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TABLE OF CONTENTS

ARTICLES

CASE NOTE

TICKING THE HOHFELDIAN BOX – AGAINST WHOM AND FOR WHOM IS TRADE SECRET PROTECTION?

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The famous box-ticking device known as the Hohfeldian scheme has been used to analyse various types of legal phenomena and stating the schemes usability is almost a platitude. However, this article presents how advantageous the scheme is within the ever-growing legal regime related to information rights. Using trade secrets and their regulation by the European Union's Trade Secret Directive as a relatively established example, this article depicts how the Hohfeldian scheme assists in defining the subject matter of trade secret protection and the parties' rights and obligations with precision, thus offering an example of how there is not only one right holder within the trade secret right context, but actually the trade secret remedy structure distributes several Hohfeldian basic positions to various subjects. However, when applying the scheme, the sui generis definition of trade secrets and their nature as an information right requires the scheme to be applied meticulously.

1 INTRODUCTION

Although in daily discussions people tend to refer insouciantly to owning trade secrets, trade secrets are considered a private property right neither in the analytical bundle of rights-sense implicit in the common law system, nor in the holistic view of the civil law tradition.[1] Nor are they categorised as private property rights in their international regulation attempts. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), a compulsory agreement for the members of the World Trade Organization (WTO),[2] placed undisclosed information within the unfair competition discipline as contrary to the possibility to grant exclusive rights. Similarly, the European Union's Directive on Trade Secrets (the Trade Secret Directive, TSD)[3] stipulates unambiguously that 'in the interest of innovation and to foster competition', the directive should not create any exclusive right to know-how

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[1] On the different property systems, see Yun-chien Chang and Henry E Smith, 'An Economic Analysis of Civil versus Common Law Property' (2012) 88 Notre Dame Law Review 1, 7.

[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C (opened for signature 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299. International protection for trade secrets can be traced to the TRIPS agreement, which contains Article 39 on the effective protection of trade secrets against unfair competition as provided in Article 10bis of the Paris Convention (1967). According to the Paris Convention, member states must provide effective protection against unfair competition. As an expression of this choice the TRIPS refers to a person 'in control' of undisclosed information, not to ownership.

[3] Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure [2016] OJ L157/1 (Trade Secret Directive). The Directive entered into force by the 5th of July 2016, with member states having an obligation to implement it by the 9th of June 2018.

or information protected as trade secrets,[4] and states that trade secrets are 'a complement' or 'an alternative to intellectual property rights'.[5] The question is further confused as trade secrets are in fact safeguarded as a constitutionally protected property right in some jurisdictions.[6] Perhaps as a repercussion of the uniquely defined subject matter, the legal categorisation of the trade secret right as a legal right is still under debate among legal scholars.[7] Categorisation of a legal entitlement is significant, because in our system with multiple, customary categories of rights, different conceptualisations of a right lead to different effects and remedies, and thus categorisations have substantial practical consequences.[8]

In today's information era data and knowledge are increasing their value as assets.[9] Information has been called the most important primary good in the society allocating power and affecting development of knowledge.[10] Trade secrets are not immune to the challenge of the modern era, where a wider group of assets and resources are fit under the term 'property'.[11] A recent study has revealed that albeit the introduction of a legal definition of the 'trade secret' in the TSD, a considerable uncertainty of what constitutes a trade secret remains within the industry.[12] Presumably the confusion results partly from the term 'trade secret' referring to two concepts: both the piece of information that the holder wants to protect, and the enforceable legal rights the holder gains against others from holding the piece of information.[13] This paper addresses the second concept as a part of the on-going debate on what kind of legal rights trade secrets are. The target is not to distinguish which genus trade secrets should be classified to, but to analyse trade secret regulation through analytical methods to gain detailed information on which and whose enforceable legal rights does the current European Union trade secret protection's remedy structure represent in practice. The assumption is that treating trade secrets as belonging to a certain genus would

[4] Trade Secret Directive, recital 16.

[5] Trade Secret Directive, recital 2.

[6] Nari Lee, 'Hedging (into) Property? Invisible Trade Secrets and International Trade in Goods' in Jonathan Griffiths and Tuomas Mylly (eds), *Global Intellectual Property Protection and New Constitutionalism - Hedging Exclusive Rights* (Oxford University Press 2021) 108.

[7] William M Landes and Richard A Posner, *The Economic Structure of Intellectual Property Law* (Belknap Press 2003) 355; Mark A Lemley, 'The Surprising Virtues of Treating Trade Secrets as IP Rights' in Rochelle C Dreyfuss and Katherine J Strandburg (eds), *The Law and Theory of Trade Secrecy: A Handbook of Contemporary Research* (Edward Elgar Publishing 2011) 109; Lee 'Hedging (into) Property?' (n 6) 106–107. See generally Lionel Bently, 'Trade Secrets: "Intellectual Property" but Not "Property"?' in Helena Howe and Jonathan Griffiths (eds), *Concepts of Property in Intellectual Property Law* (Cambridge University Press 2012).

[8] Henry E Smith, 'Emergent Property', *Philosophical Foundations of Property Law* (Oxford University Press 2013) 320–321; Lee, 'Hedging (into) Property?' (n 6) 106–107.

[9] Henrik Udsen, Jens Schovsbo & Berdien van der Donk, 'Trade Secrets Law as Part of Information Law' in Jens Schovsbo & Thomas Riis (eds), *The Harmonization and Protection of Trade Secrets in the EU - An Appraisal of the EU Directive* (Edward Elgar Publishing 2020) 25.

[10] Peter Drahos, *A Philosophy of Intellectual Property* (ANU Press Textbooks 2016) 199.

[11] Kevin Gray, 'Property in Thin Air' (1991) 50 The Cambridge Law Journal 252, 298. See also Ulla-Maija Mylly, 'Preserving the Public Domain: Limits on Overlapping Copyright and Trade Secret Protection of Software' (2021) 52 IIC 1314, 1315.

[12] European Commission, European Innovation Council and SMEs Executive Agency, Alfred Radauer, Martin Bader, Tanya Aplin, Ute Konopka, Nicola Searle, Reinhard Altenburger, Christine Bachner, 'Study on the legal protection of trade secrets in the context of the data economy: final report' (Publications Office of the European Union 2022) 75. The European Court of Justice has not yet addressed the TSD in its case law.

[13] Jorge L Contreras, 'Ownership and Assignment of Intellectual Property' in *Intellectual Property Licensing and Transactions: Theory and Practice* (Cambridge University Press 2022) 41. Contreras argues that 'the assignment of trade secrets is perhaps the least developed and understood among IP types'.

advance our understanding limitedly if we do not comprehend the normative functions of the right.[14]

The mantra-like repeated premise of the trade secret jurisprudence – both in legislative documents and in scholarly articles – is the principle that trade secret protection does not grant exclusive rights over information, as the same information can be lawfully held by multiple actors simultaneously. Currently, trade secret protection has been understood as a liability rules regime, where 'protection seems to be a form of compensation for broken promises, or a punishment for wrongdoing or causing harm'.[15] In this article, the classical Hohfeldian scheme is used as an analytical device capable of describing the trade secret holder's relation to various others[16] and vice versa, as well as how are these relations affected by the remedy structure provided via the TSD. Hohfeldian evaluations of the trade secret right have been committed before in legal literature, for example Michael Risch has listed rights and duties abstracted from the (United States) trade secret right.[17] However, no detailed analysis of how are legal entitlements formed within existing trade secret remedy structure have been found by the author. The aim of this article is partly to present how a remedy structure concerning trade secrets creates and distributes several Hohfeldian basic positions to various subjects in a manner that when recognised aids in understanding how the interests of several actors are balanced within the remedy system.

After this introduction, the article proceeds to introducing the basics of Hohfeld's scheme, its relation to property rights and the choice of the directive for the subject matter of the analysis. In the subsequent sections the scheme is applied to the trade secret right as it is construed by the TSD. The subsections are titled based on whose entitlements or disabilities constitute the focus, although the Hohfeldian incidents of other parties are also on some occasions studied in the same subsection. Due to spatial limitations and for the purpose of this article, it is sufficient to focus on Article 10 of TSD containing provisional and precautionary measures, and Article 12 containing injunctions and corrective measures once a case has been decided on the merits. A short summary will be presented lastly. The findings indicate that not only does the Hohfeldian scheme offer a precise way to define what the trade secret right entails in theory as well as in practice, but the scheme also aids in distinguishing when the trade secret 'thing' exists as well as to whom does the remedy structure distribute rights.[18]

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[14] Jerome H Reichman, 'How Trade Secrecy Law Generates a Natural Semicommons of Innovative Know-How' in Rochelle C Dreyfuss and Katherine J Strandburg (eds), *The Law and Theory of Trade Secrecy - A Handbook of Contemporary Research* (Edward Elgar Publishing 2011) 187.

[15] Nari Lee, 'Open Yet Secret – Trading of Tangible Goods and Trade Secrets' in Niklas Bruun, Graeme B Dinwoodie, Marianne Levin, Ansgar Ohly (eds), *Transition and Coherence in Intellectual Property Law: Essays in Honour of Annette Kur* (Cambridge University Press, 2020) 242, 244.

[16] Henry E Smith, *Property as the Law of Things* (2012) 125 Harvard Law Review 1691, 1696. For example Honoré has criticised Hohfeld for not noticing or not minding that Hohfelds axioms render impossible many of the uses of 'a right to which lawyers and laymen are accustomed'. Honoré does have a point, and it is worth to state that in this article, the Hohfeldian scheme is used as a tool, not as all-encompassing definition of reality. Anthony Maurice Honoré, *Rights of Exclusion and Immunities Against Divesting* (1960) 34 Tulane Law Review 453, 456.

[17] Michael Risch, 'Why Do We Have Trade Secrets?' (2007) 11(1) Marquette Intellectual Property Law Review 3, 24–25 In the article Risch is using the terms 'right' and 'duty' without distinguishing which Hohfeldian deontic position he refers to, but it becomes apparent that in the list 'right' must denote at least claim-rights and privileges.

[18] In this article, the term right is used to refer to all the Hohfeldian entitlements defined below.

2 METHOD: THE HOHFELDIAN SCHEME

2.1 THE SCHEME AND ITS NUANCES

Hohfelds influence has been momentous (his article from 1917 has over 7000 citations according to Google Scholar[19] and to celebrate his centennial impact a novel publication collecting commentaries on his work by notable scholars has recently been issued).[20] Thus, explaining the most-influential piece of his work, the well-known scheme of deontic positions, is a task where one easily tumbles in to either truisms or nuances. However, as the basics of his scheme are vital for understanding the following analysis and suggestions made in this article (and as I perceive the scheme having a lot to offer within information law jurisprudence), a brief explanation shall now ensue.

Wesley Newcombe Hohfeld was a United States legal scholar who claimed in his two articles from 1913[21] and 1917[22] that legal practitioners used ambiguous concepts, such as the term 'right', without defining these concepts properly, which lead to error in reasoning. To demonstrate, he dissected the term 'right', and created his often-cited table of eight different basic positions, which he called 'the lowest common denominators of the law'.[23] In his scheme, the basic positions contain no inherent value, but four of these eight attributes have been called entitlements (the claim-right, privilege/liberty, power, and immunity), and four disablements (duty, no-right, liability, and disability).[24] Each entitlement and disability have an unique correlation and the relationship between the holder of the entitlement and the holder of the correlative forms what Hohfeld called a jural relation.[25] Although Hohfeld was not the first to acknowledge and name different subcategories contained in the concept of a legal right,[26] instead of merely listing the subgroups, he organised them in relation to each other and thus created a scheme which has induced legal scholars to be used as a legal analytical tool while studying almost any kind of legal conundrums. His scheme is often presented as a table:[27]

Jural Opposites	right no-right	privilege duty	power disability	immunity liability
Jural Correlatives	right duty	privilege no-right	power liability	immunity disability

Table 1

[19] On the 15th of January 2023 the number of citations was 7502.
[20] Shyamkrishna Balganesh, Ted M Sichelman and Henry E Smith, *Wesley Hohfeld A Century Later: Edited Work, Select Personal Papers, and Original Commentaries* (Cambridge University Press 2022).
[21] Wesley Newcomb Hohfeld, 'Some Fundamental Legal Conceptions as Applied in Judicial Reasoning' (1913) 23(1) The Yale Law Journal 16.
[22] Wesley Newcomb Hohfeld, 'Fundamental Legal Conceptions as Applied in Judicial Reasoning' (1917) 26(8) The Yale Law Journal 710.
[23] Hohfeld 'Some Fundamental Legal Conceptions as Applied in Judicial Reasoning' (n 21) 58.
[24] Hohfeld did not himself use the words entitlement or disablement, but as they are descriptive for the two categories, they are used here.
[25] As he wanted to include both legal and equity-based relations, therefore the term jural.
[26] John W Salmond, *Jurisprudence or The Theory of the Law* (Stevens & Haynes 1902). See especially chapter X 'Legal Rights'. As Finnis has noted, all the Hohfeldian types of rights where already spoken of by Aquinas. See John Finnis, 'Natural Law: The Classical Tradition' in Jules L Coleman and Scott Shapiro (eds), *The Oxford Handbook of Jurisprudence and Philosophy of Law* (Oxford University Press 2004) 24.
[27] Hohfeld 'Some Fundamental Legal Conceptions as Applied in Judicial Reasoning' (n 21) 30.

By 'right' Hohfeld meant the term to be understood in the 'strict sense', for which a synonym 'claim' could be used.[28] Many today speak of the claim-rights, as will also this article. The correlate of the claim-right is a duty, and thus the jural relation may be expressed as if I have a *claim-right* that you pay me 100 dollars, you have a *duty* to pay me 100 dollars. A holder of a claim-right, in the Hohfeldian sense, has an entitlement that *someone else* either commits an action or refrains from committing an action. Thus, the Hohfeldian claim-right does include negative rights, that is for example the property owners the right to prevent others from interfering with the property. One example of a negative right would be a copyright holder's right that others do not commercially exploit their book.[29] In the Hohfeldian system this 'right' would be classified as the holders claim-right that outsiders not exploit the book, which would correlate with a duty of an outsider to refrain from exploiting the book.

A claim-right therefore does not depict what the holder of the claim-right may or may not do themselves – as if the deed in question is to be done or not done by the holder of the entitlement, the entitlement is labelled in the Hohfeldian system as a privilege. Thus, the privilege concerns something that its holder 'has a right to' do or not do. The correlate of the privilege is the no-right (that is – no claim-right) held by another subject that the holder of the privilege does (or not) commit a certain action. To illustrate the definition, it may be stated that when I hold a legal privilege to roam around my garden, my neighbour has a legal no-right that I do not roam there (that is – they cannot legally use remedies to not to have me roam around my garden). The no-right is probably the most controversial of the positions, and it will be further addressed below. One aspect of the scheme is that a particular jural relation – the deed and the parties – will not reveal anything about other jural relations. The claim-right of A that B stay off A's property correlates with B's duty to stay off A's property, but signals nothing on other jural relations: for example, of A's liberty to use their property themselves. Of course, both may be found as atomic elements under an umbrella idea of A's right to their property. As Drahos has noted, for Hohfeld property rights are 'a kind of institutionalized open-ended contractual relation into which an indefinite number of people can enter with the property owner, but which remains a relation between the right holder and the duty bearer'.[30] It might also surprise a reader not familiar with the scheme that a person may have both a privilege and a duty simultaneously, as if X would make a contract with Y that X enters his own land (for example to be available should Y need them), then X has both the privilege held by him as an owner of property to enter their own land, but simultaneously X would have towards Y the duty to enter the property.[31]

The elements of the two first columns are called first-order positions, and the remaining four higher- or second order positions. The latter describe whether a person can change a jural relation, or whether or not person is bound by such change by someone else. If I hold a power towards you and a certain jural relation between us, I have volitional control to alter a legal relation among us concerning a certain action. Returning to the example concerning debt, the holder of the debt usually has a power to discharge the debt and simultaneously the correlating duty. Power is also something a property holder has when they *have a right* to transfer the title to an object by selling it: thus, the person acquiring the

[28] Hohfeld 'Some Fundamental Legal Conceptions as Applied in Judicial Reasoning' (n 21) 30, 32.
[29] Drahos (n 10) 248.
[30] Drahos (n 10) 175.
[31] Hohfeld 'Some Fundamental Legal Conceptions as Applied in Judicial Reasoning' (n 21) 32.

object will gain all the rights relating to the object simultaneously as the rights (the claim-rights, privileges, powers, and immunities) of the seller will be extinguished. Liability on the other hand is the correlative of power: to be bound by alterations the power holder does regarding certain legal relations. Immunity is the correlative of disability ('no-power') and the negation of disability. If I hold a property, I have various immunities against others – and simultaneously others have a corresponding number of disabilities. As an example, others have 'no-power' to sell my property or grant others privileges to roam around by property – I would be immune to such attempts.

Lastly, an important detail regarding the following analysis on trade secrets is Kramer's division between general (or abstract) and concrete (or specific) entitlements:

> A general entitlement comprises an indefinite number of specific entitlements that instantiate it or develop it. A right against being assaulted, for example, encompasses any number of rights against being assaulted in specific ways. Of course, because generality and concreteness are matters of degree, an entitlement E can be general in relation to an entitlement F and concrete in relation to an entitlement G. For example, while the right against being assaulted is abstract vis-a-vis the rights against being assaulted in specific ways, it is specific vis-à-vis the abstract right to security.
>
> An important aspect of the relationship between general and specific entitlements is that a general entitlement can lead to new specific entitlements as circumstances evolve.[32]

Hohfelds scheme is seemingly uncomplicated, but its simplicity is partly a misnomer. As Finnis has stated, 'a superficial familiarity with the terms of the scheme spreads darkness rather widely'.[33] Exemplified by recent contributions by academics, the debate concerning the scheme is still ongoing.[34]

In this article, the scheme is chosen as a tool because albeit the fascinating and high-level legal discussion on criticism and counter-criticism the scheme has received, it has been continuously employed by different scholars in describing different areas of legal practice.[35] Kit Barker has suggested that

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[32] Matthew H Kramer, 'Rights Without Trimmings' in Matthew H Kramer (ed), *A Debate Over Rights. Philosophical Enquirie.* (Oxford University Press 1998) 42.

[33] John Finnis, 'Some Professorial Fallacies about Rights' (1972) 4 Adelaide Law Review 377, 382.

[34] Heidi M Hurd and Michael S Moore, 'The Hohfeldian Analysis of Rights' (2018) 63(2) American Journal of Jurisprudence 295; Matthew H. Kramer, 'On No-Rights and No Rights' (2019) 64(2) American Journal of Jurisprudence 213, 214; Andrew Halpin, 'No-Right and Its Correlative' (2020) 65(2) American Journal of Jurisprudence 147; Heidi M Hurd and Michael S Moore, 'Replying to Halpin and Kramer: Agreements, Disagreements and No-Agreements' (2019) 64(2) The American Journal of Jurisprudence 259; Mark McBride, 'The Dual Reality of No-Rights' (2021) 66(1) The American Journal of Jurisprudence 39.

[35] Kit Barker, '"Damages without Loss": Can Hohfeld Help?' (2014) 34 Oxford Journal of Legal Studies 631; Christopher M Newman, 'Vested Use-Privileges in Property and Copyright' (2017) 30 Harvard Journal of Law & Technology 75; Samia A Hurst and Alex Mauron, 'Assisted Suicide in Switzerland: Clarifying Liberties and Claims' (2017) 31(3) Bioethics 199; Andrew C Michaels, 'Patent Transfer and the Bundle of Rights' (2018) 83(3) Brooklyn Law Review 933; Adam Reilly, 'Is the "Mere Equity" to Rescind a Legal Power? Unpacking Hohfeld's Concept of "Volitional Control"' (2019) 39(4) Oxford Journal of Legal Studies 779; Itamar Mann, 'The Right to Perform Rescue at Sea: Jurisprudence and Drowning' (2020) 21(3) German Law Journal 598.

> Hohfeld's modern relevance is in part a facet of the durable, scientific objectivity of his analytical technique and, in part, of its disciplining nature and utility at a point in time in which rights have become highly politically charged and the set of legal relationships existing between the state and its citizens is more intricate than ever.[36]

This article does not seek to contribute anything new to the discussion on the essence of the Hohfeldian incidents but aims to present what may be done with the scheme regarding the legal protection of a non-exclusive information related right that trade secrets right is. Hohfeldian scheme offers a way to overcome conceptual ambiguity concerning the 'object' of the trade secret right and it assists in governing trade secrets not as 'things' existing in the legal practice, but more as something that the owner's relative rights attach to. The lack of a protected thing distinguishes trade secrets from property rights, which are understood to relate to 'things', to be rights in rem, contrasted to rights in personam related to obligations. It was partly Hohfelds understanding of the actual similarities between rights in rem and rights in personam, that led to challenging the rem/personam distinction.[37]

Since partly this article addresses the Hohfeldian no-right, the perhaps most unknown of his eight positions, it must be stated how the writer understands the no-right. The term no right has recently received attention from respectable scholars, whose recent contributions present how the deontic position of the no-right still raises a debate.[38] In this article, the deontic position of the no-right is used in a manner consistent with Hohfelds formulation of the no-right:

> Passing now to the question of 'correlatives,' it will be remembered, of course, that a duty is the invariable correlative of that legal relation which is most properly called a right or claim. That being so, if further evidence be needed as to the fundamental and important difference between a right (or claim) and privilege, surely it is found in the fact that the correlative of the latter relation is a 'no-right', there being no single term available the express the latter conception. Thus, the correlative of X's right that Y shall not enter on the land is Y's duty not to enter; but the correlative of X's privilege of entering himself is manifestly Y's 'no-right' that X shall not enter.[39]

Albeit Mathew Kramer, well-known academic, has challenged Hohfelds own perception on the no-right as mistaken and offered workable definition of the deontic position,[40] this article does not depart from Hohfelds own description, which despite Kramer's criticism has been maintained as such within the academic discussion.[41]

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[36] Kit Barker, 'Private Law, Analytical Philosophy and the Modern Value of Wesley Newcomb Hohfeld: A Centennial Appraisal' (2018) 38 Oxford Journal of Legal Studies 585, 586.
[37] Ole-Andreas Rognstad, *Property Aspects of Intellectual Property* (Cambridge University Press 2018) 43–44.
[38] Hurd and Moore 'The Hohfeldian Analysis of Rights' (n 34); Kramer 'On No-Rights and No Rights' (n 34); Halpin 'No-Right and Its Correlative' (n 34); Hurd and Moore 'Replying to Halpin and Kramer: Agreements, Disagreements and No-Agreements' (n 34); McBride (n 34).
[39] Hohfeld 'Some Fundamental Legal Conceptions as Applied in Judicial Reasoning' (n 21) 33.
[40] Kramer 'On No-Rights and No Rights' (n 34).
[41] Hurd and Moore 'Replying to Halpin and Kramer: Agreements, Disagreements and No-Agreements' (n 34).

2.2 THE SCHEME AND REALITY – A CASE FOR TRADE SECRET ANALYSIS

The supposition of this article is that Hohfeld's scheme is useful for trade secret analysis because the legal trade secret right and the actual thing, the trade secret information, are uniquely entangled for two reasons: the lack of publicly known depiction of the protected artefact and the sui generis legal definition. Therefore, differentiating the 'thing', that is the legal thing, in trade secret cases is especially difficult, although vital, as the legal thing defines the scope of legal protection.

Hohfeld diligently differentiated purely legal relations from the physical and mental facts. The legal and the non-legal quantities are so often confused and blended,[42] in Hohfeld's view, firstly because of their close association, and secondly because of ambiguity and looseness of legal terminology. As an example of the first reason, the term 'property' may be used to denote the subject of property, the physical object, but as frequently it refers to the legal interest or legal relations belonging to a physical object.[43] The second reason, the difficulty of mixing the legal concept with the physical entity, originates from history as many words were initially applicable to physical things.[44] Continuing with the example of property right, distinguishing the physical entity from the legal, intangible relations of owning a property is central. Concerning trade secret regulation, where no publicly known artefact is distinguishable from the legally protected entity, applying Hohfeld's approach invites accuracy.

Hohfeld's notion of physical and legal aspects resonates with Henry E. Smith's division between 'actual things in the world and legal things', and the involvement of these two kinds of 'things' in property.[45] Although the distinction of 'legal' and 'real' things is traditional, the two things are ever more blended in today's information society. For example, copyrights and patents are increasingly seen as things.[46] Legally, a trade secret right is not a right over any tangible thing,[47] but a 'thing' made by law – by what Madison calls thing-by-policy,[48] and hence the separation of the legally created and regulated (and secret) 'thing' from the 'real thing' is, as this article will later show, more delicate compared to things that are independent of the legal system or created by either publicly accessible or documented declarations.

The entanglement of things, words and legal rights is meaningful. Cohen described already in the 1930s 'thingification' as an occurrence in the field of unfair competition where courts examine commercial words and find inhering in them property rights, as the rights would be something pre-existent and the courts merely recognise them. When a property right is discovered, it entitles the plaintiff to an injunction or an award on damages, and thus

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[42] Hohfeld 'Some Fundamental Legal Conceptions as Applied in Judicial Reasoning' (n 21) 20.
[43] ibid 21.
[44] ibid 24.
[45] Henry E Smith, 'Semicommons in Fluid Resources' (2016) 20(2) Marquette intellectual property law review 195, 200.
[46] Michael J Madison, 'Law as design: objects, concepts, and digital things' (2005) 56(2) Case Western Reserve Law Review 381, 383–384. Madison gives an example of copyrights thingness the way we call copyright infringements 'stealing' (385).
[47] Julie E Cohen, 'Overcoming Property: Does Copyright Trump Privacy?' [2002] Journal of Law, Technology & Policy 375, 815. Julie Cohen has noted that although copyright law gives copyright owners right in works, not things, it is not correct to say that copyright owners could have no rights in the things embodying their works as copyright law does give the owners rights in things as proxies for rights in works.
[48] Madison (n 46) 386.

in the course of the proceedings in unfair competition cases the courts actually create and distribute a new source of economic wealth or power.[49] Trade secrets, indeed a member of the unfair competition regime, function similarly as property rights in Cohen's example as when a trade secret is found present, its holder is acknowledged to hold rights to certain remedies. A trade secret right does not grant exclusivity (and exclusion is controversial in property in general)[50] and the limitations are restricted contrasted to the limitations entailed within property rights.[51] Yet, as holder of a trade secret right does gain the possibility to prohibit others from using the trade secret, it will – following Cohen's example – signal obtaining wealth and power.

In a legal system, the elements of the Hohfeldian scheme, including all that are understood to count as legal rights, are created by the legislator by rules and by the offered remedies. Although in European Union law a Directive is not a directly applicable legal instrument as it requires action by Member States' legal authorities to be implemented in national law,[52] it serves as an example of how trade secrets are created as a legal thing by a legislative text.[53]

The TSD aimed to ensure sufficient and consistent level of civil redress in the internal market in the event of unlawful acquisition, use or disclosure of a trade secret.[54] The increase of dishonest practices aimed at trade secret misappropriation was seen as discouraging creativity and diminishing investment, thus affecting the smooth functioning of the internal market and undermining its growth-enhancing potential.[55] Recital 3, which begins with the term 'open innovation', is a manifestation of the seemingly contradictory but generally accepted basis behind the trade secret regulation: to promote idea exchange by offering functional legal redress for breaches of secrecy. The Directive's preamble accepts the important role of trade secrecy in protecting knowledge exchange between businesses and research institutions in R&D and innovation contexts.[56] Although all EU member states were

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[49] Felix S Cohen, 'Transcendental Nonsense and the Functional Approach' (1935) 35(6) Columbia Law Review 809, 815–6.

[50] Smith 'Semicommons in Fluid Resources' (n 45) 196.

[51] Trade secrets are set apart from property rights because they do not offer exclusive rights, although nothing in property theory requires unlimited rights for property to be considered property. Robert A Heverley, 'The Information Semicommons' (2003) 18 Berkeley Technology Law Journal 1127, 1157.

