cybercrime, <www.coe.int/en/web/cybercrime/the-budapest-convention> accessed 14 December 2025.

active at the global level to influence the creation of new norms and to set global standards by aiming at a certain harmonisation of the diverging rules,[25] the activities are more visible in regulating the EU's own market, with a keen eye on the protection of fundamental values.

While the EU's cybersecurity strategy thus reflects a commendable shift from reactive resilience to proactive norm-setting, the fragmented legal bases for cybersecurity – spanning internal market regulations, CSDP, and external relations – raise questions about institutional coherence and accountability. Moreover, the EU's emphasis on cyber solidarity and sanctions as tools of digital diplomacy may not be sufficient to deter State-sponsored cyber threats, particularly from actors like Russia or China. The EU's normative power in cybersecurity is further tested by its dependence on US-led intelligence sharing and the limited enforcement mechanisms for its cyber diplomacy toolbox. Without stronger operational capabilities and a unified strategic vision, the EU risks being perceived as a normative actor with limited practical influence.

Artificial intelligence and normative projection

A more novel aspect of digital diplomacy is related to the EU's global role in the regulation of AI.[26] Here also, the story starts with the adoption of internal instruments. The 2024 AI Act is the world's first horizontal AI regulation, adopting a risk-based framework.[27] It prohibits high-risk uses of AI and aims to secure the EU's digital sovereignty. At the same time, the Act is not just an internal instrument, but represents an effort to set global standards by leveraging the EU's internal market power. Indeed, the AI Act has strong extraterritorial ambitions, seeking to influence AI development globally.[28] This is emphasised again in the above-mentioned

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[25] As famously analysed by Anu Bradford, *The Brussels Effect: How the European Union Rules the World* (OUP 2019). See also on the divergence, Tatiana Nascimento Heim and Ramses A Wessel, 'The Various Dimensions of Cyberthreats: (In)consistencies in the Global Regulation of Cybersecurity' (2023) 40 Anales de Derecho 39.

[26] See, in general, Nathalie A Smuha, *The Cambridge Handbook of the Law, Ethics and Policy of Artificial Intelligence* (CUP 2025).

[27] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) [2024] OJ L2024/1689. Among the many publications on the AI Act, see for a general overview, for instance, Federico Casolari, 'A Constitutionally Oriented Reading of the EU Artificial Intelligence Act' in Luca Mezzetti (ed), *Science, Technology and Law: Mutual Impact and Current Challenges* (Bologna Press 2024) 215.

[28] See. for an extensive analysis, Riccardo Fidato and Luigi Lonardo, 'The Foreign Affairs Aspects of the Artificial Intelligence Policy of the European Union' (2025) 30 European Foreign Affairs Review 11.

2025 International Digital Strategy, as well as in the AI Continent Action Plan, adopted in the same year:[29] 'the EU will continue to engage bilaterally, regionally and multilaterally with trusted partners to attract investments in the EU, support the establishment of a global level playing field for trustworthy AI, and to promote the good governance of AI globally'.

Yet, as argued by Fidato and Lonardo, 'The EU has a problem: it is lagging behind in technological developments on Artificial Intelligence (AI). To solve it, the EU does what it does best: it regulates'. At the same time, 'AI touches virtually any policy, so Brussels' strategy can hardly work internally without a corresponding diplomacy to support it: the AI Act expressly aims at providing the EU with a strong *regulatory* basis to set a new *global* standard, with a view to achieve digital sovereignty'.[30]

The European Union has indeed progressively developed a regulatory stance on AI through various strategic initiatives. In April 2018, the European Commission published a comprehensive strategy on AI, focusing on boosting technological capacity, preparing for socio-economic disruptions, and defining an ethical framework based on EU values. This strategy already highlighted the importance of international cooperation based – as often – on the EU's idea that it 'can lead the way', in this case 'in developing and using AI for good and for all, building on its values and its strength'.[31] The 2020 White Paper on AI systematised previous efforts and introduced the EU's dual-track approach: aiming for 'excellence and trust'.[32] The AI Act, which entered into force on 1 August 2024, aims to deliver on the trust element and was adopted under the internal market provision Article 114 TFEU, emphasising the harmonisation of rules for AI technologies to ensure the proper functioning of the internal market.

Since the start of the current European Commission in December 2024, the EU has shifted its focus towards positioning itself as a global leader in AI capabilities and uses, as outlined in the above-mentioned Competitiveness Compass. This document emphasises AI industrial uptake, research and innovation, and boosting supercomputing capacity as key enablers of global AI leadership. In April 2025 the Commission launched the *AI Continent Action Plan*, a plan that set the path for Europe to become a global leader in AI.[33] This was followed in the autumn of 2025 by the *Apply AI* and the *AI in Science* strategies as the next steps in delivering this ambition and in positioning the EU to accelerate the use

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[29] Commission, 'AI Continent Action Plan' (Communication) COM(2025) 165 final.

[30] Fidato and Lonardo (n 28) 11–12.

[31] Commission, 'Artificial Intelligence for Europe' (Communication) COM(2018) 237 final.

[32] Commission, 'White Paper on Artificial Intelligence – A European Approach to Excellence and Trust' [2020] COM(2020) 65 final. See also Fidato and Lonardo (n 28) at 17.

[33] Commission, 'AI Continent Action Plan' (Communication) COM(2025) 165 final.

of AI in key sectors and science.[34] Indeed, these are not just internal instruments, but together with the AI Act are meant to allow the EU to become more of an assertive and influential global rule-maker in this area.

At the same time, the AI Act's success hinges on two critical, and uncertain, factors: compliance and competitiveness. First, the EU's ability to enforce its standards beyond its borders is untested, particularly in jurisdictions where local regulations conflict with EU norms. Second, the Act's stringent requirements may disincentivise innovation within the EU, further widening the technological gap with the US and China. The EU's normative leadership in AI governance is thus a double-edged sword: it may set global benchmarks for ethical AI, but it could also marginalise European players in the global AI race. The EU must therefore strike a delicate balance between regulatory rigour and technological pragmatism if it is to achieve its dual goals of ethical leadership and digital sovereignty.

Conclusion: challenges and limitations

Digital diplomacy has become a core component of the EU's external actions, reflecting its broader ambition to be a normative power in global digital governance. The governance and regulation of digital issues are developing strongly, partly due to their close relation to global cooperation in other areas, such as trade. Irrespective of the patchwork of soft- and hard-law instruments and cross-sectoral strategies, rather than a coherent, unified legal framework, digital diplomacy has emerged as a central component of the EU's external action. The governance and regulation of the digital sphere is evolving rapidly, driven in part by its close interconnection with other domains of global cooperation, such as trade.

Furthermore, the evolution of the EU's regulatory digital framework is increasingly characterised by what may be termed the 'externalisation' of its internal digital regime. The growing number of threats originating from actors in third countries and the risks connected to the misuse of AI have compelled the integration of digital elements into the Union's external policies, including its foreign and security policy.

While the EU has registered important successes – particularly in establishing global regulatory standards – it must address institutional and legal fragmentation if it is to fulfil its full potential. As digital threats continue to evolve and strategic competition intensifies, the Union may find it necessary to recalibrate some of its foundational principles to ensure greater agility and coherence in its external digital policies. Yet, as

[34] Commission, 'Apply AI Strategy' (Communication) COM(2025) 723 final; and Commission, 'A European Strategy for Artificial Intelligence in Science: Paving the way for the Resource for AI Science in Europe (RAISE) (Communication) COM(2025) 724 final.

Ursula Von der Leyen stated in her State of the Union speech in September 2025: 'Whether on environmental or digital regulation. We set our own standards. We set our own regulations. Europe will always decide for itself'.[35] That starting point seems important for the Union to continue playing the normative role that it has chosen for itself.

It is clear that digital diplomacy has now become an integral part of the EU's external relations machinery. The Union aspires to play a leading role in shaping technology governance, including through global standard-setting. Cybersecurity and artificial intelligence serve as notable examples of its activity in this domain. While the EU's traditional reliance on regulation is not the only factor causing its inability to lead in technological innovation and to act swiftly and effectively,[36] the developments seen in 2025 do reveal a certain change of policy and perception. The coming years will show whether the EU is capable of achieving its digital ambitions, and its future success seems to depend on addressing three key challenges. First, the EU must bridge the gap between regulatory power and technological leadership. Without a robust industrial base in digital technologies, the EU's normative influence risks being perceived as hollow. Second, the EU needs to reconcile its multilateral aspirations with geopolitical realities. In a world where digital governance is increasingly shaped by US-China rivalry, the EU's commitment to multilateralism may be tested by the need for strategic alliances and pragmatic compromises. Finally, the EU must demonstrate agility in adapting its digital policies to rapidly evolving threats, from AI-driven disinformation to cyber warfare. The EU's normative model is not inherently flawed, but its effectiveness will ultimately depend on the Union's ability to translate its values into action – and to do so with the speed and flexibility that the digital age demands.

Suggested citation: RA Wessel, 'Editorial Note: Digital Diplomacy: The EU as a Global Digital Actor' (2025) 21 CYELP VII.

[35] 2025 State of the Union Address by President von der Leyen, 9 September 2025.

[36] Bradford argued that the relation between digital regulation and technological progress is considerably more complex than what is usually seen in public debates. The entire legal and technological ecosystem in Europe is simply different from the one in, for instance, the US. See Anu Bradford, 'The False Choice Between Digital Regulation and Innovation' (2024), 118(2) Northwestern University Law Review.

DEREGULATING NEW GENOMIC TECHNIQUES: THE CHALLENGE OF AMBIGUOUS OBJECTS

Luca Knuth [*] and Ellen Vos [**]

Abstract: Plants derived through new genomic techniques (NGTs) occupy an inherently ambiguous space between genetically modified organisms and conventionally bred plants. Although created through targeted genome editing, many NGT plants are empirically indistinguishable from varieties arising naturally or through traditional breeding. This ambiguity generates corresponding regulatory and epistemic tensions: NGTs do not neatly fit the conceptual architecture that underpins the EU's process-based GMO legislation. The European Commission's 2023 Proposal for a Regulation on NGTs seeks to resolve this tension by introducing two new categories and significantly easing regulatory requirements for NGT plants deemed substantially equivalent to conventional ones. This shift from a precautionary, process-based model toward a product-based approach reflects an attempt to close conceptual uncertainties through legislative boundary-redrawing. Yet, such closure risks conflicting with the precautionary principle, which – while not mandating full authorisation procedures – requires procedural safeguards that keep decisions reversible as new knowledge emerges. Precaution is less a barrier to innovation than an institutional mechanism for learning under conditions of scientific indeterminacy. Scientific expertise itself reflects and reinforces these boundary dynamics. Beyond categorical continuity and blanket exclusion, this article points to a third option: institutionalising productive ambiguity.

Keywords: genetically modified organisms, new genomic techniques, risk regulation, EU internal market law, regulatory science, European Food Safety Authority

1 Introduction

One hundred and seventy stones lined up in rectangular metal boxes arranged into a grid-like structure: Paul Pfarr's installation *Reglement*[1]

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[1] Paul Pfarr, *Reglement* (1991). A picture can be retrieved from the artist's website: <https://paul-pfarr.de/portfolio-item/reglement/> accessed 21 November 2025.

visualises the result of a slow yet steady process of re-appropriation by nature. Once formed according to industrial norms and standards, the brick/stone surfaces were continuously worn down by the sea's constant friction. These polished, wave-washed remains of industrial production can be read as metaphorical representations of what Hans-Jörg Rheinberger phrased 'outrageous mixtures',[2] being both the product of culture *and* nature, suspended between their increasingly lost, once norm-given cuboid shapes and the sea's steady powers as the forces of the natural.[3]

Outrageous mixtures, such as those described by Rheinberger, find contemporary resonance in the products of new genomic techniques (NGTs), particularly new genomically edited plants. Like Pfarr's bricks/stones, new genomic techniques show a hybridity between biotechnological intervention and the natural. These methods – ranging from targeted mutagenesis to CRISPR-Cas systems to other forms of site-directed nucleases – allow for precise alterations of an organism's genome without necessarily introducing exogenous genetic material. Their products, in the absence of suitable detection methods, may disguise their biotechnological genealogy and, therewith, elude the former distinction between 'naturally bred' and 'genetically modified' plants. These biological artefacts can no longer be comfortably situated on either side of the nature – culture dualism. NGTs produce entities that are both artefact and organism, natural and engineered. They are ambiguous objects. That border blurred by NGTs, though, has always been fuzzy rather than impermeable: plant breeding's long history as a culturalisation technique reveals how humans have continuously intervened in what Enlightenment thought externalised as the non-human realm of nature.[4] Through ever more precise interventions in the genome, the processes of wear and tear, appropriation and re-appropriation, as visualised by Paul Pfarr's *Reglement*, reappear on the molecular scale in the shape of insertions and cuts.[5]

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[2] Hans-Jörg Rheinberger, *Iterationen* (Merve 2005) 37. The original German phrase 'unerhörte Mixturen' plays with ambiguity. Whereas a more literal translation could also be 'unheard mixtures', Rheinberger draws on Michel Serres's notion of 'scandalous objects' as developed with a view to the natural contract as a hybrid between legal and socio-biological domains. See Michel Serres, *Le contrat naturel* (Bourin 1990) 14.

[3] For a description of *Reglement*, see Walter Aue, *Orte. Gegenstände. Paul Pfarr* (HM Hauschild 1994) 41. Pointing out the Western, culturally produced and contingent, conceptualisation of the dualism, see Philippe Descola, *Beyond Nature and Culture* (Janet Lloyd tr, University of Chicago Press 2013).

[4] For a historical overview of plant breeding techniques, see Rolf HJ Schlegel, *History of Plant Breeding* (Routledge 2018).

[5] That promise is, for instance, spelled out by Jennifer A Doudna and Samuel H Sternberg, *A Crack in Creation. The New Power to Control Evolution* (HarperCollins Publishers 2017) xiii.

Outrageous mixtures challenge categorisation by escaping it. This challenge posed by 'ambiguous objects'[6] may also be a legal challenge and arguably one particularly present in EU internal market regulation. Internal market law is based on the creation of legal categories, establishing 'European objects' as legal constructs that determine which objects are marketable.[7] What these constructs attempt to frame, however, is fluid and changeable. Technological innovations convert existing products and lead to the development of entirely new ones, putting existing legal boundaries to the test.

Thus, EU internal market law must also continuously accommodate changing circumstances, adapt to evolving regulatory subjects, and address new regulatory subjects. This entails conceptual 'boundary work',[8] which often occupies heated political environments:[9] what escapes categories may trigger fears of diffusion. For instance, where cultivated meat blurs the limits of fresh meat and laboratory products, cultural references to 'Frankenburgers'[10] evoke the horror of techno-sciences turning from an emancipatory project into a threat.[11] GMO regulation in the EU has been particularly marked by such controversies.[12] The strict regulatory requirements under the EU's present GM-specific legislation are seen as hindering innovation and, thus, not doing justice to the particularity of

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[6] In the '*objet ambigu*', as coined by Hans Blumenberg, Rheinberger and Serres may find a conceptual predecessor. See Hans Blumenberg, 'Sokrates und das ›objet ambigu‹. Paul Valérys Auseinandersetzung mit der Tradition der Ontologie des ästhetischen Gegenstandes' in Franz Wiedmann (ed), *EPIMELEIA. Die Sorge der Philosophie um den Menschen. Hans Kuhn zum 65. Geburtstag* (Pustet 1964). By contrast, Paul Valéry, 'Eupalinos ou l'Architecte' in *Œuvres*, vol II, Jean Hytier (ed) (Librairie Gallimard 1960) 115 speaks of 'l'objet du monde le plus ambigu', a phrase that may be read as either 'the most ambiguous object' or 'the object of the most ambiguous world'. See Karin Krauthausen, 'Hans Blumenbergs möglicher Valéry' (2012) Zeitschrift für Kunstphilosophie 39–63 at fn 11.

[7] cf Brice Laurent, *European Objects: The Troubled Dreams of Harmonization* (The MIT Press 2022), who sees harmonisation as a legal practice of category-building, which operates through a 'dual disentanglement of European objects from their local ties, on the one hand, and of policy negotiations and the technicalities of market organization, on the other', ibid 44.

[8] The notion is borrowed from Thomas F Gieryn, 'The Demarcation of Science from Non-Science: Strains and Interests in Ideologies of Scientists' (1983) 48 American Sociological Association 781.

[9] cf Viviana Wiegleb and Antje Bruns, 'Working the Boundary: Science–policy Interactions and Uneven Knowledge Politics in IPBES' (2023) 18 Sustainability Science 1069, 1072: 'Boundary work presents a highly political, contextual, and contested process (…)'.

[10] See Ludivine Petetin, 'Frankenburgers, Risks and Approval' (2014) 5 European Journal of Risk Regulation 168.

[11] Guido Bellenghi and Luca Knuth, 'EU Food Law and the Politics of the Internal Market: The Challenge of Cultivated Meat' (2024) 17 Review of European Administrative Law 39.

[12] Maria Lee, *EU Regulation of GMOs: Law, Decision-Making and New Technology* (Edward Elgar 2008).

their regulatory subjects.[13] In 2023 and within this context, the European Commission tabled a legislative proposal on plants obtained by new genomic techniques, situating them within a new regulatory framework.[14] Aiming to shift GMO regulation from a process- to a product-centred approach, the proposal envisages two new regulatory categories: one modifying existing rules and one excluding those NGT plants and their derived products from pre-market authorisation requirements. More than two years later, the proposal is still in the legislative process.

This article asks how EU internal market law accommodates the ambiguous figurations of its regulatory objects.[15] Contrasting the current GMO legislation with those conceptual boundaries envisaged by the Commission proposal (Section 2), it analyses the implications of the present legislative debates for future GMO regulation. Thus, Section 2 reflects on the proposal's compatibility with and implications for the EU's constitutional tenets of precautionary internal market law (Section 3). Turning from a legal-doctrinal to a more theoretical perspective, the role of regulatory science bodies will be considered by drawing on an incident of conflicting views between the GMO Panel of the European Food Safety Authority (EFSA) and the French food authority on the definition of NGTs as a case in point for the intricate role and practices of regulatory science under circumstances of uncertain risk (Section 4). Whilst the Commission evokes scientific necessities for its deregulatory proposal, critiques lament a breach of the precautionary principle. Although law arguably tends to strive for clarity and certainty in its categorical assignments, it

[13] For instance, European Academies' Science Advisory Council, 'The Regulation of Genome-edited Plants in the European Union', March 2020, 6 <https://easac.eu/fileadmin/PDF_s/reports_statements/Genome_Editing/EASAC_Genome-Edited_Plants_Web.pdf> accessed 16 December 2025; Sigrid Bratlie and others, 'A Novel Governance Framework for GMO: A Tiered, More Flexible Regulation for GMOs Would Help to Stimulate Innovation and Public Debate' (2019) 20 EMBO Reports, article no 47812.

[14] Commission, 'Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625' COM (2023) 411 final (hereinafter: NGT Proposal).

[15] The present analysis will be based on the initial Commission proposal (ibid). Since the publication of the proposal, the European Parliament has adopted proposed amendments (European Parliament, 'Legislative resolution of 24 April 2024 on the proposal for a regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625' [2023] 2023/0226(COD)) and the Council has adopted its negotiating position (Council of the European Union, 'Mandate for negotiations with the European Parliament' (7 March 2025) 6426/25). Only on 4 December 2025, just as this article was being prepared for publication, the European Parliament and the Council reached a provisional agreement. See Council of the European Union, 'New Genomic Techniques: Council and Parliament Strike Deal to Boost the Competitiveness and Sustainability of Our Food Systems' (4 December 2025) <www.consilium.europa.eu/en/press/press-releases/2025/12/04/new-genomic-techniques-council-and-parliament-strike-deal-to-boost-the-competitiveness-and-sustainability-of-our-food-systems/> accessed 16 December 2025.

will be argued in the concluding Section 5 that there could also be value in temporarily maintaining NGTs plants' precarious state of ambiguity rather than dissolving it.

2 From process- to product-based GMO legislation

2.1 The current GMO legislative framework

GMO legislation is crucially based on two conceptual borders. First, it depends on differentiation between what it protects and what it protects against, its regulatory objective and its regulatory object. The central pieces defining these conceptual boundaries for the EU are Directive 2001/18 on the deliberate release into the environment of genetically modified organisms (the GMO Directive)[16] and Regulation 1829/2003 on genetically modified food and feed (the GM Food Regulation).[17] The GMO Directive originates from 1990 and was aimed at regulating the then upcoming use of biotechnology. For this line between GMO legislation's objective and object, at present, the technique of intervention into genetic material is crucial. As shown by the Directive's distinctions between varying techniques, those deemed to result in genetic modification and those deemed not to,[18] such delineation has always been somewhat more complex than the apparent clarity of the nature-culture dualism. Modification is more than intervention of any kind – and necessarily so, given thousands of years of plant cultivation practices that have shaped crops and organisms.[19] Accordingly, the conceptual line between nature to be protected and techniques to be regulated has always been one distinguishing traditional breeding practices and agricultural cultivation, on the one hand, from biotechnological interventions that enable the intentional editing of plants' genetic material, on the other.[20]

The second crucial boundary of GMO legislation results from further differentiation alongside what can be qualified as safe and therefore marketable. Risk is the crucial conceptual gauge to demarcate between those GMOs that may be spread on the fields and processed into prod-

[16] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2001] OJ L106/1.

[17] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2003] OJ L268/1.

[18] Art 2(2) GMO Directive read in conjunction with Annex I A thereto.

[19] cf, for instance, as to the interwovenness of the nature-culture-dualism and ultimately pointing to nature itself as a 'hybrid being'. See Rheinberger (n 2) 46ff.

[20] Recital 17 of the GMO Directive, stating that 'techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record' will not fall within its scope.

ucts or foods and those that remain banned from release into the environment or placement on the market. Following procedural risk analysis schemes, the current GMO legislation is based on prior approval procedures where approval is largely dependent on the positive outcome of an (environmental) risk assessment.[21] Years of controversy and gridlock have compromised the authority of these authorisation procedures.[22] In particular, some Member States have repeatedly blocked the European Commission's authorisation decisions, bringing comitology to a deadlock.[23] This ultimately led to the insertion of a differentiation mechanism unique within internal market law: pursuant to Article 26b of the GMO Directive, Member States may still prohibit the cultivation of genetically modified plants on their territory on the basis of factors other than health or the environment, which may be of a socio-economic nature.[24]

2.2 The Commission's proposal

Not known as such at the time of the adoption of the GMO Directive, NGTs call both of its conceptual borders into question. NGTs refer to targeted mutagenesis techniques which are targeted mutations in the genome without the insertion of foreign genetic material (eg natural, radiation, chemical, as well as CRISPR/CRISPR-Cas9 techniques), and to cisgenesis techniques, whereby genetic material is inserted into a recipient organism from a donor that is sexually compatible with the recipient organism. The adequacy and applicability of the traditional demarcations were first questioned before the European Court of Justice in *Confédération paysanne I*.[25] In its ruling of 2018, the Court confirmed the GMO

[21] The lynchpin of GMO legislation: Ludivine Petetin, 'Precaution and Equivalence: The Critical Interplay in EU Biotech Foods' (2017) 42 European Law Review 831, 832. Noting 'technocracy and uncritical Commission compliance with EFSA scientific assessments' in GMO approval procedures turning EFSA into 'the de facto risk manager'. See Marjolein BA van Asselt, Ellen Vos and Bram Rooijackers, 'Science, Knowledge and Uncertainty in EU Risk Regulation' in Michelle Everson and Ellen Vos (eds) *Uncertain Risks Regulated* (Routledge Cavendish 2009) 359, 378.

[22] As to the role of public aversion toward GMOs in the genesis of EU GMO legislation and early (mis-) use of safeguard clauses by Member States to undermine approvals, see Gregory C Shaffer and Mark A Pollack, 'The EU Regulatory System for GMOs' in Michelle Everson and Ellen Vos (eds), *Uncertain Risks Regulated* (Routledge Cavendish 2009) 269, 275–278.

[23] Maria Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance: GMO Regulation and Its Reform' (2015) 21 European Law Journal 622, 627.

[24] As to the genesis of Art 26b of the GMO Directive, see Maria Lee, 'GMOs in the Internal Market: New Legislation on National Flexibility' (2016) 79 The Modern Law Review 317, 319ff.

[25] Case C-528/16 *Confédération paysanne I* ECLI:EU:C:2018:583. For an in-depth analysis, see Hanna Schebesta, 'Confédération paysanne case (C-528/16): Legal Perspective on the GMO Judgment of the European Court of Justice' (2020) Revue européenne de droit de la consommation 369, 372. The ruling was largely confirmed in Case C-688/21 *Confédération paysanne II* ECLI:EU:C:2023:75, paras 43–46.

Directive's applicability to targeted mutagenesis by upholding the distinction between traditional and non-traditional causation of gene mutations.[26] This meant that, in principle,[27] organisms developed through the application of NGTs fall within the scope of the GMO Directive and within the definition of GMOs.[28]

Faced with the *Confédération paysanne I* ruling, the Commission carried out a study at the request of the Council, and concluded that the EU's GMO legislation presented clear challenges for implementation and that there were strong indications that it was not fit for purpose for some NGTs and their products, and that it needed to be adapted to scientific and technological progress.[29] Therefore, in its 2023 proposal, the Commission envisions a legislative turnaround from the present, largely process-oriented approach to a (more) result- or product-oriented one. Rather than defining the scope of GM-specific regulation by recourse to the techniques of the genetic modification applied, the result of such modifications should be the decisive factor.[30]

Operating as a *lex specialis* to the existing GMO Directive and the GM Food and Feed Regulation,[31] the Commission's proposal excludes NGT-edited plants as well as products and foods containing them from the scope of the existing frameworks – albeit to a varying extent. It defines NGT plants as any

> genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of the NGT plant.[32]

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[26] *Confédération paysanne I* (n 25) para 54.

[27] That applies at least to those NGT organisms developed after the GMO Directive was adopted. See *Confédération paysanne I* (n 25) para 51.

[28] Kai P Purnhagen and others, 'EU Court Casts New Plant Breeding Techniques into Regulatory Limbo' (2018) Nature Biotechnology 799. As to an exception, see *Confédération paysanne II* (n 25) para 64.

[29] Commission, 'Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16' SWD(2021) 92 final, 59.

[30] As to the process- versus product-based approach, see Thorben Sprink and others, 'Regulatory Hurdles for Genome Editing: Process- vs Product-based Approaches in Different Regulatory Contexts' (2016) 35 Plant Cell Reports 1494.

[31] Arts 5 and 12 of the NGT Proposal. Recital 11 of the NGT Proposal is inconsistent in as much as it indiscriminately refers to all NGT plants and products, whereas Art 5 of the NGT Proposal is plain in its broad wording.

[32] Art 3(2) of the proposal. Targeted mutagenesis and cisgenesis are defined in Art 3(4) and (5) respectively.

With this proposal, the Commission is re-drawing the boundary between what GMO legislation protects and what it regulates. This re-drawing takes shape through the creation of regulatory categories capturing what it intends to exclude: Category 1 NGT plants (NGT 1) and Category 2 NGT plants (NGT 2) (see Figure 1). NGT 1 plants are plants that fulfil the criteria of equivalence to conventional plants, set out in Annex I of the proposal, or constitute progenies of these NGT plants. This categorical boundary is drawn by a quantitative threshold of no more than 20 genetic modifications of certain types compared to its recipient or parental plant.[33] NGT 2 plants, in turn, are NGT plants other than an NGT 1 plant.[34]

Figure 1. The Commission's proposal for a regulation on NGTs.

	Present GMO Frameworks	NGT Category 2	NGT Category 1
Plants	Standard **authorisation procedure** (art. 6 GMO Directive) or **differentiated authorization** procedure (art. 7 GMO Directive) (all organisms)	**Authorisation** pursuant to art. 6 GMO Directive as modified by art. 13 NGT Proposal (plants only)	**Verification** (art. 6 NGT Proposal read in conjunction with Annex 1 thereto) (plants only)
Products (other than food and feed)	Either **authorisation** pursuant to product specific legislation or **Notification and consent** pursuant to Part C of the GMO Directive	**Authorisation** pursuant to art. 13 GMO Directive as modified by art. 14 NGT Proposal	**Verification** (art. 7 NGT Proposal read in conjunction with Annex 1 thereto)
Food	**Authorisation** pursuant to arts. 5 and 17 GM Food and Feed Regulation	**Authorisation** pursuant to arts. 5 and 17 GM Food and Feed Regulation as modified by art. 19-21 NGT Proposal	**Verification** (art. 7 NGT Proposal read in conjunction with Annex 1 thereto) However, sectoral legislation (NFR) might apply, cf recital 22 of the NGT Proposal

NGT 2 plants will remain, in principle, subject to the current regimes of the GMO Directive and the GM Food and Feed Regulation, albeit with modifications. Requirements for authorisation or consent prior to deliberate release or marketing for plants[35] and products[36] falling in Category

[33] Including progeny derived by the crossing of such plants, under the condition that there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003. See Art 3(7) of the proposal.

[34] Art 3(8) of the proposal.

[35] Art 13 of the NGT Proposal provides for derogations from Art 6 of Directive 2001/18/EC.

[36] Art 14 of the NGT Proposal provides for derogations from Art 13 of Directive 2001/18/EC.

2, as well as pursuant to the GM Food and Feed Regulation,[37] will remain in place.[38] However, evidentiary requirements concerning the safety of plants and products under Category 2 will be considerably softened and rendered more flexible than existing rules.[39] Whilst Category 2 remains subject to traceability and labelling obligations, the proposal envisages other crucial derogations. In particular, the opt-out mechanism provided for by Article 26b of the GMO Directive would be rendered inapplicable for NGTs, thus eliminating Member States' ability to restrict the cultivation of GMOs within their territory based on compelling grounds, which include socio-economic, environmental, and public policy reasons, despite prior approval having been issued.[40]

In contrast, the proposal aims to almost equate NGT 1 plants and products, including food and feed, with conventionally bred and naturally occurring plants that do not fall under the GMO legislative regime. In particular, NGT 1 plants and products will no longer be subject to pre-market authorisations.[41] Instead, the proposal stipulates a procedure for verification of their status as Category 1, resulting in a declarative decision.[42] Such a verification procedure is designed as an exclusively technical examination of whether the criteria of Annex 1 are met without any individual, substantive risk assessment.[43] The distinction between Categories 1 and 2 rests essentially[44] on the basis of a quantitative threshold defined as a maximum of 20 substituted or inserted nucleotides.[45] Presumably, this distinction would assign a significant proportion of plants falling within the scope of the NGT Regulation to NGT 1 plants.[46]

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[37] Art 19 of the NGT Proposal provides for derogations from Arts 5 and 17 of the GM Food and Feed Regulation.

[38] Art 12 of the NGT Proposal.

[39] cf n 36 and n 37.

[40] Art 25 of the NGT Proposal.

[41] Art 5 of the NGT Proposal.

[42] Art 6 of the NGT Proposal.

[43] Recital 20 of the NGT Proposal.

[44] The distinction also depends on other factors listed in Annex I to the NGT Proposal.

[45] Point 1 of Annex I to the NGT Proposal.

[46] Finja Bohle and others, 'Where Does the EU-path on New Genomic Techniques Lead Us?' (2024) Front Genome Ed 6:1377117, especially at 2, identify that of a list of 148 NGT plant applications, of those 85 assigned to fall under the scope envisioned by the NGT proposal, 94% would either clearly fall, or could be assumed to fall, under the scope of NGT Category 1. cf also J Menz and others, 'Genome Edited Crops Touch the Market: A View in the Global Development and Regulatory Environment (2020) Frontiers in Plant Science 11:586027, doi: 10.3389/fpls.2020.586027.

2.3 Re-drawing boundaries

By equating NGT 1 plants with conventional plants, the Commission's proposal envisages a re-drawing of the boundary between its subject of protection and its regulatory object, nature and biotechnological intervention, by means of the scope of the legislation. In addition, it also re-draws the line between what is qualified as marketable and what remains banned. It would replace the common mechanism of precautionary European risk regulation by delegating individual risk choices to executive decision-making, whilst tying executive discretion created thereby to procedural, primarily epistemic, limitations, essentially to legislative *a priori* authorisation. Therewith, the proposed NGT Regulation would essentially turn the risk analysis-scheme followed by both the GMO Directive and the GM Food and Feed Regulation on its head.

The Commission invokes a bundle of interconnected arguments in support of its proposal, including environmental, economic, and consumer benefits. Easing regulatory requirements would increase biotechnical innovation,[47] help step-up agricultural production, increase consumer choice by offering a wider range of products,[48] and reduce dependence on agri-food imports.[49] Crop resistance, in addition, is expected to foster pest-reduction[50] and improve climate adaptability.[51] Notably, linking the proposal to broader political strategies for a more sustainable, climate-friendly and climate-adaptable agriculture and food system,[52] the Commission also broadens the balancing exercise underlying internal market law. The traditional striking of a balance between free trade on the one hand and health and environmental protection on the other[53] now extends to addressing environmental concerns on both sides, situating it within the broader risk contexts of biodiversity loss and climate change. The actual sustainability benefits of NGT plants, however, remain clouded in uncertainty for now. Moreover, the sustainability incentives foreseen by the proposal remain limited in their reach,[54] while the proposal's de-regulatory effects apply to all NGTs falling within its envisaged scope regardless of their sustainability benefits.

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[47] See Recital 10 of the NGT Proposal.

[48] NGT Proposal 2, and Recital 38 thereof.

[49] ibid 2, placing the proposal in the context of current geo-political developments.

[50] ibid 4.

[51] ibid 11.

[52] cf Recital 3 of the NGT Proposal.

[53] cf Marjolein BA van Asselt, Michelle Everson, and Ellen Vos, 'Trade Versus Health and the Environment', in Marjolein BA van Asselt, Michelle Everson, and Ellen Vos (eds), *Trade, Health and the Environment: The European Union Put to the Test* (Routledge 2014) 3–8.

[54] Naturally, the incentives foreseen by Art 22 of the proposal apply solely to NGT 2 plants and products.

Re-drawing categorial boundaries in a complex system such as the EU internal market GMO regulation inevitably generates numerous follow-up border demarcations, which themselves have political repercussions. Beyond the sustainability aspects, many of the diverse points of contention arise as subsequent problems stemming from the proposal's category formation. Three contentious points have raised particular attention in ongoing legislative debates.

First, excluding the application of the GMO Directive's differentiation mechanism for opt-outs in accordance with its Article 26b, and putting the re-definition of the criteria for NGTs 1 in the Commission's hands, leads to considerable centralisation.[55] Any future adjustment to the criteria defining Category 1 would be subject to the democratically deficient mechanism of the implementing acts.[56]

Second, a further point of contention concerns the delimitation of conventional and organic farming (so-called 'coexistence'). The ban[57] on the use of genetically modified organisms in organic foods, as foreseen by the proposal, may collide with the absence of traceability provisions for NGT 1 organisms. *De lege lata*, remaining unchanged according to the proposal,[58] any use of genetically modified plants, including NGT plants, in organic farming is prohibited. However, the envisaged labelling of NGT 1 seeds[59] will hardly ensure coexistence in practice. Even where farmers manage to keep plant NGT 1 seeds out of their fields, the problem might sneak in through the backdoor of the food production supply chain. By the time plants are processed into foodstuffs, processors in the subsequent production chain would hardly be able to trace the plants of Category 1 contained therein.[60] The consequence could be a hidden change in what is known as organic food – below the perceptive thresholds of EU

[55] Art 27(a) of the NGT Proposal.

[56] As to the limited role of the European Parliament within the procedure of adopting implementing acts, see Guido Bellenghi and Ellen Vos, 'Rethinking the Constitutional Architecture of EU Executive Rulemaking: Treaty Change and Enhance Democracy' (2024) European Journal of Risk Regulation 1, 13–14.

[57] Especially Art 5(f)(iii), 11 Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 [2018] OJ L150/1.

[58] Art 5(2) of the NGT Proposal read in conjunction with Art 5(f)(iii) and 11 of Regulation (EU) 2018/848.

[59] Art 10 of the NGT Proposal.

[60] This argument was, *inter alia*, made in a legal expert opinion commissioned by the German parliamentary group of BÜNDNIS 90/DIE GRÜNEN: Georg Buchholz, Kommissionsvorschlag einer Verordnung über Neue Genomische Techniken (NGT): Zur Verletzung des Vorsorgeprinzips, Gutachten im Auftrag der Bundestagsfraktion Bündnis 90/Die Grünen (Berlin 2023) 38–39 <www.gruene-bundestag.de/fileadmin/dateien/downloads/Weitere_Dokumente/Gruene_im_Bundestag_Gutachten__Vereinbarkeit_des_Kommissionsvorschlags_zu_NGT_mit_dem_Vorsorgeprinzip.pdf> accessed 21 November 2025.

law. A similar downstream 'border adjustment' concerns the Novel Food Regulation.[61] While, in principle, NGT 1 food could fall within the scope of the Novel Food Regulation,[62] it is unclear whether food business operators, whom the Regulation tasks to verify whether their product falls within its scope, even know whether they are processing NGT 1 plants given the absence of traceability-requirements.[63]

Third, the patentability of NGT plants has been a major point of contention in legislative debates. A potential ban on patenting in a future NGT Regulation, arising in the discussion,[64] could run into conflict with the European Patent Convention. Formally, the European Patent Convention is not subject to European Union law and its Convention States would be obliged to respect and enforce patents, whilst such patents would be banned under EU law.

De-regulating NGTs does not dissolve the conceptual boundaries enshrined in the present GMO regulation. Conceptual boundaries reappear in new shapes and forms. The *de facto* deregulation of NGT 1 plants gives rise to subsequent legal demarcation problems, sparking political controversy, where reaching a compromise is particularly difficult and time-consuming. While the proposal secured a favourable vote in the European Parliament in 2024,[65] it took until April 2025 for the Council to finally reach a negotiating agreement,[66] therewith triggering the trilogue process.

3 Beyond precaution?

NGT plants and products thus seem to escape categorisation – being both products of biotechnological innovation and substantially equivalent to traditionally bred or naturally occurring plants. However, this ambiguous figuration is called into question from a legal perspective. Re-drawing the boundary between what is to be regulated as a GMO or GM product and what is to be treated as 'traditional' plant or product risks conflicting

[61] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 [2015] OJ L327/1 (hereinafter: NFR).

[62] Recital 22 of the NGT Proposal, referring to Art 3 (2)(vii) NFR.

[63] Buchholz (n 60) 32.

[64] Sofia S Manzanaro, 'Why Patents Keep Stalling EU Rules for Gene-edited Crops' (*Euractiv*, 13 March 2025 <www.euractiv.com/news/why-patents-keep-stalling-eu-rules-for-gene-edited-crops/> accessed 16 December 2025.

[65] European Parliament (n 15).

[66] Council of the European Union (n 15).

with the EU's commitment to the precautionary principle as enshrined in international and EU primary law.

3.1 Cartagena Protocol

Excluding NGT Category 1 plants from pre-market authorisation requirements means that these plants could enter European fields, food, and products without ever undergoing a scientific risk assessment.[67] As argued by critics, the absence of any environmental risk assessment prior to release into the environment could constitute a breach of the Cartagena Protocol (CP) on Biosafety to the Convention on Biological Diversity.[68] Following an essentially precautionary approach, according to Annex III(6) of this Protocol, the Convention parties must carry out a risk assessment on a case-by-case basis. Neither a merely technical verification procedure alone nor abstract scientific inquiries prior to the (prospective) adoption of legislative carte blanche de-regulation can meet the Protocol's clear wording.

Yet, a combination of both pre-legislative scientific studies and future verification of their status could be argued to meet the Protocol's requirements.[69] Such an argument presupposes that in pre-legislative studies an abstract scientific finding of equivalence between NGT 1 plants and naturally occurring or traditionally bred plants was made and that the verification procedure applies this finding *in concreto* to individual plants, therewith satisfying the requirement of Annex III(6) of the Cartagena Protocol.[70] As noted by Silja Vöneky and others, such an approach 'carries with it the assertion that the potential adverse effects or risks associated with NGT 1 plants are the same for all intended use cases and for all potential receiving environments, and that any further differentiation is not scientifically necessary'.[71] Whether such an approach meets the requirement of a scientifically sound risk assessment is primarily a

[67] A potential risk assessment of NGT 1 pursuant to the Novel Food Regulation would, in any case, not satisfy the requirements of the Cartagena Protocol. See Silja Vöneky and others, 'Compatibility of the EU Proposal for a Regulation on Plants Based on Certain New Genomic Techniques with the Cartagena Protocol on Biosafety' (April 2025) 30 <www.bmleh.de/SharedDocs/Downloads/DE/_Landwirtschaft/Gruene-Gentechnik/NGT-Gutachten-EU-Vorschlag.pdf?__blob=publicationFile&v=4> accessed 16 December 2025.

[68] Buchholz (n 60) 29–30. For an in-depth analysis of the proposal's compatibility with the Cartagena Protocol, see Vöneky and others (n 67) 30ff, concluding on non-compliance with the Cartagena Protocol, *inter alia*, due to the removal of a notification requirement, ibid 42.

[69] Jens Kahrmann and Georg Leggewie, 'European Commission's Plans for a Special Regulation of Plants Created by New Genomic Techniques' (2024) 9 European Papers 21, 34; Vöneky and others (n 67) 36–37.

[70] ibid.

[71] Vöneky and others (n 67) 36.

matter of science.[72] Legally, as Kahrmann and Leggewie argue, such a line of argument benefits from the Annex's flexible[73] wording.[74]

Regardless of this substantial question, however, it is questionable whether this duty to perform a risk assessment is even applicable. The Protocol applies to 'the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health'.[75] Whilst NGTs undoubtedly qualify as GMOs as defined by EU law,[76] their qualification as living modified organisms within the meaning of the Cartagena Protocol is questioned.[77] Whilst NGTs are clearly both 'biotechnological techniques' and 'modern' in as much as they have not been used in traditional breeding and selection, their capacity to overcome natural physiological reproductive or recombination barriers may be either understood as referring to the result of an individual application of a technique or as referring to the general capacity of a certain technique to achieve such a result.[78] Whereas certain applications of NGTs may not overcome natural physiological reproductive or recombination barriers, NGTs' general potentiality to do so is beyond doubt.[79] The process- versus product-oriented distinction thus reappears as an interpretative question. Excluding NGTs, in part or in total, from the scope of the Protocol would hence require overcoming its originally process-oriented *ratio*.[80]

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[72] ibid.

[73] ibid. According to Annex III(6), the required information may vary and, according to Annex III(8), the elements of a risk assessment apply only 'as appropriate'. This flexibility thus rests on terminological indeterminateness, which itself requires concretisation in a given case. Rather than utilising the leeway granted through the Cartagena Protocol, a combination of abstract pre-legislative risk assessment and subsequent technical verification is a waiver of its use in individual cases.

[74] Kahrmann and Leggewie (n 69) 34.

[75] Art 4 CP.

[76] See *Confédération paysanne I* (n 25) and Section 2.1 above.

[77] Kahrmann and Leggewie (n 69) 34–35.

[78] A living organism is defined in Art 3(g) of the CP as any living organism 'that possesses a novel combination of genetic material obtained through the use of modern biotechnology'. Modern biotechnology in that sense is defined in Art 3(i) CP as 'the application of', *inter alia*, 'in vitro nucleic acid techniques (…) that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection'. See, in more detail, Vöneky and others (n 67) 30.

[79] See, with further references, F Koller and others, 'The Need for Assessment of Risks Arising from Interactions between NGT Organisms from an EU perspective' (2023) 35(27) Environmental Sciences Europe 1, 4.

[80] Rightly sceptical: Vöneky and others (n 67) 17.

3.2 The precautionary principle

Yet, regardless of the Cartagena Protocol's applicability, the precautionary principle as a general principle of EU law and an element of its primary law binds the EU legislature.[81] The principle's key function is commonly seen in broadening decision-making discretion where scientific knowledge as to the existence or extent of a risk remains uncertain, thus serving as a 'shield' to be invoked by the regulator.[82] This way, the precautionary principle provides optionality to interrupt – theoretically infinite – knowledge production in favour of tutioristic decision-making capabilities. Thereby, the principle does not simply abolish the evidence-based mechanism underlying EU risk regulation. It is not simply the 'law of fear' as critics have suggested.[83] Rather, it demands sufficient proof for the persistence of uncertainty[84] and links broadened regulatory discretion to procedural duties, mandating:

> [...] first, identification of the potentially negative consequences for health (or the environment) of the proposed use of the substance at issue, and, secondly, a comprehensive risk assessment of the risk to health (or the environment) based on the most reliable scientific data available and the most recent results of international research.[85]

This nexus between discretion and scientific assessments is what gives the precautionary principle its double-headed figuration. On the one hand, it broadens regulatory discretion to adopt decisions in the absence of conclusive scientific evidence and, on the other, restricts this discretion through procedural duties. This proceduralised imperative to gather knowledge is, however, context dependent. Where uncertainties prevail, the principle may allow for cutting assessments short. The reg-

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[81] See Art 191(2) TFEU and, in particular, Case T392/02 *Solvay Pharmaceuticals v Council* EU:T:2003:277, para 121; Joined Cases T74/00, T76/00, T83/00 bis T85/00, T132/00, T137/00 and T141/00 *Artegodan and others v Commission* ECLI:EU:T:2002:283, paras 183–184.

[82] For the shield-and-sword-metaphor, see Joanne Scott and Ellen Vos, 'The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO' in Christian Joerges and Renaud Dehousse (eds), *Good Governance in Europe's Integrated Market* (OUP 2002) 254.

[83] Seminally, see Cass R Sunstein, *Laws of Fear* (CUP 2005). As to the criticism of the precautionary principle with further references, see Kristel de Smedt and Ellen Vos, 'The Application of the Precautionary Principle in the EU' in Harald A Mieg (ed), *The Responsibility of Science* (Springer 2022) 164.

[84] On defining uncertainty, see Anne-May Janssen and Marjolein BA van Asselt, 'The Precautionary Principle in Court: An Analysis of Post-Pfizer Case Law' in Marjolein van Asselt, Esther Versluis, and Ellen Vos (eds), *Balancing between Trade and Risk: Integrating Legal and Social Science Perspectives* (Routledge 2013) 208ff.

[85] See, for instance, Case C-77/09 *Gowan Comércio Internacional e Serviços* ECLI:EU:C:2010:803, para 73.

ulatory authority is not obliged to wait for anticipated information whatever it takes; an illustrative example can be found in the neonicotinoid case law.[86] Here, the Court emphasised the regulatory discretion of the Commission to set a deadline for EFSA, precluding consideration of the information applicants were expected to submit only later.[87] However, the duty to improve the information base might then extend beyond the precautionary measure's adoption through monitoring and with a view to the potential revision of such a measure.[88]

The precautionary principle may hence also serve as a 'sword' where a measure or lack thereof is deemed not to be restrictive enough. In the EU's limited judicial fora, contestations of measures not being restrictive enough are rare.[89] Arguably, where the objectives of effective protection of health and environment are assigned primacy through the precautionary principle,[90] a scientific information base underlying a decision not to act in light of uncertainties is equally essential. A rare example of a challenge to a legislative act's validity based on an alleged breach of the precautionary principle is the *Blaise* ruling.[91] The preliminary reference ruling delivered in 2017 found the Plant Protection Products Regulation[92] to be compatible with the principle. The Court recognised the legislature's broad discretion, where it has to 'strike a balance between several objectives and principles, and of the complexity of the application of the relevant criteria' by limiting its review to that of manifest errors.[93] Nevertheless, it derived some basic requirements for the legislative design: the obligation to generate information and knowledge may oblige legislators

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[86] See Joined Cases T-429/13 and T-451/13 *Bayer CropScience AG and Others v European Commission* ECLI:EU:T:2018:280; and Case C-499/18 P *Bayer CropScience and Bayer v Commission* ECLI:EU:C:2021:367, especially para 121. cf Giulia C Leonelli, 'Balancing Public Health and Environmental Protection and Economic Stakes? Bayer CropScience and the Court's Defence of the EU Socially Acceptable Risk Approach' (2021) 58 Common Market Law Review 1845, especially 1873. For an earlier example, see Case T-70/99 *Alpharma v Council* ECLI:EU:T:2002:210, para 173.

[87] Joined Cases T-429/13 and T-451/13 *Bayer CropScience AG and Others* (n 86) paras 314 and 500; Case C-499/18 P *Bayer CropScience and Others* (n 86) paras 135–136.

[88] See Commission, 'Communication from the Commission on the precautionary principle' (Communication) COM(2000) 1, 19.

[89] Sabrina Röttger-Wirtz, 'Case C-616/17 *Blaise and Others*: The Precautionary Principle and Its Role in Judicial Review: Glyphosate and the Regulatory Framework for Pesticides' (2020) 27 Maastricht Journal of European and Comparative Law 529, 534.

[90] See *Alpharma v Council* (n 86) para 356.

[91] Case C-616/17 *Blaise* ECLI:EU:C:2019:800.

[92] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] L309/1 (hereinafter Plant Protection Products Regulation).

[93] *Blaise* (n 91) para 50.

to make procedural arrangements that enable the 'identification of possible negative consequences' and a 'comprehensive assessment of the risks to health based on the most reliable scientific data available and the most recent results of international research'.[94]

Transferring such requirements from one legislative area to another comes with uncertainties. In the *Confédération paysanne I* ruling, the Court seemingly presumed the principal risk potential of NGT organisms and a persistent state of uncertainty which justified subjecting them to the GMO Directive's strict pre-market authorisation requirements.[95] The Court even stated that a blanket exclusion of mutagenesis-derived organisms from the scope of the GMO Directive 'would compromise the objective of protection pursued by the directive and would fail to respect the precautionary principle which it seeks to implement'.[96] The *Confédération paysanne I* ruling concerned an interpretative question of the GMO Directive and thus a legislative act expressly adopting a precautionary approach.[97] Scrutinising a potential NGT Regulation, though, would concern its validity in the absence of such a legislative commitment.

Invoking the precautionary principle as a sword against NGT de-regulation would need to draw on its procedural dimension. The proceduralisation of risk choices under the precautionary principle reveals how, from a legal perspective, every risk regulatory decision is always taken from an *ex ante* perspective of limited knowledge about future events. Risk assessment is not a matter of stating the known or expected, but an exercise in generating and evaluating knowledge that is functionally oriented towards testing the *status quo* of that knowledge and putting risk managers in as competent a position as possible.[98] Scientific knowledge is therefore not always an existing resource, but may be generated *ad hoc*.[99] The contexts of application influences the methodologies used. Risk assessment is thus the search for the unknown rather than a reiteration of what is already known.[100] Where legislative frameworks capture

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[94] *Blaise* (n 91) para 46.

[95] *Confédération paysanne I* (n 25) para 48, pointing to the referring court and 'the material before the Court' without specifying it.

[96] *Confédération paysanne I* (n 25) para 53.

[97] cf Art 1 of the GMO Directive.

[98] For instance, Case T-13/99 *Pfizer Animal Health SA v Council* ECLI:EU:T:2002:209, para 158.

[99] Karl-Heinz Ladeur, *Postmoderne Rechtstheorie: Selbstreferenz Selbstorganisation – Prozeduralisierung* (2nd edn, Duncker & Humblot 1995) 209–210. As to a moulding of application and method, see Ino Augsberg, *Informationsverwaltungsrecht* (Mohr Siebeck 2014) 10.

[100] *A fortiori*, risk assessors' tasks are not limited to gathering information of – mostly industrial – notifiers (on the role of economic actors in EU risk regulation, see Marta Morvillo

whole technological categories, contingency is inherent in the very categories forged in these legislative acts. NGTs serve as a prime example of how technological innovations craft entities that challenge existing categorisations. Such regulation always attempts to capture what remains inherently fluid.[101] Pre-structuring individualised risk choices through legislative acts is hence a balancing exercise drawing on abstractly identified uncertainties associated with a given regulatory category. Providing for individualised risk assessments is neither a mechanism to bar what is safe nor to reiterate what is known. By demanding knowledge-generation and assigning decision-making responsibilities, the principle commonly operates as a decision-enabler, not a determinant. Where individualised decisions are at stake, it may thus not necessitate intervention but instead broaden discretion. Where legislative frameworks capture whole technologies, it may need to safeguard its own future application by demanding anticipatory mechanisms that allow contingent information bases to be revisited in light of changed circumstances. Excluding NGT 1 from GMO specific requirements arguably threatens to cement a once-made regulatory choice rather than anticipate future invocations of the precautionary principle.

The precautionary principle does not in every case mandate the establishment of pre-market authorisation requirements stipulating full risk assessments.[102] There are other mechanisms to ensure that future, not yet foreseeable, risk may be mitigated. Even where no pre-market authorisation requirements exist, post-market monitoring may serve as a means to allow intervention, where yet unforeseen risks materialise. Where an approval decision is *de facto* irreversible once it has been made,[103] especially in the absence of suitable detection methods, there is nevertheless much to suggest that only anticipatory regulatory intervention can enable knowledge to be generated that allows decision-making by democratically accountable institutions on the basis of the best pos-

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and Maria Weimer, 'Who Shapes the CJEU Regulatory Jurisprudence? On the Epistemic Power of Economic Actors and Ways to Counter it' (2022) 1 European Law Open 510, 514ff) but includes own knowledge gathering and a re-evaluation of studies submitted. cf, with a view to the Plant Protection Products Regulation, Case C-616/17 *Blaise and Others* ECLI:EU:C:2019:190, Opinion of AG Sharpston, para 67.

[101] '[V]ery Rapid Development of NGTs in the Recent Years: EFSA, Updated Scientific Opinion on Plants Developed through Cisgenesis and Intragenesis' (2020) 20 EFSA Journal, article no 76211, 15.

[102] Similarly, Gerd Winter, 'The European Union's Deregulation of Plants Obtained from New Genomic Techniques: A Critique and an Alternative Option' (2024) 36 Environmental Sciences Europe, article no 47, 1, 10.

[103] The irreversibility of the release into the environment of GMOs is recognised, for instance, in recital 4 of the GMO Directive. See also *Confédération paysanne I* (n 25) para 49. cf for the CP: Ruth Mackenzie and others 'An Explanatory Guide to the Cartagena Protocol on Biosafety' (IUCN 2003) IUCN Policy and Law Paper No 46, para 52.

sible evidence.[104] As illustrated for instance by NGT 2 plants or products, the scope of risk assessments can be rendered largely flexible, allowing assessment duties to be tailored to individual plants and uncertainty profiles. To safeguard its future applicability under not yet foreseeable circumstances, the principle requires legislative anticipation through process design. This implies anticipating processes of knowledge generation and legal bases for future precautionary interventions where such a novel state of knowledge hesitates to do so. In this sense, the precautionary principle may not determine political action toward tutiorism but acts as a tool to ensure that the choice, be it one to act or one not to act in light of uncertainties not yet foreseeable, is vested in politically accountable and legally capable decision-makers.

4 Defining NGT 1 plants: a question of boundary work

4.1 Diverging opinions

The precautionary principle is not the only alleged determinant invoked in debates concerning the assignment of NGT plants and products. Whilst the precautionary principle remains remarkably absent in the proposal's text, it contains a seemingly contrasting argument, which presents its de-regulatory shift toward a product-based approach less as a choice but as a matter of necessity. The argument is one of substantial equivalence: subjecting NGT 1 plants to legislative requirements, so the Commission argues, would be disproportionate given their substantially equivalent molecular figuration to the extent of non-detectability.[105] In other words, (substantially) equivalent regulatory subjects should be treated as (substantially) equivalent in regulation.[106] NGTs' de-regulation is presented as a legal necessity triggered through scientific factualities. Being a hybrid between a scientific finding of equivalence and proportionality as a constitutional principle, such an argument presents legislative decisions as mere transpositions from scientific findings rather than a political choice.[107] In the case of NGTs, such transposition lies in the proposal's boundary work determining the crucial distinction between its two categories: the proposal attempts to define science-based criteria

[104] As to reversibility as one factor of determining the acceptability of risk levels, see, for example, Joined Cases T-429/13 and T-451/13 *Bayer CropScience* (n 86) para 124.

[105] See recital 14 of the NGT Proposal.

[106] As to substantial equivalence as both assessment methodology and regulatory strategy, see Petetin (n 21) 834; cf also Les Levidow, Joseph Murphy and Susan Carr, 'Recasting Substantial Equivalence: Transatlantic Governance of GM Food' (2007) 32 Science, Technology and Human Values 26.

[107] Such alignment of legal categories to the non-legal, scientific representations of the regulatory subject can thus be read as an ontologisation, understood as the attempt to align legal categories to alleged external realities.

delineating NGT 1 from NGT 2, thereby establishing what, being substantially equivalent to naturally occurring or traditionally bred plants, is exempted from GM-specific regulatory requirements.

The proposal was welcomed by various scientific associations, with the German Research Foundation, for example, seeing it as 'reflect[ing] the state of the art in science and the environmental and, geopolitical realities'.[108] Yet, even where broad consensus persists, science is hardly a monophonic choir. This holds in particular where risk scenarios are not easily calculable or predictable. Due to the complexity of genomes, their potential release into the environment, and the open-textured technological configuration, GMOs are a prime example of such uncertain risk scenarios.[109] Confronted with naturally limited scientific certitude as to the possibilities and severities of potential hazards, regulators paradoxically tend to resort to science to justify their decisions on these uncertain risks, a mechanism which has been coined as the 'uncertainty paradox'.[110] The Commission's rhetoric in support of the criteria to distinguish between the two categories of NGT plants can be read as an example of the uncertainty paradox at work. Despite the simplicity of the Commission's argumentation and its reliance on scientific studies,[111] the crucial quantitative delineation between the proposal's two categories, ie NGT 1 and NGT 2, in its Annex 1 has encountered some reservations.[112] The French Agency for Food, Environmental and Occupational Health & Safety (ANS-

[108] See, for instance: The German Research Foundation, 'Keeping Europe Up to Date: A Fit-for-Purpose Regulatory Environment for New Genomic Techniques' (19 July 2023) <www.dfg.de/resource/blob/289576/statement-genomic-techniques.pdf> accessed 21 November 2025.

[109] See, with further references, Marjolein BA van Asselt and Ellen Vos, 'EU Risk Regulation: The Role of Science in Political and Judicial Decision-making' in Hans-Wolfgang Micklitz and Takis Tridimas (eds), *Risk and EU Law* (Edward Elgar 2015) 117, 123; van Asselt, Vos and Rooijackers (n 21) 365–366.

[110] Marjolein BA van Asselt and Ellen Vos, 'The Precautionary Principle and the Uncertainty Paradox' (2006) 9 Journal of Risk Research 313.

[111] These are mentioned, first, in the Commission's impact assessment report. See Commission, 'Commission Staff Working Document, Impact Assessment Report' SWD(2023) 412. The questions concerning the equivalence criteria are then taken up in a Council technical paper: Council, Regulation on new genomic techniques (NGT) – Technical Paper on the rationale for the equivalence criteria in Annex I' (2023) 2023/0226(COD). As rightly pointed out by Vöneky and others (n 67) fn 224, the Commission's proposal mentions neither these documents nor the relevant studies themselves, but quotes EFSA studies, which do not engage with the relevant questions.

[112] More direct criticism is, for instance, expressed by Juliane Mundorf, Samson Simon, Margret Engelhard, 'The European Commission's Regulatory Proposal on New Genomic Techniques in Plants: A Focus on Equivalence, Complexity, and Artificial Intelligence' (2025) 37 Environmental Sciences Europe, article no 143, 1, 7: '(…) not scientifically sound'.

ES) has, most prominently,[113] called into question its suitability.[114] Called upon by the European Parliament, EFSA was asked to address ANSES's concerns.[115] Both ANSES and EFSA have come to seemingly diverging conclusions as to the potential risks and uncertainties associated with NGTs. Divergencies between EFSA's GMO Panel and ANSES concerning, in particular, these criteria from scientific perspectives, may serve as a micro case study to illustrate how not only legislative but also regulatory science practices ultimately resort to boundary work under circumstances of uncertain risks. Despite the Commission's emphasis, this scientific question underpinning the proposal is apparently ambiguous, as varying interpretative positions persist, none of which appears illegitimate at first sight.[116]

At the outset, it is noted that the Commission did not rely on EFSA[117] for the definition of an NGT 1 plant, but relied on a scientific literature analysis carried out by its own services.[118] In its opinion,[119] EFSA considers the Commission's position to be based on scientific evidence, stating that such changes could also occur in plants with 20 nucleotide modifications, and concluding that 'it is scientifically justified to consider that a

[113] The Dutch advisory Committee on Genetic Modification COGEM did not agree either with the definition in Annex 1 and noted that the criteria in Annex 1 lacked scientific foundation and needed clarification and adjustment, and proposed a new definition. See COGEM, Opinion to revise the criteria in Annex I of the EC proposal for new legislation for NGT plants (2023) CGM/231124-01 <https://cogem.net/app/uploads/2023/11/231124-01-Advice-to-amend-Annex-1-EC-NGT-proposal_ENG.pdf> accessed 21 November 2025.

[114] ANSES, Opinion on the scientific analysis of Annex I of the European Commission's Proposal for a Regulation of 5 July 2023 on new genomic techniques (NGTs) – Review of the proposed equivalence criteria for defining category 1 NGT plants (Internal request No 2023-AUTO-0189) (Maisons-Alfort 2003) <www.anses.fr/en/system/files/BIOT2023AUTO0189EN.pdf> accessed 20 November 2025.

[115] EFSA's response was commissioned as a scientific opinion pursuant to Article 29 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1, (hereinafter: GFL) by the European Parliament following publication of ANSES's analysis <https://open.efsa.europa.eu/questions/EFSA-Q-2024-00178?search=genomic&sort=lastUpdatedTime> accessed 21 November 2025.

[116] IRGC, 'Introduction to the IRGC Risk Governance Framework' (IRGC 2020) 18, defining: 'Ambiguity results from divergent perspectives on the risk, including the likelihood and severity of potential adverse outcomes'; cf also Ortwin Renn, Andreas Klinke, and Marjolein BA van Asselt, 'Coping with Complexity, Uncertainty and Ambiguity in Risk Governance: A Synthesis' (2011) 40 Ambio 231, 240.

[117] See Arts 22(2), 22(5c) and 23 GFL.

[118] European Commission Services, Technical Paper Document 14204/23, Rationale for the equivalence criteria in Annex I to the proposal for a Regulation on plants obtained by certain new genomic techniques, (16 October 2023). See Council, Interinstitutional File 2023/0226(COD).

[119] EFSA GMO Panel, 'Scientific Opinion on the ANSES Analysis of Annex I of the EC Proposal COM (2023) 411 (EFSA-Q-2024-00178)' (2027) EFSA Journal 22(7), e8894.

plant showing 20 modifications or less compared to its parental could be the result of spontaneous mutations'.[120] This disagreement between ANSES and EFSA shows that different regulatory science actors may respond differently to uncertain risk scenarios. Although, in a nutshell, EFSA's GMO Panel holds the equivalence criteria in the proposal's Annex I to be plausible, its opinion is an exercise in multi-dimensional boundary work, ie the drawing of conceptual boundaries, on at least three different levels.

A first differentiation takes implicit shape in substantial equivalence as a comparative assessment method. Equivalence does not denote equality, but a *substantial* form of equality that already incorporates, at a fundamental level, a difference between the entities compared. It thus does not claim sameness, but rather a negligible dissimilarity. In this sense, equivalence lies in the indeterminacy of the causal pathways leading to a mutation as linguistically reflected in the subjunctive mode used by the EFSA GMO Panel.[121] The notion of equivalence therefore concerns the determination of a hypothetical alternative causality. Equivalent, here, is what can be referred, with somewhat equal plausibility, to the hypothetical possibility of different causal origins. Thus, as a comparative assessment methodology, substantial equivalence does not strive for exactness. Rather, it constitutes an *ad hoc* heuristic for coping with the complexity inherent in non-static objects of inquiry and offers pragmatically oriented balancing between the desire for scientific objectivity and certitude.[122] As a comparative assessment approach, substantial equivalence depends on choices defining what spatial interactions, and what temporal range, should be considered in the comparative assessment.[123]

Applying substantial equivalence as a scientific method is not value-free but represents an operationalisation of values through judgement that is always based on contingent knowledge preceding the risk assessment.[124] Objectivity and certitude, therefore, should not be conceived as

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[120] ibid 5.

[121] ibid.

[122] FAO/WHO, 'Safety Aspects of Genetically Modified Foods of Plant Origin: Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology (World Health Organization 2000) 4; Henry I Miller, 'Substantial Equivalence: Its Uses and Abuses' (1999) 17 Nature Biotechnology 1042: 'a shorthand'.

[123] As to different scientific cultures visible in ecologists' and microbiologists' definition of these scales, see Stefan Böschen and others, 'Scientific Cultures of Non-Knowledge in the Controversy over Genetically Modified Organisms' (2006) 15 GAIA 294, 296.

[124] See, in general, Nick J Fox, 'Postmodern Reflections on "Risks" and "Life Choices"' in Deborah Lupton (ed), *Risk and Sociocultural Theory* (CUP 1999) 12: 'Inevitably, risk assessment must begin with some prior knowledge about the world, what is "probable" and what "unlikely", what is "serious", what is "trivial" or seemingly "absurd". Such judgements may derive from "scientific" sources, or may depend on "common-sense" or experiential resources; either way, the perception of a hazard's existence will depend on these judgements. How

externally given, static properties of scientific knowledge but as results of their operationalisation as values within scientific practice.[125] Hence, choosing alternative heuristics or applying substantial equivalence differently would both remain possible.[126] Relying on substantial equivalence is a regulatory choice that should arguably be taken in full knowledge of those choices made in its application.

Second, at its core, the conclusion drawn from hypothetical alternate causality towards equivalent risk propensity is not a purely descriptive, representational account of an external reality, but a claim about *causal possibilities*. Even if conservative, an estimate remains a valuational, approximative statement. Turning from representational to estimative statements, a temporal discontinuity is introduced, shifting from past to future. Its peculiarity lies in the fact that it is not mere conjecture, but firmative speculation,[127] seeking anchoring in data on past events – a temporal transposition that connects the past observance of mutations and their effects with the projected effects of technological intervention.[128] This rupture, from a historically representative to a prognostically approximative dimension of meaning, has dual implications. Both the object of inquiry, ie the 'epistemic thing',[129] and the mode of representation are displaced; the epistemic focus moves from what *is* or *has been* toward what *could be*. Such anticipation is no longer a merely observational practice. It transcends the sphere of statistical description of past events by means of temporal transposition toward a present description of hypothetical futures utilising theoretical assumptions.[130]

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the judgement is made (that is, what is counted as evidence to support the assessment), is relative and culturally contingent'.

[125] For conceptualising objectivity as a historically contingent value, see L Daston and P Galison, *Objectivity* (Zone Books 2010).

[126] eg Koller and others (n 79) 9–10.

[127] For different types of speculative practices, see Susanne Labenicht, 'Cultures of Speculation: Histories of Speculation' in Jeanne Cortiel and others (eds), *Practices of Speculation: Modeling, Embodiment, Figuration* (transcript 2020) 31–48 *passim*; for the difference between firmative and affirmative speculation, see Uncertain Commons, *Speculate this!* (Duke University Press 2013) 27.

[128] Where uncertain risks are concerned, the firmative nature of these speculative practices may reach limits in lacking data availability. Then, scientific risk assessment may increasingly have to operate in affirmative modes by considering not only what is probable but also what is potential. See van Asselt, Vos, and Rooijackers (n 21) 362.

[129] Hans-Jörg Rheinberger, *Toward a History of Epistemic Things: Synthesizing Proteins in the Test Tube* (Stanford University Press 1997) 28ff.

[130] Thus, such a risk statement rather mirrors what Elena Esposito denoted as a 'present future', a contingent prognosis that is to be distinguished from actual 'future presents'. Elena Esposito, *Die Fiktion der wahrscheinlichen Realität* (tr Nicole Reinhardt, Suhrkamp 2007) 50ff.

The third differentiation in EFSA's opinion is institutional in nature. By raising the question of whether a statement or a regulatory criterion still stands on the secure footings of science, it must demarcate its own territory vis-à-vis the regulator's. Whilst it considers the search for hypothetical, alternative causation of NGT-induced modifications to be scientifically substantiated, the definition of the quantitative threshold is flagged by EFSA as the risk manager's responsibility.[131] Resorting to the threshold of 20 modifications as foreseen in Annex I, according to EFSA's Panel, would be a 'conservative' number supported by scientific studies.[132] Yet, although the Commission's rhetoric relies[133] on a link between equivalence and risk-levels in its proposal, and ANSES's position[134] here, EFSA's Panel avoids engaging with this point, ie whether the substantial equivalence understood as a gene-edit remaining below this threshold would serve as a credible indicator of risk potentiality.[135] Instead, by holding that '(…) the proposed limit of 20 modifications for an NGT plant to be considered a Category 1 NGT is a risk management decision (…)', it seeks shelter in deferring this conclusion from substantial equivalence to risk propensity to the risk manager.[136]

4.2 Diverging opinions assessed

Scientifically, neither position needs to be invalid. Conversely, either approach can be read as expressing forms of epistemic humility. ANSES makes the limits in the current state of knowledge transparent by saying what cannot yet be said with certitude. EFSA's opinion restricts what is said to what can be said with sufficient certitude. These approaches have different implications for how the relation between scientific assessment and political choice plays out. ANSES's approach puts regulatory science

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131 EFSA GMO Panel (n 119) 5.

132 ibid.

133 Recital 13 of the Proposal clearly sets out the risk-based *ratio* underlying the differentiated regulatory approach, which is based on the presumption that NGT 1 plants show a lower degree of risk-propensity than those in Category 2. Moreover, Rec 14 of the Proposal states that NGT 1 'should be treated as plants that have occurred naturally or have been produced by conventional breeding techniques, given that they are equivalent and that their risks are comparable (…)'.

134 ANSES (n 114) 25–26, noting a 'failure to take account of the relationship between the proposed equivalence criteria and the associated risks', *inter alia,* by rejecting the assumption that the quantitatively determined substantial equivalence would translate into equivalent traits and risk levels for having 'no scientific base' and concluding a 'lack of scientific basis in terms of risk' with a view to the maximum number of modifications set out in Annex I to the Proposal.

135 EFSA GMO Panel (n 119) 5: 'These equivalence criteria are not meant to define levels of risk but to allow certain NGT plants to be classified as equivalent to conventionally bred plants (recital 14, European Commission Proposal)'.

136 ibid.

actors in a position closer to the 'fifth branch',[137] a means of governance through epistemic *ex ante* control that allows for scrutiny by explicating the information base underlying the exercise of public authority – including its limitations. Revealing presumptions and premises underpinning substantial equivalence opens an opportunity for public scrutiny of these choices. Conversely, EFSA's opinion evades any explicit engagement with the remaining uncertainties or the estimative nature of such a conclusion. Rather than explicating the limits in scientific knowledge, EFSA's panel engages in a third dimension of 'boundary work',[138] ie the practice-immanent, rhetorical self-constitution of scientists *vis-à-vis* what was intellectually excluded as non-science.[139] Here, such boundary work operates to shift responsibility for the contentious questions concerning the credibility of the conclusion from substantial equivalence to risk propensity from risk assessors to risk managers. As it has done in the past, EFSA's Panel thereby limits the scope of its own opinion by evading discussions of remaining uncertainties and rendering its opinion an assurance of plausibility.[140] Its silence on uncertainties and its only implicit recognition of ambiguity in the questions at stake foster risk managers' ontologising rhetorics and threaten to turn regulatory science bodies into 'active propagators of the uncertainty paradox'.[141]

This points to a more general finding concerning the very boundary worked on by EFSA's Panel. What is a political question and what science can provide answers to, where the realms of science and politics meet and differentiate one another, is ultimately not a fixed line separating the realm of the factual from the valuational, the objectively true from the politically biased. Science's place within risk regulation is thus not a pre-given Archimedean spot, but the result of mutual differentiation practice: on the one hand, the law distances science procedurally and institutionally from political decision-making; on the other hand, scientific practice differentiates itself from the non-scientific. This very boundary work is itself necessarily subject to context-dependent interpretation through the various actors involved and is thus both ambiguous and contingent in its figuration.[142]

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[137] Sheila Jasanoff, *The Fifth Branch: Science Advisors as Policymakers* (Harvard University Press 1998).

[138] The notion of boundary-work was coined by Gieryn (n 8).

[139] ibid 782.

[140] Uncertainty aversion and boundary work have been shown to be present in past risk assessments performed by EFSA's GMO Panel. See van Asselt, Vos and Rooijackers (n 21) 369ff.

[141] ibid 375.

[142] Gieryn (n 8) 781: 'Thus, "science" is no single thing: its boundaries are drawn and redrawn inflexible, historically changing and sometimes ambiguous ways'. cf also Sheila

Invoking the rhetoric of an objectively mediated scientific reality, and aiming to align regulatory treatment with it, risks obscuring discretion and implicitly inverts the roles of risk assessors and managers.[143] Ultimately, this mechanism may *de facto* shift decision-making capacities from politically accountable to more 'obscure' bodies.[144] Moreover, it also risks misrepresenting the realities of science.[145] Regulatory science does not mechanically mirror reality but operationalises value judgements. Determining the scales underlying substantial equivalence entails judgements of relevance; and drawing prognostic inferences from empirical studies presupposes theoretical assumptions. Even science's boundary work to differentiate itself from politics is not a matter of redrawing a stable line but a context-dependent reiteration of a boundary between non-static categories. Recognising value-operationalisation in regulatory science is not an exercise in debunking. Rather, it allows us to see the perspectivity and ambiguity within scientific practices. Governing biotechnological risks is inextricably bound to the best possible scientific knowledge. Translating such knowledge into political choice and ultimately into legal forms, however, should be based on a vision of science that is aware of its inherent value judgements and limitations. In highlighting underlying premises and making inherent limitations visible to the broader public, regulatory science, understood as a 'fifth branch', finds its true *raison d'être*, rather than in the provision of epistemic authority through proofs of plausibility.

5 Concluding remarks: 'without ambiguity, no change, ever'[146]

Boundaries, ultimately, demand assignment. They are filters that include and exclude, that permit or prohibit entrance. But new regulatory subjects may escape categorisation as is the case with NGTs and hence put legal boundaries to the test. In an attempt to accommodate for biotechnological progress and foster innovation, the Commission's proposed NGT Regulation foresees far-reaching legislative boundary work that could fundamentally alter the Union's legislative landscape governing

Jasanoff, 'Contested Boundaries in Policy-relevant Science' (1987) 17(2) Social Studies of Science 195, 224, seeing boundaries' fluidity caused not only by science's indeterminateness, but also the 'politically charged' nature of the differentiations at stake.

[143] Soemni Kasanmoentalib, 'Science and Values in Risk Assessment: The Case of Deliberate Release of Genetically Engineered Organisms' (1996) 9 Journal of Agricultural and Environmental Ethics 42, 45–46.

[144] Vesco Paskalev, 'The Clash of Scientific Assessors: What the Conflict over Glyphosate Carcinogenicity Tells US about the Relationship between Law and Science' (2020) 11(3) European Journal of Risk Regulation 524.

[145] ibid.

[146] Paul Feyerabend, *Killing Time. Autobiography.* (Chicago University Press 1995) 179.

GMOs. Such work involves new boundaries being drawn and established ones being substituted. By creating two new legislative categories, a future NGT Regulation would lower and make more flexible the regulatory burden for its NGT Category 2 whilst providing for deregulation through exclusion from GMO specific regulatory requirements for those plants and products falling within the proposal's Category 1.

Shifting from process- to product-based regulation aims to escape the political, legal, and scientific ambiguities that NGT plants exhibit. Yet, it arguably risks conflicting with the precautionary principle. Although the principle does not imply an obligation that could compel legislators to subject a particular category of technology to preventive authorisation requirements, it nevertheless establishes certain, basic procedural requirements. Its application presupposes anticipation of what remains yet unknown by establishing procedures for generating knowledge and providing legal bases allowing for action in what for the moment are unforeseeable circumstances. Instead of anticipating the yet-unknown, the proposal's legislative blanket de-regulation of NGT 1 cements a current state of knowledge through its legislative form. Although the principle may thus demand a legislative design which allows for reversing once-made decisions when new information becomes apparent, it does not provide a determinant for pre-market authorisation schemes. How to regulate NGTs is ultimately a matter of legislative discretion within the confines of EU constitutional law.

Nor can science provide for the NGT disambiguation that risk managers may long for.[147] In a broader sense of the word, ambiguity refers to openness to varying interpretative positions. It thus denotes semantic indeterminacy. As such, ambiguity is not just the persistence of diverging scientific positions. It is the potentiality of interpretative divergency. This ambiguity, arguably, is not a result of science's failure to establish conclusive findings, but a necessary feature of scientific progress. With Rheinberger, ambiguity can be seen as underpinning the operations of experimental practices: 'At the core of science as a process, of science in the making, there is ambiguity. It is ambiguity that incites science to get away from the actual state of the art toward an open future'.[148] Experimental systems are creative exercises of recursive differentiation, providing material arrangements allowing the yet indeterminate epistemic thing to materialise as traces to be transposed into data and assembled

[147] Harald A Mieg, 'Science as a Profession: And Its Responsibility' in Harald A Mieg (ed), *The Responsibility of Science* (Springer 2022) 67, 84.

[148] Hans-Jörg Rheinberger, 'On Science and Philosophy' (2018) 5 Crisis & Critique 341, 345. cf Rhein Berger (n 129) 28: '(…) a genuinely polysemic procedure defined by ambiguity, not one just limited by finite precision'.

into models.[149] Such ambiguity does not vanish in scientific statements intended to inform decision-makers' choices. Given the inherent fluidity of its subject, assessing the uncertainties of NGT plants inevitably involves choices that balance objectivity, certitude, and pragmatic reasons to provide the best possible predictive statements to inform political decision-makers. As the application of substantial equivalence to NGTs illustrates, the practices of regulatory science operationalise value judgements rather than offering value-free, purely mechanical observation. Instead of rubberstamping scientific opinions and shielding behind rhetorical images of scientific conclusiveness, risk managers should actively engage with the choices and limitations inherent in the information they receive. For this to happen, regulatory science bodies need to disclose rather than avoid these limitations. When EFSA's GMO Panel shifts responsibility onto risk managers by resorting to boundary work rather than engaging with controversies and remaining uncertainties, it risks reinforcing the Commission's tendency to hide behind science.

In scientists' operationalisation of ambiguity in their attempts 'to get away from the actual state of the art', one may find a parallel in the arts. Pfarr's installation *Reglement* does not resolve the hybridity of the bricks/stones; it curates it. The arrangement into metal boxes evokes the rational order of regulatory classification — the metal grid as an emblem of law's ambition to systematise, to produce comparability, and to contain. One might read the installation as showing regulation's failure to catch what has already fled its conceptual containers by its fragmentary shape. Yet, one might equally see it as showing the stones' hybrid genealogy: what becomes visible in the space in-between the bricks/stones and their cuboid grid is what has become invisible through marine erosion: the once norm-given, industrial shape reappears as the negative, empty space in-between. Instead of treating ambiguity as a deficit to be overcome, the installation preserves the stone's ambiguous state. Therewith, ambiguity becomes a productive condition for reflection – a site where the boundaries between nature and culture, between object and norm, are continually renegotiated.[150] Hence, scientific and artistic practices are dwelling on, rather than dissolving, ambiguity. This shows how there might be value in provisionally stabilising a state of indeterminacy rather than striving for certainty and finality.[151] From a legal perspective, though, deciding remains inescapable. And the law often strives for clear boundaries to foster legal certainty. Ultimately, NGT plants and

[149] Tracing these steps, see Hans-Jörg Rheinberger, *Split and Splice: A Phenomenology of Experimentation* (University of Chicago Press 2023) 11ff.

[150] cf Aue (n 3).

[151] Mary Shelley's literary image of Frankenstein's monster teaches us that hybridity is not inherently bad; after all, the monster was capable of holding moral values and feeling love.

products will either have to be granted access to fields and the market or remain barred therefrom. Yet, where regulatory procedures face ambiguity, inclusivity rather than exclusion is crucial.[152] And where knowledge remains inherently provisional, learning remains an indefinite routine rather than a finite process.

Instead of maintaining and visualising NGT's inherent ambiguity, both positions on how to deal with NGT plants and products, their inclusion in GMO legislation's scope or their exclusion through deregulation, seek to stabilise meaning where meaning is in flux. The assumption underpinning the categorical distinction envisaged in the Commission's proposal is that certain genomic alterations, when technically verifiable as potentially achievable through conventional breeding, may be deemed natural enough to warrant regulatory exemption. In effect, the regulatory *objet ambigu* is then reclassified as a non-object of regulation. What remains is a legal fiction of purity, produced through a technical verification procedure that conceals rather than engages with the entanglement of culture and nature that NGTs embody. The law thus restores its categorical comfort at the price of denying the very ambiguity it is confronted with. The typical precautionary mechanism of pre-market authorisation requirements, in turn, stabilises indeterminacy by providing for proceduralisation rather than legislative assignment *carte blanche*. Risk analysis as a procedural schism underpinning the current GMO legislation reflects science's provisionality and opens *fora* for deliberation that – in principle – may reach beyond more narrow scientific grounds. As defective as the underlying separation of science and policy may be,[153] it does serve as a legally structured site for coordination between scientific and political rationalities.[154] Yet, invoking the precautionary principle as a supra-legislative imperative demanding NGTs assimilation into GMO legislation's established tracks may equally produce closure. Transmuting from precaution to prohibition by establishing evidentiary requirements in excess of the uncertainties at stake, the principle's rigid application could foreclose the exploratory governance that novel biotechnologies re-

[152] See Renn and others (n 116) 235 and 237.

[153] See, for instance, Karl-Heinz Ladeur, 'The Introduction of the Precautionary Principle into EU Law: A Pyrrhic Victory for Environmental Protection? Decision-Making under Circumstances of Complexity in Multi-Level Political Systems' (2003) 40 Common Market Law Review 1455, 1465. In the US context, see Deborah G Mayo and Rachelle D Hollander, *Acceptable Evidence: Science and Values in Risk Assessment* (OUP 1991) xi; Vern R Walker, 'The Myth of Science as a "Neutral Arbiter" for triggering Precautions' (2003) 26 Boston College International and Comparative Law Review 197, 252. With a view to EU GMO regulation, see Kasanmoentalib (n 143) 42.

[154] cf Maria Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance: GMO Regulation and Its Reform' (2015) 21(5) European Law Journal 622, 627.

quire.[155] Insofar as the principle is mobilised to enforce categorical continuity – to treat the novel as if it were already known – it may equally obstruct the very reflexivity that ambiguity calls for. In this sense, reliance on precaution as an imperative for categorical continuance mirrors the tendency to suppress hybridity through de-regulation.

A third option could reside in the border territory between the opposing tendencies of ontological alignment and categorical containment. Exploring this border-territory rather than striving for one-sided assignment could sustain a space of openness where uncertainty and ambiguity are operationalised. This would mean re-inventing the verification procedure foreseen by the NGT proposal[156] to turn it into such an intermediary zone allowing regulatory practice to accommodate gradations of (non-)knowledge, evolving understandings of risk and uncertainty, and societal implications of its regulatory subject. Instead of seeking quantitative assurance, such an extended verification process would need to involve qualitative judgement about the need for further assessment and create a forum for coordination between science and societal preferences. In this sense, regulation could become an exercise in maintaining productive ambiguity – an institutionalised experiment in keeping categories permeable long enough for learning to occur. By widening the boundary rather than policing it, EU law could reflect the dynamic co-production of knowledge and normativity,[157] allowing the governance of NGTs to mirror the contingent, experimental nature of the sciences that risk regulation both depends on and aims to regulate.

Suggested citation: L Knuth and E Vos, 'Deregulating New Genomic Techniques: The Challenge of Ambiguous Objects' (2025) 21 CYELP 1.

[155] See Ino Augsberg, *Informationsverwaltungsrecht. Zur kognitiven Dimension der Steuerung von Verwaltungsentscheidungen* (Mohr Siebeck 2014) 60–69.

[156] Arts 6 and 7 of the NGT Proposal.

[157] As to the conceptual genesis and meaning of co-production, see Brice Laurent, 'Co-production' in Ulrike Felt and Alan Irwin (eds), *Elgar Encyclopedia of Science and Technology Studies* (Elgar 2024) 13–23; For its application to EU internal market law, cf the contributions in Maria Weimer and Anniek De Ruijter (eds), *Regulating Risks in the European Union: The Co-Production of Expert and Executive Power* (Hart Publishing 2017).

UNITARY PATENT AND THE UNIFIED PATENT COURT: ATTRACTIVE FOR SMEs?

Ivana Božac *

Abstract: The Unitary Patent Package (UPP) was conceived as a means of simplifying and centralising patent protection and enforcement across participating EU Member States. The introduction of a supranational patent jurisdiction and a unitary protection system was intended to reduce costs and enhance legal certainty for patent holders, particularly those belonging to the category of small and medium-sized enterprises (SMEs). Historically, these enterprises have faced challenges associated with the complexity and expense of fragmented national systems.

Two years after the entry into force of the UPP, the present paper examines early empirical data to assess the extent to which SMEs have engaged with the Unitary Patent (UP), and to evaluate the UPP's attractiveness as a solution for European SMEs, in light of existing patent protection options.

Keywords: Unitary Patent Package (UPP), Unified Patent Court (UPC), small and medium-sized enterprises (SMEs), patent enforcement

1 Introduction

In force since 1 June 2023, the Agreement on a Unified Patent Court (UPC Agreement)[1] established the Unified Patent Court (UPC), a supranational tribunal with exclusive jurisdiction over European patents with unitary effect (unitary patents, UPs), as well as, unless formally opted out, 'classic' European patents[2] (EPs) valid in the EU Member States that

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[1] Agreement on a Unified Patent Court [2013] OJ C175/1 (UPC Agreement) Arts 3–5.

[2] European patents (EPs) for which the application is dealt with by the European Patent Office (EPO) under the procedures laid down in the European Patent Convention (Convention on the Grant of European Patents (European Patent Convention, EPC) (signed 5 October 1973, as revised by the Act revising Art 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000) 1065 UNTS 199, (EPC)). The UPC Agreement does not permit parties to opt out of the UPC's jurisdiction for matters concerning Unitary Patents. See Annette Kur, Thomas Dreier and Stefan Luginbühl, *European Intellectual Property Law: Text, Cases and Materials* (2nd edn, Edward Elgar 2019) 155.

have ratified the agreement.[3] Together with Regulation (EU) 1257/2012, which confers unitary effect on European patents,[4] and Regulation (EU) 1260/2012, which establishes the necessary translation regime,[5] the UPC Agreement forms the core of the Unitary Patent Package (UPP) and represents the most significant reform of the European patent framework in recent times.[6]

The UP/UPC system was originally promoted as a mechanism to significantly enhance the protection of innovation within the European single market. It was expected to deliver substantial cost reductions in relation to both the filing of patents with unitary effect and the enforcement of rights, which are now centralised before the UPC and are automatically effective across all participating Member States.[7] The creation of a unitary and specialised patent jurisdiction was intended to promote greater legal certainty and system coherence by addressing former fragmentation, whereby a patent could be invalidated in one jurisdiction but remain enforceable in another due to divergent judicial outcomes.[8] A

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[3] The UPC Agreement was signed by EU Member States on 19 February 2013, with the exception of Croatia, Poland and Spain. For a historical overview, see, for example, Kur, Dreier and Luginbühl (n 2) 150–151. On 1 June 2023, 17 Member States had ratified the UPC Agreement: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia and Sweden. Romania's subsequent ratification raised the total to 18. Thus, six EU Member States have not ratified the UPC Agreement (Cyprus, the Czech Republic, Greece, Hungary, Ireland, and Slovakia). Up-to-date ratification data are available at Council of the European Union, 'Agreement on a Unified Patent Court (UPC)' <www.consilium.europa.eu/en/documents/treaties-agreements/agreement/?id=2013001> accessed 14 June 2025. The fact that countries such as Croatia and Spain are not currently part of this system because they have not ratified the UPC Agreement does not prevent Croatian or Spanish legal or natural persons from applying for a UPC or being involved in related disputes.

[4] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L361/1.

[5] Regulation (EU) No 1260/2012 of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements [2012] OJ L361/89.

[6] Justine Pila and Paul L C Torremans, *European Intellectual Property Law* (2nd edn, OUP 2019) 599. For a critical analysis of the UPC Agreement constitutional design and an examination of the adverse economic effects of the unitary patent system, see Dimitris Xenos, 'European Patent System: Failures in Constitutional Design Crippling Essential Safeguards against Adverse Economic Effects' in Luc Desaunettes-Barbero, Fernand de Visscher, Alain Strowel, Vincent Cassiers (eds), *The Unitary Patent Package & Unified Patent Court: Problems, Possible Improvements and Alternatives* (Ledizioni 2023) 123–145. Art 20 UPC Agreement; Art 267 TFEU.

[7] See, for example, Commission, 'A Single Market for Patents: The Unitary Patent System <https://single-market-economy.ec.europa.eu/system/files/2023-06/Patent%20Package_Unitary%20Package%20System_V8.pdf> accessed 9 June 2025.

[8] Emanuela Arezzo, 'Divisional Applications and Patent Portfolios in Europe: Will Patenting Strategies Change after the Introduction of the Unitary Patent and the UPC?' (2025) 74(3) GRUR International 205, 213 and the sources cited therein.

coherent body of UPC case law could also influence national judicial approaches, fostering greater interpretative convergence[9] and potentially diminishing the quasi-normative role long held by the EPO's Technical Boards of Appeal. These boards have historically served as the primary supranational source of patent adjudication.[10]

The UPC is an international court[11] common to all EU Member States that have ratified the UPC Agreement.[12] Article 20 of the UPC Agreement affirms the primacy of Union law, and Article 267 TFEU obliges the court to seek preliminary rulings from the Court of Justice of the European Union where necessary.[13] Article 31 of the UPC Agreement further provides that the international jurisdiction of the UPC shall be determined in accordance with Regulation (EU) No 1215/2012 (Bruxelles I *bis*),[14] or under the Convention on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters (Lugano Convention).[15] Thus, the UPC is not an EU institution; it operates in a manner comparable to a national court with supranational jurisdiction.[16]

During the UPP negotiations, policy-makers emphasised the structural needs of small and medium-sized enterprises (SMEs).[17] For in-

[9] cf Giorgia Galeotta, Tamar Khuchua and Martin Stierle, 'Public Access to the Register of the Unified Patent Court: Unprecedented Transparency with Unfounded Limitations' (2025) 20(1) Journal of Intellectual Property Law & Practice 23, 24 and 31.

[10] Aurora Plomer, 'The EPO as Patent Law-Maker in Europe' (2019) 25(1) European Law Journal 57.

[11] Dimitris Xenos (n 6) 125 and 127.

[12] Art 1(2) UPC Agreement.

[13] Art 20 UPC Agreement; Art 267 TFEU.

[14] Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast) [2012] OJ L351/1.

[15] Convention on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters (Lugano Convention) [2007] OJ L339/3, concluded between the EU, Norway, Iceland and Switzerland. See Pila and Torremans (n 6) 601.

[16] Arezzo (n 8) 213. For a detailed study on the UPC's position within the judicial system of the EU, see Hanns Ullrich, 'The Unified Patent Court' (2023) 42 Yearbook of European Law 135. For a critical analysis of the distinction between an EU national court and the UPC when referring a question to the CJEU, see Dimitris Xenos (n 6) 126–127.

[17] According to the European Commission's Recommendation of 2003, the category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million and/or an annual balance-sheet total not exceeding EUR 43 million. Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises [2003] OJ L124/36, Annex Art 2(1)–(3). The EU SME Definition is a 'structural tool to identify those enterprises that are confronted with market failures and particular challenges (eg access to finance) due to their size, and therefore are allowed to receive preferential treatment in public support'. The initial definition dates back to 1996 while the current one was issued in 2003 and confirmed in 2021. In fact, the later evaluation confirmed that 'the SME definition remains a relevant and fit for purpose tool

stance, the Commission's 2011 impact-assessment explicitly identified translation, validation and maintenance fees as 'so costly and complex that [EU-wide patent protection] is inaccessible to many inventors and companies; in particular, SMEs often prefer an informal protection of their innovations'.[18] This diagnosis framed the drafting process: negotiators sought fee levels and procedural rules that would neutralise the cost barrier without eroding the system's financial viability.

Accordingly, the EPO later adopted a fee schedule in which (i) renewal fees for a UP are linked to the cumulative cost of renewal of 'classic' EPs in four MSs, and (ii) SMEs, universities and non-profits are entitled to compensation for post-grant translation expenses when they file in an EU language other than English, French or German.[19] The Council of the EU has repeatedly presented these measures as a deliberate attempt to make the new regime 'attractive' to SME users.[20] By the eve of the system's launch, the Commission was still emphasising that the UPC/UP represented a 'powerful tool for European companies, and especially SMEs, [and]… a one-stop-shop for patent protection and enforcement in the EU'.[21] Thus, the legislative history indicates that the UPP was designed with consideration for the distinctive characteristics and economic importance of SMEs.

At the same time, a contrasting perspective in the literature, endorsed by a number of academics and several Member States, asserts that the UPP will offer only modest tangible advantages to EU-based SMEs[22] while introducing significant new risks. According to this per-

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to identify the enterprises most confronted with disadvantages due to their size. It has also clearly been effective in limiting the proliferation of SME definitions at both the EU level and in the Member States and thus contributed to levelling the playing field for SMEs. No evidence was found that points to a need for revision'. Commission, 'Commission Staff Working Document: Evaluation of Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises' (2003/361/EC) SWD (2021) 279 final, 28 September 2021, 60.

[18] Commission, 'Commission Staff Working Document: Summary of the Impact Assessment' SEC (2011) 483 final (13 April 2011) 3 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=swd:SEC_2011_0482> accessed 9 June 2025.

[19] Council of the European Union, 'Progress Report on the Unitary Patent Package' 6070/23 (20 February 2023) 5–6 <https://data.consilium.europa.eu/doc/document/ST-6070-2023-INIT/en/pdf> accessed 9 June 2025.

[20] ibid 6.

[21] Commission, 'Intellectual Property: Harmonised EU Patent Rules Boost Innovation, Investment and Competitiveness in the Single Market' IP/23/2454 (27 April 2023) <https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip_23_2454/IP_23_2454_EN.pdf> accessed 9 June 2025.

[22] For instance, Xenos argued that empirically SMEs account for barely 10% of granted EPs, while large firms capture more than 80%, so any putative fee reductions or wider territorial reach will benefit those already dominant rather than the firms the EU claims to support. According to him, the real effect of the UPP is to shift bargaining power and

spective, the UPP is likely to shift bargaining power and market space towards large corporations, often from outside the EU, thereby exacerbating existing technological and economic disparities. It is argued that the result will be an increase in patent imports, litigation costs, and competitive barriers, leaving economies that rely heavily on SMEs particularly vulnerable to the system's adverse effects.[23]

Drawing on empirical data from the first two years after the Unitary Patent Package (UPP) came into force, this paper examines the uptake of the Unitary Patent (UP) by SMEs and evaluates the UPP's attractiveness as a solution for European SMEs, in light of existing patent protection options.

It assesses the extent to which SMEs have engaged with the UP/UPC, considering whether the UPP has begun to deliver its stated objectives of enhanced accessibility and efficiency. However, it does not explicitly analyse the attractiveness of the UP/UPC framework for SMEs that rely on access to third-party technology to operate or grow.

2 Initial interest in UPs by SMEs

The UP was created to streamline the processes of validation, maintenance, and enforcement of patents, a goal welcomed by patentees across Europe, particularly SMEs.[24] Although the European Patent Convention (EPC) had previously centralised the grant procedure through

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market space towards large, often non-EU corporations, amplifying existing technological and economic disparities both between and within Member States, resulting in an increase in patent imports, litigation costs, and competitive barriers, and leaving SME-dependent economies uniquely exposed to the new system's adverse consequences. Dimitris Xenos, 'The Impact of the European Patent System on SMEs and National States' (2020) 36(1) Prometheus 51; Dimitris Xenos, 'Unconstitutional Supranational Arrangements for Patent Law: Leaving out the Elected Legislators and the People's Participatory Rights' (2019) 28 Information and Communications Technology Law 131. Similarly, Plomer argues that the new UP package, including the UPC, will benefit large foreign multinationals and be much less valuable to small and medium-sized innovative European companies, which will risk becoming prey to infringement actions in a new and complex system. See Aurora Plomer, 'The Unified Patent Court and the Transformation of the European Patent System' (2020) 51 IIC 791. It is noteworthy that certain Member States that did not sign the UPC Agreement, such as Poland, or that chose not to ratify the UPC Agreement after signature, including Hungary and the Czech Republic, have expressed similar concerns. These Member States have based their position on national impact assessment studies on the UPC, which have indicated the potential for significant losses and negative effects on SMEs. For a detailed overview, see Xenos (n 6) 135–137.

[23] François Wéry, 'New IP Strategy for Businesses in Europe in the Light of the Unitary Patent and the Unified Patent Court' in Luc Desaunettes-Barbero, Fernand de Visscher, Alain Strowel, Vincent Cassiers (eds), *The Unitary Patent Package & Unified Patent Court: Problems, Possible Improvements and Alternatives* (Ledizioni 2023) 405–407.

[24] Silvia Ellena, 'Unitary Patent System Key for European SMEs, But Not All Countries Ready to Join' (*Euractiv*, 5 July 2023) <www.euractiv.com/section/economy-jobs/news/

the EPO, the UP goes further by eliminating the need for national registration, translation, and validation[25]. Following the granting of a patent, patentees may obtain and maintain UP protection in 18[26] and potentially up to 24 or more EU Member States through a single procedure, with the EPO functioning as a one-stop administrative body.[27]

Applications for a UP – a European patent with unitary effect – must be submitted within one month of the EPO's decision to grant a European patent.[28] By that stage, applicants must evaluate whether the UP, either alone or in combination with conventional European or national patents, aligns with their strategic and financial objectives.[29]

The territorial scope of the UP is a critical factor in determining its level of attractiveness. At present, nine EU states – including Spain, Poland and Ireland – are not part of the UP, and several key European economic partners, such as the United Kingdom, Switzerland, Turkey, and Norway, are permanently excluded because the mechanism is limited to EU members.[30]

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unitary-patent-system-key-for-european-smes-but-not-all-countries-ready-to-join/> accessed 31 May 2025.

[25] Xenos, 'Impact of the European Patent System' (n 22) 16.

[26] According to section 1.5.1 of the Unitary Patent Guidelines, the territorial scope of a UP covers the territories of those EU Member States participating in enhanced cooperation on UP protection and in which the UPC Agreement is in force at the time of registration of the unitary effect. The scope remains the same for the entire lifetime of the Unitary Patent and is not extendable to the participating Member States that ratify the UPC Agreement after its unitary effect has been registered. The territorial scope of each individual Unitary Patent is shown in the Register for unitary patent protection. Details on the territorial scope of the UP in the participating Member States with overseas territories (ie Denmark, France, Netherlands) may be found in the EPO publication entitled 'National measures relating to the Unitary Patent', which is available on the EPO website. See European Patent Office, 'Unitary Patent Guidelines' (in force on 1 April 2025, Notice from the EPO dated 3 December 2024, OJ EPO 2025, A6, 31 January 2025) <www.epo.org/en/legal/guidelines-up/2025/index.html> accessed 15 June 2025.

[27] European Patent Office, 'Costs of a Unitary Patent and Reductions for Small Entities' <www.epo.org/en/service-support/faq/law-practice/unitary-patent/costs-unitary-patent-and-reductions-small-entities> accessed 31 May 2025.

[28] According to Art 9(1)(g) of Regulation (EU) No 1257/2012 'a request for unitary effect … is submitted … no later than one month after the mention of the grant is published in the European Patent Bulletin'.

[29] For a detailed analysis of the costs impact of the UP/UPC system, see Wéry (n 23).

[30] ibid 394. As Wéry observes, this limited participation has two principal implications. From a business perspective, major markets outside the UK and Spain still require separate EP validations and annual fees. From a legal perspective, the number of patent types within the EU actually increases from two (national and validated EPs) to three (including UPs). During the transitional period, EPs are further divided between those subject to the UPC's jurisdiction and those which have opted out of it. Consequently, the European patent landscape may initially become even more fragmented (ibid, 394–395).

Given that the territorial scope of a UP remains limited to 18 of the 39 EPC contracting States, applicants targeting markets beyond this zone – such as the UK, Spain, Switzerland, or Turkey – must consider additional national validations and pay annual fees to national offices for their maintenance.[31]

Historically, EPs, including those held by SMEs, were not validated in more than a few participating States.[32] In such instances, the UP may not represent a financially optimal solution.[33] Furthermore, once unitary effect is granted it can only be limited, transferred, or revoked in respect of *all* participating Member States, and cannot be narrowed to a smaller territory.[34] This provision creates the inherent 'geographical and hence, financial rigidity': once granted, its territorial scope cannot be subsequently reduced.[35] In contrast, an EP allows the patentee to discontinue renewals in selected countries over time, thereby adjusting costs to market relevance.[36]

Nevertheless, ownership of a UP, with broad coverage across a majority of EU Member States, may constitute a strategic asset for SMEs. Such territorial breadth can enhance the investment appeal, support licensing strategies, and generate revenue from jurisdictions where the

[31] ibid 394. See also Domien Op de Beeck and Henri Kaikkonen, 'UPC Blog Series: Part 4: The UPC and UP: Considerations for SMEs' (*Bird & Bird*, 6 June 2023) <www.twobirds.com/en/patenthub/shared/insights/2023/global/upc-blog-series-part-4-the-upc-and-up-considerations-for-smes> accessed 31 May 2025.

[32] The importance of national patents for SMEs was highlighted by the participants to the Workshops on the Economic Effects of the Unitary Patent and the Unified Patent Court, underscoring that national patents remain vital for SMEs and that their removal would undermine these firms' commercial prospects: applicants typically file first at national level before pursuing a European patent and later drop the national application, as dual protection is not possible in most Member States. Whether an SME ultimately needs a pan-European right depends on its business model; national patents would lose salience only if the Unitary Patent were paired with SME-specific fee reductions and an effective small-claims track before the UPC. Even so, the workshop's prevailing view was that national patents constitute an indispensable instrument for SMEs and should be retained. EPO Economic and Scientific Advisory Board, *Workshops on the Economic Effects of the Unitary Patent and the Unified Patent Court: Report* (Munich, 3–4 December 2013) 13.

[33] The primary justification for the UP was cost reduction. Proponents of the new system advanced the argument that it would result in a reduction of expenses through a reduction of annual fees, a simplification of translation requirements, and the elimination of national validation fees. Wéry evaluates this claim quantitatively and concludes that for patents covering only a few key markets, savings under the UP are minimal, and that the new system becomes financially advantageous only for patentees seeking protection in many countries and maintaining patents for more than a decade. Wéry (n 23) 397–398.

[34] Art 3(2) (third sub-paragraph) of Regulation (EU) No 1257/2012 provides that: 'A European patent with unitary effect shall have a unitary character. … It may only be limited, transferred or revoked, or lapse, in respect of all the participating Member States'.

[35] Op de Beeck and Kaikkonen (n 31).

[36] ibid.

patentee lacks a direct commercial presence.[37] Moreover, SMEs may benefit from financial incentives specifically associated with UP protection. For instance, translation costs[38] may be compensated, and SMEs can opt to submit a 'licence of right' declaration to the EPO.[39] This statement signals the patentee's willingness to license the invention in return for equitable remuneration. Beyond facilitating commercial partnerships, the declaration confers a 15% reduction in UP renewal fees, thus enhancing the cost-effectiveness of UP ownership.[40]

According to the joint EPO–EUIPO study of January 2025, firms that hold formal intellectual property rights (IPR) demonstrate higher revenue per employee, generate greater employment, and offer superior wage levels than their counterparts lacking an IP portfolio. The study found that these positive associations between IPR ownership and economic performance were especially pronounced for SMEs. However, fewer than 10% of European SMEs currently hold any formal IPR.[41]

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[37] See, for example, European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, 'Annual Report on European SMEs 2024/2025 – SME Performance Review 2024/2025' (Publications Office of the EU 2025) <https://data.europa.eu/doi/10.2760/7714438> accessed14 June 2025; and European Patent Office and EU Intellectual Property Office, 'Intellectual Property Rights and Firm Performance in the EU' (Firm-Level Analysis Report, January 2025) <https://link.epo.org/web/publications/studies/en-ipr-performance-study.pdf> accessed 15 June 2025.

[38] According to recital 5 of Regulation 1260/2012 (n 5) '[s]uch translation arrangements should ensure legal certainty and stimulate innovation and should, in particular, benefit small and medium-sized enterprises (SMEs). They should make access to the European patent with unitary effect and to the patent system as a whole easier, less costly and legally secure'.

[39] Small entities, including SMEs, individuals, universities, non-profit organisations and public research institutions, may claim a 500 translation-cost compensation when their application is filed in an EU language other than English, French or German. To qualify, the proprietor must submit, together with the unitary-effect request, a declaration confirming their status as a natural person, SME, non-profit, university, or public research body. This compensation complements the reductions in filing and examination fees available under Rule 8(1) of the Rules relating to Unitary Patent Protection (UPR) for applications and examination requests filed in designated EU languages. Furthermore, any proprietor who lodges a licence-of-right statement – which permits third-party use of the invention – receives an additional 15% reduction in renewal fees falling due after the statement's registration. European Patent Office, 'Rules Relating to Unitary Patent Protection' (Decision of the Select Committee of the Administrative Council of the European Patent Organisation, 15 December 2015, last amended 13 November 2024) <www.epo.org/en/legal/up-upc/2022/upr.html> accessed 15 June 2025.

[40] Rule 12 UPR. See also European Patent Office, 'Are There Any Reductions for Small Entities, Such as SMEs, Start-ups and Universities?' <www.epo.org/en/service-support/faq/law-practice/unitary-patent/costs-unitary-patent-and-reductions-small-0> accessed 31 May 2025.

[41] European Patent Office and EU Intellectual Property Office (n 37) 12, 14. The report was based on an analysis of over 119,000 European firms from all 27 EU Member States, over a ten-year period (2013-2022), and covers patents, trademarks and designs registered at the EPO, EUIPO, and at national and regional IP offices. Compare also the EPO press release

The first-year data published by EPO in an anniversary release on 1 June 2024 showed that SMEs (including individual inventors) accounted for 35.5% of all UP requests filed by European proprietors.[42] Thus, more than a third of all EU-based owners choosing unitary effect were SMEs, surpassing initial expectations.[43]

A following operational report to the EPO's Select Committee, providing an overview of UPs on 31 August 2024, noted that in the first half of 2024 SMEs 'continued to represent a very large share of UP owners … accounting for 32.2% of the total'.[44] The same document shows a 35.8% uptake rate among *all* EU patentees in 2024, with several smaller economies above 50% (eg Latvia 83%, Slovakia 76.5%, Malta 72.7%).[45]

The latest statistics from the EPO's Patent index 2024 indicate that unitary protection was requested for 25.6% of all EPs granted by the EPO in 2024. Furthermore, patentees from Europe had the highest uptake rate, with 36.5% of their EPs transformed into UPs.[46] According to the accompanying press release, the requests for unitary protection in 2024 increased by 53% compared to 2023, while smaller entities showed even greater interest in the system, with European SMEs and universities having an uptake rate of 57.5%.[47]

Thus, contrary to some earlier predictions based on historical patent protection data,[48] recent EPO communications indicate that SMEs constitute approximately 35% of all UP requests and convert nearly 60%

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of 19 September 2024, where the EPO President observed that only 9% of SMEs in the EU own formal IP rights, such as patents: European Patent Office, 'EPO President Sets Out priorities for SME Support <www.epo.org/en/news-events/news/epo-president-sets-out-priorities-sme-support> accessed 31 May 2025.

[42] European Patent Office, 'Unitary Patent Exceeds Projections in Its Inaugural Year: SME Uptake Highlights Key Benefits' (Press release, 1 June 2024) <www.epo.org/en/news-events/press-centre/press-release/2024/1158768> accessed 15 June 2025.

[43] cf Xenos, 'Impact of the European Patent System' (n 22) 27.

[44] European Patent Office, 'Unitary Patent Operational Report' SC/14/24 (September 2024) 7 <https://link.epo.org/web/documentation/documentation/en-sc-24-14.pdf> accessed 15 June 2025.

[45] ibid 3.

[46] According to data on the EPO website, on 3 February 2025, a breakdown of patent applications originating from European countries shows that 71% of them were filed by large companies, 22% by individual inventors and SMEs, and 7% by universities and public research organisations. This indicates a significant proportion of applicants at the EPO are smaller entities. There are no recent data specifically on UP uptake by EU SMEs <www.epo.org/en/about-us/statistics/patent-index-2024> accessed 15 June 2025.

[47] European Patent Office, 'European Innovation Remains Robust, with Demand for Patents Sustained at a High Level' <www.epo.org/en/news-events/news/european-innovation-remains-robust-demand-patents-sustained-high-level> accessed 15 June 2025.

[48] See Xenos, 'Impact of the European Patent System' (n 22) 27; and Plomer (n 22) 795.

of their granted EPs into UPs, highlighting the system's early appeal to smaller enterprises.[49]

However, these figures should be interpreted with caution. As indicated by both scholarly commentary[50] and the joint EPO–EUIPO study published in January 2025,[51] the overall level of patenting activity among EU-based SMEs remains comparatively low. Moreover, an increase in UP requests cannot be taken as evidence of the system's effectiveness, particularly since the practical and jurisprudential contours of the UP/UPC framework are still emerging. These considerations will be examined in greater detail in the following section.

3 UPC litigation dynamics and implications for SMEs

The Unified Patent Court (UPC) is the second pillar of the UPP. It was intended to become the single court for all patent litigations involving UPs and eventually – after the 'opt-out' period[52] – all EPs. The UPC was created to remedy the fragmentation of patent enforcement under the EPC, whereby EPs must be validated, litigated, and enforced separately in each contracting State, with attendant translation requirements, fees, and parallel proceedings. Recital 2 of the UPC Agreement expressly states how:

> the fragmented market for patents and the significant variations between national court systems are detrimental for innovation, in particular for small and medium-sized enterprises which have difficulties

[49] See Antonio Campinos, 'European Patent Office to Help Secure Europe's Competitive Edge' (sponsored opinion article, *Euractiv*, 13 May 2025) <www.euractiv.com/section/tech/opinion/european-patent-office-to-help-secure-europes-competitive-edge/> accessed 15 June 2025.

[50] Krista Rantasaari, 'Panorama of the Issues for SMEs and Possible Solutions' in Luc Desaunettes-Barbero, Fernand de Visscher, Alain Strowel, Vincent Cassiers (eds), *The Unitary Patent Package & Unified Patent Court. Problems, Possible Improvements and Alternatives* (Ledizioni 2023) 441-441. Compare also Xenos, 'Impact of the European Patent System' (n 22) 27; Plomer (n 22) 795; Wéry (n 23) 402-404.

[51] European Patent Office and EU Intellectual Property Office (n 37) 12, 14.

[52] Article 83 UPC Agreement - Transitional regime. During a transitional period that will end on 1 June 2030, patentees who opt for the conventional route of obtaining an EP and validating it as a bundle of national rights may file an opt-out request if they do not wish their granted EP to fall under the jurisdiction of the UPC. It is important to note that this transitional period may be extended by a period of up to seven years. Furthermore, the option to opt-out is not available in circumstances where a UP is requested; rather, it is only possible where the patentee pursues classical national validations of the EP. Following the expiry of the transitional period, existing opt-outs will remain effective; however, it will no longer be possible to file any new opt-outs. All EPs granted thereafter will fall within the jurisdiction of the UPC for those EU Member States that have ratified the UPC Agreement. For those states, direct national filings will be the only means of avoiding the UPC. See eg Wéry (n 23) 404–405.

> to enforce their patents and to defend themselves against unfounded claims and claims relating to patents which should be revoked.[53]
>
> The Agreement goes on to say that:
>
> The Unified Patent Court should be devised to ensure expeditious and high quality decisions, striking a fair balance between the interests of right holders and other parties and taking into account the need for proportionality and flexibility.[54]

The UPC thus introduces a centralised forum, expected to deliver swift enforcement of infringement claims or the central revocation of invalid patents before a specialised judiciary with expertise in patent law.[55] Whether SMEs will truly benefit from such streamlined litigation mechanism, however, remains a complex question.[56]

At present, the UPC's jurisdiction is confined to UPs and to EPs that have not been opted out. Opted-out EPs, and those validated in non-participating countries, remain under the exclusive jurisdiction of national courts. As a result, the UPC cannot (yet) create full uniformity across the EU, since the validity and infringement of opted-out or external patents must still be litigated nationally, further fragmenting the litigation landscape.[57]

In a nascent tribunal such as the UPC, trust-building is essential.[58] The very prospect of a single action voiding a patent across all participat-

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[53] See also Esther van Zimmeren and Federica Baldan, 'The Future Role of the Unified Patent Court in Safeguarding Coherence in the European Patent System' (2015) 52(6) Common Market Law Review 1529, 1575.

[54] Recital 5 of the UPC Agreement.

[55] See eg Katrin Cremers, Michael Ernicke, Frank Gaessler and others, 'Patent Litigation in Europe' (2017) 44 European Journal of Law & Economics 1, 38 and the UPC first annual report: UPC Annual Report 2024 (PDF, 2025) <www.unified-patent-court.org/sites/default/files/upc_documents/UPC_AR_2024_HD_digital_version_double_page_compressed.pdf> accessed 8 June 2025.

[56] cf Martin Stierle, 'The Rise of the Unified Patent Court: A New Era' (2023) 54(5) IIC – International Review of Intellectual Property and Competition Law 631.

[57] Wéry observes that true harmonisation depends on two variables: the number of participating countries and the duration of the transitional period. With only 18 Member States in the system, achieving full harmonisation of case law remains unattainable. Even if more States join, patents that have opted out will remain valid for years, which will delay the establishment of a coherent body of UPC jurisprudence — potentially until the 2050s if the transitional period is extended (Wéry (n 23) 407-408). He describes patentees based in non-participating Member States as potential 'free riders', as they can benefit from the advantages of the UP – for instance, by obtaining unitary protection if they wish – while remaining shielded from competitors' UPs within their domestic markets. He argues that this configuration allows such companies to gain market advantages without facing the same patent constraints (ibid 405).

[58] Van Zimmeren and others identify three key challenges to trust: the politicised genesis of the UPC; the opt-out mechanism for 'classic' EPs during the transitional period under

ing States further fuels uncertainty, potentially motivating patentees to adopt a prudent approach and remain within national systems.[59] Recent commentary has also suggested that the UPC Agreement's procedural framework may structurally favour patentees, yet centralised revocation exposes even rights-holders to comprehensive attack. [60]

According to Article 49 of the UPC Agreement, proceedings before the Central Division (CD) are to be conducted in the language of the patent.[61] In contrast, in actions before a local or regional division (LD or RD), the language of the proceedings may be any of the official languages of the contracting Member State in which the relevant division is hosted, or alternatively, any other language designated by the relevant contracting Member State pursuant to Article 49(2). Furthermore, the parties may agree to use the language in which the patent was granted as the language of the proceedings (Article 49(3)). However, under Article 49(5) of the UPC Agreement, upon a request by one of the parties, and after hearing the other parties and the relevant panel, the President of the Court of First Instance may, 'on grounds of fairness and taking into account all relevant circumstances, including the position of the parties, in particular the position of the defendant', decide to designate the language in which the patent was granted as the language of proceedings.[62]

The available statistical data indicate a marked trend towards the use of English as the predominant procedural language before the UPC.[63]

Article 83(3) of the UPC Agreement might be interpreted as a lack of trust in the system; and the complexity of the Court's institutional design, which may raise doubts as to its impartiality and independence. Indeed, under the Rules of Procedure, parties may both opt out of the UPC and choose among divisions of the Court of First Instance, an unusual degree of procedural flexibility liable to encourage forum shopping. While such flexibility benefits individual litigants, widespread reliance on the opt-out – available since 1 March 2023 – may slow the UPC's caseload growth and impede its consolidation as a central forum. Esther van Zimmeren, Bjorn Kleizen and Patricia Popelier, 'Trust in Specialised Courts: The Unified Patent Court (UPC) as a Case Study to Disentangle Trust Dynamics and Trust-Building Mechanisms' (2024) 17(1) Erasmus Law Review 93, 97. The authors differentiate trust from legitimacy, while noting their interdependence. They argue that trust precedes legitimacy, particularly in newly established courts. Therefore, trust-building is essential to secure broader legitimacy for the UPC. ibid, 95.

[59] Arezzo (n 8) 214

[60] Martina Dani, 'The Bifurcation Challenge at the Unified Patent Court' (2025) 20(1) Journal of Intellectual Property Law & Practice 16, 17; Arezzo (n 8) 214.

[61] Article 49(6) of the UPC Agreement.

[62] According to Article 49(4) of the UPC Agreement, the competent panel may also decide on the use of the language in which the patent was granted as the language of proceedings with the agreement of the parties, on grounds of convenience and fairness.

[63] Statistical reports ('Case Load of the Court Since Start of Operation in June 2023') were regularly updated on the UPC website until the end of June 2025, allowing insights in the data concerning languages used in front of the CFI. See eg Unified Patent Court, 'Case Load of the Court Since Start of Operation in June 2023 – Update End March 2024' <www.uni-

Concerning the proceedings in front of the CFI, as of June 2025, English was employed in 54% of cases before the CFI while German was used in 39% of cases.[64] This is in contrast to the figures reported in March 2024, when German was still the predominant language of proceedings at 47%, while 45% of proceedings were conducted in English.[65] Given the prevalence of English-language patents at the EPO,[66] the overwhelming majority of revocation actions filed before the CD are conducted in English (88% in 2024). At present, both German- and English-language proceedings are widely used: according to the 2024 UPC Annual Report, 51% of infringement proceedings are conducted in German, while 41% are conducted in English. It is evident that a significant proportion of the proceedings before the UPC are now conducted in English, with 52% of all cases falling into this category.[67]

A recent decision of the UPC Court of Appeal (UPC CoA) concerning the application of Article 49(5) of the UPC Agreement, and involving an SME, has attracted the attention of practitioners and scholars.[68] In fact, on 17 April 2024, the UPC CoA issued an order concerning the change of language of proceedings in *Curio Bioscience Inc v 10x Genomics Inc* (Case UPC_CoA_101/2024 ApL_ 12116/2024).[69] The UPC CoA found that a 'rel-

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fiedpatentcourt.org/sites/default/files/upc_documents/Case%20load%20of%20the%20Court_end%20March%202024.pdf> and Case Load of the Court Since Start of Operation in June 2023 – Update 30 June 2025, 3 <www.unifiedpatentcourt.org/sites/default/files/upc_documents/Case%20load%20of%20the%20Court_30%20June%202025.pdf> accessed 19 July 2025. Information on the overall use of languages in court proceedings in front of the UPC are available in the UPC Annual Report 2024 (n 55) 80.

[64] Unified Patent Court, 'Case Load of the Court – Update 29 March 2024' <www.unifiedpatentcourt.org/en/news/case-load-court-update-29-march-2024> accessed 19 July 2025.

[65] Unified Patent Court, 'Case Load of the Court Since Start of Operation in June 2023 – Update 30 June 2025' <www.unifiedpatentcourt.org/sites/default/files/upc_documents/Case%20load%20of%20the%20Court_30%20June%202025.pdf> accessed 19 July 2025.

[66] The EPO has made available an online dashboard that provides, inter alia, information on the languages used for UP requests and their corresponding translations. In 2024, English was the procedural language of 75% and language of translation for 25% of the requests: European Patent Office, 'Statistics & Trends Centre' <www.epo.org/en/about-us/statistics/statistics-centre#/unitary-patent> accessed 15 June 2025.

[67] UPC Annual Report 2024 (n 55) 80.

[68] See eg Laura Jennings, 'UPC Favours SMEs for Language Change: Claimants Ordered to Sue in the Language of the Granted Patent' (*D Young & Co*, 18 April 2024) <www.dyoung.com/en/knowledgebank/articles/upc-smes-language-change> accessed 14 June 2025; and Pfrang T, 'Court of Appeal Rules on Language of Proceedings: Considering the Challenges Faced by Small and Medium-sized Enterprises (SMEs)' (*Meissner Bolte UPC Blog*, 23 April 2024) <www.meissnerbolte.com/de/upc/upc-blog/court-of-appeal-rules-on-language-of-proceedings/> accessed 14 June 2025.

[69] The case concerned a request for provisional measures initiated before the Düsseldorf Local Division, where the language of proceedings was German. The patent in question was granted in English. The defendant submitted a request to change the language of the proceedings from German to English, which was subsequently forwarded to the President

evant circumstance related to parties is their size relative to each other' and that '[a] multinational company with a substantial legal department has more resources to deal with and coordinate international disputes in different languages than a small company with limited resources that is only active on a limited number of markets'.[70] Nevertheless, it stressed that Article 49(5) of the UPC Agreement 'provides that in particular the position of the defendant is to be taken into account. If the outcome of balancing of interests is equal, the position of the defendant is the decisive factor'.[71] Thus, the CoA did observe that it is evident that the defendant is a smaller company than the plaintiff and that the disadvantage of the language of the proceedings being different from their company language would be a heavier burden for the former. The UPC CoA subsequently held that, when assessing a request to change the language of proceedings to that of the patent on grounds of fairness, all relevant circumstances must be considered – primarily those related to the specifics of the case and the parties' respective positions, with particular emphasis on the defendant's situation. If the outcome of the balancing of interests is equal, the position of the defendant is the decisive factor. In particular, the CoA indicated that the language of the patent as the language of proceedings cannot be unfair for the claimant.[72] Thus, although the CoA did not base its decision on the defendant's status as an SME, it expressly stated that the parties' relative size is a relevant circumstance that should be taken into account when deciding on the change of the language of the proceedings.

The clarifications provided by the CoA of the UPC in the aforementioned order are to be welcomed, namely when it comes to SMEs. The list of criteria to be taken into account when changing the language to that of the patent provides necessary clarity and explicitly refers to the issue of the effects of potential forum shopping on a defendant taken by surprise by an action brought before a division that is remote and in a language they do not master.[73]

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of the Court of First Instance. This request was denied on 26 February 2024. Curio Bioscience lodged an appeal against that decision, which was upheld by the CoA. In its decision, the CoA provided clarification on the interpretation of Article 49(5) UPCA, emphasising that the relevant circumstances must be primarily related to the specific case and the positions of the parties involved. Furthermore, the CoA elucidated what specific considerations are generally not pertinent.

[70] Para 24.

[71] Para 28.