[52] Julie Dickson, 'Directives in EU Legal Systems: Whose Norms Are They Anyway?' (2011) 17 European Law Journal 190, 194–195.

[53] The fact that EU directives do not address private entities directly does not hinder an analysis on how a norm affects legal relations of private entities, because all legal norms – including those on competence – are ultimately directed towards the courts and other authorities. This is because eventually it is the courts' reactions to the conduct by legal subjects what the norms adjust, even in cases where the norms would direct private individuals. Norms affect private individuals, but the effect is indirect as legal subjects edit their behaviour based on their expectations on courts' reactions. Alf Ross, *Om Ret Og Retfærdighed : En Indførelse i Den Analytiske Retsfilosofi* (2. opl., Nyt nordisk forlag 1966) 45 It might not surprise the reader that reference to scandinavian realism surfaces at some point of this article, as Alf Ross is famous for his Article 'tu-tu', where he addresses the use of legal terms. He notes, regarding property, that the word is not a real thing – 'it is nothing at all, merely a word, an empty word devoid of all semantic reference'. Could we say the same thing about trade secrets?; Alf Ross, 'Tû-Tû' (1957) 70(5) The Harvard Law Review 812. Already Axel Hägerström and Wilhelm Lundstedt wieved that the term 'right' cannot be used to express a concept since it does not refer to any natural facts. Ross viewed that a term 'right' can be used technically, as a tool of representation of various legal positions among people. Jes Bjarup, 'The Philosophy of Scandinavian Legal Realism' (2005) 18 Ratio Juris 1, 12–13.

[54] Trade Secret Directive, recital 10.

[55] ibid recital 4.

[56] ibid recital 3.

bound by the TRIPs agreement at the time of enacting the TSD,[57] there were important differences in the member states' legislation as regards trade secrets – beginning from basics such as the definition of the trade secret.[58] Thus, the Directive is set to harmonise trade secret protection. Regarding the legal nature of the right, the Directive's statement that it does not aim to reform or harmonise the law on unfair competition in general[59] implies that trade secrets would belong to the unfair competition regime.[60] The Directive covers both substantive (Articles 2 to 5) and procedural (Articles 6 to 15) law regarding trade secrets.[61]

3 HOHFELDIAN WAY TO EXPRESS THE TRADE SECRET RIGHT

The focus of this and the two following chapters is on the application of the Hohfeldian scheme on the trade secret right as defined by the TSD. From another angle, the focus is on how the trade secret right defined in the TSD conforms with the Hohfeldian definitions. This article will not consider the distribution of the Hohfeldian incidents between the EU and the Member States but concentrates on how the TSD allocates the incidents among the relevant legal persons affected by a trade secret dispute.

The Hohfeldian scheme requires the content of the jural relation to be accurately specified, and thus forming, what I call, Hohfeldian sentences from the Directive requires a careful review of the Directive as a whole. As the purpose of this study is foremost theoretical, it is sufficient to follow the legislative text despite the occasionally manifold orders, although when applied to an existing trade secret case, an ad hoc assessment on practical details would provide the base for analysis.

The aim of the Directive is to lay down rules on the protection against the unlawful acquisition, use and disclosure of trade secrets (Art 1, point 1). Although not implicitly stated, it becomes clear from the TSD that it is the trade secret holder who is protected.[62] According to Art 2, point 2, a trade secret holder is someone who lawfully controls a trade secret, which in turn is, according to point 1, information that (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) it has commercial value because it is secret; (c) it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret. Art 3 defines lawful acquisition, use and disclosure of trade

[57] Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) [1994] OJ L336/1.
[58] For example, not all member states had adopted national definitions of a trade secret of the unlawful acquisition, use or disclosure of a trade secret, and there was no consistency as regards their civil law remedies. Trade Secret Directive, recital 6. More on the differences between the trade secret legislations of the member states, see Hogan Lovells International LLP, 'Report on Trade Secrets for the European Commission' (23 September 2011) <https://ec.europa.eu/docsroom/documents/38002> accessed 27 January 2023.
[59] Trade Secret Directive, recital 17.
[60] Unfair competition is generally accepted to be one of the disciplines of industrial property. See WIPO, 'Intellectual property reading material' (Geneva 1998) 124, and UNCTAD-ICTSD, 'Resource Book on TRIPS and Development' (Cambridge 2005) 527.
[61] Tanya Aplin, 'The Limits of Trade Secret Protection in the EU' in Sharon K Sandeen, Christoph Rademacher and Ansgar Ohly (eds), *Research Handbook on Information Law and Governance* (Edward Elgar Publishing 2021) 174.
[62] For example, recitals 4, 6 and 7 refer to trade secret *holders* when discussing remedies for trade secrets.

secrets, whereas Art 4 stipulates on the unlawful equivalents in point 2 (unlawful acquisition), point 3 (unlawful use and disclosure) and points 4-5 (third party liability).

In the Hohfeldian sense, following the definition of a trade secret and referring to the holders as A and the possible infringer as B, A's abstract trade secret right would be A's (claim-)right vis-à-vis B that B not unlawfully acquire, use or disclose A's trade secret.[63] All of the elements must be present: A's claim-right encompasses solely unlawful actions as described in Art 4 points 2–5 and applies exclusively to trade secrets as they are defined in Art 2 point 1 (albeit seemingly obvious, the distinction between a trade secret and 'mere information' is worth emphasising). A's trade secret right could also be stated as a claim-right vis-à-vis B that B does not commit actions defined in Art 4.

Contrasted to the general use of the phrase 'to have a right to' a certain liberty, the TSD does not imply anything about A's liberty to actually use the trade secret (apart from the scope of the Directive). Phrase 'to have the right to free speech' exemplifies: the phrase is often used to signal both the liberty-right (to speak) and the related claim-rights,[64] especially to the claim-right that the state shall refrain from ex-ante actions preventing speech. But 'to have a trade secret right' does not similarly indicate a liberty-right to use the trade secret.[65] A's use of their trade secret right might be prohibited due to various other regulations – such as data protection or patent regulation, and so forth. Yet it would be perfectly valid to state that according to the Hohfeldian scheme B has a no-right vis-à-vis A that A not acquire, use, or disclose the trade secret. In this sense, due to the correlative axiom, A would be perceived to be the holder of a liberty – the jural relation is just specifically within the context of the TSD.

The Hohfeldian formation of the trade secret right, as stated above, is abstract (or general).[66] The abstract right itself connotes nothing on enforceability, as the enforceability will occur according to the stipulations of the TSD. When A reckons that its abstract trade secret right is infringed, the norms rooted in the TSD grant A power and liberty to seek redress by issuing a remedy at the court. On the ground of A's requests and based on the details of each actual case, the court will generate more concrete Hohfeldian jural relations based on the original abstract rights between not only the parties, but when necessary, the parties and outsiders as well. Thus, the abstract right-duty -relation is the foundation or a bundle of multiple different and more specific ad hoc duties such as the duty to stop producing an infringing good.[67]

The next chapters will focus on the enforcement mechanisms of the TSD, concentrating on scenarios according to Arts 10 and 12. The analysis is done based on a

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[63] I do not suggest this would be the only way to construe the holders trade secret right, but for the purpose of this article, this is sufficient.

[64] Thomas D Perry, 'Reply in Defense of Hohfeld' (1980) 37(2) Philosophical Studies: An International Journal for Philosophy in the Analyte Tradition 203, 204.

[65] Generally property rights are understood to signal both the liberty to use and the claim-right that others not use, although neither are without exceptions as most of the laws restricting certain types of conduct have an effect on what we may do with our property. See Newman (n 35) 76–77. See generally on the relationship between right to exclude and Hohfeldian liberties Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information* (2007) 116(8) Yale Law Journal 1742.

[66] Kramer 'Rights Without Trimmings' (n 32) 41. Kramer distinguishes between abstract (general) and concrete (specific) rights.

[67] ibid 41. Kramer notes that an abstract entitlement comprises an indefinite number of specific entitlements that instantiate it or develop it.

hypothetical situation where an (alleged) infringement incites the (alleged) trade secret holder to request for remedies. The Articles define the possible legal outcome and include general provisions on the cause of the proceedings. Following the Hohfeldian definition of the trade secret right as described before in this chapter, and the stipulations of the Directive, the aim in the next two chapters is to define which Hohfeldian incidents can be distinguished, and how do the proceedings affect the original trade secret right. Arts 11 and 13, which include circumstances which must be considered when assessing the remedies and thus are significant when balancing the interests of parties outside the dispute (such as the general public), are only addressed limitedly due to space limitations.

4 TRADE SECRET RIGHT IN A STATE OF UNCERTAINTIES: PRECAUTIONARY MEASURES

4.1 GENERAL ASSESSMENTS

Obviously, courts typically assess civil law matters because the parties hold opposing views on rights, duties and other jural relations which they cannot themselves settle, and thus they hand the matter to a public authority. Within the trade secret context, due to the multielement definition of the trade secret right itself, the uncertainty is more profound in the preliminary state before a legal action and covers more aspects than in most property or intellectual property court cases. The uncertainty factor of trade secret cases is linked to there being no material limitations to trade secret subject matter, and the uncertainty surfaces during the proceedings because there has been ex ante no official verification of the existence of the right or substantive communication of the protected intangible object or delineation of a secret's scope by law,[68] and neither has there been any public acceptance on the trade secret right.[69] A judgement on the merits is the first 'official' declaration that there is a trade secret, signalling the existence of A's claim-right that others not unlawfully acquire, use or disclose it. Nevertheless, the existence of a trade secret does not yet state anything regarding the thing B is holding or whether B has acted unlawfully. Although a comparison between what B has acquired and A's trade secret shall be done, identicality of B's and A's objects will not signal a trade secret infringement.

If A charges B for breaking his duty not to infringe A's trade secret right (the claim-right defined above), A can resort to the remedies offered by the TSD. Before the case is decided on its merits, A has the possibility to resort to the provisional and precautionary measures of Art 10. The measures are applicable in a situation of uncertainty: it is uncertain whether B has infringed A's claim-right, and no binding legal proclamation whether A actually is a trade secret holder exists. Of course, uncertainty is a general characteristic of precautionary measures., and different factors are to be considered to proportionality of such a remedy.[70] After the plaintiff has initiated the action with a sincere belief of their trade secret related rights, a possibility that the information does not fulfil the trade secret criteria exists

[68] Lee, 'Hedging (into) Property?' (n 6) 118.
[69] Even after the proceedings there will be no public assessment on whether or not there is a trade secret – not only axiomatically because of the secretive nature of the right but also with regard to Art 9 and 15, which state that the trade secret must remain confidential during the use of remedies.
[70] Trade Secret Directive, art 11.

in a similar manner as there are rejected patent applications and copyright cases where the object of the dispute is found to belong either to someone else than the plaintiff or even to the public sphere. Precautionary measures are meant to be fast, but as stated in Recital 26, the right for a defense and principle of proportionality should still be respected. The requirements for speed and diligence are discordant, which Art 11 addresses by guiding authorities to both request reasonable evidence from the plaintiff, and on what to assess.[71] According to Art 11, it is enough for the court to reach a 'sufficient degree of certainty' that A has a trade secret right and that B has committed an unlawful act regarding the trade secret.[72] Art 11 states multiple circumstances to be taken into account before granting the measures, and as the Article is not subject to minimum harmonisation, the list should be, albeit the wording, interpreted as exhaustive, or at minimum so that the member states cannot maintain or introduce other circumstances in national law to be taken into account if it would strengthen the grounds for awarding an injunction.[73]

Turning to the Hohfeldian assessment of Art 10, the use of remedies creates a new stage on rights – a more concrete stage, where the right and the correlative again hold a similar degree of specificity.[74] A's *general* claim-right that B does not unlawfully acquire, use and disclose A's trade secret could, according to Art 10, lead to concrete entitlements as stipulated in points (a) - (c), which will signal the concrete derivative right-duty relations between A and B.[75] A's claim-right concerning the trade secret may produce via court a concrete entitlement – for example – *the claim-right to have B stop producing the infringing goods* (point b).

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[71] Rafal Sikorski, '*Towards a More Orderly Application of Proportionality to Patent Injunctions in the European Union*' (2022) 53 IIC - International Review of Intellectual Property and Competition Law 31. Sikorski notes that similar factors as provided in Art 13 [similar to that of Art 11] could be considered when granting patent injunctions.

[72] The uncertainty of the occurrence of an infringement seems to be acknowledged within Art 10 as it refers to the alleged infringer. The following Art 11 on conditions of application and safeguards might explain why it is not contained within Art 10, as Art 11 sets three conditions of which the judicial authorities must be recently certain before ordering the measures: a) a trade secret exists, b) the applicant is the trade secret holder, and c) the trade secret has been acquired unlawfully. But as the unlawful conduct is also mentioned in Art 11, it does not satisfactorily explain why the Art 10 refers to the alleged infringer and not to the alleged trade secret holder, a question which is left unresolved for now.

[73] These circumstances are set to balance the interests of the parties other than the trade secret holder. Thomas Riis, 'Enforcement of rights in trade secrets' in Jens Schovsbo, Timo Minssen, & Thomas Riis (eds) *The Harmonization and Protection of Trade Secrets in the EU - An Appraisal of the EU Directive* (Edward Elgar Publishing 2020) 227–228.

[74] 'Suppose, once again, that A is owner of Blackacre, and that B drives his automobile over A's lawn and shrubbery. A's primary right in rem is thereby violated, and a secondary right in personam arises in favor of A and against B, -an "obligatio", to use the term of Mr. Justice Holmes'. A may sue B at law for damages and get, as a result of the "primary stage" of the proceeding, an ordinary legal judgment in personam for (say) $500. Such judgment would "merge" or extinguish A's secondary right in personal together with B's secondary duty, and would create a (new) judgment obligation-right in personam and correlative duty-for the payment of $500. Such judgment would be binding even though the judgment debtor, B, had no assets whatever. Thus, if B's judgment duty is not performed or discharged, a new action can, in most jurisdictions, be based thereon; though in some of the latter costs are denied to the plaintiff if the new action be brought without special reasons'. Hohfeld 'Fundamental Legal Conceptions as Applied in Judicial Reasoning' (n 22) 760.

[75] Kramer 'Rights Without Trimmings' (n 32) 42.

4.2 HOHFELDIAN INCIDENTS DURING TRADE SECRET PROCEEDINGS

4.2[a] A's Power

Point 1 of Art 10 states that the competent judicial authorities may order the remedies *at the request of the trade secret holder,* signalling A's power to create new, concrete entitlements – albeit it happens via enforceable decision by a court. Hohfeld viewed the use of power broadly as any act by which a person volitionally changes the existing jural relations.[76] Therefore, however obscure it might intuitively sound, Hohfelds analytical tool does, by definition, consider that one exercises power when changing existing jural relations by hitting another person in the face.[77] An abstract power encompasses many more concrete power–liability -relations. A would have the power to decide not to seek a remedy through legal proceedings, and after a judgement, they may have the power to decide whether the judgement is enforced against B.[78]

Hohfeld did not himself consider the aspect that in the modern society, A's and B's concrete duties are often imposed by a court order, and not directly by power exercised by the parties themselves.[79] If A's right is infringed upon, A could arguably have a claim-right towards the state that the state provides a means to remedy, but related to power, it would thus be the court, not A, that holds real power to bring about legal alterations to jural relations. Barker has proposed that A could be seen to hold a power to create a power in the court to impose new public duties on B, as the court's power is contingent on A's decision of applying for injunctive relief. If the court could issue an injunctive relief automatically due to A's application, then A could be seen to control B's new duties, but as injunctive relief is technically discretionary, the matter is less clear.[80] Kramer notes that to be 'authorized' by legal or moral norms to demand or waive the enforcement of a claim is formally equivalent to holding a power (conferred by legal or moral norms) which enables one to choose between the demand and the waiver.[81]

Kramer's view is agreeable, although I suggest that the question of who holds power may be understood in the following way: once A issues a request in court, the court becomes under a duty to deal with A's request. Court has a duty towards A in the sense that if the court does not handle A's request, A could appeal to an authority responsible for court supervision. A would have a similar power to appeal should the court act unlawfully, for example by exceed the limits of its discretion. It is under A's volitional control to request a court to issue an injunction, thus bringing about a new claim-right-duty -relation between themselves and the court. Issuing a decision on B regarding duties related to the injunction should not be seen under a volitional control of the court, as the court is bound to decide the case – even if the court would dismiss A's case on procedural grounds. A's power to grant the court power does not mean that A would have to control how the court uses its

[76] On the broad and narrow concept of power, see Reilly (n 35).
[77] Kramer 'Rights Without Trimmings' (n 32) 103–104.
[78] ibid 63.
[79] On the analysis of legal power, see generally Andrew Halpin, 'The Concept of a Legal Power' (1996) 16 Oxford Journal of Legal Studies 129.
[80] Barker "'Damages without Loss": Can Hohfeld Help?' (n 35) 651. A would also impose a power in the court that the court imposes powers among the enforcement authorities.
[81] Kramer 'Rights Without Trimmings' (n 32) 63.

power. Therefore, in this paper the plaintiff A is seen to hold the power in relation to the issuance of injunctions by the court. A's power entails the possibility to outline the subject of the procedure and the injunctions which the court may impose. Thus, in Hohfeldian sense, the point 1 stands for A's power – the right to get alterations to the first-order rights, which here means to give birth to new claim-right-duty-relations between A and B. As is required by the correlative axiom, A's power would correlate with (first of court but ultimately) B's liability.

4.2[b] A's Ostensible Liberty

Simultaneously with the power, A holds a liberty to resort to the remedies (vis-à-vis B – as B would have a no-right that A does not resort to the remedies) and A may withdraw their request any time (although depending on the stage of the proceedings by withdrawing A might impose new duties on themselves, for example the duty to reimburse the defendants costs). Regarding trade secrets, A's liberty to resort to remedies is ostensible as they might not have the possibility to stay passive.[82] A trade secret ceases to be a trade secret once it enters the public sphere and is no longer secret, and the trade secret protection requires its holder to commit to 'reasonable efforts' to maintain secrecy. Therefore, the reason why the trade secret holder needs the court procedure to keep the infringer from disclosing the information does not only derive from preventing the infringer's unjust enrichment from the trade secret, but correspondingly from the aspiration to maintain the (still only supposed) trade secret status of the information. This compulsory element in trade secret injunction cases should be considered when balancing the interests of the parties, as a lack of injunction could lead to the total termination of the trade secret. Interestingly, as volitional control is decisional control over the exercise or non-exercise of the power,[83] the compulsory element of trade secret proceedings also questions whether A has 'volitional control' – a requirement for Hohfeldian power – over the use of the remedies.

4.2[c] B's Immunity or Liability

If the court requests a rejoinder from B (which is not self-evident in precautionary measures that should be fast, though diligent), the possibility to prevent A's request with objections and counterevidence do not signal B's power, because by successfully defending and preventing A's request B would not change any existing jural relation, but only retain the status quo that existed before the procedure. Instead, a successful defense would signal B's immunity vis-à-vis A concerning A's request for alterations to jural relations based on the trade secret right and Art 10. And consequently, B's immunity would signal A's correlating disability. B would maintain against A the liberty to use the intangible 'thing' A would have considered to be their trade secret.

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[82] This is partly acknowledged in recital 26. Robert P. Merges has addressed the issue of limited liberties of intellectual property owners, though he suggests that the existence of a liberty right concerning certain behaviour would entail that third parties could not prevent the behaviour. See Robert P Merges, 'What Kind of Rights Are Intellectual Property Rights?' in Rochelle C Dreyfuss and Justine Pila (eds), *The Oxford Handbook of Intellectual Property Law* (1st edn, Oxford University Press 2018) 68.
[83] Reilly (n 35) 790–791.

Then again, B's defense can be seen as applying power over court – as it would impose the court with a duty vis-à-vis B to take B's statement into consideration and thus limit the discretion of the court. It is not meaningful to go deep into the nuances of procedural rights as the purpose of this paper was to offer a preliminary appraisal of the usability of the Hohfelds scheme on the TSD, especially relating to those among private entities.

A legal trade secret proceeding might, because of B's rejoinder and court discretion, end up declaring that A holds no trade secret, but only mere information, and thus has no rights related to a trade secret. Such a declaration would indeed be remarkable for A and seemingly alter the reality as A had perceived it, but in legal reality no jural relations would have been changed. In such a case neither A nor B should be seen to have exercised a Hohfeldian power, as A's trade secret would then have either never existed or seized to exist independently of B's requests, and therefore no alterations to legal relations are made once the court merely declares the inexistence of trade secrecy as a fact.

The distinction between trade secrets and 'mere information' is problematic as information is not only intangible, non-rival, and non-exclusive, but also substitutable as a piece of information can be 'replaced' by another similar one.[84] As the trade secret right only protects the holder from certain unlawful deeds related to the trade secret, deeds which are related to substitute information should not be always considered infringing. If a third-party reverse engineers information identical to a protected trade secret, the original trade secret status of the information is not affected.[85] Art 3 stipulates on the scenario when the third party has lawfully acquired the trade secret. The articles headline reads 'Lawful acquisition, use and disclosure of trade secrets', and Paragraph 3 lists four means which are considered as lawful acquisition of trade secrets, including as independent discovery and creation or reverse engineering. The headline stipulates on 'trade secrets', which naturally refers to the trade secret holder *A's* perception of the information (or the perception that the information is a trade secret of the trade secret holder A). Naturally for the information to constitute *B's* trade secret, B would have to independently commit to the reasonable steps to keep the information secret in order for B to hold a trade secret right over the information. Before an overall assessment of whether B has committed the reasonable steps to maintain the secrecy of the information, B should be considered to hold only 'mere information'. Thus, although B might have immunity against A's attempts to have new claim-right-duty -relations instituted because B would have not breached their duty not to lawfully acquire, use or disclose the trade secret – as B would have had the liberty to lawfully acquire, use or disclose A's trade secret (and A the correlating no-right that B not acquire, use or disclose A's trade secret). But – and this is a distinctive feature of the trade secret object – B would have had the liberty to acquire, use or disclose 'mere' *information*, as B might have been oblivious that the information B had acquired is regarded as a trade secret by A. In such a situation it would seem nonsensical to speak *from B's point of view* that they have acquired, used, or disclosed anyone's *trade secret* – since in the hands of B the information is not automatically B's trade secret. Even if the information would be identical to what A considers their trade secret, if B would lawfully have the information without any obligations to A, to label the information *A's trade secret* would signify nothing to B, who is also lawfully holding the information.

[84] Heverley (n 51) 1140.
[85] Lee 'Hedging (into) Property?' (n 6) 120–121.

Trade secret subject matter is information, as has already been emphasised, but mere information never constitutes a trade secret as the trade secret always requires more: it requires certain conduct from its holder and also a certain degree of knowledge from persons usually dealing with such information. This distinction is made in Arts 11(3) and Art 13(2), which refer to a situation where remedial measures are revoked (emphasis added) 'if the *information* in question no longer meets the requirements of point (1) of Article 2 for reasons that cannot be attributed directly or indirectly to the respondent'. The distinction of mere information and trade secrets, and protection only of the latter, is substantial because the scope of protection is rooted in the purpose and justification of trade secrecy.

4.2[d] B's Power

The Directive's definition of what constitutes unlawful use is wide and extends the liability to those who gain the trade secret from the original infringer. Therefore, the alleged infringers are also those who have not known that their actions were unlawful (though they should have known from the circumstances). Similar requirement for extending trade secret protection is found in the TRIPS agreement which requires member states to extend liability to third parties.[86] Thus, A's request of remedies will link to the procedure to those who are connected to B through a 'chain of knowledge.'[87] As the Directive allows the occurrence of situations where the alleged infringer began their disputed conduct in good faith, placing an injunction on them – especially in a situation where the existence of the trade secret is uncertain – might cause unreasonable harm, and thus Paragraph 2 balances the interests of A and B.[88]

According to Art 10, Paragraph 2, B may lodge guarantees to avoid the use of the remedies otherwise issued according to Paragraph 1. Contrasted to Paragraph 1, Paragraph 2 does not explicitly state who may request the measure. An alleged infringer B would resort to it presumably when they feel justified to defend against A's primary claim-right, that is in a situation where B believes that A does not have a trade secret claim-right vis-à-vis B or when they trust they have a right to use the information. Contrasted to successfully defending against the requests made by A, where the capability to defend did not signal power, Paragraph 2 does grant its initiator the possibility to get the court issue and enforce new jural relations. B's existing liberty to use the object of dispute, the trade secret, would be made contingent to B lodging guarantees, after which A could not intervene with B's continuous use of the 'alleged' trade secret. A would be liable when B places the guarantees.

In Hohfeldian terms, B holds power to get the court under a duty to impose B with a liberty to lodge guarantees and thereafter become temporarily immune to the possibility of remedial measures they would be otherwise targeted with B according to Paragraph 1. Stating that the alternative measure is B's right, even power, has similar rhetorical force as has the

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[86] Agreement on Trade-Related Aspects of Intellectual Property Rights (Marrakesh, Morocco, 15 April 1994). The footnote 10 of Art 39(2) states that '[f]or the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition'.

[87] Lee 'Hedging (into) Property?' (n 6) 108.

[88] Recitals 29 and 30 address these situations.

statement of 'copyright user rights',[89] that is, holding a legally enforceable right is usually a sign of society's approval.

If B would be willing to continue the trade secret infringing action, they would have no alternative but to lodge the guarantees – thus the requirement for guarantees could be seen as a duty. But because continuing the allegedly infringing action is B's choice, they should be seen to be under no duty to lodge the guarantees – and the lack of duty implies a privilege. Contrastingly, in such a case A would hold a no-right that B not lodge guarantees.

Once B resorts to the alternative remedy thus continuing the allegedly illicit conduct, who would hold a claim-right to the guarantees? According to the Paragraph, the guarantees are intended to compensate the trade secret holder, obviously should A's claims later succeed. Therefore, A holds a contingent claim-right described by Andrew Halpin in relation to the guarantees, because A's right to be reimbursed by the guarantees may or may not arise depending on future circumstances of the case,[90] that is, especially of a declaration of B's infringement. But here the question of acquiring the guarantees must be separated from B lodging them, as the lodging and acquiring obviously are different deeds. The holder of the correlative for B's duty may be found by applying the two mutually exclusive and rivalrous theories on right, the interest and will theories. As A could be seen to have an interest to the claim-right regarding the guarantees, as the guarantees are to compensate A's losses, a promoter of the interest theory of rights would argue that A has the claim-right. A promoter of the will theory would come to a similar conclusion, as A would be the one who would hold enforcement power should B break their duty to lodge the guarantees.[91] Thus A should be seen to hold the claim-right that B lodges guarantees, would B use their power in relation to Paragraph 2.

Paragraph 2 offers an example of how the Hohfeldian basic positions do not hold intrinsic values, as one cannot state duties or no-rights to be automatically undesirable. After lodging the guarantees, B would have a claim-right against A that A does not interfere with them using the object of dispute – the 'thing' A alleges to be their trade secret, and A would have a duty not to interfere.

Regarding the alternative measure, B's request would alter the jural relations between A and B, but it will not affect the original trade secret (claim-)right of A which will remain intact,[92] because A would continue to have a right that B not use their trade secret *unlawfully* – nevertheless, when preliminary measures are applied, B may contest the trade secret right and acquire liberty to continue to use the alleged trade secret backed with a claim-right that A not interfere with B's usage, as long as B fulfils the duty to pay guarantees.

[89] See generally Tito Rendas, 'Are Copyright-Permitted Uses "Exceptions", "limitations" or "User Rights"? The Special Case of Article 17 CDSM Directive' (2022) 17(1) Journal of Intellectual Property Law and Practice 54.
[90] Andrew Halpin, 'Rights, Duties, Liabilities, and Hohfeld' (2007) 13(1) Legal Theory 23, 31. Halpin gives the example of trespassing. Even though there would exist a liberty to use reasonable force to eject a trespasser, one might not have to resort to this liberty if no-one trespasses.
[91] For an account of the two rival and mutually exclusive theories on rights debate, see generally David Frydrych, 'The theories of rights debate' (2018) 9 Jurisprudence 566.
[92] Kit Barker arrives to a similar conclusion related to infringements of property - Barker '"Damages without Loss": Can Hohfeld Help?' (n 35) 640.

5 INJUNCTIONS AND CORRECTIVE MEASURES ON THE MERITS

5.1 A'S CLAIM-RIGHT AFTER A DECLARATION OF A TRADE SECRET RIGHT

The straight-forward Art 12 provides a suitable point of further reference to illustrate how the Hohfeldian incidents and their correlatives may be used to make trade secret protection comprehensible. The prerequisite for Art 12 is a judicial decision declaring that A has a trade secret right vis-à-vis B, that is that there exists a trade secret, A is its holder, and that B has committed unlawful action against A.

Once the information A holds has been verified as a trade secret, there may exist a reasonable conjecture that A could derive concrete entitlements against not only B, but also others based on that trade secret. But as A's trade secret (claim-)right only covers unlawful actions, the factor of unlawfulness must be separately examined in all future incidents. If C would lawfully use or acquire A's trade secret (for example because of the applicability of Art 3 of the Directive), C would not break their duty concerning A's trade secret claim-right. As C holds a liberty vis-à-vis A regarding the *lawful* acquiring, use or disclosure of *A's trade secret*, A would have a correlating no-right that C not lawfully acquire, use or disclose A's trade secret. The no-right and liberty must be precisely defined to refer to *A's trade secret*, since only A's trade secret right and trade secret status has been assessed. The same information that constitutes A's trade secret may in the hands of third parties be 'mere information', as they might not have fulfilled the reasonable steps to maintain secrecy. This precision comes afore when the Hohfeldian scheme is applied: the correlating positions must have the precise, same content – just from the opposite directions.

Instead of traditional property law right bundles or clusters, where the existence of a something labelled as a property right signals the plausible existence of certain Hohfeldian basic positions against each member of the rest of the world, trade secrets should be more fundamentally understood as ad hoc. This ad hoc element is linked to the 'peculiar' aspect of trade secrets (contrasted to intellectual properties) where there exists no publicly accessible artefact which could disclose the relevant information, but instead the holder must present and prove in each individual case that the defendant has committed unlawful action in violation of trade secrecy rules. Manifestations of the secret are perceived individually and thus an abstract IP object cannot be found.[93] This does not purport that trade secret cases would not have a general aspect as I will describe below.

But are not all rights in our legal realm similarly ad hoc? An example of my house serves as an example of how Hohfeldian positions exist on a property right.[94] While the

[93] Alexander Peukert, *A Critique of the Ontology of Intellectual Property Law* (Cambridge University Press 2021) 60. Peukert argues this being the reason why trade secret protection would still be viewed as a tort or delict instead of a fungible exclusive property right in an abstract object.

[94] Karl Olivecrona, discussing the thoughts of Axel Hägerström makes an example of house ownership and points out that a right of the owner of a certain house cannot consist of the fact of protection offered by the state to the owner, as the right to protection is the prerequisite of the protection. Karl Olivecrona, 'The Legal Theories of Axel Hägerström and Wilhelm Lundstedt' (1959) 3 Scandinavian Studies in Law 125, 128. Olivecrona proposes another example on page 143, describing the vagueness of stating to have a 'right to a house'.

property right would generally include that I have a claim-right that you do not enter my house, there are several situations where you actually would not have a duty not to enter my home (but you could even have a legal duty to enter). In Hohfeldian terms, the lack of a duty not to enter impels that I do not have a claim-right towards you not to enter my house, and thus you would have the liberty to enter, as the liberty to do something is the opposite of a duty to refrain from doing X. Property rights are never absolute in terms that the owner's claim-rights or privileges would be consistent, or perpetually enforceable by state coercion. In civil law judicial systems, jural relations are crafted by the legislator, who also regulates the possible limitations and exceptions.[95]

When Art 12 is applicable, the situation is fundamentally different from the preliminary measures of Art 10, where the existence of a trade secret was only a supposition by A.[96] A judgement on the merits is the first 'official' declaration that there is a trade secret, signalling A's claim-right that others not unlawfully acquire, use, or disclose it. Nevertheless, the existence of a trade secret does not yet state anything regarding B or the element of unlawfulness. Following a classification by Parchomovsky and Stein, who specify intellectual property defenses to three categories, trade secret cases always include a general and an individual component. Parchomovsky and Stein depict *class* and *general* defenses as those that do not only serve the parties part-taking in the trial but extend their impact on third parties. By contrast, *individualised* defenses are limited to the case at bar, creating 'a limited immunity zone'.[97] In trade secret cases, an example of individualised defense is reverse engineering, where a trade secret exists but the defendant has lawfully acquired it. Reverse engineering based defense would only benefit the defendant in question,[98] but if a court accepts a general defense such as that the information is of 'public interest', it would end up annulling the trade secrecy protection altogether.[99] Put in Hohfeldian terms, an individualised defense would only affect the jural relation between the parties A and B, but a successful general defense would affect A's relation to all possible opponents, because it extinguishes A's claim-right altogether. The components of the trade secret right – the claim-right of A that others not unlawfully acquire, use or disclose their trade secret – are placed under scrutiny at the proceedings, and thus, a trade secrecy dispute will always include a general and an individualised component, the first one being the existence of the trade secret and the latter meaning whether there has been an unlawful action.

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[95] On the five notions of a right, and of right to property, see Hugh Breakey, 'Who's Afraid of Property Rights? Rights as Core Concepts, Coherent, Prima Facie, Situated and Specified' (2014) 33 Law and Philosophy 573, 579–584, 591–593.

[96] As set in Article 11 and discussed afore, there should be 'sufficient' evidence of trade secret infringement before the injunctions. But it has been shown that injunctions are granted almost automatically with little or no discretion. Sikorski (n 71) 4. Sikorski is referring to Jorge L. Contreras & Martin Husovec, 'Issuing and Tailoring Patent Injunctions – A Cross-Jurisdictional Comparison and Synthesis', in Jorge L. Contreras (ed), *Injunctions in Patent Law: A Trans-Atlantic Dialogue on Flexibility and Tailoring* (Cambridge University Press 2022) 8–10.

[97] Gideon Parchomovsky and Alex Stein, 'Intellectual Property Defences' (2013) 113(6) Columbia Law Review 1483, 1484–1486.

[98] ibid 1509.

[99] ibid 1510.

5.2 A'S POWER TO REQUEST NEW CLAIM-RIGHTS

Once the court declares that A has a trade secret right, A has the access to the measures provided in Art 12. A's possibility is limited by Art 5, which lists four cases where the measures, procedures and remedies may be dismissed. As with court proceedings generally, the respondent has the right to argue against the plaintiff in order to get the charges discarded or altered. A detailed account of defenses, the powers imbedded in them and how the defenses operate in practice are not discussed here.

Art 12 Paragraph 1 is a list of possible measures which A, the plaintiff, may request from the court. Because of the nature of trade secrets as information, the unlimited scope of their subject matter, and the use of them as a form of protection in any branch of industry, the possible measures vary greatly dependent on the case. All the measures are obviously targeted 'against' the infringer. To exemplify, A may claim the court to order that B stop disclosing the trade secret. Court's ruling would set B with a duty to stop the disclosure of the trade secret. The holder of the correlative claim-right would be A, who might use a government proxy to monitor or coercively ensure that B fulfils the duty. Another example could be a duty of B to destroy materials containing the trade secret, which would correlate with A's claim-right that B does so.

Do these new concrete jural relations emerge only once the court issues decision regarding them, or have they existed included within the trade secret right, and the court just makes them enforceable? As trade secrets do not require registration to enter into force, the existence of a trade secret right commences when a trade secret fills the requirements (set out in the Directive). In this sense, a trade secret right comprises of an indefinite number of specific entitlements already from the moment they exist, but it is the defendants unlawful conduct that then leads to enforcement of the entitlement imbedded within the abstract right.

5.3 THIRD PARTY INCIDENTS

5.3[a] Contractual Partners as Infringers

It is apparent from Art 12 that although the measures are directed 'against the infringer', they will not concern only the original infringer, but possible contractual parties as well. The contractual parties might themselves be infringers by the definition of the TSD, as an infringer is defined as any person who has unlawfully acquired, used or disclosed a trade secret,[100] and because the unlawful acquisition, use and disclosure of the trade secret includes deeds done by those who 'ought, under the circumstances, to have known that the trade secret had been obtained directly or indirectly from another person who was using or disclosing the trade secret unlawfully'. The effects of the remedies against certain contractual parties are mitigated with the possibility to resort to alternative measures, monetary compensations, provided by Art 13. Art 13 provides a list similar to what is found in Art 11 of circumstances which have to be considered when issuing remedies.

[100] Article 2.

5.3[b] Charitable Organisations

According to Paragraph 3, if the trade secret holder requests, the court may impose a duty on the infringer to deliver the goods to either themselves, or to charitable organisations. Thus, A is granted a power to have the court impose the infringer-defendant with a new duty, but vis-à-vis whom would this duty be? After a court has issued a decision with such an ordinance, the charitable organisation would have the possibility to reclaim enforcement from an executive authority (a will theory view of a right holder) and they would be the one having an interest to receive the goods (an interest theory view of a right holder), the charitable organisation would be holding the claim-right. The jural relation between the charitable organisation and the infringer arises from the court decision, issued by an exercise of power by the trade secret holder. The ones who hold the correlating liability would be the infringer and the charitable organisation, both having their own secondary level jural relation with A.

5.4 COURT DISCRETION AS POWER

Paragraph 4 allocates financial responsibility, or in Hohfeldian terms a duty, on the respondent, as the judicial authorities are granted the power to institute the infringer, the respondent, a duty to economically compensate the referred measures. The stipulations concerning the expenses and economic hindrances underlines the economic quality of trade secrets and seem to be independent of the applicant request for the instituted remedial measures. As the measures of paragraph 1 and Paragraph 3 are ordered 'at the request of the applicant', Paragraph 4 does not include such a requirement, thus signalling that the discretion – and power – is left for the court to specifically order the respondent compensate the measures. The ones liable for the court's orders would be both of the parties. A duty to compensate for the measures is a general duty, which would be a base for following and more concrete duties to reimburse the relevant costs at insistence.

6 SUMMARY

Arguably any rights protection regimes would benefit from a deeper understanding on the limitations in the scope of protection currently entailed within the regimes. The Hohfeldian scheme is a refined analytical tool and applying it to a concrete legislative instrument quickly leaves one breathless. As is visible from the analysis above, applying the scheme on trade secret right requires that one stays loyal to the precise definition of both the tool and the right, as specified by law, without omitting any features. Hohfeld himself used the scheme in presenting case analyses of how judges had gone astray when using words such as right, duty or privilege without understanding alterations in the content of the terms.

Concerning findings related to trade secrets, this Articles main findings can be summarised two.

First, the found Hohfeldian sub-elements emphasise that the trade secret right remedy structure of the TSD does allocate rights – claim-rights, liberties, powers, and immunities – to parties other than the original holder. These rights include the defendants' power to resort to alternative measures and their possibility get the 'alleged' trade secret declared void on the

course of the proceedings. The plaintiffs right to the protection of a trade secret by precautionary measures consist of a power and a liberty to get the court issue relevant injunctions, although the liberty is ostensible, thus causing suspicion on whether they hold a power in relation to the overall use of remedies. When the court grants the defendant the right to continue the allegedly infringing action, the holder of the trade secret gains a claim-right that the defendant lodges guarantees to ensure possible compensation. The defendant holds power and a liberty regarding the issuance of the alternative measure according to Art 10, to which the defendant could resort to should they believe they have reasonable cause to defend against A's trade secret right. The alternative measure would be that the defendant would gain a liberty to use the alleged trade secret temporarily, if they would fulfil their duty (towards the plaintiff) that they lodge the guarantees.

Second, this article suggests that the scheme does assist in defining what the trade secret right entails in practice as well as defining where the trade secret 'thing' exists, and where the entity is only mere information. Especially when referring to a third-party B who acquires A's 'trade secret' lawfully, for example via reverse engineering. A's trade secret right includes a no-right that B lawfully acquire A's trade secret, which correlates with B's liberty to acquire A's trade secret. Using the Hohfeldian scheme with precision, the nominator 'A's' must be included, as although after the acquiring B is holding information identical to A's trade secret (that is, A's trade secret), the information might not in the hands of B constitute B's trade secret, but only be 'mere information' that B lawfully holds.

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PROCESSING PERSONAL HEALTH DATA IN THE CONTEXT OF THE EUROPEAN ONLINE PHARMACY MARKET: LAWFUL BASES UNDER THE GDPR AND SWEDISH LAW

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In recent years, the European online pharmacy market has grown significantly and is expected to continue to grow at a rapid pace. One of the key factors that can further catalyse this growth is the personal health data that online pharmacies may collect. If online pharmacies process these data lawfully and with the public interest in mind, this may provide the opportunity to positively transform not only the online pharmacy market but also the entire healthcare industry. In order to maximise the benefits of these personal health data for improving public health but at the same time protect European citizens' privacy, further analysis of the data protection laws and their applicability in the context of the online pharmacy market is necessary. Currently, there still lacks clarity, for example, regarding the lawful bases under the GDPR for processing personal health data for online advertising purposes. This article therefore identifies three key purposes for which online pharmacies may choose to process personal health data, namely for prescribing medicines, online advertising and scientific research, and assesses the lawful bases under the GDPR that may be applicable to them. Swedish law will also be addressed in order to provide an example of the interaction between national laws and the GDPR when processing personal health data in the online pharmacy markets of Member States.

1 INTRODUCTION

The online pharmacy market is beginning to take off in Europe, especially in the aftermath of the Covid 19 pandemic. It is estimated that during the period 2019-2025, it will grow at a CAGR of over 15%.[1] For example, in Sweden, which is one of Europe's most developed online pharmacy markets, pharmaceutical e-commerce is worth 5-6% of the total e-commerce market.[2] Furthermore, 98% of all postcodes in Sweden received prescription medicines from online pharmacies.[3] Another growing market in Europe is Germany. It is

* The author of this text is currently a PhD student at Uppsala University researching the entrance of dominant online platforms into the European online pharmacy market and whether certain strategies that they may use can be considered anti-competitive under European competition law. The author would like to thank Santa Slokenberga, Senior Lecturer at Uppsala University, and Vladimir Bastidas, Prefect of the Law Faculty at Uppsala University, for their valuable feedback and comments during the process of writing this article. In particular, Santa's extensive knowledge of the GDPR and the health industry has been extremely helpful.

[1] Shop Apotheke, 'Annual Report 2021' (2016) Pg. 50 <https://corporate.shop-apotheke-europe.com/en/investorrelations/publikationen/> accessed 15 November 2022.

[2] Swedish Competition Authority et al, 'Joint Nordic Report: Online Pharmacy Markets in the Nordics' (2021) 6. Sweden is one of the most advanced countries in Europe in terms of the provision of online pharmacy services. Prescription medicines can be sold online and are processed through an advanced e-prescription system. Furthermore, Sweden also allows for online only pharmacies meaning there is no requirement to also provide a brick-and-mortar pharmacy to the consumer.

[3] ibid 46.

estimated that revenue in the German online pharmacy market will reach over 1 billion US dollars in 2022.[4]

The potential of this market has attracted big players in the US and Europe such as Amazon Pharmacy, MEDS and Shop Apotheke.[5] Through investments in innovation, these companies are creating comprehensive online pharmacies with features such as online marketplaces, telehealth apps and medication management all being incorporated into their services.[6] Due to these advancements, there is great potential to transform the healthcare industry in Europe and have an impact not only on the product supply chain, such as providing patients with quick home deliveries,[7] but more importantly, on the information supply chain allowing for health data to be easily transferred throughout the entire healthcare system.[8] Furthermore, the large amounts of health data collected by online pharmacies, if used lawfully, can help to greatly improve the healthcare system both through drug discovery and drug repurposing as well as pharmacovigilance. Yet, in order to maximise the potential that online pharmacies can have on the healthcare system, there must be clarity as to the ways in which online pharmacies can lawfully process health data.

The European General Data Protection Regulation[9] (GDPR) addresses the processing of personal health data although gaps in knowledge still exist as to its interpretation in different contexts. For example, whether online pharmacies can process personal health data in certain scenarios such as for the purpose of advertising lacks a straightforward answer under the GDPR. Even though the GDPR has been subject to extensive scholarly debate, there is generally a gap in the literature regarding the processing of personal health data by online pharmacies and its compatibility with the GDPR.

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[4] Statista, 'Online Pharmacy – Germany' <https://www.statista.com/outlook/dmo/digital-health/ehealth/online-pharmacy/germany> accessed 15 November 2022.

[5] Amazon Pharmacy is the online pharmacy business belonging to Amazon which was created in 2020. Amazon Pharmacy does not operate an online pharmacy service in Europe just yet although the Amazon Pharmacy trademark was registered in the EU in 2020. See EUIPO, 'Amazon Pharmacy Trademark Information' <https://euipo.europa.eu/eSearch/#details/trademarks/018178963> accessed 15 November 2022. MEDS is a Swedish online pharmacy operating only in Sweden. Shop Apotheke is a German online pharmacy operating in several European Member States.

[6] Shop Apotheke has developed an online marketplace and also incorporated 'Smart Patient' into its service which is a leading company in providing support to patients to improve medication management. See Shop Apotheke, 'Annual Report 2021' (n 1) 10 and 14. MEDS has been collaborating since 2019 with Kry, a Swedish telehealth app, allowing patients to easily purchase their prescriptions that were obtained from doctors on the Kry app through the MEDS webpage. See Kry, 'Kry och MEDS samarbetar för smidigare och snabbare vård' (*Kry*, 20 November 2019) <https://www.kry.se/press/nyheter/kry-och-meds-samarbetar-for-smidigare-och-snabbare-vard/> accessed 15 Novemeber 2022. Amazon also operates an online marketplace and has for example collaborated with MEDS in Sweden to allow them to sell their products through Amazon Marketplace. See Daniel Norman, 'Meds samarbetar med Amazon: "Första gången vi säljer utanför vår egen butik"' (*Market*, 12 October 2021) <https://www.market.se/affarsnyheter/affarsutveckling/meds-samarbetar-med-amazon-forsta-gangen-vi-saljer-utanfor-var-egen-butik/> accessed 15 November 2022.

[7] Sathiadev Mahesh and Brett Landry, 'Online Pharmacies: E-strategy and Supply Chain for Pharmaceutical Products', [2016] 115 <https://www.academia.edu/1342308/ON_LINE_PHARMACIES_E_STRATEGY_AND_SUPPLY_CHAIN_FOR_PHARMACEUTICAL_PRODUCTS> accessed 15 November 2022.

[8] ibid.

[9] 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 [2016] OJ L119/1. In the following footnotes, this regulation will be referred to as 'GDPR' which is an acronym for the European General Data Protection Regulation.

This paper therefore seeks to explore the different ways in which online pharmacies can process health data under the GDPR in order to achieve their business interests, while at the same time contributing to the protection of the individual's fundamental right to privacy. In order to fulfil this objective, this paper will be divided into the following parts: Part 2 will briefly assess the importance of health data and consumer privacy in the online pharmacy market. Parts 3, 4 and 5 will then address the main purposes for which an online pharmacy can process health data and then examine how such processing may be lawfully carried out under the GDPR and Swedish law. Part 3 will address processing for dispensing prescription medicines, part 4 will address processing for online advertising and lastly, part 5 will address processing for scientific research. The reason for choosing these purposes is first, dispensing prescriptions is the core activity of an online pharmacy and second, both online advertising and scientific research are key processing activities for online pharmacies to significantly improve their services and gain a competitive advantage.[10] Although data protection rules applicable to health care generally stem from the GDPR, its application still largely depends on national specifications. Therefore, Swedish law will be used in this paper as an example of how to apply the different lawful bases under the GDPR in the context of an EU Member State's national laws. Furthermore, only the national provisions that are relevant for the specific processing purposes will be addressed as a general assessment of the Swedish legal framework for health data is outside the scope of this article.

2 THE IMPORTANCE OF HEALTH DATA AND CONSUMER PRIVACY IN THE ONLINE PHARMACY MARKET

This part aims to emphasise the benefits for public health that may arise from the lawful processing of personal health data by online pharmacies. The growth of large market actors such as Amazon Pharmacy, MEDS and Shop Apotheke has the potential to transform the healthcare industry in Europe. Patients could be able to access an enormous variety of medicines at competitive prices which may be delivered to patients' doorsteps, in some cases within several hours. With regards to home delivery, this might have enormous benefits for older or disabled patients and those living in rural areas who may have better accessibility to pharmaceutical care and services. Furthermore, patients with chronic illnesses could also benefit as they will have their prescriptions sent through the post every month and thus are more likely to adhere to their medication dosages.[11] Yet although these advantages can have the potential to bring great value to the patients using an online pharmacy, the added value compared to going down to a local brick and mortar pharmacy is not that significant, especially when addressing consumers that are neither old age, disabled or chronically ill.[12]

[10] For example, accurate advertisements will improve the quality of the online pharmacy service and make it more attractive for users. This will allow online pharmacies to grow and maximise network effects between the users. Scientific research will help online pharmacies gain insights on for example adverse reactions to drugs and thus provide patients with better advice.

[11] Patients with type II diabetes mellitus were found to have achieved a significantly higher proportion of days covered with online pharmacy services compared to patients who utilised a standard brick and mortar pharmacy. See Phil Schwab et al, 'A Retrospective database study comparing diabetes-related medication adherence and health outcomes for mail-order versus community pharmacy' (2019) 25(3) Journal of Managed Care and Specialty Pharmacy PL 332.

[12] Sathiadev Mahesh and Brett Landry, 'Online Pharmacies: E-strategy and Supply Chain for Pharmaceutical Products', (*Academia*, 2016) 122

The real added value to the healthcare system as a whole is not the great variety of medicines on offer or the quick home deliveries but rather the enormous amount of information that online pharmacies can process and then supply throughout the entire value chain.[13] In a typical scenario, physicians provide patients with basic information on medicine use and then a brick and mortar pharmacist will provide additional information such as usage warnings, allergic reactions and potential inter-drug reactions.[14] An online pharmacy however has the potential to provide a lot more in terms of additional information. This it can do through internally or externally analysing the large amounts of data it collects 24/7 from, for example, patient reviews as well as follow ups and consultations online with its pharmacists. This analysis can provide far more accurate assessments of potential patient risks and also help inform patients through Q&As about any doubts they have during their prescription cycle.[15] In addition, an online pharmacy can also ensure that data is more efficiently communicated among pharmacists, physicians and manufacturers.[16] For example, online pharmacies can become the point of contact between individual physicians and manufacturers by reporting back to them regarding side effects and performances of the administered medicines.[17] An online pharmacy's ability to process and communicate large amounts of data is what will differentiate them from normal brick and mortar pharmacies.

The benefits of efficient processing and communicating of data for Europe and the world could be immense. Public health may be greatly improved as pharmacies will be able to deliver more efficient, sustainable and high-quality healthcare services to patients.[18] Key market failures in the online pharmacy market may also be reduced. For example, asymmetries of information in the pharmaceutical distribution chain are high as patients lack the adequate knowledge regarding the medicines they buy.[19] Online pharmacies could eliminate this asymmetry between manufacturers, pharmacies and patients due to the greater efficiency they provide in the information supply chain.[20] Furthermore, both governments as well as consumers could save enormous sums of money due to better adherence by

<https://www.academia.edu/1342308/ON_LINE_PHARMACIES_E_STRATEGY_AND_SUPPLY_CHAIN_FOR_PHARMACEUTICAL_PRODUCTS> accessed 15 November 2022. Mahesh and Landry argue that, with regard to the online pharmacy market, '[t]he efficiencies gained from product supply chain changes using eBusiness approaches are small'.

13 ibid 119.

14 ibid.

15 Mahesh and Landry (n 12) 119.

16 Swedish Competition Authority et al, 'Joint Nordic Report: Online Pharmacy Markets in the Nordics' [2021] 15.

17 Mahesh and Landry (n 12) 121.

18 Pharmaceutical Group of the European Union, 'Position Paper on Big Data & Artificial Intelligence in Healthcare' [2019] 2, 5. Public expenditure on health and long-term care in the EU has been increasing over the past decades is estimated to account for 8.5% of GDP. Member States' ability to provide high quality care to all will greatly depend on whether their health systems can manage use the potential of big data in health care to become more resilient and sustainable. The PGEU also states that 'innovative solutions that make use of digital technologies, including eHealth, Big Data, AI are seen by the European Commission as opportunities to transform healthcare systems'.

19 Declan Purcell, 'Competition and Regulation in the Retail Pharmacy Market' (2004) 14 Studies in Public Policy, Trinity College Dublin, 6 <http://www.tara.tcd.ie/handle/2262/60273> accessed 15 November 2022.

20 Mahesh and Landry (n 12) 115.

patients to their prescribed medication.[21] It is estimated that non-adherence to prescription medication in the European Union is estimated to cost €1.25bn annually.[22]

In order for online pharmacies to be able to maximise the efficiencies in the information supply chain, there must be clarity regarding the processing of health data in the context of the European online pharmacy market. Currently, approximately 30% of the entire world data volume is being generated by the healthcare industry.[23] This demonstrates the importance of health data but also the required urgency to clarify the legal framework. Furthermore, organisations and professionals throughout the world identify privacy as one of the biggest challenges for using data in health care. The Pharmaceutical Group of the European Union has for example identified privacy as an important challenge that must be addressed in order to keep patients' trust in the health system unchanged.[24] This applies not only to medical services, but also to online pharmacies as essential actors in ensuring accessibility to medicinal products.

3 PROCESSING PERSONAL HEALTH DATA FOR DISPENSING PRESCRIPTION MEDICINES

In order to address the lawful bases for processing of personal health data in the EU, it is necessary to first explain the general structure that the GDPR establishes. First, Article 6(1) provides a list of lawful bases for processing personal data.[25] These include for example consent, compliance with a legal obligation or performance of a task carried out in the public interest.[26] Second, if the data being processed falls under a special category of data such as personal health data, these lawful bases do not suffice. As the GDPR considers the processing of special categories of personal data to be of such a significant risk to an individual's fundamental right to privacy, as a rule, it is prohibited.[27] This prohibition however has exceptions thus allowing the processing of such categories of personal data as long as one of the conditions that enable lifting of the prohibition set out in Article 9(2) GDPR is met.[28] The lawful bases under Article 9(2) are for example explicit consent, the provision of health or social care or reasons of public interest in the area of

[21] Please see the section on Scientific Research in part 5 of this paper which addresses the benefits of data collected by online pharmacies to improve non-adherence of prescription medicines.
[22] Pharmaceutical Group of the European Union, 'Targeting Adherence: Improving Patient Outcomes in Europe through Community Pharmacists' Intervention' [2008] 4.
[23] Greg Wiederrecht et al, 'The health care data explosion' (*Royal Bank of Canada*) <https://www.rbccm.com/en/gib/healthcare/episode/the_healthcare_data_explosion> accessed 15 November 2022.
[24] PGEU, 'Position Paper on Big Data & Artificial Intelligence in Healthcare' (n 18) 6. Privacy has also received attention in this context outside the EU. For example, the Chief Privacy Officer for Express Scripts, the largest independent Pharmacy Benefit Manager in the US, has identified privacy as one of the biggest challenges to using data in health care. See Janna Lawrence, 'Could Big Data be the Future of Pharmacy?' (*The Pharmaceutical Journal*, 20 April 2017) <https://pharmaceutical-journal.com/article/feature/could-big-data-be-the-future-of-pharmacy> accessed 15 November 2022.
[25] GDPR, art 6(1).
[26] ibid.
[27] ibid art 9(1).
[28] ibid art 9(2). The GDPR adds these additional requirements as it considers that there is a far higher risk for individuals having their fundamental right to privacy violated in the case of processing special categories of personal data.

public health. It is important to note that Member State national laws may also provide for more specifications regarding the different lawful bases under Article 9(2) GDPR.