[72] Namely, the CoA observed that both companies are based in the United States, that English is the predominant language in the relevant technological field, and that the evidence presented by both parties, particularly the infringement evidence submitted by 10x Genomics and the defensive materials submitted by Curio Bioscience, is primarily in English. These were identified as being of significant importance.

[73] Anna Lawrynowicz-Drewek, 'Le droit processuel appliqué au contentieux des brevets à l'aune de la Juridiction unifiée du brevet: quel rôle pour la Cour de justice de l'Union européenne?' (PhD thesis, Université de Strasbourg 2024) 332.

Indeed, the new system's structure may paradoxically create extensive opportunities for forum shopping when initiating legal proceedings against an alleged infringer.[74] Article 33(1) of the UPC Agreement is particularly flexible from the patentee's perspective. In practice, this broad range of options can be detrimental to alleged infringers, who may, at the patentee's discretion, be sued before any one of several local, regional, or central divisions.[75] Consequently, should the claimant opt to initiate an infringement action in a division situated geographically distant from the alleged infringer's place of residence or business, the defendant may be obliged to undertake their defence in an unfamiliar country and language, potentially within a remarkably brief procedural timeframe.[76]

By contrast, potential infringers do not enjoy a comparable degree of choice. A revocation action or an action for a declaration of non-infringement must generally be brought before the central division (except where revocation is sought by way of counterclaim). For parties seeking to challenge validity and located outside the two contracting Member States hosting sections of the central division, this requirement may constitute a significant procedural barrier. It seems clear that both claimants and defendants will seek to select a forum that maximises their chances of a favourable outcome, and the choice of division will depend on various factors aligned with the parties' strategic objectives.[77]

Against this backdrop, the CoA's stance on relative party size and the defendant's burden in the *Curio Bioscience* case is particularly relevant for SMEs dealing with a claimant-driven forum and language choices.

Another of the key reform objectives is the UPC's procedural efficiency. The Rules of Procedure aim to ensure that first-instance decisions are made within twelve months of the claim being filed. Although this might compare favourably with the slower pace of national proceedings, such an accelerated timeline could hinder defendants' capacity to prepare ef-

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[74] ibid. See also: Rantasaari (50) 455; Marie Liens, Thomas Leconte and Stéphanie Rollin de Chambonas, 'Practitioners' Views on the UPC and the Opt-out' in Luc Desaunettes-Barbero, Fernand de Visscher, Alain Strowel, Vincent Cassiers (eds), *The Unitary Patent Package & Unified Patent Court: Problems, Possible Improvements and Alternatives* (Ledizioni 2023) 431.

[75] According to Article 33(1) of the UPC Agreement, a patent holder may choose to initiate infringement proceedings before: (i) the local or regional division of the contracting Member State where the actual or threatened infringement has occurred or may occur; (ii) the local or regional division of the contracting Member State where the alleged infringer has their residence or principal place of business; or (iii) the central division, if the defendant has no place of business in a contracting Member State or if the relevant contracting Member State has no local division and does not participate in a regional division.

[76] Liens, Leconte and Rollin de Chambonas (n 74) 432.

[77] cf Zimmerman and others (n 58) on the impact of such practices on the UPC's consolidation as a central forum.

fective defences.[78] Representation before the UPC is, in principle, mandatory[79] and it can be provided either by a lawyer authorised to practise before a court of a contracting Member State,[80] or by 'European patent attorneys who are entitled to act as professional representatives before the European Patent Office pursuant to Article 134 of the EPC and who possess the appropriate qualifications'.[81] In *Suinno Mobile & AI Technologies Licensing Oy v Microsoft Corporation* (UPC_CoA_563/2024), the CoA clarified that in-house attorneys may act as representatives before the UPC. However, a corporate representative with significant administrative or financial authority within the party cannot serve as that party's representative.[82] This interpretation may (still) have a more adverse effect on SMEs than on larger enterprises.[83]

While rapid adjudication enhances legal certainty, it may undermine fairness and access to justice, particularly for SMEs and defendants without substantial in-house patent departments.[84] The UPC's rigorous

[78] Wéry (n 23) provides a detailed comparison with EPO opposition proceedings, in which parties have longer time limits: nine months to oppose a patent after it has been granted and four to six months to respond. By contrast, a UPC defendant has just three months from receiving the statement of claim to file a counterclaim for revocation, supported by full evidence and argumentation. The patentee then has two months to reply, after which further procedural steps follow at one-month intervals. Given the complexity of claim construction, prior-art searches across multiple jurisdictions, expert analyses and laboratory testing, Wéry deems these deadlines to be extremely tight and resource-intensive (ibid, 409–412).

[79] The three exceptions to this rule concern appeals against decisions taken by the EPO in the exercise of its administrative tasks, the filing or withdrawal of an 'opt-out' declaration, or applications for legal aid. See Lawrynowicz-Drewek (n 73) 71.

[80] Art 48(1) of the UPC Agreement.

[81] Art 48(2) of the UPC Agreement. The list of qualified representatives is available on the UPC website: <www.unifiedpatentcourt.org/en/registry/representation/results> accessed 14 June 2025.

[82] According to para 22 of the UPC CoA order issued on 11 February 2025, 'no corporate representative of a legal person, or any other natural person who has extensive administrative and financial powers within the legal person, – whether as a result of holding a high-level management or administrative position or holding a significant amount of shares in the legal person – may serve as a representative of that legal person, regardless of whether said corporate representative of the legal person or natural person is qualified to act as a UPC representative in accordance with Art 48(1) or (2) UPCA'.

[83] In the initial ruling, the court determined that UPC representatives cannot be independent if 'employed or financially dependent on their client or who has, within the represented body, extensive administrative and financial powers'. The case has caused concern among in-house representatives within the patent community, raising also the issue of the particularly harmful impact of such a decision on SMEs, 'who may struggle to afford the costs of outside counsel'. See eg Maura O'Malley, 'IP Bodies Urge UPC to Reconsider Ban on In-house Lawyers Appearing Before It' (*Global Legal Post*, 27 January 2025) <www.globallegalpost.com/news/ip-bodies-urge-upc-to-reconsider-ban-on-in-house-lawyers-appearing-before-it-1488271907> accessed 15 June 2025.

[84] Wéry (n 23) 412–413.

procedures and demanding qualification criteria for representatives may unintentionally favour large multinational firms, thereby undermining one of its founding objectives: to make patent protection more accessible and efficient for all market participants.

Importantly, SMEs are statistically more likely to be defendants than claimants in patent disputes.[85] Many SMEs are litigation-averse, yet the jurisdiction of the UPC will increase their exposure to enforcement actions, given that the UPC's procedural features, such as accelerated timelines, flexible language regimes, forum shopping, and the broad scope of its rulings – may encourage claimants, including non-European entities, to pursue litigation.[86] Arguably, the claimant-friendly nature of proceedings could strain SMEs lacking dedicated legal teams.[87] Moreover, unlike some national systems, the UPC may require an SME defendant to bear not only its own legal and court costs but also those of the prevailing party.[88] Meanwhile, legal aid under the UPC is limited to natural persons.[89] Thus, SMEs that are legal persons cannot obtain legal aid under the UPC framework, and those that lose an infringement action may indeed be liable not only for their own fees but also for a substantial share of their opponent's costs.[90]

For SMEs operating in only one or two jurisdictions, existing national courts may suffice for resolving disputes. Similarly, the EPO opposition procedure may remain a preferred route for challenging patents, as

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[85] See Katrin Cremers and others, 'Patent Litigation in Europe' (2013) ZEW – Centre for European Economic Research Discussion Paper No 13-072, 9–11; Op de Beeck and Kaikkonen (n 31).

[86] Plomer (n 22) 795. Wéry further contends that the predominance of English is likely to enhance accessibility for foreign entities, while at the same time potentially disadvantaging companies originating from smaller European jurisdictions (n 23) 405–406.

[87] Op de Beeck and Kaikkonen (n 31).

[88] Up to 2,000,000 for cases above 50,000,000. See Decision of the Administrative Committee of 24 April 2023 on the scale of ceilings for recoverable costs (D-AC/10/24042023-E) adopted pursuant to Rule 152(2) UPC Rules of Procedure <www.unified-patent-court.org/sites/default/files/upc_documents/d-ac_10_24042023_ceiling_e_for-publication.pdf> accessed 8 June 2025.

[89] Rule 71(1) of the UPC Agreement states: 'A party who is a natural person … may at any time apply for legal aid'. See also the UCP Court of First Instance - Munich Local Division order ORD_4250/2025 of 27 January 2025 (Case UPC_CFI_244/2024 and UPC_CFI_786/2024, Snowpixie Co, Ltd v Golf Tech Golfartikel Vertriebs Gmbh).

[90] Ghidini observes that '[t]he problem of costs is even more relevant as the early experience of litigations before the UPC apparently contradicts the Commission's optimistic assumption with respect to benefits for SMEs (however shielded, by the "protective letter" ex Rule of Procedure 207 of the Agreement, against the risk of issuance of injunctions *inaudita altera parte*). Indeed, the early experience seemingly evidences the UPC as a preferred forum of "multinational' plaintiffs"'. Gustavo Ghidini, 'Review of European Patent Law: The Unified Patent Court and the European Patent Convention' [Book review] (2025) 74 GRUR Int 302, 303.

it typically incurs lower costs than UPC litigation.[91] Although SMEs are eligible for a 60% reduction in UPC court fee**s** for infringement actions,[92] litigation before the UPC is nonetheless likely to be costlier than in some national courts.[93]

It is important to reiterate that the UPC has jurisdiction over EPs as well, unless an opt-out has been filed in due time.[94] In this context, maintaining an invalid patent risks substantial liability: loss in revocation proceedings entails court and adverse party costs, while the revocation itself may simultaneously affect up to 18 States: competitors – whether or not they hold patents – can, by a single action, challenge a substantial part of a patent portfolio. Consequently, it may be preferable for the patent holder to defer participation in the new system and instead rely on the opt-out safeguard provided by the UPC Agreement.[95] Larger corporations may mitigate this risk by combining UPs with divisional EPs according to the strength of the underlying inventions,[96] but such strategies are often financially inaccessible to SMEs.[97]

As observed by some authors, the UP/UPC framework is likely to deliver its greatest value to large (foreign) multinationals – entities capable of internalising multi-jurisdictional litigation risks and deploying sophisticated portfolio-management tactics – while offering comparatively limited benefit to innovative European SMEs, which may face increased exposure to infringement and revocation actions under a novel and com-

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[91] Op de Beeck and Kaikkonen (n 31).

[92] Rule 370(8) of the Rules of Procedure of the Unified Patent Court (Decision of the Administrative Committee of the UPC, 8 July 2022, entered into force 1 September 2022) (UPC Rules of Procedure) <rop_en_25_july_2022_final_consolidated_published_on_website.pdf> accessed 15 June 2025. According to Art 63 para 3 of the UPC Agreement '…The Court fees shall be fixed at such a level as to ensure a right balance between the principle of fair access to justice, in particular for small and medium-sized enterprises, micro-entities, natural persons, non-profit organisations, universities and public research organisations and an adequate contribution of the parties for the costs incurred by the Court, recognising the economic benefits to the parties involved, and the objective of a self-financing Court with balanced finances. The level of the Court fees shall be reviewed periodically by the Administrative Committee. Targeted support measures for small and medium-sized enterprises and micro entities may be considered'.

[93] Wéry (n 23); Op de Beeck and Kaikkonen (n 31). See also, for example, Barker Brettell, 'How Do I Decide Whether to Opt Out of the Unified Patent Court' <www.barkerbrettell.co.uk/how-do-i-decide-whether-to-opt-out-of-the-unified-patent-court/> and Mewburn Ellis, 'The Unitary Patent and the Unified Patent Court Explained' <www.mewburn.com/law-practice-library/the-eu-unitary-patent-and-the-unified-patent-court-explained> accessed 8 June 2025.

[94] cf (n 52).

[95] Arezzo (n 8) 214.

[96] cf Arezzo (n 8) 216.

[97] Op de Beeck and Kaikkonen (n 31).

plex judicial architecture.[98] The UP's extensive geographical reach increases the likelihood of conflicts that had previously not existed, and a patentee's decision to secure a UP may affect competitors in markets previously deemed irrelevant, prompting revocation actions or oppositions that would not otherwise have arisen.[99]

Finally, as a multinational judicial body, the UPC necessarily synthesises diverse national legal traditions. A case in point is the UPC CoA's recent decision on public access to documents – interpreting Rule 262(1)(b) of the Rules of Procedure more broadly than earlier orders of the Munich Section and departing from established national practices.[100] This ruling marks a significant development in patent-law transparency and may shape future litigant behaviour as the UPC's jurisprudence and institutional credibility continue to evolve.[101]

The UPC's early caseload vividly illustrates its rapid operationalisation:[102] since the Court of First Instance began work on 1 June 2023, it had registered 883 cases by 31 May 2025, underscoring both its immediate relevance and the volume of disputes directed into the new system.[103] However, the data published in the UPC's annual report and on its website do not permit the identification of SMEs as parties,[104] nor do they support full-text searching of the case law or provide timely English translations that would allow insights into SME involvement in UPC litigation. Consequently, structural and doctrinal analysis must, for the time being, substitute for robust empirical assessments of SME participation.

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[98] Plomer (n 22) 795. See also Xenos, 'Impact of the European Patent System' (n 22) 27 and Ghidini (90). Furthermore, recent EPO statistics show that large multinationals indeed are among the UP top users (n 46).

[99] Wéry (n 23); Op de Beeck and Kaikkonen (n 31).

[100] Galeotta, Khuchua and Stierle (n 9) 31.

[101] ibid.

[102] cf van Zimmeren, Kleizen and Popelier (n 58) 93. See also Mathieu Klos, 'EPO Statistics Show Surge in Unitary Patents' (JUVE Patent, 20 February 2025) <www.juve-patent.com/people-and-business/epo-statistics-show-surge-in-unitary-patents/> accessed 14 June 2025.

[103] See Unified Patent Court, 'Case Load of the Court Since the Start of Operation in June 2023: Update 31 May 2025 <www.unifiedpatentcourt.org/sites/default/files/upc_documents/Case%20load%20of%20the%20Court_31%20May%202025.pdf> accessed 15 June 2025.

[104] cf Unified Patent Court, Annual Report 2024 <www.unified-patent-court.org/sites/default/files/upc_documents/UPC_AR_2024_HD_digital_version_double_page_compressed.pdf> accessed 8 June 2025. On 12 May 2025, we submitted to the UPC Registry a request for information regarding litigant profiles and the identification of SMEs (or confirmation of the absence thereof). As of the date of submission of this paper, no response has been received.

When considered as a whole, these features indicate that while the UPC's objective is to reduce fragmentation and enhance access to high-quality patent adjudication, its practical implementation is likely to be most beneficial to large corporations that possess the capacity to absorb litigation risk and invest in advanced procedural and portfolio strategies. Conversely, SMEs may encounter heightened exposure to infringement and revocation actions, linguistic and forum-related disadvantages, and shoulder elevated relative costs and risks within the new system.

In light of these heightened risks, SMEs need to strategically evaluate all available alternatives, including the continued filing of national patents.[105] Although national rights may lack the pan-European coverage of a UP, they remain outside the UPC's jurisdiction and afford greater flexibility in tailoring costs and risks to an enterprise's specific market priorities.[106]

4 Conclusion

Given the current transitional landscape, the future trajectory of patent strategies in Europe remains uncertain. Organisations are likely to construct layered portfolios, judiciously combining traditional EPs, which result in bundles of national rights, with patents granting unitary effect under the UPP regime. Moreover, a multi-national judicial body like the UPC will inevitably reflect a range of legal and cultural perspectives. Consequently, the institutional novelty of the UPC and the evolving nature of its jurisprudence are expected to give rise to divergent approaches. Risk-averse patentees may thus prefer to opt out of UPC jurisdiction where allowed, thereby avoiding centralised revocation exposure. Conversely, firms possessing robust legal infrastructures and greater financial flexibility might tailor their strategies, leveraging both UPC and EP routes according to invention strength, desired territorial scope, and risk tolerance.

The increasing adoption of unitary patents by SMEs, as evidenced by recent EPO statistics, will almost certainly be accompanied by a corresponding increase in infringement and revocation proceedings before the UPC in the future. While the UP/UPC framework presents considerable strategic opportunities for innovative SMEs, it also brings a series of unprecedented procedural, financial, and legal challenges. SMEs should

[105] See Daniel Borgogni, 'The Doctrine of Equivalents at the Unified Patent Court: A Comparative Analysis of the Main EPC Jurisdictions and a Shot at Harmonization' (2025) 74(4) GRUR International 331, 339; Arezzo (n 8) 216.

[106] Arezzo (n 8) 216.

therefore undertake a thorough appraisal of all available options and adjust both their IP-filing strategies and their dispute-readiness to thrive in this transformed European patent landscape.

Ultimately, the attractiveness of the UPC/UPP system for any given SME will depend on a number of factors, most notably the composition and maturity of its patent portfolio, its risk tolerance and resource base, and the extent to which future case law and trust in this nascent judicial system solidify. At present, with jurisprudence still in its emerging phase, it remains too early to draw definitive conclusions.

Suggested citation: I Božac, 'Unitary Patent and the Unified Patent Court: Attractive for SMEs?' (2025) 21 CYELP 31.

THE EU PHARMACEUTICAL PACKAGE: WILL IT STRIKE A BALANCE BETWEEN STIMULATING RESEARCH AND FACILITATING EQUAL ACCESS?

Tomislav Sokol *

Abstract: Through the revision of EU pharmaceutical legislation, the Commission has tried to solve the problem of unequal access to medicines within the EU, while also making Europe more competitive in the global pharmaceutical market. Even though there are some positive aspects in the Commission proposal, such as cutting the deadlines for conducting the marketing authorisation procedure, there are also issues which can be seen as problematic and representing a step backwards in terms of promoting innovation within Europe. The Parliament is taking a more realistic and balanced approach between the need to stimulate research and innovation on one hand, and to facilitate equal access to medicines on the other. In relation to the issue of antimicrobials, the Parliament is combining a number of push and pull incentives, thereby motivating the industry to create new antimicrobials, but also ensuring these antimicrobials are finally developed and made accessible for European patients. All this means that the final text aiming at striking a balance between stimulating innovation and enabling equal access should follow, as far as possible, the balanced approach of Parliament. The revision of the pharmaceutical legislation is not a silver bullet to resolve all the problems relating to equal access. The revision of the Transparency Directive, which would at least accelerate national pricing and reimbursement decisions and set a strong enforcement mechanism, would definitely improve patients' equality and make new medicines more accessible for them. Finally, the revision of the cross-border healthcare legislation, which would simplify the legal framework and make it more understandable for patients, would provide all European citizens with the same, or at least a similar, opportunity to avail themselves of best-quality treatments and medicines anywhere in the EU.

Keywords: cross-border healthcare, equal access to medicines, innovation, pharmaceutical legislation, regulatory data protection, research, transferable exclusivity voucher.

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1 Introduction

Healthcare primarily belongs to the competences of the Member States of the European Union. It is prescribed in Article 168 of the Treaty on the Functioning of the European Union (TFEU) that the organisation and financing of healthcare is a national prerogative, while European actions in this field are to be limited to supporting and complementing national activities and policies.

One area which represents an exception to the described situation concerns the regulation of medicines (medicinal products, pharmaceuticals). According to Article 168 TFEU, the European Parliament and the Council, acting via the ordinary legislative procedure, may adopt 'measures setting high standards of quality and safety for medicinal products and devices for medical use'. The precursor of Article 168, Article 152 of the Treaty Establishing the European Community (EC Treaty), was used, along with Article 95 of the EC Treaty (the current Article 114 TFEU) on harmonising the internal market, as the legal basis for the adoption of existing pharmaceutical legislation.[1] This legislation represents the legal framework for the authorisation and placing on the market of certain categories of priority innovative medicines, evaluation being conducted by the European Medicines Agency (EMA) with the final decision being made by the European Commission, through the centralised Union procedure.[2]

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[1] European Parliament and Council Regulation (EC) 726/2004 of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004] OJ L136/1. See also European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67 and European Parliament and Council Regulation (EU) 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC [2014] OJ L158/1. See also J Borg and others, 'Strengthening and Rationalizing Pharmacovigilance in the EU: Where Is Europe Heading to?' (2011) 34 Drug Safety 187, 193; G Permanand, E Mossialos and M McKee, 'Regulating Medicines in Europe: The European Medicines Agency, Marketing Authorisation, Transparency and Pharmacovigilance' (2006) 6 Clinical Medicine 87, 88; J Regnstrom and others, 'Factors Associated with Success of Market Authorisation Applications for Pharmaceutical Drugs Submitted to the European Medicines Agency' (2010) 66 European Journal of Clinical Pharmacology 39, 40; S Vogler and others, 'Pharmaceutical Policies in European Countries in Response to the Global Financial Crisis' (2011) 4 Southern Med Review 69.

[2] Medicines which are subject to the centralised procedure include: medicinal products which have been developed by means of 'recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, hybridoma and monoclonal antibody method'; 'advanced therapy medicinal products'; medicinal products containing a new active substance for treating 'acquired immune deficiency syndrome, cancer, neurodegenerative disorder, diabetes, auto-immune diseases and other immune dysfunctions, viral diseases'; orphan medicinal products. See Regulation 726/2004 (n 1) Annex I.

According to the Commission, the said legislation has resulted in the authorisation of 'safe, efficacious and high-quality medicinal products'.[3] However it has not resolved the problem of unequal access to medicines for patients across the European Union. To tackle this problem, the Commission has proposed a major revision of the legal framework, with two legislative proposals, a directive and a regulation.[4] Among others, two specific objectives of the reform have been stated: making sure 'all patients across the EU have timely and equitable access to safe, effective, and affordable medicines' and offering 'an attractive innovation and competitiveness friendly environment for research, development, and production of medicines in Europe'.[5] The aim of this paper is to determine whether the said reform is fit for achieving the mentioned objectives and which improvements should be undertaken to strike the right balance between them.

The paper starts with an analysis of the current situation in the EU relating to access to medicines on one hand and facilitating innovation on the other. It then analyses the reform proposed by the Commission and the position adopted by the European Parliament in the first reading aiming to improve the proposal. The paper then compares the two approaches and tries to determine how to achieve the right balance between innovation and access at the Union level.

2 State of play

Throughout its existence, EU pharmaceutical legislation, regulating conditions for authorising medicines and placing them on the European market, has been successful in terms of ensuring the safety and efficacy of medicines available for patients in the European Union.[6] According to

[3] Commission, 'Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC' COM (2023) 192 final, 26 April 2023 (Directive Proposal) Explanatory Memorandum.

[4] Commission, 'Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006' COM (2023) 193 final, 26 April 2023 (Regulation Proposal).

[5] See Regulation Proposal (n 4) Explanatory Memorandum.

[6] See Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Reform of the pharmaceutical legislation and measures addressing antimicrobial resistance' (2024) 1. On the different stages of development and marketing of new medicines, called the 'cycle of innovation', see G Bache, M Flear and T Hervey, 'The Defining Features of the European Union's Approach to Regulating New Health Technologies' in M Flear and others (eds), *European Law and New Health Technologies* (OUP 2013) 11–12.

the European Federation of Pharmaceutical Industries and Associations (EFPIA), EMA has, since it was founded in 1995, given recommendations to the European Commission to authorise more than 1,500 new medicines, and the Union regulatory framework has helped attract more than EUR 41 billion in annual investments in research and development by the pharmaceutical industry in the EU.[7] EU regulations can be a powerful stimulus for innovation in general,[8] and there are arguments that with pharmaceutical legislation this has generally been the case, with 1,160 medicines being authorised from 2005 to 2020 through the centralised procedure (through EMA and the European Commission) and more than 17,000 medicines, primarily generic ones, being authorised via mutual recognition and decentralised procedures during the said period.[9]

There is also special legislation in two priority areas, namely rare diseases and children's diseases.[10] These rules have been developed to

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[7] See EFPIA, 'Regulatory Road to Innovation' <www.efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/regulatory-road-to-innovation/#> accessed 24 July 2024.

[8] See J Pelkmans and A Renda, 'How Can EU Legislation Enable and/or Disable Innovation' (2014) European Commission (July) 1. Support for the competitiveness of the European pharmaceutical industry and securing a high level of innovation have been acknowledged as some of the main policy objectives of the EU in the pharmaceutical sector also in the literature. See L Hancher, 'The EU Pharmaceuticals Market: Parameters and Pathways' in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010) 635–636.

[9] See Commission, 'Commission Staff Working Document Impact Assessment Report Accompanying the documents Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006' (2024) 17. This procedure can be summarised as follows: 'Pharmaceutical companies that wish to follow the centralised procedure submit a dossier to the European Medicines Agency (EMA). The dossier is assessed by the Committee for Medicinal Products for Human Use (CHMP), the EMA's medicines assessment committee. The CHMP has in principle 210 days to reach a final decision. This period may be suspended to allow the company to answer questions. Companies can also give verbal explanations relating to the dossier they have submitted. The CHMP produces an opinion which is sent to the European Commission and used in reaching the final decision. The European Commission usually adopts the CHMP's opinion in all respects. Once a favourable decision has been made, the Summary of Product Characteristics (SmPC) and the package leaflet are determined. A European Public Assessment Report (EPAR) is produced. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. The EPAR can be found on the EMA website'. See to that effect Medicines Evaluation Board, 'Centralised Procedure' <https://english.cbg-meb.nl/topics/mah-centralised-procedure> accessed 24 July 2024. On the approval process, see, also, I Abed, 'The Approval Process of Medicines in Europe' (2014) 23 Medical Writing 117.

[10] European Parliament and Council Regulation (EC) 141/2000 of 16 December 1999 on orphan medicinal products [2000] OJ L18/1 (Orphan Drugs Regulation). See also Euro-

direct investments into research and the development of orphan medicinal products and medicinal products for paediatric use. According to the Commission, the said regulatory framework led to redirecting investments into previously neglected areas through a combination of rewards, incentives and obligations. This is something Member States could not have done by themselves due to the small number of patients affected, as well as market fragmentation.[11] The EU has, until now, authorised more than 200 orphan medicines for patients suffering from rare diseases which have become available faster and more broadly for EU patients and has facilitated the creation of a 'paediatric research environment' in the Union.[12]

The main regulatory tools for stimulating innovation and the development of medicines in the EU are market exclusivity and regulatory data protection. Regulatory data protection means that an applicant who wants to obtain marketing authorisation cannot rely on the data from the file concerning previously authorised medicines during the protection period. This represents an important incentive for the companies developing innovative medicines, enabling them to have an essentially privileged market position within the said time. According to Regulation

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pean Parliament and Council Regulation 1901/2006 (EC) of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 [2006] OJ L378/1 (Paediatric Regulation). Rare diseases include life-threatening or very serious conditions which affect no more than five in 10,000 people in the EU. See Regulation 141/2000 Art 3 and Commission, 'Orphan Medicinal Products' <https://health.ec.europa.eu/medicinal-products/orphan-medicinal-products_en> accessed 24 July 2024. According to the paediatric medicines legislation, applications for marketing authorisation have to include paediatric investigation plans (PIPs), unless a waiver or a deferral has been granted. See to that effect Regulation 1901/2006 Art 7.

[11] See Commission, 'Commission Staff Working Document Executive Summary of the Evaluation Joint Evaluation of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use, and Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products' (2020) 2. On the other hand, there are also some differing views arguing that progress has not been satisfactory, especially at the very beginning. See to that effect R Joppi, V Bertele and S Garattini, 'Orphan Drugs, Orphan Diseases. The First Decade of Orphan Drug Legislation in the EU' (2013) 69 European Journal of Clinical Pharmacology 1009, 1014. The paediatric medicines legislation has had minor impact on the development of orphan medicinal products for children, resulting in longer time to market authorisation, but has enabled the further paediatric development of medicines still off-label to children. See to that effect A R Kreeftmeijer-Vegter and others, 'The Influence of the European Paediatric Regulation on Marketing Authorisation of Orphan Drugs for Children' (2014) 9 Orphanet Journal of Rare Diseases 1, 15. In the first ten years of the paediatric medicines legislation, 273 new medicines appropriate for use in children were authorised in the European Union. See to that effect P A Tomasi and others, 'Enabling Development of Paediatric Medicines in Europe: 10 Years of the EU Paediatric Regulation' (2017) 19 Paediatric Drugs 505.

[12] See Commission (n 10) and Commission (n 11) 2.

726/2004, authorised medicines can benefit from an eight-year period of data protection and a ten-year period of marketing protection which may be extended to eleven years if there is a new therapeutic indication bringing significant clinical benefit when compared to existing therapies.[13]

Furthermore, it is prescribed by Directive 2001/83 that a medicine does not have to undergo pre-clinical tests and clinical trials if the applicant company is able to prove that the pharmaceutical in question is a generic or an authorised reference medicine. Such a generic medicine may not be placed on the market for ten years from the initial authorisation of the reference product, which may be extended to a maximum of eleven years if there is a new indication bringing significant clinical benefit.[14] In addition, according to the Orphan Drugs Regulation, when a medicine has been authorised with an orphan designation, the EU and the Member States may not grant marketing authorisation or extend an existing marketing authorisation, for the same therapeutic indication, relating to a similar medicine, for a period of ten years.[15] This period may be extended to twelve years when the results of studies carried out are reflected in the summary of the product characteristics addressing the paediatric population and completed in accordance with an agreed paediatric investigation plan.[16]

It can be seen that an elaborate system of incentives for the development of new medicines has been established in the EU, with significant success. The described EU legal framework has generally contributed to stimulating innovation and the development of new medicines in the European Union and generally resulted in an increased number of marketing authorisations in the Union territory. This sounds pretty positive, but, if one looks at global developments and the competitiveness of the

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[13] See Regulation 726/2004 (n 1) Art 14.

[14] See Directive 2001/83 (n 1) Art 10. See on this issue, for example, EFM 't Hoen and others, 'Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation' (2017) 10 Journal of Pharmaceutical Policy and Practice 1, 3; and C Schoonderbeek and B Jong, 'Regulatory Exclusivities for Medicinal Products for Human Use in the EU' (2015) 5 Pharmaceutical Patent Analyst 5, 5–6.

[15] This period may be cut to six years 'if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, inter alia, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity'. See Orphan Drugs Regulation (n 10) Art 8. On this topic, see, for example, E Brosset and A Mahalatchimy, 'EU Law and Policy on New Health Technologies' in T Hervey, C Young and L Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar 2017) 213–214.

[16] See Paediatric Regulation (n 10) Art 37. A paediatric-use marketing authorisation can also be obtained for medicines developed specifically for children. If it is granted, the same eight years' data protection and 10 years' market protection periods under Regulation 726/2004 (n 1) Art 14 will apply. See Paediatric Regulation (n 10) Arts 1, 30, 38.

EU in that setting, the picture looks slightly different. According to a report prepared for EFPIA in 2002, the amount of investment made by pharmaceutical companies in the development of new medicines in the United States and Europe differed by only EUR 2 billion in favour of the US, while in 2020 that difference extended to EUR 25 billion. China has also become very active in this area and narrowed the enormous gap which had existed before, by increasing production capacity and focusing on investments in research hubs and clinical trials. Private expenditure for R&D in China grew fivefold between 2010 and 2020. Of the total R&D investments made in the United States, Europe, Japan and China in 2020, 31% took place in Europe, while the figure was 41% in 2001. During the same period, China increased its share from 1% to 8%. This means that, even though the expenditure in Europe is increasing, the rate of that increase is much slower than it is for the main global competitors.[17]

Furthermore, rapidly advancing new developments in the pharmaceutical sector, including, for example, personalised medicines, have set new challenges for the ever more complex system run by EMA. The review time of marketing authorisation by EMA has been significantly longer than by the Food and Drug Administration (FDA) in the United States. For anticancer medicines undergoing the standard regulatory approval procedure, the review time was 304 days (median) by the FDA and 343 days (median) by the EMA, while the difference was even bigger (123 days) for expedited regulatory approval procedures.[18]

Obtaining marketing authorisation at the EU or national level does not mean that a medicine is already available for patients within the Union. Most medicines become available after they have been placed on the list of medicines covered by the national social security system (health insurance or a national health service)[19] in a given Member State. These decisions fall solely within the powers of the Member States, ac-

[17] See T Wildson and others, 'Factors Affecting the Location of Biopharmaceutical Investments and Implications for European Policy Priorities' (2022) 1, 2, 11. On the emergence of China as a major global competitor, see A C Santos Akkari and others, 'Pharmaceutical Innovation: Differences between Europe, USA and "Pharmerging" Countries' (2016) 23 Gestão & Produção 365, 377.

[18] See F da Costa Gonçalves, E Demirci and A Zwiers, 'A Detailed Analysis of Expedited Regulatory Review Time of Marketing Authorization Applications for New Anticancer Drugs in the US and EU' (2022) 15 Clinical and Translational Science 1959, 1962.

[19] Social security means a statutory system based on the principle of solidarity, providing protection against a lack of earnings, or against particular costs in the event of the occurrence of a recognised social risk, such as needing healthcare. See Danny Pieters, *Social Security: An Introduction to the Basic Principles* (2nd edn, Kluwer Law International 2006) 2–3, 87–88. Social security coverage has different dimensions: breadth relates to the extent of the population covered; depth concerns the number and character of the covered services; height means the extent (percentage) of the costs of the covered services. See to that effect

cording to Article 168 TFEU, while Union legislation sets some basic principles and procedural requirements on how the national procedures on making such decisions are to be carried out.[20]

Data show that there are huge gaps in terms of the availability of medicines between different Member States, the situation generally being worse in smaller eastern countries of the EU. For instance, according to the European Commission, 152 new medicines were authorised between 2016 and 2019 through the centralised EU procedure and 133 of them were accessible in Germany, while in Member States like Romania or the Baltic countries, fewer than 50 of these were available to patients in 2020. The average time of access after marketing authorisation, for example, was four months in Germany, compared to two years or more in Romania.[21] According to EFPIA's latest data from the beginning of 2024, the access gap between the highest and lowest Member State is 84% in the four-year period. According to the same data, the total number of medicines (authorised by the EU from 2019 to 2022) available to patients in EU Member States varies from 147 out of 167 in Germany to only six in Malta. The second-worst performing Member State is Lithuania with 14.[22] The situation is even worse for cancer medicines where in Germany the rate of availability is 46 out of 48 centrally approved oncology medicines, while in Lithuania there are only three, and none in Malta.[23] For orphan medicines, 56 out of 63 centrally authorised medicines are available in Germany, and only one in Lithuania, three in Malta, etc.[24] Thus, it can be seen that inequality of access to innovative medicines in the European Union is quite severe, creating essentially first- and second-class citizens in terms of healthcare protection. The background to this is very complex, as are the potential solutions, which will be further explained in the following sections as part of the discussion on the potential actions that can be taken at the EU level on the said issue.

S Smith, 'The Irish "Health Basket": A Basket Case?' (2010) 11 European Journal of Health Economics 343, 344.

[20] On the Member States' approval process for the coverage of medicines, see Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems [1989] OJ L40/8 (Transparency Directive).

[21] See Commission (n 9) 17–18.

[22] See M Newton and others, 'EFPIA Patients WAIT Indicator 2023 Survey' (2024) 2, 9–10.

[23] For example, in the non-EU country of North Macedonia, seven oncology medicines, authorised between 2019 and 2022, are available. This is two times more than in Lithuania. See Newton and others (n 22) 18–19.

[24] See Newton and others (n 22) 26–27. In general, patients in Germany, France and the Scandinavian countries are able to access larger numbers of medicines in a shorter period than in other Member States. See to that effect A Detiček and others, 'Patient Access to Medicines for Rare Diseases in European Countries' (2018) 21 Value in Health 553, 559.

A specific issue concerns the development of new antibiotics and anti-microbial resistance (AMR). Antimicrobial medicines are crucial for the protection of public health in today's world and form the backbone of modern healthcare systems. However, their timespan is limited, since, over time, mutated pathogens which survive exposure to these medicines result in the pharmaceuticals' inefficiency due to AMR.[25] Between 2016 and 2020, according to a technical report by the European Centre for Disease Prevention and Control (ECDC), AMR was responsible for a number of attributable deaths in the EU, ranging from 30,730 in 2016 to 38,710 in 2019.[26] Conversely, the pipeline for the development of new antimicrobials which could tackle the resistant pathogens is very weak, because 'an apparent market failure and the lack of market incentives has led to underinvestment by big pharma companies in new compounds'.[27]

It can be seen from the analysis presented above that the EU legal framework regulating conditions for the marketing of medicines in the common European market has generally been successful in terms of ensuring the safety and efficacy of medicines in the Union. It has also produced some results in terms of stimulating research and the development of new pharmaceuticals, through a system of incentives relating to regulatory data protection and market protection. However, the EU is increasingly lagging behind global competitors in the field of medical innovation, namely the USA, while China is accelerating and reducing the gap at an increasing rate. In terms of access to medicines, extreme inequalities persist among the Member States of the EU, with smaller countries in eastern and southern Europe particularly lagging behind larger national markets in the north and west. A special problem concerns market failure to develop new antimicrobials, making the EU unable to tackle the major public health problem of deaths attributable to AMR. The described situation sets the stage for an in-depth reform of the relevant EU legislation which will be presented next.

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[25] See R Bonnifield and A Towse, 'Estimating the European Union's Return on Investment from an Ambitious Program to Incentivize New Antibiotics' (*Center for Global Development*, 8 December 2022) 1.

[26] See H Merk and others, 'Assessing the Health Burden of Infections with Antibiotic-Resistant Bacteria in the EU/EEA 2016–2020' (2022) European Centre for Disease Prevention and Control 4.

[27] See Commission (n 9) 17. On the issue of AMR-attributable deaths, see, for example, A Casini and others, 'Attributable Deaths and Disability-adjusted Life-years Caused by Infections with Antibiotic-resistant Bacteria in the EU and the European Economic Area in 2015: A Population-level Modelling Analysis' (2019) 19 The Lancet Infectious Diseases 56, 59.

3 Commission proposal

Reform of EU pharmaceutical legislation was unveiled on 26 April 2023. It consists of two intertwined legal instruments: the Directive Proposal and Regulation Proposal. It has a dual legal basis, Article 168 TFEU and Article 114 TFEU, reflecting the different general objectives the Commission is trying to accomplish: guaranteeing 'a high level of public health by ensuring the quality, safety and efficacy of medicinal products for EU patients' and harmonising 'the internal market for the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States'. Four specific objectives are stated, two of which have already been mentioned and are the focus of this paper (facilitating access and stimulating innovation), in addition to ensuring security of supply for all patients in the EU and making medicines more environmentally sustainable.[28]

The first important area which needs to be mentioned concerns regulatory data protection as one of the main tools for stimulating medical innovation and research in the European Union. Here, the Commission has proposed a major reform of the existing system of incentives. It consists of reducing the baseline period of data protection from eight to six years, with an additional two years granted for supplying the medicine in every Member State, six months for an 'unmet medical need', six months for conducting comparative clinical trials, and one year for an additional therapeutic indication where the medicine provides a significant clinical benefit in comparison with existing therapies.[29] Within the said periods, no one can refer to the same data to make a subsequent application for marketing authorisation and may not place on the market the medicine concerned by this subsequent marketing authorisation for a period of two years after the expiry of the regulatory data protection.[30]

There are two main novelties in the proposed reform. The first relates to emphasising the modulation of incentives, whereby the duration of the regulatory data protection period heavily depends on fulfilling additional conditions in the areas which are considered a policy priority. The other consists of tying these additional incentives to releasing and continuously supplying the medicine into the supply chain 'in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorisation is valid' within two years of obtaining marketing authorisation (three

[28] See Directive Proposal (n 3); and the Regulation Proposal (n 4) Explanatory Memorandum.

[29] See Directive Proposal (n 3) Arts 81–82.

[30] ibid, Art 80.

years for SMEs, not-for-profit entities, and undertakings which have received no more than five centralised marketing authorisations).[31]

To obtain the prolongation, the holder of the marketing authorisation (a pharmaceutical company) has to apply for a variation of the marketing authorisation. As part of this application, it has to submit documents from the Member State concerned showing that the mentioned condition of supplying the medicine has been met, or waiving the said requirement. The condition of supplying the medicines (market launch) is considered to have been met if a positive reimbursement decision has been made by the national social security system of the said Member State. National authorities would need to confirm within 60 days of the marketing authorisation holder's request that it complies with the prescribed condition, issue a statement of non-compliance with reasoning, or alternatively provide a statement of non-objection for the prolongation of the regulatory data protection period. If the Member State does not respond within the said deadline, it will be considered that it has provided a statement of non-objection.[32]

Another important issue concerns the concept of unmet medical need affecting the incentives provided. According to the Commission proposal, a medicine addresses an unmet medical need if at least one of its therapeutic indications concerns 'a life threatening or severely debilitating disease' and the following conditions are met: there is no authorised medicine in the EU for treating such a disease, or, even though there are authorised medicines, there is still high morbidity and mortality in the Union; the use of the medicine 'results in a meaningful reduction in disease morbidity or mortality for the relevant patient population'.[33]

In the area of rare diseases, big changes are envisaged as well. The most important one relates to the modulation of incentives and the reduction of the baseline market exclusivity period for orphan medicines, in a similar manner as with regulatory data protection. A medicine is considered an orphan medicine if it treats a life-threatening or chronically debilitating condition and the said condition does not affect more than five in 10,000 persons in the EU, if there is no satisfactory method of prevention, diagnosis, or treatment of the said condition that has been authorised in the EU or, where it does exist, the medicine in question would be of significant benefit to those affected by that condition.[34]

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[31] ibid, Arts 81–82.

[32] ibid, Art 82.

[33] ibid, Art 83.

[34] See Regulation Proposal (n 4) Art 63.

The baseline market exclusivity period is set at nine years, a reduction from the currently prescribed ten years, while this has been extended to ten years for medicines addressing high unmet medical need.[35] An additional year is to be given if the market launch condition is met.[36] A medicine is considered to address a high unmet medical need if there is no medicine authorised in the EU for such a condition or where, despite medicinal products being authorised, the applicant proves that the orphan medicine, in addition to providing a significant benefit, 'will bring exceptional therapeutic advancement'; and the use of the orphan medicine 'results in a meaningful reduction in disease morbidity or mortality for the relevant patient population'.[37]

Unlike in the other areas where the baseline incentives have been reduced, the Commission has proposed additional incentives to stimulate investments into the development of new antimicrobials and to tackle the existing market failure. Tackling the problem of the lack of new antimicrobials is important in terms of stimulating innovation and bringing the new antimicrobials to European patients. The main novelty here concerns the transferable exclusivity voucher, created to incentivise innovation in developing new antimicrobials. This voucher will provide an additional year of regulatory data protection to the developer of a priority antimicrobial, which the developer can either use for its own medicines or sell it to another marketing authorisation holder. A priority antimicrobial is one which provides a significant clinical benefit concerning antimicrobial resistance and has at least one of the following characteristics:

(a) it represents a new class of antimicrobials;

(b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;

(c) it contains an active substance not previously authorised in a medicinal product in the Union that addresses a multi-drug resistant organism and serious or life threatening infection.[38]

Finally, an important change relates to the procedural provisions of the pharmaceutical legislation with respect to the deadlines for the authorities concerned to make the relevant decisions in the process of authorising new medicines in the EU. According to the proposed reform, EMA will have 180 instead of 210 days for conducting its evaluation and, for medicines which are of major public health or therapeutic innovation

[35] ibid, Art 71.

[36] ibid, Art 72.

[37] ibid, Art 70.

[38] ibid, Art 40.

interest, only 150 days.[39] For the authorisation, the Commission should in principle make the final decision within 46 instead of 67 days.[40]

The described reform essentially means that baseline incentives for medical research and innovation have been reduced and a large part of them is tied to launching a medicine in all the Union Member States. This represents a big task for the companies developing new medicinal products, especially smaller companies, even though they have one additional year to fulfil the market launch condition in all the Member States. Besides, the wording is unclear on what happens in situations where the request for reimbursement has been made by the marketing authorisation holder but the national social security authorities have not made the relevant decision. It is prescribed that the Member State concerned can waive the condition of launching the medicine in their own territory, but there is no clear duty to do so. Thus, there is much uncertainty on whether marketing authorisation holders could be effectively penalised for reasons outside their control. The provisions on unmet medical need are not defined clearly and broadly enough and could exclude from additional incentives, for example, medicines improving the quality of life of a significant number of patients. A similar situation also exists with orphan medicines and market exclusivity. On the other hand, the introduction of the transferable exclusivity voucher and the reduction of time for making marketing authorisation decisions can be seen as steps forward in stimulating research and innovation in the EU, with some concerns, relating to the voucher's complexity and costs, which will be further addressed in the following paragraphs.

4 Parliament position

After several months of negotiations, the position of the European Parliament in the first reading was adopted on 10 April 2024.[41] On regulatory data protection, the Parliament proposes a baseline period of seven years and six months, which is one year and six months longer than

[39] ibid, Art 6 and Regulation 726/2004 (n 1) Art 6.

[40] See Regulation Proposal (n 4) para 49.

[41] See European Parliament legislative resolution of 10 April 2024 on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM(2023)0192 – C9-0143/2023 – 2023/0132(COD)) (Parliament Position on the Directive Proposal) and European Parliament legislative resolution of 10 April 2024 on the proposal for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM(2023)0193 – C9-0144/2023 – 2023/0131(COD)) (Parliament Position on the Regulation Proposal).

proposed by the Commission. An additional twelve months is proposed to be granted for an 'unmet medical need', six months for conducting comparative clinical trials and six months if a significant share of research and development, both preclinical and clinical, has taken place within the EU and at least partly in collaboration with public entities, such as university hospitals, located in the Union.[42] A general cap of an eight years and six months maximum period of regulatory data protection is also proposed[43] in order to prevent the accumulation of very long periods of data protection. The obligation not to place on the market the medicine concerned by the subsequent marketing authorisation for a period of two years after the expiry of the regulatory data protection is to be extended by one year if the marketing authorisation holder obtains, during the data protection period, an authorisation for an additional therapeutic indication, with a significant clinical benefit.[44]

The whole part on market launch conditionality has been deleted.[45] The deleted provision has been replaced by a duty, on the part of the marketing authorisation holders, to submit an application for pricing and reimbursement upon a request by a national social security system. This application has to be made within one year after making the request (two years for SMEs, not-for-profit entities, and undertakings which have received no more than five centralised marketing authorisations).[46] Member States have to decide on pricing and reimbursement within the deadlines set by Directive 89/105 (Transparency Directive)[47] and, if they fail to do so, the marketing authorisation holder's obligation is considered to have been fulfilled.[48] For orphan medicines and advanced therapy medicines, the marketing authorisation holder may make the application for pricing and reimbursement only in those Member States with a relevant patient population. Member States may also waive the marketing authorisation holder's obligation to make the application.[49]

Relating to rare diseases, the baseline market exclusivity period is set at nine years, as in the Commission proposal, while this has been extended to eleven years for medicines addressing high unmet medical

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[42] See Parliament Position on the Directive Proposal (n 41) amendments 199–202.

[43] ibid, amendment 206.

[44] ibid, amendment 196.

[45] See Parliament Position on the Directive Proposal (n 41) amendment 207.

[46] This can be prolonged by six months following a reasoned notification of the marketing authorisation holder to the relevant authority. See Parliament Position on the Directive Proposal (n 41) amendment 174.

[47] Transparency Directive (n 20).

[48] See Parliament Position on the Directive Proposal (n 41) amendment 174. The Commission may also exempt certain medicines from the described obligation.

[49] See Parliament Position on the Directive Proposal (n 41) amendment 174.

need (unlike the Commission proposal, which provides for ten years for high unmet medical need).[50] The definition of what constitutes a high unmet medical need has been rearranged. According to the Parliament, an orphan medicine addresses a high unmet medical need if there is no medicine authorised in the EU for such a condition, or, where a medicine is authorised for such a condition, in addition to having a significant benefit, it will bring exceptional therapeutic advancement, and the use of the orphan medicine 'results in a meaningful reduction in disease morbidity or mortality for the relevant patient population'.[51] A provision has also been added whereby the Commission is to facilitate the joint procurement of centrally authorised medicinal products at the EU level on Member States' behalf and upon their request.[52]

When compared to the Commission proposal, the Parliament position introduces many significant changes relating to antimicrobials and the voucher. The voucher is to provide twelve, nine or six months of extra data protection for a medicine depending on the importance of the pathogen it is counteracting. Thus, the Commission is to set up the eligibility of pathogens for the said protection periods in accordance with the WHO priority pathogens list or an equivalent established at EU level, 'with 12 months of data protection for an authorised product ranked "critical", 9 months of data protection for those ranked "high" and 6 months of data protection for those ranked "medium"'.[53] Furthermore, financial pull incentives in the form of milestone payments and joint procurement with the subscription model scheme are also introduced to provide additional incentives for research and for the development of new antimicrobials. The Commission, in consultation with EMA, is to award milestone payments and support to potential priority antimicrobials addressing the priority pathogens, and to set up criteria for granting these payments 'taking into account the costs of the development of that stage and the anticipated costs of the next stage of development'. Milestone payments may not be accumulated with the vouchers.[54] The payments will have to be used for the following purposes:

> (a) to further develop the priority antimicrobial;
>
> (b) to apply for a marketing authorisation […];
>
> (c) to conduct antimicrobial stewardship and access plans […]; and
>
> (d) where relevant, to apply for the joint procurement agreement.[55]

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50 See Parliament Position on the Regulation Proposal (n 41) amendment 204.

51 ibid, amendments 201–202.

52 ibid, amendment 209.

53 ibid, amendment 151.

54 ibid, amendment 147.

55 ibid, amendment 147.

Furthermore, Member States may engage in a voluntary joint procurement scheme on the basis of an agreement with the Commission. The agreement needs to be in the form of a multi-year subscription and include the following conditions:

(a) delinkage or partial delinkage of funding from the volume of sales of the antimicrobial;

(b) commitment to continuous and sufficient supply in pre-agreed quantities;

(c) commitment to the antimicrobial stewardship and access plans as referred to in Article 17(1), point (a) [of revised Directive 2001/83/EC];

(d) commitment to the environmental risk assessment as referred to in Article 22 [of revised Directive 2001/83/EC];

(e) submission of a global access plan to supply third countries in critical need, including through development partners or voluntarily licensing.[56]

It can be seen that the Parliament position tries a different approach in terms of balancing the need to stimulate research on one hand and facilitating equal access on the other. This will be evaluated against the Commission proposal in the following section.

5 A way forward?

In terms of balancing the need to stimulate research and the development of new medicines on one hand and the need to facilitate equal access on the other, important differences between the Commission and the Parliament can be seen. The Parliament uses a more realistic approach of providing an obligation to launch only in those Member States in which there is a need for a concrete medicine (which may not be the case for all medicines, especially those for patients suffering from rare diseases), tying it in with the Member States' fulfilling their duties (in terms of deadlines for making decisions) under the Transparency Directive. In this way, developers of new medicines are not penalised for things which are outside their control, namely the time it takes for Member States to make pricing and reimbursement decisions. The Parliament position also takes into account that there are rare diseases for which there may be no patients in certain (smaller) Member States, meaning there is no point in forcing the developers to make applications for related orphan medicines for these national markets. In such cases, there

[56] ibid, amendment 148.

will also be no interest on the part of national social security systems to make pricing and reimbursement decisions within the deadlines set by the Transparency Directive. The Commission proposal already contains the possibility to waive the said obligation, but the decision rests solely with the Member States, which creates great uncertainty for developers and is, thus, not an ideal solution. Still, according to the Parliament, if a concrete need arises, medicines will have to be provided within a certain deadline, which is definitely a step forward when compared to the current situation where there is no such obligation.

By increasing the baseline regulatory data protection period, when compared to the Commission proposal, the Parliament emphasises the importance of predictability for developers when making their investment plans for the development of new medicines. It is true, as the Commission stated in the Explanatory Memorandum to the proposal, that the reduced period of data protection is still competitive when compared to other regions.[57] On the other hand, the regulatory environment needs to be looked at holistically. Hence, the EU has to provide a comparative advantage in one area in which it can act by way of concrete legislation and that is by strengthening, or at least not reducing, the period of regulatory data protection. The fact that, despite the current system of incentives, the EU has been lagging behind the USA in the last two decades shows that reducing the existing incentives for research and innovation could hardly make the EU more competitive in the global market.

Modulation is still there in the Parliament position, which is good from the point of view of streamlining the incentives for those areas where the needs are the highest. Additionally, the introduction of a cap can be seen as a positive thing as well, because it makes sure that there cannot be a prolonged accumulation of regulatory data protection periods of more than ten years, which could result in an unreasonable burden on national budgets and could hamper access to medicines in different Member States.

One particular area in which there has been plenty of criticism of the Commission proposal, in terms of going too far in protecting the interests of developers, concerns the transferable exclusivity voucher. It has been called a 'flawed incentive', which would create a very complex system, increase costs, lead to new antibiotics not being available, and produce negative consequences for the development of biosimilars.[58] The EFPIA has since responded to these arguments by emphasising that there are solutions regarding how to make the system not overly com-

[57] See Directive Proposal Explanatory Memorandum (n 3).

[58] See, for example, C Ardal and others, 'Transferable exclusivity voucher: a flawed incentive to stimulate antibiotic innovation' (2024) 403 *The Lancet* e2.

plicated, that the voucher would decouple the incentive for the antibiotic from payment, accelerating price negotiations at the national level, that the rules can be made clearer and that the benefits generally outweigh the costs.[59] Still, the Parliament tried to streamline the voucher by providing a stronger incentive (longer data protection) in those areas where the situation is critical, but also providing additional pull incentives in the form of milestone payments and joint procurement with a subscription model. The goal is that those entities which are actually engaged in new antibiotic medicine development benefit from the new system. The conditions for granting milestone payments should ensure that the antimicrobial concerned is developed to the point of marketing authorisation and made available to patients, while multi-year subscription should increase the predictability of the system and also ensure stewardship and appropriate use. Overall, the Parliament position offers a more balanced system of push and pull incentives, making sure that the industry is incentivised to develop new antimicrobials, but also ensuring that these antimicrobials are finally developed and made accessible to European patients.

When one looks at the situation in the Council, it becomes clear that striking a balance (which is the very topic of this paper) will be one of the hardest things on which to find political agreement. The Belgian presidency addressed the question of incentives and proposed to introduce a cap of eleven years of data and market protection and to award one year of market protection instead of one year of regulatory data protection for an additional therapeutic indication. It also supported the Commission proposal on incentives for orphan medicines. The presidency emphasised that the criteria for identifying medicines addressing unmet medical needs should be objective and measurable. Finally, it submitted four different scenarios on the question of equal access in all Member States, ranging from Member States having to make a request to a company within a certain timeframe to have a medicine on its market, to decoupling incentives from access altogether (similar to the Parliament position).[60] As stated by the progress report on the pharmaceutical package that the ministers of the Employment, Social Policy, Health and Consumer Affairs Council took note of on 3 December 2024, the following remain the main outstanding issues on which there is no political agreement as of the end of 2024 (the end of the Hungarian rotating pres-

[59] See EFPIA, 'Transferable exclusivity voucher: a flawed incentive to stimulate antibiotic innovation' (*The Lancet*, 9 February 2023, EFPIA-BEAM Rejoinder) <www.efpia.eu/news-events/the-efpia-view/statements-press-releases/efpia-rejoinder-lancet-article/#_ftn1> accessed 29 August 2024.

[60] See Council, 'Incentives system within the proposed pharma package: ways forward to achieve an agreement in the Council' (2024) 5–9.

idency): modulation of incentives; ensuring more equal market access and continuous supply of innovative medicines for all EU Member States; and the voucher.[61]

In addition to what has already been mentioned, it has to be emphasised that the EU pharmaceutical legislation, whose primary aim is ensuring the safety and efficacy of new medicines on the EU market, is not a silver bullet which can solve all the problem of inequality of access in the EU. This is the case because, as already stated in the introductory paragraphs, pricing and reimbursement of medicines is primarily a national competence and it is the last step determining when a certain medicine becomes available for patients. Hence, the EU may not harmonise national definitions of health policy and the organisation of healthcare, including the allocation of funding, as its primary objective. On the other hand, the EU may adopt measures, including harmonisation, which affect human health.[62] This possibility has been interpreted rather broadly in the past by the Court of Justice (CJEU). According to its jurisprudence, the EU legislator may adopt measures, using legal bases for the harmonisation of the internal market, even if 'public health protection is a decisive factor in the choices to be made'.[63] Therefore, any measure having some connection with the internal market and free movement may be adopted, even when its primary aim is essentially related to healthcare. As this example, as well as others like COVID-19, shows us, the possibilities of Union action in the area of healthcare primarily depend on political will, not legal limitations.[64] Very few areas of national health law remain unaffected by EU law.[65]

Of course, the financial capabilities of various Member States are very different, with Romania being at the bottom of per capita spend-

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[61] See Council, 'Information from the Presidency on the progress achieved in the examination of the Revision of the pharmaceutical package' (2024) 8; and Council, 'Employment, Social Policy, Health and Consumer Affairs Council (Health) 3 December 2024' <www.consilium.europa.eu/en/meetings/epsco/2024/12/03/> accessed 8 January 2025.

[62] See K Purnhagen and others, 'More Competences Than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak' (2020) 11 European Journal of Risk Regulation 300.

[63] See Case C-380/03 *Federal Republic of Germany v European Parliament and Council of the European Union* ECLI:EU:C:2006:772, para 39. It has been stated in the literature that the importance of health policy for our everyday life has led to the recognition of certain related fundamental rights at the EU level, even as (formally) part of other EU policies. See A de Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (OUP 2019) 91.

[64] See Purnhagen and others (n 62) 306.

[65] See T Hervey, 'EU Law and Policy on New Health Technologies' in S Garben and L Gormley (eds), *Health Law* (OUP 2024) 9.

ing in the EU.[66] One possible solution coming from the industry could be equity-based tiered pricing, meaning that the ability to pay across countries is considered in the prices of innovative medicines. This would essentially mean that Member States with fewer resources would pay a lower price and those with more resources would pay a higher one.[67] Such a solution could only be applied in a voluntary setting, because any legal binding legislation would require a Treaty change granting more powers to the EU to introduce a centralised procedure for price setting, which does not seem to be realistic at the moment.[68] The proposal by the industry for a voluntary system, based on the confidentiality of prices,[69] could be a solution, but the lack of transparency in that system is something that would certainly be a cause for concern for national social security systems and other stakeholders.

Still, even within the existing framework, the amendment of two other pieces of EU legislation could lead to certain benefits for patients in terms of equality of access. The first is the revision of the Transparency Directive. This piece of legislation was adopted in 1989 and has never been amended, thus showing the lack of political will for a stronger EU regulation in this area. It sets certain very broadly defined principles for making pricing and reimbursement decisions, focusing primarily on the transparency of the system and making sure that all developers of new medicines (applicants for a pricing and reimbursement decision) are treated equally, without discrimination. Furthermore, it sets a deadline for a final decision, after which a medicine may be made available for patients, for a maximum of 180 days. The underlying principle of the Directive is minimum interference in the organisation of national social security systems.[70] It is also important that national decisions contain

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66 See EUROSTAT, 'Healthcare Expenditure Statistics: Overview' <https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_expenditure_statistics_-_overview&oldid=625409#Healthcare_expenditure> accessed 29 August 2024.

67 See EFPIA, 'A Shared Approach to Supporting Equity Based Tiered Pricing Discussion Document' <www.efpia.eu/media/636825/a-shared-approach-to-supporting-equity-based-tiered-pricing.pdf> accessed 29 August 2024. See on this issue also A Towse and others, 'European Union Pharmaceutical Markets: A Case for Differential Pricing?' (2015) 22 International Journal on the Economics of Business 263.

68 See Towse and others (n 67) 270.

69 See EFPIA (n 67) 5.

70 See Transparency Directive (n 20) Arts 1–7. See, on this piece of legislation and the principle of minimum interference, for example, Case C-20/22 *Syndicat Les Entreprises du médicament (LEEM) v Ministre des Solidarités et de la Santé* ECLI:EU:C:2022:1028, para 21. Of course, Member States still need to respect EU law, including the Transparency Directive, but other pieces of pharmaceutical legislation as well. See, to that effect, Case C-29/17 *Novartis Farma SpA v Agenzia Italiana del Farmaco (AIFA) and Others* ECLI:EU:C:2018:931, para 50.

reasoning.[71] Even though the EU does not have the power to harmonise reimbursement and price setting, it could determine some of the basic guiding principles or criteria for national social security institutions making these decisions. If this is politically not feasible, at least prescribing and enforcing concrete sanctions for Member States not complying with the set deadlines for making reimbursement decisions, and shortening those deadlines, would be a big step forward for equality of access to what we have now, where no provisions on sanctions are contained in the Directive.

Finally, revision of EU legislation on cross-border healthcare could contribute to reducing differences in access to medicines and treatment within the EU. This area is currently regulated by the EU regulation on social security coordination, the oldest piece of EU legislation on patients' rights,[72] and the directive on cross-border healthcare[73] which serves as

[71] See Joined Cases C-271/14 and C-273/14 *LFB Biomédicaments SA and Others v Ministre des Finances et des Comptes publics and Ministre des Affaires sociales et de la Santé* ECLI:EU:C: 2015:237, para 31.

[72] See Regulation (EC) 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems [2004] OJ L166/1 (Regulation 883/2004); and T Hervey and J McHale, *European Union Health Law: Themes and Implications* (CUP 2015) 189–190.