In the case of an online pharmacy wishing to process personal health data, it must adopt a two-step approach by firstly identifying a lawful basis under Article 6(1) and then additionally identifying a lawful basis in order to lift the prohibition under Article 9(2). The application of this two-step approach will in the following paragraphs be carried out in order to identify the correct lawful bases for each of the different purposes of processing. It is important to lastly mention that according to Article 9(4), 'Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health'.[29] In this paper, Swedish law will be the focus with respect to Article 9(4).

3.1 PURPOSE

The first common purpose for processing personal health data is to dispense prescription medicines to patients. When a customer requests a prescription medicine from an online pharmacy, an online pharmacist will have to process the health information on the prescription and check for example the patient's identity number and contact details as well as the prescription and medical information.[30] According to recital 35 of the GDPR, information collected about a natural person during the provision of healthcare services, which includes pharmacy services, will be considered health data.[31] In this case, an online pharmacy is providing an essential healthcare service therefore the personal data being processed is likely to fall under personal health data. Furthermore, although not referring specifically to prescriptions, the European Data Protection Board (EDPB) has stated that information, such as medical history and results of examinations, collected by a healthcare provider in a patient record constitutes personal health data.[32] A patient's prescriptions are normally kept in their medical history records therefore this implies that information on a prescription will most probably constitute personal health data.[33] In addition, the European Data Protection Supervisor (EDPS) has specifically stated that personal health data 'would normally include medical data (e.g. doctor referrals and *prescriptions*, medical examination reports, laboratory tests, radiographs)'.[34]

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[29] ibid art 9(4).

[30] Apotek Hjartat Privacy Policy <https://www.apotekhjartat.se/om-oss/var-personuppgiftsbehandling/> accessed 15 November 2022.

[31] GDPR, recital 35.

[32] European Data Protection Board, 'Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak' [2020] 5. The scope of what constitutes personal health data is extremely broad. In Opinion of the AG Athanasios Rantos in Case C-252/21 *Meta Platforms and Others* EU:C:2022:704, visiting and clicking integrated buttons on for example third party websites/apps was considered to constitute personal health data.

[33] European Commission, 'Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format' [2019] OJ L39/18, Annex Point 2.1. The EU Commission has proposed a Baseline for the European electronic health record exchange format which includes e-prescriptions.

[34] European Data Protection Supervisor, 'Guidelines concerning the processing of health data in the workplace by Community institutions and bodies' [2009] 2.

3.2 LAWFUL BASES

The first step in the GDPR for processing personal health data for the dispensing of prescription medicines will require finding a lawful basis under Article 6(1). There are several lawful bases that could be chosen from the list such as consent,[35] for the performance of a contract,[36] compliance with a legal obligation[37] or for the performance of a task carried out in the public interest.[38]

From the previously mentioned options, the appropriate choice of a lawful basis will often depend on the laws of the Member State where an online pharmacy operates. With regards to compliance with a legal obligation in Sweden, Act (2009:366) on trade in medicinal products states that a pharmacy that has a license to sell medicines must supply all prescribed medicinal products as soon as this can be done.[39] The Swedish online pharmacies Apotek Hjartat and Apoteket.se use this lawful basis as grounds for processing.[40] In the case of processing for the performance of a task carried out in the public interest, one could argue that the overall purpose of a community pharmacy is to perform a task carried out in the public interest however, in Sweden, this is not clearly established by law.[41]

Processing for the performance of a contract is also a suitable option since when a patient purchases prescription medicines from an online pharmacy, a valid contract is established with the patient and the processing of personal health data in the prescription is necessary to perform the contract.[42] For example, the Swedish online pharmacy Apotea chooses this lawful basis for processing personal health data in prescriptions.[43] With regards

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[35] GDPR, art 6(1)(a).
[36] ibid art 6(1)(b).
[37] ibid art 6(1)(c).
[38] ibid art 6(1)(e).
[39] Act (2009:366) on trade in medicinal products (lag (2009:366) om handel med läkemedel), 6 § paragraph 3 states that pharmacies must 'supply all prescribed medicinal products, and all prescribed goods covered by the Act (2002:160) on medicinal product benefits, etc. as soon as this can be done'. Furthermore, 9a § states that 'When dispensing a prescription, a pharmacist shall provide information and advice in accordance with 6 § paragraph 11 and shall perform such other tasks as are of particular importance for the safe handling and use of the medicinal product'. 6 § paragraph 11 states that pharmacies must 'provide individual and producer-independent information and advice on medicinal products, the replacement of medicinal products, the use of medicinal products and self-care to consumers and ensure that the information and advice is provided only by staff with sufficient competence for the task'. One could also interpret 9a § as constituting a legal obligation to process personal health data in prescriptions in order to provide information and advice on medicinal products including their use and replacement. All translations in this footnote were made by the author of this article.
[40] Apotek Hjartat and Apoteket.se use compliance with a legal obligation as their lawful basis. See Apotek Hjartat Privacy Policy (n 30); see also Apoteket.se Privacy Policy <https://www.apoteket.se/kundservice/integritetspolicy/> accessed 15 November 2022.
[41] Community Pharmacy GDPR Working Party, 'The General Data Protection Regulation and associated legislation Part 1: Guidance for Community Pharmacy' [2018] 8. The Community Pharmacy GDPR Working Party in the UK identified the performance of a task carried out in the public interest as generally an adequate lawful basis although not specifically for dispensing prescription medicines. It is important to note however that according to recital 45 of the GDPR, where processing is necessary for the performance of a task carried out in the public interest, the processing should have a basis in Union or Member State law. See also Chap.2, 2 § Paragraph 1 of Act (2018:218) with Additional Provisions to the EU Data Protection Regulation. In Sweden there is no clear law establishing that pharmacies carry out a task in the public interest.
[42] European Data Protection Board, 'Guidelines 2/2019 on the processing of personal data under Article 6(1)(b) GDPR in the context of the provision of online services to data subjects' [2019] 9. The EDPB states that the requirements for the processing being necessary for the performance of a contract are that the processing takes place in the context of a valid contract and that the processing is necessary in order so that the particular contract with the data subject can be performed.
[43] Apotea Privacy Policy <https://www.apotea.se/integritetspolicy> accessed 15 November 2022.

to consent, this is a valid lawful basis although it is important to consider that the GDPR establishes that consent may be withdrawn at any time.[44] Additionally, consent must be freely given meaning that the data subject cannot feel compelled to give consent.[45] Consent therefore might be problematic when the patient depends on the online pharmacy to provide them with their prescription medicines as they may feel compelled. This would suggest that consent would be more suitable as a safeguard rather than a lawful basis in itself.[46]

On the other hand, as an online pharmacy is processing extremely sensitive personal health data, ensuring that the patient is aware of the processing taking place is important. This might suggest that consent may in fact be the most appropriate lawful basis. Yet for practical reasons, relying only on consent to dispense prescription medicines may pose unnecessary hurdles for online pharmacies offering secondary care that could be resolved by other valid lawful bases. Although processing personal health data in this context poses a risk to the patient's fundamental right to privacy, a legal obligation and the performance of a contract are sufficiently strong lawful bases to justify processing. Furthermore, when processing for the performance of a contract, Advocate General (AG) Rantos has clarified that the processing must be objectively necessary meaning that there cannot exist realistic, less intrusive alternatives.[47] There are no realistic, less intrusive alternatives to prescribe a medication as the pharmacist must look at the patient's personal health data. Therefore, the potential risk to the privacy of the individual that may arise from the processing is justified.

In addition to a lawful basis under Article 6, a legal basis to lift the general ban to process health data in Article 9(1) GDPR needs to be established under Article 9(2). In this case, potentially suitable lawful bases are explicit consent,[48] reasons of substantial public interest,[49] the provision of health or social care or treatment,[50] the establishment and reasons of public interest in the area of public health.[51] With regards to explicit consent, this might again serve as an additional safeguard however for the reasons mentioned above, it may be difficult to demonstrate that explicit consent was given and furthermore, explicit consent may create unnecessary hurdles when providing secondary care. Additionally, reasons of substantial public interest under Article 9(2)(g) may be harder to prove and furthermore, they must be established in EU or Member State law that provides for suitable and specific measures to safeguard the fundamental rights and interests of the data subject.[52]

In the case of reasons of public interest in the area of public health, the GDPR provides some examples of this lawful basis in Article 9(2)(i) such as 'protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices.'[53] One could argue in this case that the processing by an online pharmacy of personal health data when dispensing prescription

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[44] GDPR, art 7(3).
[45] European Data Protection Board, 'Guidelines 05/2020 on consent under Regulation 2016/679' [2020] 7.
[46] Directorate General Santé of the European Commission, 'Assessment of the EU Member States' rules on health data in the light of GDPR' [2021] 29. Online pharmacies can use a lawful basis such as compliance with a legal obligation together with consent as an additional safeguard in case of uncertainty.
[47] Opinion of AG Rantos in Case C-252/21 *Meta Platforms and Others* (n 32), para 54.
[48] GDPR, art 9(2)(a).
[49] ibid art 9(2)(g).
[50] ibid art 9(2)(h).
[51] ibid art 9(2)(i).
[52] ibid art 9(2)(g).
[53] ibid art 9(2)(i).

medicines guarantees the high standards of quality and safety of health care. Recital 54 of the GDPR elaborates that 'public health' in the context of Article 9(2)(i) should be understood as all elements related to health including for example healthcare needs and the provision of health care.[54] In any case, this would have to be established in EU or Member State law and furthermore, this law has to provide for suitable and specific measures to safeguard the rights and freedoms of the data subject.[55] In Sweden, this is not addressed in the Data Protection Act although it is mentioned in its preparatory works (these texts have legal authority in Sweden).[56] According to the preparatory works, the Swedish Government considered that including a specific provision in Swedish law was not necessary for Article 9(2)(i) GDPR to be applicable in Sweden and furthermore, the requirement of confidentiality of special categories of personal data was already addressed in other laws relating to healthcare thus providing for appropriate and specific measures to safeguard the rights and freedoms of the data subject.[57]

Another highly relevant lawful basis for processing personal health data in this context is for the provision of health or social care or treatment.[58] Shop Apotheke for example uses this as its lawful basis for dispensing prescription medicines.[59] Looking to Article 9(2)(h) in the GDPR, it states that processing may be carried out for the provision of health or social care or treatment 'on the basis of Union or Member State law *or* pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3'.[60] Therefore when using this lawful basis, it might be the case that a provision for the processing of personal health data in the context of health or social care or treatment is established in Union or Member State law but this is not necessary.[61] Instead, an online pharmacy can rely on the fact that it is a health professional and that there is a contract with the patient when dispensing prescription medicines.[62] It is important to note that in addition to entering into a contract with the patient, the processing must be under the responsibility of a professional subject to the obligation of professional secrecy under Union or Member State law.[63] In

[54] ibid recital 54.
[55] ibid art 9(2)(i).
[56] Government bill [prop.] 2017/18:105 Data Protection Act.
[57] Government bill 2017/18:105 (n 56) 96.
[58] Community Pharmacy GDPR Working Party, 'The General Data Protection Regulation and associated legislation Part 1: Guidance for Community Pharmacy' [2018] 8. The Community Pharmacy GDPR Working Party in the UK identified the provision of health or social care or treatment as relevant for community pharmacies.
[59] Shop Apotheke Privacy Policy <https://www.shop-apotheke.com/datenschutz.htm> accessed 15 November 2022.
[60] GDPR, art 9(2)(h), emphasis added.
[61] In Sweden, 8 § paragraph 1 point 1 of the Pharmacy Data Act (2009:367) states that personal data may be processed if it is necessary for 'the dispensing of prescribed medicinal products, and such prescribed goods as are covered by the Act (2002:160) on medicinal product benefits etc., and for measures in connection with the dispensing'. Furthermore, 9(a) § states that 'Personal data referred to in Article 9(1) of the EU Data Protection Regulation (sensitive personal data) may be processed on the basis of Article 9(2)(h) of the Regulation, provided that the obligation of professional secrecy in Article 9(3) of the Regulation is met'. These translations were made by the author of this article.
[62] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [2011] OJ L88/45. In Article 3(2)(f), the definition of 'health professional' includes a pharmacist.
[63] GDPR, art 9(3).

Sweden, a pharmacist's obligation of professional secrecy is established in the Patient Safety Act.[64]

4 PROCESSING PERSONAL HEALTH DATA FOR ONLINE ADVERTISING

4.1 PURPOSE

The following part will address how online pharmacies may process personal health data for online advertising. In this case, an online pharmacy might be interested in sending its customers via email, sms or other channels relevant information as well as offers based on previous purchases or the use of the web page.[65] In particular, this will involve placing customers into a specific segment based on purchasing history, age, sex and specific preferences.[66] With regards to personal data concerning customer purchases, this may include click data meaning that the customer has demonstrated an interest in the product but not necessarily purchased it.[67] Online pharmacies may also want to use these data to create recommender systems that suggest products based on what they know about the consumer.[68] Additionally, they may wish to create a profile on the customer by inferring the health status of the individual based on certain observations gathered from non-sensitive data.

The advantages of this type of processing may benefit both the online pharmacy and the consumer.[69] On the one hand, the online pharmacy can increase its sales to consumers which in turn will provide it with even more data. The consumer may benefit by receiving product recommendations that are based on their current health status. For example, an online pharmacy could process personal health data collected from a patient's prescription which shows that this patient has diabetes. The online pharmacy could then send the consumer product recommendations such as blood sugar level testing kits. In this case, the consumer's health will be improved since they will be sold the most adequate and relevant products for their conditions.

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[64] Chap. 6, 12 § and 16 § of Patient Safety Act (2010:659).

[65] MEDS Privacy Policy <https://www.meds.se/integritetspolicy/> accessed 15 November 2022. MEDS is one of the largest online pharmacies in Sweden and sells both non-prescription and prescription medicines. It is also important to mention that data regarding a data subject's visit to a web page, eg an online pharmacy website, can constitute personal health data. The definition of what constitutes personal health data is extremely broad. See Opinion of AG Rantos in Case C-252/21 *Meta Platforms and Others* (n 32).

[66] MEDS Privacy Policy (n 65).

[67] ibid. As previously mentioned, the scope of personal health data is extremely broad and therefore click data will most probably constitute personal health data. See fn 65 in this text.

[68] Recommender systems are not the same as targeted advertisements as they only recommend products that the user might like based on search queries and do not specifically target users with advertisements. The author has included recommender systems in this part due to their similarity to online advertising. They are fundamental for online platforms, such as online pharmacies, as they are a valuable source of network effects and help platforms to grow. Users provide data to the platform which allows the platform to help new users with suggestions for products based on the observations of past users. They also have the potential to reduce search costs for the users. See Paul Belleflamme and Martin Peitz, *The Economics of Platforms: Concepts and Strategy* (Cambridge University Press 2021) 60.

[69] In certain cases, the consumer will be a patient depending on the type of products that they are purchasing.

4.2 LAWFUL BASES

The first step in the GDPR for processing health data for the purpose of online advertising requires identifying a legal basis under Article 6(1). The possible options are consent,[70] necessary for the performance of a contract[71] and the legitimate interests of the controller.[72] Necessary for the performance of a contract and legitimate interests will be addressed first as in the case of consent, the first and second steps under article 6 and 9 GDPR directly complement each other and therefore will be addressed together.[73]

With regards to necessary for the performance of a contract, some of the requirements have already been addressed in part 3 with reference to AG Rantos' Opinion. In this Opinion, he provides the general requirements for processing personal data for personalised content, such as when using recommender systems.[74] When specifically applying this to personalised advertisements, he mentions that it is important to assess the 'degree of personalisation' of the advertising that is objectively necessary.[75] He states that consideration must also be had to the fact that the data being used in that case came from sources outside the Facebook website.[76] Applying this to online pharmacies and personalised advertisements, this lawful basis could be relied on as long as the data being collected comes from their own websites and not cookies on other websites. However, this lawful basis may be hard to justify as an online pharmacy, unlike Facebook, does not rely on personalised advertisements as the core of its business model.

In the case of legitimate interests, the GDPR has stated that this lawful basis might be used for direct marketing purposes however this concept is quite vague.[77] Furthermore, it is explained in recital 47 that a controller wishing to use legitimate interests as a lawful basis must carry out a balancing test to ensure that the interests or the fundamental rights and freedoms of the data subject do not override the interests of the controller.[78] This balancing test will require a case by case interpretation and means that there is no legal certainty as to whether the GDPR will permit the processing of personal health data for this purpose.

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[70] GDPR, art 6(1)(a).
[71] ibid art 6(1)(b).
[72] ibid art 6(1)(f).
[73] ibid art 6 and 9 GDPR.
[74] Opinion of AG Rantos in Case C-252/21 *Meta Platforms and Others* (n 32), para 56. One important criterion which he identifies is to what extent the processing corresponds to the expectations of an average user. With regards to recommender systems, they are more likely to fall under necessary for the performance of a contract rather than targeted advertisements as they are probably within the expectations of the average user. On the other hand, the Swedish Authority for Privacy Protection has stated that a digital marketplace that wants to suggest products to users based on their search queries cannot rely on necessary for the performance of a contract as this is not objectively necessary for the provision of the service. See Swedish Authority for Privacy Protection, 'Processing of personal data for the provision of online services' <https://www.imy.se/verksamhet/dataskydd/dataskydd-pa-olika-omraden/foretag/behandling-av-personuppgifter-vid-tillhandahallande-av-onlinetjanster/> accessed 29 December 2022.
[75] Opinion of AG Rantos in Case C-252/21 *Meta Platforms and Others* (n 32), para 64.
[76] ibid.
[77] GDPR, recital 47. In the Opinion of AG Rantos in Case C-252/21 *Meta Platforms and Others* (n 32), it states that the notion of 'legitimate interest' is rather elastic and open ended. Direct marketing purposes are also mentioned when addressing legitimate interests (footnote 84 of the Opinion).
[78] GDPR, recital 47.

AG Rantos has elaborated on a set of cumulative conditions to help apply legitimate interests.[79] These conditions were applied by the Court of Justice of the European Union to the equivalent provision before the GDPR was enforced. They require that

> first, the pursuit of a legitimate interest by the data controller or by the third party or parties to whom the data are disclosed; second, the need to process personal data for the purposes of the legitimate interests pursued; and third, that the fundamental rights and freedoms of the person concerned by the data protection do not take precedence.[80]

With regards to the final point involving the balancing of interests, AG Rantos refers to recital 47 of the GDPR which states that it is essential to take into consideration the reasonable expectations of the data subject based on their relationship with the controller.[81] Furthermore, the fact that the legitimate interest is a purely economic interest as well as the potential impact on the user, in that case of Facebook, should be taken into consideration.[82] What AG Rantos' assessment demonstrates is that applying legitimate interests in the context of marketing purposes is far from straightforward. This still leaves room for legal uncertainty, in particular with regards to its application in the context of the online pharmacy market. For example, whether an online pharmacy processing a user's personal non-health data to provide healthcare product recommendations is a purely economic interest requires more clarification as product suggestions may also serve the purpose of improving the health of the users.

Since legitimate interests and necessary for the performance of a contract are only lawful bases under Article 6(1) of the GDPR, it is also necessary to proceed with the second step to identify a lawful basis under Article 9(2). Under the second step, the two relevant lawful bases are explicit consent and data that have been manifestly made available to the public by the data subject.[83] In the case of data manifestly made public by the data subject, this has been addressed by the EDPB in the context of targeted advertising.[84] Here the EDPB states that this assessment requires a case-by-case review and that the word 'manifestly' entails a high threshold for relying on this exemption.[85]

Manifestly making data available to the public has also been addressed in AG Rantos' Opinion in a similar context.[86] AG Rantos considered whether visiting or clicking buttons integrated on websites or apps, such as dating websites/apps, which reveal special categories

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[79] Opinion of AG Rantos in Case C-252/21 *Meta Platforms and Others* (n 32).
[80] ibid para 59. For an understanding of how to apply these provisions, see paras 60-66.
[81] ibid para 62.
[82] ibid.
[83] The other possible options under Article 9(2) GDPR are reasons of substantial public interest or for the provision of health or social care or treatment. To argue that advertising products to consumers falls within these lawful bases is questionable. Furthermore, they both establish that the processing must be 'necessary' for these reasons and arguing that advertising is 'necessary' is unlikely to succeed. See Article 9(2)(e) for data made manifestly public by the data subject.
[84] European Data Protection Board, 'Guidelines 8/2020 on the targeting of social media users' [2020]. Here the EDPB defines the targeting of social media users as including personalised advertising.
[85] ibid 35. The EDPB also lists several elements that are relevant when carrying out an assessment such as the nature of the social media platform and whether it is intrinsically linked with connection with close acquaintances (eg online dating platforms).
[86] Opinion of AG Rantos in Case C-252/21 *Meta Platforms and Others* (n 32).

of personal data about the data subject, can be considered manifestly making data available to the public. He provides an interesting assessment and interprets the adverb 'manifestly' to require the data subject to be *fully aware*, by an *explicit act*, that he or she is making sensitive personal data public.[87] Furthermore, he mentions that since making data manifestly public is an exception to the general prohibition under Article 9(1) GDPR, the application of the provision should be applied stringently.[88] AG Rantos does not however specifically address the notion of 'public' in this context although he mentions the term 'general public'[89] and not a specific group of people, even if they are part of the general public. Finally, he concludes in his reasoning that visiting websites or apps is not manifestly making data public since this information is only available to the administrator of the website.[90] With regards to clicking on buttons integrated into the websites or apps, he states that although the data subject is clearly expressing their wish to share certain sensitive information about themselves to the public outside the website/app, this is done with the intention of reaching a specific group of people and not the general public as a whole.[91]

AG Rantos' reasoning regarding visiting websites/apps is quite logical due the data being available only to the administrator and not the general public however his assessment regarding integrated buttons is more questionable. In the case being addressed, this was in the context of Facebook like and share buttons being integrated into third party websites/apps outside the Facebook webpage.[92] AG Rantos' reasoning casts some doubts as an individual should be fully aware that by clicking a like button on a dating website, there runs the risk that they are revealing sensitive information about themself to the general public. The only reason that this would not be the case is if only the friends of the individual who were signed up on Facebook were able to see the like click but normally anyone, in particular Facebook users in general, can see the like clicks on third party websites.[93]

On a final note, this Opinion still leaves questions unresolved such as, for example, whether an individual leaving a comment on a dating website falls under manifestly making sensitive personal data available to the public. The EDPB states that an individual explicitly stating on their social media page for example that they are a member of a political organisation is considered manifestly making data public however in this scenario, the individual has simply commented and has not mentioned their sexual orientation.[94] Could the difference be that the individual, in the case of actively writing a post, is 'fully aware' that it would be made available to the general public whereas clicking a like button is not? Or is this also a case of not being 'fully aware' since leaving a comment is not the same as explicitly stating your sexual orientation? There is still ambiguity in this regard and further clarification is required.

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[87] ibid para 42.
[88] ibid.
[89] ibid para 44.
[90] ibid para 44.
[91] ibid.
[92] Opinion of AG Rantos in Case C-252/21 *Meta Platforms and Others* (n 32) para 44. See footnote 54 of the Opinion.
[93] The EDPB states that elements such as the accessibility of the page where the sensitive data is published and whether the data subject has published the sensitive data him or herself should be taken into consideration. See EDPB, 'Guidelines 8/2020 on the targeting of social media users' (n 84) 35.
[94] EDPB, 'Guidelines 8/2020 on the targeting of social media users' (n 84) 32. Here the EDPB defines the targeting of social media users as including personalised advertising.

With regards to consent, this is probably the most plausible lawful basis due to the uncertainties surrounding manifestly making data public.[95] The EDPB has addressed consent for the processing of special categories of data, which includes health data, for targeting social media users.[96] The EDPB in its guidelines shows particular concern for the processing of special categories of data for advertising although it does suggest the legality of this practice under the GDPR.[97] In order to process special categories of data for advertising, the EDPB states that the controller will need to identify a lawful basis under Article 6 of the GDPR as well as an additional lawful basis under Article 9(2) GDPR.[98] With regards to the lawful bases under Article 9(2), it identifies explicit consent as a valid option.[99]

In the context of the online pharmacy market, it is relevant to point out that the EDPB also permits explicit consent as a lawful basis for using inferred or combined special categories of personal data to categorise individuals for targeted advertisements.[100] This would suggest that as long as the customer has provided explicit consent, personalised advertisements for non-prescription medicines may be based on inferences regarding the health status of an individual from observed data. Allowing online pharmacies to infer the health status of an individual is however controversial as it involves profiling. Separate explicit consent should therefore be required both for processing personal health data provided by the data subject to the online pharmacy and for any processing for the purpose of inferring the health status of data subjects. For example, a data subject may not object to an online pharmacy processing personal health data on their prescriptions for offering targeted advertisements. However, the data subject may be less comfortable with the online pharmacy inferring their health status based on additional data they collect such as the supplements and food products they consume.[101] This is an important distinction as using personal data to create inferences regarding the health status of an individual involves profiling which can result in a significant violation of an individual's fundamental right to privacy.

In order to obtain explicit consent, it will have to be obtained with strict adherence to regulations and guidelines. One interpretation of explicit consent in the context of an online pharmacy market processing personal health data can be derived from the EDPB guidelines on consent under the GDPR.[102] Although these guidelines do not refer to health data and online advertising, they at least provide some understanding of the expectations of EU regulators when obtaining explicit consent. Examples provided for correctly obtaining explicit consent are to create 'Yes' and 'No' checkboxes which clearly state that 'I, hereby, consent to the processing of my data (for the purpose of) […].'[103] Additionally, a two-step verification can also be used which firstly provides the data subject with an email that allows

[95] See Shop Apotheke's Privacy Policy (n 59). Shop Apotheke, for example, uses consent as a lawful basis for processing of personal data regarding certain products or marketing campaigns.
[96] EDPB, 'Guidelines 8/2020 on the targeting of social media users' (n 84) 9. Here the EDPB defines the targeting of social media users as including personalised advertising.
[97] ibid 5.
[98] ibid 30.
[99] ibid.
[100] ibid 32. The EDPB provides an example such as inferring someone's state of health from the records of their food shopping combined with data on the quality and energy content of foods.
[101] EDPB, 'Guidelines 8/2020 on the targeting of social media users' (n 84).
[102] EDPB, 'Guidelines 05/2020 on consent under Regulation 2016/679' (n 45).
[103] ibid 21.

them to accept the purpose of processing and secondly provides them with a verification link that must be clicked, either via SMS or with a verification code.[104]

Although these guidelines are reasonable, further clarifications are required. With regards to statements such as "'I, hereby, consent to the processing of my data (for the purpose of) […]', more detailed examples are necessary as data subjects may not fully understand the complexity of the processing of their personal health data for online advertising. Online pharmacies may for example create ambiguous statements when requesting a data subject to provide explicit consent in order to base targeted advertising on inferences regarding their individual health status. The average user of an online pharmacy may not understand the implications of granting consent for this type of processing. Therefore, more concrete examples could be provided by the EDPB and data protection authorities on how to define the different marketing purposes for processing personal health data.

Another potential source for addressing the use of health data for advertisements is the EU Commission's Draft Code of Conduct on privacy for mobile health applications.[105] This document, which has been criticised and is still not final, addresses the question of how mobile health apps can show advertisements in its app.[106] Firstly, it requires that the use of advertisements must be clearly authorised by the user prior to the app being installed.[107] Secondly, it requires that consent be obtained either through an opt-out or opt-in option depending on the context.[108] If the app uses contextual advertising shown in the app, meaning without sharing personal data to a third party and does not require the processing of information specifically linked to an individual, then a prior opt-out consent option may be provided to the customer.[109] However, in the case that the advertising uses personal data which is shared to a third party or that personal data is used to create user profiles across multiple apps and services, or because data concerning health is processed to target customers, then prior opt-in consent must be obtained.[110] Furthermore, this consent must be explicitly given by the data subject.[111]

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[104] ibid.

[105] European Commission, 'Draft Code of Conduct on privacy for mobile health applications' [2016]. <https://digital-strategy.ec.europa.eu/en/library/code-conduct-privacy-mhealth-apps-has-been-finalised> accessed 29 December 2022. It is important to note here that this Draft refers to Article 29 Working Party's Opinion 2/2010 on online behavioural advertising suggesting that the Commission still considers this Opinion to be relevant.

[106] Osborne Clarke, 'mHealth apps: The Code of Conduct on Privacy, explained' (*Osborne Clarke*, 18 July 2018) <https://www.osborneclarke.com/insights/mhealth-apps-the-code-of-conduct-on-privacy-explained> accessed 15 November 2022.

[107] European Commission, 'Draft Code of Conduct on privacy for mobile health applications' (n 105) 13. Note here that this is following the same requirements in Article 29 Working Party's Opinion 2/2010 on online behavioural advertising which establishes the need for *prior* explicit consent.

[108] ibid.

[109] ibid. The Commission uses an example of an app that monitors blood sugar concentration levels for diabetes patients. If ads are placed on the app for products to help diabetes patients and these ads are not based on specific blood sugar measurements of a customer, this will only require prior consent with an opt-out option. It is important to mention that explicit consent is not needed as there is no processing of health data since, although these ads target patients with health products, they are general ads based on the context of the app and not on the individual's health data.

[110] ibid.

[111] ibid.

If we apply this in the context of the online pharmacy market, should online pharmacies wish to implement targeted advertising using personal data from their customers, they would be able to do so as long as, prior to registering, there is an opt-in consent option demonstrating that the customer has actively chosen to tick the box. Furthermore, by drawing upon the previous example found in the EDPB guidelines on online advertising, explicit consent should also be obtained by using a clear statement stating that 'I, hereby, consent to the processing of my data (for the purpose of) […]' with an additional two-step verification procedure through email.

With regards to the various legal bases in the GDPR, (explicit) consent should be the preferred option for processing personal health data for online advertising as relying on necessary for the performance of a contract, legitimate interests and making data manifestly available to the public are more problematic due to the uncertainty regarding their application. It is important however to emphasise the potential benefits of targeted marketing as providing personalised content may improve the overall experience of the user of an online pharmacy service.[112] Furthermore, personalised recommendations of health products relying on personal health data can also have a public health benefit since citizens can receive suggestions based on their previous or current illnesses. Recommending health products can for example prevent risks of negative reactions to certain medicines as well as providing additional benefits to patient treatment.[113] Yet, due to the significant risk to the individual's fundamental right to privacy and the fact that the interest that is being balanced against this is primarily of a private nature, (explicit) consent should be the preferred option.[114] Furthermore, the possibility of allowing a data subject to provide (explicit) consent ensures that the efficiencies from recommending products are possible but only when the data subject is fully aware.

It is important to note that (explicit) consent also has its risks since the data subject cannot feel compelled to provide consent.[115] Due to these risks, online pharmacies may refrain from processing personal health data for online advertising altogether. To ensure that data subjects are protected but also that online pharmacies continue to offer the possibility of more personalised content, providing clear guidelines on how to obtain (explicit) consent for processing personal health data for online advertising is recommended. In particular, it is advisable to emphasise that (explicit) consent *must* be clearly and specifically requested for each separate purpose, as suggested above, and that the purposes for processing are written in layman's terms. It may also be a good suggestion to advise online pharmacies to incorporate a clearly visible notice on their privacy policy stating that the data subject is not obliged in any way whatsoever to provide (explicit) consent for the processing of their personal health data for online advertising and that refusing to do so will not have any

[112] See fn 68.
[113] See above section 4.1 on recommender systems.
[114] AG Rantos states that in the case of personalised advertising as a legitimate interest, the purely economic nature of the processing should be taken into consideration. AG Rantos considers that personalised advertising is of a purely economic nature however this might not be entirely true when recommending health products. See Opinion of AG Rantos in Case C-252/21 *Meta Platforms and Others* (n 32), para 64.
[115] See fn 45.

significant impact on the quality of the service being provided.[116] These suggestions may help to minimise the risk that the data subject is unaware of what they were consenting to.

In the case of Swedish law, pharmacies can process personal data, even if not within the standard activities of a pharmacy, if the data subject has provided explicit consent.[117] The activities listed in Swedish law, where processing of data for pharmacies is valid, are for example the dispensing of prescribed medicinal products, health-related customer service, systematic and continuous development and quality assurance of outpatient pharmacies and administration, planning, monitoring and evaluation of outpatient pharmacy activities and the production of statistics.[118] Advertising is not included in this list although one could argue that the purpose is a health-related customer service in the case that an online pharmacy offers the patient additional products that could aid in their treatment. Lastly, the Swedish Data Protection Authority has specifically addressed processing for behavioural advertising.[119] In this context, the authority addresses necessary for the performance of a contract although it generally dismisses this lawful basis for behavioural advertising.[120] Furthermore, it states that relying on the fact that personalised advertising indirectly finances the service is not sufficient to rely on this lawful basis.[121]

5 PROCESSING PERSONAL HEALTH DATA FOR SCIENTIFIC RESEARCH

5.1 PURPOSE

Scientific research purposes are also a way for online pharmacies to extract value from the health data they collect. Over recent years, Big Data[122] for scientific research is becoming increasingly more valuable due to advancements in machine learning and artificial intelligence. Now more than ever before, online companies are able to access and process enormous quantities of quality data from consumers on an ongoing basis. The benefits for public health research are immense and can help pharmacies, physicians and pharmaceutical companies provide more accurate treatments for patients.[123] For example, in the area of mobile health (mHealth), the ability to extract additional conclusions from previously unrelated data sets will give researchers new insights for medical research.[124] By combining big data sets, researchers can link certain diseases such as obesity, cardiovascular or

[116] There will always be a deterioration in the quality of the service if you don't provide your personal data since your experience will be less personalised, in particular with regards to recommender systems. Therefore, the word 'significant' is suggested.
[117] 6 § Paragraph 2 of the Pharmacy Data Act (2009:367).
[118] ibid 7 §.
[119] Swedish Authority for Privacy Protection, 'Processing of personal data for the provision of online services' <https://www.imy.se/verksamhet/dataskydd/dataskydd-pa-olika-omraden/foretag/behandling-av-personuppgifter-vid-tillhandahallande-av-onlinetjanster/> accessed 29 December 2022
[120] ibid.
[121] ibid.
[122] PGEU, 'Position Paper on Big Data & Artificial Intelligence in Healthcare' (n 18) 3. According to the PGEU, 'In healthcare, Big Data refers to large routinely or automatically collected data, which is electronically stored. This data can be reused and comprise links among existing databases to improve health system performance'.
[123] ibid 5.
[124] European Data Protection Supervisor, Opinion 1/2015, 'Mobile Health, Reconciling technological innovation with data protection' [2015] 9.

depression to data obtained from wearable devices such as human behaviour, lifestyles, geographic area etc.[125] Pharmacists also have an important role in mHealth and even eHealth as more and more patients are asking for advice on how to interpret personal health data they acquire from various sources such as media, the internet and mobile apps.[126] This requires the pharmacist to interpret personal health data through wearable devices and digital points-of-care tests which have an extremely important role in early detection of undiagnosed chronic disease and potential adverse events and also the monitoring of adherence and effectiveness of therapies.[127]

The potential for collecting valuable research data for online pharmacies is infinite. Through the collection of these data, online pharmacies together with scientific researchers can mine large data sets to determine the most effective treatments for specific conditions, identify certain patterns of drug side effects and also patterns of hospital readmissions.[128] For example, a pharmacy could use prescription data to identify and take action against prescribers who exhibit extreme patterns of use of 'high-risk drugs'.[129] This could be done by comparing this information with what the average prescribing of those drugs is in a geographic area. Once the prescribers who are prescribing excessive amounts of 'high-risk drugs' are identified, they may be contacted to ask for explanations as to why they do so and if an insufficient explanation is provided, an online pharmacy could choose not to fill prescriptions issued by these providers. It should be noted here that the possibility of not filling prescriptions of certain providers might be problematic under the laws of Member States in the EU. In Sweden, there is a legal obligation for pharmacies to supply all prescription medicines as soon as possible.[130] Choosing to not fill certain prescriptions will likely infringe this law.

Further uses of personal health data for scientific research include analysing health data gathered from patients to predict whether they might not adhere to their prescribed medicines. Express Scripts, one of the largest pharmacy benefit managers in the United States, collected 22 million gigabytes of healthcare data from 83 million patients to identify whether they were at risk of non-adherence.[131] By identifying multiple dimensions of variables that can influence adherence such as drug related characteristics (side effects experience or physician experience with drug), factors related to the condition itself (patient tenure or adherence to other drugs), healthcare system factors (expertise of physician or dispensing pharmacy), and socio demographic and patient factors (demographics or household stability), Express Scripts was able to identify patients at high risk of non-adherence.[132] If a patient was at risk of non-adherence, Express Scripts would provide

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[125] ibid.
[126] PGEU, 'Position Paper on Big Data & Artificial Intelligence in Healthcare' (n 18) 3.
[127] ibid.
[128] Carolyn Ma et al, 'Big data in pharmacy practice: current use, challenges, and the future' (2015) 4 Integrated Pharmacy and Research Practice PL 91, 92.
[129] ibid 94. This study was carried out by CVS Pharmacy in the US which used two 2 years worth of data to identify and take action against prescribers who exhibited extreme patterns of use of 'high- risk drugs'. CVS then elected not to fill the prescriptions of certain prescribers that could not justify these extreme patterns.
[130] See fn 39.
[131] Lawrence (n 24).
[132] Jason Hichborn et al, 'Improving patient adherence through data-driven insights', (*Mckinsey*, December 14, 2018) <https://www.mckinsey.com/industries/life-sciences/our-insights/improving-patient-adherence-through-data-driven-insights> accessed 15 November 2022.

personalised interventions by assigning the patient to a therapeutic resource centre where groups of pharmacists and nurses with disease specific experience were on hand to provide expert advice via telephone on medicine adherence.[133] Express Scripts claims that for hepatitis C patients, the support it provided has cut that rate of non-adherence to curative treatment from 8.3% to 4.8% saving approximately 30,000 dollars in medicine costs for patients.[134] It also claims that by using over 300 factors to predict patient adherence for more than 12 different diseases including diabetes and high blood pressure, it has managed to obtain a 94% accuracy rate in its predictions.[135]

With regards to the destination of health data for scientific research, it is not always the case that online pharmacies will have to outsource it to specialised life science companies or academic institutions. This will provide significant competitive advantages in the case that the research is not shared with rivals. In the case of Big Tech companies, Google, through its comparative online shopping services for pharmacies and Amazon, through its online pharmacy service, will be able to collect and use valuable research data internally to perform their own studies on health-related issues. Alphabet, Google's parent company, already has its own life science companies called Verily and Calico. Although recently disbanded, Amazon had potentially entered the life science industry by partnering with Berkshire Hathaway and JP Morgan to reportedly achieve a better satisfaction of their respective workforces.[136] Furthermore, in 2021, Jeff Bezos invested in a biotech startup called Altos Labs that studies human ageing.[137] Concerns have been raised regarding Big Tech companies collecting data for scientific research. Their ability to construct large repositories of data on public health, fitness, genomic and health records and thus control and establish the rules of access to large-scale databases could allow them to reshape the domain according to their values and interests.[138] Furthermore, the large data sets they collect on individuals' health and lifestyle could result in significant risks to privacy.[139]

5.2 LAWFUL BASES

It is important to note that when dealing with personal data being processed for the purpose of scientific research, there are two types of data usages. The importance of making this distinction is that depending on the type of use, the lawful basis will be different.[140] In the first case, there is primary use which means that personal health data is directly collected for

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133 Lawrence (n 24).
134 ibid.
135 ibid.
136 Caterina Lucchini, 'Amazon's first steps into the business of life sciences' (*Pharma World* 13 April 2018) <https://www.pharmaworldmagazine.com/amazons-first-steps-into-the-business-of-life-sciences/> accessed 15 November 2022.
137 Antonio Regalado, 'Meet Altos Labs, Silicon Valley's latest wild bet on living forever' (*MIT Technology Review,* September 4 2021) <https://www.technologyreview.com/2021/09/04/1034364/altos-labs-silicon-valleys-jeff-bezos-milner-bet-living-forever/> accessed 15 November 2022.
138 Luca Marelli, Giuseppe Testa and Ine Van Hoyweghen, 'Big Tech platforms in health research: Re-purposing big data governance in light of the General Data Protection Regulation's research exemption' (2021) 8(1) Big Data and Society SAGE Journals <https://journals.sagepub.com/doi/full/10.1177/20539517211018783> accessed 15 November 2022.
139 ibid.
140 EDPB, 'Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak' (n 32) 6.

the purpose of scientific research.[141] In the second case, there is secondary use which means personal health data is further processed for another purpose than that for which it was initially collected.[142] Secondary use is the most relevant in the context of data collected by online pharmacies.

With regards to specific lawful bases under the GDPR for the primary use of health data for scientific research, Article 9(2)(j) provides a lawful basis when processing is necessary for scientific research purposes.[143] According to the GDPR, processing of personal data for scientific research purposes should be interpreted in a broad manner 'including for example technological development and demonstration, fundamental research, applied research and privately funded research'.[144] Furthermore, the GDPR specifies that scientific research should also include studies carried out in the 'public interest in the area of public health'.[145] The EDPS has taken its own view regarding the definition of scientific research stating that in order for the research to fall within the specific protection regime of the GDPR, '3) the research is carried out with the aim of growing society's collective knowledge and wellbeing, as opposed to serving primarily one or several private interests'.[146]

These definitions do not mean that private actors, such as an online pharmacy cannot carry out scientific research. Profit-seeking commercial companies and not only academics or public institutions may carry out scientific research according to the GDPR.[147] The key is that the research is carried out in the public interest. Although the public interest requirement is reasonable as large private corporations should not be able to use European citizens' personal health data for their own economic interests, there still exists uncertainty as to how to define public interest in this context. This is problematic as loopholes may be found and can pose significant threats to an individual's fundamental right to privacy. Furthermore, large technology platforms are increasingly becoming gatekeepers of valuable personal health data for scientific research[148] which they may use for objectives that should in fact fall outside the notion of public interest in the GDPR. The current EU legal framework and guidelines are currently insufficient to address these concerns. Vague definitions provided by the EDPS such as when 'research is carried out with the aim of growing society's collective knowledge and wellbeing'[149] do not provide sufficient clarity and therefore further explanations are required.

In this regard, much welcome action is beginning to be taken at a European level to guarantee that health data is used for public interest purposes. The European Health Data Space (EHDS) regulation, currently being proposed by the European Commission, is becoming of increasing relevance in the area of health data and scientific research in

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[141] ibid.
[142] ibid.
[143] GDPR, art 9(2)(j).
[144] ibid recital 159.
[145] ibid.
[146] European Data Protection Supervisor, 'A Preliminary Opinion on data protection and scientific research' [2020] 12.
[147] EDPS, 'A Preliminary Opinion on data protection and scientific research' (n 146) 11. Recital 159 of the GDPR makes reference to Article 179(1) TFEU which allows for private actors to conduct scientific research.
[148] Jane Thomason 'Big tech, big data and the new world of digital health' (2021) 5(1) Global Health Journal, 2 <https://www.sciencedirect.com/science/article/pii/S2414644721000890> accessed 22 December 2022.
[149] EDPS, 'A Preliminary Opinion on data protection and scientific research' (n 146) 12.

Europe.[150] The objective of the EHDS is to create a common space where natural persons can easily control their electronic health data.[151] It will also make it possible for researchers, innovators and policy makers to access this electronic health data in a trusted and secure way that ensures and safeguards the privacy of European citizens.[152] The EHDS will be relevant for large technology platforms as well as online pharmacies as they will be considered data holders and thus will have a duty to make a vast array of electronic health data available on these common spaces.[153] The current EHDS proposal logically does not permit using the health data on these common spaces for advertising purposes.[154] There are of course disadvantages to the EHDS such its potential to limit the incentives of private entities to collect and process vast amounts of valuable health data but this discussion is beyond the scope of this article.

With regards to other lawful bases under the GDPR for the processing of personal health data for scientific research, the EDPS has provided clarifications in one of its preliminary opinions.[155] For example, it mentions explicit consent as a suitable option when processing for scientific research.[156] What is interesting here is that if an online pharmacy relies on explicit consent rather than scientific research under Article 9(2)(j) GDPR, this would suggest that they could use personal health data for research that does not have to serve the public interest. This could result in the exploitation of personal health for questionable purposes. It could also provide them with significant competitive advantages, especially for dominant players, who may use their health data insights to eliminate rivals.[157] Yet if the individual is fully aware of what they are consenting to, from a strictly data protection law perspective, processing for non-public interests should be possible.

In addition to explicit consent, public interest in the area of public health under Article 9(2)(i) GDPR is also mentioned as a lawful basis for processing special categories of personal data for research.[158] This is in line with the GDPR which states that scientific research may include studies in the public interest in the area of public health.[159] Again, there is ambiguity as to the definition of public interest. In this context, the EDPS refers to CJEU case law which states that it must imply a 'pressing social need' as opposed to private or commercial advantages.[160]

On a final note, it is important to mention that although the GDPR permits the use of health data for scientific research purposes other than explicit consent, if an online pharmacy were to rely on legal bases such as scientific research or public interest in the area of public

[150] Commission, 'Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' COM (2022) 197 final.
[151] ibid.
[152] ibid.
[153] ibid. See Article 33(1) of the proposal for an extensive list of electronic health data that must be made available for secondary use. Furthermore, Article 33(3) states that this electronic health data includes data processed for the provision of health or care or for public health or collected by entities and bodies in the health or care sectors.
[154] ibid. See Article 35(c).
[155] EDPS, 'A Preliminary Opinion on data protection and scientific research' (n 146).
[156] EDPS, 'A Preliminary Opinion on data protection and scientific research' (n 146) 19.
[157] This is particularly concerning in the case of Big Tech platforms that are increasingly more present in the healthcare industry.
[158] EDPS, 'A Preliminary Opinion on data protection and scientific research' (n 146) 23.
[159] ibid.
[160] ibid.

health, it is required that there is a provision either in Union law or the national law of the relevant Member States. Therefore, in the absence of Union or national law allowing for scientific research on the basis of public interest or scientific research, an online pharmacy could not rely on these articles for processing personal health data for scientific research purposes. National laws in this context will be discussed at the end of this section with Swedish law as an example.

Regarding secondary use of personal data under the GDPR, this is permitted for scientific research purposes under Article 5(1)(b). This article provides that personal data should only be collected for specified, explicit and legitimate purposes and not for other purposes that are incompatible with the initial purpose of processing.[161] There are however exceptions to this rule. Article 5(1)(b) states that 'further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes'.[162] Therefore, should a controller wish to further use personal data that it has collected lawfully from a data subject for scientific research purposes, this will be a compatible purpose with the initial purpose and will not require obtaining the data subject's consent or identifying a Union or Member State law permitting the secondary use. In order for the processing for the initial purpose to be considered lawful, it will have to comply with the requirements in Article 6(1) and Article 9(2) GDPR.

Although scientific research purposes are considered compatible with the initial purpose of collecting personal data, the GDPR provides some additional requirements in order to ensure sufficient protection for the data subject. These requirements are firstly that the controller of the personal data, when further processing the data, must have 'assessed the feasibility to fulfil (scientific) purposes by processing data which do not permit or no longer permit the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data)'.[163] The wording of this recital is not particularly clear as it is not established whether anonymisation or pseudonymisation is required. In order to find an interpretation, one may look elsewhere in the GDPR. Article 89(1) of the GDPR seems to provide further clarification stating that further processing for scientific purposes should be carried out through anonymisation if possible.[164] In the case that anonymisation is not possible, pseudonymisation should be implemented as a safeguard.[165] Even though an answer exists in the GDPR, the lack of clarity regarding the appropriate safeguards is problematic and requires an explanation from the EDPB. Due to the significant risks to the individual's fundamental right to privacy, it is essential that both the private and public sector are clearly aware of the safeguards that they need to implement and act accordingly.

In addition to the requirement concerning anonymisation and pseudonymisation, the GDPR also requires that when the controller intends to further process personal data for a purpose other than that for which it was collected, the data subject must be provided with

[161] GDPR, art 5(1)(b).
[162] ibid. Recital 50 of the GDPR also confirms this exception.
[163] GDPR, recital 156.
[164] ibid art 89(1).
[165] ibid.

information on the new purpose of processing by the controller.[166] This does not require that the controller provide the data subject with a new lawful basis. The data subject must simply be informed that their personal data will be used for a new purpose which in this case is for scientific research.

Although the GDPR provides guidance on the secondary use of personal data for scientific research purposes, the provisions referred to above do not provide any clarity in the case of personal *health* data. The EDPB has however provided some guidance on this matter. More concretely, the EDPB has addressed the question of whether a healthcare provider collecting personal health data from patients and wishing to use those data for a scientific research project is considered compatible with further processing.[167] Here, the EDPB responds that the controller will have to take into account the lawful bases under Article 9 GDPR since health data is involved.[168] Additionally, the EDPB states that even if the healthcare provider relies on a lawful basis in Article 9 GDPR for the initial purpose of processing, this lawful basis might not extend to the processing of health data for scientific research purposes.[169] What this means is that should a healthcare provider, eg an online pharmacy, collect personal health data for the purpose of prescribing medicines and, rely on for example the provision of health care under Article 9(2)(h) GDPR as a lawful basis, this lawful basis may not extend to further processing for scientific research purposes and therefore an exemption based on Union or Member State's law for the processing of health data for scientific research purposes must be identified. This is in line with Article 9(2) GDPR when processing for scientific research purposes.[170]

The opinion of the EDPB is also in line with the EU Commission's Draft Code of Conduct on privacy for mobile health applications, which addresses personal data collected via my mHealth apps for secondary purposes, eg for 'big data' analysis.[171] As previously mentioned, this Draft Code of Conduct is not a final draft and is still subject to revision.[172] According to the Commission, secondary processing of special categories of personal data for scientific research purposes is compatible with the original purpose for which the personal data was collected if done in accordance with any national or EU level rules adopted for such secondary processing.[173] What this means is that according to the Commission, further processing of personal health data for scientific research purposes is not automatically compatible with the original purpose of processing, as would be the case for personal data under Article 5(1)(b) GDPR, but rather requires the identification of an exemption based on Union or MS law as required in Article 9(2) GDPR for the processing of health data for scientific research purposes.[174]

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166 ibid art 13(3).
167 European Data Protection Board, 'EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research' [2020] 7.
168 GDPR, art 9.
169 EDPB, 'EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research' (n 167) 7.
170 GDPR, art 9(2).
171 European Commission, 'Draft Code of Conduct on privacy for mobile health applications' (n 105).
172 Osborne Clarke (n 106).
173 European Commission, 'Draft Code of Conduct on privacy for mobile health applications' (n 105) 14.
174 GDPR, art 5(1)(b).

The Commission also clarifies in the Draft Code of Conduct that the controller of the personal data must comply with the principle of data minimisation[175] and furthermore, whenever possible, to anonymise or pseudonymise the personal data.[176] This requirement of anonymisation or pseudonymisation is in line with recital 156 of the GDPR.[177] Furthermore, the Draft Code of Conduct provides that processing of non-anonymised and non-pseudonymised data for scientific purposes should only take place if all other options are exhausted.[178] Lastly, it is important to note that the secondary use of personal health data is only possible for historical, statistical and scientific purposes and not for example big data analytics for market research or communication of health data to insurance companies or employers.[179]

The secondary use of personal health data is also addressed in eTRIX's Code of Practice on secondary use of medical data in scientific research projects which is a legally binding document and was funded by the European Union.[180] In this Code of Practice, the objective is to provide a set of harmonised rules in the EU applicable to secondary use of medical data.[181] With regards to secondary use of personal medical data for scientific purposes, this Code of Practice establishes that the data controller, eg an online pharmacy, must verify that the initial data collection complied with all the applicable legal and ethical requirements and that the secondary use meets current legal and ethical standards.[182] Furthermore, the secondary use of medical data in scientific research shall be anonymised and if this is not possible, the reasons must be justified and documented and the data used shall be pseudonymised.[183] Lastly, the Code of Practice states that in the case of secondary use of personal health care data for research projects, it must be based on either explicit consent of the data subject or on a national law or decision by a competent data protection supervisory authority.[184] Again, there is no automatic compatibility for further processing of personal health data for scientific purposes which is in line with the EDPB and the EU Commission's position.

The EDPB, the EU Commission and eTRIX's Code of Practice all provide the same guidelines regarding the secondary processing of personal health data for scientific research purposes. What may be concluded from these legal instruments is that although the GDPR does not require an additional lawful basis for the further processing of non-special categories of personal data for scientific purposes, it does require an additional lawful basis for further processing of personal *health* data for scientific purposes. These lawful bases are either explicit consent or a national law or decision by a competent data protection

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[175] Article 5(1)(c) of the GDPR defines data minimisation as the act of ensuring that personal data collected by a processor is 'adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed'. Data minimisation should be applied for all types of processing.
[176] European Commission, 'Draft Code of Conduct on privacy for mobile health applications' (n 105) 14.
[177] GDPR, recital 156.
[178] ibid.
[179] ibid.
[180] Innovative Medicines Initiative eTRIX, 'Code of Practice on Secondary Use of Medical Data in Scientific Research Projects' [2016]. This project was partly funded by the European Union.
[181] Innovative Medicines Initiative eTRIX (n 180) 9. By medical data, the Code of Practice refers to 'Any data concerning patients or study participants health, collected within the context of health care or clinical trials (e.g., name, address, living conditions, health data, life style habits, social security number, image data…)'.
[182] ibid 13.
[183] ibid 13. The Code of Practice establishes rules for anonymization and pseudonymisation in pages 14 to 16.
[184] ibid 18.

supervisory authority permitting the further processing of personal health data for scientific research. In addition to identifying a lawful basis, a controller must justify that it has done its utmost to try to anonymise and pseudonymise as well as comply with the data minimisation principle. It is important to mention that if an online pharmacy manages to anonymise the personal data it collects from patients, there is no need to identify an additional lawful basis as the GDPR is not applicable to anonymised personal data.[185] An additional lawful basis would only need to be identified if the data could not be anonymised. Lastly, the data subject must also be informed of the new purpose of processing, in this case for scientific research.

The fact that all of the previously mentioned legal instruments provide the same guidelines is a positive note as there seems to be a general consensus at an EU level regarding the requirements for secondary processing of special categories of personal data. Preventing the compatibility possibility under Article 5(1)(b) GDPR from extending to processing special categories of personal health data is a logical measure. Due to the great risk that this type of processing poses for the individual's fundamental right to privacy, allowing for processing for a secondary purpose such as scientific research without obtaining a new legal basis would provide little protection. Although this is a positive requirement, the fact that there still exists ambiguity regarding the definition of scientific research, in particular the notion of 'public interest', means online pharmacies relying on a new legal basis such as scientific research may still find loopholes.

Lastly, with regards to processing personal health data for the purpose of scientific research in Sweden, there is no specific legislation regulating this matter.[186] This issue was discussed in the preparatory works for the Swedish Data Protection Act although it was considered that the GDPR combined with additional safeguards in other national laws were sufficient.[187] In the case of Article 9(2)(j) allowing for processing for scientific research purposes, the requirement of the GDPR for a national law to establish this lawful basis is not fulfilled in Sweden and thus relying on this article is problematic. Some scholars have argued that, generally, the lawful basis for processing special categories of personal data in Sweden is public interest which would include public interest in the area of public health under Article 9(2)(i) GDPR.[188] In the case of private research such as that carried out by pharmaceutical companies, as it is less likely that the public interest requirement will be fulfilled, explicit consent would be the appropriate legal basis.

Explicit consent may also be the only possible legal basis for processing health data for research in Sweden as is established in certain cases under the Ethical Review Act.[189] With regards to secondary use of personal health data for scientific research purposes, Swedish law does not provide any specifications on this matter and therefore the aforementioned interpretation of the GDPR should be relied upon. Finally, the Swedish Data Protection

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[185] Article 2(1) GDPR states that '[t]his Regulation applies to the processing of personal data […]'. Article 4(1) defines personal data as 'any information relating to an identified or identifiable natural person'. Anonymised data does not relate to an identifiable natural person and therefore lies outside the scope of the GDPR.