[73] See Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare [2011] OJ L88/45 (Directive 2011/24). The Directive and the case law have been thoroughly analysed in the literature. See, for example, S de La Rosa, 'The Directive on Cross-border Healthcare or the Art of Codifying Complex Case Law' (2012) 49 CML Rev 15; M Peeters, 'Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Healthcare' (2012) 19 European Journal of Health Law 29; K Raptopoulou, 'The Directive on Cross-border Health Care: Signalling the Coordination or the Harmonisation of Public Health Systems?' (2012) European Journal of Social Law 193; G Strban, 'Patient Mobility in the European Union: Between Social Security Coordination and Free Movement of Services' (2013) 14 ERA Forum 391; J van de Gronden, E Szyszczak, U Neergaard and M Krajewski (eds), *Health Care and EU Law* (TMC Asser Press 2011). It needs to be mentioned that Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU [2021] OJ L458/1 (HTA Regulation) was adopted in 2021. It defines HTA as 'a multidisciplinary process that summarises information about the medical, patient and social aspects and the economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner'. The HTA Regulation has deleted the provisions of Directive 2011/24 on health technology assessment and created an EU system of HTA whereby Member States need to take into account European joint clinical assessments in their national HTAs. However, joint clinical assessments do not cover the economic evaluation of health technologies (the latter is subject to voluntary cooperation), which means that this system will, presumably, only have a minor impact on national pricing and reimbursement decisions. See HTA Regulation Arts 2, 13, 23, 35. On the HTA Regulation, see, for example, T Hwang and K Vokinger, 'New EU Regulation on Health Technology Assessment of Cancer Medicines' (2022) 23 The Lancet Oncology e58.

a codification of EU law on freedom to provide healthcare services.[74] The two sets of rules are rather similar, but still different in terms of the obligation to obtain prior authorisation for treatment abroad (when patients cannot obtain adequate treatment in their state of residence or affiliation), the tariffs, and the procedure under which the coverage is carried out. Under social security coordination, prior authorisation is generally required, and patients are covered on the basis of the state of treatment rules and tariffs.[75] Under the directive, patients are entitled to obtain healthcare without prior authorisation except for cases of hospital treatment, treatments involving major medical equipment and treatments or providers presenting a risk for the patient or the population and tariffs of the state of affiliation are applicable.[76] This makes it extremely complicated for patients to understand and exercise the rights which are guaranteed to them by EU law. Thus, it is not surprising that only 0.05% of EU citizens avail themselves of the possibilities prescribed by the directive on cross-border healthcare.[77]

Merging the two sets of rules, preferably in a directly applicable regulation, would help simplify things and streamline the process for patients. Furthermore, explicitly prescribing a right to a 'second opinion' for difficult or atypical cases, meaning that patients would have the right to request that specialists from one Member State seek the advice of specialists from another Member State within a single system, would also help patients from different Member States to have more equal access to the most advanced therapies and medicines anywhere in the EU. This has already been stated by the European Parliament resolution on strengthening Europe in the fight against cancer in 2022.[78] Thus, the EU legislator has additional possibilities to reduce inequalities in access within the EU, and the pharmaceutical package is certainly not an instrument which could resolve all the problems which exist today.

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[74] See, for example, Case C-158/96 *Raymond Kohll v Union des caisses de maladie* ECLI:EU:C:1998:171; Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust* ECLI:EU:C:2006:325; Case C-777/18 *WO v Vas Megyei Kormányhivatal* ECLI:EU:C:2020:745; Case C-243/19 *A v Veselības ministrija* ECLI:EU:C:2020:872. On this case law, see, for example, V Hatzopoulos, '*Killing* National Health and Insurance Systems but *Healing* Patients? The European Market for Health Care Services After the Judgments of the ECJ in *Vanbraekel* and *Peerbooms*' (2002) 39 CML Rev 683.

[75] See Regulation 883/2004 (n 72) Art 20.

[76] See Directive 2011/24 (n 73) Arts 7–8.

[77] See European Court of Auditors, 'EU Actions for Cross-border Healthcare: Significant Ambitions but Improved Management Required' (2019) 4.

[78] See European Parliament resolution of 16 February 2022 on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy (2020/2267/INI) paras 55, 62. On the right to a second opinion, see, also, Case C-538/19 *TS and Others v Casa Națională de Asigurări de Sănătate and Casa de Asigurări de Sănătate Constanța* ECLI:EU:C:2021:809, para 58.

6 Conclusion

The Commission has set very ambitious goals with its proposal for the revision of EU pharmaceutical legislation. It has tried to solve the problem of unequal access to medicines within the EU, while also making Europe more competitive in the global pharmaceutical market. The crucial aspect here is how to strike the right balance between the need to stimulate research and innovation on one hand and ensure equality of access on the other. Even though there are some positive aspects in the Commission proposal, such as cutting the deadlines for conducting the marketing authorisation procedure, there are also issues which can be seen as problematic and representing a step backwards in terms of promoting innovation within Europe, such as the reduction of the baseline regulatory data protection period.

The Parliament is taking a more realistic and balanced approach by providing an obligation to launch in those Member States where there is a need for a concrete medicine. By increasing the baseline regulatory data protection period, the Parliament highlights the importance of predictability for developers when making their investment plans for the development of new medicines. The Parliament also retains the concept of modulation, which is good from the point of view of streamlining the incentives to those areas where the needs are the greatest. Furthermore, by introducing a cap, the Parliament makes sure that there cannot be a prolonged accumulation of regulatory data protection periods of more than ten years, which could result in an unreasonable burden on national budgets and hamper access to medicines in different Member States. In relation to the issue of antimicrobials, the Parliament combines a number of push and pull incentives, thereby motivating the industry to create new antimicrobials, but also ensuring these antimicrobials are finally developed and made accessible to European patients. All this means that the final text aiming at striking a balance between stimulating innovation and enabling equal access should follow, as far as possible, the balanced approach of Parliament.

Revision of the pharmaceutical legislation is not a silver bullet to resolve all the problems relating to equal access. Revision of the Transparency Directive, which would at least accelerate national pricing and reimbursement decisions and set a strong enforcement mechanism, would certainly improve the equality of patients and make new medicines more accessible to them. Finally, revision of the cross-border healthcare legislation, which would simplify the legal framework and make it more accessible to patients, would particularly help those who are unable to access adequate medical treatment in the Member State in which they live and provide all European citizens with the same, or at least a sim-

ilar, possibility to avail themselves of the best quality treatments and medicines anywhere in the EU.

Suggested citation: T Sokol, 'The EU Pharmaceutical Package: Will It Strike a Balance Between Stimulating Research and Facilitating Equal Access?' (2025) 21 CYELP 53.

IT TAKES (AT LEAST) TWO TO TANGO IN THE RHYTHM OF AI-ENABLED DISCRIMINATION: HOW THE AI ACT COMPLEMENTS EU NON-DISCRIMINATION LAW

Konstantinos Lamprinoudis *

Abstract: Despite the elaborate equality and non-discrimination legislation in the European Union (EU), the current legal framework has been widely deemed ill-suited to properly address discriminatory instances that may emerge from the use of algorithms and Artificial Intelligence (AI) technologies. Nevertheless, the potential synergies between the EU Artificial Intelligence Act (AI Act) and non-discrimination law remain underexplored. This article suggests that the AI Act may complement EU non-discrimination rules for the purpose of combatting AI-enabled discrimination in a threefold manner: a) by prohibiting certain AI systems that are prone to produce discriminatory outcomes; b) by regulating the requirements that AI systems need to comply with in order to minimise the risk of discrimination; and c) by enabling the persons affected by discriminatory effects to seek legal protection. Each of these prohibitive, regulatory, and enabling functions of the AI Act are examined in turn, with emphasis placed on their interplay with the existing non-discrimination legislation at EU level. Finally, the article concludes that, apart from the significant complementarities between the two legal regimes both at the level of substantive protection granted to individuals and at the level of enforcement, there are other pieces of EU legislation implicated by the AI Act that may also be applicable when addressing AI-enabled discrimination.

Keywords: AI Act, non-discrimination law, EU law, bias, complementarity

1 Introduction

The risk of algorithms used in decision-making practices to discriminate against certain individuals or entire societal groups, thus perpetuating or amplifying existing inequalities, is already well known.[1] Amid

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[1] For a detailed overview of the various ways in which algorithms may lead to discrimination, see most prominently the pioneering work of S Barocas and A Selbst, 'Big Data's Disparate Impact' (2016) 104(3) California Law Review 671. See also eg EU Fundamental Rights Agency (FRA), 'BigData: Discrimination in Data-Supported Decision Making' (European Union Publication Office 2018).

the surge of Artificial Intelligence (AI)[2] in various sectors of the economic and social reality in recent years, concerns about the potentially unfair, biased, or discriminatory outcomes of AI systems have been increasingly raised by scholars and policymakers around the world.[3] In particular, the Council of Europe's Framework Convention on AI requires all signatory parties to adopt measures that 'respect equality, including gender equality, and the prohibition of discrimination' during the lifecycle of AI systems, and that are also directed towards 'overcoming inequalities to achieve fair, just and equitable outcomes'.[4] Similarly, within the context of the European Union (EU), the High-Level Expert Group on AI appointed by the European Commission has, among other things, called for 'diversity, non-discrimination and fairness' as one of the key requirements to achieve 'trustworthy AI'.[5]

Despite the elaborate equality and non-discrimination legislation at EU level,[6] the current legal framework has been widely deemed ill-suited

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[2] See the definition adopted by the Organisation for Economic Cooperation and Development (OECD), 'Recommendation of the Council on Artificial Intelligence' (OECD/LEGAL/0449, 2019) as amended by the 'Explanatory Memorandum on the Updated OECD Definition of an AI System' (OECD Artificial Intelligence Papers, No 8, March 2024).

[3] See eg E Ferrara, 'Fairness and Bias in Artificial Intelligence: A Brief Survey of Sources, Impacts, and Mitigation Strategies' (2024) 6 Sci 2024; X Ferrer and others, 'Bias and Discrimination in AI: A Cross-Disciplinary Perspective' (2021) 40(2) IEEE Technology and Society Magazine 72. On the difference between the terms 'bias' and 'fairness' deployed mostly in computer science, statistics, and ethics, on the one hand, and the legal notions of 'discrimination' and 'equality', on the other hand, see J Gerards and R Xenidis, 'Algorithmic Discrimination in Europe: Challenges and Opportunities for Gender Equality and Non-Discrimination Law' (European Commission, Publications Office of the European Union 2021) Section 1.5.1, 47.

[4] See Art 10 of the Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law (Council of Europe Treaty Series No 225, 5 September 2024).

[5] See Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Region – Building Trust in Human-Centric Artificial Intelligence' COM (2019) 168 final, 5-6, in the sense that AI systems should be developed and used in a way that 'includes diverse actors and promotes equal access, gender equality and cultural diversity, while avoiding discriminatory impacts and unfair biases'. See also several dispersed references to the need for non-discriminatory AI in other official EU documents: Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Region – Artificial Intelligence for Europe' COM (2018) 237 final; Commission, 'White Paper on Artificial Intelligence – A European Approach to Excellence and Trust' COM (2020) 65 final; Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Region – Fostering a European Approach to Artificial Intelligence' COM (2021) 205 final.

[6] Apart from certain EU primary law provisions, this framework consists of a set of so-called 'Equality Directives'. See Council Directive 79/7/EEC of 19 December 1978 on the progressive implementation of the principle of equal treatment for men and women in matters of social security [1978] OJ L6/24; Council Directive 2000/43/EC of 29 June 2000

to properly redress algorithmic or AI-enabled discrimination due to several shortcomings.[7] Most importantly, EU non-discrimination law covers instances of disadvantageous treatment of persons or groups based only on specific personal attributes known as 'protected characteristics' or 'prohibited grounds of discrimination' that are exhaustively listed in the so-called 'Equality Directives' (ie sex, racial or ethnic origin, religion or belief, age, disability, and sexual orientation), and solely in certain areas of life (eg employment, access to goods and services, etc), with the ensuing level of protection varying between the different protected characteristics.[8] Yet, algorithmic tools may often unfairly differentiate between people based on their classification into new, non-traditional groups that do not necessarily correlate with prohibited grounds of discrimination or proxies of these grounds.[9] In addition, although the list of personal traits protected by the right to non-discrimination enshrined in Article 21(1) of the EU Charter of Fundamental Rights (Charter) is open-ended and includes more characteristics than the ones safeguarded under the Equality Directives, the scope of application of the said provision is lim-

implementing the principle of equal treatment between persons irrespective of racial or ethnic origin [2000] OJ L180/22; Council Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation [2000] OJ L303/16; Council Directive 2004/113/EC of 13 December 2004 implementing the principle of equal treatment between men and women in the access to and supply of goods and services [2004] OJ L373/37; Directive 2006/54/EC of the European Parliament and of the Council of 5 July 2006 on the implementation of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation (recast) [2006] OJ L204/23.

[7] See, among others, Gerards and Xenidis (n 3); R Xenidis and L Senden, 'EU Non-Discrimination Law in the Era of Artificial Intelligence: Mapping the Challenges of Algorithmic Discrimination' in U Bernitz and others (eds), *General Principles of EU Law and the EU Digital Order* (Kluwer Law International 2020); R Xenidis, 'Tuning EU Equality Law to Algorithmic Discrimination: Three Pathways to Resilience' (2020) 27(6) Maastricht Journal of European and Comparative Law 736; R Xenidis, 'When Computers Say No: Towards a Legal Response to Algorithmic Discrimination in Europe' in B Bro ek, P Palka and O Kanevskaia (eds), *Research Handbook on Law and Technology* (Edward Elgar Publishing 2023).

[8] For this 'hierarchy' of prohibited grounds under EU non-discrimination law, see eg L Waddington and M Bell, 'More Equal than Others: Distinguishing European Union Equality Directives' (2001) 38(3) Common Market Law Review 587, 587; E Howard, 'The Case for a Considered Hierarchy of Grounds in EU Law' (2006) 13(4) Maastricht Journal of European and Comparative Law 445, 445. However, as the Equality Directives only provide for minimum harmonisation, it is up to the Member States to opt for a more extensive protection in their national legislation, by prohibiting discrimination also on the basis of other grounds and/or in other areas of life.

[9] See Gerards and Xenidis (n 3) Section 2.2, 62–66. See also J Gerards and F Zuiderveen Borgesius, 'Protected Grounds and the System of Non-Discrimination Law in the Context of Algorithmic Decision-Making and Artificial Intelligence' (2022) 20(1) Colorado Technology Law Journal 1; S Wachter, 'The Theory of Artificial Immutability: Protecting Algorithmic Groups Under Non-Discrimination Law' (2022) 97(2) Tulane Law Review 149; M Leese, 'The New Profiling: Algorithms, Black Boxes, and the Failure of Non-Discriminatory Safeguards in the European Union' (2014) 45(5) Security Dialogue 494, 502, 504.

ited only to cases of implementation of EU law, as per Article 51(1) of the Charter.[10] Furthermore, the already blurred dichotomy between the concepts of 'direct' and 'indirect discrimination' traditionally deployed in the EU non-discrimination doctrine is considered an uneasy fit with the particularities of discriminatory algorithmic operations.[11] When it comes to enforcement, on the other hand, the opaque nature of algorithmic tools, especially in the case of advanced AI machine-learning models, commonly referred to as the 'black box',[12] is most likely to hinder the persons affected from proving that they have been discriminated against when trying to bring a *prima facie* case of discrimination before courts.[13] In fact, these persons may sometimes not even be aware that they have suffered discriminatory treatment.[14] In view of these challenges, recourse to data protection rules, notably those included in the General Data Protection Regulation (GDPR),[15] has often been portrayed as a promising means to provide effective tools to individuals affected by discriminatory algorithmic decisions.[16]

However, the potential synergies between the much-acclaimed EU Artificial Intelligence Act (AI Act)[17] and non-discrimination law remain

[10] Charter of Fundamental Rights of the European Union [2016] OJ C202/389. As clarified by the Court of Justice of the EU (CJEU) in this regard, the fundamental rights guaranteed in the Charter are applicable in all situations governed by EU law. See Case C-617/10 *Åkerberg Fransson* ECLI:EU:C:2013:105, paras 19–22.

[11] See eg Gerards and Xenidis (n 3) Section 2.3, 67–73, arguing though that the concept of indirect discrimination is probably more apt compared to its direct counterpart to address the challenges of algorithmic discrimination. For arguments against the alleged diminishing relevance of direct discrimination in the field of algorithms, see J Adams-Prassl, R Binns and A Kelly-Lyth, 'Directly Discriminatory Algorithms' (2023) 86(1) Modern Law Review 144.

[12] See eg F Pasquale, *The Black Box Society: The Secret Algorithms That Control Money and Information* (Harvard University Press 2015). See also J Burrell, 'How the Machine "Thinks": Understanding Opacity in Machine Learning Algorithms' (2016) 3(1) Big Data and Society.

[13] See Gerards and Xenidis (n 3) Section 1.4.4, 45–46. On the burden of proof in discrimination cases in EU law, see Art 8 of Directive 2000/43/EC, Art 10 of Directive 2000/78, and Art 9 of Directive 2004/113/EC. See also K Henrard, 'The Effective Protection against Discrimination and the Burden of Proof: Evaluating the CJEU's Guidance Through the Lens of Race' in U Belavusau and K Henrard (eds), *EU Anti-Discrimination Law Beyond Gender* (Hart 2019).

[14] See Gerards and Xenidis (n 3) Section 2.4, 11, 73–75.

[15] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L119/1.

[16] See eg P Hacker, 'Teaching Fairness to Artificial Intelligence: Existing and Novel Strategies Against Algorithmic Decision-Making Under EU Law' (2018) 55(4) Common Market Law Review 1143.

[17] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139

underexplored. The AI Act constitutes a hybrid form of regulation, in the sense that, albeit designed as a product safety instrument laying down uniform rules for the development, marketing, and use of AI systems with the aim of improving the functioning of the EU internal market, it is also intended to ensure a high level of fundamental rights protection as enshrined in the Charter, including individuals' right to non-discrimination.[18] As such, the AI Act aligns with the horizontal equality clause of Article 10 of the Treaty on the Functioning of the European Union (TFEU) pursuant to which the need to combat discrimination is to be taken into account in all policy areas of EU law.[19] This is also particularly evident in the AI Act's preamble, which extensively refers to the discrimination risks posed by various AI tools, thus reflecting the EU legislator's increased concern about the adverse consequences of AI technologies in this regard.[20]

By definition, the AI Act applies exclusively to systems that qualify as 'AI systems', to the exclusion of all other automated or algorithmic systems.[21] Yet, it is only those AI systems giving rise to the most significant risks to fundamental rights that fall under the AI Act's regulatory

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and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) [2024] OJ L2024/1689. See in particular, recitals 27–28, 31, 44–45, 48, 54–58, 67, and 70.

[18] See Art 1(1) and recitals 1 and 8 of the AI Act. See also M Almada and N Petit, 'The EU AI Act: Between the Rock of Product Safety and the Hard Place of Fundamental Rights' (2025) 62(1) Common Market Law Review 85, 119.

[19] Consolidated Version of the Treaty on the Functioning of the European Union [2016] OJ C202/47. On Art 10 TFEU and 'equality mainstreaming' in EU law, see A Timmer, 'Editorial: Mainstreaming Equality in EU Law and Beyond' (2023) 19(3) Utrecht Law Review 1; E Muir, V Davio and L van der Meulen, 'The Horizontal Equality Clauses (Arts 8 & 10 TFEU) and Their Contribution to the Course of EU Equality Law: Still an Empty Vessel?' (2022) 7(3) European Papers 1381.

[20] See eg recitals 28, 31, 32, 44, 48, 56–60 of the AI Act. See also Commission, 'Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts' COM (2021) 206 final, point 3.5.

[21] According to Art 3(1) of the AI Act, an 'AI system' is any 'machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments'. As specified by recital 12 of the AI Act, AI systems present distinct features that distinguish them from 'simpler traditional software systems or programming approaches' and, as such, do not cover 'systems that are based on the rules defined solely by natural persons to automatically execute operations'. See also in detail Commission, 'Guidelines on the definition of an artificial intelligence system established by Regulation (EU) 2024/1689 (AI Act)' [2025] C(2025) 924 final, points 6, 61–62, emphasising that no automatic determination or exhaustive list of AI systems can be provided, but rather whether a given system fulfils the criteria to be considered an AI system depends on its specific architecture and functionality.

regime. Following such a 'risk-based approach',[22] the AI Act covers four categories of AI systems: i) those of unacceptable risk, which are prohibited under Article 5; ii) those of high risk defined under Article 6 in conjunction with Annex III, which are subject to a set of requirements and obligations under Articles 8–27; iii) those of limited risk, which are subject to transparency obligations under Article 50; and iv) those of minimal or no risk, which remain largely unregulated and are subjected to a merely voluntary application of the requirements applicable to high-risk systems under Article 95.

Against this background, this article attempts to shed more light on the ways in which the AI Act complements EU non-discrimination law for the purpose of addressing AI-enabled discrimination. I argue, in particular, that the AI Act contributes to this aim in a threefold manner: a) by prohibiting certain uses of AI that are prone to produce discriminatory outcomes; b) by regulating the requirements that AI systems need to comply with in order to minimise the risk of discrimination; and c) by enabling the persons affected by the discriminatory effects of AI systems to seek legal protection.[23] Accordingly, this article examines in turn each of these prohibitive, regulatory, and enabling functions of the AI Act, emphasising their interplay with the existing non-discrimination rules (Sections 2, 3 and 4 respectively). Finally, the article concludes that, apart from the significant complementarities between the two legal regimes both at the level of substantive protection granted to individuals and at the level of enforcement, there are other pieces of EU legislation implicated by the AI Act that may also be applicable when addressing AI-enabled discrimination (Section 5).

2 The prohibitive function

The AI Act's 'prohibitive function' is set out in Article 5, which consists of a list of prohibited AI practices. This provision prohibits the placing on the EU market, putting into service, or the use of AI systems for certain practices considered particularly harmful because they conflict,

[22] See the Commission's Guidelines on the definition of an AI system (n 21) point 63. Pursuant to recital 26 of the AI Act, this risk-based approach means that the applicable rules are tailored to the intensity and scope of the risks that the AI system concerned can generate. On this approach in AI governance more generally, see M Kaminski, 'Regulating the Risks of AI' (2023) 103 Boston University Law Review 1347.

[23] This taxonomy draws upon a similar typology of US legislation relating to the regulation of AI technologies as proposed in 'Resetting Antidiscrimination Law in the Age of AI' (2025) 138(6) Harvard Law Review 1562, which identifies four primary methods by which various federal and state bills target AI-enabled discrimination: a) prohibition on certain uses of AI; b) regulation of some procedural requirements for the use of AI; c) regulation of the inputs used in AI decision-making; and d) regulation of the outputs produced by AI systems.

among other things, with the value of equality and the right to non-discrimination, as clarified by the Commission's Guidelines in this regard.[24] Furthermore, the AI Act gives teeth to these prohibitions by providing for severe administrative fines in the case of non-compliance.[25] Although subject to various exceptions, notably in the field of law enforcement and migration, the AI Act's prohibitive function not only ensures that practices entailing severe risks of discriminatory outcomes are in principle legally banned, but it also sets the tone for what is perceived as ethically or socially permissible use of AI in the EU.[26] From this perspective, in addition to their strictly legal nature, the AI Act's prohibitions have some sort of symbolic value, signalling the red lines of the EU legal order with regard to the standards of fundamental rights' protection, including non-discrimination, below which AI practices cannot fall.[27]

Be that as it may, Article 5 of the AI Act does not affect the prohibition of AI practices infringing other pieces of EU legislation.[28] Even where the use of an AI system is not prohibited by the AI Act itself, it could still be deemed unlawful on the basis of other primary or secondary EU law, including non-discrimination law, which remains fully applicable.[29] For instance, this would be the case where an AI tool relies on individuals' sex to calculate different insurance premiums and benefits contrary to Directive 2004/113,[30] or where such an AI system screens the CVs of job applicants and automatically rejects those with foreign-sounding names in violation of Directive 2000/43. Consequently, one could reasonably wonder what added value the AI Act's prohibitions really provide beyond the existing EU non-discrimination legal framework.

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[24] See Commission, 'Guidelines on prohibited artificial intelligence practices established by Regulation (EU) 2024/1689 (AI Act)' [2025] C(2025) 5052 final, point 8. See also recital 28 of the AI Act.

[25] See Art 99(3) of the AI Act. The concrete rules on penalties and other enforcement measures applicable to the infringements of the AI Act are to be laid down by the Member States, pursuant to Art 99(1) thereof.

[26] See C Rudschies and I Schneider, 'The Long and Winding Road to Bans for Artificial Intelligence: From Public Pressure and Regulatory Initiatives to the EU AI Act' (2025) 4(57) Digital Society 9–10.

[27] See similarly in this regard K Yeung, A Howes and G Pogrebna, 'AI Governance by Human Rights-Centred Design, Deliberation and Oversight: An End to Ethics Washing' in M Dubber, F Pasquale and S Das (eds), *The Oxford Handbook of AI Ethics* (OUP 2020).

[28] See Art 5(8) of the AI Act.

[29] See recital 45 of the AI Act. See also the Commission's Guidelines on prohibited AI practices (n 24) point 43.

[30] See Art 5(1) of the said Directive. The former second paragraph of Art 5, which allowed Member States to opt for proportionate differences in individuals' premiums and benefits where the use of sex is a determining factor in the assessment of risks based on relevant and accurate actuarial and statistical data, was declared invalid by the CJEU in its landmark judgement in Case C-236/09 *Test-Achats* ECLI:EU:C:2011:100.

To answer this question, I will examine below each of the prohibited AI practices listed in Article 5 of the AI Act, namely those relating to harmful manipulation, deception, or exploitation, social scoring, crime risk assessment, biometric categorisation, untargeted scraping of facial images, emotion recognition, and real-time biometric identification. Far from engaging in a detailed analysis of these practices and all their adverse consequences for the individual's fundamental rights, I will emphasise their discriminatory potential and then highlight how the AI Act's prohibitions may converge with or even extend the protective reach of EU non-discrimination legislation in this regard.

2.1 Harmful manipulation, deception, or exploitation

The first two prohibitions in Article 5(1) of the AI Act target AI systems that deploy subliminal, purposively manipulative or deceptive techniques (Article 5(1)(a)) or exploit any vulnerabilities of natural persons or groups thereof due to their age, disability, or a specific social or economic situation (Article 5(1)(b)), with the objective or the effect of materially distorting the behaviour of such persons in a manner that may cause them significant harm. As both of these prohibitions aim at protecting individuals against AI practices that subvert and impair their autonomy, decision-making, and free choices, they may complement each other.[31] However, whereas the primary focus of the prohibition in Article 5(1)(a) is placed on the nature of the techniques deployed by the AI system in question, it is the characteristics of the persons affected and the exploitation of their specific vulnerabilities that lie at the core of the prohibition in Article 5(1)(b).[32] Accordingly, where both provisions seem applicable, Article 5(1)(a) will take precedence if such exploitation occurs regardless of the specific vulnerabilities of the persons concerned, while Article 5(1)(b) will apply instead if the AI-enabled exploitation affects particularly vulnerable people due to their age, disability, or specific socioeconomic situation.[33] Given that the prohibition in Article 5(1)(b) is explicitly based on certain personal attributes of the individuals or groups concerned in a similar way as non-discrimination law, the rest of my analysis here will deal mostly with that provision in particular.

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[31] See recital 29 of the AI Act. See also the Commission's Guidelines on prohibited AI practices (n 24), points 59, 122.

[32] See the Commission's Guidelines on prohibited AI practices (n 24), points 123–124. For a detailed analysis of the subliminal, manipulative, or deceptive nature of the techniques covered by Art 5(1)(a) of the AI Act, see the Commission's Guidelines on prohibited AI practices (n 24), points 63–75.

[33] ibid, point 125.

By referring to 'people with vulnerabilities' instead of 'vulnerable people', Article 5(1)(b) of the AI Act seems to endorse a context-specific understanding of the notion of 'vulnerability',[34] in the sense that certain categories of people are not inherently vulnerable but may become so in specific circumstances, with their vulnerability emerging from multiple different sources.[35] Hence, the emphasis placed by Article 5(1)(b) on human vulnerabilities indicates a more substantive vision of equality in this regard that goes beyond the prohibition of discrimination based on defined personal characteristics.[36] Such vulnerabilities may encompass a wide array of categories, including cognitive, emotional, physical, and other forms of susceptibility that can affect the ability of persons to make informed decisions or otherwise influence their behaviour.[37]

On the one hand, as concerns vulnerabilities due to age or disability, one can think, for instance, of AI systems that exploit the cognitive decline and reduced digital literacy of older people by targeting unnecessary insurance policies or deceptive investments schemes to them, or those that exploit the limited intellectual capacity of mentally disabled persons to influence them to purchase expensive medical products.[38] In this regard, the parallels with non-discrimination law are evident, since both age and disability are also protected traits pursuant to Directive 2000/78.[39] However, whereas discrimination on these grounds is prohibited only in the field of employment and occupation, the prohibition of the AI Act is framed in rather broad terms, not being confined to any specific area. Furthermore, because of the limited material scope of Directive 2000/78, the concept of 'disability' in EU non-discrimination law has been consistently interpreted as comprising any limitation which

[34] See G Malgieri, *Vulnerability and Data Protection Law* (OUP 2023) 96–97.

[35] See F Luna, 'Elucidating the Concept of Vulnerability: Layers Not Labels' (2009) 2(1) International Journal of Feminist Approaches to Bioethics 121. For a conceptual framework of human vulnerability as 'algorithmic vulnerability' tailored to address the particularities of AI technologies, see SA Teo, 'Artificial Intelligence, Human Vulnerability and Multi-Level Resilience' (2025) 57 Computer Law and Security Review, article no 106134.

[36] For the relation between vulnerability and substantive equality, see M Fineman, 'The Vulnerable Subject: Anchoring Equality in the Human Condition' (2008) 20(1) Yale Journal of Law and Feminism. See also with regard to the case law of the European Court of Human Rights (ECtHR) L Peroni and A Timmer, 'Vulnerable Groups: The Promise of an Emerging Concept in European Human Rights Convention Law' (2013) 11(4) International Journal of Constitutional Law 1056, 1074–1082. For the distinction between formal and substantive equality, see eg T Loenen, *The Conceptualization of Equality and Non-Discrimination as Legal Standards: From Formal to More Substantive Equality* (Brill/Nijhoff 2025); S Fredman, 'Providing Equality: Substantive Equality and the Positive Duty to Provide' (2005) 21(2) South African Journal on Human Rights 163.

[37] See the Commission's Guidelines on prohibited AI practices (n 24) point 102.

[38] ibid, points 108, 117.

[39] See also explicitly ibid, point 138.

may hinder a person's full and effective participation in professional life on an equal basis with other workers, and thus relates only to the context of exercising a professional activity.[40] In contrast, as specified by recital 29 of the AI Act, 'disability' under Article 5(1)(b) is to be understood within the meaning of Directive 2019/882, namely as referring more broadly to any impairment which may hinder their full and effective participation in society on an equal basis with others.[41] Thus, the AI Act fully aligns with the definition of disability adopted by the United Nations Convention on the Rights of Persons with Disabilities, to which the EU is also a party.[42]

On the other hand, vulnerabilities based on specific social or economic situations may indicatively concern persons living in extreme poverty, ethnic or religious minorities, migrants, or refugees, covering not only stable and long-term characteristics but also transient circumstances, such as temporary unemployment or over-indebtedness.[43] Unlike EU non-discrimination law which does not recognise socioeconomic status as a prohibited ground of discrimination in itself,[44] the prohibition of Article 5(1)(b) of the AI Act aims to ensure that AI technologies do not perpetuate or exacerbate existing inequalities by exploiting the vulnerabilities of socially or economically disadvantaged individuals.[45] Yet, since socioeconomic status may intersect with various prohibited grounds of discrimination, such as racial origin, ethnicity, or religion, it can often be used as a proxy linked to these grounds and thereby trigger the applicability of the relevant non-discrimination rules.[46]

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[40] See eg Case C-354/13 *FOA* ECLI:EU:C:2014:2463, paras 53–54; Case C-363/12 *Z* ECLI:EU:C:2014:159, paras 76–77; Case C-13/05 *Chacón Navas* EU:C:2006:456, paras 41–43.

[41] See Art 3(1) of Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services [2019] OJ L151/70. See also explicitly the Commission's Guidelines on prohibited AI practices (n 24) point 108.

[42] See Art 1 of the United Nations Convention on the Rights of Persons with Disabilities (CRPD) adopted in New York on 13 December 2006. See also Council Decision of 26 November 2009 concerning the conclusion, by the European Community, of the United Nations Convention on the Rights of Persons with Disabilities [2009] OJ L23/35.

[43] See recital 29 of the AI Act. See also the Commission's Guidelines on prohibited AI practices (n 24) points 109, 112.

[44] See S Ganty and JC Benito-Sanchez, 'Expanding the List of Protected Grounds within Anti-Discrimination Law in the EU' (Equinet 2021) 36–37. Yet, Art 21(1) of the Charter also prohibits discrimination on the grounds of social origin and property. For an interesting analysis as to why discrimination on socioeconomic criteria should not be protected under Art 21 of the Charter, see Case C-715/20 *KL v X* ECLI:EU:C:2023:281, Opinion of AG Pitruzzella, paras 71–81. For the opposite view, see S Ganty, 'Poverty as Misrecognition: What Role for Antidiscrimination Law in Europe?' (2021) 21(4) Human Rights Law Review 962.

[45] See the Commission's Guidelines on prohibited AI practices (n 24) point 110.

[46] ibid, points 111, 138. For the intersection of socioeconomic considerations with other prohibited grounds, see S Atrey, 'The Intersectional Case of Poverty in Discrimination Law' (2018) 18 Human Rights Law Review 411.

Accordingly, where an AI system targets persons in specific socioeconomic conditions based on proxies that closely correlate with protected characteristics, or disproportionately affects such persons that at the same time belong to protected social groups,[47] both Article 5(1)(b) of the AI Act and EU non-discrimination law may apply at the same time.[48] This will be the case, for example, of an AI-predictive algorithm that is used to target with advertisements for predatory financial products persons who are in a dire financial situation and live in low-income neighbourhoods predominantly inhabited by people of a particular ethnic origin.[49] However, where the persons concerned are targeted merely on the basis of their socioeconomic situation without any correlation to protected characteristics, such targeting will not be captured by non-discrimination rules but may only fall under the scope of Article 5(1)(b) of the AI Act, as long as it constitutes a deliberate feature of the system's algorithmic design, or the providers or deployers of that system are aware of the reasonably likely harm that their system may cause and have not taken appropriate corrective measures.[50] The added value of Article 5(1)(b) also manifests in cases where, although an AI system deploys socioeconomic data as a proxy for protected characteristics, the exploitative AI-driven practice in question takes place in a social context that is not covered by the protective cloak of the EU Equality Directives. For instance, an AI system which exploits socioeconomic data to target persons with disabilities living in precarious conditions with advertisements for predatory medical services will fall outside the scope of Directive 2000/78,[51] but may still be prohibited under Article 5(1)(b) of the AI Act alone or combined with Article 21(1) of the Charter.

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[47] See the Commission's Guidelines on prohibited AI practices (n 24) points 110–111.

[48] As per point 138 of the Commission's Guidelines on prohibited AI practices (n 24), the AI Act's prohibitions do not affect prohibitions based on other grounds or discriminatory practices that do not entail significant harms and that are already prohibited by EU non-discrimination law.

[49] This example is a combination of the ones mentioned in the Commission's Guidelines (n 24), points 110–111.

[50] See the Commission's Guidelines on prohibited AI practices (n 24) point 110, distinguishing between such instances of 'direct discrimination' against socially or economically disadvantaged persons which are covered by the AI Act's prohibition, and those of 'indirect discrimination' which are not automatically considered to exploit these persons' vulnerabilities, as is the case, for example, of AI systems that are inadvertently biased (eg due to tainted training data) and disproportionately impact disadvantaged persons. Thus, instances of 'indirect discrimination' on the basis of individuals' socioeconomic condition alone, without any correlation to protected characteristics, are likely to fall through the cracks of both Art 5(1)(b) of the AI Act and EU non-discrimination law, unless such AI-enabled discrimination is based on those individuals' social origin or property, thus being captured by Art 21(1) of the Charter. However, it is noted that those instances may still be prohibited under Art 5(1)(a) of the AI Act.

[51] This is because Directive 2000/78 does not cover access to goods and services.

In any event, AI systems that exploit the vulnerabilities of individuals belonging to vulnerable groups other than those defined by age, disability, or a specific socioeconomic situation are left outside the scope of Article 5(1)(b) of the AI Act.[52] By way of illustration, targeting homosexual, bisexual or trans persons with social media advertisements for so-called 'conversion therapies',[53] or pregnant women with advertisements for pricy pregnancy- or maternity-related products, is not prohibited under the AI Act, unless it somehow results from the exploitation of vulnerabilities related to the age, disability, or socioeconomic status of the persons concerned. The question raised here is whether the personal scope of Article 5(1)(b) of the AI Act could be extended in the light of Article 21(1) of the Charter so as to cover also vulnerabilities relating to other personal traits protected therein. In my view, a Charter-conforming interpretation of Article 5(1)(b) of the AI Act would dictate a positive answer. Regardless, such instances may still be captured by Article 5(1)(a) if they leverage on the specific vulnerabilities and weaknesses of the affected persons.[54] Thus, to the extent that such AI practices may also fall outside the scope of non-discrimination law,[55] the complementary nature of the AI Act's prohibitions of manipulative, deceptive, and exploitative systems under Article 5(1)(a)-(b) proves to be of great practical importance in this regard.

2.2 Social scoring

The prohibition in Article 5(1)(c) of the AI Act addresses AI-enabled evaluation or classification of individuals or groups based on their social behaviour or personal characteristics that leads to detrimental or

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[52] See the Commission's Guidelines on prohibited AI practices (n 24) point 103.

[53] See eg H Horton and J Cook, 'Facebook Accused of Targeting Young LGBT Users with "Gay Cure" Adverts' (*The Telegraph*, 25 August 2018) <https://tinyurl.com/5be2jkdf> accessed 20 November 2025; J Hesse, '"Love Is Love": Media Firm Uses LGBT Language to Send Anti-Gay Message' (*The Guardian*, 23 January 2018) <https://tinyurl.com/4yz99ahz> accessed 20 November 2025.

[54] See the Commission's Guidelines on prohibited AI practices (n 24) point 125. These practices could also fall within the scope of Art 21(1) of the Charter. As concerns (trans) gender identity, however, this possibility is questionable: although not mentioned in that provision, gender identity could still be considered as falling under the notion of 'sex' or explicitly recognised as a prohibited ground *per se*, but this scenario remains uncertain for the time being.

[55] This is because discrimination on grounds of sexual orientation under Directive 2000/78 is only prohibited in matters of employment and occupation, while (trans)gender identity has been granted protection only when forming part of prohibited sex discrimination in the context of gender reassignment surgeries. See eg the judgment in Case C-13/94 *P v S and Cornwall County Council* ECLI:EU:C:1996:170. As for equal treatment between women and men in access to and in the supply of goods and services, Directive 2004/113 explicitly excludes advertising from its scope of application. See Art 3(3) thereof.

unfavourable treatment, especially where the data used for this purpose originates from unrelated social contexts or where the treatment is disproportionate to the gravity of the social behaviour. As recital 31 of the AI Act explicitly recognises, given that AI systems enabling these so-called 'social scoring' practices may lead to discriminatory or unfair outcomes for certain individuals and groups and result in their exclusion from society, the AI Act's prohibition in this regard is intended to safeguard, among other things, the right to non-discrimination and the EU value of equality, including equal access to public and private services.[56]

Such practices are increasingly prevalent across the EU: one could think, notably, of the notorious 'childcare benefits scandal' (*toeslagenaffaire*) in the Netherlands concerning the deployment of a self-learning algorithm by the Dutch Tax Administration to assess childcare benefit applications that resulted in falsely targeting thousands of parents from families of lower economic status or an ethnic minority background.[57] Similarly, the algorithm used by the Dutch Education Executive Agency (DUO) to calculate the risk of students committing fraud with the grant for students living away from home was declared discriminatory by the Dutch Data Protection Authority.[58] Likewise, the Danish government's fraud control algorithm used for the distribution of social benefits was found likely to discriminate against people with disabilities, low-income individuals, migrants, and marginalised racial groups,[59] while the ma-

[56] See the Commission's Guidelines on prohibited AI practices (n 24) point 148.

[57] See eg 'Dutch Scandal Serves as a Warning for Europe Over Risks of Using Algorithms' (*Politico*, 29 March 2022) <https://tinyurl.com/yemdeuby> accessed 20 November 2025. For a detailed overview of how this system led to discrimination as well as racial profiling, see the report of Amnesty International, 'Xenophobic Machines: Discrimination Through Unregulated Use of Algorithms in the Dutch Childcare Benefits Scandal' (October 2021) <https://tinyurl.com/mtrsk2mx> accessed 20 November 2025. Dealing with follow-up discrimination claims brought by the victims of the benefits affair, the Dutch Institute of Human Rights found that the selection criteria used by the Tax Administration for the discontinuation and recovery of childcare benefits indirectly discriminated against them on the basis of their foreign origin. See College voor de Rechten van de Mens, oordeelnummers 2023–101, 2023–102, 2023–103, 2 October 2023. See also the Institute's preliminary investigation, College voor de Rechten van de Mens, 'Vooronderzoek naar de Vermeende Discriminerende Effecten van de Werkwijzen van de Belastingdienst/Toeslagen' <https://tinyurl.com/usybvx98> accessed 20 November 2025.

[58] See Autoriteit Persoonsgegevens, 'DUO's Approach to Fraud Found to Be Discriminatory and Illegal' (11 November 2024) <https://tinyurl.com/4yn4zxc3> accessed 20 November 2025. See also Autoriteit Persoonsgegevens, 'Onderzoeksrapport fraudeaanpak DUO' <https://tinyurl.com/4v4d7hpt> accessed 20 November 2025. The Data Protection Authority concluded that DUO's algorithm gave rise to direct discrimination based on the students' type of education, distance from the parents' home, and younger age, while also indirectly discriminating against students with a non-European migration background.

[59] See Amnesty International, 'Coded Injustice: Surveillance and Discrimination in Denmark's Automated Welfare State' (November 2024) <https://tinyurl.com/3murv64h> accessed 20 November 2025.

chine-learning system deployed by Sweden's Social Insurance Agency for the same purposes was also found prone to disproportionately flag women, individuals with a foreign background, low-income earners, and individuals without a university degree.[60]

In cases where AI-enabled social scoring is based directly or indirectly on a protected ground of discrimination, this practice, apart from being banned under the AI Act, will be further captured by EU non-discrimination law.[61] However, social scoring practices are not always prohibited, but only in cases where all the conditions of Article 5(1)(c) of the AI Act are cumulatively fulfilled.[62] Pursuant to recital 31 of the AI Act, the prohibition of social scoring does not affect lawful evaluation practices of individuals that are carried out for a specific purpose in accordance with EU and national law.[63] This means that AI scoring systems, which generate a social score by evaluating or classifying individuals, will fall outside the scope of Article 5(1)(c) of the AI Act if they comply with EU sectoral legislation that specifies which type of data can be used as relevant and necessary for the specific legitimate purpose of evaluation and ensures that any detrimental or unfavourable treatment is justified and proportionate to the social behaviour concerned.[64]

By way of illustration, when examining whether an AI-based credit scoring system used by creditors or third entities, such as credit information agencies, to assess a customer's financial creditworthiness and determine their access to credit accordingly is covered by the AI Act's prohibition, the relevant point of reference will be the revised Consumer Credit Directive (CCD).[65] Article 18(3) of the said Directive requires that creditworthiness assessments be based solely on information of an economic or financial nature relating to the consumer's income and expenses and other financial and economic circumstances (eg evidence of

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[60] See Amnesty International, 'Sweden: Authorities Must Discontinue Discriminatory AI Systems Used by Welfare Agency' (November 2024) <https://tinyurl.com/kr8m6x6r> accessed 20 November 2025.

[61] See Art 5(8) of the AI Act and the Commission's Guidelines on prohibited AI practices (n 24) point 181.

[62] See the Commission's Guidelines on prohibited AI practices (n 24) point 175.

[63] See recital 31 of the AI Act.

[64] See the Commission's Guidelines on prohibited AI practices (n 24) points 176–177.

[65] ibid, points 177 (fn 126) 182, and Directive (EU) 2023/2225 of the European Parliament and of the Council of 18 October 2023 on credit agreements for consumers and repealing Directive 2008/48/EC [2023] OJ L2023/2225. For a detailed overview of this Directive, see O Cherednychenko, 'On the Bumpy Road to Responsible Lending in the Digital Marketplace: The New EU Consumer Credit Directive' (2024) 47 Journal of Consumer Policy 241. For the impact of the AI Act on credit scoring in general, see G Spindler, 'Algorithms, Credit Scoring, and the New Proposals of the EU for an AI Act and on a Consumer Credit Directive' (2021) 15(3–4) Law and Financial Markets Review 239.

income or other sources of repayment, information on financial assets and liabilities, or on other financial commitments).[66] However, the use of sensitive data within the meaning of Article 9(1) GDPR, such as those revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, is prohibited, and so is the use of data obtained from social networks.[67] Accordingly, whereas AI credit scoring systems based on the financial and economic circumstances of the persons concerned to determine their eligibility for a loan will most likely not fall under the scope of Article 5(1)(c) of the AI Act,[68] by contrast, systems relying on other categories of data, such as those drawn from the individuals' social media[69] or smartphone,[70] will be prohibited. Hence, by pointing to the CCD's specification of the type of data that can be deployed for evaluating the borrowers' credit default risk, the AI Act incorporates in its prohibition of AI-enabled social scoring the discrimination concerns relating to the use of so-called 'alternative' data in credit scoring practices, which are opposed to 'traditional' financial data.[71]

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[66] See also recital 55 CCD, further pointing to the European Banking Authority's (EBA) 'Guidelines on loan origination and monitoring' (EBA/GL/2020/06, 29 May 2020), which provide guidance on the categories of data that may be used for the purposes of creditworthiness assessments (Annex 2).

[67] The same prohibitions also apply when creditors consult credit databases under Art 19(5) CCD. In this regard, the final text of Art 18 CCD follows the recommendations made by the European Data Protection Supervisor (EDPS) in its Opinion 11/2021, points 11–18. However, contrary to what was proposed by the EDPS (Opinion 11/2021, points 17, 41), the use of search query data and online browsing activities is not expressly prohibited, nor are the categories of data that may be used to draw up a personalised offer clearly delineated. As a result, it is possible that a consumer receives, for instance, a predatory loan following an analysis of their search queries that reveal their urgent need to obtain credit. See M L Montagnani and C Paulesu, 'Towards an Ecosystem for Consumer Protection in the Context of AI-based Credit Scoring' (2022) 33(4) European Business Law Review 557, 578.

[68] Nevertheless, absent the conditions of Art 5(1)(c), AI-driven credit scoring systems may still qualify as high-risk in accordance with Art 6(2) combined with Annex III(5)(b) of the AI Act. In that case, compliance with the requirements laid down in relation to high-risk AI systems may ensure that such AI systems do not constitute prohibited social scoring practices. See the Commission's Guidelines on prohibited AI practices (n 24) point 172.

[69] See T Groenfeldt, 'Lenddo Creates Credit Scores Using Social Media' (*Forbes*, 29 January 2015) <https://tinyurl.com/3mu989me> accessed 20 November 2025.

[70] See H King, 'This Startup Uses Battery Life to Determine Credit Scores' (*CNN*, 24 August 2016) <https://tinyurl.com/43mw25h3> accessed 20 November 2025.

[71] Regarding the use of such alternative data not necessarily connected to the individual's financial standing, see M Hurley and J Adebayo, 'Credit Scoring in the Era of Big Data' (2016) 18 Yale Journal of Law and Technology 148; K Langenbucher, 'Consumer Credit in the Age of AI: Beyond Non-Discrimination Law' (European Corporate Governance Institute, Law Working Paper No 663/2022, LawFin Working Paper No 42, 2022). See also N Aggarwal, 'The Norms of Algorithmic Credit Scoring' (2021) 80(1) Cambridge Law Journal 42; N Collado-Rogriguez and U Kohl, 'All Data Is Credit Data: Personalised Consumer Credit Score and Non-Discrimination Law' in U Kohl and J Eisler (eds), *Data-Driven Personalisation in Markets, Politics and Law* (CUP 2021). In fact, among the market developments brought about by digitalisation which prompted the modernisation of the existing

2.3 Crime risk assessment

As per Article 5(1)(d) of the AI Act, AI systems assessing or predicting the risk of individuals committing a criminal offence, based solely on their profiling or on assessing their personality traits and characteristics, are prohibited. By associating indicators with the likelihood of a crime occurring, these systems identify patterns within historical data about previously committed crimes and then create individual risk scores to inform law enforcement activities and criminal justice decisions at any stage, such as during the prevention and detection of crimes (eg for the planning of police task forces, monitoring high-risk situations or locations, or conducting controls of persons predicted as potential offenders, etc), but also during the investigation, prosecution, and execution of criminal penalties (eg for assessing the risk of re-offending in the context of decisions about pre-trial detention, probation, or early release).[72] The characteristics assessed for these purposes may indicatively include individuals' nationality, place of birth, place of residence, number of children, level of debt, or type of car.[73] Real-world uses of such AI-enabled predictive systems abound across EU Member States and beyond.[74]

However, the use of historical crime data to predict other persons' future behaviour is likely to perpetuate or even reinforce existing biases, in particular against certain racial or ethnic groups that may be over-represented in criminal records, thereby giving rise to discriminatory racial or ethnic profiling.[75] Since such data-based AI models may influence law enforcement authorities to repeatedly target people from the same over-represented demographics in a disproportionate manner, the output they generate will then be fed back into the system, resulting

framework in the field of consumer credit, particularly important was the use of alternative categories of data, raising concerns over the discrimination risks of algorithmic decisions. See Commission, 'Staff Working Document, Impact Assessment Report accompanying the Proposal for a Directive of the European Parliament and of the Council on consumer credits' SWD (2021) 170 final 3, 18, 27.

[72] See the Commission's Guidelines on prohibited AI practices (n 24) points 190–191.

[73] See recital 42 of the AI Act. According to the Commission's Guidelines on prohibited AI practices (n 24) point 198, this list is only illustrative and not exhaustive.

[74] For an overview of such systems deployed in Europe, see Fair Trials, 'Automating Injustice: The Use of Artificial Intelligence and Automated Decision-Making Systems in Criminal Justice in Europe' (9 September 2021) Section 1.1, 8–18 <https://tinyurl.com/3xscz4n9> accessed 20 November 2025.

[75] See the Commission's Guidelines on prohibited AI practices (n 24) point 190. See also K Lum and W Isaac, 'To Predict and Serve?' (2016) 13(5) Significance 14. Regarding discrimination in racial or ethnic profiling practices in general, see FRA, 'Towards More Effective Policing, Understanding and Preventing Discriminatory Ethnic Profiling: A Guide' (Publications Office of the European Union 2010).

in self-perpetuating 'feedback loops'.[76] This was the case, notably, of the 'COMPAS' tool used in the US criminal justice system to assess individuals' recidivism risk, which was found to incorrectly generate higher risk rates for black persons and for people of Hispanic origin.[77] In a similar vein, the algorithm deployed in a Dutch town to predict the risk of 'mobile banditry' among car drivers or passengers was accused of targeting mostly persons with Eastern European nationalities and/or of Roma ethnicity.[78] Such discriminatory outcomes may also arise due the use of protected personal traits or proxies thereof as variables into the systems concerned. For instance, it has been revealed that the 'HART' system used in the United Kingdom to assess the risk of suspects re-offending in the future and to advise accordingly on whether to charge them or release them into a rehabilitation programme relied on ethnicity data or socioeconomic proxy information, including postcodes.[79]

It is noted that the prohibition in Article 5(1)(d) of the AI Act applies irrespective of whether the personal traits, on the basis of which crime predictions are performed, constitute protected characteristics under non-discrimination law, or whether they form part of sensitive categories of data in the sense of the Law Enforcement Directive, which explicitly prohibits profiling based on such data that results in discrimination against natural persons.[80] Yet, insofar as such practices are targeted at individuals belonging to protected social groups, they will also be cap-

[76] See Ensign and others, 'Runaway Feedback Loops in Predictive Policing' (2018) 81 Proceedings of Machine Learning Research 1–12; L Bennett Moses and J Chan, 'Algorithmic Prediction in Policing: Assumptions, Evaluation, and Accountability' (2018) 28(7) Policing and Society 806.

[77] See J Angwin and others, 'Machine Bias' (*ProPublica*, 23 May 2016) <https://tinyurl.com/46fez35j> accessed 20 November 2025. See also, M Hamilton, 'The Biased Algorithm: Evidence of Disparate Impact on Hispanics' (2019) 56(4) American Criminal Law Review 1553.

[78] See Amnesty International, 'We Sense Trouble: Automated Discrimination and Mass Surveillance in Predictive Policing in the Netherlands' (EUR 35/2971/2020, 28 November 2020) <https://tinyurl.com/srzsr5bz> accessed 20 November 2025.

[79] See Big Brother Watch, 'Briefing on Algorithmic Decision-Making in the Criminal Justice System' (January 2020) 7–11 <https://tinyurl.com/mr3bhasd> accessed 20 November 2025.

[80] See Art 11(3) of Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA [2016] OJ L119/89. Pursuant to Art 10 of the said Directive, special categories of personal data include those revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data, and those concerning health or a person's sex life or sexual orientation. The categories of data considered as 'sensitive' largely correspond to the prohibited grounds of discrimination under the EU Equality Directives and Art 21(1) of the Charter, even though they do not fully overlap with those.

tured by Article 21(1) of the Charter, the application of which is triggered by virtue of the AI Act's prohibition that brings AI-enabled crime risk assessments under the scope of EU law.[81] In this regard, Article 5(1)(d) of the AI Act is of great added value, considering, on the one hand, that the EU Equality Directives are only applicable to certain economic settings and not to the field of the State's law enforcement activities,[82] and, on the other hand, that the Law Enforcement Directive applies only to the processing of personal data, excluding aggregate or anonymous data, which do not relate to an identified or identifiable person, but may often be processed by AI systems.[83] Furthermore, the outright prohibition contained in Article 5(1)(d) of the AI Act seems more apt for addressing the systemic and structural nature of certain discriminatory practices, such as racial or ethnic profiling, which is often overlooked or not effectively captured in the context of individual discrimination claims.[84]

That said, AI systems employed to support human assessments of the involvement of a person in a criminal activity that is based on objective and verifiable facts linked to a criminal activity are not covered by Article 5(1)(d) of the AI Act. Likewise, location- or geospatial or place-based crime predictions, which do not entail an assessment of a specific individual but merely make predictions about the likelihood of a crime being committed in certain areas, fall outside the scope of the AI Act's prohibitions, unless the risk score of the place or location constitutes an aspect in the profiling of a person.[85] Nevertheless, these two categories of AI risk assessments may still fall within the ambit of EU non-dis-

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[81] In the context of the European Convention on Human Rights (ECHR), instances of discriminatory profiling can be captured by Art 14 (prohibition of discrimination) combined with other ECHR provisions, as well as by Art 1 of Protocol No 12 to the Convention of 4 November 2000 (general prohibition of discrimination). Given that Art 21(1) of the Charter corresponds to Art 14 ECHR in the sense of Art 52(3) of the Charter, the CJEU may thus rely on the case law of the ECtHR on discriminatory racial or ethnic profiling. For an overview of such case law, see ECtHR's Press Unit, 'Factsheet - Racial Profiling' (May 2024) <https://tinyurl.com/bdd3cup9> accessed 20 November 2025.

[82] For a different view on the applicability of Directive 2000/43 in racial or ethnic profiling, see J Klaas, R Beets and M Hendrickx, 'Guide on Strategic Litigation to Combat Ethnic Profiling in the European Union' (Public Interest Litigation Project (PILP-NJCM) 2020) 29 <https://tinyurl.com/yj4ek48y> accessed 20 November 2025.

[83] See recital 21 of the said Directive and the definition of 'personal data' under Article 3(1) thereof.

[84] Regarding racial profiling as structural discrimination, see eg N Crowley, 'To Name and Address the Underlying Problem: Structural Discrimination on the Ground of Racial or Ethnic Origin' (European Commission, Publications Office of the European Union 2022). See also N Dube, 'Wa Baile v Switzerland: An Implicit Acknowledgment of Racial Profiling as Structural Discrimination' (*Strasbourg Observers*, 26 March 2024) <https://tinyurl.com/3wuynhmm> accessed 20 November 2025.

[85] See the Commission's Guidelines on prohibited AI practices (n 24) points 212–213. For an overview of such systems in Europe, see Fair Trials (n 74) Section 1.2, 19–26.

crimination rules if they are correlated with prohibited grounds, such as racial or ethnic origin. On the one hand, even in cases of hybrid or semi-automated systems where humans are somehow involved in the decision-making process, the latter tend to favour the outcomes produced by the AI systems regardless of how inaccurate or biased they may be, due to the perception that such systems are generally neutral and reliable, a phenomenon known as 'automation bias'.[86] On the other hand, with regard to geographic crime prediction practices, these may often also prove to be discriminatory, as was the case, for instance, of the 'CAS' system deployed in the Netherlands to predict crime rates in specific areas by relying, among other predictors, on the number of 'non-Western' individuals living in those areas.[87] In such instances, if totally innocent residents of allegedly high-risk areas are incorrectly targeted, the doctrine of discrimination by association becomes of particular relevance in a way similar to the one upheld by the CJEU in *CHEZ*.[88]

2.4 Untargeted scraping of facial images

Article 5(1)(e) of the AI Act prohibits the use of AI systems to create or expand facial recognition databases through the untargeted scraping of facial images from the internet or CCTV footage. This practice entails the automatic extraction of data or content containing human faces (eg pictures, videos) along with any associated information (eg geo-localisation, names of the persons depicted) from different sources, such as websites, social media platforms, or CCTV material (eg surveillance cameras installed in airports, streets, parks, etc), without a specific focus on a given individual or group of individuals, in order to build-up a database capable of finding any match between the faces collected therein and digital photos of people.[89] The AI Act's prohibition in this regard comes as a response to the emergence of highly controversial tools like the ones developed by the US company 'Clearview AI' and the Polish website 'PimEyes', which have attracted considerable scrutiny for raising serious

[86] See Fair Trials (n 74) Section 3.1, 34. On the problem of automation bias in general, see eg K Mosier and others, 'Automation Bias: Decision Making and Performance in High-Tech Cockpits' (1998) 8(1) The International Journal of Aviation Psychology 47.

[87] See Fair Trials (n 74) Section 1.2.1, 19–20. See also S Oosterloo and G van Schie, 'The Politics and Biases of the "Crime Anticipation Systems" of the Dutch Police' (Proceedings of the International Workshop on Bias in Information, Algorithms, and Systems co-located with 13th International Conference on Transforming Digital Worlds (iConference 2018) 2018) <https://tinyurl.com/4u84pmfv> accessed 20 November 2025.

[88] See Case C-83/14 *CHEZ Razpredelenie Bulgaria* ECLI:EU:C:2015:480. See also eg G Von Toggenburg, 'Discrimination by Association: A Notion Covered by EU Equality Law?' (2008) 3 European Law Reporter 82.

[89] See the Commission's Guidelines on prohibited AI practices (n 24) points 226–228.

privacy-related concerns.[90] Such tools may be widely deployed by both public authorities, notably for law enforcement purposes, and various private entities, including banks, retail stores, and entertainment companies, or by anyone wishing to identify another person for any possible reason.[91]

Apart from their incompatibility with EU data protection rules,[92] AI-driven scraping systems and the ensuing facial recognition databases can also eventually enable or facilitate the discriminatory treatment of certain individuals or groups. To give some examples, such systems may lead to the erroneous arrests of persons of certain racial or ethnic origin when utilised by the police to identify suspects of crimes;[93] they may be relied on by supermarkets to deny access to their premises to undesired customers belonging to socioeconomically disadvantaged communities;[94] they may be used by an employer to check whether a job candidate has attended any gay events and thus decide whether or not to hire that person based on their presumed sexual orientation; or they may be privately used by individuals for gender-based cyberviolence and harassment, such as to stalk women, expose trans people, or identify sex workers.[95]

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[90] See K Hill, 'The Secretive Company That Might End Privacy as We Know It' (*The New York Times*, 18 January 2020) <https://tinyurl.com/3dsz5pfe> accessed 20 November 2025; D Gershgorn, 'This Simple Facial Recognition Search Engine Can Track You Down Across the Internet' (*Medium*, 9 June 2020) <https://tinyurl.com/yvcvppf4> accessed 20 November 2025.

[91] See R Mac, C Haskins and L McDonald, 'Clearview's Facial Recognition App Has Been Used by the Justice Department, ICE, Macy's, Walmart, and the NBA' (*BuzzFeed.News*, 28 February 2020) <https://tinyurl.com/26bse9fr> accessed 20 November 2025; R Metz, 'Anyone Can Use This Powerful Facial-Recognition Tool - And That's a Problem' (*CNN*, 4 May 2021) <https://tinyurl.com/yv6tusxr> accessed 20 November 2025.