[186] Magnus Stenbeck, Sonja Eaker Fält, and Jane Reichel, 'Swedish Law on Personal Data in Biobank Research: Permissible But Complex' in Santa Slokenberga, Olga Tzortzatou and Jane Reichel (eds), *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe* (Springer 2021) 385.

[187] Government bill 2017/18:105 (n 56) 96. Preparatory works in Sweden have legal authority.

[188] Magnus Stenbeck et al (n 186) 385.

[189] 1 § of the Ethical Review Act (2003:460) states that the Act 'contains regulations concerning the ethical vetting of research concerning humans and biological material from humans. It also contains regulations concerning consent to such research'.

Authority has provided some vague guidance on the application of Article 9(2)(j) for scientific research purposes in the context of clinical research.[190] For example, when addressing whether the processing can be considered proportionate to the purpose pursued, it states that it is crucial to clearly identify the risk and consequences to the data subject as a result of the processing.[191] Furthermore, it suggests appropriate safeguards that could be used such as opt-out options allowing for the individual to object.[192]

6 CONCLUSIONS

This article has demonstrated the importance of personal health data for the European online pharmacy market and how these data might lead to the potential transformation of the healthcare industry. Through the rich sources of personal health data that they have access to, online pharmacies have the ability to collect vast amounts of valuable health data that if used correctly, can improve the lives of patients all across Europe. For example, we have seen the ability of online pharmacies to detect potential adverse reactions and patients at risk of non-adherence. Furthermore, data from for example patient reviews, patient purchase trends and pharmacist consultations could be extremely valuable for drug discovery and pharmacovigilance. In addition, the ability of online pharmacies to improve the information supply chain throughout the healthcare system to ensure greater coordination and information exchanges between the different actors will have an enormous impact on health care.

This article has also attempted to help maximise these benefits that online pharmacies can create for health care by providing more clarity, and possibly more legal certainty, regarding the legal instruments applicable to the processing of personal health data in the online pharmacy market. By identifying three key scenarios where online pharmacies may process personal data, namely for dispensing prescription medicines, online advertising and scientific research, and interpreting how the GDPR and Swedish law regulates them, this article has intended to provide online pharmacies with more legal certainty thus allowing them to maximise the utility of these health data without infringing the data subject's fundamental right to privacy.

With regards to the current legal instruments analysed in this text and their ability to regulate the processing of personal health data by online pharmacies, this paper has demonstrated that work still needs to be done. Important areas that still need to be developed are for example the processing of personal health data for online advertising. In particular, balancing legitimate interests in the case of personalised advertisements still leaves a lot of room for interpretation in the context of the online pharmacy market. There also exists uncertainties as to what constitutes manifestly making data available to the public when processing for online advertising. Both of these issues pose a serious risk to the fundamental right to privacy of the data subject, in particular due to the sensitivity of the data being processed. Hopefully more clarifications will be provided in future guidelines and case law.

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[190] Swedish Authority for Privacy Protection, 'Yttrande över Personuppgiftsbehandling vid antalsberäkning inför klinisk forskning' <https://www.imy.se/remissvar/personuppgiftsbehandling-vid-antalsberakning-infor-klinisk-forskning/> accessed 29 December 2022.

[191] ibid.

[192] ibid.

National laws can also help to provide more concrete rules applicable to specific sectors. Additionally, the definition of scientific research needs to be further addressed as notions such as 'public interest' and 'with the aim of growing society's collective knowledge and wellbeing' still allow room for loopholes for large corporations serving private interests. The EHDS however is a welcome proposal by the European Commission and will certainly ensure that health data used by online pharmacies can be accessed by everyone and ultimately used for the public interest. National laws implementing the GDPR provisions on processing for scientific research purposes will also play an extremely important role in defining public interest.

On a final note, future legal instruments adopted at an EU and national level regarding the processing of personal health data by online pharmacies should always try to find the right balance in order to facilitate the use of personal health data to transform the healthcare system and at the same time protect the individual's fundamental right to privacy. As has been demonstrated in this article, the potential of analysing vast amounts of personal health data by online pharmacies to innovate and benefit public health is immense. Finding this balance is of course a complex task and will require significant discussions between the private, academic and public sectors.

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WALKING THE LINE IN TIMES OF CRISIS: EU FUNDAMENTAL RIGHTS, THE FOUNDATIONAL VALUE OF THE RULE OF LAW AND JUDICIAL RESPONSE TO THE RULE OF LAW BACKSLIDING

STOYAN PANOV*

The research focus of the paper is on the relation between general principles, fundamental rights and the rule of law in the EU. The role of the judiciary is evaluated through the prism of the jurisprudence of the Court of Justice of the EU (CJEU) with a particular focus on the formula, introduced in the Associação Sindical dos Juízes Portugueses judgment and subsequent decisions by the CJEU, related to the rule of law and independence of the judiciary. A thorough assessment of the relation between fundamental rights, foundational values of the EU such as the rule of law and effective judicial protection through the methodological evaluation of the effectiveness and functional interpretation is included. The core of the research reflects the functional approach of the CJEU with respect to judicial independence as the condition for effective protection of fundamental rights and EU law. Especially crucial is the role of national courts for upholding the rule of law on EU level. The role of the EU's Rule of Law Report mechanism, introduced in 2020, is analysed as judicial independence forms an essential part of the reports. The EU Rule of Law reports serve as illustrations of the underlying problems, related to the rule of law and in particular the independence of the judiciary and effective judicial protection and related enforcement and implementation issues.

1 INTRODUCTION

The rule of law situation in the European Union (EU) and some EU Member States such as Hungary and Poland requires a careful assessment of the relation between general principles, fundamental rights and foundational values of the EU. The added value of the paper is discernible in contextualising the jurisprudential development of the nexus of fundamental rights, general principles and foundational values of the EU with recent mechanisms and responses, pertaining to the rule-of-law crisis. The paper inherently includes a careful examination of the nexus between fundamental rights and the rule of law as a foundational value in the EU legal order. The core of the research focuses on the role of the judiciary through the prism of the jurisprudence of the Court of Justice of the EU (CJEU) with a particular emphasis on the formula, introduced in the *Associação Sindical dos Juízes Portugueses* judgment and subsequent decisions by the Court of Justice in several rule-of-law-related cases. The jurisprudence of the CJEU has been influential in establishing the relevant standards of the independence of the judiciary within the foundational value of the rule of law. The analysis aims to reflect on the

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relation between fundamental rights, foundational values of the EU such as the rule of law and effective judicial protection through the methodological evaluation of the effective and functional and quasi-normative interpretation, amounting to a critical reconstruction of the nexus. Moreover, the research includes a detailed analysis of other cases of relevance, labelled under the term 'horizontal checks' by national courts. In this manner, it will be pertinent to reflect what role the core standards play against the deference to constitutional identity. The paper analyses the role of the European Commission with regards to the Rule of Law Report mechanism introduced in 2020 as judicial independence forms an essential part of the reports. The EU's Rule of Law reports serves an illustration of the underlying problems, related to the rule of law and in particular the independence of the judiciary and effective judicial protection.

The Montesquieu's ideal of the rule of law is even more demanding when already existing threats to judicial independence and separation of branches are amplified and politicised as in the creeping encroachment of unrestricted power when 'the insecurity of arbitrary government, and the discrimination of injustice' erode the rule of law.[1] Constitutions function as checks on the exercise of power since 'these checks reflect a kind of distrust of those who wield the authority of the state, at least with respect to protection of individual rights, and that distrust is at its greatest when it comes to the exercise of executive power'.[2]

The analysis concludes with assessment of the risk function to the independence of the judiciary and the resilience of the constitutional framework on national and supranational levels. The ultimate aim of the paper is to analyse the ongoing rule of law crisis in the EU, as it requires a re-assessment of the conceptual relations between general principles, fundamental rights and the rule of law.

2 OVERVIEW OF FUNDAMENTAL RIGHTS AND THE RULE OF LAW NEXUS IN THE EU LEGAL ORDER

In order to understand the interplay between the relation between general principles, fundamental rights and the rule of law in the EU, the starting point of the inquiry is inherently Article 2 of the Treaty on European Union (TEU) which enshrines the values of the Union:

> The Union is founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities.

The role of Article 2 TEU is fundamental in the application and enforcement of the rule of law in the EU. The normative foundations of the EU legal order, enshrined in Article 2 TEU, are at the apex of categories of norms and sources of Union law.[3] This is also reflected in recent

[1] Judith N Shklar, 'Political Theory and the Rule of Law' in Judith N Shklar and Stanley Hoffmann (eds), *Political Thought and Political Thinkers* (University of Chicago Press 1998) 36.
[2] John Ferejohn and Pasquale Pasquino, 'The Law of the Exception: A Typology of Emergency Powers' (2014) 2(2) International Journal of Constitutional Law 210.
[3] Allan Rosas and Lorna Armati, *EU Constitutional Law: An Introduction* (Hart Publishing 2012) 53.

interpretation by the CJEU in cases concerning the rule of law and fundamental rights in Poland and Hungary.[4]

At first sight, the language of Article 2 TEU seems to differentiate between human rights, including fundamental rights, and the rule of law as a foundational value of the Union. Fundamental rights constitute general principles of EU law, a primary source of EU law, enshrined in the EU's Charter of Fundamental Rights (CFR). Article 6 TEU indicates that 'the rights, freedoms and principles set out in the Charter of Fundamental Rights […] which shall have the same legal value as the Treaties' in terms of hierarchy of sources of Union law.

The codification of fundamental rights in the CFR aims at making the fundamental principles clearer as a primary source of law. Fundamental rights can be envisaged as 'a common set of minimum standards below which human rights conditions must not fall' in the European integration process.[5] Moreover, the fundamental principles of the EU, including the principles of liberty, democracy and respect for human rights as well as fundamental freedoms in Article 6(1) TEU 'form part of the very foundations of the Community legal order'.[6] The foundational values, the general principles of EU law as well as the CFR form part of the primary law of the EU legal order and each continues to exist as a separate and distinct but interrelated source of EU law.[7]

As the language of the TEU does not explicitly state the relation between fundamental rights and the rule of law as a foundational value of the Union, the jurisprudence of the CJEU plays a crucial role in the process of interpretation of the nexus between the two concepts. Although the CJEU was not originally created to adjudicate on fundamental rights issues and as there might be some confusion with respect to the categorisation of the rule of law as a value or a principle under EU law, the Court of Justice has gained more and more relevance in this field throughout the years of European integration.[8]

EU's legal architecture including the Treaties 'constitutes the constitutional charter of a Community based on the rule of law' along with other principles such as direct effect and supremacy of EU law, primacy, effective judicial review, mutual trust and cooperation.[9] Pursuant

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[4] See Stoyan Panov, 'The Effect of Populism on the Rule of Law, Separation of Powers and Judicial Independence in Hungary and Poland' in Jure Vidmar (ed), *European Populism and Human Rights* (Brill Nijhoff Leiden 2020).

[5] Jochen A Frowein, Stephen Schulhofer, and Martin Shapiro, 'The Protection of Fundamental Rights as a Vehicle of Integration' in Mauro Cappelletti, Monica Seccombe and Joseph Weiler (eds) *Integration through Law* (Walter de Gruyter 1986) 231.

[6] Joined Cases C-402/05 P and C-415/05 *P Kadi and Al Barakaat International Foundation v Council and Commission* EU:C:2008:461, para 304. See also Rosas and Armati (n 3) 53.

[7] Rosas and Armati (n 3) 57.

[8] Sonia Morano-Foadi and Stelios Andreadakis, *Protection of Fundamental Rights in Europe: The Challenge of Integration* (Springer 2020) 6, 27. See also, Xavier Groussot, Anna Zemskova and Katarina Bungerfeldt, 'Foundational Principles and the Rule of Law in the European Union: How to Adjudicate in a Rule-of-Law Crisis, and Why Solidarity is Essential' (2022) 1 Nordic Journal of European Law 1, 2.

[9] Opinion 1/91 EU:C:1991:490, para 166. See also, Xavier Groussot and Johan Lindholm, 'General Principles: Taking Rights Seriously and Waving the Rule-of-Law Stick in the European Union' in Katja S Ziegler et al (eds), *Constructing Legal Orders in Europe: General Principles of EU Law, Edward Elgar, Forthcoming*, Lund University Legal Research Paper No. 01/2019 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3361668>

to the primacy principle, established in the *Costa v ENEL* case, the EU law is 'an independent source of law [that] could not […] be overridden by domestic legal provisions, however framed'.[10] Moreover, the EU law is construed as a self-referential system in which the CJEU interprets EU law. Hence, EU law is an independent source of law, characterised by primacy, direct effect, supremacy and exhibiting special characteristics as laid down in Articles 13 to 19 TEU.[11] The primacy of EU law is founded on the *Costa* judgment as well as the subsequent uniform application of EU law across the Member States that relies on while not being undermined by the constitutional traditions of the Member States.[12] As the EU law forms part of the national legal orders, the primacy doctrine resembles 'an incoming tide […] It flows into the estuaries and up the rivers. It cannot be held back'.[13]

The rule of law is indispensable for the integration process and integral to EU's values and their function. The primary sources of EU law require that judicial review must be exercised with respect to the conformity and consistent interpretation of EU law.[14] Pertinent to the function of judicial review and consistent interpretation, application and enforcement of EU law is the role of national courts. As seen below, the independence of the judiciary, including national courts, is indispensable requirement for the rule of law. The rule of law has played an essential role in the development of the EU as well as in practice of the EU institutions and the case-law of the CJEU.[15]

The interplay between foundational values and fundamental rights in the EU legal order can also be examined through the doctrine of constitutionalism. For the purpose of this paper, constitutionalism means the processes of 'locating, allocating, distributing and channelling jurisdiction and powers among specified, "constituted" legal institutions […] [I]t typically also specifies certain fundamental rights of citizens that agencies of government are legally obliged to respect'.[16] Constitutionalism can also be construed as the authority and competence of a government to regulate the rights and privileges of its subjects with clearly established limitations on such powers according to accessible and established set of criteria and rules, which would be particularly relevant for the analysis of judicial independence in some EU Member States.[17] In this sense, constitutionalism inherently incorporates the examination of the legislative and

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accessed 27 January 2023, 25. For the principle of solidarity, see Groussot et al, 'Foundational Principles and the Rule of Law' (n 8) 11.

[10] Case 6/64 *Costa v ENEL* EU:C:1964:66.

[11] See Morano-Foadi and Andreadakis (n 8) 67.

[12] See Case C-11/70 *Internationale Handelsgesellschaft mbH v Einfuhr- und Vorratsstelle für Getreide und Futtermittel (Solange I)* EU:C:1970:114, para 3; Case C-399/11 *Stefano Melloni v Ministerio Fiscal* EU:C:2013:107, para 59; Case C-26/62 *NV Algemene Transport- en Expeditie Onderneming van Gend & Loos v Netherlands Inland Revenue Administration* EU:C:1963:1, para 12.

[13] *HP Bulmer Ltd v J Bollinger SA* [1974] Ch 401, 418. See also, Rosas and Armati (n 3) 66.

[14] Case C-294/83 *Parti écologiste 'Les Verts' v European Parliament* EU:C:1986:166, para 23.

[15] See Laurent Pech, 'A Union Founded on the Rule of Law': Meaning and Reality of the Rule of Law as a Constitutional Principle of EU Law' (2010) 6(3) European Constitutional Law Review 359. See also, Koen Lenaerts, 'The Rule of Law and the Coherence of the Judicial System of the European Union' (2007) 44(6) Common Market Law Review 1625.

[16] Martin Krygier, 'Tempering Power' in Maurice Adams, Anna Meuwese and Ernst Hirsch Ballin (eds), *Constitutionalism and the Rule of Law* (Cambridge University Press 2017) 39.

[17] Dieter Grimm, 'Does Europe Need a Constitution?' (1986) 18(24) Journal of Legal Pluralism 1, 38.

judicial framework with focus on the interaction between the rule of law, fundamental rights and democracy.[18]

The next methodological step is to examine the jurisprudence of the CJEU on the topic. The CJEU has recently linked fundamental rights and the rule of law with a special emphasis on the rule of law incorporating judicial independence and impartiality and effective judicial protection.[19] In this manner, the jurisprudence of the CJEU outlines whether the rule of law as a value of the Union has been used as a compliance tool through the application and enforcement of fundamental rights as analysed in the following section.[20]

3 FROM PORTUGAL THROUGH MALTA AND POLAND TO LUXEMBOURG: THE CJEU'S RULE OF LAW FORMULA

The appropriate analysis of the current interplay between fundamental rights and the rule of law requires an examination of the complex role of the supranational and national judiciaries in the EU legal order. This is so as the judiciary plays a central role in the application and enforcement of EU law. The unique legal order of the EU is established upon the sincere cooperation between the judiciaries of all EU Member States and the supranational Court in Luxembourg: 'the guardians of the legal order and the judicial system of the European Union are the Court of Justice and the courts and tribunals of the Member States'.[21] This is also reflected in the language of Article 19(1) TEU, which stipulates that 'Member States shall provide remedies sufficient to ensure effective legal protection in the fields covered by Union law' through their judiciaries. Moreover, the role of the judiciary on national and supranational levels is affirmed as indispensable to 'the preservation of the very nature of the law established by the Treaties'.[22] In this manner, the functioning of the judiciary, including the independence of the judiciary, would be directly relevant for the effective protection of fundamental rights.

The effective protection of fundamental rights and functioning of the EU legal order require that EU law is not limited or hindered by domestic implementation or other acts of domestic nature as this would directly challenge the EU primacy in national legal orders.[23] The independence of national courts is a condition for the principles of EU law such as primacy, direct effect, and supremacy to function effectively and to avail judicial redress against public authorities. This approach is reflected in a series of recent judgments, in which the CJEU has shed more light on the intricate interplay of fundamental rights, the rule of law and principles of Union law such as independence of the judiciary. In the following sub-sections, three judgments

[18] Sumit Bisarya and W Elliot Bulmer, 'Rule of Law, Democracy and Human Rights: The Paramountcy of Moderation' in Maurice Adams, Anna Meuwese and Ernst Hirsch Ballin (eds), *Constitutionalism and the Rule of Law* (Cambridge University Press 2017) 125.

[19] See Case C-619/18 *Commission v Poland (Independence of the Supreme Court)* EU:C:2019:531, and Case C-192/18 *Commission v Poland (Independence of Ordinary Courts)* EU:C:2019:924.

[20] See Theodore Konstadinides, *The Rule of Law in the European Union: The Internal Dimension* (Hart Publishing 2017) 169. See also, Groussot and Lindholm (n 9).

[21] Opinion 1/09 *Accord sur la création d'un système unifié de règlement des litiges en matière de brevets* EU:C:2011:123, para 66.

[22] ibid para 83.

[23] See Morano-Foadi and Andreadakis (n 8) 31.

are selected as case studies to illustrate the crystallisation of the relevant sources of Union law which concern the independence of the judiciary. The cases were selected in terms of their role and significance in the development of the interpretive design to the nexus of fundamental rights, rule of law and general principles of EU law.

3.1 *ASSOCIAÇÃO SINDICAL DOS JUÍZES PORTUGUESES* FORMULA AND THE FOUNDATIONAL VALUE OF THE RULE OF LAW

The examination starts with the *Portuguese Judges* case as it was one of the first decisions in which the CJEU introduced how the foundational value of the rule of law would be applied and interpreted in its jurisprudence. The case illustrates one of the important elements of the rule of law doctrine, namely the independence and impartiality of the judiciary.

The methodology of the CJEU in assessing judicial independence as necessary to be present and protected by the Member States is founded on delineating the material scope of Article 19(1) TEU, in concrete that 'that provision relates to "the fields of covered by Union law", irrespective of whether the Member States are implementing Union law, within the meaning of Article 51(1) of the Charter'.[24] Article 19 TEU serves as the expanding mechanism of the scope of application of EU law in seemingly internal cases to the Member States, such as related to the overall structure and function of the domestic judiciary.[25] In this manner, the CJEU focuses its interpretation on the justiciability of Article 19(1) TEU with an emphasis on the obligation on Member States to provide effective legal protection. Article 19(1) TEU 'gives concrete expression to the value of the rule of law'.[26] This is the rule of law part of the novel formula: the effective legal protection is a concrete manifestation of the rule of law value and ensures 'compliance of EU law', which constitutes the essence of the rule of law.[27] In this manner, the obligation to provide effective judicial remedies on part of the EU and its Member States anchors the crucial function of the independent judiciary on EU and national levels.

A similar methodology is applied in some infringement proceedings under Article 258 TFEU, related to the independence of the judiciary and effective judicial protection, as in the *Commission v Poland (Retirement Age)* case.[28] The case concerned the compatibility of the Law amending the Law on the system of ordinary courts and certain other laws, resulting in lowering the retirement age for judges and prosecutors in Poland.[29] The Court reads Article 19(1) TEU in light of Article 47 CFR, 'in particular, to the guarantees inherent in the right […] to an effective remedy, so that the first of those provisions entails that preservation of the independence of bodies such as the ordinary Polish courts, which are entrusted […] with the task of interpreting and applying EU law, must be guaranteed'.[30] The effective judicial protection

[24] Case C-64/16 *Associação Sindical dos Juízes Portugueses* EU:C:2018:117, para 29.
[25] Groussot and Lindholm (n 9) 14.
[26] Case C-64/16 *Associação Sindical dos Juízes Portugueses* (n 24), para 32.
[27] ibid para 35.
[28] See *Commission v. Poland (Independence of Ordinary Courts)* (n 19).
[29] ibid paras 16, 24.
[30] ibid paras 85, 98-99.

is a general principle of EU law, enshrined in Article 19(1)(2) TEU.[31] Therefore, in order to rule on the application or interpretation of EU law, domestic courts should 'meet the requirements of effective judicial protection'.[32]

The bridge to the second part of the formula is cast in the affirmation by the CJEU that the rule of law as well as human rights are foundational values, enshrined in Article 2 TEU, which necessitate mutual trust between the courts and tribunals of the Member States.[33] This principle includes trust by all Member States to implement and enforce EU law with respect to the fundamental principles and values of the EU.[34] Moreover, the principle of sincere cooperation in Article 4(3) TEU obliges Member States to ensure the application of and respect for EU law.[35] The responsibility of ensuring judicial review in the EU and respective Member States in line with the duty to provide effective legal protection of individual rights constitutes 'a general principle of EU law stemming from the constitutional traditions common to the Member States, which has been enshrined in Articles 6 and 13 of the [ECHR] […], and […] now affirmed by Article 47 of the Charter'.[36]

The third part of the formula ensures the effective protection through the existence and function of a court's independence per Article 47 CFR. The problem of effective protection of fundamental rights by functioning and independent domestic judiciary is one of the core issues, raised in multiple EU's Rule of Law reports, as seen below. The CJEU correctly identifies that the access to 'an independent and impartial tribunal previously established by law' is linked to the fundamental right of an effective remedy. The independence of the judiciary is applicable to both national and supranational judicial bodies.[37] This is so because the principle of judicial cooperation includes the preliminary ruling mechanism under Article 267 TFEU and, crucially, 'that mechanism may be activated only by a body responsible for applying EU law which satisfies, inter alia, that criterion of independence'.[38] The same approach is affirmed in the infringement proceedings cases where the CJEU proclaims that effective judicial protection requires that maintaining the independence of the judiciary is 'essential, as confirmed by the second paragraph of Article 47 of the Charter'.[39] As judicial independence is grounded in the constitutional traditions of all EU Member States, national courts are incremental for providing effective remedy and implementation of EU law. In a sense, national courts functionally 'speak' the language of the general jurisprudence of EU law and the CJEU. The Court's reasoning reads as a direct reply to the instances of restrictions and even cases of enforcement against domestic judges in Hungary utilising the preliminary ruling procedure as seen below.

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[31] *Commission v Poland (Independence of Ordinary Courts)* (n 19), para 100.
[32] ibid para 103.
[33] *Associação Sindical dos Juízes Portugueses* (n 24), para 30.
[34] See Opinion 2/13 *Adhésion de l'Union à la CEDH* EU:C:2014:2454, para 166.
[35] *Associação Sindical dos Juízes Portugueses* (n 24), para 34. See also, Opinion 1/09 (n 21), para 69.
[36] *Associação Sindical dos Juízes Portugueses* (n 24), para 35.
[37] ibid para 42. See also, Case C-506/04 *Wilson* EU:C:2006:587, para 49.
[38] *Associação Sindical dos Juízes Portugueses* (n 24), para 43. See also, Case C-284/16 *Achmea* EU:C:2018:158, para 3: 'the judicial system as thus conceived has as its keystone the preliminary ruling procedure provided for in Article 267 TFEU'.
[39] *Commission v Poland (Independence of Ordinary Courts)* (n 19), para 105. See also, *Commission v Poland (Independence of the Supreme Court)* (n 19), para 58.

The formula concludes with the requirement for the existence of independent judiciary. In order for the values and principles analysed above to be effective and present in the legal order of the EU, the courts must exercise judicial functions fully autonomously, without being subject to any hierarchical constraints or subordinated to any other domestic body. Moreover, the judiciary should not take 'orders or instructions from any source whatsoever', and the corresponding protection 'against external interventions or pressure liable to impair independent judgment of its members and to influence their decision' shall be ensured.[40]

In the *Retirement Age* case, the Court furthers the analysis by interpreting the internal and external aspects of judicial independence through the principle of irremovability. Dismissal or other disciplinary proceedings with adjudicating functions 'must provide the necessary guarantees in order to prevent any risk of that disciplinary regime being used as a system of political control of the content of the judicial decisions', requiring a procedure incorporating the protections under Articles 47 and 48 CFR.[41] The protection also includes 'types of influence which are more indirect'.[42]

What is noticeable is that the CJEU seemingly stops short of including judicial independence as a general principle on its own standing, but the interpretation clearly indicates that the rule of law emanates from and interwoven with the duty of effective judicial protection by an independent and autonomous national court. The independence of the judiciary is vital for effective legal protection through judicial review in the EU, as Member States are tasked with guaranteeing that national courts are independent, impartial and autonomous.[43] Moreover, the development of the rule-of-law doctrine in the recent CJEU jurisprudence indicates that the effectiveness of remedies, laid down in EU law and the constitutional traditions of all Member States, is not sufficient. There is a structural and functional angle of the independence of the judiciary on national level which is ultimately responsible for upholding effective remedies. In this manner, the independence of the judiciary serves a foundational, primal function in the architecture of the EU legal order. This finding is particularly relevant for the issues, raised on multiple occasions in the EU's Rule of Law Reports in Hungary and Poland.

It is through the rule-of-law-related cases that the CJEU has been able to provide the interpretation of the substantive link between the fundamental rights, general principles and values of the Union with a special focus on the principles of judicial independence, impartiality and irremovability as the core elements and binding mechanisms of the rule of law.[44] Judicial independence thus has played the connecting, binding role of the application of EU law through Article 19 TEU and the enforceability of Article 2 TEU.[45] In this manner, the *Portuguese Judges* case can be seen as a fundamental moment for the effective monitoring of judicial independence on EU level.

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[40] *Associação Sindical dos Juízes Portugueses* (n 24), para 44. See also *Wilson* (n 37), para 51; *Commission v Poland (Independence of Ordinary Courts)* (n 19), paras 109-110.
[41] *Commission v Poland (Independence of Ordinary Courts)* (n 19), para 114.
[42] ibid para 120.
[43] See Grossout and Lindholm, *General Principles* (n 9) 8.
[44] See Dimitry Kochenov and John Morijn, 'Augmenting the Charter's Role in the Fight for the Rule of Law in the European Union' (2020) Reconnect Working Paper No. 11, 10.
[45] ibid 13. See also, Groussot et al, 'Foundational Principles and the Rule of Law' (n 8) 7.