[92] See explicitly the Commission's Guidelines on prohibited AI practices (n 24) point 238. For an overview of the legal actions against Clearview AI and the fines imposed on it by Data Protection Authorities across various EU Member States, see noyb, 'Criminal Complaint Against Facial Recognition Company Clearview AI' (28 October 2025) <https://tinyurl.com/2c6k9cnu> accessed 20 November 2025.

[93] See K Hill, 'Wrongfully Accused by an Algorithm' (*The New York Times*, 24 June 2020) <https://tinyurl.com/bdzjmuu3> accessed 20 November 2025; E Stokes, 'Wrongful Arrest Exposes Racial Bias in Facial Recognition Technology' (*CBS News*, 19 November 2020) <https://tinyurl.com/mus76pp9> accessed 20 November 2025. See also J Cebreros, 'Facial Recognition Technology and Wrongful Arrests in the Digital Policing Era' 100 (2025) Washington Law Review Online 33-51.

[94] See Big Brother Watch, 'Biometric Britain: The Expansion of Facial Recognition Surveillance' (23 May 2025) 100-4 <https://tinyurl.com/3rz4a877> accessed 20 November 2025. See also GDPRhyb, 'AEPD (Spain) - PS/00120/2021' <https://tinyurl.com/32cz6e43> accessed 20 November 2025.

[95] See European Parliament, 'PimEyes: The Fundamental Rights Implications of Private Use of Facial Recognition Technology and Biometric Databases' (Parliamentary question E-002586/2022, 14 July 2022). See also J Wakefield, 'PimEyes Facial Recognition Website

Even though the prohibition of Article 5(1)(e) of the AI Act targets only the creation or expansion of facial recognition databases and not the concrete act of biometric identification through facial recognition,[96] it significantly contributes to the prevention of AI-enabled discrimination. Unlike EU non-discrimination law which can potentially capture solely the discriminatory outcomes of facial recognition technologies as such and not the relevant databases, unless these are based on prohibited classifications,[97] the AI Act intervenes here at an earlier stage by prohibiting the creation or expansion of the relevant databases in the first place. Furthermore, contrary to the EU Equality Directives, Article 5(1)(e) of the AI Act is not confined to specific walks of life but rather applies across sectors.

2.5 Emotion recognition

According to Article 5(1)(f) of the AI Act, the marketing and use of AI systems to identify or infer emotions of natural persons in the areas of workplace and educational institutions are prohibited.[98] These systems enable the identification or inference of a wide range of emotions, such as happiness, sadness, anger, surprise, disgust, embarrassment, excitement, shame, contempt, satisfaction, or amusement, on the basis of the biometric data of the persons concerned relating, for instance, to basic facial expressions, such as a frown or a smile, or gestures such as the movement of hands, arms or head, or characteristics of those persons' speech, such as a raised voice or whispering.[99] However, since the expression of emotions varies considerably across different cultures and situations, and even across different people within a single situation,[100] emotion recognition tools have been criticised for lacking sufficient accuracy and reliability, but also for being prone to generate discriminatory outcomes.[101] In particular, research has demonstrated that such tools

"Could Be Used by Stalkers"' (*BBC*, 11 June 2020) <https://tinyurl.com/mr634yxv> accessed 20 November 2025.

[96] See the Commission's Guidelines on prohibited AI practices (n 24) point 237. For the rules governing biometric identification systems see below Section 2.7.

[97] On the discriminatory potential of facial recognition technologies, see below Section 2.7.

[98] See Art 3(39) and recital 44 AI Act. See also the Commission's Guidelines on prohibited AI practices (n 24) points 244–245.

[99] See Art 3(39) and recital 18 of the AI Act. See also the Commission's Guidelines on prohibited AI practices (n 24) points 247–252.

[100] See L Feldman Barrett and others, 'Emotional Expressions Reconsidered: Challenges to Inferring Emotion from Human Facial Movements' (2019) 20(1) Psychological Science in the Public Interest 1.

[101] See recital 44 of the AI Act. See also the Commission's Guidelines on prohibited AI practices (n 24) point 241.

may present higher error rates for people with darker skin tone, being more likely to predict those people as having negative emotions (eg anger, sadness, etc) even when they are smiling;[102] they may perceive emotions more accurately for younger adults than for older persons;[103] and they may show gender bias in the form of an accuracy gap between men and women.[104]

The prohibition of AI-based emotion recognition systems under Article 5(1)(f) of the AI Act explicitly applies only in situations related to work or education, given the imbalance of power existing in those settings.[105] For example, the use of such systems by an employer during the recruitment process, or by an educational institution during admissibility tests for new students, is prohibited.[106] To the extent that these AI tools could lead to detrimental or unfavourable treatment of certain persons or whole groups, such instances will also amount to prohibited discrimination, without prejudice to the respective material scope of each Equality Directive. This means that, whereas discriminatory emotion recognition systems used in the context of work will be captured by EU non-discrimination secondary legislation regardless of whether they affect people because of their racial or ethnic origin, sex, religion, age, disability, or sexual orientation, similar systems used in the context of education will be captured only in cases where they discriminate against certain persons based on their racial or ethnic origin under Directive 2000/43.[107] Nevertheless, this limit can be overcome by the simultaneous application of Article 5(1)(f) of the AI Act and Article 21(1) of the Charter in this regard.

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[102] See R Khan and C Stinson, 'Auditing Facial Emotion Recognition Datasets for Posed Expressions and Racial Bias' (2025) arXiv abs/2507.10755 [cs.CV] <https://tinyurl.com/yc5z3nuh> accessed 20 November 2025.

[103] See E Kim and others, 'Age Bias in Emotion Detection: An Analysis of Facial Emotion Recognition Performance on Young, Middle-Aged, and Older Adults' (AIES '21: Proceedings of the 2021 AAAI/ACM Conference on AI, Ethics, and Society, 19–21 May 2021) 638 <https://tinyurl.com/3merafm8> accessed 20 November 2025.

[104] See A Domnich and G Anbarjafari, 'Responsible AI: Gender Bias Assessment in Emotion Recognition' (2021) arXiv abs/2103.11436 [cs CV] <https://tinyurl.com/4hy76uvc> accessed 20 November 2025. For biases in facial recognition in relation to gender, ethnicity, and age, see also J Pahl and others, 'Female, White, 27? Bias Evaluation on Data and Algorithms for Affect Recognition in Faces' (FAccT '22: Proceedings of the 2022 ACM Conference on Fairness, Accountability, and Transparency, 21–24 June 2022) 973 <https://tinyurl.com/yctkfhv6> accessed 20 November 2025.

[105] See recital 44 of the AI Act.

[106] See the Commission's Guidelines on prohibited AI practices (n 24) points 254–255.

[107] This is because education is excluded not only from the scope of Directive 2000/78, which applies solely in the field of employment, but also from that of Directive 2004/113 (see Art 3(3) thereof).

It is further noted that, by prohibiting outright any AI-powered emotion recognition practices in work- or education-related situations, Article 5(1)(f) of the AI Act applies irrespective of whether such practices affect individuals on the basis of prohibited grounds under EU non-discrimination law. Conversely, AI systems, which are intended to detect the emotional state of individuals in all other domains than the workplace or education and thus fall outside the ambit of Article 5(1)(f) AI Act,[108] may still be prohibited by the EU non-discrimination rules if they fall within the personal and material scope thereof. This will be the case, for instance, where a customer of a given ethnicity is mistakenly perceived as too angry by an emotion recognition camera when entering a retail store, thus being denied access to certain products.

However, the legal protection granted against the risk of discrimination of emotion recognition tools remains incomplete. The use of such AI systems risks falling through the cracks of both Article 5(1)(f) of the AI Act and non-discrimination law where the disadvantageous treatment of individuals stemming from an erroneous identification or inference of their emotions occurs in an area of life other than work or education and at the same time is not covered by the material scope of the Equality Directives. By way of illustration, where a person's emotions are misunderstood due to a certain medical condition or physical impairment that results in temporary or permanent paralysis of that person's facial muscles, thereby leading to a misdiagnosis for healthcare purposes,[109] neither Article 5(1)(f) of the AI Act nor Directive 2000/78 are applicable. Yet, it is in the context of law enforcement and migration, asylum, or border control management that this gap in protection is most remarkable. This is because AI-based emotion recognition technologies, such as lie detectors ('polygraphs'), may be largely deployed in these areas with potentially adverse consequences for the fundamental rights of the persons affected, including their right to non-discrimination.[110]

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[108] For a non-exhaustive overview of the areas, in which AI emotion recognition tools may be used, see the Commission's Guidelines on prohibited AI practices (n 24) point 240. These systems are, however, considered to be of high risk, pursuant to Annex III(1)(c) of the AI Act, and are subject to additional transparency requirements under Art 50. Besides, emotion recognition systems may also be prohibited in certain cases by virtue of Art 5(1)(a) and (b). See in this regard the Commission's Guidelines (n 24) point 266.

[109] See K Vemou and A Horvath, 'EDPS TechDispatch on Facial Emotion Recognition' (European Data Protection Supervisor, Issue 1, 2021) <https://tinyurl.com/2jkkccjr> accessed 20 November 2025.

[110] Although such technologies are not currently used at the EU borders, their development has been tested by EU-funded projects. See eg R Picheta, 'Passengers to Face AI Lie Detector Tests at EU Airports (*CNN*, 2 November 2018) <https://tinyurl.com/47jb82jv> accessed 20 November 2025. For more details, see J Sánchez-Monedero and L Dencik, 'The Politics of Deceptive Borders: "Biomarkers of Deceit" and the Case of iBorderCtrl' (2020) 25(3) Information, Communication and Society 413; D Ozkul, 'Automating Immigration and Asylum:

2.6 Biometric categorisation

The prohibition of Article 5(1)(g) of the AI Act covers AI systems that categorise individuals based on their biometric data to deduce or infer a number of sensitive characteristics, namely their race, political opinions, trade union membership, religious or philosophical beliefs, sex life, or sexual orientation.[111] Such categorisation may rely on the physical and physiological features (eg face, skin, eye and hair colour, hand patterns, ear shape, fingerprints, voice, etc.) or behavioural characteristics of the persons concerned (eg keystroke, gait, way of moving, etc), based on which those persons are assigned to specific categories.[112] To give a few examples, prohibited biometric categorisation systems may include a system claiming to be capable of deducing an individual's race from their voice, or their religious affiliation from their tattoos,[113] or a filter categorising users of a social media platform according to their assumed political opinions or sexual orientation by analysing the photos they have uploaded on the platform in order to send them targeted advertisements.[114]

The relevance of EU non-discrimination law is evident in this respect, given that some of the categories to which individuals are assigned based on their biometric features may overlap with protected attributes under the EU Equality Directives and Article 21(1) of the Charter.[115] More

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The Uses of New Technologies in Migration and Asylum Governance in Europe' (Algorithmic Fairness and Asylum Seekers and Refugees (AFAR) Project, Refugee Studies Centre, University of Oxford, 2023) 26–27.

[111] See also recital 30 of the AI Act. For the definition of a 'biometric categorisation system', see Art 3(40) of the AI Act. For a detailed analysis of biometric technologies and the data protection and privacy risks they entail, see Article 29 of the Data Protection Working Party (Art 29 Working Party, the predecessor of the current European Data Protection Board), 'Opinion 3/2012 on developments in biometric technologies' (WP193, 27 April 2012).

[112] See the Commission's Guidelines on prohibited AI practices (n 24) point 278. For a definition of 'biometric data' under the AI Act, see Art 3(34) thereof.

[113] See the Commission's Guidelines on prohibited AI practices (n 24) point 283.

[114] ibid, point 280. Regarding the use of Facebook pictures to extract information about a person's personality traits, see C Segalin and others, 'What Your Facebook Profile Picture Reveals about Your Personality' (Proceedings of the 25th ACM International Conference on Multimedia (MM '17), 23–27 October 2017) 460 <https://tinyurl.com/4sky9384> accessed 20 November 2025. For the ability of facial recognition technology to reveal individuals' "liberal" or "conservative" political affiliation, see M Kosinski, 'Facial Recognition Technology Can Expose Political Orientation from Naturalistic Facial Images' (2021) 11 (article no 100) Scientific Reports. For the ability of algorithms to detect the sexual orientation of persons from their face images, see Y Wang and M Kosinski, 'Deep Neural Networks Are More Accurate than Humans at Detecting Sexual Orientation from Facial Images' (2018) 114(2) Journal of Personality and Social Psychology 246; J Leuner, 'A Replication Study: Machine Learning Models Are Capable of Predicting Sexual Orientation from Facial Images' (2019) arXiv:1902.10739 [cs.CV] <https://tinyurl.com/yu9aax9k> accessed 20 November 2025.

[115] See the Commission's Guidelines on prohibited AI practices (n 24) point 278.

specifically, the personal scope of the AI Act's prohibition of biometric categorisation is partly broader compared to that of EU non-discrimination law, by also encompassing characteristics of a sensitive nature that are not recognised as prohibited grounds of discrimination (ie trade union membership and sex life), but also partly narrower, by leaving aside other personal traits that are protected against discrimination (ie sex and age).[116] Moreover, unlike the EU Equality Directives, whose material scope is limited to certain walks of life, Article 5(1)(g) of the AI Act seems to apply horizontally across sectors except for law enforcement. Accordingly, whereas, for instance, an AI-powered tool used by an employer to detect the sexual orientation of job candidates from their face images on their CVs and directly reject homosexual candidates without any interview will be captured by both Directive 2000/78 and the AI Act's prohibition, a similar system deployed by a retail store to recognise homosexual parents using a given social media platform and preclude them from receiving targeted advertisements for baby care products will fall outside the scope of Directive 2000/78, but will still be prohibited under Article 5(1)(g) of the AI Act alone or in combination with Article 21(1) of the Charter. Yet, as in the case of Article 5(1)(b) of the AI Act, the question remains here whether this article could be interpreted in the light of Article 21(1) of the Charter so as to capture also discriminatory outcomes resulting from AI-driven biometric categorisation of individuals based on characteristics other than those mentioned in the AI Act's prohibition, notably sex and age.[117]

In any case, the labelling or filtering of biometric datasets through biometric categorisation systems on the basis of all the characteristics referred to in Article 5(1)(g) of the AI Act, including in the area of law enforcement, falls outside the scope of the prohibition. The rationale behind this derogation is precisely the need to guarantee equal representation for all demographic groups in the relevant datasets and, by extension, to prevent discrimination arising from biased data.[118] In fact, such labelling operations may even be needed sometimes to ensure compliance with the AI Act's requirements for high-risk AI systems under Articles 10 and 17 thereof.[119] However, the legislative choice to leave any categorisation of biometric data in the area of law enforcement outside the realm of Article 5(1)(g) of the AI Act altogether is rather regrettable. As law enforcement constitutes one of the main fields where biometric data are widely used,

[116] The similarity between the characteristics referred to in Art 5(1)(g) of the AI Act and those listed under Art 9(1) GDPR and Art 10 of the Law Enforcement Directive is easily noticeable.

[117] Yet, the Commission's Guidelines on prohibited AI practices (n 24) point 288 seem to preclude this possibility.

[118] See the Commission's Guidelines on prohibited AI practices (n 24) point 285.

[119] ibid.

any discriminatory outcomes stemming from the AI-enabled categorisation of individuals into clusters based on such data risk falling through the cracks of both non-discrimination law and the AI Act.

2.7 Real-time biometric identification

Pursuant to Article 5(1)(h) of the AI Act, the use of real-time biometric identification (RBI) systems in publicly accessible spaces for law enforcement purposes is in principle prohibited yet subject to certain exceptions envisaged in Article 5(1)(h)(i)–(iii), pursuant to which the use of such systems may be permitted when authorised by Member States' national legislation and as long as the conditions and safeguards provided for by Article 5(2)–(7) are met.[120] The limited ban of RBI technologies constitutes the outcome of a political compromise between the European Parliament and the Council of Ministers, having been one of the most contentious issues during the negotiation process for the adoption of the AI Act.[121] Although the significant derogations featured in the final version of Article 5 of the AI Act admittedly mitigate the AI Act's prohibition in relation to RBI practices, they do not detract from the predominantly prohibitive function of the said provision, the wording and structure of which clearly indicate that, as a rule, such AI-based practices are prohibited.[122] This will be the case when the strict requirements of Article 5(2)–(7) of the AI Act are not fulfilled, such as in the absence of detailed domestic Member State law that expressly allows the use of real-time RBI for one or more of the objectives listed in Article 5(1)(h)(i)–(iii) of the AI Act, or where no fundamental rights impact assessment has been carried out by the law enforcement authority concerned pursuant to Article 5(2) of the AI Act, or where no prior authorisation has been granted by a judicial or an independent administrative authority as per Article 5(3).

RBI within the meaning of Article 5(1)(h) of the AI Act refers to AI systems deployed in physical spaces accessible to an undetermined number of people (eg shops, restaurants, banks, stadiums, museums, public

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[120] According to Art 5(5) of the AI Act, it is up to the Member State to decide whether and in which of the three situations of Art 5(1)(h)(i)–(iii) the use of RBI systems in publicly accessible spaces for law enforcement purposes will be permitted in their territory. For a detailed analysis of the prohibition of RBI systems under the AI Act, see the Commission's Guidelines on prohibited AI practices (n 24) points 326–424. See also A Giannini and S Tas, 'AI Act and the Prohibition of Real-Time Biometric Identification: Much Ado about Nothing?' (*Verfassungsblog*, 10 December 2024) <https://tinyurl.com/46krmw8a> accessed 20 November 2025.

[121] See eg L Bertuzzi, 'AI Act: MEPs Mull Narrow Facial Recognition Technology Uses in Exchange for Other Bans' (*Euractiv*, 6 November 2023) <https://tinyurl.com/33fcty5w> accessed 20 November 2025.

[122] I am thankful to one of the anonymous reviewers of this article for inviting me to address this 'paradox'.

transport, roads, squares, etc) in order to perceive multiple natural persons simultaneously and identify them, without their active involvement, typically at a distance, by comparing those persons' biometric data with the data contained in a database, whereby the capturing of such data and the comparison and identification process all occur without a significant delay.[123] Most notably, these tools may include live surveillance cameras working with AI-driven facial recognition techniques that scan, for example, all incoming visitors to a concert hall or all passengers in metro stations.[124]

It is known, however, that AI-powered biometric identification technologies may produce biased results or entail discriminatory effects, with their accuracy varying across different demographic groups.[125] More specifically, facial recognition systems have been found likely to lead to false positive outputs for people of specific racial or ethnic origins, mostly for dark-skinned women;[126] they have been found to be less reliable for children and younger people,[127] biased against persons with face disabilities or craniofacial differences,[128] and prone to misclassify transgender individuals.[129] The adverse consequences of potential misidentifications by these systems are particularly far-reaching when operating in real-time in the field of law enforcement, which covers all activities carried out by public authorities (eg the police, prosecutors, etc) or on their behalf (eg

[123] See Art 3(35), (41)-(42) as well as recitals 17 and 19 of the AI Act. See also the Commission's Guidelines on prohibited AI practices (n 24) points 297–318.

[124] See the Commission's Guidelines on prohibited AI practices (n 24) points 306–311.

[125] See recital 32 of the AI Act. See also eg SA Magnet, *When Biometrics Fail: Gender, Race, and the Technology of Identity* (Duke University Press 2011); P Grother, M Ngan and K Hanaoka, 'Face Recognition Vendor Test (FRVT) Part 3: Demographic Effects' (National Institute of Standards and Technology, NISTIR 8280, December 2019) <https://tinyurl.com/yrkj8bh7> accessed 20 November 2025.

[126] See F Bacchini and L Lorusso, 'Race, Again: How Face Recognition Technology Reinforces Racial Discrimination' (2019) 17(3) Journal of Information, Communication and Ethics in Society 321; J Buolamwini and T Gebru, 'Gender Shades: Intersectional Accuracy Disparities in Commercial Gender Classification' (2018) 81 Proceedings of Machine Learning Research 77.

[127] See D Michalski, SY Yiu and C Malec, 'The Impact of Age and Threshold Variation on Facial Recognition Algorithm Performance Using Images of Children' (Proceedings of International Conference on Biometrics, 2018) 217–224 <https://tinyurl.com/2r98xz4w> accessed 20 November 2025; FRA, 'Facial Recognition Technology: Fundamental Rights Considerations in the Context of Law Enforcement' (Publications Office of the European Union 2020) 289.

[128] See MK Scheuerman, J Paul and J Brubaker, 'How Computers See Gender: An Evaluation of Gender Classification in Commercial Facial Analysis and Image Labeling Services' (2019) 3(CSCW) Proceedings of the ACM on Human-Computer Interaction 1; O Keyes, 'The Misgendering Machines: Trans/HCI Implications of Automatic Gender Recognition' (2018) 2(CSCW) Proceedings of the ACM on Human-Computer Interaction 1.

[129] See S Byrne-Haber, 'Disability and AI Bias' (*Medium*, 11 July 2019) <https://tinyurl.com/4a735y9a> accessed 20 November 2025.

public transport companies, sports federations, banks, etc) for the prevention, investigation, detection, or prosecution of criminal offences, or the execution of criminal penalties, including safeguarding against and preventing threats to public security.[130] This is due to the immediate impact and limited opportunities for further checks or corrections in relation to the real-time use of RBI tools, which, apart from raising serious concerns about enabling mass surveillance and infringing the fundamental rights and freedoms of individuals,[131] may also reinforce police bias against certain marginalised minorities or be misused for political, religious, racial/ethnic, or other persecution.[132] A striking example in this respect is drawn from Hungary's newly adopted legislation allowing the police to use real-time facial recognition technology to identify and fine participants in Pride events, which have been banned in the context of the Hungarian government's aggressive policy agenda against sexual and gender diversity.[133]

Unlike non-discrimination law, the use of real-time RBI systems is prohibited under the AI Act irrespective of whether the affected individuals belong to any specific social group. Yet, to the extent that such systems may explicitly target or disproportionately affect persons with protected characteristics under the EU Equality Directives or Article 21(1) of the Charter, the protection granted under the two legal regimes may sometimes overlap, provided that the RBI systems in question are actually prohibited by failing to comply with the requirements set out in Article 5(2)–(7) of the AI Act.

Nevertheless, significant loopholes still exist. All other uses of RBI systems that are not covered by Article 5(1)(h) of the AI Act, such as their deployment by private actors or for purposes other than law enforcement, are not prohibited under the AI Act.[134] In those instances, though, the EU non-discrimination rules still apply, capturing any potential discriminatory outputs of such systems against members of protected social groups. The same holds, most importantly, with regard to the retrospective use of RBI systems for law enforcement purposes, which escapes the AI Act's

[130] See Art 3(46) of the AI Act. See also the Commission's Guidelines on prohibited AI practices (n 24) points 319–325.

[131] See recital 32 of the AI Act.

[132] See L Arnold, 'How the European Union's AI Act Provides Insufficient Protection Against Police Discrimination' (*Journal of Law and Social Change*, 14 May 2024) <https://tinyurl.com/mznk8598> accessed 20 November 2025.

[133] See P Haeck and C Körömi, 'Hungary on EU Watchlist Over Surveillance at Pride' (*Politico*, 25 April 2025) <https://tinyurl.com/3fd9xz3c> accessed 20 November 2025.

[134] See the Commission's Guidelines on prohibited AI practices (n 24) points 425–428. Instead, these systems fall within the category of high-risk AI systems in accordance with Art 6 and Annex III(1)(a) thereof.

prohibition and is considered high-risk, being subject to the additional safeguards provided for in Article 26(10) of the AI Act. Whereas real-time RBI technologies enable the capturing of individuals' biometric data, the comparison and identification to occur 'instantaneously, near-instantaneously or in any event without a significant delay' by relying on 'live' or 'near-live' material, in the case of 'post' systems, the biometric data have already been captured and the comparison and identification happen only after a significant delay through material generated before the use of the system on the persons concerned (eg recorded CCTV camera footage).[135] Given that the devices used for real-time and *ex post* RBI are usually one and the same with different functionalities, the discrimination risks will be equally high in both instances, thus making the AI Act's differentiated approach on a purely temporal basis rather problematic.[136]

3 The regulatory function

The largest part of the AI Act concerns AI systems that pose a high risk to EU public interests and fundamental rights. As per Article 6 of the Act, apart from systems that are used as safety components of products or are products themselves, AI systems will qualify as high risk if used in one of the pre-defined areas mentioned under Annex III of the Act, with the Commission being empowered to amend the list of high-risk systems in light of evolving technological developments.[137] When classifying an AI system as high risk, the extent of the adverse impact caused by that system on fundamental rights protected by the Charter, including non-discrimination and gender equality, is of particular relevance.[138] However, the fact that certain AI systems are deemed as high risk under the AI Act does not indicate that their use is lawful under other pieces of EU or national law.[139] As noted before, the prohibition of certain AI practices under other legal instruments, including non-discrimination legislation, remains unaffected by the AI Act.[140]

In fact, most of the high-risk systems listed in Annex III raise serious discrimination concerns, as also explicitly acknowledged by the AI Act's preamble.[141] For example, the use of RBI systems may lead to biased results and entail discriminatory effects based on age, ethnicity, race,

[135] See recital 17 of the AI Act.

[136] See the Commission's Guidelines on prohibited AI practices (n 24) point 310.

[137] See Arts 6(6)–(8) and 7 of the AI Act and recital 52 thereof.

[138] See recital 48 of the AI Act.

[139] See recital 63 of the AI Act.

[140] See Art 5(8) of the AI Act.

[141] Pursuant to Art 6(3) of the AI Act, where an AI system referred to in Annex III does not pose a significant risk of harm to fundamental rights, it will not be considered high risk.

sex or disabilities,[142] while historical patterns of discrimination, among others, against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation, may also be perpetuated by AI systems deployed in education (eg to determine access or admission)[143] and employment (eg for the recruitment or selection of natural persons).[144] Another area in which there is a high risk of discrimination against persons or groups as a result of the use of AI technologies is the access to and enjoyment of essential private or public services where AI systems may be deployed for a wide range of purposes, such as to determine the eligibility of natural persons for public assistance benefits and services,[145] to evaluate the creditworthiness of natural persons or establish their credit score,[146] or to assess risk and determine pricing for life and health insurance.[147] Similar concerns are raised with regard to AI systems used in the context of law enforcement (eg to assess the risk of a natural person becoming the victim of criminal offences or the reliability of evidence),[148] or migration, asylum and

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Nevertheless, if that system performs profiling of natural persons, it will always be deemed high-risk.

[142] See recital 54 and Annex III(1) of the AI Act. See also Section 2.7.

[143] See recital 56 and Annex III(3) of the AI Act. See also eg D Gándara and others, 'Inside the Black Box: Detecting and Mitigating Algorithmic Bias Across Racialized Groups in College Student-Success Prediction' (2024) 10 AERA Open; R Kizilcec and H Lee, 'Algorithmic Fairness in Education' in W Holmes and K Porayska-Pomsta (eds), *Ethics in Artificial Intelligence in Education: Current Challenges, Practices, and Debates* (Routledge 2022).

[144] See recital 57 and Annex III(4) of the AI Act. See also eg C Rigotti and E Fosch-Villaronga, 'Fairness, AI and Recruitment' (2024) 53 Computer Law and Security Review 105966; Z Chen, 'Ethics and Discrimination in Artificial Intelligence-Enabled Recruitment Practices' (2023) 567 Humanities and Social Sciences Communications. A real-life case in this regard is Amazon's AI recruitment system which was found to disadvantage female job applicants. See J Dastin, 'Insight: Amazon Scraps Secret AI Recruiting Tool that Showed Bias Against Women' (*Reuters*, 11 October 2018) <https://tinyurl.com/ms3fvhhh> accessed 20 November 2025.

[145] See recital 58 and Annex III(5)(a) of the AI Act. A notorious real-world example in this area is offered by the Dutch fraud detection system 'SyRI', which was declared incompatible with fundamental rights by the District Court of the Hague. See Rechtbank Den Haag, zaaknummer C-09-550982-HA ZA 18-388, 5 February 2020 ECLI:NL:RBDHA:2020:1878.

[146] See recital 58 and Annex III(5)(b) of the AI Act, pointing out that such systems may not only perpetuate historical patterns of discrimination but even create new forms of discriminatory impacts. On the discriminatory potential of credit scoring systems, see eg Hurley and Adebayo (n 71); Langenbucher (n 71).

[147] See recital 58 and Annex III(5)(c) of the AI Act. See in this regard eg M van Bekkum, F Zuiderveen Borgesius and T Heskes, 'AI, Insurance, Discrimination and Unfair Differentiation: An Overview and Research Agenda' (2024) arXiv:2401.11892 [cs.CY] <https://tinyurl.com/yc2mmnz9> accessed 20 November 2025.

[148] See recital 59 and Annex III(6) of the AI Act. See in this regard eg G González-Fuster, 'Artificial Intelligence and Law Enforcement: Impact on Fundamental Rights' (European Parliament's LIBE Committee, PE 656.295, July 2020) <https://tinyurl.com/3a8vm2v4> accessed 20 November 2025.

border control management (eg to assist the competent authorities in the examination of applications for asylum and visa or residence permits).[149]

Against this background, the AI Act's so-called 'regulatory function' consists of laying down a number of stringent mandatory requirements and obligations in Articles 8–27 that the 'providers' and 'deployers' of high-risk AI systems must comply with in order to prevent or mitigate any discriminatory outcomes.[150] Even though the AI Act could potentially be viewed as a regulatory instrument in its entirety, the term 'regulatory function' is deployed here as specifically relating to the conditions under which high-risk systems can be placed on the market, put into service, and used, with the aim of minimising the risk of those systems giving rise to AI-enabled discrimination. Accordingly, the AI Act establishes a set of harmonised rules that are complementary to the existing EU non-discrimination legislation.[151]

More specifically, the providers of high-risk AI systems must, inter alia, apply appropriate data governance practices; establish risk and quality management systems; draw up and keep the necessary technical documentation; guarantee effective human oversight of the systems' use; and ensure record-keeping as well as transparency, accuracy, robustness, and cybersecurity.[152] The deployers, for their part, are primarily required to take any appropriate technical and organisational measures ensuring that high-risk systems operate in accordance with the instructions for their use; to assign human oversight to natural persons; and to conduct an assessment of the systems' impact on fundamental rights.[153] To guarantee continuous compliance with these *ex ante* conformity requirements for AI systems, the AI Act also entrusts both providers and deployers with an *ex post* monitoring obligation for the purpose of identifying any need to take corrective or preventive actions in a timely man-

[149] See recital 60 and Annex III(7) of the AI Act. See in this regard eg C Dumbrava, 'Artificial Intelligence at EU Borders: Overview of Applications and Key Issues' (European Parliamentary Research Service, PE 690.706, July 2021) <https://tinyurl.com/5n83kjw2> accessed 20 November 2025.

[150] See recitals 64 and 66 of the AI Act. For the definition of the terms 'provider' and 'deployer' of AI systems, see Art 3(3) and (4) of the AI Act. Depending on the context, the provider and deployer of a certain AI system may overlap, where the same entity produces and uses that system, for example in the case of an AI credit scoring system developed 'in house' by a financial institution for its own business. See also Art 25(1) of the AI Act listing the circumstances under which a deployer of a high-risk system or any other third party is to be considered a provider.

[151] See recital 9 of the AI Act, referring to 'fundamental rights' in general.

[152] See Arts 9–19 of the AI Act.

[153] See Arts 26–27 of the AI Act. The obligation to carry out a fundamental rights impact assessment applies exclusively to deployers of the high-risk AI systems mentioned in Annex III(5)(b) and (c) of the AI Act.

ner.[154] Non-compliance with the aforementioned requirements and obligations may lead to the imposition of hefty administrative fines on the operators concerned.[155]

This entire set of rules delineating the AI Act's framework that applies to high-risk AI systems is intended to ensure respect of individuals' fundamental rights, such as their right to not be discriminated against. However, a detailed examination of how all technical requirements and obligations imposed on providers and deployers of AI systems may contribute to combatting discrimination or bias largely exceeds the scope and space of this article. For the purposes of my present analysis, I will exclusively focus below on Article 10 of the AI Act on data quality, governance, and de-biasing, being the only provision which is expressly meant to address the risk of AI-enabled discrimination.

3.1 Data quality, management, and de-biasing

Pursuant to Article 10(1) and (3), the datasets used for training, validation, and testing of such systems must be 'relevant, sufficiently representative, and to the best extent possible, free of errors and complete' in view of the system's intended purpose, while also having the appropriate statistical properties.[156] Since the data fed as input into an AI system determine the outputs generated, the high quality of data plays a crucial role in ensuring that AI systems perform as intended and do not result in prohibited discrimination, especially where the outputs may influence the inputs used for future operations, leading to 'feedback loops'.[157] Accordingly, biases embedded in the training data of AI systems constitute one of the main sources of algorithmic discrimination;[158] when the underlying data are inherently biased, the results provided by the AI systems concerned will be inclined to perpetuate and even amplify existing discrimination, in particular against persons belonging to certain vulnerable groups.[159] Such tainted data usually result from sampling bias, whereby some population segments are misrepresented, or from histor-

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[154] See Art 72 of the AI Act combined with Art 3(25) for providers, referring to the establishment of a 'post-market monitoring system', and Art 26(5) for deployers.

[155] See Art 99(4) of the AI Act.

[156] A similar requirement for data to be accurate and kept up to date also exists under Art 5(1)(d) GDPR.

[157] See recital 67 of the AI Act.

[158] See Barocas and Selbst (n 1); Hacker (n 16) 1146–1148. See also P Hacker, 'A Legal Framework for AI Training Data: From First Principles to the Artificial Intelligence Act' (2021) 13(2) Law, Innovation and Technology 257.

[159] This is commonly known in computer science as 'garbage in, garbage out'. See eg Xenidis and Senden (n 7) 156.

ical biases.[160] This will be the case, for instance, when an AI system developed by a financial institution for the purpose of automating loan decisions has been trained with data that contain, among other things, the postal codes of applicants and stem from a period when loans were more readily granted to people living in wealthier neighbourhoods, thereby perpetuating discrimination against residents of low-income neighbourhoods having a migration background.[161]

In light of these considerations, Article 10(2)(f) and (g) of the AI Act requires providers of high-risk AI systems to subject the training, validation, and testing datasets of their systems to data governance and management practices that involve an examination of possible biases, and provide for appropriate measures to detect, prevent, and mitigate any biases identified.[162] However, the AI Act does not define what 'bias' is nor does it determine how to measure it.[163] Further guidance at this point is thus crucial, given the variety of technical mechanisms developed in recent years for the purposes of ensuring fairness and mitigating biases, known as 'fairness metrics'.[164] However, these metrics are not always fit to meet the legal requirements of the EU non-discrimination framework.[165] Under these circumstances, it still remains unclear how de-biasing is to be effectively achieved in practice.[166]

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[160] See Hacker (n 16) 1146–1148; Barocas and Selbst (n 1) 680.

[161] See Data Protection Authority of Belgium, 'Artificial Intelligence Systems and the GDPR: A Data Protection Perspective' (December 2024) 9.

[162] See recital 67 of the AI Act.

[163] See S Wachter, 'Limitations and Loopholes in the EU AI Act and AI Liability Directives: What This Means for the European Union, the United States, and Beyond' (2024) 26(3) Yale Journal of Law and Technology 671, 688. According to the High-Level Expert Group on Artificial Intelligence set up by the European Commission, 'Assessment List for Trustworthy AI' (2020) 23, 'bias' is defined as 'systematic and repeatable errors in a computer system that create unfair outcomes, such as favouring one arbitrary group of users over others'. See also Gerards and Xenidis (n 3) Section 1.5.1, 47.

[164] See Wachter (n 163) 688. For the main definitions and measures of algorithmic fairness, see among many others D Pessach and E Shmueli, 'Algorithmic Fairness' (2020) arXiv:2001.09784 [cs.CY] <https://tinyurl.com/4tw6x2mp> accessed 20 November 2025; S Verma and J Rubin, 'Fairness Definitions Explained' (IEEE/ACM International Workshop on Software Fairness (FairWare) 29 May 2018).

[165] See in detail S Wachter, B Mittelstadt and C Russel, 'Bias Preservation in Machine Learning: The Legality of Fairness Metrics Under EU Non-Discrimination Law' (2021) 123(3) West Virginia Law Review 735. See also H Weerts and others, 'Algorithmic Unfairness Through the Lens of EU Non-Discrimination Law: Or Why the Law Is Not a Decision Tree' (Proceedings of the 2023 ACM Conference on Fairness, Accountability, and Transparency, Chicago, June 2023).

[166] See M van Bekkum, 'Using Sensitive Data to De-Bias AI Systems: Article 10(5) of the EU AI Act' (2025) 56 Computer Law and Security Review (Article 106115) 10, suggesting that the de-biasing obligation should be clarified either by supervisory authorities or through the adoption of harmonised standards.

That said, in order to ensure the detection and correction of biases, Article 10(5) of the AI Act explicitly allows providers to process special categories of personal data listed in Article 9(1) GDPR. As such, Article 10(5) is explicitly intended to prevent discrimination that might result from bias in AI systems.[167] The question as to the necessity of using such sensitive data as variables in algorithmic models to prevent the emergence of discriminatory outcomes has given rise to heated academic debate, not least because Article 9 GDPR in principle bans the collection of sensitive data.[168] It has been argued, though, that without knowledge of such data, providers of high-risk AI systems could not audit their systems for potential proxies that are likely to indirectly discriminate against certain protected groups of persons.[169]

In any event, the possibility of de-biasing AI systems through recourse to sensitive data applies only exceptionally and 'to the extent that it is strictly necessary', while also being subject to fundamental rights safeguards and several data protection requirements. This means that the removal of bias should only take place as far as this is mandated by Article 10(2)(f) and (g) of the AI Act, and as long as the provider has designed their intervention in the least intrusive way, in the sense that they must have clearly determined which biases will be targeted, which data will be used, and what risk of unlawful access to data exists.[170] At the same time, the provider must comply with a list of conditions under Article 10(5)(a)–(f) along with other requirements set out in the GDPR, including those of Article 9(2) thereof.[171] In this regard, as specified by

[167] See recital 70 of the AI Act.

[168] See M van Bekkum and F Zuiderveen Borgesius, 'Using Sensitive Data to Prevent Discrimination by Artificial Intelligence: Does the GDPR Need a New Exception?' (2023) 48 Computer Law and Security Review (Article 105770). See also I Žliobait and B Custers, 'Using Sensitive Personal Data May Be Necessary for Avoiding Discrimination in Data-Driven Decision Models' (2016) 24 Artificial Intelligence and Law 183.

[169] See van Bekkum (n 166) 2–3.

[170] ibid, 9–11.

[171] ibid, 11–14. For an overview of the interplay between the AI Act and the GDPR regarding data processing for the development of AI systems, see Data Protection Authority of Belgium (n 161). See, however, Commission, 'Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2016/679, (EU) 2018/1724, (EU) 2018/1725, (EU) 2023/2854 and Directives 2002/58/EC, (EU) 2022/2555 and (EU) 2022/2557 as regards the simplification of the digital legislative framework, and repealing Regulations (EU) 2018/1807, (EU) 2019/1150, (EU) 2022/868, and Directive (EU) 2019/1024 (Digital Omnibus)' COM (2025) 837 final. According to recital 33 and Art 3(3) of this Proposal, a new exception would be inserted into the GDPR, namely Article 9(2)(k) and (5), allowing the use of sensitive data not only for the debiasing of AI systems but also for the training, testing, or validation of such systems in general. For more details on the Commission's Digital Omnibus Proposal, see eg H Ruschemeier, 'The Omnibus Package of the EU Commission: Or How to Kill Data Protection Fast' (*Verfassungsblog*, 17 November 2025) <https://tinyurl.com/yc3hzhet> accessed 20 November 2025.

recital 70 of the AI Act, the processing of sensitive data for the purpose of bias correction under Article 10(5) constitutes a matter of 'substantial public interest' within the meaning of Article 9(2)(g) GDPR, as it ensures the protection of the individuals' right to non-discrimination.[172] Therefore, Article 10(5) of the AI Act reflects the legislator's attempt to strike a proper balance between data protection and non-discrimination law with regard to AI de-biasing and, as such, it can contribute to making AI systems less discriminatory.[173]

4 The enabling function

The AI Act did not originally provide for any redress mechanisms for the persons affected by AI systems. Despite repeated references in the Proposal's preamble to the protection of fundamental rights, the obligations imposed on providers and deployers did not give rise to any corresponding right of individuals to seek justice where these obligations have not been complied with, especially if the persons concerned have suffered discriminatory or otherwise unfair or harmful effects by AI-based outcomes.[174] This blind spot was eventually addressed by the European Parliament during the legislative procedure through the introduction of concrete rights and remedies to the benefit of individuals subjected to AI systems.[175]

The final version of the AI Act, as it currently stands, enables or empowers victims of AI-enabled discrimination or bias to seek effective legal redress, by granting them the right to file a complaint with the respective market surveillance authority entrusted with the implementation of the AI Act at the national level of each Member State, and the right to receive explanations about AI decision-making, while also empowering national

[172] See S De Luca and M Federico, 'Algorithmic Discrimination Under the AI Act and the GDPR' (European Parliamentary Research Service, PE 769.509, 26 February 2025). It has also been argued, though, that the most plausible ground for such data processing seems to be a concrete 'legal obligation' in the sense of Art 6(1)(c) GDPR to which providers of AI systems are subject under Art 10(2) of the AI Act. See van Bekkum (n 166) 14.

[173] See M van Bekkum (n 166) 7, 11, providing a detailed analysis of the conditions and limits of this provision.

[174] See European Data Protection Board (EDPB) and EDPS, 'Joint Opinion 5/2021 on the Proposal for a Regulation of the European Parliament and of the Council Laying down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act)' (18 June 2021) points 8–9, 18.

[175] See Amendments adopted by the European Parliament on 14 June 2023 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts COM (2021)0206 - C9-0146/2021 - 2021/0106(COD)' (P9_TA(2023)0236) amendments 627–630.

equality bodies to access the relevant technical documentation.[176] These three mechanisms together constitute what I call the 'enabling function' of the AI Act, which exists without prejudice to and in parallel with any other administrative or judicial remedies already available under EU or national non-discrimination law,[177] including the right of the persons concerned to file a discrimination claim before a national equality body, their right to challenge a discriminatory decision affecting them, as well as their right to request compensation or reparation for the loss and damage sustained because of discriminatory conduct.[178] Accordingly, in the following paragraphs, I will examine how recourse to the aforementioned means of legal redress provided for by the AI Act may complement, facilitate, or even reinforce the existing mechanisms under the non-discrimination framework.

4.1 Right to lodge a complaint with a market surveillance authority

The only actual remedy available to individuals under the AI Act is the right to submit complaints to the relevant market surveillance authority, pursuant to Article 85, which is granted to any person who believes that a provision of the AI Act has been infringed.[179] Each Member State must establish or designate at least one such authority, as per

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[176] See Arts 85, 86 and 77(1) of the AI Act respectively.

[177] See Art 85 and recital 170 of the AI Act.

[178] See Arts 13 and 15 of Directive 2000/43, Art 17 of Directive 2000/78, as well as Arts 18, 20, and 25 of Directive 2006/54. See also Art 6(2) of Council Directive (EU) 2024/1499 of 7 May 2024 on standards for equality bodies in the field of equal treatment between persons irrespective of their racial or ethnic origin, equal treatment in matters of employment and occupation between persons irrespective of their religion or belief, disability, age or sexual orientation, equal treatment between women and men in matters of social security and in the access to and supply of goods and services, and amending Directives 2000/43/EC and 2004/113/EC [2024] OJ L2024/1499. For more details, see C Tobler, 'Remedies and Sanctions in EC Non-Discrimination Law: Effective, Proportionate and Dissuasive National Sanctions and Remedies, with Particular Reference to Upper Limits on Compensation to Victims of Discrimination' (European Commission, Publications Office of the European Union 2005). For an overview of national enforcement practices, see R Iordache and I Ionescu, 'Effectively Enforcing the Right to Non-Discrimination: Promising Practices Implementing and Going Beyond the Requirements of the Racial Equality and Employment Equality Directives' (European Commission, Publications Office of the European Union 2021); I Chopin and C Germaine, 'A Comparative Analysis of Non-Discrimination Law in Europe 2024: The 27 EU Member States Compared' (European Commission, Publications Office of the European Union 2024) Sections 4 and 5.

[179] Section 4 of Chapter IX of the AI Act titled 'Remedies' comprises both the right to file a complaint and the right to explanations under Arts 85 and 86, respectively, as well as Art 87 on the reporting of infringements and protection of reporting persons. However, as I argue later, the right to explanations does not actually constitute a remedy as such but rather enables the exercise of other remedies available under EU or national law. Likewise, the Whistleblower Directive (EU) 2019/1937 of the European Parliament and of the Council

Article 70(1) of the AI Act, with the task of ensuring that the AI systems, which are marketed in their respective territory, comply with the requirements set out in the AI Act.[180] In this regard, the system of market surveillance and compliance of products established by the Product Safety Regulation applies in its entirety to AI systems covered by the AI Act.[181]

Given the broad formulation of Article 85 of the AI Act, the complaints lodged with a market surveillance authority may concern any infringement of the AI Act's provisions, most prominently those relating to prohibitions or to the obligations of providers and deployers of AI systems. One can think, for instance, of a person who has been denied access to credit in an allegedly discriminatory way due to an AI-generated credit score. In that case, the person affected may file a complaint claiming that they have been subjected to a prohibited AI social scoring system within the meaning of Article 5(1)(c) of the AI Act which used data from their social networks; or that their credit score has been calculated on the basis of a high-risk system without them having been informed about the use of such a system, as required by Article 26(11) of the Act; or that the explanations they obtained from the credit institution concerned are not sufficiently clear and meaningful, in violation of Article 86(1). However, even though no minimum threshold of proving an infringement is required for filing such complaints, and despite the significant benefits of the explanations obtained under Article 86(1), it will probably be quite challenging for individuals to convincingly argue that certain requirements under the AI Act have not been complied with, not least because of their inherently technical nature.

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of 23 October 2019 on the protection of persons who report breaches of Union law [2019] OJ L305/17, does not provide any actual remedies to the persons concerned.

[180] According to Art 74(6) of the AI Act, as concerns high-risk AI systems marketed or used by financial institutions regulated under the EU financial services law, the national authority in charge of the financial supervision of those institutions under that legislation should also be designated, within its respective competences, as the market surveillance authority for the purposes of the AI Act. For instance, when it comes to an AI system deployed by a credit institution in a certain Member State to evaluate consumers' creditworthiness or credit score for access to loans, the market surveillance authority under the AI Act will be the national supervisory authority designated pursuant to the CCD. If that AI system is used to determine access to a credit agreement secured by a mortgage, then the relevant market surveillance authority may be the one defined by the Mortgage Directive 2014/17/EU of the European Parliament and of the Council of 4 February 2014 on credit agreements for consumers relating to residential immovable property and amending Directives 2008/48/EC and 2013/36/EU and Regulation (EU) No 1093/2010 [2014] OJ L60/34. Other competent authorities in the field of financial services that can be designated as market surveillance authorities for the purposes of the AI Act include those defined by the legal instruments referred to in recital 158 of the AI Act.

[181] See Art 74(1) and recital 156 of the AI Act, referring to Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 [2019] OJ L169/1.

Be that as it may, any complaints submitted by the persons affected are to be taken into account by the relevant market surveillance authorities for the purpose of conducting their activities in accordance with the Product Safety Regulation.[182] It will thus rest ultimately upon these authorities, which benefit from extensive investigative and enforcement powers, to establish whether an infringement of the AI Act has actually occurred and then take appropriate measures, including, most importantly, the imposition of fines under Article 99.[183] Regrettably, though, the AI Act lacks a corresponding right of individuals to an effective judicial remedy against the market surveillance authorities, where those authorities do not handle a complaint or do not inform the person concerned about the progress or outcome of the complaint lodged.[184] Pursuant to Article 99(10), such a right seems to be available only to those subject to penalties or other enforcement measures, such as the providers and deployers of AI systems, thus excluding natural persons affected by those systems.

It follows from the foregoing that the right to file a complaint combined with the risk of fines in the event of non-compliance with the AI Act does not really offer proper redress to the affected individuals themselves, such as victims of AI-driven discrimination. Rather, this mechanism may benefit those persons only indirectly through the deterrent effect it exercises on operators, encouraging them to comply with their obligations under the AI Act and thereby to meet the required standards of fundamental rights' protection, including equality and non-discrimination. As such, it merely complements the existing remedies enjoyed by individuals under other EU or national law, such as non-discrimination law.

4.2 Right to explanations

Far more promising than Article 85 of the AI Act, is Article 86, which grants to any person subjected to a decision taken on the basis of a high-risk AI system the right to obtain from the deployer explanations of the individual AI-driven decision concerning them. This right clearly corresponds to the obligation of providers under Article 13(1) and (3)(iv) of the

[182] See Art 85 of the AI Act and Art 11(3)(e) of the Product Safety Regulation. The market surveillance activities of the relevant authorities are listed in Art 11 of the said Regulation.

[183] For the powers granted to market surveillance authorities, see Art 14 of the Product Safety Regulation. The market surveillance measures that the relevant authorities can take if they find that a certain AI system does not conform with the requirements of the AI Act are laid down in Art 16 of the said Regulation.

[184] Interestingly, although the European Parliament proposed the inclusion of such a right, this did not eventually make it into the AI Act's final text. See the Amendments adopted by the European Parliament (n 175) amendment 629.

AI Act to develop their AI systems in such a way as to ensure that their operation is sufficiently transparent, while also providing to deployers the necessary information that is relevant to explain the systems' output. Concepts such as 'transparency', 'interpretability', or 'explainability' have become buzzwords in almost every discussion about algorithmic and AI-based operations, although their exact definition still remains blurry and goes far beyond the scope of this article.[185] In fact, the quest for so-called 'eXplainable AI' (XAI) has become a fast-growing research field of its own at the crossroads of law, ethics, and computer science, exploring the development of methods that enable humans to understand and interpret the underlying rationale of AI results.[186]

As clarified by recital 171 of the AI Act, the explanations offered by deployers under the Act are meant to provide a basis on which the affected persons are able to exercise their rights.[187] Accordingly, far from being a remedy in itself, the AI Act's right to explanations constitutes an 'enabler' of remedies, by ensuring the effective exercise of individuals' rights provided for by other EU or national law. These may include, most notably, the rights conferred on individuals by Article 22(3) GDPR, or the similar rights enshrined in Article 18(8) CCD in the context of creditworthiness assessments, but also the remedies granted under the

[185] On the meaning of these concepts, see eg C Castelluccia and D Le Métayer, 'Understanding Algorithmic Decision-Making: Opportunities and Challenges' (Panel for the Future of Science and Technology, European Parliamentary Research Service, European Parliament, 2019) 26. For the lack of common understanding of these terms in the context of AI systems, see AB Arrieta and others, 'Explainable Artificial Intelligence (XAI): Concepts, Taxonomies, Opportunities and Challenges Toward Responsible AI' (2020) 58 Information Fusion 82. See also, with a focus on EU law instruments, D Schneeberger and others, 'The Tower of Babel in Explainable Artificial Intelligence (XAI)' in A Holzinger and others (eds), *Machine Learning and Knowledge Extraction* (Springer 2023); P Hacker and JH Passoth, 'Varieties of AI Explanations Under the Law: From the GDPR to the AIA, and Beyond' in A Holzinger and others (eds), *xxAI - Beyond Explainable AI* (Springer 2022).

[186] See eg A Adadi and M Berrada, 'Peeking Inside the Black-Box: A Survey on Explainable Artificial Intelligence (XAI)' (2018) 6 IEEE Access 52138. For an overview of such XAI methods, see A Holzinger and others, 'Explainable AI Methods: A Brief Overview' in A Holzinger and others (eds), *Machine Learning and Knowledge Extraction* (Springer 2023).

[187] In this regard, the AI Act's right to an explanation constitutes an expression of 'rights-enabling transparency' in the terms used by Hacker and Passoth (n 185) 344. See Case C-203/22 *Dun & Bradstreet Austria* ECLI:EU:C:2025:117, paras 55–56, where the Court explicitly ruled that the right of access to information under Art 15(1)(h) GDPR is intended to enable the individuals concerned to effectively exercise the rights conferred on them by Art 22(3) GDPR, namely the right to express their point of view on that decision and to contest it, while emphasising that the rights enshrined in Art 22(3) GDPR would not satisfy in full their purpose if the persons affected by an automated decision were not able to understand the reasons behind that decision. See in a similar vein Case C-817/19 *Ligue des droits humains* ECLI:EU:C:2022:491, para 195, where the Court pointed out that the opacity of machine learning technologies might deprive the persons concerned of their right to an effective judicial remedy under Article 47 of the Charter.

EU non-discrimination legislation.[188] Besides, the explanations obtained may also be instrumental for the exercise of the right to file a complaint with a market surveillance authority under Article 85 of the AI Act, by exposing possible irregularities regarding compliance with the Act, such as the existence of inaccurate or biased datasets.

Taking a closer look at the conditions for the application of Article 86(1) of the AI Act, one cannot help but draw a comparison with the similarly worded provision of Article 22(1) GDPR, which triggers the applicability of the right to obtain information under Article 15(1)(h) GDPR. The right to explanations established under the AI Act concerns any decision taken by the deployer 'on the basis of the output from a high-risk AI system' and which 'produces legal effects or similarly significantly affects that person in a way that they consider to have an adverse impact on their health, safety or fundamental rights'.[189] Although the notion of a 'decision producing legal effects or similarly significant effects' corresponds to that of Article 22(1) GDPR, Article 86(1) of the AI Act further draws an explicit link between the impact of such a decision and individuals' fundamental rights.[190] Such a reference to fundamental rights aligns with the AI Act's declared objective to ensure a high level of protection for the rights enshrined in the Charter and should be interpreted as encompassing also equality and non-discrimination, given the Act's explicit acknowledgement of the adverse impact that AI systems may have on these rights.[191] Moreover, unlike Article 22(1) GDPR that refers to decisions 'based solely on automated processing', the scope of Article 86(1) of the AI Act is significantly broader, as it concerns any decision taken 'on the basis of output', thus covering also decisions that entail

[188] In *Dun & Bradstreet Austria* (n 187) para 54, the Court also noted that the right to information is necessary to enable the persons affected to exercise their right to rectification, to erasure, or to restriction of processing in accordance with Arts 16, 17 and 18 GDPR respectively, their right to object to the processing of their data under Art 21 GDPR, their right of action and their right to compensation conferred by Arts 79 and 82 GDPR respectively.

[189] As argued by L Metikoš and J Ausloos, 'The Right to an Explanation in Practice: Insights from Case Law for the GDPR and the AI Act' (2025) Law, Innovation and Technology 1, the reference to the person's own considerations reflects an underlying balancing exercise that is left for the decision-subject to undertake.

[190] See A Engelfriet, *The Annotated AI Act: Article-by-Article Analysis of European AI Legislation* (ICTRecht 2024) 291. For a definition of the notion of a 'decision producing legal effects or similarly significant effects' under Art 22(1) GDPR, see Art 29 Working Party, 'Guidelines on Automated Individual Decision-Making and Profiling for the Purposes of Regulation 2016/679' (WP251rev.01, 3 October 2017, as last revised and adopted on 6 February 2018) 22. As the CJEU ruled in Case C-634/21 *SCHUFA Holding (Scoring)* ECLI:EU:C:2023:957, paras 44–50, this concept also covers the establishment by a credit information agency of a probability value in the form of a credit score, on which a third party, such as a credit institution, to which the score is transmitted, draws strongly to establish, implement, or terminate a contractual relationship with the person concerned.

[191] See eg recitals 48, 54, 56–60 of the AI Act and implicitly Article 10 thereof.

some degree of human involvement.[192] This extended reach of the AI Act's right to explanations is particularly important due to the risk of automation bias traced even in hybrid or semi-automated decision-making processes.[193] On the other hand, though, the application of Article 86(1) of the AI Act is limited to those decisions reached through the use of (high-risk) AI systems, whereas Article 22(1) GDPR applies to automated decision-making in general, a concept capturing both algorithmic and AI-driven decisions.[194]

Turning to the type of explanations that must be provided by the deployer, Article 86(1) of the AI Act specifies that these must be 'clear and meaningful' and concern 'the role of the AI system' in the decision-making procedure as well as 'the main elements of the decision'. Following the CJEU's ruling in *Dun & Bradstreet Austria* that the right of individuals to receive 'meaningful information about the logic involved' in automated decision-making pursuant to Article 15(1)(h) GDPR combined with Article 22(1) is tantamount to 'a genuine right to an explanation',[195] there is no reason to interpret the AI Act's concept of 'explanations' in a different way. Accordingly, persons affected by an AI-based decision will be entitled to receive explanations of the procedure, principles, and input data that were actually used to obtain the specific result concerning them.[196] These explanations must be further provided in a concise, transparent, intelligible and easily accessible form, while general information about complex algorithms (eg the scoring formula behind an AI-generated credit score) does not satisfy this requirement.[197] Whether such an explanation further requires the implementation of XAI techniques will depend on the concrete application context and the functioning of the specific AI

[192] See A Engelfriet (n 190) 291. For the definition of decision-making 'based solely on automated processing' under Art 22(1) GDPR, see Art 29 Working Party, 'Guidelines on Automated Individual Decision-Making' (n 190) 20–21.

[193] See Fair Trials (n 74) Section 3.1, 34.

[194] See in this regard T Rodríguez de las Heras Ballell, 'Guiding Principles for Automated Decision-Making in the EU' (European Law Institute 2022) 9. Nevertheless, it follows from the broad definition of AI systems in Art 3(1) of the AI Act that these cover any system using AI technologies, including those that do not involve the processing of personal data within the meaning of Art 4(1) GDPR but can still adversely affect individuals' interests or fundamental rights. See EDPB and EDPS, 'Joint Opinion 5/2021' (n 174), point 16, 8.

[195] See *Dun & Bradstreet Austria* (n 187) para 57.

[196] ibid, para 58. This so-called 'local' explanation of a specific individual decision under the AI Act has also been advocated by D Schneeberger and others (n 185) 71. See also Hacker and Passoth (n 185) 349–350, 363–364, warning though that a local explanation may create a 'misleading illusion of simplicity' of the decision-making process.

[197] See *Dun & Bradstreet Austria* (n 187) paras 59–61, where the Court also noted that the complexity of the operations carried out cannot relieve the controller of the duty to provide an explanation.

system deployed.[198] Be that as it may, the disclosure of the most important features of individual AI outputs can contribute to the detection of possible discrimination, as affected persons will be able to determine to what extent an AI-based decision might have been driven by variables correlated with protected attributes under EU non-discrimination law.[199]

Nevertheless, as per Article 86(3) of the AI Act, the right to explanations established therein applies only to the extent that such a right is not otherwise provided for under EU law. In fact, apart from the now expressly recognised right to obtain an explanation under Article 15(1)(h) GDPR, a similar sector-specific right is provided for by Article 18(8)(a) CCD[200] and Article 76(5) of the Anti-Money Laundering Regulation.[201] Accordingly, where the conditions set out by these provisions are fulfilled, persons affected by AI-based decision-making may rely on the right to explanations enshrined therein, to the exclusion of Article 86(1) of the AI Act. In any case, it follows from this matrix of partly overlapping rights established under different EU law instruments that victims of discriminatory or unfair AI decisions will always be entitled, one way or another, to obtain explanations about AI-generated decisions affecting them.

Regrettably, however, unlike Article 22(3) GDPR, the right to an explanation under Article 86(1) of the AI Act is not accompanied by a corresponding right of persons affected by an AI-driven decision to request human intervention, to express their point of view, and to contest that decision.[202] Under these circumstances, the existing remedies provided for by EU or national law become highly relevant. As concerns victims of AI-enabled discrimination or bias, in particular, they may challenge

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[198] See Hacker and Passoth (n 185) 345–346, 363–364, emphasising that explanations need to be adapted to different contexts, goals, and addressees.

[199] See also in the same vein ibid 365, referring to 'fairness-enabling transparency'.

[200] Individuals' right to an explanation under Art 18 CCD forms part of a broader right 'to request and obtain from the creditor human intervention', comprising also the right to express their own point of view to the creditor, and to request a review of the assessment of their creditworthiness and of the credit granting decision by the creditor. However, Art 18(8)(a) and recital 56 CCD specify that such a right exists only without prejudice to the application of the GDPR. For more details, see Ž korjanc 'The Right to Explanation of a Credit Score: A Holistic Approach under the GDPR, AI Act, and Directive (EU) 2023/2225 on Credit Agreements for Consumers' (2025) 6(3) Global Privacy Law Review 91.

[201] Regulation (EU) 2024/1624 of the European Parliament and of the Council of 31 May 2024 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing [2024] OJ L2024/1624, which explicitly grants this right to explanation for decisions resulting from both automated and AI-based processes.

[202] See also Art 18(8) CCD, pursuant to which, apart from the right to an explanation, persons affected by automated credit decisions can further express their view and request a human assessment on behalf of the creditor. For its part, Art 76(5) of the Anti-Money Laundering Regulation provides the right of the persons concerned to challenge the automated decision in question.

the decision in question on the basis of non-discrimination legislation but only insofar as one or more prohibited grounds or proxies thereof are triggered. If this is not the case or it is not proved to be so, those persons may have recourse to their respective rights under Article 22(3) GDPR, provided that the AI-enabled decision-making process concerned is fully automated in the sense of Article 22(1). For the rest, and regardless of the degree of automation of the decision-making, the right to compensation under both non-discrimination law and the GDPR, as well as the remaining set of rights conferred on individuals by the GDPR, remains fully available.

4.3 Access to documentation by national equality bodies

Rather overlooked so far is Article 77(1) of the AI Act. This provision empowers national authorities or bodies which supervise or enforce the respect of fundamental rights obligations under EU law to request and access any documentation related to the use of high-risk AI systems that is deemed necessary for effectively fulfilling their mandates. As specified by recital 157 of the Act, such a possibility also explicitly concerns national equality bodies established in each Member State under the EU Equality Directives with the duty to implement EU non-discrimination law and monitor its application at national level.[203]

To understand why access to technical documentation about AI systems is crucial for equality bodies to effectively exercise their competences in the field of AI-driven discrimination, one should first look at what such documentation entails. Pursuant to Article 11 of the AI Act, the documentation drawn up and kept by the provider of a high-risk system demonstrates whether that system complies with the requirements of the AI Act and must contain, at a minimum, the elements set out in Annex IV thereof. Among these elements features a detailed description of the system's key design choices, including the rationale and assumptions made with regard to persons or groups for whom the system is intended, its main classification choices, and the relevance of the different parameters deployed; information about the metrics used to measure potentially discriminatory impacts; and detailed information about the system's limitations in performance, including the degree of accuracy for specific persons or groups of persons, as well as the foreseeable unintended outcomes and sources of discrimination risks in view of the system's intended purpose.[204]

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[203] For the role and competences of these national equality bodies, see T Kádár, 'Equality Bodies: A European Phenomenon' (2018) 18(2–3) International Journal of Discrimination and the Law 144.

[204] See Annex IV(2)(b), (2)(g), and (3) of the AI Act.

Accordingly, when faced with discrimination claims of individuals affected by AI-generated decisions, access to such technical documentation may prove to be a tool of major practical assistance in the hands of national equality bodies for the purpose of proving and assessing the potentially discriminatory nature of the high-risk systems concerned. If the documentation provided is insufficient to ascertain whether an infringement of non-discrimination rules has occurred, equality bodies may also request the market surveillance authority to organise the testing of the AI system through technical means.[205]As such, the AI Act not only leaves the competences of national equality bodies intact but it further strengthens them by adding new tools to their legal toolbox under the EU and national non-discrimination framework.[206] This is particularly important, taking into account that the so-called 'individual-rights-based' approach that is currently prevalent in the enforcement of EU non-discrimination law is rather ill-suited to address the challenges posed by algorithmic and AI-based decision-making, which argues in favour of increased reliance on public enforcement mechanisms in this field.[207]

5 Concluding remarks

It follows from the preceding analysis that the AI Act complements to a considerable extent EU non-discrimination law when it comes to combatting AI-enabled discrimination both at the level of substantive protection granted to individuals and at the level of enforcement. Each of the three different functions performed by the AI Act contributes in this direction by assuming a distinct role.

More specifically, through its prohibitive function, the AI Act targets certain harmful AI practices, which may not always be captured by the EU non-discrimination framework, and thus results in expanding the personal and material scope of the latter. This is all the more so, considering that Article 5 of the AI Act suffices to bring the practices concerned within the ambit of the Charter, thereby triggering the applicability of Article 21(1) thereof. It is noted in this regard that the AI Act's prohibitions explicitly cover practices that are likely to produce not only discriminatory but also unfair or biased outcomes that would otherwise fall outside the reach of EU non-discrimination law.[208] Indeed, Article

[205] See Art 77(3) of the AI Act.

[206] See Art 77 and recital 157 of the AI Act.

[207] See Xenidis and Senden (n 7) section IV.1. See also Gerards and Xenidis (n 3) 11, 76–77.

[208] See eg the Commission's Guidelines on prohibited AI practices (n 24) points 148, 165, 190. For the difference between the notions of 'bias' and 'discrimination', see eg Gerards and Xenidis (n 3) 47; Gerards and Zuiderveen Borgesius (n) 7, suggesting a distinction between instances of differentiation based on protected grounds that fall under the scope of

5 of the AI Act applies without even necessarily requiring any finding of discrimination whatsoever. Rather, it prohibits certain AI practices merely due to the unacceptable risks they inherently entail for individuals' fundamental rights, including their right to non-discrimination. As such, the prohibitions in Article 5 of the AI Act may also be of great value from a procedural point of view, by discharging the persons affected from the burden of proving the *prima facie* discriminatory design or effects of the specific AI system in question.[209] In addition, the AI Act's prohibitive function permits action at various points in the AI value chain, including at the earlier stages of an AI system's lifecycle, such as when placing it on the market and putting it into service, even before its actual deployment.[210] This is particularly useful, given that the desired protection under non-discrimination legislation often comes too late.[211]

As concerns its regulatory function, the AI Act reinforces the EU non-discrimination framework through its preventative and safety logic.[212] This is because it provides for specific requirements that aim to minimise the risk of AI-driven discrimination throughout the AI systems' lifecycle, particularly in relation to the design and quality of the datasets used for the development of AI systems, along with a number of other obligations.[213] Although under EU non-discrimination law a certain practice may sometimes be found discriminatory even before its implementation and without the existence of any identifiable victims,[214] it is doubtful whether and at which precise stage of an AI system's lifecycle non-discrimination rules could step in to capture that system's potentially discriminatory effects prior to their use. In this regard, Article 10 of the AI Act makes it possible to detect early on where biases lie in the functioning of an AI system and take appropriate action to remedy them. Besides, since the AI Act applies horizontally across all sectors,[215] its regulatory function contributes to the prevention or mitigation of AI-en-

non-discrimination law and other types of unfair differentiation in the context of AI technologies. This distinction also seems to be recognised by the AI Act. See eg recital 27 referring to 'discriminatory impacts and unfair biases that are prohibited by Union or national law', recitals 32 and 52 using the terms 'biased results' and 'discriminatory effects', and recital 70 referring to 'discrimination that might result from the bias in AI systems'.

209 See similarly in this regard 'Resetting Antidiscrimination Law in the Age of AI' (n 23) 1571.

210 See the Commission's Guidelines on prohibited AI practices (n 24) point 42.

211 See Hacker (n 158) 279.

212 See the Commission's Guidelines on prohibited AI practices (n 24) point 42.

213 See the Commission's AI Act Proposal (n 20) point 1.2.

214 See Case C-54/07 *Feryn* ECLI:EU:C:2008:397, para 23; Case C-81/12 *Asocia ia Accept* ECLI:EU:C:2013:275, para 36.

215 See recital 9 of the AI Act. The AI Act does not apply, however, to areas falling outside the scope of EU law, nor to AI systems for military, defence or national security purposes, nor to

abled discrimination beyond the limited areas of life covered by the EU Equality Directives.

Lastly, the AI Act's enabling function strengthens not only the private enforcement of EU non-discrimination law by individual victims of discrimination but also the public one entrusted to national equality bodies. As already shown above in Section 4.1, the right to lodge a complaint with a market surveillance authority can only benefit the persons concerned in an indirect way, while this is also the case for the power granted to equality bodies to request access to technical documentation about high-risk systems, which may be of paramount importance to individuals having recourse to the administrative means of redress that are available before these authorities under non-discrimination law. The right to explanations under Article 86 of the AI Act may instead prove to be a more powerful tool for those persons to overcome the challenges posed by the lack of transparency of AI models and, by extension, to successfully bring their discrimination claims before courts. All in all, it can be concluded that instead of providing individuals with proper means of redress against instances of AI-driven discrimination on its own,[216] the AI Act rather enables them to avail themselves more effectively of the mechanisms already existing under EU or national non-discrimination legislation. This becomes particularly evident, taking also into account that no civil liability regime is established for providers or deployers of AI systems in the event of violation of the AI Act's rules, as this would be covered by a different legal instrument, namely the AI Liability Directive,[217] which is, however, about to be withdrawn by the European Commission due to an alleged lack of foreseeable agreement between the Member States.[218] Thus, it is only on the basis of non-discrimination provisions that claims for damages or reparation of loss suffered due to the discriminatory effects of an AI-based decision may be sought by the individuals affected.

Apart from the aforementioned significant complementarities between the AI Act and EU non-discrimination law, it should also not be overlooked that the AI Act's provisions are expressly meant to complement other pieces of EU law, thus creating a patchwork of different legal instruments that may be potentially applicable when addressing AI-en-

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those specifically developed and put into service for the sole purpose of scientific research and development. See Art 2(3)ff.

[216] See similarly in this regard Arnold (n 132).

[217] Commission, 'Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive)' [2022] COM/2022/496 final.

[218] See the Commission's work programme 2025, 'Moving Forward Together: A Bolder, Simpler, Faster Union' COM (2025) 45 final, 11 February 2025, Annex IV, point 32.

abled discrimination. For instance, the prohibition of using AI systems for social scoring practices under Article 5(1)(c) of the AI Act largely relies on the types of data that may be deployed for creditworthiness assessments by reference to the specific provisions of the CCD. Similarly, the prohibition of AI-based crime predictions based on certain personal traits pursuant to Article 5(1)(d) of the AI Act corresponds to the prohibition of discriminatory profiling on the basis of sensitive categories of data under the Law Enforcement Directive, while when a person wishes to file a complaint with a market surveillance authority, the relevant procedure will be governed by the Product Safety Regulation. Most prominently, the AI Act's right to explanations applies only where this right is not already granted by other provisions of EU legislation, such as Article 15(1)(h) GDPR or Article 18(8) CCD. It therefore seems that combatting discrimination in the field of AI operations may sometimes 'take more than two to tango'.

It is too early to say whether and to what extent the AI Act will be interpreted and applied as a standalone legal instrument or in parallel with EU non-discrimination law, in particular Article 21(1) of the Charter. A test case in this respect could perhaps arise in the near future with regard to Hungary's envisaged use of AI facial recognition technologies in Pride events, which has been deemed by civil society organisations contrary to Article 5(1)(h) of the AI Act, urging the European Commission to take action accordingly.[219] In the same vein, it is yet to be seen how the AI Act's rules may interact with other pieces of EU secondary sectoral legislation in cases of discriminatory AI systems. In any event, it will certainly contribute to the diversification of the existing tools against discrimination available under EU law.

Suggested citation: K Lamprinoudis, 'It Takes (At Least) Two to Tango in the Rhythm of AI-Enabled Discrimination: How the AI Act Complements EU Non-Discrimination Law?' (2025) 21 CYELP 77.

[219] See Civil Liberties Union for Europe, EDRi, European Center for Not-for-Profit Law (ECNL) and Hungarian Civil Liberties Union, 'Legal Analysis: New Biometric Surveillance Laws in Hungary Violate the Prohibition of Real-Time Remote Biometric Identification Under the AI Act' (28 April 2025) <https://tinyurl.com/ynchuwrx> accessed 20 November 2025; ECNL, Liberties and the Hungarian Civil Liberties Union, 'Civil Society Calls on Commission to Act: Hungary Escalates Rule of Law Breaches by Banning Pride Scheduled for 4 October 2025' (29 September 2025) <https://tinyurl.com/bdfxrt4j> accessed 20 November 2025.

FROM THE AI ACT TO A EUROPEAN AI AGENCY: COMPLETING THE UNION'S REGULATORY ARCHITECTURE

Georgios Pavlidis *

Abstract: As artificial intelligence (AI) technologies continue to advance, effective risk assessment, regulation, and oversight are necessary to ensure that AI development and deployment align with ethical principles while preserving innovation and economic competitiveness. The adoption of the EU AI Act marks an important step in this direction, establishing a harmonised legal framework that includes detailed provisions on AI governance, as well as the creation of the European AI Office. This paper revisits the question of whether a more robust supranational agency dedicated to AI is still warranted and explores how such a body could enhance policy coherence, improve risk assessment capacities, and foster international cooperation. It also argues that a strengthened EU-level agency would also serve the Union's strategic aim of securing digital and technological sovereignty.

Keywords: artificial intelligence, European Union, EU AI Act, supranational agency, AI agency, regulatory fragmentation, risk-based approach, technological sovereignty.

1 Introduction

Artificial intelligence (AI) technologies and applications are rapidly expanding and being commercialised across numerous sectors, including healthcare, commerce, transportation, finance, and beyond.[1] Nevertheless, the growth of AI has also given rise to serious ethical, societal, and legal challenges (section 2).[2] For this reason, effective risk assess-

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[1] Commission, 'Building Trust in Human Centric Artificial Intelligence' (Communication) COM (2019) 168 final.

[2] Organization for Economic Co-operation and Development, 'Advancing Accountability in AI: Governing and Managing Risks Throughout the Lifecycle for Trustworthy AI' (2023) 349 OECD Digital Economy Papers 26; Michael Littman and others, 'Gathering Strength, Gathering Storms: The One Hundred Year Study on Artificial Intelligence (AI100), 2021 Study Panel Report' (Stanford University, September 2021).

ment, regulation, and oversight of AI are required to ensure that this growth aligns with ethical principles without hindering innovation (section 3). The objective of this paper is to examine whether the establishment of a supranational agency on AI would fit this imperative and how the current European Union (EU) legal and institutional framework—particularly following the establishment of the EU AI Office—needs to be reinforced to address AI risks (section 4).

Many jurisdictions have taken increasing steps to regulate AI,[3] but disparities exist in their approaches to AI standards and enforcement mechanisms. This fragmentation is suboptimal because AI products and services transcend national borders, and attempting to regulate a global issue at multiple local levels has consistently proven to be an uphill battle.[4] Even where effective norms are adopted at the national level, enforcing them in a borderless and interconnected digital environment will be a challenge.[5] International organisations such as the Organization for Economic Co-operation and Development (OECD) and the United Nations Educational, Scientific and Cultural Organization (UNESCO) have proposed guidelines,[6] but they lack binding regulatory power. For its part, the recently adopted Council of Europe's Framework Convention on AI faces significant challenges on the path to effective implementation

[3] In addition to the EU action, which is discussed in this paper, see the legislative initiatives on AI in Brazil (Projeto de Lei n° 2338, de 2023), in China (2021 Regulation on Recommendation Algorithms; 2022 Rules for Deep Synthesis; 2023 Draft Rules on Generative AI), and in Canada (Draft Law C-27, Digital Charter Implementation Act 2022, Part 3: Artificial Intelligence and Data Act). The United Kingdom intends to enhance the responsibilities of its current regulatory bodies, such as the Information Commissioner's Office, the Financial Conduct Authority, and the Competition and Markets Authority, rather than implementing comprehensive new legislation to regulate AI, which differs from the approach taken by the EU. These organisations will have authority to offer guidance and supervise the utilisation of AI within their specific domains of jurisdiction; UK Secretary of State for Science, Innovation and Technology, 'A Pro-Innovation Approach to AI Regulation' (Policy Paper, 2023) <www.gov.uk/government/publications/ai-regulation-a-pro-innovation-approach/white-paper> accessed 14 September 2025.

[4] Jonathan Wiener, 'Think Globally, Act Globally: The Limits of Local Climate Policies' (2007) 155 University of Pennsylvania Law Review 1961; James Bushnell, Carla Peterman, and Catherine Wolfram, 'Local Solutions to Global Problems: Climate Change Policies and Regulatory Jurisdiction' (2008) 2(2) Review of Environmental Economics and Policy 175.

[5] Julia Hörnle, *Internet Jurisdiction - Law and Practice* (OUP 2021). This holds especially true within the realm of cloud computing. On this issue, see Christopher Millard (ed), *Cloud Computing Law* (2nd edn, OUP 2021) and Dinesh Soni and Neetesh Kumar, 'Machine Learning Techniques in Emerging Cloud Computing Integrated Paradigms: A Survey and Taxonomy' (2022) 205 Journal of Network and Computer Applications 103419. See also Isabelle Bousquette, 'The AI Boom Is Here - The Cloud May Not Be Ready' *The Wall Street Journal* (10 July 2023).

[6] OECD, Recommendation of the Council on Artificial Intelligence, OECD/LEGAL/0449, 22 May 2019; UNESCO, Recommendation on the Ethics of Artificial Intelligence, Document No SHS/BIO/PI/2021/1, 2021.

and, by its nature, cannot achieve global applicability.[7] Thus, disparities between national legal frameworks on AI are very likely to remain unaddressed. The lack of a global framework is likely to complicate compliance and hinder innovation, as legal uncertainty and varying regulatory requirements will persist across jurisdictions.[8] Although fragmentation may sometimes be creative in global governance,[9] it must be avoided in the context of AI regulation, as it might impede the effective management of the significant societal impacts of AI, including issues related to bias, accountability, and transparency.

For the EU, the adoption of the AI Act[10] constitutes an important milestone in establishing a harmonised and risk-based regulatory framework for AI across the 27 Member States. However, despite this important step, challenges remain regarding the standard-setting, as well as the supervision and enforcement of the rules on AI. The EU AI Office—established under the AI Act—is intended to perform many coordination and oversight functions. However, its powers and structure are more limited than what might be envisioned for a full-fledged supranational agency. This limitation is particularly significant given the AI Act's dual character: while framed as economic regulation to secure the internal market, its provisions fundamentally address fundamental rights, safety, and broader societal risks.[11] This expansive scope distinguishes it from traditional product-safety legislation and strengthens the case for a more specialised supranational body with the stronger oversight powers necessary to protect citizens, not just markets. A logical next step in the EU's regulatory trajectory would be the consolidation of AI governance functions within a dedicated and strengthened EU agency on AI. Such an agency could serve as a central authority to support standard-setting, enforcement of the AI Act, and cross-border coordination. If proper-

[7] The Council of Europe's Committee of Ministers had mandated the Committee on Artificial Intelligence (CAI) to elaborate a framework Convention on the development and application of AI, based on the standards of the Council of Europe <www.coe.int/en/web/artificial-intelligence> accessed 20 October 2025.

[8] Peter Cihon, Matthijs Maas, and Luke Kemp, 'Fragmentation and the Future: Investigating Architectures for International AI Governance' (2020) 11(5) Global Policy 545.

[9] Amitav Acharya, 'The Future of Global Governance: Fragmentation May be Inevitable and Creative' (2016) 22(4) Global Governance 453.

[10] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) [2024] OJ L 2024/1689. See also European Commission, Proposal for a Regulation laying down harmonized rules on artificial intelligence (Artificial Intelligence Act), COM(2021) 206 final.

[11] Marco Almada and Nicolas Petit, 'The EU AI Act: Between the Rock of Product Safety and the Hard Place of Fundamental Rights' (2025) 62 Common Market Law Review 85.

ly designed, it would strengthen Europe's ability to promote innovation and uphold its strategic goal of technological sovereignty, while also safeguarding fundamental rights. As this paper will argue, advancing this institutional development is timely and necessary given the fast-paced evolution of AI.

2 The thrills and perils of AI's ascendance

There are estimates that the global AI market, valued at $428 billion in 2022, will grow to more than $2 trillion by 2030.[12] By then, it is also anticipated that AI will contribute $15.7 trillion to the worldwide economy or a 14% increase in global gross domestic product (GDP), surpassing the present collective economic output of China and India.[13] AI-driven technologies also promise to enhance labour productivity by as much as 40% across a spectrum of 16 industries by 2035.[14] Not surprisingly, the business world, especially Big Tech, is experiencing AI fever and the majority of AI investment now comes from private sources. In 2023, the United States led with 62.5 billion in private AI investment, followed by China with 7.3 billion; that same year, the EU and the United Kingdom combined attracted 9 billion in private investment in the sector.[15] At the business level, the number of companies using AI capabilities (natural-language generation, robot process automation, computer vision, etc) had increased to 78% by October 2025, up from 55% percent in 2023,[16] while an astonishing 83% of companies view the incorporation of AI into their business strategies as a priority.[17]

The capabilities of AI justify this excitement within the business world, but concerns arise about the associated risks. Historically, this has been true for most emerging novel technologies,[18] but in the context of AI, many of these concerns appear to be well founded. Indeed, ethical

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[12] Fortune Business Insights, 'Artificial Intelligence Market' (Market Research Report, April 2023).

[13] PWC, 'Sizing the Price: What's the Real Value of AI for Your Business and How Can You Capitalise?' (PWC Report 2017).

[14] Accenture, 'Why Artificial Intelligence is the Future of Growth' (Accenture Report 2016).

[15] European Parliament, 'AI investment: EU and global indicators' (European Parliamentary Research Service, March 2024).

[16] McKinsey, 'The State of AI: How Organizations Are Rewiring to Capture Value' (McKinsey Survey, March 2025).

[17] Falon Fatemi, '3 Ways Artificial Intelligence Is Transforming Business Operations' *Forbes* (29 May 2019).

[18] Bernard Cohen, 'The Fear and Distrust of Science in Historical Perspective' (1981) 6(3) Science, Technology, & Human Values 20; Marita Sturken, Douglas Thomas, and Sandra Ball-Rokeach, *Technological Visions: Hopes and Fears That Shape New Technologies* (Temple University Press 2004).

dilemmas become more pronounced as AI systems increasingly influence decisions with consequences for humans, especially in sensitive domains such as healthcare, credit scoring, policing, and the criminal justice system.[19] In these domains, the potential for bias and discrimination within AI systems could inadvertently perpetuate preexisting inequalities.[20] This raises issues such as fairness, responsibility, openness, and how these principles should be incorporated into legal frameworks. Furthermore, security concerns take centre stage as the growing dependence on AI creates fresh opportunities for cyberattacks, data compromises, and other malicious uses and abuses of AI.[21] In addition to these difficulties, the consolidation of power and data within a small group of dominant tech companies or entities gives rise to concerns regarding the possible abuse of this authority in markets, public discussions, and even political procedures.[22] Finally, the looming prospect of job displacement is significant, with automation and AI-driven processes posing a threat in terms of reshaping industries, amplifying disparities in the labour market, and profoundly transforming the employment landscape.[23]

Nevertheless, identifying the risks is usually much easier than building consensus on the necessary policy and legal responses.[24] For example, although there is agreement on the need to address the ethical aspects of AI decision-making, policy responses require a prior and

[19] Jacob O Arowosegbe, 'Data Bias, Intelligent Systems and Criminal Justice Outcomes' (2023) 31(1) International Journal of Law and Information Technology 22; Abdul Malek, 'Criminal Courts' Artificial Intelligence: The Way It Reinforces Bias and Discrimination' (2022) 2 AI and Ethics 233; Michael Bücker and others, 'Transparency, Auditability, and Explainability of Machine Learning Models in Credit Scoring' (2022) 73 Journal of the Operational Research Society 70; Georgios Pavlidis, 'Deploying Artificial Intelligence for Anti-money Laundering and Asset Recovery: The Dawn of a New Era' (2023) 26(7) Journal of Money Laundering Control 155.

[20] This may be due to several factors, such as biased training data, data collection methods, feature selection, and feedback loops. See Frederik Zuiderveen Borgesius, 'Discrimination, Artificial Intelligence, and Algorithmic Decision-Making' (Council of Europe Study 2018).

[21] European Union Agency for Cybersecurity, 'Artificial Intelligence Cybersecurity Challenges' ENISA Report (2020); Europol, 'Malicious Uses and Abuses of Artificial Intelligence' Europol Report (2021); on computer-related crimes and virtual criminality, see Ian Lloyd, *Information Technology Law* (9th edn, OUP 2020).

[22] Nick Srnicek, 'Platform Monopolies and the Political Economy of AI' in John McDonnell (ed), *Economics for the Many* (Verso 2018) 152–163; Pieter Verdegem, 'Dismantling AI Capitalism: The Commons as an Alternative to the Power Concentration of Big Tech' (2022) AI & Society <https://doi.org/10.1007/s00146-022-01437-8> accessed 14 September 2025.

[23] OECD, 'Artificial Intelligence and Employment' (Policy Brief 2021); see also Accenture, 'A New Era of Generative AI for Everyone' (Accenture Report 2023). According to this report, 40% of all working hours can be impacted by Large Language Models (LLMs) like GPT-4.

[24] Charlotte Stix and Matthijs Maas, 'Bridging the Gap: The Case for an Incompletely Theorized Agreement on AI Policy' (2021) 1 AI and Ethics 261.

clear definition of fairness and bias.[25] Such a definition might be highly dependent on context, leading to differing interpretations, while legal definitions of bias may also differ from one jurisdiction to another. Therefore, any attempt to regulate AI must overcome serious obstacles, such as the definition of AI systems, the criteria for the classification of risks, as well as the scope and criteria of transparency, explainability, and due diligence obligations that will be imposed on AI developers and users.[26]

3 The shift towards enforceable AI regulations and supervision

Several public and private organisations have developed or are developing sets of soft-law principles for AI governance,[27] attempting to balance technological innovation with responsible AI. A notable example is the set of non-binding guidelines adopted by the EU in 2019, which are closely related to the principles adopted by the OECD some weeks later in the same year.[28] Nevertheless, the soft-law approach to AI appears to be gradually giving rise to a more robust legislative approach, not only in the EU with its ambitious AI Act but also in other jurisdictions.[29] In this 'race to AI regulation',[30] jurisdictions are seeking to develop new binding rules on AI, supported by enforcement mechanisms. The choice between hard and soft law has attracted scholarly attention across various domains of law and governance.[31] We contend that the transition from soft to hard law is both timely and suitable in the context of AI, given the magnitude of the risks associated with this emerging technology. This does not mean that soft-law rules should be discarded as a policy tool; they provide the benefits of flexibility and adaptability and can be

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[25] Vincent Müller, 'Ethics of Artificial Intelligence and Robotics' in Edward Zalta (ed), *Stanford Encyclopedia of Philosophy* (Stanford University 2020).

[26] Leilani Gilpin and others, 'Explaining Explanations: An Overview of Interpretability, of Machine Learning' (2019) ArXiv <http://arxiv.org/abs/1806.00069> accessed 14 September 2025.

[27] Ryan Budish, 'AI's Risky Business: Embracing Ambiguity in Managing the Risks of AI' (2021) 16 Journal of Business & Technology Law 259.

[28] Commission, Ethics Guidelines for Trustworthy AI, High-Level Expert Group on AI, 8 April 2019; OECD, Recommendation of the Council on Artificial Intelligence, OECD/LEGAL/0449, 22 May 2019.

[29] Anu Bradford, 'The Race to Regulate Artificial Intelligence: Why Europe Has an Edge Over America and China' *Foreign Affairs* (27 June 2023); see also the legislative initiatives described in n 3.

[30] Nathalie Smuha, 'From a Race to AI to a Race to AI regulation: Regulatory Competition for Artificial Intelligence' (2021) 13(1) Law, Innovation and Technology 57.

[31] Christine Chinkin, 'The Challenge of Soft Law: Development and Change in International Law' (1989) 38(4) International & Comparative Law Quarterly 850; Kenneth Abbott and Duncan Snidal, 'Hard and Soft Law in International Governance' (2000) 54(3) International Organization 421; Bryan Druzin, 'Why Does Soft Law Have any Power Anyway?' (2017) 7(2) Asian Journal of International Law 361.

utilised to complement hard law, serving as mutually reinforcing components in AI regulation.[32] Nevertheless, there is a need for a set of binding regulations, with enforcement mechanisms and sanctions as a deterrent against non-compliance.[33]

There is a welcome degree of international convergence around key principles for the deployment and use of AI—particularly transparency, accountability, data privacy and protection, fairness, inclusivity, and the prevention of bias and discrimination.[34] Not surprisingly, there is no convergence around specific definitions and implementation criteria for these principles. Indeed, national approaches to these issues depend on the respective economic, business, and technological landscape. Some countries adopt a 'laissez-faire' approach, avoiding any interference with technological innovation, while others may opt for stringent regulations and broader definitions of the AI systems that fall under them. The challenge will be to promote cooperation among jurisdictions in the form of bilateral or multilateral agreements on data sharing, the development of common principles and standards on AI, and coordinated action around the enforcement of rules when AI systems cross international boundaries.[35] Such cooperation should be embedded throughout the domestic rulemaking context, which should consider existing international instruments, assess impacts beyond borders, and streamline mutual recognition of procedures.[36]

Regarding oversight of AI, governments may entrust it to dedicated agencies or departments, either new or evolved. These agencies may be responsible for developing policies and guidelines, monitoring compliance, and enforcing regulations. Some jurisdictions may opt for the model of industry self-regulation, where industry associations and tech companies develop their own guidelines and best practices. This form of privatisation of regulation can be beneficial under certain circumstanc-

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[32] Gregory Shaffer and Mark Pollack, 'Hard Versus Soft Law in International Security' (2011) 52 Boston College Law Review 1147.

[33] Emer O'Hagan, 'Too Soft to Handle? A Reflection on Soft Law in Europe and Accession States' (2004) 26(4) Journal of European Integration 379; Jan Klabbers, 'The Undesirability of Soft Law' (1998) 67 Nordic Journal of International Law 381.

[34] Jessica Fjeld and others, 'Principled Artificial Intelligence: Mapping Consensus in Ethical and Rights-based Approaches to Principles for AI' (Berkman Klein Center for Internet & Society Report, 2020).

[35] Peter Cihon, 'Standards for AI Governance: International Standards to Enable Global Coordination in AI Research and Development' (Center for the Governance of AI, Future of Humanity Institute, Oxford, Technical Report, 2019) <www.governance.ai/research-paper/standards-for-ai-governance-international-standards-to-enable-global-coordination-in-ai-research-development> accessed 14 September 2025.

[36] OECD, 'International Regulatory Co-operation' (OECD Best Practice Principles for Regulatory Policy, 2021).

es[37] but has been the subject of criticism for producing weak and ineffective norms due to barriers to inter-firm collective action, lenience in the face of noncompliant behaviour and free-rider problems, lack of public participation or oversight, and so on.[38] A better alternative would be a hybrid model of meta-regulation, which favours collaboration and interaction among government agencies, industry, and other stakeholders to develop policies and binding rules.[39]

To achieve these goals in a supranational context, a range of supervisory mechanisms are available.[40] The simplest option would be to follow a national supervisory model supported by the harmonisation of certain substantive rules at supranational level. In this model, national supervisory authorities would supervise the application of harmonised rules on AI within their jurisdictions, emphasising independence and cooperation among themselves, without the oversight or even coordination of a supranational body. A second option would be to introduce a two-layer framework with national supervisory authorities and a supranational body, which would play simply an advisory and coordinating role.[41] A third option would be to establish a strengthened supranational agency and entrust it with significant supervisory powers, such as direct supervision of certain entities and activities.

Regardless of the model used, the key challenge is the evolving technological landscape, which often outpaces regulatory efforts. Regulators and supervisors will continue to struggle to keep up with new AI applications, while their initiatives may have unintended consequences, such as restraining innovation or creating excessive compliance burdens and costs. The concept known as the law of unintended consequences is frequently mentioned, but consistently disregarded by politicians and

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[37] Margot Priest, 'The Privatization of Regulation: Five Models of Self-Regulation' (1998) 29(2) Ottawa Law Review 233.

[38] William Bendix and Jon MacKay, 'Fox in the Henhouse: The Delegation of Regulatory and Privacy Enforcement to Big Tech' (2022) 30(2) International Journal of Law and Information Technology 115; Ian Maitland, 'The Limits of Business Self-Regulation' (1985) 27(3) California Management Review 132.

[39] Cary Coglianese and Evan Mendelson, 'Meta Regulation and Self Regulation' in Robert Baldwin, Martin Cave, and Martin Lodge (eds), *The Oxford Handbook of Regulation* (OUP 2010); Ifeoma Elizabeth Nwafor, 'AI ethical Bias: A Case for AI Vigilantism (Allantism) in Shaping the Regulation of AI' (2021) 29(3) International Journal of Law and Information Technology 225.

[40] Madeleine McNamara, 'Starting to Untangle the Web of Cooperation, Coordination, and Collaboration: A Framework for Public Managers' (2012) 35(6) International Journal of Public Administration 389.

[41] Georgi Gitchev, 'The Governance of the AI Act: Your Questions Answered' (*European AI Alliance Blog*, 4 March 2022) <https://futurium.ec.europa.eu/en/european-ai-alliance/blog/governance-ai-act-your-questions-answered> accessed 14 September 2025.

prevailing public sentiment.[42] In the context of information technology, poorly-designed regulation may result in undesirable and unforeseen consequences, such as de-risking, barriers to entry, excessive compliance burdens, adverse effects on competition, and privacy and security concerns.[43] Therefore, policymakers must strike the right balance between innovation and regulation without hindering investments in AI or putting businesses and tech companies in an unfavourable position vis-à-vis their global competitors.[44]

4 The EU AI Office is not enough: why the EU needs a full-fledged AI agency

At the EU level, the adoption of the EU AI Act promises to bring about greater clarity by ensuring that the rights and responsibilities of AI developers and users are interpreted consistently within the EU single market. The Act introduces a single, directly applicable set of rules for the development, placing on the market, and use of AI systems, replacing fragmented national approaches. The Act categorises AI systems based on the level of risk they pose (eg unacceptable risk, high-risk, limited risk), ensuring that obligations (such as conformity assessments, transparency duties, or prohibitions) are clear and proportionate to the risks involved.[45] The Act provides standardised procedures and requirements for AI systems, especially high-risk systems, including documentation, record-keeping, human oversight, and post-market monitoring. These elements promise to instil increased confidence among businesses, investors, and consumers while preventing the practice of seeking more favourable regulatory environments, at least within the EU single market.

The EU AI Office, established under the AI Act, will play a role in coordinating the implementation of the regulation, developing guidance, facilitating expert cooperation, and monitoring emerging AI trends. However, it is not an independent regulatory body but operates within the European Commission, with limited powers in direct supervision, en-

[42] Rob Norton, 'Unintended Consequences' (*EconLib* 2023) <www.econlib.org/library/Enc/UnintendedConsequences.html> accessed 14 September 2025.

[43] This was the case of the so-called 'Crypto-Wars' and the attempt of several countries to limit the public's access to strong cryptography, in order to facilitate decryption by national intelligence agencies; see Cian Murphy, 'The Crypto-Wars Myth: The Reality of State Access to Encrypted Communications' (2020) 49 Common Law World Review 245; Paul McLaughlin, 'Crypto Wars 2.0: Why Listening to Apple on Encryption Will Make America More Secure' (2016) 30 Temple International and Comparative Law Journal 353.

[44] Georgios Pavlidis, 'Europe in the Digital Age: Regulating Digital Finance without Suffocating Innovation' (2021) 13(2) Law, Innovation and Technology 464.

[45] Nicoletta Rangone and Luca Megale, 'Risks Without Rights? The EU AI Act's Approach to AI in Law and Rule-Making' (2025) European Journal of Risk Regulation 1.

forcement, and binding decision-making. It lacks the legal autonomy and institutional strength of fully fledged EU agencies such as the European Data Protection Supervisor (EDPS), the European Medicines Agency (EMA), or the European Securities and Markets Authority (ESMA). As such, while it represents an important step forward, it does not close the debate on whether a dedicated, supranational EU AI agency—with greater independence, enforcement authority, and cross-border supervisory capacity—may still be necessary to ensure uniform application of the AI Act, safeguard fundamental rights,[46] and strengthen Europe's strategic position in global AI governance.

While the AI Act champions foundational EU values like democracy, fundamental rights, and the rule of law, its success hinges on translating these principles into practice.[47] The AI Office's integration within the European Commission risks its functional independence and raises concerns about politicisation. Furthermore, its bureaucratic structure may stifle the dynamic stakeholder engagement essential for agile governance, as participation is constrained by standard Commission procedures rather than flexible, purpose-built channels. These institutional shortcomings highlight the advantages of a structurally independent agency. Legislators naturally seek to control agencies, but overly tight reins—meant to ensure accountability—can ultimately cripple an agency's capacity to develop effective policy solutions.[48] Several factors underscore the need for a more powerful supranational EU agency dedicated to overseeing certain AI-related matters. The first factor is the inherently transnational nature of AI technologies. AI systems, by design, operate beyond the confines of national borders, coupled with the fact that data flow across countries almost without restrictions. In this context, the impact of AI applications is global and not limited to specific jurisdictions. Second, the stakes are high: AI poses serious ethical and societal challenges, security risks, and human rights risks, thereby requiring a collective approach at the level of standard-setting and enforcement. Indeed, a patchwork of national regulatory mechanisms would lead to fragmentation and harmful regulatory competition (a race to the bottom), allow forum shopping, and undermine the effectiveness of regulation.[49]

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[46] Francesca Palmiotto, 'The AI Act Roller Coaster: The Evolution of Fundamental Rights Protection in the Legislative Process and the Future of the Regulation' (2025) 16 European Journal of Risk Regulation 770.

[47] Nathalie Smuha and Karen Yeung, 'The European Union's AI Act: Beyond Motherhood and Apple Pie?' in Nathalie A Smuha (ed), *The Cambridge Handbook of the Law, Ethics and Policy of Artificial Intelligence* (CUP 2025).

[48] Berthold Rittberger and others, 'The Competence-Control Dilemma and the Institutional Design of European Union Agencies' (2024) 37 Governance 1413.

[49] Frank Biermann and others, 'The Fragmentation of Global Governance Architectures: A Framework for Analysis' (2009) 9(4) Global Environmental Politics 14.

Regarding oversight and enforcement, national interventions on AI uses by public authorities would be needed, but the inevitable differences in the responsibilities and traits of national supervisors might produce inconsistent levels of quality and efficacy in AI supervision across the EU, even if substantive rules are effectively harmonized. These challenges necessitate a more integrated and supranational supervisory structure, based on a centralization model that guarantees uniform enforcement, enables better coordination, and curbs forum shopping.[50]

This rationale is further supported by broader institutional developments within the EU. In the last decade, there has been a manifest trend in favour of such EU-centralised supervision and 'agencification' in the implementation of EU law.[51] In this model, EU agencies must not be seen as autonomous regulators at the federal level, such as in the case of the division of authority between federal and state bureaucracies in the United States; the EU model favours administrative networks and the development of networked institutional relations between the EU and national bodies.[52] A successful example would be the model for the prudential supervision of credit institutions by the European Central Bank, which acquired supranational powers in 2014 and now follows a direct supervision model for systemically important banks.[53]

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[50] Filipe Brito Bastos and Przemysław Pałka, 'Is Centralised General Data Protection Regulation Enforcement a Constitutional Necessity?' (2023) 19 European Constitutional Law Review 487.

[51] Edoardo Chiti, 'Decentralized Implementation: European Agencies' in Robert Schütze and Takis Tridimas (eds), *Oxford Principles of European Union Law: The European Union Legal Order* (OUP 2018) 748–776; Mira Scholten, Marloes van Rijsbergen, 'The Limits of Agencification in the European Union' (2015) 15(7) German Law Journal 1223; Takis Tridimas, 'Financial Supervision and Agency Power: Reflections on ESMA' in Niamh Nic Shuibhne and Laurence Gormley (eds), *From Single Market to Economic Union: Essays in Memory of John A. Usher* (OUP 2012) 55.

[52] Johanes Saurer, 'Supranational Governance and Networked Accountability Structures: Member State Oversight of EU Agencies' (2011) 2(1) European Journal of Risk Regulation 51; see also Herwig Hofmann, 'Mapping the European Administrative Space' (2008) 31 West European Politics 662; Ellen Vos, 'Independence, Accountability and Transparency of European Regulatory Agencies' in Damien Geradin, Rodolphe Muñoz & Nicolas Petit (eds), *Regulation through Agencies in the EU* (Edward Elgar 2005) 120; Wolfgang Weiß, 'Agencies versus Networks: From Divide to Convergence in the Administrative Governance in the EU' (2009) 61 Administrative Law Review 45.

[53] Less significant institutions, which are the vast majority of euro area banks, are supervised by national competent authorities (NCAs), under ECB oversight (indirect supervision); see Gianni Lo Schiavo, 'The Single Supervisory Mechanism (SSM) and the EU Anti-Money Laundering Framework Compared: Governance, Rules, Challenges and Opportunities' (2022) 23 Journal of Banking Regulation 91. It has been correctly pointed out how existing EU agencies can serve as a model facilitating the copying of institutional trends from other policy domains; Laurens van Kreij, 'How Have EU Legislators Established EU Agencies with Enforcement Tasks? Case Studies of the European Aviation Safety Agency and the European Medicines Agency' (2025) 63 Journal of Common Market Studies 590.

Despite legitimate concerns regarding the expanding role of EU agencies in law enforcement, this power can be counterbalanced by safeguards, including the non-delegation doctrine,[54] procedural protections, the right to good administration, and judicial review of EU agencies' acts. However, jurisprudence such as the Meroni and ESMA short-selling cases[55] reveals that while the Lisbon Treaty advanced the legitimisation of agencies, the precise scope of their powers remains critically undefined. The European Court of Justice's lenient approach in ESMA short selling failed to provide clarity or to compel the Union Legislator and Member States to define jurisdictional boundaries.[56] This persistent legal ambiguity will likely fuel further agencification, making it imperative to mitigate the accompanying risks of a deepening democratic deficit and unresolved accountability gaps.

The establishment of the EU AI Office is a step in the right direction. However, we argue that its mission should not be limited to supporting and coordinating national supervisors; it should also include policy development, standard-setting, monitoring, enforcement, and direct supervision for systematically important entities. Closely related is the task of threat assessment and risk management, which can provide valuable insights into the evolving risks of AI applications and thus help shape regulatory decisions.[57] Indeed, even after the adoption of the EU AI Act, harmonising AI regulations will remain a complex and unremitting task. To keep pace with new opportunities and risks, the new EU agency on AI would have to opt for an agile and adaptable approach to standard-setting.[58] This would include iterative and flexible assessment cycles and updates to the standards, using technological solutions to improve the quality of evidence, encouraging public and stakeholder engagement, and employing non-legally binding approaches as an alternative or com-

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[54] Marta Simoncini, *Administrative Regulation beyond the Non-Delegation Doctrine: A Study on EU Agencies* (Hart 2018).

[55] Cases C-9/56 & C-10/56 *Meroni & Co, Industrie Metallurgiche, SpA v High Authority of the European Coal and Steel Community* ECLI:EU:C:1958:7; Case C-270/12 *United Kingdom v European Parliament and Council* ECLI:EU:C:2014:18.

[56] Miroslava Scholten and Marloes van Rijsbergen, 'The Limits of Agencification in the European Union' (2014) 15 German Law Journal 1223.

[57] Martin Lundgren and Ali Padya, 'A Review of Cyber Threat (Artificial) Intelligence in Security Management' in T Sipola, T Kokkonen, and M. Karjalainen (eds), *Artificial Intelligence and Cybersecurity* (Springer 2023); Nikolaos Doukas, Peter Stavroulakis, and Nikolaos Bardis, 'Review of Artificial Intelligence Cyber Threat Assessment Techniques for Increased System Survivability' in M Stamp, M Alazab, and A Shalaginov (eds), *Malware Analysis Using Artificial Intelligence and Deep Learning* (Springer 2021).

[58] Wendell Wallach and Gary Marchant, 'An Agile Ethical/Legal Model for the International and National Governance of AI and Robotics' (Proceedings of the 2018 AAAI / ACM Conference on Artificial Intelligence, Ethics and Society, 2018) <www.aies-conference.com/2018/contents/papers/main/AIES_2018_paper_77.pdf> accessed 14 September 2025.

plement to traditional regulatory instruments.[59] The new agency should also be involved in the authorisation of 'regulatory sandboxes', which allow for reduced regulatory requirements and regulatory waivers and enable firms to test new technology models.[60] A new and strengthened EU agency on AI could also play a role in fostering research and innovation and providing capacity building and training. In this context, the ENISA model could also be used as a point of reference.[61] Its mandate would extend beyond regulatory sandboxes to include proactive measures like real-time audits, mandatory incident reporting, and EU-wide risk mapping, producing assessments more comprehensive and timelier than any national body could achieve. Centralising data would enable cross-sectoral learning, while harmonised guidelines and direct SME support would lower compliance costs and foster a truly integrated market for AI.

The structure of a new and strengthened EU agency on AI would need to include various components, to ensure its independence and effectiveness. First, a governing board comprising representatives from Member States, in particular, representatives from national supervisory authorities, as well as AI experts, would be entrusted with providing policy direction and ensuring alignment with EU values and principles. The board would also be responsible for all biding decisions on directly supervised entities or decisions regarding national supervisory authorities. Second, establishing an independent administrative board of review, following the model of the European Central Bank and the EU Anti-Money Laundering Authority (AMLA),[62] would allow the handling of appeals against binding decisions in a manner that is complementary (ie not alternative) to court proceedings. Third, specialised technical committees could focus on specific domains, such as the use of AI in finance and criminal justice. These committees would be entrusted with the development of sector-specific standards and guidelines, which would be endorsed by the governing board, following the model of AMLA. Fourth,

[59] OECD, 'Practical Guidance on Agile Regulatory Governance to Harness Innovation', OECD Regulatory Policy Committee, GOV/RPC(2021)14/FINAL, 2021.

[60] OECD, 'The role of sandboxes in promoting flexibility and innovation in the digital age' (Going Digital Toolkit Policy Note, 2020) <www.oecd.org/en/publications/the-role-of-sandboxes-in-promoting-flexibility-and-innovation-in-the-digital-age_cdf5ed45-en.html> accessed 14 September 2025.

[61] Dimitra Markopoulou, Vagelis Papakonstantinou, and Paul de Hert, 'The New EU Cybersecurity Framework: The NIS Directive, ENISA's Role and the General Data Protection Regulation' (2019) 35(6) Computer Law & Security Review 105336; Jukka Ruohonen, Sami Hyrynsalmi, and Ville Leppänen, 'An Outlook on the Institutional Evolution of the European Union Cyber Security Apparatus' (2016) 33(4) Government Information Quarterly 746.

[62] Georgios Pavlidis, 'The Birth of the New Anti-money Laundering Authority: Harnessing the Power of EU-wide Supervision' (2024) 31 Journal of Financial Crime 322.

an administrative unit would be required to manage day-to-day operations, budget issues, and coordination with Member States and other stakeholders. In this context, an executive director would manage the administrative unit and represent the AI agency. There would also be the need for mechanisms to ensure accountability and public scrutiny of the agency's organs and activities. This could be achieved through the organisation of compliance assessments and regular reporting, such as to the European Parliament and the Council, which are often called upon to ensure transparency, integrity, and accountability at the EU level.[63] This would address growing concerns about the accountability of EU-level agencies, which are often viewed as powerful and unaccountable bureaucracy.[64]

The establishment of a strengthened EU agency on AI should not lead to duplication, overlap, or inconsistencies with existing regulatory bodies, which would do more harm than good by accentuating legal uncertainties.[65] Therefore, the new AI agency would coordinate closely with existing bodies, such as ENISA, the European Data Protection Board and the European Union Agency for Fundamental Rights, and sector-specific bodies and would streamline rules and procedures through collaborative efforts. A more complex challenge involves structuring coexistence and coordination between a new EU AI agency and national regulatory bodies to prevent conflicts and ensure a uniform regulatory playing field. This is critical because the implementation of the AI Act is a shared responsibility, involving both established EU institutions like the Commission and new bodies like the AI Office, alongside national authorities.[66] The coordination problem is especially acute in Member States where national supervisory authorities lack full independence. Here, a supranational agency could act as a crucial counterweight, guaranteeing consistent enforcement while accommodating diverse national traditions. To bridge these institutional differences, formalised cooperation mechanisms, such as joint supervisory teams, mandatory peer reviews, and binding mediation, would be indispensable.

The EU agency on AI should have the powers to ensure that national bodies abide by the same high standards because high-quality regulation at a certain level of governance can be compromised by poor

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[63] European Parliament, 'Transparency, Integrity and Accountability in the EU Institutions', Briefing, European Parliament's Committee on Petitions, 2019.

[64] Madalina Busuioc, *European Agencies: Law and Practices of Accountability* (OUP 2013).

[65] Vera Lúcia Raposo, 'Ex Machina: Preliminary Critical Assessment of the European Draft Act on Artificial Intelligence' (2022) 30(1) International Journal of Law and Information Technology 88.

[66] Claudio Novelli and others, 'A Robust Governance for the AI Act: AI Office, AI Board, Scientific Panel, and National Authorities' (2025) 16 European Journal of Risk Regulation 566.

regulatory policies and practices at other levels in multi-level regulatory governance models.[67] The model of AMLA could be followed in this context, in which national authorities supervise certain activities and entities, while the supranational agency focuses on supervising high-risk entities; it also supports national authorities and promotes supervisory convergence. Therefore, direct EU supervision is applied only when there is evidence that national action alone is insufficient. This is consistent with the principle of subsidiarity, which recognises that national supervisory authorities will not be removed but will become part of an integrated supervisory system, even if direct supervision for some entities is transferred to the EU.[68] This is also consistent with the principle of proportionality, which entails giving adequate but not excessive authority and resources to EU bodies.[69] Finally, a strengthened EU agency on AI would also support mutually beneficial public–private partnerships[70] as well as an open and continuous dialogue with the AI industry, civil society organisations, and academia, following the model of the Financial Action Task Force and its dialogue with the private sector and other stakeholders in the field of anti-money laundering.[71]

Most importantly, a strengthened EU agency on AI, in contrast to the EU AI Office, would need to have functional and budgetary independence which is a key issue for new agencies. The EU would have to ensure that adequate funding, staff, and expertise are channelled to the new body to support its operations. Funding sources may include a combination of fees paid by industry stakeholders, contributions from Member States, and funding from the EU budget. Furthermore, the new agency would have functional autonomy – which means it would enjoy decision-making discretion and be able to resolve policy or managerial issues without

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[67] Delia Rodrigo, Lorenzo Allio, and Pedro Andres-Amo, 'Multi-Level Regulatory Governance: Policies, Institutions and Tools for Regulatory Quality and Policy Coherence', OECD Report, 2009.

[68] Christoph Henkel, 'The Allocation of Powers in the European Union: a Closer Look at the Principle of Subsidiary' (2002) 20 Berkeley Journal of International Law 359; Gabriel Moens, John Trone, 'The Principle of Subsidiarity in EU Judicial and Legislative Practice: Panacea or Placebo' (2015) 41 Notre Dame Law School Journal of Legislation 65; Oxana Pimenova, 'Subsidiarity as a regulation principle in the EU' (2016) 4(3) The Theory and Practice of Legislation 381.

[69] Merijn Chamon, *EU Agencies: Legal and Political Limits to the Transformation of the EU Administration* (OUP 2016); Darren Harvey, 'Federal Proportionality Review in EU Law: Whose Rights are they Anyway?' (2020) 89(3-4) Nordic Journal of International Law 303; see also Wolf Sauter, 'Proportionality in EU Law: A Balancing Act?' (2013) 15 Cambridge Yearbook of European Legal Studies 439.

[70] Nutavoot Pongsiri, 'Regulation and Public private Partnerships' (2002) 15(6) International Journal of Public Sector Management 487.

[71] Mark Seidenfeld, 'Empowering Stakeholders: Limits on Collaboration as the Basis for Flexible Regulation' (1999) 41 William and Mary Law Review 411.

external interference – although interplay and consultations between actors at various levels, including the European Commission, would still be conceivable.[72] In the context of regulations establishing new European supervisors, the independence principle is consistently adopted to ensure that independence problems at the national level are not transferred to the EU level or vice versa.[73] Similar means of oversight, based on independence and expertise, align perfectly with complex and rapidly advancing domains such as AI.[74]

Nevertheless, there are concerns and objections to be addressed. A recurring theme in the process of European integration has been the fear of the potential loss of sovereignty.[75] The field of AI will be no exception. Indeed, Member States may consider that relinquishing considerable control over AI regulation and oversight to a supranational EU agency will limit their ability to address AI-related issues in accordance with national priorities and preferences. As with many EU initiatives, the optimal solution is a body designed for collaborative governance with Member States, integrating national perspectives into AI policy while respecting subsidiarity and proportionality. Critically, any such agency must align with the Court of Justice's jurisprudence on delegated powers. While the aforementioned Meroni and ESMA short-selling doctrines prohibit delegating wide discretionary powers without adequate safeguards, they permit delegation when powers are clearly circumscribed, subject to judicial review, and necessary to achieve Treaty objectives. A carefully designed AI Agency, with structured accountability and oversight, would operate firmly within these established legal boundaries.

Furthermore, concerns regarding bureaucratic inefficiency and red tape constitute a popular perception and recurrent point of criticism against the EU.[76] For this reason, the design of a new and strengthened

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[72] Per Lžgreid, Koen Verhoest, and Werner Jann, 'The Governance, Autonomy and Coordination of Public Sector Organizations' (2008) 8 Public Organization Review 93.

[73] Annetje Ottow, 'Independent Supervisory Authorities: A Fragile Concept' (2012) 39(4) Legal Issues of Economic Integration 419.

[74] Michelle Everson, 'Independent Agencies: Hierarchy Beaters?' (1995) 1(2) European Law Journal 180.

[75] Raffaele Bifulco and Alessandro Nato, 'The Concept of Sovereignty in the EU: Past, Present and the Future' (RECONNECT – Reconciling Europe with its Citizens through Democracy and Rule of Law, Working Paper, 2020; Ole Waever, 'Identity, Integration and Security: Solving the Sovereignty Puzzle in EU Studies' (1995) 48(2) Journal of International Affairs 389; Neil MacCormick, 'The Maastricht-Urteil: Sovereignty Now' (1995) 1(3) European Law Journal 259; Martin Loughlin, 'Why Sovereignty?' in Richard Rawlings, Peter Leyland, and Alison Young (eds), *Sovereignty and the Law: Domestic, European and International Perspectives* (OUP 2013) 34–49.

[76] Wim Voermans and others, 'Codification and Consolidation in the European Union: A Means to Untie Red Tape' (2008) 29 Statute Law Review 65.

EU agency on AI should prioritise the principles of agility and responsiveness, eg ensure a meaningful and timely role in the development of draft technical standards. This institutional design choice corresponds to the mission of such an EU agency, that is, to solve the cooperation problems that international actors face in the specific area of AI governance.[77]

The institutional foundation of such an agency could rest on Articles 114 and 352 TFEU, with the latter serving as a flexibility clause and fallback legal basis. This approach has a clear precedent: Article 114 was the basis for the European Banking Authority, while Article 352 (formerly Article 308 EC) was used for the European Union Agency for Fundamental Rights. Establishment would require a new Regulation, adopted under the ordinary legislative procedure, to amend the AI Act, thereby guaranteeing the full democratic involvement of both the European Parliament and the Council. The successful precedent of the AMLA proves that even with Treaty constraints on the delegation of powers, a supranational agency can be granted robust authority if it is constructed with sufficient accountability mechanisms and review procedures.

5 Concluding remarks

As AI technologies advance, numerous jurisdictions are likely to establish their own AI agencies, which will inevitably add to the complexity of global AI governance.[78] The EU must engage with international partners and help create global AI standards and shared ethical frameworks and principles, hopefully with the positive contribution of the United Nations and the G20.[79] This will ensure the interoperability of AI systems and foster innovation and international trade in AI products and services. Nevertheless, as mentioned earlier, there is no universally agreed-upon set of standards for AI, which leaves the door open for further regulatory divergence.

The EU, assisted by the EU AI Office, or a future strengthened EU agency on AI, should promote international collaboration in the form of bilateral or multilateral agreements that deal with information exchanges, mutual administrative and judicial assistance in cross-border cases,

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[77] This corresponds to the model proposed by Barbara Koremenos, Charles Lipson and Duncan Snidal, 'The Rational Design of International Institutions' (2001) 55(4) International Organization 761.

[78] Karen Alter, Kal Raustiala, 'The Rise of International Regime Complexity' (2018) 14(1) Annual Review of Law and Social Science 329.

[79] Eugenio Garcia, 'Multilateralism and Artificial Intelligence: What Role for the United Nations?' in Maurizio Tinnirello (ed), *The Global Politics of Artificial Intelligence* (Routledge 2020) 1-20; Thorsten Jelinek, Wendell Wallach & Danil Kerimi, 'Policy Brief: The Creation of a G20 Coordinating Committee for the Governance of Artificial Intelligence' (2021) 1 AI and Ethics 141.

data sharing, common responses to AI-related threats, etc.[80] A strengthened EU agency on AI should be seen as a part of the future international AI ecosystem, which would gradually be enriched with specialised regulatory and supervisory bodies in many countries. In this environment, this agency would be the voice of the EU in the global collaborative effort to develop AI standards and ethical frameworks and collectively address AI and cybersecurity threats.[81]

Nevertheless, it is incumbent upon the EU to exercise circumspection in this context. While a collaborative vision of global AI governance is an ethically sound and justified approach, sober assessment dictates that one must expect significant global antagonism and a strenuous race to leverage AI, as numerous countries are poised to endorse strategic policies and commit significant financial investment to catalyse innovation in this field. In this context, the EU must be vigilant against serious risks, such as instances of intellectual property theft and science espionage, cross-border data migration towards jurisdictions with less stringent data protection regulations, global startup ecosystem competition with other countries, and competition relating to incentives and public expenditure on research and development.[82] Therefore, the EU must develop effective mechanisms to elevate its 'technological sovereignty'.[83] In practice, this means that the EU must avoid relying on a limited number of third-country suppliers to obtain technologies, such as AI, which are essential for startups and the EU economy in general.[84] If designed correctly, a strengthened EU agency on AI could deliver on this promise by accelerating a unified approach to AI regulation and promoting innovation through knowledge dissemination and resource pooling. For this reason, establishing such an agency should be a matter of priority.

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[80] Eleonore Pauwels, 'The New Geopolitics of Converging Risks: The UN and Prevention in the Era of AI' (United Nations University, Centre for Policy Research, Technical Report, 2019) <https://i.unu.edu/media/cpr.unu.edu/attachment/3472/PauwelsAIGeopolitics.pdf> accessed 14 September 2025.

[81] Alan Bundy, 'Preparing for the Future of Artificial Intelligence' (2017) 32 AI & Society 285.

[82] Wolfgang Dierker, 'Technologische Souveränität: Begriff und Voraussetzungen im transatlantischen Kontext' (2023) 103(6) Wirtschaftsdienst 386; see also European Parliament, 'Key Enabling Technologies for Europe's Technological Sovereignty' (European Parliamentary Research Service Study, 2021).

[83] Although there are various interpretations, the term generally refers to a form of collective control of digital content and/or infrastructures; Stephane Couture, Sophie Toupin, 'What Does the Notion of "Sovereignty" Mean when Referring to the Digital?' (2019) 21(10) New Media & Society 2305; Francesco Crespi and others, 'European Technological Sovereignty: An Emerging Framework for Policy Strategy' (2021) 56(6) Intereconomics 348.

[84] European Innovation Council, 'Statement on Technological Sovereignty' (Annex to the Statement of the EIC pilot Advisory Board at the launch of the EIC, 2021) <https://eic.ec.europa.eu/system/files/2021-03/EIC%20Advisory%20Board%20statement%20at%20launch%20of%20EIC_1.pdf> accessed 14 September 2025.

Despite rapid advancements in new technologies, the development of legal frameworks often lags behind, mainly due to the complexity of the legislative process and the need for consensus among multiple actors.[85] We argue that there is a need to expedite EU efforts to establish supranational oversight. A strengthened EU AI agency could provide significant benefits by averting the emergence of a fragmented and decentralised landscape characterised by varying approaches and enforcement attitudes among EU Member States and, more broadly, different geographical and cultural clusters.[86] With the EU AI Act, there has been a shift from soft-law principles to hard-law regulations, which is timely and appropriate in the context of AI. The next logical step is the establishment of a robust supranational authority on AI with powers and responsibilities in threat assessment, standard-setting, supervision, and enforcement. Of course, concerns about loss of sovereignty and bureaucratic inefficiency should be addressed. This could be achieved through collaboration with Member States, agile agency design, transparency, and public accountability mechanisms.[87] Finally, a new and strengthened agency should have access to the necessary resources (funding, staff, technology) and, most importantly, enjoy a high degree of independence to accomplish its mission and promote close coordination with public and private stakeholders and public bodies, both at the EU and national levels, to avoid duplication or inconsistency of efforts.

Suggested citation: G Pavlidis, 'From the AI Act to a European AI Agency: Completing the Union's Regulatory Architecture' (2025) 21 CYELP 125.

[85] Gary Marchant, Branden Allenby, and Joseph Herkert (eds), *The Growing Gap Between Emerging Technologies and Legal-ethical Oversight: The Pacing Problem* (Springer 2011).

[86] Lewin Schmitt, 'Mapping Global AI Governance: A Nascent Regime in a Fragmented Landscape' (2022) 2 AI Ethics 303; Niels van Berkel and others, 'A Systematic Assessment of National Artificial Intelligence Policies: Perspectives from the Nordics and Beyond' in NordiCHI '20 Proceedings of the 11th Nordic Conference on Human-Computer Interaction: Shaping Experiences, Shaping Society' 2020.

[87] Marijn Janssen and others, 'Transparency-by-design as a Foundation for Open Government' (2017) 11(1) Transforming Government: People, Process and Policy 2; Madalina Busuioc, 'European Agencies and their Boards: Promises and Pitfalls of Accountability Beyond Design' (2012) 19(5) Journal of European Public Policy 719.