In some of the infringement proceeding cases, the question on the separation of powers is also reviewed by the CJEU. As seen below in the Rule of Law Reports on Poland and Hungary, backsliding of the rule of law and increasing pressure and influence by the executive and legislative branches over the judicial system are outlined as one of the primary systemic problems. For example, the ambiguous role of the Minister of Justice in Poland to decide whether or not to authorise the continuation of judges' appointments beyond the retirement age, based on vague and unverifiable criteria and whose decision is not subject to judicial review, creates reasonable doubt 'as to the imperviousness of the judges concerned to external factors', thus failing to comply with the irremovability principle.[46] Poland fails to fulfil its obligations under Article 19(1)(2) TEU. The interpretation of the CJEU in rule-of-law-related infringement proceedings utilises the rule of law value as a doctrinal anchor. Hence, a mechanism to launch systemic infringement proceedings in situations where the independence of the judiciary is systematically breached, reflected in a pattern of violations, may be appropriate.[47]

3.2 DEVELOPMENTS OF THE *ASSOCIAÇÃO SINDICAL DOS JUÍZES PORTUGUESES* FORMULA: *THE MALTESE JUDGES (REPUBBLIKA)* AND *DISCIPLINARY CHAMBER* JUDGMENTS

If the *Portuguese Judges* case can be considered to introduce a rule-of-law formula, similar in its quintessential value to *Costa* and *Van Gend en Loos*, the *Maltese Judges (Repubblika)* and the *Disciplinary Chamber* judgments may be the mid-point of the journey so far. The Maltese case concerned a referral from the Maltese Constitutional Court on the Prime Minister's discretion to appoint members of the judiciary.[48] The question that the CJEU had to answer was whether the national provision on the appointment of the judiciary was compatible with Article 19(1) TEU and Article 47 CFR, focusing on the principle of effective judicial protection and the right to an effective remedy before a tribunal for rights and freedoms, guaranteed by EU law,[49] as well as whether the national provisions are precluded per Article 19(1) TEU second subparagraph on conferring on the Head of Government a decisive power in the process for appointing members of the judiciary.[50]

The *Portuguese Judges* formula was replicated in the *Maltese Judges* case by reminding that the independence of the courts, inherent in the process of adjudication, forms the essence of the effective judicial protection and the fundamental right to a fair trial under Article 47 CFR as well as the safeguarding of the common values enshrined in Article 2 TEU 'in particular the value of the rule of law'.[51] The two levels of effective protection interact as Article 47 CFR ensures the individual right of an effective judicial protection, stemming from EU law, while

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[46] *Commission v Poland (Independence of Ordinary Courts)* (n 19), paras 124-125. See also, *Commission v Poland (Independence of the Supreme Court)* (n 19), para 96.
[47] See Kim Lane Scheppele, 'Constitutional Coups in EU Law' in Maurice Adams, Anna Meuwese and Ernst Hirsch Ballin (eds), *Constitutionalism and the Rule of Law* (Cambridge University Press 2017) 472-473.
[48] Case C-896/19 *Repubblika v Il-Prim Ministru* EU:C:2021:311, para 10.
[49] ibid paras 38, 40.
[50] See ibid para 47.
[51] ibid para 51.

Article 19(1)(2) TEU works on a macro-level by ensuring that 'the system of legal remedies established by each Member State guarantees effective judicial protection in the fields covered by EU law'.[52] In this manner, the material scope of Article 19(1)(2) TEU is dogmatically affirmed to include the values of judicial independence and effectiveness. The separation of powers plays an essential role in safeguarding the independence of the judiciary as the adoption of judiciary appointments should not create reasonable doubt with respect 'to the imperviousness of the judges concerned to external factors and as to their neutrality with respect to the interests before them, once they have been appointed as judges'.[53]

3.2[a] The Disciplinary Chamber Judgment

The same line of reasoning was applied in the recent *Disciplinary Chamber* judgment with respect to the establishment of two new disciplinary chambers in Poland and the corresponding failures of Poland to fulfil its obligations under Article 19(1)(2) TEU and Article 267(2)-(3) TFEU.[54] The case directly responds to the issues with the independence of the judiciary in Poland, outlined in the EU's Rule of Reports in 2020 and 2021. In the judgment, it was established that the disciplinary regime of the judiciary must meet the guarantees of effective legal protection in the process of challenging the decisions of such bodies as they are 'are essential for safeguarding the independence of the judiciary'.[55] Correspondingly, a body as the Disciplinary Chambers in Poland must offer 'all the necessary guarantees as regards its independence and impartiality'.[56]

In order to determine whether the criteria of the independence and impartiality of the disciplinary body required by EU law were met, the Court of Justice applied a novel methodological approach by analysing the legal framework of the disciplinary bodies within 'the wider context of major reforms concerning the organisation of the judiciary in Poland'.[57] In that regard, it was not surprising that the CJEU took the opportunity to reflect about the compatibility of the overall national rules of the process of appointing judges, *inter alia* at the Disciplinary Chamber level, as the national conditions must comply with the requirements under Article 19(1) TEU.[58]

Moreover, the Court went further in its examination of the judiciary system in Poland and looked at the role and composition of the National Council of the Judiciary (KRS). As seen below, the functioning and composition of the judicial councils is a recurring theme in the EU's Rule of Law Reports. The recent changes in Poland have mandated that the executive and the legislative branches appoint 23 out of 25 members of the KRS. The Court concluded that such changes 'are liable to create a risk […] of the legislature and the executive having a greater influence over the KRS and of the independence of that body being undermined'.[59] *In toto,* the

[52] *Repubblika* (n 48), para 52.
[53] ibid para 57.
[54] Case C-791/19 *European Commission v Poland (Disciplinary Chamber)* EU:C:2021:596, paras 8, 27.
[55] ibid para 61.
[56] ibid para 81.
[57] ibid para 88.
[58] ibid para 95.
[59] ibid para 104.

circumstances around the creation and composition of the Disciplinary Chamber along with the direct and indirect influence of the executive and legislative branches give rise to a reasonable doubt as to the imperviousness of the Disciplinary Chamber which results in such a body 'not being seen to be independent or impartial […]. Such a development constitutes a reduction in the protection of the value of the rule'.[60] The importance of the *Disciplinary Chamber* should not be underestimated as it introduces an institutional assessment of the functioning of the judiciary and its relation with the rule of law and fundamental values of the EU.

3.2[b] The Non-Regression Principle

The most significant contribution of the *Maltese Judges* case to the jurisprudence in the area of the independence of the judiciary and the rule of law is the non-regression principle. The CJEU explicitly reminds the Member States that they have voluntarily committed to the values of Article 2 TEU as early as the accession process to the EU under Article 49 TEU.[61] This is an innovative approach that creates a link to the accession conditionality continuing through the commencement of the membership in the Union. The non-regression principle stipulates that '[a] Member State cannot therefore amend its legislation in such a way as to bring about a reduction in the protection of the value of the rule of law, a value which is given concrete expression by, inter alia, Article 19 TEU'.[62] Crucially, any regression in the laws on the organisation of the judiciary is prohibited as such 'negative development would undermine the independence of the judiciary'.[63] In this manner, the membership of the Union necessitates a progressive protection of the rule of law and precludes backsliding. Moreover, the non-regression principle directly responds to the convenient hiding behind the membership in the EU once a State joins the EU if backsliding of the rule of law occurs. In other words, the value of the rule of law is foundational and characteristic for the EU State from the start of the accession period and continuing through the EU membership with a clear reminder that once achieving a membership status cannot result in deviation from and erosion of the foundational values of the Union. To the contrary, the membership in the EU requires progressive abidance and implementation of the Union's values.

The CJEU affirmed the quintessential role of the rule of law as a foundational value in its February 2022 *Budget Conditionality Mechanism* judgment. The case dealt with the recently introduced general regime of conditionality for the protection of the Union budget and the rule of law.[64] The CJEU affirmed that the EU can implement protective and preventive mechanisms, as the rule of law and solidarity among Member States solidifies the trust between them. This is so because the respect for the rule of law and the other values in Article 2 TEU are at 'the very

[60] *European Commission v Poland (Disciplinary Chamber)* (n 54), para 112.
[61] *Repubblika* (n 48), para 61.
[62] ibid para 62.
[63] ibid para 63. See also, Joined Cases C-354/20 PPU and C-412/20 PPU *Openbaar Ministerie (Indépendance de l'autorité judiciaire d'émission)* EU:C:2020:1033, para 40.
[64] Joined Cases C-156/21 and C-157/21 *Hungary and Poland v European Parliament and Council of the European Union* EU:C:2022:97.

identity of the European Union as a common legal order'.[65] Moreover, the rule of law is 'a value common to the European Union and the Member States which forms part of the very foundations of the European Union and its legal order', imposing a duty on the EU Member States to abide by that constitutive value.[66] What is noticeable here is that the CJEU thickens the rule-of-law normative approach by explicitly linking it to the protection of fundamental rights. Through its jurisprudence, the Court solidifies the non-regression principle as the foundation for offering a response to the backsliding practices in some EU Member States.

The non-regression principle reasoning was affirmed in the *Disciplinary Chamber* judgment as 'any regression of [Member States'] laws on the organisation of justice is prevented, by refraining from adopting rules which would undermine the independence of the judges'.[67] The interpretation of the Court unambiguously established the scope of 'courts and tribunals' to include Disciplinary Chamber models to fall under the remit of Article 19(1) TEU along with Article 47 CFR in order for those courts to meet the requirements of effective judicial protection.[68] In essence, one ponders whether after the *Maltese Judges* and *Disciplinary Chambers* judgments, domestic judges can disapply or set aside any provision of national law, including constitutional clauses or other legislative or normative acts of general or specific application, based on the principle of supremacy,[69] especially in the scope of Article 19(1)(2) TEU - Article 47 CFR.

Another interlinked significant institutional point, raised in the *Disciplinary Chamber* case, concerns the organisation of the judiciary at Member State level and the non-regression principle. In this manner, the Court fine-tunes the principle. It is undisputed that the organisation of justice falls within the Member States' competences including various disciplinary designs and regimes on members of the judiciaries with the proviso that the Member States must safeguard 'the independence of the courts called upon to rule on questions concerning the application or interpretation of EU law, in order to ensure the effective judicial protection […] required by the second subparagraph of Article 19(1) TEU'.[70] In that vein of reasoning, the disciplinary regime must not be used as a façade for political control or pressure on judges, and 'the disciplinary liability of judges should be limited to entirely exceptional cases […] and be governed […] by objective and verifiable criteria' in order to avoid any risk of external pressure on the content of judicial decisions.[71]

The language by the Court of Justice concerning the protection of imperviousness of the judges against external pressure and deterrent effect, which may affect the neutrality of the judges, is categorical and absolute.[72] The normative context of a vaguely phrased discretionary power of the head of the Disciplinary Chamber falls within the ambit of Article 47(2) CFR as judges must exercise their competence to interpret and apply EU law without the risk of the

[65] *Hungary and Poland v European Parliament and Council of the European Union* (n 64), para 127.
[66] ibid para 128. See also, Groussot et al, 'Foundational Principles and the Rule of Law' (n 8) 2.
[67] *European Commission v Poland (Disciplinary Chamber)* (n 54), para 51.
[68] ibid paras 55, 59.
[69] See Case C-106/77 *Simmenthal* EU:C:1978:49, para 21.
[70] *European Commission v Poland (Disciplinary Chamber)* (n 54), para 136.
[71] ibid para 139-140.
[72] ibid para 157.

disciplinary regime, especially when investigations against judges can be reopened.[73] Ultimately, the core function of Article 267 TFEU to set up a dialogue between the courts of the Member States and the Court of Justice would be compromised if a national rule exists that impairs the ability of the national court to refer questions for a preliminary ruling, including subjecting national judges to disciplinary proceedings or sanctions due to their decision to refer cases to the CJEU.[74]

As the role of the judiciary within the constitutional structure at domestic as well as EU levels is firmly established and defended in the analysed cases, it is no major leap to conclude that the jurisprudence of the CJEU with respect to the linkage between Article 49 TEU, Article 19(1)(2) TEU and Article 2 TEU is a moment of constitutionalisation of the rule of law as foundational value of the Union and every Member State. The interpretation of the Court here sounds like a solution to the issues, raised in the EU's Rule of Law Reports with respect to the structure and independence of the judiciary. The cases analysed above serve as the normative and functional foundation of the jurisprudence, concerning the nexus between the rule of law, independence of the judiciary and protection of fundamental rights in the EU legal order. The CJEU has been active in securing an institutionalisation of the normative and functional foundation of the rule of law in the EU in order to protect the judiciary from various exogenous pressures and heavy politicisation. The next section introduces another layer to the framework, namely the particular effect of the nexus when fundamental rights in the process of the implementation of the European Arrest Warrant are concerned and the effect of judicial independence in the requesting State.

4 HORIZONTAL CHECK OF JUDICIAL INDEPENDENCE BY NATIONAL COURTS

The above-mentioned cases reached the CJEU through either infringement proceeding, initiated by the Commission, or through the preliminary ruling Article 267 TFEU pathway. This study includes another angle to the independence of the judiciary assessment and its role in the protection of fundamental rights and the rule of law on Union level. This method is labelled as a horizontal check by domestic courts of other Member States vis-à-vis the function of the judiciary in another Member States when it concerns the applicability and enforcement of EU law. It is an important contribution to the protection of the value of the rule of law as it enables national courts of Member States to evaluate other domestic courts in Member States where there are problems with the rule of law and protection of fundamental rights.

4.1 THE EUROPEAN ARREST WARRANT CASES AND THE RULE OF LAW

The leading authority in providing the power of national courts to check the rule of law conditions in other Member States is the *LM* case with respect to the mutual recognition

[73] *European Commission v Poland (Disciplinary Chamber)* (n 54), paras 193, 197.
[74] ibid paras 226-227.

principle in the European Arrest Warrant mechanism.[75] The case concerned the execution of the EAW from Ireland to Poland as LM contended that the legislative reforms in the judiciary in Poland would deny him the right to a fair trial and the extradition would expose him to a real risk of flagrant denial of justice in contravention to Article 6 ECHR.[76] The High Court in Ireland through the preliminary ruling procedure referred the question to the CJEU whether the executing judicial authority needs to make further assessment to the exposure of the relator to the risk of unfair trial where his trial would take place 'within a system no longer operating within the rule of law'.[77] In essence, the CJEU had to adjudicate whether the guarantee of a fair trial under Article 1(3) of the EAW Framework Decision 2002/584 can be upheld in criminal proceedings when there is evidence of a real risk of breach of fundamental rights in a Member State under an ongoing Article 7(1) TEU procedure with respect to Article 47(2) CFR on account of systemic and generalised deficiencies of the independence of the judiciary in the issuing Member State.[78]

The CJEU bases its assessment on a familiar method through the emphasis on the applicability of the principle of mutual trust as Member States shall be considered to be complying with EU law at large and fundamental rights via the principle of mutual recognition, save for exceptional circumstances.[79] The CJEU in July 2018 applies the formula introduced in the *Portuguese Judges* case in early 2018 with respect to the requirement of judicial independence to form part of the essence of the fundamental rights to a fair trial,[80] as the CJEU defines and assesses the impartiality and independence of the judiciary through the prism of the rule of law as a foundational value under Article 2 TEU, specifically expressed in Article 19 TEU and the effective judicial protection under Article 47 CFR. In the application to the particular case, it is inherent in the EAW mechanism that 'the criminal courts of the other Member States […] meet the requirements of effective judicial protection, which include, in particular, the independence and impartiality of those courts'.[81] Hence, the CJEU lays down the conditions under which the EAW executing authorities would determine whether there is a real risk of a breach of the relator's fundamental right to an independent tribunal, *ergo,* a breach of the right to a fair trial, protected under Article 47(2) CFR.[82]

Another pertinent case, dealing with the overall structure and independence of the judiciary, is *XY* judgment of 2022, in which the issue of the fundamental right to a fair trial before a tribunal previously established by law in Poland with respect to the appointment of judges by the recently restructured National Council of Judiciary (NCJ) is at stake.[83] The ultimate

[75] Case C-216/18 *PPU Minister for Justice and Equality (LM)* EU:C:2018:586.
[76] ibid para 16.
[77] ibid para 25.
[78] Article 1(3) of the EAW Framework Decision states: 'This Framework Decision shall not have the effect of modifying the obligation to respect fundamental rights and fundamental legal principles as enshrined in Article 6 of the Treaty on European Union'.
[79] *LM* (n 75), para 36. See also, Case C-404/15 *Aranyosi and Căldăraru* EU:C:2016:198.
[80] *LM* (n 75), para 48.
[81] ibid para 58.
[82] ibid para 59.
[83] Joined Cases C-562/21 and C-563/22 *PPU Openbaar Ministerie (XY)* EU:C:2022:100, paras 14-15.

question that CJEU had to answer dealt with the appointment of members of the judiciary and the conditions under which the transferring authority may refuse to surrender the relator for a custodial sentence, detention order or a criminal prosecution under the EAW where there is a real risk of breach of the person's fundamental right to a fair trial before a tribunal established by law.[84] The case is of particular importance as the CJEU reviewed the conditions of determination of the existence of or in increase in systemic or generalised deficiencies with respect to the independence of the judiciary through the prism of the right to a fair trial before a lawfully established tribunal through an assessment of appointment procedure of judges on domestic level.

The two cases are methodologically important as they utilise a two-prong test of independence and impartiality of the judiciary. The assessment begins with the operation of the system of justice in the receiving Member States, based on 'material that is objective, reliable, specific and properly updated', including information released in a proposal under Article 7(1) TEU proceedings.[85] It is triggered when the issuing Member State is subject to a reasoned proposal for a clear risk of a serious breach of the rule of law under Article 7(1) TEU and the existence of material to indicate that there are systemic deficiencies in the issuing Member State's judiciary.[86] The same first step is affirmed in the *XY* case.[87]

The test, introduced in *Wilson,* with respect to the independence and impartiality of the judiciary is used in the specific context.[88] The external assessment of the independence of the judiciary follows the familiar formula from the *Portuguese Judges*, namely 'the court concerned exercises its functions wholly autonomously, without being subject to any hierarchical constraints or subordinated to any other body and without taking orders or instructions from any source whatsoever'.[89] The objective criterion aims to immunise the concerned domestic court from external interventions and pressure to influence its decisions. It should be noted that in the first prong the assessment of imperviousness of the judiciary is narrowed in its scope to a particular court that participates in the EAW proceedings.

The *XY* case builds on the *LM* first prong assessment by including the possibility for review of the judicial appointment decisions, inherently linked to the requirement for a tribunal previously established by law. Here the Court noted that the 'established by law' ultimately enshrines the rule of law as it directly concerns the judicial appointment procedure, although not every irregularity in the appointment procedure would constitute a *per se* breach.[90] What matters is the overall assessment on basis of evidence that is objective, reliable, specific and properly updated, including relevant factors such as

> constitutional case-law of the issuing Member State, which challenges the primacy of EU law and the binding nature of the ECHR as well as the binding force of judgments

[84] *XY* (n 83), para 39.
[85] *LM* (n 75), para 61.
[86] ibid para 69.
[87] *XY* (n 83), para 52.
[88] *Wilson* (n 37), para 50.
[89] *LM* (n 75), para 63.
[90] *XY* (n 83), paras 70-71.

> of the Court of Justice and of the European Court of Human Rights relating to compliance with EU law and with that convention of rules of that Member State governing the organisation of its judicial system, in particular the appointment of judges.[91]

As the *LM* and *XY* cases concern the AFSJ, it should be noted that the suggested assessment affirms further the equivalence principle, according to which 'save in exceptional circumstances, to consider all other Member States to be complying with EU law and particularly with the fundamental rights recognised by EU law'.[92] However, the recent development in the jurisprudence with respect to the functional review and assessment of the existence of systemic flaws based on substantial grounds for believing so may render cooperation between EU Member States incompatible with EU law in certain exceptional circumstances.[93] In this manner, the assessment is personalised in order to assess the specific conditions in the receiving State.[94]

The second prong is the internal, subjective aspect which concerns the impartiality of the judiciary and the individualised effect on the relator's rights. It guarantees equal distance from the parties and objectivity, for example.[95] The two-prong test requires clear rules as regards 'the composition of the body and the appointment, length of service and grounds for abstention, rejection and dismissal of its members' along with a foreseeable and established disciplinary regime, which is the connection to the rule of law values as enshrined in Article 2 TEU.[96]

The *XY* case similarly applies the second prong in a conjunctive manner with respect to the first prong. The second prong 'individualises' the systematic or generalised deficiencies of the first prong through an assessment of 'a tangible influence on the handling of his and her criminal case'.[97] *In concreto*, the test includes an examination of the existence of substantial grounds for considering that the appointment and composition of the judges is such as 'to affect that person's fundamental right to a fair trial before an independent and impartial tribunal previously established by law […] in the criminal proceedings'.[98]

Although in some criminal proceedings the identity of the judge would not be known at the moment of the transfer of the relator, there are procedural guarantees which can be taken into consideration when evaluating the real risk of the relator's right to a fair trial in the receiving jurisdiction. For example, factors of assessment may include whether there is a procedural possibility to request the rejection of one or more members of the bench for breach of the relator's fundamental rights in the issuing State, and whether it is possible to trigger such a claim for rejection and potential for appeal, based on the available information before the sending

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[91] *XY* (n 83), para 80.
[92] Opinion 2/13 (n 34), para 191.
[93] See Joined Cases C-411/10 and C-493/10 *NS and ME* EU:C:2011:865, para 86 with regard to Dublin III Regulation.
[94] See Morano-Foadi and Andreadakis (n 8) 77.
[95] *LM* (n 75), para 65.
[96] ibid paras 66-67.
[97] *XY* (n 83), para 83.
[98] ibid para 88.

State.[99] The assessment of the real risk of breach of the right to a fair trial before an independent and impartial tribunal established by law is a case-by-case based with respect to the procedure of the appointment of the judge(s), which may include the possibility of the procedure and effective function of the request to reject one or more of the judges to be taken into account.[100]

Upon carrying the test and taking into account the relator's personal situation and nature of the offence, if there are substantial grounds for believing that the relator would run a real risk of a breach of his/her fundamental right to a fair trial, then the surrender or transfer should not continue according to Article 1(3) of the EAW Framework Decision.[101] The threshold for not extraditing the relator is automatically passed if the European Council has adopted an Article 7(2) TEU decision, indicating a serious and persistent breach of the foundational values of the EU in the issuing Member State, including the rule of law, and the Council would suspend the application of the EAW mechanism to the breaching Member State, thus requiring an automatic refusal to surrender on part of the executing authorities.[102]

4.2 ASSESSMENT OF THE 'HORIZONTAL CHECK' APPROACH

The added value of the co-application of Article 19(1) TEU and Article 47(2) CFR per *LM* and *XY* cases has allowed the CJEU to 'wed' the substance of the right with the context of independence of the national judiciary, including a review of the disciplinary and appointment mechanisms. However, a possible critique may include the eventual negative effects of the backsliding in the respective Member States through the inclusion of the 'substantive' Article 19 TEU - Article 47 CFR kind of rule of law.[103] The core of such criticism is that the remedial effect of individual rights is different from addressing systemic deficiencies in the national judiciary system. The *XY* judgment provides the opportunity to clarify the applicable tests when there are systemic and generalised issues with the overall composition of the judiciary and appointment procedure through the lens of the right to a fair trial before an independent and impartial tribunal previously established by law. Moreover, the two-prong test related to the EAW cases shows the CJEU in a restrictive and restrained role. This might be explained by the purpose of the EAW to disallow for impunity hotspots in the EU by complicating the proper functioning of the EAW.

The functional interpretation of the CJEU by putting Article 47 CFR as the contextualising and doctrinal element in expressing a right to an effective remedy and a right to a fair trial in conjunction with Article 2 TEU under the value of the rule of law allows the CJEU to circumvent the restriction imposed in Article 51 TEU. However, such an interpretive approach might limit the applicability of Article 47 CFR as a free-standing provision in order to protect other

[99] *XY* (n 83), paras 90, 99.
[100] ibid para 99.
[101] *LM* (n 75), paras 74, 79.
[102] ibid para 72.
[103] See Kochenov and Morijn (n 44) 11.

fundamental rights, such as the right to privacy or freedom of expression.[104] On the other hand, as seen above in the *LM* case, Article 47(2) CFR played the central role in the adjudication of the case and successfully incorporated it with other rights, fundamental principles and foundational values such as the rule of law.

Another discernible issue is the horizontal assessment that the national courts need to perform according to the two-prong test in *LM* and *XY* cases. The individual assessment of the domestic courts involved in the administration of criminal law and extradition may necessitate detailed knowledge about the structure, organisation and functioning of the judiciary in the issuing State, based on available material. Although it is beyond doubt that 'when the separation of powers is being destroyed in one of the Member States and the independence of the courts is threatened, it would be unreasonable to expect justice in individual cases',[105] the two-step test indicates a more calibrated evaluation.

At first view, this can be criticised as a missed opportunity for the Court of Justice to lay down a more normative-oriented human-rights-oriented approach in the relationship between the presumed mutual trust between the Member States and the fundamental protections under Article 47 CFR. The *XY* case seems to bring the jurisprudence closer to a more normative-oriented approach, linked with the fundamental issue of a fair trial before a lawfully established tribunal. In that case, it is noticeable that the CJEU does not shy away from relying on the standards of the jurisprudence of the ECtHR on the particular issue.[106] This is a welcome development and it would not be surprising if the ECtHR sees an increase of cases on the subject matter of the two-prong test under Article 6 ECHR. Moreover, the recent mechanism of the Rule of Law Reports may aid domestic judges in assessing the overall situation in other Member States as the Reports contain valuable evidence of the state of the art at the current moment with respect to the status of the judiciary.

The assessment and application of the two-prong test above may also politicize the decision-making process of the courts in the sending/executing State.[107] The second prong of the test requires the relator to prove how the systematic breach in the receiving Member State would individually affect his/her rights.[108] However, the CJEU derived its formulation of the standard through analogy from the Article 4 CFR (the prohibition of torture, inhuman and degrading treatment). At first sight, the horizontal nature of the assessment may be compromised and the functioning of the EAW mechanism which is inherently built on the mutual recognition principle would be affected.[109] The counter-factual argument would indicate

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[104] Kochenov and Morijn (n 44) 13. See also, Matteo Bonelli and Monica Claes, 'Judicial Serendipity: How Portuguese Judges Came to the Rescue of the Polish Judiciary: ECJ 27 February 2018, Case C-64/16, *Associação Sindical dos Juízes Portugueses*' (2018) 14(3) European Constitutional Law Review 622, 634.
[105] Kochenov and Morijn (n 44) 15.
[106] See eg *XY* (n 83), paras 78-80
[107] See Kochenov and Morijn (n 44) 15.
[108] Dimitry Kochenov and Petra Bárd, 'The Last Soldier Standing? Courts versus Politicians and the Rule of Law Crisis in the New Member States of the EU' (2019) 1 European Yearbook of Constitutional Law 243, 274.
[109] See Stoyan Panov, 'Harmonize, Recognize or Minimize: A Borderless European Judicial Space? The Application of the European Arrest Warrant and Its Effect on EU Integration' (2014) 3 The Birmingham Journal for Europe.

a one-prong assessment in which national judiciaries that are not independent according to the material available before the authorities of the sending State would constitute a violation of the rule of law value, *ipso* a violation of the right to fair trial. Nonetheless, such a reading would obviate or limit the applicability of the mutual trust principle and may lead to a fragmented regime of 'rule-of-law' courts vs. 'captured' courts. The same interpretation is affirmed in the *XY* case, although the second prong allows for a prospective overall assessment of the possibilities to seek removal of judges, appointed in contravention to the principle of judicial independence and tribunal established by law. It is also doubtful whether Article 47 CFR would be 'clarified' more as a free-standing clause if subsumed within the fundamental value or institutional assessment of the judiciary in the requesting Member State. What is unambiguous is that the CJEU has been consistent in its reliance on a functional interpretation of the rule of law and fundamental rights protections.