JUDICIAL INDEPENDENCE UNDER ARTICLE 19(1) TEU AND ARTICLE 267 TFEU: UNTANGLING THE GORDIAN KNOT

Ana Altabas [*]

Abstract: This paper explores the conflicting relationship between Article 19(1) TEU and Article 267 TFEU in the Court of Justice's case law, particularly in the context of the ongoing rule-of-law crisis in Poland and Hungary. On one hand, Article 267 TFEU presumes that national courts are sufficiently independent to submit references; on the other, some courts simultaneously fail to satisfy stricter standards of independence required under Article 19(1) TEU. Since references are often submitted by courts whose independence has been under attack, the question arises about whether such requests should be held admissible. The paper analyses the Court's answer to this dilemma in three Grand Chamber judgments – Banco de Santander, Getin Noble Bank, *and* LG, *and advances two key hypotheses. First, the three-case saga demonstrates that the Court has moved away from the original scope and purpose of Article 19(1) TEU and Article 267 TFEU as a result of a political decision to limit engagement with 'tainted' Polish courts. Second, irrespective of how these legal bases might be applied, the Court's judgments should not result in the exclusion of national courts from the preliminary reference procedure. Such an approach would undermine the key mechanisms of the functioning of EU law – the uniform application and effectiveness of EU law – and would compromise the parties' right to a fair trial, while weakening mechanisms for combating the 'rule-of-law crisis'.*

Keywords: judicial independence, Court of Justice, Article 19(1) TEU, Article 267 TFEU, Banco de Santander, Getin Noble Bank, LG.

1 Introduction

In recent years, Poland has become a persistent battlefield between judges who were unlawfully appointed and their independent colleagues,

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suffering from a condition called 'rule-of-law backsliding'.[1] Lawfully appointed judges have frequently used the preliminary reference mechanism to voice their concerns over the unlawful appointment of their colleagues. At other times, their 'dependent' counterparts would likewise pose questions on judicial independence to legitimise their position or discredit their colleagues.[2] Article 267 TFEU[3] has traditionally allowed all national courts to submit references.[4] However, as preliminary references have sometimes been misused, the Court has faced a tough question – should it allow references from 'tainted' Polish courts? And how would answering that question affect the relationship between Article 267 TFEU and Article 19(1) TEU?[5] Should the thresholds of the two provisions be equated to block references from compromised courts, or should the Court adopt a more nuanced approach that reflects their distinct purposes?

Understanding this dilemma requires a closer look at how the Court has shaped the concepts of independence under both provisions. As Reyns explains, independence has a dual role in EU law – it is both a formal admissibility requirement under Article 267 TFEU and a substantive obligation imposed on Member States under Article 19(1) TEU and Article 47 of the Charter.[6] Article 267 TFEU initially allowed all national courts to participate in the judicial dialogue; its aim was to expand the number of participants in the procedure, rather than exclude national courts from it. For this reason, the criterion of independence was scrutinised leniently.[7] Article 19(1) TEU, on the other hand, requires a more stringent analysis, since it was developed to shield national judiciaries

[1] Kim Lane Scheppele and Laurent Pech, 'What Is Rule of Law Backsliding?' (*VerfBlog*, 2 March 2018) <https://verfassungsblog.de/what-is-rule-of-law-backsliding/> DOI: 10.17176/20180302-181145 accessed 1 September 2025.

[2] Dimitry Kochenov and Petra Bárd, 'Kirchberg Salami Lost in Bosphorus: The Multiplication of Judicial Independence Standards and the Future of the Rule of Law in Europe' (2022) 60 Journal of Common Market Studies 150; see also Anna Wójcik, 'Keeping the Past and the Present Apart' (*Verfassungsblog*, 26 April 2022) <https://verfassungsblog.de/keeping-the-past-and-the-present-apart/> accessed 1 July 2024.

[3] Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C326/47.

[4] Case C-718/21 *LG v Krajowa Rada S downictwa* ECLI:EU:C:2023:150, Opinion of AG Rantos, para 21.

[5] Consolidated Version of the Treaty on European Union [2012] OJ C326/13.

[6] Charlotte Reyns, 'Saving Judicial Independence: A Threat to the Preliminary Ruling Mechanism?' (2021) 17 European Constitutional Law Review 2; Consolidated Version of the Charter of Fundamental Rights of the European Union [2012] OJ C326/391.

[7] Takis Tridimas, 'Knocking on Heaven's Door: Fragmentation, Efficiency and Defiance in the Preliminary Reference Procedure' (2003) 40 Common Law Market Review 9.

from the executive branch's interference.[8] In the 'rule-of-law crisis', the two bodies of case law form a Gordian knot – all national courts are presumed independent enough to submit references under Article 267 TFEU, yet some may simultaneously fail to satisfy the standards of independence under Article 19(1) TEU. Would, then, breaches of Article 19(1) TEU necessarily imply that the threshold of Article 267 TFEU is not met, or do the two provisions operate independently of each other?

This conflict between the two strands of case law was addressed in three Grand Chamber judgments: *Banco de Santander*,[9] *Getin Noble Bank*,[10] and *LG*.[11] In *Banco de Santander*, the Court essentially unified all legal bases for judicial independence,[12] holding that a body not independent under Article 19(1) TEU is also not considered independent under Article 267 TFEU. This tied the Gordian knot, as it suggested that references from non-independent courts would be blocked. However, in *Getin Noble Bank* and *LG* the Court adopted a middle-way approach: it presumed that national courts satisfy the *Dorsch* criteria,[13] unless a final international or national decision leads to the conclusion that Article 19(1) TEU read in the light of Article 47 of the Charter is violated.[14] This was precisely the result of *LG,* where the Court declined participation in the dialogue of one of the most influential chambers of Polish courts – the Chamber of Extraordinary Control and Public Affairs of the Polish Supreme Court.[15]

This paper critically examines the results of these judgments by laying down two key hypotheses. First, it argues that the three-case saga has reshaped the purpose and scope of Article 19(1) TEU and Article 267 TFEU, reflecting the Court's reluctance to engage in dialogue with 'tainted' national courts.

Second, regardless of the choice of legal bases, the paper contends that the Court should not exclude national courts from the preliminary reference procedure. First, declining their participation could result in

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[8] See also Matteo Bonelli and Monica Claes, 'Judicial Serendipity: How Portuguese Judges Came to the Rescue of the Polish Judiciary' (2018) 14 European Constitutional Law Review 622, 639.

[9] Case C-274/14 *Banco de Santander SA* ECLI:EU:C:2020:17.

[10] Case C-132/20 *BN and Others v Getin Noble Bank SA* ECLI:EU:C:2022:235.

[11] Case C-718/21 *LG* ECLI:EU:C:2023:1015.

[12] See also Alejandro Sánchez Frías, 'A New Presumption for the Autonomous Concept of "Court or Tribunal" in Article 267 TFEU' (2023) 19 European Constitutional Law Review 320, 334–335.

[13] Case C-54/96 *Dorsch Consult* ECLI:EU:C:1997:413.

[14] *Getin Noble Bank* (n 10) para 72; *LG* (n 11) para 44.

[15] *LG* (n 11) para 78.

courts that apply EU law but cannot seek interpretation from the Court, turning them into blind spots on the radar of the Court of Justice. This would compromise the ultimate aim of the preliminary reference procedure – ensuring the uniformity and effectiveness of EU law.[16] Second, as a result, EU law could be applied incorrectly and could compromise parties' right to a fair trial.[17] Third, lawfully appointed judges sitting in panels with their unlawfully appointed colleagues should be able to challenge their independence, as it opens up a valuable avenue for combating the 'rule-of-law crisis'.

Beyond the risks this entails for the functioning of EU law, the paper argues that excluding national courts from the preliminary reference mechanism is also not an effective solution to the 'rule-of-law crisis'. Other measures of the EU's 'rule-of-law toolbox' seem to offer more_efficient solutions, while not compromising the uniformity and effectiveness of EU law.

The paper is divided into two further sections. The first examines settled case law under Article 267 TFEU and Article 19(1) TEU, underscoring the differences between the two provisions not expressly acknowledged by the Court. The second analyses the three cases: *Banco de Santander*, *Getin Noble Bank* (accompanied by the Opinion of Advocate General Bobek),[18] and *LG*. The final part of that section examines a series of cases that followed *LG*, which have so far received limited attention in academic circles.

2 Conflicting case law under Article 19(1) TEU and Article 267 TFEU

2.1 Article 267 TFEU: case law and purpose

Before the Court undertook the task of assessing whether national judicial systems preserve the separation of powers, it developed the notion of independence under Article 267 TFEU in a different context. Early cases examined whether the preliminary reference procedure may be expanded to encompass a wider range of administrative bodies. In this way, the Court acted as a rational decision-maker, aiming to increase the protection of uniformity by allowing a wider range of bodies at a lower level to seek interpretation of EU law.[19] As a result, the requirement of

[16] Reyns (n 6) 12.

[17] ibid.

[18] Case C-132/20 *Getin Noble Bank SA* ECLI:EU:C:2021:557, Opinion of AG Bobek.

[19] Tridimas (n 7) 30.

independence under Article 267 TFEU was scrutinised leniently.[20] Since the Court was more concerned with expanding the number of participants, it was less preoccupied with scrutinising substantive standards of independence. Rather, a functional approach was developed – namely, the body concerned must perform a judicial function, as opposed to an administrative function, and precisely one of the distinctions between judicial and administrative functions is independence.[21] As Advocate General Darmon stated in *Corbiau*, the idea of independence 'is an integral element of the judicial function'.[22]

The relaxed approach to judicial independence is evident from the first cases, such as *Pretore di Salò*. In that case, the Court concluded that Italian *pretori* are considered independent under Article 267 TFEU even though they are judges who combine the functions of a public prosecutor and an examining magistrate.[23] It merely stated that the Court can reply to requests for a preliminary ruling if they emanate 'from a court or tribunal which has acted in the general framework of its task of judging, independently and in accordance with the law, cases coming within the jurisdiction conferred on it by law'.[24] In *Corbiau*, independence was vaguely outlined as 'acting as a third party in relation to the authority which adopted the decision forming the subject-matter of the proceedings'.[25] Later cases – *Dorsch Consult*,[26] *Köllensperger and Atzwanger*,[27] and *Gabalfrisa*[28] relaxed the criterion of independence even further.[29] It was analysed so leniently that Advocate General Ruiz-Jarabo Colomer remarked that even questions referred by Sancho Panza as governor of the island of Barataria would be accepted.[30]

Yet, in *Wilson* the Court fortified the requirement of independence under Article 267 TFEU, aligning it with the practice of the ECtHR.[31] It moved beyond a purely functional approach and filled in the substance

[20] ibid.

[21] ibid, 28; Reyns (n 6) 3.

[22] Case C-24/92 *Corbiau* ECLI:EU:C:1993:59, Opinion of AG Darmon, para 10.

[23] Case 14/86 *Pretore di Salò* ECLI:EU:C:1987:275, para 7.

[24] ibid.

[25] Case C-24/92 *Corbiau* ECLI:EU:C:1993:59, para 15.

[26] *Dorsch* (n 13).

[27] Case C-103/97 *Köllensperger and Atzwanger* ECLI:EU:C:1999:52.

[28] Joined Cases C-110/98 to C-147/98 *Gabalfrisa* ECLI:EU:C:2000:145.

[29] Reyns (n 6) 3.

[30] Case C-17/00 *De Coster* ECLI:EU:C:2001:366, Opinion of AG Ruiz-Jarabo Colomer, para 14.

[31] Case C-506/04 *Wilson* ECLI:EU:C:2006:587; see references in *Wilson*, paras 51 and 53; Reyns (n 6) 4.

of the criterion by adding two dimensions of independence – external and internal. External independence requires protection from outside pressure that could undermine judicial decision-making, while internal independence, closely tied to impartiality, ensures a level playing field for the parties to the proceedings.[32] A threshold for determining breaches of independence was established, as rules must be such as to 'dismiss any reasonable doubt in the minds of individuals as to the imperviousness of that body to external factors and its neutrality with respect to the interests before it'.[33]

Although the requirement of independence was tightened, it should be remarked that *Wilson* was not concerned with assessing the admissibility of references under Article 267 TFEU. Instead, the Court relied on the concept of a 'court or tribunal' under Article 267 TFEU to decide whether the *Ordre des avocats du barreau de Luxembourg* satisfied the requirements of Article 9 of Directive 98/5 on the free movement of lawyers, which obliges Member States to provide remedies before a 'court or tribunal' against negative registration decisions.[34] The Court's aim, therefore, was not to restrict access to the preliminary reference procedure, but to guarantee that individuals had access to an independent body under the Directive.[35]

Nonetheless, the Court stuck with the substantive content of independence in deciding on the admissibility of preliminary references of administrative bodies and later used it as a foundation for creating the substantive obligations under Article 19(1) TEU.[36]

However, this comes with an important side note. The strengthened requirement of independence was not originally intended to be used against national courts. As Advocate General Rantos highlighted, the Court has traditionally carried out the 'independence test' in regard to bodies outside national judicial systems, rather than bodies considered 'courts or tribunals' under national law.[37] The interest of the Court was to protect uniformity at a higher level and not to lower it by excluding national judicial bodies. Although these judgments predate the Court's more direct engagement with the 'rule-of-law crisis', their significance lies in reflecting the original intention of Article 267 TFEU: to secure the uniformity and effectiveness of EU law.

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[32] *Wilson* (n 31) paras 51–52; Reyns (n 6) 4.

[33] *Wilson* (n 31) para 53.

[34] ibid 43; Bonelli and Claes (n 8) 638–639.

[35] Bonelli and Claes (n 8) 638-639; Reyns (n 6) 4.

[36] Reyns (n 6) 4.

[37] *LG*, Opinion of AG Rantos (n 4) para 21.

2.2 Article 19(1) TEU: case law and purpose

Building upon the case law under Article 267 TFEU, the Court established a substantive obligation under Article 19(1) TEU for Member States to 'provide remedies sufficient to ensure effective legal protection in the fields covered by Union law'.[38] The case law under Article 19(1) TEU is quite recent, starting with *Portuguese Judges*[39] in 2018, and *Commission v Poland (Independence of the Supreme Court)*[40] in 2019.

In *Portuguese Judges*, the Court for the first time assumed jurisdiction in deciding on matters of the judicial architecture of Member States.[41] The referring court submitted the question whether the temporary reduction of judges' salaries was in accordance with Article 19(1) TEU and Article 47 of the Charter. Although the Court ultimately ruled that the measure did not violate judicial independence, the judgment paved the way for safeguarding the independence of the Polish and Hungarian judiciary.[42] The Court decided not to rely on Article 47 of the Charter, which could also have been invoked, since Article 47 of the Charter can only be applied in cases where Member States are implementing EU law in the meaning of Article 51(1) of the Charter.[43] Instead, it applied Article 19(1) TEU, establishing that the material scope of Article 19(1) TEU applies to all 'the fields covered by Union law, irrespective of whether the Member States are implementing Union law within the meaning of Article 51(1) of the Charter'.[44] Therefore, by relying on Article 19(1) TEU and not Article 47 of the Charter, the Court has significantly extended its jurisdiction to scrutinise various elements of national judicial systems. Since the judgment in *Portuguese Judges*, Article 19(1) TEU can be invoked in all cases concerning any national courts which might apply EU law, virtually encompassing all cases before the courts of the Member States.[45]

Furthermore, in the explanation of the judgment, it was emphasised that the principle of effective judicial protection of individuals' rights enshrined in Article 19(1) TEU is a general principle of EU law, stemming

[38] Reyns (n 6) 4; second paragraph of Article 19(1) TEU (n 5).

[39] Case C-64/16 *Associação Sindical dos Juízes Portugueses v Tribunal de Contas* ECLI:EU:C:2018:117 *(ASJP)*.

[40] Case C-619/18 *Commission v Poland* ECLI:EU:C:2019:531.

[41] Bonelli and Claes (n 8) 622–623.

[42] ibid.

[43] Laurent Pech and Sébastien Platon, 'Rule of Law Backsliding in the EU: The Court of Justice to the Rescue? Some Thoughts on the ECJ Ruling in Associação Sindical Dos Juízes Portugueses' (*EU Law Analysis,* 13 March 2018) <https://eulawanalysis.blogspot.com/2018/03/rule-of-law-backsliding-in-eu-court-of.html> accessed 20 June 2024.

[44] *ASJP* (n 39) para 29.

[45] Pech and Platon (n 43).

from the common traditions of the Member States and Articles 6 and 13 ECHR[46] and Article 47 of the Charter, which enshrine the right to effective judicial protection.[47]

The Court established that Article 19 TEU is a concrete manifestation of the principle of the rule of law enshrined in Article 2 TEU and stated that: 'The very existence of effective judicial review designed to ensure compliance with EU law is of the essence of the rule of law'.[48] It obliged Member States to ensure that the 'courts or tribunals' meet the requirements of effective judicial protection under Article 19(1) TEU, which entails an independent judiciary.[49] The requirements under Article 19(1) TEU were linked to access to an independent tribunal enshrined in Article 47 of the Charter.[50] It famously stated that the independence presupposes:

> that the body concerned exercises its judicial functions wholly autonomously, without being subject to any hierarchical constraint or subordinated to any other body and without taking orders or instructions from any source whatsoever, and that it is thus protected against external interventions or pressure liable to impair the independent judgment of its members and to influence their decisions.[51]

The reason for the Court's intervention in Member States' judicial matters was to ensure effective judicial protection. Without an independent judiciary, the effectiveness of EU law would be at stake.[52] As the Court stated in paragraph 43 of the judgment: 'The independence of national courts and tribunals is, in particular, essential to the proper working of the judicial cooperation system embodied by the preliminary ruling mechanism under Article 267 TFEU'.[53]

A year later, the Court finally dealt with the Polish rule-of-law crisis in *Commission v Poland*[54] following the path created in *Portuguese Judges*. This was the first case in which it declared breaches of Article 19(1)

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[46] Convention for the Protection of Human Rights and Fundamental Freedoms [1950].

[47] *ASJP* (n 39) para 35.

[48] ibid, paras 32, 36.

[49] ibid, paras 37, 40–42.

[50] ibid, para 41.

[51] *ASJP* (n 39) para 44.

[52] Miguel Poiares Maduro, 'General Report on the Rule of Law in the European Union: Development and Challenges on the European Union Role in Protecting the Rule of Law' (2023) 1 Mutual Trust, Mutual Recognition, and the Rule of Law; The XXX FIDE Congress in Sofia, 2023: Congress Publications 23.

[53] *ASJP* (n 39) para 43.

[54] *Commission v Poland* (n 40).

TEU, thus solidifying its jurisdiction in dealing with rule-of-law issues.[55] The Court found that Poland had failed to fulfil its obligations under the second paragraph of Article 19(1) TEU due to the new Law on the Supreme Court that lowered the retirement age of judges of the Supreme Court holding office at that moment from 70 to 65 years. It also endowed the Polish President with discretionary power to decide on the extension of judges' terms past retirement.[56] The ruling further confirmed that under Article 19(1) TEU, every Member State must ensure that bodies acting as 'courts or tribunals' within the meaning of EU law provide effective judicial protection in fields covered by EU law.[57]

It follows from the aforementioned that independence under Article 19(1) TEU was developed in a context different from that under Article 267 TFEU. Rather than serving to regulate participation in the preliminary reference procedure, it emerged in response to sustained attacks on the Polish and Hungarian judiciary. The following sub-section analyses how these distinct contexts have resulted in specific differences between the two provisions.

2.3 Article 267 TFEU and Article 19 TEU: cutting through the Gordian knot

The Court has not explicitly set the boundaries between Article 267 TFEU and Article 19(1) TEU in rule-of-law cases. However, Advocates General have repeatedly proposed a clearer differentiation between these legal bases.

Advocate General Bobek stated that legal provisions governing judicial independence differ in terms of their function and objective. As a result, the thresholds for their breaches and the intensity of the Court's review of compliance with these provisions vary accordingly.[58]

Under Article 267 TFEU, the concept of a 'court or tribunal' has a functional nature: to identify which national bodies are entitled to engage in the preliminary reference procedure.[59] Consequently, the Court's review of independence is more relaxed.[60] Article 19(1) TEU, on the oth-

[55] Piotr Bogdanowicz and Maciej Taborowski, 'How to Save a Supreme Court in a Rule of Law Crisis: The Polish Experience: ECJ (Grand Chamber) 24 June 2019, Case C-619/18 *European Commission v Republic of Poland*' (2020) 16 European Constitutional Law Review 306.

[56] *Commission v Poland* (n 40).

[57] ibid, para 55.

[58] *Getin Noble Bank*, Opinion of AG Bobek (n 18) para 36

[59] ibid, para 50; Joined Cases C-748/19 to C-754/19 *Prokuratura Rejonowa w Mińsku Mazowieckim* ECLI:EU:C:2021:403, Opinion of AG Bobek (n 50), para 166.

[60] *Prokuratura Rejonowa*, Opinion of AG Bobek (n 59) para 166.

er hand, imposes much stricter requirements of judicial independence, requiring an in-depth analysis of the national judicial system.[61] Unlike Article 267 TFEU, it imposes on Member States a general obligation to 'provide remedies sufficient to ensure effective legal protection'.[62] It covers only systemic breaches of a certain gravity unlikely to be self-corrected by domestic remedies. In brief, it is an extraordinary remedy for extraordinary cases, going beyond the individual file.[63]

As Advocate General Bobek clarified, the functional approach under Article 267 TFEU does not imply that the referring court is lawfully composed or that its judges have been lawfully appointed. Concerns about judicial appointments in Poland may indeed raise serious rule-of-law issues, but those are to be assessed under Article 19(1) TEU and Article 47 of the Charter, not Article 267 TFEU.[64]

Other Advocates General have reached similar conclusions. AG Rantos supported AG Bobek's differentiation of legal bases, while adding that the 'minimalist' reading of independence under Article 267 TFEU does not collide with the principle of cooperation between the national courts and the Court. It also safeguards the role of preliminary references in protecting individuals' rights through which individuals may 'avail themselves of the effective judicial protection guaranteed by EU law'.[65]

Moreover, AG Tanchev emphasised that the examination of the independence of a 'court or tribunal' under Article 267 TFEU is a 'qualitatively different exercise' from the evaluation of the requirements of judicial independence under Article 47 of the Charter and Article 19(1) TEU.[66] In the context of the preliminary ruling mechanism under Article 267 TFEU, the Court addresses questions related to the procedure before it, specifically concerning which bodies are entitled to submit references. This mechanism aims to establish dialogue between the Court and national courts to ensure the uniform interpretation of EU law. Under Article 47 of the Charter and Article 19(1) TEU, the Court conducts a substantive analysis of judicial independence. However, AG Tanchev noted that Article 52(3) of the Charter mandates that EU law must guarantee judicial independence to at least the standard set by Article 6(1) ECHR.

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[61] ibid, para 164.

[62] Second paragraph of Article 19(1) TEU; *Getin Noble Bank*, Opinion of AG Bobek (n 18) para 37.

[63] *Getin Noble Bank*, Opinion of AG Bobek (n 18) para 39; *Prokuratura Rejonowa*, Opinion of AG Bobek (n 59) para 164.

[64] *Getin Noble Bank*, Opinion of AG Bobek (n 18) paras 75–76.

[65] *LG*, Opinion of AG Rantos (n 4) para 22.

[66] Joined Cases C-585/18, C-624/18 and C-625/18 *AK v Krajowa Rada Sądownictwa and CP DO v Sąd Najwyższy* ECLI:EU:C:2019:551, Opinion of AG Tanchev, para 111.

Therefore, if the Court's case law under Article 267 TFEU falls short of this minimum threshold, it must be brought up to this standard.[67]

Scholars have also observed other differences between the two provisions. In particular, Article 267 TFEU is applied to decide whether a specific body is allowed to make a reference for the first time, whereas Article 19(1) TEU usually imposes obligations on bodies already regarded as part of the European judicial system.[68]

Although the differentiation suggested by the Advocates General falls in line with the provisions' original purpose, the Court has not always followed their logic. The next section examines how the Court has intertwined Article 19(1) TEU and Article 267 TFEU in a more complex system for assessing the admissibility of references and the negative consequences that arise therefrom.

3 The three-case saga

3.1 Banco de Santander

In *Banco de Santander*, the main dispute did not concern rule-of-law issues, but related to matters of tax law. Although the Court had already decided on a similar issue in *Gabalfrisa*,[69] it decided to realign its case law under Article 267 TFEU with the more recent developments under Article 19(1) TEU.[70]

The question arose whether the Central Tax Tribunal, which referred the questions, is a 'court or tribunal' under Article 267 TFEU.[71] The Court found that it undoubtedly satisfies the criteria that it is established by law, that it is permanent, that its jurisdiction is compulsory, that its procedure is *inter partes*, and that it applies rules of law. However, the problem occurred in relation to the criterion of independence.[72]

Here, the Court decided to depart from its ruling in *Gabalfrisa* in 2000, where it decided that Spanish Tax Tribunals fulfil the requirement of independence under Article 267 TFEU, and consequently are considered 'courts or tribunals' under Article 267 TFEU. Independence was analysed leniently, concluding that Spanish legislation ensured the separation of functions in Tax Tribunals between, on one hand, departments responsible for management, clearance and recovery of tax and,

[67] ibid, paras 112–114.

[68] Reyns (n 6) 6; see also: Bonelli and Claes (n 8) 639.

[69] *Gabalfrisa* (n 28).

[70] *Banco de Santander* (n 9) para 55.

[71] ibid, para 50.

[72] ibid, para 52–53.

on the other, Tax Tribunals which rule on complaints lodged against the decisions of those departments.[73] Advocate General Saggio in *Gabalfrisa* and Advocate General Ruiz-Jarabo Colomer in *De Coster* criticised this relaxed approach, pointing out that Tax Tribunals do not satisfy the requisite requirements of impartiality and irremovability because its members may be dismissed at the discretion of the Minister.[74]

In *Banco de Santander*, the Court decided to take a more stringent stance in the light of the newly developed case law starting from the *Portuguese Judges*.[75] It recalled paragraph 43 of *Portuguese Judges* which linked independence under Article 19(1) TEU with the preliminary reference procedure in Article 267 TFEU:

> the independence of national courts and tribunals is essential to the proper working of the judicial cooperation system embodied by the preliminary ruling mechanism established by Article 267 TFEU, in that, in accordance with the settled case-law of the Court referred to in paragraph 51 of the present judgment, that mechanism may be activated only by a body responsible for applying EU law which satisfies, inter alia, that criterion of independence.[76]

With this perspective, the Court continued to examine the independence of the Central Tax Tribunal, concluding that the body does not fulfil the external and internal aspect of independence, and is thus not considered a 'court or tribunal' under Article 267 TFEU.[77]

Therefore, the Court unified its approach to Article 19(1) TEU and Article 267 TFEU,[78] regardless of the original purpose of Article 267 TFEU. In this way it established a more rigorous standard of independence, not only for complying with the substantive obligations of EU law, but also for passing the admissibility stage. This drift away from the original purpose of Article 267 TFEU comes with certain consequences, especially relevant for the Polish 'rule-of-law crisis'. Although the case concerned Spanish administrative bodies, by referring to *Portuguese Judges*, it appears that the departure from *Gabalfrisa* aimed at creating a path towards the exclusion of some Polish courts from the dialogue. As seen in *Portuguese Judges,* the problems of separation of powers in Poland are at times indirectly addressed in cases concerning other Member States.

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[73] ibid, para 54.

[74] Joined Cases C-110/98 and C-147/98 *Gabalfrisa* ECLI:EU:C:1999:489, Opinion of AG Saggio, para 16; *De Coster*, Opinion of AG Ruiz-Jarabo Colomer (n 30) para 28.

[75] *Banco de Santander* (n 9) para 55.

[76] ibid, para 56; *ASJP* (n 39) para 43.

[77] *Banco de Santander* (n 9) paras 68, 77, 80.

[78] See also: Sánchez Frías (n 12) 334–335.

Together with *Miasto Lowicz*, delivered the same year, and *IS*, delivered a year later, this judgment demonstrates the Court's restrained approach during that period to references concerning the 'rule-of-law crisis'.[79]

The culmination of this reserved approach in *Banco de Santander* opened the door to adverse effects on the overall functioning of EU law.

First, the principal aims of the preliminary reference procedure – the effectiveness and uniformity of EU law – could come into question if judges of non-independent courts are barred from seeking interpretation or from challenging the validity of EU law.[80] The jurisprudence of the Court is not created by the Court alone, but by constant cooperation with national courts responsible for enforcing EU law. The preliminary reference is a dialogue between two significant interlocutors – one traditionally tasked with the interpretation of EU law, and the other with its application. The importance of the second interlocutor – national courts – should not be forgotten. Indeed, their submission of preliminary references is a *conditio sine qua non* for addressing tough interpretative issues that arise only in the process of applying the law. Without the submission of preliminary references by national courts, the complex EU law questions they routinely deal with would remain unanswered, resulting in diverging application of the law. Therefore, the submission of references by national courts is a precondition for ensuring the uniformity and effectiveness of EU law.

Even in the 'rule-of-law crisis' the Court should not discredit references coming from judges of 'tainted' courts. The lack of independence in the appointment process does not inherently mean that the judges concerned are reluctant to apply EU law. On the contrary, these judges still continue applying it, but with a greater risk of applying it incorrectly, thus putting at stake the effectiveness of EU law.[81] Moreover, to exclude these judges would also place the Court in a contradictory position: it would undermine the very objective of safeguarding the effectiveness of EU law, which justified its intervention in matters of judicial independence in the first place.

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[79] Joined Cases C-558/18 and C-563/18 *Miasto Łowicz* ECLI:EU:C:2020:234; Case C-564/19 *IS* ECLI:EU:C:2021:949. *Miasto Lowicz* faced heavy criticism for declaring inadmissible requests from judges fearing disciplinary charges, as it discouraged judges who were the most concerned with the 'rule-of-law crisis' from ever reaching the Court of Justice; see also Luke Dimitrios Spieker, 'The Court Gives with One Hand and Takes Away with the Other' (*Verfassungsblog*, 26 March 2020) <https://verfassungsblog.de/the-court-gives-with-one-hand-and-takes-away-with-the-other/> accessed 27 June 2024. In *IS*, the Court similarly refrained from assessing the appointment process of Hungarian judges, declaring the reference inadmissible due to the absence of a connecting factor between the provisions of EU law and the dispute in the main proceedings.

[80] Reyns (n 6) 12.

[81] ibid.

However, even if the Court still found it necessary to exclude some national courts from the dialogue, it would be reasonable to expect a higher level of cooperation of EU institutions and all Member States in a more regulated procedure._By analogy, the suspension of Member States' voting rights in the legislative process is constructed as a complex multi-levelled procedure, involving the European Parliament, the Commission, the Council, and the European Council, requiring the unanimity of Member States.[82]

Second, the incorrect application of EU law would undermine individuals' right to a fair trial enshrined in Article 47 of the Charter,[83] which is a precondition for ensuring other fundamental rights. Paradoxically, as Advocate General Wahl stated in *Torresi*:

> the very reasons which plead in favour of a strict application of Article 6 of the ECHR and Article 47 of the Charter seem rather to urge a less rigid interpretation of the concept of 'court or tribunal' for the purposes of Article 267 TFEU.[84]

Individuals' rights to a fair trial would not be protected if the Court decided to strictly examine the requirements of a 'court or tribunal' under Article 267 TFEU.[85]

Lastly, instead of remedying the Polish 'rule-of-law crisis', the Court further tightened the Gordian knot: if lawfully appointed judges from structurally 'dependent' courts are deemed not independent under Article 267 TFEU, they would paradoxically be barred from challenging the independence of their colleagues. Independent judges, although threatened by disciplinary sanctions, are still willing to point out the systemic issues within their judicial system. They have been allies in the combat

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[82] For further insights on the Article 7 TEU procedure, see Steve Peers, 'EU Law Analysis: Can a Member State Be Expelled or Suspended from the EU? Updated Overview of Article 7 TEU' (*EU Law Analysis*, 4 April 2022) <https://eulawanalysis.blogspot.com/2022/04/can-member-state-be-expelled-or.html> accessed 1 July 2024. According to Article 7 (1) TEU, the Council, with a four-fifths majority and the Parliament's consent, on a reasoned proposal by one third of the Member States, the European Parliament, or the Commission, may determine a clear risk of a serious breach of values enshrined in Article 2 TEU. Article 7(2) TEU, known as the 'red card process', allows the European Council, by unanimity and a proposal from one-third of Member States or the Commission, after obtaining the consent of the European Parliament, to determine a serious and persistent breach of values enshrined in Article 2 TEU after inviting the Member State to submit observations. The procedure is tough, as it requires Member States' unanimity. Subsequently, the Council, by a qualified majority, can suspend certain rights of the Member State, including voting rights in the Council, while considering the impact on individuals and legal entities.

[83] *Getin Noble Bank*, Opinion of AG Bobek (n 18) para 68.

[84] Joined Cases C-58/13 and C-59/13 *Torresi* ECLI:EU:C:2014:265, Opinion of AG Wahl, para 48.

[85] ibid, para 49.

against the corrupted Polish system, providing useful inside information on the executive branch's interference. By initiating proceedings, they enable the Court to declare violations of judicial independence in the preliminary reference procedure and oblige Poland to realign with EU standards. For such judges, this channel is indispensable, as they cannot rely on the Commission's discretionary initiation of infringement proceedings. Some violations have never been addressed by the Commission, or have not been addressed promptly.[86] Even if the Court finds violations in infringement proceedings, the violations are declared *ex post facto*, after persistent systemic breaches have already caused severe harm to the system. Therefore, the only effective way for judges to pose questions in the 'rule-of-law crisis', and receive timely answers, is through the preliminary reference procedure where the Court is obliged to respond.

3.2 Getin Noble Bank

3.2.1 Advocate General Bobek's opinion in Getin Noble Bank

Getin Noble Bank gave the Court a second chance to review its approach in dealing with the references emanating from non-independent judges. This case, unlike *Banco de Santander*, directly concerned rule-of-law issues, as a judge of the Polish Supreme Court questioned the independence of judges of the Appeal Court of Wroclaw due to their appointment during the Communist era.[87] In a plot-twist, his independence was challenged by the Polish Ombudsman due to the major flaws in his appointment.[88] The referring judge was appointed by the President of the Republic in spite of the suspended Resolution of the Krajowa Rada S downictwa (National Council of the Judiciary, hereinafter: KRS) by the Supreme Administrative Court.[89] Due to the intervention of the Polish Minister for Justice/General Prosecutor, with whom the referring judge had strong personal ties, the judge was eventually appointed to his position.[90] Some academics pointed out the duplicitous motives of the referring judge who in effect tried to solve two problems at once – to legitimise his own position (given that he was not recognised as a lawful judge by the ECtHR, and thus not considered lawful by authorities across all the

[86] Laurent Pech, 'Polish Ruling Party's "Fake Judges" before the European Court of Justice: Some Comments on (Decided) Case C-824/18 AB and (Pending) Case C-132/20 *Getin Noble Bank*' (*EU Law Analysis*, 7 March 2021) <https://eulawanalysis.blogspot.com/2021/03/polish-ruling-partys-fake-judges-before.html> accessed 17 June 2024.

[87] *Getin Noble Bank*, Opinion of AG Bobek (n 18) para 4.

[88] ibid, paras 26–27.

[89] ibid, para 44.

[90] ibid.

EU Member States) and to discredit his colleagues.[91] The Court faced the anticipated dilemma – to engage in a dialogue with a 'fake' judge, or to risk creating a blind spot, thus putting at stake the principal aim of the preliminary reference procedure.

Advocate General Bobek opted for the former stance, proposing a more relaxed approach to the formal requirement of independence under Article 267 TFEU. After suggesting a clearer differentiation between the legal bases (see section 2.3), he proposed that the Court follow an institutional approach to the admissibility of references under Article 267 TFEU, rather than examine the independence of each individual judge.[92]

Starting from the *Vaassen-Göbbels* case,[93] the Court has not analysed whether specific persons that have submitted a reference individually satisfy the *Dorsch* criteria. Admissibility has always been and indeed should be assessed in regard to the institution that submitted the reference, rather than the individuals composing it, as long as the institution is not 'hijacked' or made 'captive' by other branches of power.[94] Furthermore, Advocate General Bobek applied the institutional approach to the two requirements of a 'court or tribunal' contested by the Polish Ombudsman: 'established by law' and 'independence'.[95]

First, he stated that the criterion 'established by law' under Article 267 TFEU means that the referring body must be provided for in national law. The purpose of this requirement was to exclude from the preliminary reference bodies which were established by virtue of contracts, precisely certain forms of arbitration panels.[96] He connected this to the *Nordsee* case,[97] in which the Court explicitly denied the German arbitration court access to the preliminary reference procedure.[98] Unlike 'established by law' in the meaning of Article 6(1) ECHR, 'established by law' under Article 267 TFEU does not concern the examination of individual appointments of the referring judges. Article 6(1) ECHR, replicated in the EU legal order in Article 47 of the Charter, and Article 267 TFEU should not be equated, as their purposes differ. While Article 267 TFEU aims to identify bodies in Member States which may submit a reference,

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[91] Kochenov and Bárd (n 2).

[92] *Getin Noble Bank*, Opinion of AG Bobek (n 18) paras 51–72.

[93] Case 61-65 *Vaassen-Göbbels* ECLI:EU:C:1966:39.

[94] *Getin Noble Bank,* Opinion of AG Bobek (n 18) paras 52, 78, note 17.

[95] ibid, paras 44–45, 49–64.

[96] ibid, para 54.

[97] Case 102/81 *Nordsee* ECLI:EU:C:1982:107.

[98] *Getin Noble Bank*, Opinion of AG Bobek (n 18) para 55.

the purpose of Article 47 of the Charter is to protect individuals' rights to an effective remedy and a fair trial.[99]

Regarding the requirement of 'independence' under Article 267 TFEU, AG Bobek emphasised that in the previous case law the Court's focus was not on individual judges, but on the structural independence of the referring body from both the parties in the dispute and from any external influence.[100]

Lastly, AG Bobek finished the admissibility part with four systemic reasons why the Court should continue examining a 'court or tribunal' in the meaning of Article 267 TFEU in relation to the institutions, and not individuals composing the institutions.[101]

First, he argues that it would be counterintuitive to cut from the dialogue bodies which exercise judicial functions in a Member State and which seek answers regarding the interpretation and application of EU law. Since the Court's judgments are binding on all national courts, such courts demonstrate a willingness to cooperate with the Court and apply EU law correctly.[102]

Second, individual parties in the main proceedings have the right to have the relevant EU law provisions applied correctly as a part of their right to an effective remedy and to a fair trial enshrined in Article 47 of the Charter. Hence, an institutional approach to defining a 'court or tribunal' within the meaning of Article 267 TFEU would be more in line with Article 47 of the Charter.[103]

Third, the admissibility stage is not an appropriate point to assess the independence and impartiality of individual judges, as this endeavour requires a detailed and in-depth analysis. Moreover, if independence were scrutinised in great detail at the admissibility stage, then the requirements of either Article 47 of the Charter or Article 19 TEU would be examined both at the admissibility stage, and on the merits if that stage were reached. Hence, the analysis would potentially become somewhat circular.[104]

Fourth, there is an issue of horizontal consistency of the Court's case law. Advocate General Bobek found rather puzzling the suggestion that the Court should accept or decline the reference based on

[99] ibid, paras 59–61.

[100] *Getin Noble Bank*, Opinion of AG Bobek (n 18) paras 62–63.

[101] ibid, para 66.

[102] ibid, para 67.

[103] ibid, para 68.

[104] ibid, para 69.

the 'quality' of the individual judge(s). Examining the integrity of judges, conflicts of interest in a specific case, possible allegations of corruption, and similar intricacies is not the Court's task under Article 267 TFEU.[105]

Lastly, Advocate General Bobek concluded that the body in question is a 'court or tribunal' within the meaning of Article 267 TFEU with two important caveats.[106]

First, the notion that the referring court is considered a 'court or tribunal' under Article 267 TFEU does not mean that the body is independent under Article 19(1) TEU and/or Article 47 of the Charter.[107]

Second, ultimately, the individuals may still be important. Advocate General Bobek proposed that if an institution is composed of a greater number of individuals who are not independent, such an institution would then be completely cut off from dialogue with the Court. This situation might occur when, for instance, the pattern of issues with appointment shows that political influence is exercised over the decision-making process.[108] The proposed exception remains rather unclear. *Pech* and *Platon* justifiably ask: what would the threshold be? At what point would an institution become hijacked? Which individual would be the last straw?[109] It remains unclear whether some sort of threshold should be set, and what this would be, or whether the breaches should be assessed on a case-by-case basis, which would leave the national courts wondering whether they are allowed to submit a reference.[110] Additionally, this exception risks opening Pandora's box – if an entire tier of the judiciary is appointed unlawfully, would the Court completely shut the door on a large part of a State?

Besides, what if a minority of judges loyal to the executive influence the rest of the judges in lower positions? Can one rotten apple spoil the whole barrel? Some may argue that independent judges may be susceptible to pressure from their non-independent peers, a phenomenon commonly described as the *chilling effect*.[111] Such risks are particular-

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[105] ibid, para 70.

[106] ibid, para 74.

[107] ibid, paras 75–76.

[108] ibid, paras 77–78.

[109] Laurent Pech and Sébastien Platon, 'How Not to Deal with Poland's Fake Judges' Requests for a Preliminary Ruling: A Critical Analysis of AG Bobek's Proposal in Case C-132/20' (*VerfBlog*, 28 July 2021) <https://verfassungsblog.de/how-not-to-deal-with-polands-fake-judges-requests-for-a-preliminary-ruling/> DOI: 10.17176/20210729-020032-0 accessed 17 June 2024.

[110] Pech and Platon (n 109).

[111] See more about the 'chilling effect' in Laurent Pech, 'The Concept of Chilling Effect Its Untapped Potential to Better Protect Democracy, the Rule of Law, and Fundamental

ly relevant when independent judges sit in panels alongside 'dependent' judges, who may also serve as presidents of panels or courts. In these circumstances, the threat of disciplinary sanctions may dissuade them from applying EU law. However, if the Court decides to exclude such courts, what would the criteria be for establishing that a judge is 'dependent' despite his lawful appointment? It would almost be impossible to determine in each specific case whether a lawfully appointed judge was feeling 'peer pressure' and decided to take the path of least resistance, especially at the admissibility stage.

Lastly, if the Court determines that an institution is hijacked, then no judge from that court, regardless of its overall lawful appointment, would be able to submit a reference.[112] Although Advocate General Bobek leans towards enabling dialogue with non-independent judges, this exception poses issues for the uniformity and effectiveness of EU law in all fields regulated by EU law. Moreover, it bars independent judges from questioning the lawfulness of their colleagues' appointment.

3.2.2 Judgment of the Court in Getin Noble Bank

The Court mostly followed Advocate General Bobek's Opinion and departed from its ruling in *Banco de Santander*. Unlike in *Banco de Santander,* the Court distinguished between the concept of judicial independence under Article 267 TFEU, Article 19(1) TEU, and Article 47 of the Charter.[113]

It found the reference admissible, as it considered the referring judge a 'court or tribunal' under Article 267 TFEU.[114] The Court refrained from determining the lawfulness of the referring judge's appointment. Rather, it established a presumption that a preliminary ruling that emanates from a national court or tribunal satisfies the *Dorsch* criteria.[115] As Advocate General Rantos noted, this presumption reflects the Court's standing in *FORMAT Urządzenia i Montaże Przemysłowe*,[116] *Koleje Ma-*

Rights in the EU' (2021) Open Society European Policy Institute <www.opensocietyfoundations.org/uploads/c8c58ad3-fd6e-4b2d-99fa-d8864355b638/the-concept-of-chilling-effect-20210322.pdf> accessed 17 June 2024.

[112] Pech and Platon (n 109).

[113] Paweł Filipek, 'Drifting Case-Law on Judicial Independence: A Double Standard as to What Is a "Court" under EU Law? (CJEU Ruling in C-132/20 Getin Noble Bank)' (*Verfassungsblog*, 13 May 2022) <https://verfassungsblog.de/drifting-case-law-on-judicial-independence/> accessed 18 June 2024.

[114] *Getin Noble Bank* (n 10) para 76.

[115] ibid, para 69.

[116] Case C-879/19 *FORMAT Urządzenia i Montaże Przemysłowe* EU:C:2021:409.

zowieckie,[117] *WŻ*,[118] *Zakład Ubezpieczeń Społecznych I Oddział w Warszawie*[119] and other cases, in which the Court did not investigate whether the Polish Supreme Court is independent under Article 267 TFEU.[120] In *Getin Noble Bank*, the Court recalled its rulings in *Reina* and *Prokuratura Rejonowa*, where it held that:

> it is not for the Court to determine whether the order for reference was made in accordance with the rules of national law. The Court is therefore bound by an order for reference made by a court or tribunal of a Member State, in so far as that order has not been rescinded on the basis of a means of redress provided for by national law.[121]

It also stated that the preliminary ruling procedure is the keystone of the judicial system established by the Treaties, which has the objective of securing uniformity in the interpretation of EU law.[122]

The presumption may nevertheless be rebutted where a final judicial decision handed down by a national or international court or tribunal leads to the conclusion that the judge constituting the referring court is not an independent and impartial tribunal previously established by law for the purposes of Article 19(1) TEU, read in the light of Article 47 of the Charter.[123]

The Court also followed Advocate General Bobek's Opinion by making an exception to the presumption in the case of a court that is deemed to be captured or hijacked.[124] However, it did not establish further rules on how the national courts' capture by the executive branch would be determined.

Finally, the Court enabled the referring judge to join the dialogue by applying the mentioned presumption that had not been rebutted by a final decision of a national or international court or tribunal.[125] It is interesting to point out that prior to issuing the judgment, the ECtHR delivered a judgment in *Advance Pharma* declaring that the judge that submitted a reference in *Getin Noble Bank* was not a court previously es-

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[117] Case C-120/20 *Koleje Mazowieckie* EU:C:2021:553.

[118] Case C-487/19 *WŻ* ECLI:EU:C:2021:798.

[119] Case C-866/19 *Zakład Ubezpieczeń Społecznych I Oddział w Warszawie* EU:C:2021:865.

[120] *LG*, Opinion of AG Rantos (n 4) para 21, note 35.

[121] Case 65/81 *Reina* ECLI:EU:C:1982:6, para 7; Joined Cases C-748/19 to C-754/19 *Prokuratura Rejonowa w Mińsku Mazowieckim* ECLI:EU:C:2021:403, para 44; *Getin Noble Bank* (n 10) para 70.

[122] *Getin Noble Bank* (n 10) para 71.

[123] ibid, para 72.

[124] ibid, para 75.

[125] ibid, para 73.

tablished by law.[126] Although the decision was not final, the Court did not reopen the oral part of the procedure while waiting for the decision of the ECtHR to become final. It still remains unclear why it refused to do so.[127]

By establishing the presumption, at first it seems that the concept of a 'court' under Article 267 TFEU and a 'court' under Article 19(1) TEU and Article 47 of the Charter were separated,[128] which would be in line with Reyns' suggestions.[129] As stated in the judgment, even if a national court is presumed independent under Article 267 TFEU, it does not necessarily imply that it constitutes an independent and impartial tribunal previously established by law, for the purposes of Article 19(1) TEU or Article 47 of the Charter.[130]

However, if the presumption is rebutted, Article 19(1) TEU and Article 47 of the Charter impose both substantive obligations and formal requirements. In the upside-down logic of this judgment, the Court first examines the substance, on the basis of which it may *a maiore ad minus* conclude that the threshold of Article 267 TFEU is not met. Interestingly, independence under Article 267 TFEU was initially used to shape independence under Article 19(1) TEU. In *Getin Noble Bank*, however, the opposite happened: independence under Article 19(1) TEU impacted the assessment of the concept of a 'court or tribunal' under Article 267 TFEU. This new legal framework departs from previous case law in which Article 19(1) TEU and Article 47 of the Charter were not envisaged as admissibility requirements. One of the possible reasons for this shift is the Court's intention to align its case law with that of the Strasbourg Court, which has consistently held that Polish courts do not meet the standard of an 'independent and impartial tribunal established by law'.[131]

Additionally, the Court departed from its previous case law on another point. Although the presumption follows the institutional approach, it may be rebutted by conducting an individual assessment of referring judges, which differs from the Court's original stance.

This shift from previous case law is not automatically negative. From early landmark cases such as *Van Gend en Loos*[132] and *Costa*,[133]

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[126] *Advance Pharma* App no 1469/20 (ECtHR 3 February 2022).

[127] Filipek (n 113).

[128] ibid.

[129] Reyns (n 6) 12-13.

[130] *Getin Noble Bank* (n 10) para 75.

[131] See, for instance, the following judgments of the ECtHR: *Advance Pharma* (n 127); *Dolińska-Ficek and Ozimek v Poland* App nos 49868/19 and 57511/19 (ECtHR, 8 November 2021).

[132] Case 26-62 *Van Gend En Loos* ECLI:EU:C:1963:1.

[133] Case 6-64 *Costa v ENEL* ECLI:EU:C:1964:66.

the Court has continuously adapted EU law provisions in the light of changing political contexts. In the 'rule-of-law crisis', a degree of flexibility enables the Court to adjust its approach to the changing circumstances. Yet, when such adaptability results in a departure from case law, it raises concerns regarding legal certainty and the coherence of the Court's jurisprudence. Arguably, Advocate General Bobek's proposal offers a clearer picture of how these provisions would be applied and thus a higher level of legal certainty. Ultimately, however, the most pressing issue lies less in the theoretical discussion over the boundaries between the legal bases and more in the practical consequences that arise from it.

The exception to the presumption still poses risks to the uniformity and effectiveness of EU law. At the moment, about one quarter of ordinary and administrative judges have been appointed under procedures that compromise judicial independence.[134] Currently, the presumption would protect most national courts due to a lower number of national and international decisions on independence. However, if the ECtHR or the Court finds that most or all Polish or Hungarian courts are not independent under Article 6(1) ECHR or Article 19(1) TEU, a large part of the State could be cut off from the preliminary reference procedure. Nonetheless, in contrast to some critical voices after *Getin Noble Bank*,[135] I believe that this judgment is an advancement on *Banco de Santander* rather than a step back, as it provides clearer criteria for excluding national courts from the dialogue, thereby enabling most courts at the moment to submit references.

The ruling has attracted criticism due to the Court's willingness to engage in dialogue with an unlawfully appointed judge, which some contend amounts to legitimising an unlawful appointment.[136] They argue that it enables bogus judges, who were never judges in the first place, to claim in the media that they are recognised as lawful judges in the eyes of the Court of Justice.[137] Although these arguments are compelling, it is questionable whether the Court has legitimised the referring judge, since in the previous case of *WŻ* it had indicated a breach of Article 19(1)

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[134] *LG*, Opinion of AG Rantos (n 4) para 25; Marcin Szwed, 'Restoring the Integrity of Judicial Appointments: The Venice Commission and Council of Europe's Opinion on Poland', *ConstitutionNet*, International IDEA, 7 November 2024 <https://constitutionnet.org/news/voices/restoring-integrity-poland-judicial-appointments> accessed 28 November 2024.

[135] Filipek (n 113); Barbara Grabowska-Moroz, 'Judicial Dialogue about Judicial Independence in terms of Rule of Law Backsliding' CEU Democracy Institute Working Papers, No 12, 2023, available at SSRN: https://ssrn.com/abstract=4450094 or http://dx.doi.org/10.2139/ssrn.4450094.

[136] Grabowska-Moroz (n 135) 22; see also Pech and Platon (n 109).

[137] Pech (n 86).

TEU in the appointment process similar to that in *Getin Noble Bank*.[138] Moreover, allowing non-independent judges to pose questions relating to the independence of their colleagues would allow the Court of Justice to affirm the legitimacy of judges whose independence was unjustly challenged. In this way, the Court would shield them from further attacks from their non-independent colleagues. Precisely this happened in the *Getin Noble Bank* judgment, where the Court claimed that Article 19(1) TEU and Article 47 of the Charter were not breached by the initial appointment of (contested) judges during Communism.[139]

Furthermore, some academics claim that *Getin Noble Bank* is problematic from the perspective of the *Bosphorus* presumption, arguing that EU law poses a threat to the proper functioning of the ECHR within its territory in order to attain short-term goals, and that it lowers the standard of independence far below the standard of Article 6(1) ECHR.[140] However, I do not agree. Article 6(1) ECHR has a different function from that of Article 267 TFEU. It protects individuals' right to a fair trial, distinct from the formal identification of bodies able to submit a reference. A more relaxed approach to independence under Article 267 TFEU does not mean a lenient approach to Article 19(1) TEU and Article 47 of the Charter. In fact, following Advocate General Wahl's logic in *Torresi*, a less stringent analysis of independence under Article 267 TFEU would achieve a higher level of protection of individuals' rights. Effectively, it would allow individuals to have their claims heard before a 'natural judge' (the Court).[141]

3.3 The judgment in LG

LG is essentially a case rebutting the presumption set in *Getin Noble Bank*, thus manifesting the concerns relating to cutting the dialogue with a large part of the Polish judiciary set out in the previous sub-section. In deciding on the admissibility of a reference submitted by the Chamber of Extraordinary Control and Public Affairs of the Polish Supreme Court, the Court declared that one of the most influential Polish chambers, dealing with extraordinary complaints, electoral disputes, the validity of referendums and elections, is not a 'court or tribunal' under Article 267 TFEU.[142] *LG* marks the first case in which a national court – remarkably, the chamber of the Supreme Court – was not considered a 'court or tri-

[138] *WŻ* (n 118) para 162.

[139] *Getin Noble Bank* (n 10) para 134.

[140] Kochenov and Bárd (n 2); Grabowska-Moroz (n 135) 18.

[141] *Torresi*, Opinion of AG Wahl (n 86) paras 48–49.

[142] *LG* (n 11) paras 12, 78.

bunal' under Article 267 TFEU, thus establishing a precedent for further rejections of references emanating from 'tainted' courts.

The main dispute concerned a familiar issue about extending judges' terms past retirement at the discretion of the KRS. However, again in the plot-twist, the referring court's independence was rebutted due to the unlawful appointment of judges. The President of the Republic appointed the referring judges despite the Supreme Administrative Court annulling the KRS resolution on which these appointments were based.[143] Besides, at the time of the new appointments of the judges of the Supreme Court, the process of election of the members of the KRS had arbitrarily changed, coming even more under the influence of the legislative and executive.[144]

The Court rebutted the presumption that the *Dorsch* criteria were fulfilled based on the final decisions of the ECtHR in *Dolińska-Ficek and Ozimek v Poland*,[145] and of the Polish Supreme Administrative Court.[146] In *Dolińska-Ficek and Ozimek v Poland*, the ECtHR found that the appointment of the judges of the Chamber of Extraordinary Control and Public Affairs represented a flagrant breach of the requirement of a 'tribunal established by law' in Article 6(1) ECHR.[147] The ECtHR identified two major breaches. First, the Court found a manifest breach in the radical change of the election model: the election of the fifteen judicial members of the KRS shifted from election by their peers to election by parliament. The second breach involved the President of the Republic appointing judges to the Chamber of Extraordinary Review and Public Affairs of the Supreme Court despite an interim measure by the Supreme Administrative Court to stay the implementation of the Resolution of the KRS. The ECtHR criticised the President's actions as showing blatant disregard for judicial independence and the rule of law, relying on the Court of Justice's judgments in *AB* and *WŻ*.[148]

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[143] ibid, paras 31, 33.

[144] ibid, para 57.

[145] *Dolińska-Ficek and Ozimek v Poland* (n 131).

[146] Judgment of the Naczelny Sąd Administracyjny (Supreme Administrative Court) of 21 September 2021.

[147] *LG* (n 11) para 32; Johan Callewaert, 'The Polish Chamber of Extraordinary Review and Public Affairs Not an "Independent and Impartial Tribunal Established by Law": Judgment by the ECHR in the Case of Dolińska-Ficek and Ozimek v Poland' (Prof. Dr. iur. Johan Callewaert, 21 November 2021) <https://johan-callewaert.eu/the-polish-chamber-of-extraordinary-review-and-public-affairs-not-an-independent-and-impartial-tribunal-established-by-law-judgment-by-the-echr-in-the-case-of-dolinska-ficek-and-ozi/> accessed 1 July 2024.

[148] Callewaert (n 147); Case C-824/18 *AB, CD, EF, GH, IJ v Krajowa Rada Sądownictwa* ECLI:EU:C:2021:153.

At the national level, the Supreme Administrative Court annulled the Resolution of the KRS which was the basis for appointing the judges of the Chamber of Extraordinary Review and Public Affairs. It also condemned the legislative amendments prohibiting appeals on the appointment of judges of the Supreme Court and the change in the election of members of the KRS.[149]

Based on these judgments, the Court undertook its own analysis to assess whether these findings in the light of the Court's case law can rebut the presumption established in *Getin Noble Bank*. By doing so, it explicitly emphasised that it was the only body responsible for interpreting EU law.[150] The Court found manifest breaches of Article 19(1) TEU read in the light of Article 47 of the Charter, which led to the conclusion that the referring court was not a 'court or tribunal' under the meaning of Article 267 TFEU.[151] Hence, the Court further affirmed the new relationship of these provisions at the admissibility stage, while adding Article 6(1) ECHR to the mix. It did not follow Advocate General Rantos' Opinion, in which he proposed the same differentiation of legal bases as Advocate General Bobek: Article 19(1) TEU pertains to systemic breaches of independence, Article 47 of the Charter ensures individuals' right to effective judicial protection, and Article 267 TFEU determines the bodies that can join the preliminary reference procedure.[152] Contrary to the Court's findings, Advocate General Rantos considered that the breaches of Article 6(1) ECHR cannot lead to the conclusion that the threshold of Article 267 TFEU has not been met. Article 6(1) ECHR has the purpose of safeguarding individuals' rights to a fair trial, which can play a role in the application of Article 47 of the Charter, but not in the assessment of independence under Article 267 TFEU.[153] Yet, by acknowledging the violations of Article 6(1) ECHR, it seems that the Court aimed to align its case law with the jurisprudence of the Strasbourg court.

While it is not surprising that the Court found systemic deficiencies in the appointment of judges of the Supreme Court, until this ruling, breaches of Article 19(1) TEU had not been the cause of the inadmissibility of references submitted by national courts, let alone the Polish Supreme Court. This outcome raises serious concerns both for the uniformity of EU law and for the protection of individual rights, since the chamber of the highest national court, tasked with adjudicating the

[149] *LG* (n 11) para 56.

[150] ibid, para 46.

[151] ibid, paras 58, 77–78.

[152] *LG*, Opinion of AG Rantos (n 4) para 20.

[153] ibid, para 35.

most complex legal issues, is effectively barred from seeking interpretative guidance from the Court.

On top of this, the ruling clashes directly with *CILFIT*, as the court of last instance is ultimately banned from submitting a reference.[154] Consequently, it seems that in most proceedings no national court would be under the obligation to refer. Such an understanding severely diminishes the uniformity of EU law, thus creating blind spots far beyond the Chamber of Extraordinary Control and Public Affairs. This fear of removing considerable parts of the Polish judiciary from the EU's judicial system was also highlighted by Advocate General Rantos,[155] which yet remained unacknowledged by the Court. It would be interesting to see how the Court will resolve this conflict. Will it declare that the courts below the Supreme Court are courts of final instance under EU law, although this contravenes national law?

4 Aftermath of the three-case saga

After *LG*, the Court has in a number of cases repeatedly declined references from the Chamber of Extraordinary Control and Public Affairs, as well as the Civil Chamber of the Polish Supreme Court.[156] As the referring judges were appointed in similar circumstances as those in *LG*, the references were declared inadmissible or manifestly inadmissible.

These rulings further deepen the concerns expressed in the previous sections.

First, the Court has entrenched the blind spot with regard to the Chamber of Extraordinary Control and Public Affairs, while also extending it to the Civil Chamber of the Polish Supreme Court.[157] These judgments may have a ripple effect on other Polish courts whose judges were appointed in a similar manner, thus raising a pressing question – where will the Court draw the line? Applying this standard rigorously could result in barring a quarter of Polish judges from the preliminary reference procedure, stretching the blind spots to the extreme limits. Worse still, if this approach were to spill over onto other Member States, the consequences for the uniformity of EU law could be even more alarming.

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[154] Case 283/81 *Srl CILFIT and Lanificio di Gavardo SpA v Ministry of Health* ECLI:EU:C:1982:335.

[155] *LG*, Opinion of AG Rantos (n 4) para 25.

[156] See Case C-390/23 *Rzecznik Finansowy* ECLI:EU:C:2024:419; Case C-326/23 *CWSA and Others v Prezes Urzędu Ochrony Konkurencji i Konsumentów* ECLI:EU:C:2024:940; Case C-43/22 *Prokurator Generalny v DJ and Others* ECLI:EU:C:2024:459; Case C-720/21 *Rzecznik Praw Obywatelskich* ECLI:EU:C:2024:489; Case C-22/22 *TSA v Przewodniczący Krajowej Rady Radiofonii i Telewizji* ECLI:EU:C:2024:313.

[157] Regarding the Civil Chamber of the Supreme Court, see Case *CWSA* (n 156).

Second, orders in *Prokurator Generalny v DJ and Others*[158] and *Rzecznik Praw Obywatelskich*[159] underline the potential concerns for rule-of-law cases. In these orders, the Court examined whether a panel composed of two judges appointed under the contested procedure at issue in *LG* and a lay-judge could submit a preliminary reference. Although the lay-judge had not been appointed in the same circumstances, the Court held that the presence of even a single unlawfully appointed judge suffices to deprive the body of participation in the preliminary reference procedure.[160] This conclusion was based on an incorrect interpretation of *Simpson*.[161] In that case, the Court reviewed judgments of the General Court, which had held that the unlawful appointment of a third panel member amounted to a breach of Article 47 of the Charter. While the Court acknowledged the irregularities of the judge's appointment, it considered them insufficiently serious to constitute a violation of the right to a fair trial.[162] Consequently, the Court set aside the judgments of the General Court. By contrast, in *Prokurator Generalny v DJ and Others* and *Rzecznik Praw Obywatelskich* the Court appeared to adopt the overruled reasoning of the General Court, thereby declaring that the flaws in the appointment of one judge violate both Article 19(1) TEU and Article 47 of the Charter, thus resulting in the manifest inadmissibility of the reference.[163]

Besides the incorrect reading of *Simpson*, the Court continued to rely heavily on the individual assessment of judges' independence under Article 267 TFEU, instead of following the originally intended institutional approach. Since the presence of even one unlawfully appointed judge on the bench may block the dialogue, lawfully appointed judges could be barred from seeking interpretation of EU law, as well as questioning the independence of their colleagues. This seems an unfair and unnecessary punishment for both the judges willing to cooperate with the Court and the parties involved in the proceedings. In fact, allowing judges to submit references regarding the 'rule-of-law crisis' would be more effective than ultimately blocking the dialogue. It is precisely their initiation of preliminary references that has enabled the development of

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[158] *Prokurator Generalny v DJ* (n 156).

[159] *Rzecznik Praw Obywatelskich* (n 156).

[160] *Prokurator Generalny v DJ* (n 156) paras 28–29; *Rzecznik Praw Obywatelskich* (n 157) paras 29–30.

[161] *Prokurator Generalny v DJ* (n 156) para 28 refers to Joined Cases C-542/18 RX-II and C-543/18 RX-II *Erik Simpson v Council of the European Union and HG v European Commission* ECLI:EU:C:2020:232 *(Simpson).*

[162] *Simpson* (n 161) paras 81–82.

[163] *Prokurator Generalny v DJ* (n 156) paras 29–30; *Rzecznik Praw Obywatelskich* (n 156) paras 28–29.

the refined case law under Article 19(1) TEU and will continue to further fuel its progress.

Considering these heavy risks to the overall functioning of EU law, it would be beneficial for the Court to rethink its strategy towards unlawfully appointed Polish judges. Blocking the judicial dialogue is a rather ill-suited sanction, as it targets both lawfully and unlawfully appointed judges regardless of their willingness to apply EU law. This measure is based on an incorrect assumption that unlawfully appointed judges are inherently unwilling to apply EU law or that they seek to obstruct justice by posing preliminary references. While such cases may exist, references such as the one submitted in *TSA v Przewodnicz cy Krajowej Rady Radiofonii i Telewizji* rebut this myth.[164] In that case, an unlawfully appointed judge submitted a question concerning TV advertisements targeting children, showing the judge's concern for the correct application of EU law. The request was nonetheless declared inadmissible solely due to the irregularity of the appointment.[165] Thus, the Court again put at stake the uniformity and effectiveness of EU law, risking the incorrect application of EU law, and consequently the parties' right to a fair trial.

Other mechanisms seem more suitable for tackling this issue on a larger scale. For instance, imposing financial sanctions and freezing access to EU funds create more concrete financial and political incentives for governments to restore judicial independence than excluding some individual judges from the dialogue. The latter sanction punishes more the judges willing to cooperate with the Court and the litigants concerned than the judges aiming to sidestep EU law obligations. Namely, such judges would hardly be troubled by exclusion from the dialogue. Furthermore, such a measure does not solve the root cause of the issue – it is a sign of disregard towards Polish judges, without any concrete mechanisms or incentives for the State as a whole to remedy the underlying structural deficiencies. Blocking EU funding, although not sufficient on its own to resolve the rule-of-law crisis, puts pressure on the Polish government, incentivising it to take further steps towards restoring the rule of law. The proceedings before the Court complement this measure, providing more guidance as to the concrete measures to take.

Finally, the developments in 2024 reveal a striking contrast between the two powerful EU institutions. After a change in the Polish government, the Commission acknowledged this as a positive development by unblocking €137 billion in EU funds.[166] In May 2024, it decided to close

[164] *TSA v Przewodniczący Krajowej Rady Radiofonii i Telewizji* (n 156).

[165] ibid, paras 11 and 24.

[166] 'Poland's Efforts to Restore Rule of Law Pave the Way for Accessing up to €137 Billion in EU Funds' (*European Commission* 29 February 2024) <https://ec.europa.eu/commis-

the Article 7(1) TEU procedure for Poland and declared that 'there is no longer a clear risk of a serious breach of the rule of law in Poland within the meaning of that provision'.[167] On the other hand, in the same year, the Court repeatedly issued orders against Polish Supreme Court judges. Ultimately, whether these institutional approaches converge will remain an important factor in shaping the EU's response to the ongoing rule-of-law issues.

5 Conclusion

This paper has examined two interrelated questions. First, how the Court's stance towards engaging with the Polish judiciary has shaped the relationship between Article 19(1) TEU and Article 267 TFEU. Second, whether the Court should engage in the dialogue with judges of non-independent courts, or instead risk turning parts of Poland into blind spots on the EU's judicial map.

In regard to the first question, the paper has shown that while Advocates General have proposed a clearer delineation of these provisions, the Court has moulded their application depending on its changing stance on engaging with the Polish judiciary. In *Banco de Santander* it first unified Article 19(1) TEU, Article 47 of the Charter, and Article 267 TFEU, irrespective of the different purposes of these provisions. The equal thresholds of the provisions signal that the Court initially aimed to exclude 'dependent' courts from the dialogue. Then, in *Getin Noble Bank* and *LG*, the Court acknowledged the flaws of this approach, and consequently, in cases where the presumption applies, made a more nuanced distinction between Article 19(1) TEU, Article 47 of the Charter, and Article 267 TFEU. However, in the case where the presumption is rebutted, as in *LG*, breaches of substantive obligations under Article 19(1) TEU read in conjunction with Article 47 of the Charter, can lead to the conclusion that the threshold of Article 267 TFEU was not met. This approach departs from earlier case law where Article 19(1) TEU imposed substantive obligations, while Article 267 TFEU laid down formal requirements that were analysed leniently. Besides, to rebut the presumption, the Court relies on an individual assessment of judges' independence, as opposed to the originally performed institutional approach. The paper underscores that this shift from the original purposes of EU law provisions should be

sion/presscorner/detail/en/ip_24_1222> accessed 1 July 2024; Jorge Liboreiro, 'Poland Exits Article 7, the EU's Special Procedure on Rule of Law' (*euronews* 29 May 2024) <www.euronews.com/my-europe/2024/05/29/poland-exits-article-7-the-eus-special-procedure-on-rule-of-law> accessed 1 July 2024.

[167] 'Daily News 29 / 05 / 2024' (*European Commission* 29 May 2024) <https://ec.europa.eu/commission/presscorner/detail/en/mex_24_2986> accessed 1 July 2024.

viewed as a reflection of the Court's political decision to limit engagement with Polish 'dependent' judges.

Although retailoring legal provisions is not in itself negative, the second question points to the worrying consequences arising from such an approach. First, the principal aims of the preliminary reference procedure – the uniformity and effectiveness of EU law – are put at stake if national courts are excluded from the dialogue. Second, this may result in the incorrect application of EU law that would compromise the parties' rights enshrined in Article 47 of the Charter.[168] Third, by blocking certain judges from the procedure, the Court is in effect cutting off a valuable legal avenue for combatting the 'rule-of-law crisis'.

Weighing these risks against other instruments in the EU's 'rule-of-law toolbox' reveals that excluding judges from the preliminary reference procedure carries greater risks while offering fewer benefits. Measures such as financial sanctions and the conditionality mechanism do not affect the fundamental principles of the functioning of EU law – uniformity and effectiveness – yet provide strong incentives to remedy the underlying structural issues. Together with the preliminary reference and infringement procedure, they address the root problems of national judicial systems. It appears that blocking judicial dialogue would not be a valuable contribution to the toolkit, but would instead add dead weight to the broader effort to safeguard the uniform and effective application of EU law. To this end, the Court should be careful to preserve the procedure considered as the keystone of the judicial system established by the Treaties.[169]

Suggested citation: A Altabas, 'Judicial Independence Under Article 19(1) TEU and Article 267 TFEU: Untangling the Gordian Knot' (2025) 21 CYELP 145.

[168] Reyns (n 6) 12.

[169] Opinion 2/13 ECLI:EU:C:2014:2454, para 176.

COURTS ON TRIAL: IN SEARCH OF LEGITIMATE INTERPRETATIONS AND REVIEWS

BOOK REVIEW ESSAY

Davor Petrić [*]

Martijn van den Brink, *Legislative Authority and Interpretation in the European Union* (Oxford University Press 2024, ISBN: 9780198900085) 272 pp, £90.00.

Nik de Boer, *Judging European Democracy: The Role and Legitimacy of National Constitutional Courts in the EU* (Oxford University Press 2023, ISBN: 9780192845238) 384 pp, £115.00.

The two monographs I discuss in this review are part of a book series published by Oxford University Press in 2023 and 2024, featuring several impressive accounts of the key jurisprudential questions of the European Union (EU) constitutional order.[1] Written by Martijn van den Brink (Leiden University) and Nik de Boer (University of Amsterdam), they stand out for their solid theoretical grounding and ambitious doctrinal approaches. Each author takes one judicial juggernaut – the Court of Justice of the EU (ECJ, the Court) and the German Federal Constitutional Court (GFCC) – and explores their relationship with their respective legislators, using concepts like legitimacy, authority, or institutional capacity as analytical yardsticks.

Both books can roughly be divided into two parts (of unequal length and structure). In the first parts, the authors engage with the *ought*-questions. For instance, van den Brink asks why the ECJ should defer to the EU legislator, whereas de Boer asks why national constitutional courts,

[*] Faculty of Law, Department of European Public Law, University of Zagreb, PhD (Zagreb), LLM (UMich); ORCID: 0000-0001-7737-2150; email: davor.petric@pravo.unizg.hr. I am grateful to Martijn van den Brink and Nik de Boer for allowing me to invite myself to sit as a discussant of their books, alongside Ana Bobić and Cristina Fasone, in their 'Author Meets Reader' session at the European Law Unbound Society (ELU-S) Inaugural Conference 'European Law Unbound – What kind of Europe should we reach for?' held on 25–27 September 2025 at the Charles University Prague. I apologise to both authors if I have misunderstood or misrepresented their thoughts and arguments due to inattentive reading or to the challenge of discussing in fewer than twenty pages what they brilliantly developed in more than 500 pages (jointly). All such unintentional errors and failures are mine.

[1] Besides these two, I would single out *The Jurisprudence of Constitutional Conflict in the European Union* (OUP 2022) by Ana Bobić, *The Legislative Priority Rule and the EU Internal Market for Goods: A Constitutional Approach* (OUP 2022) by Eadaoin Ní Chaoimh, and *EU Values Before the Court of Justice: Foundations, Potential, Risks* (OUP 2023) by Luke Dimitrios Spieker.

including the GFCC, should act with restraint when reviewing the constitutionality of EU law. Here, both authors show great understanding of the main debates in political theory (van den Brink) and philosophy (de Boer), which is a testament to their formation in academic disciplines (formally) outside law. This undoubtedly enriches their contributions to the jurisprudence of EU law. In the second parts, the authors engage with the *is*-questions. For instance, van den Brink discusses how the ECJ can defer to the EU legislator, ie how the legislative intent is properly identified, and de Boer how the GFCC can monitor the effects of EU law in the German legal system, ie the proper attitude of a national constitutional court towards matters of EU law that have already been approved by the national legislator. With these latter questions, which belong to the domain of legal doctrine, I have certain issues, as I will explain later.

What also brings the two books together is their reliance on the same influential contemporary legal philosophers and their major works, such as Jeremy Waldron and his famous case against judicial review.[2] One of the underlying messages of the books is that we should pay greater attention to the legislatures, a fair point given how court-centric legal scholarship has traditionally been, and not only in Europe. From this follows the call for more judicial deference to the choices made in the political process.[3] Again, this seems reasonable and something that even those courts deemed the most activist, such as the ECJ, would agree on and follow in the majority of their rulings, as van den Brink shows in his case studies. Yet the final step, which was supposed to give us – and the courts – guidance on when and how to defer to the legislators, supranational and national, remains to my mind somewhat questionable and uncertain.

In what follows, I first examine each book in turn and discuss their major arguments, before exploring in more detail what I consider to be their main contributions as well as the points at which, in my view, they fall short or leave us hanging.

The ECJ and the EU legislator's intentions

Van den Brink starts off by giving reasons against normative conceptions of political and institutional legitimacy that are output-based – which would typically be 'team courts' – and in favour of those that are

[2] Jeremy Waldron, 'The Dignity of Legislation' (1995) 54 Maryland Law Review 633; *Law and Disagreement* (OUP 1999); and 'The Core of the Case Against Judicial Review' (2006) 115 Yale Law Journal 1346.

[3] Here it is not difficult to notice, as Ana Bobić remarked in a panel discussion, that both authors are Dutch, given how this national legal tradition typically sees the relationship between the courts and the legislatures and their respective roles and legitimacy.

input-based – which would be 'team legislators' (Chapter 2). His problem with output-based legitimacy, often mobilised behind the ECJ and its rulings, is that it seems impossible to agree (morally speaking) on the desirability of any of the outputs produced in the judicial process, which we would take as relevant, be it effectiveness, containment of national externalities, or justice. In his view, it is inevitable that different people will reasonably disagree about all this. Therefore, instrumentalist and outcome-oriented interpretation of EU law will inevitably result in inconsistent methodology, because it is likely that the judgment on what makes an outcome desirable might change from case to case due to the pervasiveness of the said reasonable disagreement.

Instead, van den Brink defends an input-oriented legitimacy of the EU legislature. This is not formulated as democratic legitimacy based on the political equality of EU citizens, on which conception it fails. Rather, it is formulated as demoi-cratic legitimacy based on the 'republican value of freedom as non-domination'. It means that Member States do not dominate their citizens (or minorities) internally, and at the same time are not dominated externally by other States or by the EU itself.

Demoi-cracy at the EU level is contained in the legislative institutions and decision-making procedures, including the Council and the Parliament as co-legislators, as well as in national parliaments in their role as the watchmen of subsidiarity. And the Court of Justice can easily obstruct demoi-cracy, given that national peoples cannot control the EU judiciary in the same way as they can the EU legislature and legislative procedure. Hence, for the sake of increased political legitimacy of EU governance, van den Brink calls for a particular institutional balance where the EU legislature is the main source of EU law-making and the principal arena for exercising EU authority. In this balance, the Court of Justice should in principle defer to the choices made by the EU legislature. Such an approach in the interpretation of EU law should offer more stability and predictability in judicial decision-making, including more methodological coherence and consistency.

After dealing with political and institutional legitimacy, van den Brink turns to institutional capacity (Chapter 3). He shows how on this account, too, the EU legislature is superior to the EU judiciary since it is more capable of achieving both legal and social change. This means that the legislator is better able to generate higher-quality legal output and greater social acceptance of its outputs than the judiciary.

In van den Brink's view, the legislator's capacities are greater than the judiciary's for two reasons. One is the epistemic qualities of the legislative process. The legislator has access to greater expertise and knowledge, more resources (including time), stronger processing and predict-

ing capacities, more deliberative capacities, greater inclusiveness, and so on. The other reason is the rule-of-law qualities of legislative acts. The legislative rules are on average clearer, more coherent, and practical, whereas the judicial 'rules' (ie pronouncements) are on average vaguer, principle-based, built incrementally, and less predictable when it comes to their application.

The legislator is better than the judiciary, van den Brink writes, in achieving social change too, ie inducing compliance from its addressees, be it individuals or Member States, for the following reasons. On one hand, the ECJ case law produces weaker adjustment pressure and can be contained and resisted by domestic actors more than EU legislation. On the other hand, EU legislation is more likely to be complied with by private actors, since it is more easily accessible than the case law, and national judges and lawyers appearing before them are more likely to rely on EU legislation.

Bringing these two lines of argument together – legitimacy which grounds political authority, and capacity which grounds epistemic authority – van den Brink proposes a theory of judicial deference. It requires deference to the legislator's choices, yet with a particular approach to the interpretation of primary law (the Treaties and the Charter): instead of adopting a rigid approach, the ECJ should rather opt for a lighter, flexible and adaptable one. A rigid approach would leave too much discretion to the Court in the interpretation of primary law, potentially restricting the interpretation of secondary law. By contrast, a flexible approach modifies the traditional view of the Court as the sole, exclusive interpreter of primary law, so that if secondary legislation is incompatible with the primary law as interpreted by the Court there is no other choice but to invalidate it. Now, the picture shows the Court as not being the only interpreter of primary law; other institutions take part in that process as well, resulting in a form of interpretive pluralism.[4]

Martijn van den Brink then gives some examples to show that the ECJ – not only as a normative matter but as an empirical one too – by and large already follows, and has followed from the earliest days, (t)his modified approach. So, in the case law concerning matters such as free movement of goods, free movement of services, and EU citizenship law, he finds proof that the Court as a rule is highly deferential to legislative choices and that deference has always been its default position. By the same token, the Court itself seems perfectly willing to share interpretive responsibility with the EU legislator and act as its faithful agent.

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[4] cf Gareth Davies, 'Does the Court of Justice Own the Treaties? Interpretative Pluralism as a Solution to Over-constitutionalisation' (2018) 24 European Law Journal 358.

The examples provided concern three different types of review (Chapter 4). The first is the legislative process review, which involves interinstitutional disputes over the legislative procedure and the legal basis. The second is the *ultra vires* review, which concerns the control of the principles of conferral, subsidiarity, and proportionality, which ought to ensure that the EU legislator remains within the limits of EU competence, and which mainly relate to the Union's functional competences such as the internal market legal basis under Article 114 TFEU. And the third is the fundamental rights review, which concerns the compliance of secondary law with the basic human rights guaranteed in the EU constitution.

The standard of review that the ECJ applies, ie its strictness, is context dependent.[5] Of three types of review, van den Brink identifies only the fundamental rights review as being inappropriately exercised given that it is based on too strict scrutiny. Namely, the Court allows the EU legislator to do only what is 'strictly necessary' to achieve the legitimate aim, whereas in other types of review the legislator can do everything except what would be 'manifestly inappropriate' to reach the aim pursued. In van den Brink's assessment, the EU legislator should be granted even greater discretion when it intentionally seeks to strike a balance between fundamental rights restrictions and the protection of other public interests, similar to what we find in the 'margin of appreciation' doctrine of the European Court of Human Rights.

All in all, van den Brink's account challenges previous writings that have viewed the EU legislator as being the subordinated agent of the Court, which merely elaborates the existing case law when adopting subsequent legislation.[6] He shows that the legislator is not acting in the 'shadow of the case law', but has extensively worked on specifying many Treaty provisions, to which the ECJ has responded positively and has mostly deferred to the legislative choices expressed in secondary law. So, in his view, the relationship between the EU's legislative and judicial branches is not as imbalanced as many have suggested, which is a good thing. To improve it further, van den Brink provides a *vade mecum* for

[5] It also varies in vertical and horizontal dimensions. For instance, the ECJ reviews national restrictive measures in a stricter manner than the comparable EU measures on account of the differing representation of socio-political interests in the national as opposed to the EU decision-making procedure; and the ECJ applies the same level of scrutiny when reviewing EU legislative and EU executive/administrative measures, although the argument from political (institutional) legitimacy would require the latter to be scrutinised more strictly, whereas the argument from institutional capacity (expertise and resources) would require the same scrutiny or even greater deference to the EU executive/administrative institutions.

[6] cf Gareth Davies, 'The European Union Legislature as an Agent of the European Court of Justice' (2016) 54 Journal of Common Market Studies 846.

the Court on how to correctly identify the legislative intentions in order to defer to them (Chapter 7).

His guideline for the identification of legislative intent in the interpretation of EU law is 'literal meaning in context'. How might that work? First, he dismisses a pure literal interpretation as a way of discerning legislative intent. He does not subscribe to the view that EU law is radically indeterminate. Rather, he notes that more agreement exists on the meaning of EU law than typically thought, which is why an analytically more appropriate and descriptively more accurate term for EU law would be that it is 'underdeterminate'.[7] Van den Brink does admit, though, that literal interpretation in EU law on its own is inadequate given the complexity of legislative language and its multilingual nature, which adds an additional layer of vagueness and the potential for linguistic discrepancies.[8] Limiting ourselves solely to linguistic considerations would, in his view, leave out important contextual information and therefore underestimate the intention of the EU legislator.

So, van den Brink suggests that the legislative context is decisive in concluding whether or not the literal meaning is the *intended meaning*. And what does he include in the legislative context? Everything (or almost everything) that the ECJ itself counts as relevant context, as elaborated in *CILFIT*:[9] other provisions found in the legislative acts in question or other (related) acts, the objectives of those acts, legislative history (*travaux préparatoires*), the state of evolution of EU law, and so on. Basically, everything except the Treaties – or the Court's exclusive interpretation of them – which needs to be loosened when interpreting EU legislation. It also has to be accepted that the EU legislator likewise can interpret the Treaties when enacting secondary law. In van den Brink's words, 'the *CILFIT* requirement that legislation must be interpreted "in light of provisions of EU law as a whole" must be construed narrowly' (at 221), so that the Treaties should be left out of this 'whole'.[10] In other words, the Treaties should not

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[7] Meaning that while there may not be *only one right answer*, it does not follow that there are *no wrong answers* to the questions of interpretation of EU law either; besides, the case law of the ECJ adds further to the determinacy of EU law. For a general discussion of this idea of the 'underdeterminacy' of law, see Lawrence Solum, 'On the Indeterminacy Crisis: Critiquing Critical Dogma' (1987) 54 University of Chicago Law Review 462.

[8] Although van den Brink does not tell us in detail how frequent the instances of linguistic discrepancies are (they are very rare), and whether that should play a role in rejecting (or embracing) literal interpretation.

[9] Case 283/81 *CILFIT* ECLI:EU:C:1982:335, para 20.

[10] Typically, the Treaties as the 'higher law' would count as the relevant context (even the most relevant context) for the interpretation of hierarchically lower secondary law, under the assumption that lower law must be interpreted in conformity with the higher law, which is a condition of its validity; and also, under the assumption that the (EU) legislator intends to enact valid or constitutional legislation, which is compatible with the higher law. cf Case

count as part of the relevant legislative context, and there should be no obligation to interpret secondary law in conformity with the Treaties if doing so would prejudice the legislative intent.

And here is van den Brink's crucial contribution to the vast literature on the interpretation of EU law: the intention of the EU legislator should be ascertained by excluding primary law (and the ECJ's interpretations of it) in the interpretation of secondary law, so that greater deference could be given to the EU legislator.

The GFCC and the constitutional review of EU law

Nik de Boer examines the legitimacy of national constitutional courts in reviewing the application of EU law in their domestic legal orders. Unsurprisingly, his study focuses on arguably the most influential national court and the one most capable of affecting the course of EU integration. But tying his account to a judicial outlier is at the same time a limitation of his study, which de Boer himself acknowledges. Indeed, the apex courts of other Member States are unlikely to possess the same political clout and institutional authority as their German counterpart, which reduces the generalisability of the book's argument.

In any event, de Boer's point of departure is the critique of constitutional pluralism.[11] His main concern with this school of thought is its celebration of resistance to, and contestation of, EU law that comes from the highest national courts and of the dialogue between these courts and the ECJ that follows from there, which supposedly drives integration forward. This enthusiasm overlooks the fact that judicial process can disable political debate and legitimate disagreement on matters of EU and national constitutional orders. Much like van den Brink, de Boer shares the view that political institutions are generally better placed than judiciaries – given the greater political legitimacy and institutional capacity of the former – to deal with key constitutional questions. This is despite the fact, which he rightly acknowledges, that the EU political process is characterised by the domination of national executives over their respective legislators, and that national courts' reactions are often not aimed against outcomes produced in the political process but against judicial lawmaking, as many things are settled before the ECJ.[12]

218/82 *Commission v Council* ECLI:EU:C:1983:369, para 15; and Joined Cases C-402/07 and C-432/07 *Sturgeon* ECLI:EU:C:2009:716, para 47.

[11] Note that van den Brink is likewise critical of constitutional pluralists (Chapter 6), but on account of their purported overemphasis on the indeterminacy of EU law and the 'incompletely theorised agreements' which EU decision-making, in their view, dominantly produces.

[12] Although de Boer notes that the book discusses the case law of national courts as a response to the ECJ's lawmaking, this aspect remains somewhat in the background.

The introductory parts discuss in great detail the legitimacy of judicial (constitutional) review in general (Chapter 2) and in the EU context more specifically (Chapter 3). For me, the most interesting and useful point is the juxtaposition of two opposite approaches to these questions. As de Boer argues, 'legal constitutionalists' who defend the judicial review and its legitimacy typically paint a distorted picture of the legislative process and at the same time an idealised picture of the judicial process. And vice versa, 'political constitutionalists' idealise the legislative process and misrepresent the workings of the judicial process. The former put great faith in courts as counter-majoritarian institutions which are there to safeguard individual rights and prevent the tyranny of the majority. The latter hail legislatures as public forums in which elected representatives of the people come together to deliberate rationally and in good faith and decide on matters of the common good. The democratic credentials of the legislatures are undoubtedly much greater than those of the judiciary. But which branch of government is better suited to decide on constitutional questions, be it fundamental rights, division of powers, democracy, sovereignty, or identity?

De Boer continues his argument by saying that constitutions can be seen to be institutionalising certain preconditions for just and legitimate democratic governance. These are, most importantly, institutions and procedures that enable the formation of popular will and individual rights and mechanisms for their protection. This is where the tension inherent in every liberal constitutional democracy lies: the tension between 'liberal', particular, rights, and individual interests on one hand, and 'democratic', general, majoritarianism, and collective interests of society on the other – which are all ingrained in the same constitutional document.

In de Boer's view, the meaning, import, and requirements of these preconditions are not self-evident from the constitutional text, nor can they be fully articulated in advance or in the abstract. Rather, they are inevitably subject to different reasonable interpretations. As such, these fundamental constitutional preconditions should remain within the democratic process and be subject to political debate. Citing Jürgen Habermas, he agrees that 'the preconditions for democratic legitimacy must themselves be subject to ongoing political deliberation' (at 19). For this reason, de Boer argues that judicial review cannot be justified just by saying that constitutional courts safeguard the preconditions for just and legitimate democratic governance. Instead, the justification for judicial review should be that courts are better than the legislature at ensuring that the political process takes place in accordance with these preconditions. So, the key is to compare the abilities of the judiciary with the abilities of the legislature and to determine who is more successful

in performing the task of deliberating and deciding on the constitutional preconditions.

Against this background, de Boer approaches the case law of the GFCC, and questions how this court's review of EU law has affected the democratic process in Germany. In particular, he examines three famous episodes featuring constitutional review: namely, review of the ratification of the Maastricht Treaty (Chapter 4), review of the Union's response to the euro crisis (Chapters 5 and 6), and review of the Union's handling of the Covid-19 pandemic which came in the aftermath of the ruling on the European Central Bank's (ECB) Public Sector Purchase Programme (PSPP) (Chapter 7).

It can immediately be noticed that, besides being limited to an extraordinary court, the examples de Boer gives are all extraordinary cases, which occurred in exceptional or even emergency circumstances – and it is not without reason that we are warned that '[g]reat cases, like hard cases, make bad law'[13] (and, by extension, could it be that they make equally bad material for scholarly observations?). Moreover, all these cases were decided by the Second Senate, so we hear only one half of the GFCC; hence, it would be interesting to see whether and how the First Senate's landmark rulings, such as in *Solange I* and *II*, which likewise addressed democracy issues in the context of EU integration, would fit the same narrative.

The first example – the Maastricht Treaty ruling that introduced the *ultra vires* review of EU law[14] – had in de Boer's view a negative impact on the political process in Germany. True, the GFCC did provide a forum for Euro-sceptics to voice their concerns about the progress of integration and challenge the constitutionality of the EU Treaties, which somewhat shook the otherwise uniformly pro-EU domestic politics. This was made possible through a wide interpretation of the right to vote guaranteed under the German Basic Law, based on a very Germany-first understanding of democracy, which is a piece of the 'eternity clause' that contains unamendable constitutional principles. By setting out in this ruling several important constitutional limits to future EU integration, the GFCC became the favourite door for Euro-sceptics to knock on. However, with such a strict and defensive interpretation of the German constitution, the GFCC went beyond providing an additional avenue for political contestation and in effect put a straitjacket on German politics for decades to come. As de Boer writes, by 'elevat[ing] the Euro-criti-

[13] US Supreme Court, *Northern Securities v United States*, 193 US 197 (1904) 400 (Justice Oliver Wendell Holmes, dissenting).

[14] BVerfG, 2 BvR 2134/92, 2 BvR 2159/92, Order of the Second Senate of 12 October 1993, ECLI:DE:BVerfG:1993:rs19931012.2bvr213492.

cal viewpoint to the level of unamendable constitutional law', the GFCC 'ultimately end[ed] up constraining the room for political debate in the Bundestag' (at 282).

The second example – events that coincided with the euro crisis, such as the establishment of the European Financial Stability Facility, the European Stability Mechanism, and the banking union – had mixed outcomes. On one hand, constitutional reviews of several measures adopted at the EU or intergovernmental level remained largely uncontested in the German political arena. Hence, the GFCC's interventions limited the space for democratic debate on integration in economic and monetary matters. Consequently, the GFCC's interpretations of the questions of democracy and competences seemed to have 'reified' the politics of austerity, fiscal discipline, and budgetary sovereignty, thus exhausting every constitutional reserve for further EU integration in these areas. On the other hand, as a side effect of this succession of cases, the Bundestag scored some important points. The GFCC's interventions made a decisive contribution to the strengthening of parliamentary oversight over executive actions at the EU level. The Karlsruhe court relentlessly insisted on the Bundestag's information and participation rights in EU affairs. This made the German parliament one of the strongest national parliaments when it comes to a voice in EU affairs, and blunted executive dominance over parliament, thereby saving (some) room for politics.

The third and final example was a culmination of the earlier interventions and brought the most dramatic moment – the GFCC's *ultra vires* ruling in *PSPP*.[15] Yet this turned out to be a storm in a teacup. For their part, German elected politicians and executive officials openly challenged and contested the Karlsruhe court's reading of the provisions of the Basic Law and the EU Treaties as well as its application of the proportionality principle. The GFCC itself closed the judgment with a rather weak cry, instructing the federal government, the Bundestag, and the Bundesbank to resolve the issue. At the same time, it raised legitimate concerns about the ECB's mandate, actions, and lack of democratic oversight, which contributed to political debate not only in Germany but also elsewhere in the EU.

De Boer sees the *PSPP* ruling as a form of weak constitutional review, which for him is a blueprint for the legitimate engagement of constitutional courts in EU affairs. In situations like this, judges only signal constitutional problems that are caused by action at the EU level and thus trigger political debate – but, crucially, do not impose a solution themselves. Rather, they invite elected politicians to work out a solu-

[15] BVerfG, 2 BvR 859/15, Judgment of the Second Senate of 5 May 2020, ECLI:DE:BVerfG:2020:rs20200505.2bvr085915.

tion through the democratic process, and at the same time do not tie their hands in contesting judicial interpretations, thereby recognising that constitutional interpretation is a task jointly shared by the political and judicial branches. So, de Boer's suggestion is that the national constitutional review should as a rule be weak, ie limited and deferential. In this way, constitutional courts can enable democratic deliberation and contestation instead of constraining the political process and over-judicialising fundamental questions of EU integration. In his view, questions concerning the limits of EU integration (the *ultra vires* review) and national identity (constitutional identity review) are primarily political questions, which require a judgment formed through the political process by democratically legitimated institutions that possess greater resources, and not in courtrooms. But he still accepts that in exceptional cases strong constitutional review may be justified to question issues of the democratic legitimacy of Union institutions and decision-making 'that are beyond reasonable disagreement' (at 291).

To align constitutional review with this model, de Boer in the end discusses possible institutional adaptations. The one concerning the practice of constitutional courts is the 'declaration of incompatibility': after finding that EU law and national constitutions cannot be interpreted as coexisting in harmony, constitutional courts should merely declare the incompatibility – but stop short of disapplying EU law. Such a declaration would highlight serious constitutional issues without simultaneously undermining the primacy of EU law. The next step would be to initiate the preliminary ruling procedure and enter into a dialogue with the ECJ. And if following the ECJ's ruling the same constitutional concerns persist, constitutional courts should still not hit the emergency brake but pass the buck to the legislator for a final call. In this setup, the authority of constitutional courts would shift from the power of ultimate sanction (disapplying EU law) to the power of reasoned argument, which is meant to force the national legislature to act.

On the flipside, de Boer also suggests that Member States could introduce domestic political overrides of judicial rulings that interfere with EU integration, or simplify constitutional amendment procedures for matters falling within the scope of EU law. And at the EU level, Member States could strengthen political safeguards to keep the Union's powers in check in a more efficient and legitimate manner, for example by finding ways for the greater involvement of national parliaments in EU affairs or by introducing political overrides of the ECJ's interpretations of the Treaties, so that constitutional courts would less frequently be forced to act as the last line of defence. This is where this author comes back to one of the ideas underlying both books – moving beyond court-centric solutions to explore political options.

Of jurisprudential weaknesses...

The two books are, among other things, about judicial reasoning, and in both we find suggestions on how the courts should interpret the law and review legislation. Each author agrees that since the ECJ and the GFCC should be more deferential to the political process, they should also be more open towards political reasons when interpreting the Treaties and the Basic Law.

For his part, Martijn van den Brink rightly notes the overlap between law and politics, and even claims that legal positivism – and the ECJ is for good reasons considered to be a positivist court[16] – should openly embrace the political dimension. However, in his book, it is not always clear whether he distinguishes between different contexts of interpretation, so-called 'discovery' and 'justification',[17] a distinction commonplace in jurisprudence. There is a significant difference between how a court *makes* a judgment and how it *justifies* that judgment. Similarly, there is a difference between how a court finds (or should find) the legislative intent and how it justifies (or should justify) that finding. Greater clarity and precision regarding these dimensions of judicial decision-making would strengthen van den Brink's account. As it stands, it is not clear how he would evaluate the following scenarios: having the ECJ in practice show greater deference to the EU legislator yet with limited reasoning and narrow justification that include strictly legal arguments; or having the ECJ adopt elaborate reasoning with proper justification that includes political and moral arguments, even if in some cases it would end up being less deferential?

Similarly, Nik de Boer argues that constitutional courts, when performing an *ultra vires* or identity review of EU law, would do better if they engaged openly with arguments that arose in prior political debates, because political institutions might have reasonably thought of and raised sound constitutional points. From this, it seems that de Boer is talking about the justification, and that in his view courts should include in their reasoning more moral and political arguments for the sake of legitimacy, transparency, and efficiency. The problem with this, however, is that not many political arguments can be directly or easily translated into legal discourse, and that many (if not all) courts are suspicious of such kinds of arguments – as most (continental, civil law) European courts are strongly positivist in their reasoning practices. And the reason for their suspicion might be precisely the desire not to overstep what

[16] cf Giulio Itzcovich, 'The European Court of Justice' in András Jakab, Arthur Dyevre and Giulio Itzcovich (eds), *Comparative Constitutional Reasoning* (CUP 2017) 277, 302ff.

[17] cf Bruce Anderson, '*Discovery' in Legal Decision-Making* (Springer 1996).

is formally considered to be the judicial function, and hence to preserve the (illusion of) separation of powers between the lawmakers and the courts. Likewise, some would not want to see the courts (if only the apex courts) becoming openly *political*; they would say that the courts need to stay (boringly) *legal*, and that it is important for them to keep alive the fiction of 'objective law that is separate from politics' in order to preserve the foundations of society.

Another challenge for van den Brink's argument more specifically concerns the central concept he works with – the legislative intent – which was rejected a while ago by all serious legal theorists, some of whom considered it to be theoretically indefensible, deceptive, 'conceptually confused' and 'empirically impossible'.[18] He takes on the main criticism of the legislative intent in (EU) law, which says that, first, collective actors cannot form intentions at all; and second, even if they could, their intentions could not be ascertained. Van den Brink finds a way out of these problems in the social choice theory (see Chapter 5, replete with details), which in his view extends to the legislatures. Basically, what could, building on this theory, enable the formation of collective intent in the legislature are things like the delegation of power to political parties, the role of agenda-setters, the workings of the legislative committees, and so on. However, precisely these things detract from the democratic legitimacy of the legislator, which is one of the grounds (next to institutional capacity) of van den Brink's theory of legislative primacy over the judiciary. Jeremy Waldron, whose case against judicial review both books heavily rely on, would agree that the very reasons we have for granting authority to the legislature and the legislation it enacts are the same reasons for not granting authority to the views or intentions of particular legislators.[19] Van den Brink seems to admit this problem himself, when noting that it is the inequality among individual legislators that makes the legislature capable of reasoned collective action (at 156). If I understand correctly, his comeback is that although some individual intentions (political majority, agenda-setters, legislative committees …) may be decisive in the *formation* of legislative intentions which influence the content of legislation, they are irrelevant for the *identification* of legislative intent. (Recall: it is identified by figuring out 'literal meaning in context'). So, to determine legislative intent, we do not have to know the

[18] Although it is constantly present in legal scholarship, then as well as now. See Heidi M Hurd, 'Interpreting Authorities' in Andrei Marmor (ed), *Law and Interpretation: Essays in Legal Philosophy* (Clarendon Press 1997) 405. For a recent take that I ran into, see Francesca Poggi and Francesco Ferraro, 'From the Ideal Legislator to the Competent Speaker: Uncovering the Deception in Legislative Intent' (2024) 15 Jurisprudence 464.

[19] See Jeremy Waldron, 'Legislators' Intentions and Unintentional Legislation' in Andrei Marmor (ed), *Law and Interpretation: Essays in Legal Philosophy* (Clarendon Press 1997) 329, 348–349.

individual intentions of anyone involved in the formation of that intent. Convinced?

... and moral uncertainties

The two books share the same assumption, which anchors their accounts: the notion of 'reasonable disagreement', and, by extension, what would, and what would not, go beyond this. Since in a democratic society we cannot avoid reasonable disagreement over things like justice, sovereignty, power, identity, democracy, or rights, those that decide on these moral and ethical questions should have legitimacy and authority; hence, since the political process is superior to the judicial process on those two counts, judicial review should be more limited and exceptional, and judges should be more deferential to the elected legislators. But neither of the authors gives enough space to explain how we can know when a disagreement is 'reasonable' and when 'unreasonable', and who is to tell what kind of '(dis) agreement' we are talking about – between lawyers, politicians, scholars, laypeople – and what they consider 'reason(able)' in the first place? This raises questions about some of their specific claims and arguments.

For instance, de Boer suggests that in exceptional situations, constitutional courts would be justified in exercising a strong review if they step in to address problems that are 'beyond reasonable disagreement'. Otherwise, they should settle for a weak and limited review. Let us say that judicial review addresses democratic legitimacy problems at the EU level, and as a result we get a stronger national parliament with greater information and participation rights in EU decision-making. The outcome would thus be more democracy, a stronger democratically legitimated national legislator, and a more democratised EU. That such an outcome is a good and desirable thing should be 'beyond reasonable disagreement'.[20] So far, so good.

However, things become less clear when de Boer moves from the general to the specific. The example he gives to describe a situation in which a strong review is justified does not help, in my view, to distinguish between what is 'beyond reasonable disagreement' and what is not. The case in question is *Neuner Gremium*.[21] The issue concerned the delegation of budgetary powers by the Bundestag to a special parlia-

[20] Although here de Boer, for some reason, does not say 'beyond reasonable disagreement', which is a phrase he repeats twenty or thirty times in the book, but 'less subject to reasonable disagreement'. I cannot be sure whether or not this (subtle?) difference changes the entire meaning or perhaps reveals that he is aware of the difficulty of distinguishing between 'reasonable' and 'unreasonable disagreement' – and all the degrees in between.

[21] BVerfG, 2 BvE 8/11, Judgment of the Second Senate of 28 February 2012, ECLI:DE:BVerfG:2012:es20120228.2bve000811.

mentary subcommittee made up of nine members of the budgetary committee, which was supposed to decide on measures concerning the EU's financial assistance ('bailouts') to eurozone countries in cases of urgency and confidentiality, thereby replacing the decision of the parliamentary plenary. The GFCC unanimously found that such an extensive delegation of the Bundestag's powers and budgetary responsibility to a smaller group of parliamentarians was unconstitutional. The judicial intervention to safeguard the parliament's decision-making powers was, in de Boer's view, beyond reasonable disagreement. But it is interesting to see how the original decision was made and how it ended up before the Karlsruhe court. During the debate on the legislative proposal, the governing coalition parties – at that time the Christian democrats (CDU/CSU) and liberals (FDP) – and the Greens did not see any constitutional issues, unlike the left (Die Linke) and social democrats (SPD). The meeting with constitutional experts saw 'a heated exchange' (at 224). The social democrats proposed an amendment to limit the special subcommittee's powers and the situations in which it could act, but it was rejected. Yet they eventually voted for the proposed legislation, as did all the other parties apart from the left. After the vote in the Bundestag, two members of the social democrats challenged the legislation before the GFCC against the position of their own party, claiming that the rules concerning the special subcommittee violated their rights as members of the Bundestag under Article 38 of the Basic Law which enshrines the principle of representative democracy. And, as we have seen, the GFCC ruled in their favour. But I wonder how that ruling was beyond reasonable disagreement, when almost 90 percent of elected parliamentarians thought that the legislation was constitutional, and legal scholars were divided (as they always are) on the question of its constitutionality.

A similar issue I found in van den Brink's account, in part where he explains why his proposed theory of interpretation in accordance with the legislative intent is preferable to competing theories of interpretation that are purposive.[22] Here, following Frederick Schauer's work,[23] he introduces a fine distinction between the different purposes pursued by the EU legislator when enacting legal rules. Some purposes are individual and substantive, like non-discrimination, free movement, or fair treatment, which the EU legislator may aim to fulfil with specific rules in EU legislation. But other purposes are broader and more systemic, and the EU legislator may be aiming to fulfil them as a general matter with every

[22] As the most influential account of purposivism in the interpretation in EU law, he cites Miguel Maduro's 'Interpreting European Law: Judicial Adjudication in a Context of Constitutional Pluralism' (2007) 1 European Journal of Legal Studies 137.

[23] Frederick Schauer, *Playing by the Rules: A Philosophical Examination of Rule-Based Decision-Making in Law and in Life* (Clarendon Press 1991, reprinted in 2002).

rule in the act (and with every act in the same manner). Think of efficiency (say, of decision-making), clarity (certainty and predictability for the individuals), the reduction of arbitrariness (of public authorities vis-à-vis individuals), and separation of powers (between decision-makers), which are all important components of the rule of law. It is undeniable that the EU legislator, when enacting legislation, pursues all of these goals and purposes. But van den Brink's theory puts greater premium on systemic purposes. He argues that the ECJ should interpret EU law to reflect these systemic purposes, even if such interpretation were contrary to a specific substantive purpose, because in this way the Court better honours the political authority of the EU legislator. So, rules should generally be followed, and they must constrain the ECJ, even if following them would lead to bad outcomes in individual cases.

Although such an interpretive directive could be criticised, I have no issues with it. But consider the follow up: van den Brink later writes that rules should be followed, but not if the outcome would be 'grossly unfair or otherwise nonsensical' (at 179) – in other words, if it would be 'beyond reasonable disagreement' that the outcome is wrong and reprehensible. The question then becomes how to know which outcomes are 'grossly unfair' or 'arbitrary' or 'nonsensical', and which not. What are the criteria for assessing this? And if there is an unavoidable disagreement in democratic societies about moral and ethical questions, would it even be possible to know when van den Brink's theory of interpretation reached its limit? I did not find answers to these questions or practical examples to help and enable interpreters to follow van den Brink's directive.

Context always helps

Certainly, the more context, the better, in everything, including in legal scholarship. I do not think that either of the books is dramatically short of relevant context. But still, it is always possible that some readers will miss some important background to help them better understand the main points.

What I missed in particular in de Boer's account is more discussion of the unique German legal context. For instance, he discusses how some of the GFCC's rulings effectively foreclosed political debate on certain questions of EU integration. But the question that always came back to me was how the Karlsruhe court became so exceptionally authoritative, influential, respected, and dominant that some of its judgments were able to pass virtually uncontested by the political elites. The reasons go back well before the Maastricht Treaty ruling in the early 1990s, which is basically when de Boer's case study starts. And this question is even more important when you remember that no (constitutional) court con-

trols either the 'sword' or the 'purse'. As the 'the least dangerous branch', courts cannot impose or force their choices on the political branches of the government or the public. They can only persuade the relevant audience in the rightness of their interpretations of the constitution and the law. And moreover, constitutional justices are elected by the very same parliamentarians, whose acts they are supposed to control.

These are relevant points if we want to generalise de Boer's account and apply it to other national constitutional courts. There is arguably no high court that holds the same authority or occupies the same position in the domestic legal and political order. Therefore, in other Member States, high courts may already be showing proper deference to the democratic process and reviewing matters pertaining to EU affairs in a limited manner, hence not constraining the debate on EU integration; and vice versa, the rulings of high courts concerning EU affairs may be regularly (and successfully) contested by the political branches.

I am aware that this critique may not be fair, because a detailed historiography and sociology of the GFCC would probably require a whole new monograph. And de Boer does recognise that constitutional justices enjoy exceptional authority in Germany (and not only there, I would add, because high courts in other Member States love referring to their rulings). He also mentions that constitutional interpretation in Germany is a matter largely viewed as the exclusive province of legal experts (at 290), and references interesting titles that contain more background on this point. One of the referenced works is by Michaela Hailbronner, who wrote that such an emphasis on expert authority in the interpretation of the Basic Law 'mak[es] German constitutional patriotism a rather Catholic affair and heighten[es] risks of policy distortion'.[24] It is true that one could read these works to learn more about this German specificity (I have not). But I still think that had we heard a little more on this question in de Boer's book, it would have added significantly to the whole story. The same applies to the discussion of whether and in what ways the changes at the bench during the three decades covered by de Boer affected the GFCC's attitude and exercise of the constitutional review of EU law; as well as to the question of whether the Karlsruhe court's emergence as a favourite door for Euro-sceptics and populists to knock on somehow contributed to their rise in the political arena, and whether this ultimately brought more scepticism within the judicial branch and greater contestation of its judgments.

[24] Michaela Hailbronner, *Traditions and Transformations: The Rise of German Constitutionalism* (OUP 2015) 176; another work by the same author that de Boer cites is 'We the Experts: Die geschlossene Gesellschaft der Verfassungsinterpreten' (2014) 53 Der Staat 425 (the German title translates into 'the closed society of constitutional interpreters').

The specific German legal and political context made me wonder about the democratic credentials of courts. Both authors argue (and I agree) that legislators have greater democratic legitimacy than courts. This holds especially when we look at the matter horizontally, ie the ECJ vis-à-vis the EU legislator,[25] or the GFCC vis-à-vis the Bundestag. But what if we look at things vertically? How much lower is the democratic legitimacy of national constitutional courts vis-à-vis the EU legislator? Constitutional justices are usually selected via qualified majorities through national parliaments although they are not directly accountable to them. But what about the EU legislator? We have the European Parliament as the only institution that is directly elected in a democratic process (although in a number of Member States voter turnout is disappointingly low); indirectly selected commissioners that are accountable to the European Parliament; and indirectly 'delegated' ministers that are accountable to their national parliaments. How legitimate is this legislator from a national perspective? Germany certainly has a strong voice in EU affairs, with the most seats in the European Parliament and greater influence on the voting in the Council. But there, German representatives sit alongside others from different Member States – including some countries that can no longer be considered democratic! Does this matter?

We can also factor in the spatial and cultural proximity of these institutions. EU decision-making is typically seen as more remote from the everyday lives of EU citizens, who are less familiar with the political discussions in Brussels or Strasbourg due to (among other things) a lack of common European media space. However, national constitutional courts (certainly the German one) might be a more regular feature for citizens – eg German citizens are more likely to follow more closely the German media and to be more familiar with political disputes that end up in Karlsruhe. Besides, there is a very liberal interpretation of the rules on standing (*locus standi*) which allows many individuals and groups to bring constitutional challenges in Germany, and so on. Could any of this matter when we discuss the democratic legitimacy of national constitutional courts' review of EU law?

Let us take some examples from de Boer's book. The Maastricht Treaty was agreed unanimously by all Member States, including Ger-

[25] Note, however, that the ECJ is usually considered to enjoy the greatest trust of EU citizens among all EU institutions, as shown by Eurobarometer public opinion surveys. The reasons may be found in its perceived independence, impartiality, or expertise, or lesser exposure to partisan politics. See eg R Daniel Kelemen, 'The Political Foundations of Judicial Independence in the European Union' (2012) 19 Journal of European Public Policy 43; or Eurofound, *Societal Change and Trust in Institutions* (Publications Office of the EU 2018). However, it is also true that 'trust' does not necessarily translate into '(democratic) legitimacy'.

many. In the process of national ratification, which ended up with parliamentary approval, there was political discussion about the merits of the new treaty. So, the national democratic process clearly expressed a (positive) view on the matter. And only then did the GFCC step in to express its own view, which, as we have seen, was based on a defensive and not particularly EU-friendly interpretation of the Basic Law. But other cases were different. In the *PSPP* ruling, the GFCC was not reviewing an EU decision that had been approved in a democratic process in Germany or adopted by the EU legislator. It was a decision made by the unelected and unaccountable European Central Bank (whose validity was subsequently confirmed by the ECJ).[26] Can we say that in this setting it was the GFCC that can be called democratically illegitimate?

This problem raises some interesting questions for de Boer's theory of legitimate constitutional review of EU law, according to which national courts should be deferential to the national political process and democratic choices made therein. So, when it comes to unanimously adopted EU acts – certain regulations, directives, and decisions, including the Treaties – we know that the political branches have already endorsed them. There is therefore something for constitutional courts to defer to. But when it comes to EU acts that do not require unanimity, things may be a bit different. Let us say that a Member State in the Council was against some proposed secondary legislation but ended up among the outvoted. Assuming that the national minister's mandate was deliberated and determined by the national parliament, which happens,[27] should a constitutional court take that into account when presented with a challenge to the adopted EU legislation and defer to the democratic choices expressed in the domestic political process? Although such a scenario might sound hypothetical – but what about Hungary or PiS-ruled Poland? – de Boer's theory invites further exploration in this respect, both as a general matter as well as at the level of individual Member States.

The cure

The last set of remarks I have concern the precepts the authors offer for legitimate judicial interpretation of EU law and for its review by national constitutional courts.

Let us take van den Brink's percept first, his 'golden rule' of interpretation and how to identify legislative intent, which are two prongs of

[26] In Case C-493/17 *Weiss* ECLI:EU:C:2018:1000.

[27] Or worse, if the national legislator objected to the proposed legislation on account of an alleged violation of the principles of subsidiarity and proportionality, as envisaged in Protocol (No 2) on the application of the principles of subsidiarity and proportionality, annexed to the TEU and TFEU by the Treaty of Lisbon.

his theory that he considers to be 'better than other theories at prescribing how meaning must be ascribed to EU law' (at 17).[28]

Firstly, as I have already explained, van den Brink suggests that EU law needs to be interpreted in a way that reflects systemic purposes, even if the outcome is incompatible with a specific substantive purpose. This is how, he continues, the authority of the EU legislator is best respected. So, his theory gives weight to different criteria or standards of interpretation – systemic concerns outweigh the particular. But what he does not develop are meta-criteria for choosing amongst different systemic purposes that in a particular case may pull the ECJ in opposite directions. For instance, if one outcome of interpretation is aligned with legal certainty, hence making the legal obligations predictable, and the other outcome leads to more efficient decision-making which is another important systemic concern, how can we decide which interpretation better represents the political authority of the EU legislator? And can there even be interpretive directives that are both intelligible and useful for the interpreters in these situations (situations that are, I suspect, probably exceptional)?

Secondly, van den Brink's formula for ascertaining the intent of the EU legislator is, as mentioned above, 'literal meaning in context'. And the 'context' includes everything (except in certain cases the Treaties), from related legislative acts, the objectives of those acts, preambles, legislative history, and so on. But here again, what we do not have are criteria for 'breaking the tie' when different pieces of this context point to different conclusions. For instance, the literal meaning of a provision may indicate one thing about the legislative intent, whereas its objective or legislative history or other provisions may suggest another.[29] There is nothing in van den Brink's theory to assist us or the ECJ in navigating this interpretive difficulty, except perhaps to say the following: 'when the theory runs out, anything goes, but these are extremely rare cases in which there is nothing anyway to constrain judicial discretion'. Perhaps in those cases we enter 'into the deepest waters of normative constitu-

[28] Among these other theories, he counts instrumentalism, purposivism, and textualism.

[29] The only thing I could distinguish is between legally binding and legally non-binding elements of legal context: the enacted text of legal provisions and their objectives clearly stated in the operative parts of the legislative acts would belong to the former, whereas the preambles of legislative acts and their legislative history would belong to the latter. cf Case C-162/97 *Nilsson and Others* ECLI:EU:C:1998:554, para 54: '[T]he preamble to a [Union] act has no binding legal force and cannot be relied on as a ground for derogating from the actual provisions of the act in question'; and Joined Cases C-283/94, C-291/94 and C-292/94 *Denkavit Internationaal* ECLI:EU:C:1996:387, para 29: 'Expressions of intent on the part of Member States in the Council [...] have no legal status if they are not actually expressed in the legislation'.

tional and political theory'[30] in which no legal theory can offer conclusive solutions.

Van den Brink's theory of interpretation of EU law raises additional important questions. These concern the claim that the Treaties (and the ECJ's interpretations of them) should not count as part of the relevant legislative context if this prejudices the legislative intent. One potential issue, in my view, is not that this approach would reverse the traditional hierarchy of sources – making secondary law, in a sense, superior to primary law,[31] but that the political authority of the (current) legislator would seem to count for more than the authority of the (historical) Treaty-maker (ie constitution-maker). There may be a way out for van den Brink's theory on this point, but I am not sure that he goes on to address it adequately in the book. After all, the Treaty-makers have established a system in which it is the task of the ECJ to 'ensure that in the interpretation and application of the Treaties the law is observed'. And the Treaties have been subjected to constitutionally defined ratification procedures in every Member State, involving either qualified majorities in the parliament or popular referenda. I wonder what van den Brink's take would be on this question of political authority of the EU constitution-maker and whether it affects his theory of interpretation.

The claim that the Treaties (and the ECJ's interpretations of them) should not feature in the determination of the legislative intent also leaves us with the following question – what about the Charter? The Charter, after all, has the same legal value as the Treaties. Van den Brink's theory suggests that the Charter forms an important part of the relevant context, but likewise needs to be construed narrowly – again, in order not to prejudice the legislative intent. In reality, as van den Brink himself shows (Chapter 4), the ECJ regularly leaves the Treaty somewhat aside when interpreting secondary law. But in my estimate, it never (or very exceptionally) leaves out the Charter, either when interpreting legislation in conformity with the Charter or in subjecting legislative choices to the proportionality test. Does this make the Charter hierarchically superior to the Treaties? Is the Charter, perhaps in conjunction with the values enumerated in Article 2 TEU – which mostly lists fundamental

[30] The phrase is from Neil MacCormick, 'Argumentation and Interpretation in Law' (1995) 9 Argumentation 467, 479.

[31] And the explanation van den Brink offers is that the interpretation of the Treaties is not an exclusive domain of the ECJ, but that the EU legislator legitimately co-interprets it. In this sense, we would only have primary law being interpreted to accommodate a particular formulation of secondary law and thus retain its validity; or, the EU legislator's version of primary law, in which the adopted legislation would fit, would be higher than the ECJ's version of primary law.

rights anyway, which make up more than half of the twelve values found in that provision – the real *Grundnorm* of the EU legal order?[32]

Let us move on to de Boer's precept for the legitimate constitutional review of EU law, which requires greater judicial deference to the choices made in the democratic political process. His general claim is that we need 'more room for political decision-making that allows for conflict and disagreement' as well as 'more democratic politics, not more courts' in the EU (at 296). (Martijn van den Brink would probably agree and for his part say that we need more demoi-cracy in the EU.)

Our understanding of democracy (and politics) is probably conceived with the historical experiences of European nation-states in mind. But there is always the question of the 'translatability' of normative concepts from the national/state context to the EU setting.[33] How successfully can we transfer the concept of democracy from national contexts – requiring, among other things, political equality, accountability, majority rule, and a certain proximity of decision-making to the citizenry – to a specific supranational context where all those things are lacking, and where we have no European demos nor a proper political sphere in the first place? And what can we expect from attempts to inject more democracy of this sort into the Union, especially in an era of lasting crisis of liberal constitutional democracy everywhere? An era in which at least one legislative seat (in the Council) is permanently occupied by a State which no one considers to be democratic anymore... Perhaps the solution for the EU lies in less traditional democracy (although not necessarily in more judge-made law).

At the same time, some could argue that EU integration was launched and developed precisely to escape the (democratic) conflicts, disagreements, and contestations that de Boer calls for, for better or for worse. They may say that the EU was made to prevent clashes over political ideologies and different theories of democratic or 'good' society, which would lead to its collapse.[34] Therefore, we have the central role of

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[32] cf the discussion in Luke Dimitrios Spieker, 'A Turn to Hierarchy: Conceptualising Substantive Hierarchies in EU Primary Law' in Luigi Lonardo and Alezini Loxa, *The Reasoning of the Court of Justice of the EU: A Normative Assessment* (OUP 2026, forthcoming), who proposed a hierarchical, pyramidal reorganisation of EU primary law: the founding values from Article 2 TEU as the EU's constitutional core at the top, the provisions of the Treaty and Charter that give specific expression to EU values as the EU's 'proper' constitutional law at the level below, and the remaining provisions of EU primary law as the EU's 'ordinary' constitutional law at the third and final level.

[33] Discussed recently by none other than Martijn van den Brink, 'Political, Not (Just) Legal Judgement: Studying EU Institutional Balance' (2024) 3 European Law Open 89.

[34] cf Andrew Williams, 'Taking Values Seriously: Towards a Philosophy of EU Law' (2009) 29 Oxford Journal of Legal Studies 549.

law, legalism, and courts (European and national),[35] all in the service of economic integration built around a common market, which ought to guarantee the survival of sovereign European nations in a globalised world. Perhaps van den Brink and de Boer are right when they say that we have reached the limits of the idea of 'integration through law' in the EU, and that things need to be changed, democratised, and politicised. But perhaps they are not right. Either way, the debate is far from over.

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The two monographs I have discussed in this review are exceptional pieces of scholarship. They complement and build upon each other so well that they can be read side by side, almost as if they were the product of a single mind.

The opening chapters are particularly strong, where the authors expound on the theoretical backgrounds to their analyses. Yet they do not merely reproduce existing knowledge in legal theory and the philosophy of legal interpretation, judicial review, or the legitimacy of courts and legislators. They offer many original insights, and link general points found elsewhere to the EU multi-level legal and institutional context. For this reason, both books can be recommended to anyone interested in these fundamental topics of EU constitutional law (and everyone should indeed have an interest in them). The authors address complex topics in clear and elegant prose, making the books suitable for both students and senior scholars. Given their extensive use of case law, they should be interesting and useful material for legal practitioners, too, including judges.

Some minor issues I had upon completing both books, as I have described them here, left me slightly underwhelmed. After they started so strongly, drawing me in with carefully constructed arguments from chapter to chapter and progressing without losing momentum or thrill, I expected a finale that would knock me off my feet. That did not happen, alas! But this is no fault of van den Brink or de Boer. Perhaps it is unreasonable to expect that there will come a book to completely transform one's thinking about law and courts. Still, these two kept me thinking hard, as I hope can be seen from these lines.

[35] cf Signe Rehling Larsen, 'Varieties of Constitutionalism in the European Union' (2021) 84 Modern Law Review 477, 482ff, describing the EU's constitutionalism as a variation of a post-fascist constitutionalism, which is borne out and grounded in a 'fear of the people' and works to prevent 'an "excess" of democracy', and whose characteristics are strong counter-majoritarian institutions, extensive judicial review, '[a] highly formalised, legalised and depoliticised [and hence constrained] understanding of democracy' in which 'the Constitutional Court [in the EU, the ECJ] is the unequivocal guardian of the constitution'.

A thought that captures what I want to convey is: 'The Holy Grail, once we have obtained it, always becomes a tin cup'.[36] Yet these books are fascinating and graceful cups indeed.

A final reflection concerns the common theme of these books – what Jeremy Waldron calls 'against judicial review'. One of the classic comebacks of those who do not trust courts to keep the democratic political process in check and save us from slipping into the abyss is that, in the darkest of times, judges remained motionless. They could do little to prevent what was coming, be it the extreme examples of the rise of national-socialism or fascism in the first half of the twentieth century, or some milder examples of democratic and rule-of-law 'backsliding' in certain countries (and not only in the EU) in the early decades of the twenty-first century. I think that as things stand most would agree with this description of historical examples of judicial power(lessness). But I also believe that a better question is this: would people who lived through such times agree? The individuals who went before the courts seeking justice? The dictators-in-the-making or wannabe authoritarians who had to answer some annoying questions coming from the bench, or find a legal argument to evade judicial control, or a way to capture, 'stuff', and subjugate the courts? Were they all indifferent to the judicial branch, convinced that judges are, by and large, irrelevant and impotent, and thus nothing to be worried about? That, to me, is the question that matters.

Suggested citation: D Petrić, 'Courts on Trial: In Search of Legitimate Interpretations and Reviews (Book Review Essay)' (2025) 21 CYELP 175.

[36] Found in JC Smith, 'Machine Intelligence and Legal Reasoning' (1998) 73 Chicago-Kent Law Review 277, 309.