5 EFFECTIVE AND FUNCTIONAL INTERPRETATION?

One of the principles of interpretation that the EU has relied upon in the mentioned cases is the functional interpretation to guarantee efficacy of the legal order and the applicability of the corresponding doctrines.[110] Ever since *Van Gend*, the EU legal order has been characterised by the uniform and effective functioning, based on the network of EU's and national courts where the domestic judge is an 'ordinary judge of the Union law'.[111] Article 47 CFR has been essential in determining the effective implementation of the rule of law doctrine in the jurisprudence of the CJEU. Hence, it is pertinent to underline how the CJEU approaches the issue of efficacy and essence of the fundamental right to a fair trial and judicial remedy. The right could be assessed subjectively through the right holder's perception, or objectively, based on the function of the right in the legal order.[112]

The objective institutional approach aims at evaluating whether the essence of the right is impacted to a degree that its meaning is lost for nearly all individuals.[113] A corollary pathway is to examine whether the nucleus of the affected right is compromised to a degree that the limitation would empty of content and casts doubt on the right's existence.[114] Ultimately, the functional approach examines whether the infringed right through an exception or practice is rendered ineffective or close to extinguished, an issue of particular relevance in instances of backsliding of the rule of law.[115] The objective, functional-oriented approach has been utilised in the rule-of-law cases, discussed above. In this manner, the nexus between general principles, fundamental rights and the rule of law as a foundation value of the EU has been primarily a

[110] Groussot and Lindholm, *General Principles* (n 9) 12.
[111] *Simmenthal* (n 69), paras 14–21.
[112] Mark Dawson, Orla Lynskey, and Elise Muir, 'What is the Added Value of the Concept of the "Essence" of EU Fundamental Rights?' (2019) 20(6) German Law Journal 763, 765.
[113] Sébastien Van Drooghenbroeck and Cecilia Rizcallah, 'The ECHR and the Essence of Fundamental Rights: Searching for Sugar in Hot Milk?' (2019) 20(6) German Law Journal 904.
[114] See Koen Lenaerts, 'Limits on Limitations: The Essence of Fundamental Rights in the EU' (2019) 20(6) German Law Journal 779.
[115] *Regner v Czech Republic* App no 35289/11 (ECtHR, 19 September 2017), para 50.

doctrinal construct. The right's violations can be appropriately assessed in a case-by-case manner by taking into account all relevant facts and context.[116] For example, such an approach is evident in the second part of the individual assessment formula in the *LM* and *XY* cases.

Moreover, the CJEU has used the Article 2 TEU - Article 19 TEU - Article 47 CFR pathway as the interpretive design to link the efficacy of fundamental rights and values of EU law in order to expand the scope of protection and application of EU law.[117] The doctrinal inclusion of the principle of effective judicial remedy must be anchored in corresponding practice in the EU and all Member States, which necessitates the independence of the judiciary in the EU legal order. It has been noted that values are difficult to enforce.[118] The CJEU in the *LM* and *XY* cases also designed a two-prong test to examine the breadth and depth of the breach, based on material evidence, related to the independence of the judiciary in Member States. This is important as the analysis of the Court is anchored in a positive, objective assessment of the degree of functioning of the judiciary in other Member States, coupled with the degree of the alleged violation of the particular right from a normative perspective. In this manner, a check is performed on whether the exercise of the particular right is possible whatsoever in the respective legal system, a step prior to assessing whether the right is interfered with or without legitimate reasons to do so.[119] Ultimately, through a functional approach, the CJEU has substantively amalgamated a normative scope of the nexus of the rule of law and fundamental rights, which is evidenced by the reintroduction of the referrals to the jurisprudence of the ECtHR in the *XY* case.

This is the line of reasoning of the absence of or compromised system of a judicial remedy, related to the effective protection of a right under EU law.[120] In other words, the lack of judicial remedy affects the effective judicial protection of the normative essence of the fundamental right.[121] In this manner, the principle of effectiveness may play a similar function as an essence in the protection of the fundamental right in question but also generating a normative justification for an overall value-based protection.[122] For example, the essence approach has been utilised in the *LM* case:

> The requirement of judicial independence forms part of the *essence of the fundamental right to a fair trial*, a right which is of cardinal importance as a guarantee that all the rights which individuals derive from EU law will be protected and that the values common to the Member States set out in Article 2 TEU, in particular the value of the rule of

116 Dawson, Lynskey and Muir (n 112) 770.
117 ibid 767.
118 See Dimitry Kochenov, 'The EU and the Rule of Law - Naïveté or a Grand Design?' in Maurice Adams, Anna Meuwese and Ernst Hirsch Ballin (eds), *Constitutionalism and the Rule of Law* (Cambridge University Press 2017) 425.
119 cf Maja Brkan, 'The Essence of the Fundamental Rights to Privacy and Data Protection: Finding the Way through the Maze of the CJEU's Constitutional Reasoning' (2019) 20(6) German Law Journal 864.
120 See Dawson, Lynskey and Muir (n 112) 773.
121 See Kathleen Gutman, 'The Essence of the Fundamental Right to an Effective Remedy and to a Fair Trial in the Case-Law of the Court of Justice of the European Union: The Best is Yet to Come?' (2019) 20(6) German Law Journal 884.
122 Dawson, Lynskey and Muir (n 112) 774.

> law, will be safeguarded […] the very essence of effective judicial review designed to ensure compliance with EU law is of the essence of the rule of law.[123]

The essence is rooted in the actual and realisable effective protection of fundamental rights and the rule of law. The essence of the fundamental rights is linked to the protection of foundational values of the EU such as the rule of law.

The problem with the functional approach stems from the difficult to synthesise 'one singular essence of the fundamental right to an effective remedy and to a fair trial embodied in Article 47 of the Charter'.[124] Another critique is linked to assessing the complexity of the *LM-XY* two-prong test as the deductive approach seems to be a better fit for the predictable and foreseeable feature of the rule of law in terms of clear and discernible legal expectations.[125] This, however, as pointed above, would lead to the necessity to introduce a convergent, norm-based understanding of fundamental rights and values in all domestic legal orders of the Union, which opens the door of the well-known discussion on the essential principles behind the CFR framework.[126] Nevertheless, the increased cross-fertilisation with number of cases pending before the ECtHR with thematic on the independence of the judiciary and the rule of law may create the needed charge for crystallisation of the nexus through a normative-based approach.

The issue also goes to the heart of European integration: how to achieve the coveted balance between 'supranational regulatory power […] and national democratic and constitutional legitimacy'.[127] The balancing act in the functional effectiveness doctrine lies in the degree the supranational institutions act as principals in the integration process and monitor the Member States as the agents of integration.[128] The empowerment of the national courts through preliminary rulings or directly checking the efficiency of the judicial system in other Member States per *Portuguese Judges* and the *LM* formulas indicates a degree of decentralisation and horizontal check of the applicability of fundamental rights and values of the EU and effectiveness of domestic legal orders within the EU.[129] Such a development is congruent with the functionality approach, outlined above. In this manner, the horizontal scheme of enforcement of EU law is anchored in the ability of domestic judicial authorities to act on behalf of the EU. The *Portuguese Judges, LM* and *XY* cases specify that through the preliminary procedure national courts have an important role in the enforcement of EU law rather than the so-called diagonal application of EU law by the CJEU against Member States.[130] The independence of the

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[123] *LM* (n 75), paras 48, 51.
[124] See Gutman (n 121) 884.
[125] See also, Dawson, Lynskey and Muir (n 112) 771.
[126] See Piet Eeckhout, 'The EU Charter of Fundamental Rights and the Federal Question' (2002) 39(5) Common Market Law Review 945.
[127] Peter L Lindseth, 'Between the 'Real' and the 'Right': Explorations Sling the Institutional-Constitutional Frontier' in Maurice Adams, Anna Meuwese and Ernst Hirsch Ballin (eds), *Constitutionalism and the Rule of Law* (Cambridge University Press 2017) 84-85.
[128] ibid 87.
[129] Koen Lenaerts and Jose A Gutiérrez-Fons, 'A Constitutional Perspective' in Robert Schütze and Takis Tridimas (eds), *Oxford Principles of EU Law* (Oxford University Press 2018) 119.
[130] See Csongor István Nagy, 'The Diagonality Problem of EU Rule of Law and Human Rights: Proposal for an Incorporation *à l'europeenne*' (2020) 21(5) German Law Journal 838, 843.

judiciary assessment on EU and domestic levels creates a spill-over effect on the necessity for national judicial organs to be independent and impartial.[131] In particular, the organs of the Member States, including the judiciary, are obligated to interpret national law consistently with secondary EU law as well as with fundamental rights or other general principles of EU law.[132]

In the above-mentioned cases, the jurisprudence of the CJEU includes in the scope of Article 51 CFR the duty of Member States to enforce the CFR and fundamental rights in their respective domestic legal orders. The unique feature of the EU system is that the protection of fundamental rights and values is assessed through the principle of effectiveness while maintaining the balance of national constitutional identities as the rule of law is a foundational value of all EU Member States.[133] Moreover, Article 4(2) TEU ensures 'the national identities [of the Member States], inherent in their fundamental structure, political and constitutional'. The architecture of the EU legal order envisages a harmonious interpretation of the constitutional traditions of the Member States and the fundamental rights in the CFR as laid down in Article 52(4) CFR. However, the foundational values listed in Article 2 TEU serve as 'super-primary' law as the Article enshrines the ultimate constitutional principles shared in all Member States and the EU.[134] What is unequivocal now is that the crucial role of protection of fundamental rights and foundational values such as the rule of law in the EU is functionally and doctrinally anchored in the jurisprudence of the CJEU.

6 THE ROLE OF THE EUROPEAN COMMISSION AND THE EU'S REPORTS ON THE RULE OF LAW

In order to understand and analyse the relation of fundamental rights and the rule of law, the underlying theme of the EU's Rule of Law Reports is selected as an orienteer and reflection of the issues, related to the rule-of-law backsliding phenomenon. It relates to the overall situation of the rule of law in the EU through the role of the Commission in the recently introduced Rule of Law Report system. The attempt here is not to capture the whole mechanism but to illustrate some of the pressing issues that relate to the rule of law, addressed in the paper above. What is incontrovertible is that the EU's Rule of Law reports since 2020 capture the essential legal problems that have been widely litigated before the CJEU, namely the nexus of fundamental rights protections, the rule of law as a foundational value of the EU as well as the role of the judiciary.

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[131] cf Kim Lane Scheppele, 'Enforcing the Basic Principles of EU Law through Systemic Infringement Actions' in Carlos Closa and Dimitry Kochenov (eds) *Reinforcing Rule of Law Oversight in the European Union* (Cambridge University Press 2016) 105.

[132] See Case C-275/06 *Promusicae* EU:C:2008:54, paras 68-69. See also, Rosas and Armati (n 3) 74.

[133] Bernhard Schima, 'EU Fundamental Rights and Member State Action After Lisbon: Putting the ECJ's Caselaw in Its Context' (2015) 38 Fordham International Law Journal 1097, 1113–14. See also Nagy (n 130) 858.

[134] Rosas and Armati, (n 3) 59. See also, Groussot et al, 'Foundational Principles and the Rule of Law' (n 8) 4.

6.1 OVERVIEW OF THE EU'S RULE OF LAW REPORT MECHANISM

The EU's Rule of Law Report mechanism offers a general and essential snapshot of the current situation in every Member State with respect to the independence of the judiciary among other areas such as anti-corruption framework and media freedom. The EU introduced the Rule of Law Report mechanism in 2020. The report procedure enables the Commission to evaluate every EU Member State on an annual basis as the strengthening of the rule of law is a priority for the effective functioning of the Union. The first report of 30 September 2020,[135] followed by the 2021 Rule of Law report of 20 July 2021[136] and the 2022 Rule of Law report of 13 July 2022[137] affirmed the goal of the EU institutions to reinforce the rule of law through promotion of the value and prevention of rule of law problems. It methodologically focuses on significant developments in four areas or pillars: justice system, anti-corruption framework, media pluralism, and institutional issues linked to checks and balances including Covid-related legislation and practices.[138] The aim is to facilitate cooperation on an inter-institutional level along with the Member States.

For the purposes of this paper, the pillar of the justice system is particularly important. The Commission uses the effectiveness and functionality approach to evaluate if effective judicial review ensures compliance with EU law as a fundamental aspect of the rule of law as it directly refers to CJEU's *Portuguese Judges* and *Commission v Poland* cases as well as more recent cases such as the *Maltese Judges* judgment, addressed in detail above.[139] The Commission looks at data from the Eurobarometer on the perception of the independence of the judiciary as well as various institutional efforts to strengthen judicial independence such as national judicial councils or procedures on appointment of judges. Moreover, the Reports emphasise the safeguards to ensure the sufficient independence of the prosecution from undue political pressure as part of judicial independence.[140]

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[135] European Commission, '2020 Rule of Law Report: The Rule of Law Situation in the European Union' COM (2020) 580 final, 2.

[136] European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: 2021 Rule of Law Report on the Rule of Law Situation in the European Union' COM (2021) 700 final.

[137] European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: 2022 Rule of Law Report on the Rule of Law Situation in the European Union' COM (2022)500 final.

[138] EU Rule of Law Report 2020 (n 135) 3-4. In terms of methodology, the Commission states, 'The country chapters rely on a qualitative assessment carried out by the Commission, focusing on a synthesis of significant developments since January 2019 introduced by a brief factual description of the legal and institutional framework relevant for each pillar. The assessment presents both challenges and positive aspects, including good practices. The Commission has ensured a coherent and equivalent approach by applying the same methodology and examining the same topics in all Member States, while remaining proportionate to the situation and developments' - EU Rule of Law Report 2020 (n 135) 5. See also, EU Rule of Law Report 2021 (n 136) 4-5.

[139] Rule of Law Report 2020 (n 135) 8; Rule of Law Report 2021 (n 136) 28-29; Rule of Law Report 2022 (n 137) 5.

[140] Rule of Law Report 2020 (n 135) 9. See also, *Kövesi v Romania*, App no 3549/19 (ECtHR, 5 May 2020), para 208. For example, in Bulgaria, the reports specifically focus on the (lack of) accountability of the Prosecutor General as part of the independence of the judiciary assessment, especially noticeable in the 2021 Rule of Law Report. See, European Commission, '2020 Rule of Law Report: Country Chapter on the Rule of Law Situation in Bulgaria' SWD (2020) 301 final, 4. See also, European Commission, '2021 Rule of Law Report: Country Chapter

6.2 EU'S RULE OF LAW REPORTS 2020, 2021 AND 2022 AND JUDICIAL INDEPENDENCE

Judicial independence remains an issue in some Member States. The problems, identified by the Commission, primarily relate to the functioning and capacity of judicial councils in the line of assessing structural concerns, directly influencing the backsliding of the rule of law and increasing pressure and influence by the executive and legislative branches over the judicial system.[141] The findings are not surprising as the effectiveness and functionality approach is applied in the reports. For example, the independence of the National Judicial Council (NJC) is put under strain in Hungary as well as the procedure of the appointment to the Supreme Court outside the regular appointment procedure in 2020.[142] The 2021 Rule of Report on Hungary commences with a reminder that the NJC continues to face challenges with respect to the balance between its competences and function and the President of the National Office for the Judiciary in terms of the management of the courts.[143] The individual country report goes into detail on the independence of the judiciary by focusing on describing the issues with lack of effective oversight over the NOJ President, thus leading to potential arbitrary decisions in the management of the judicial system, which continues in 2021.[144] The same issue remains pertinent as the Rule of Law Report 2022 contains specific recommendations.[145] The topic of the structure and function of judicial councils with respect to the right to fair trial before an independent and impartial tribunal previously established by law would be particularly relevant for the development in the jurisprudence of the CJEU.

Moreover, specific examples for denting the effectiveness of the legal order are provided such as the *Kuria* declaratory decision on prohibiting District Court judges to use the Article 267 TFEU procedure. Some disciplinary proceedings have been instituted against judges issuing preliminary reference. This goes to the core of the issue of the effective protection of fundamental rights and functioning of the EU legal order.[146] Additionally, the election of the new *Kuria* president also raises concerns with respect to the appointment of a top judicial post with the involvement of a judicial body and submission of the judiciary to the undue influence of the legislative branch.[147] The issues were reaffirmed as unresolved in the 2022 Rule of Law Report on Hungary.

In Poland, the analysis focuses on the existing Article 7(1) TEU proceedings as well as on the infringement proceedings with respect to the Supreme Court's Disciplinary Chambers,

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on the Rule of Law Situation in Bulgaria' SWD (2021) 701 final, 3-5. See also, Groussot et al, 'Foundational Principles and the Rule of Law' (n 8) 9.

[141] Rule of Law Report 2020 (n 135) 10, and Rule of Law Report 2021 (n 136) 8-9.

[142] Rule of Law Report 2020 (n 135) 10.

[143] European Commission, '2021 Rule of Law Report: Country Chapter on the Rule of Law Situation in Hungary' SWD (2021) 714 final, 3.

[144] European Commission, '2020 Rule of Law Report: Country Chapter on the Rule of Law Situation in Hungary' SWD (2020) 316 final, 3. See, Rule of Law Report 2021: Hungary (n 143) 6.

[145] Rule of Law Report 2022 (n 137) 6. See European Commission, '2022 Rule of Law Report: Country Chapter on the Rule of Law Situation in Hungary', SWD (2022) 517 final, 2.

[146] See Rule of Law Report 2020: Hungary (n 144) 4.

[147] Rule of Law Report 2021: Hungary (n 143) 5-6.

covered in detail above. The focus of the report in Poland is on the series of more than 30 laws related to the restructuring of the justice system. It also includes a detailed section on the politically appointed National Council of the Judiciary.[148] Additionally, the report of 2020 emphasises the creation of the Disciplinary Chamber and the Chamber of Extraordinary Control and Public Affairs in 2018-2019 with concrete effect on judicial independence, subject to infringement proceedings before the CJEU.[149] In this line, the Commission highlights the restrictive disciplinary regime which lacks an effective judicial review mechanism, also reflected in a series of breaches found by the CJEU.[150] Similar issues remain unresolved and illustrated in the Rule of Law Report 2022 despite Poland's commitments in the Recovery and Resilience Plan to dismantle the Disciplinary Chambers of the Supreme Court which continues to decide on cases concerning judges.[151]

Other examples include issues with the composition and functioning of the Supreme Judicial Council in Bulgaria, which remain pertinent in the 2021 Rule of Law Report, and systemic problems with the independence of the judiciary and recent reforms in Slovakia.[152] In Bulgaria, one of the issues is linked to the absence of accountability of the Prosecutor General and his structural and decisive control over the Prosecutors' chamber function remain unresolved with a particular focus on the powers of the Prosecutor General over the Supreme Judicial Council in 2021 and the introduction of a mechanism for a special Prosecutor to investigate the Prosecutor General, which was subsequently declared unconstitutional on 11 May 2021.[153] The Commission notes that under the Recovery and Resilience Plan, Bulgaria has committed to establish an effective mechanism for the accountability and criminal liability of the Prosecutor General and the possibility for judicial review of Prosecutor decisions not to open investigation.[154]

The rule of law is based on institutional checks and balances. They are important for the effective functioning of the judicial system as they concern '[the] transparent, accountable, democratic and pluralistic process for enacting laws, the separation of powers, the constitutional and judicial review of law', among others.[155] Constitutional reforms play a crucial role in strengthening the rule of law and checks and balances, especially when such reforms create and enable new pathways for citizens 'to challenge the exercise of executive or legislative power'.[156] Civil society also needs to be protected.

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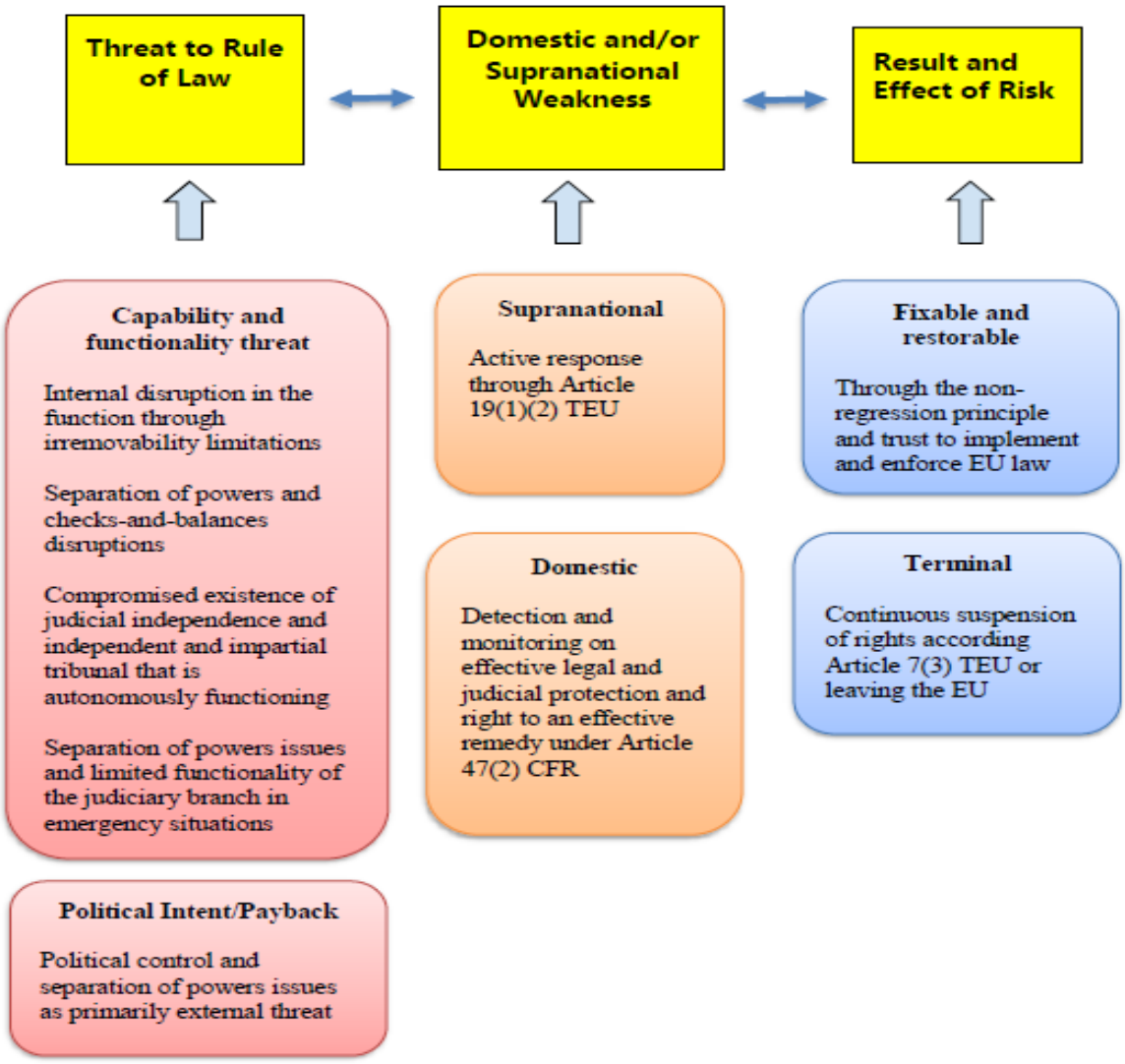
[148] European Commission, '2020 Rule of Law Report: Country Chapter on the Rule of Law Situation in Poland' SWD (2020) 320 final, 4.
[149] ibid 5. See also, Rule of Law Report 2021 (n 136) 8.
[150] See European Commission press release of 29 April 2020, IP/20/772. See *European Commission v Poland (Disciplinary Chamber)* (n 54).
[151] Rule of Law Report 2022 (n 137) 7-8.
[152] Rule of Law Report 2020 (n 135) 10-11. Rule of Law Report 2021: Bulgaria (n 140) 5-6.
[153] See Rule of Law Report 2020 Bulgaria (n 140) 5. See also, *Kolevi v Bulgaria* App no 1108/02 (ECtHR 5 November 2009), paras 121-136. See also, Rule of Law Report 2021: Bulgaria (n 140) 3-4.
[154] Rule of Law Report 2022 (n 137) 7. See also, European Commission, '2022 Rule of Law Report: Country Chapter on the rule of law situation in Bulgaria', SWD (2022) 502 final, 4-5.
[155] Rule of Law Report 2020 (n 135) 20.
[156] ibid 1. See also, Rule of Law Report 2021 (n 136) 20-22.

Backsliding has been observed in new restrictive regulations on foreign-funded civil society organisations within the EU.[157] Another problematic practice is the expedited legislative procedure to amend or introduce structural reforms in the judiciary without necessary consultation and deliberation. For example, in Poland the legislature spent on average 18 days on the series of more than 30 laws on the judiciary.[158] Moreover, the *res judicata* and non-retroactivity principles and legal certainty were undermined by the novel competence of the Supreme Court in Poland to review ordinary courts' decisions dating back 20 years.[159] Lingering problems remain in the area of appointments to the Supreme Court in Poland, subject of various judgments by the CJEU and ECtHR, as examined above.[160] The examples above provide a snapshot of some recurring systemic and structural factors associated with the backsliding phenomenon in the rule of law and the independence of the judiciary as a whole. The problems remain lingering in various Member States. The CJEU has provided a detailed functional and doctrinal foundation for the EU institutions to react to the rule-of-law backsliding phenomenon. What remains to be seen is the enforcement against the breaching Member States and its effectiveness.

7 THE RISK FUNCTION AND RESILIENCE OF EFFECTIVE JUDICIAL PROTECTION

In conclusion, in order to crystallise and synthesise the effectiveness and functionality approach in situations of backsliding of the rule of law, the risk to the rule of law as a foundational value can be represented as a function of the threat to the rule of law, domestic and national institutional weaknesses in their structure and function, and result and effect of the materialisable risk. These parameters should be assessed cumulatively as they cannot be addressed individually.[161] The essential task is the applicability of the effective judicial protection formula along with the enforcement mechanism of various EU institutions involved in the process. The risk assessment could be illustrated in the following graph below:

[157] See C-78/18 *Commission v. Hungary* EU:C:2020:476.
[158] See Rule of Law Report 2020: Poland (n 148) 16.
[159] ibid.
[160] Rule of Law Report 2022 (n 137) 7.
[161] The risk assessment methodology is based on resilience strategies for institutional systems. See eg DoD, 'Resilient Military Systems and the Advanced Cyber Threat' (2013) 29.



As constitutionalism and the rule of law serve to limit the arbitrary use of power, 'they also channel, direct, facilitate and inform infrastructural change'.[162] Moreover, the link to the separation of powers is clearly discernible as if all powers are accumulated in the same entity or person, 'whether of one, a few, or many, and whether hereditary, self-appointed or elective', such a system of concentration of power 'may justly be pronounced the very definition of tyranny'.[163] This is clearly identified as one of the main multisystem threats to the rule of law as a foundational value. The projection of political influence for various motives such as payback or removing any constraints through the tempering of the separation of powers is identified as creating internal and external threats to the independence of the judiciary.

The EU system resembles a constitutional pluralist model in which there might exist competing constitutional claims and interpretations, as seen above by different domestic legal

[162] Krygier (n 16) 56.
[163] See Alexander Hamilton, James Madison and John Jay, *The Federalist Paper No. 47* (Penguin 1987).

order, but there must be a supranational judicial avenue to accommodate and ultimately resolve such tensions.[164]

Maduro uses the metaphor of a musical score in which melodies of different instruments are played and the musicians may change their roles but at the end an overall sound is produced in harmony. In that line, it is not surprising that sometimes we observe a more active and engaged Court of Justice, especially when the rule-of-law score is being played wrongly by the musicians in some Member States.[165] As far as the frictions are fixable, reversible or restorable, the effect of the risk may be minimised and the weaknesses in the system of enforcement may limited on domestic and supranational levels. However, if the risk effect or result is terminal, then one may envisage that the situation enters the realm of the existence of a serious and persistent breach of Union values under Article 7(2) and the corresponding Article 7(3) TEU sanctioning mechanism or ultimately leaving the Union.[166]

8 CONCLUSION

Is the EU moving towards 'positive constitutionalism' according to Holmes' definition in the sense of a supranational framework that regulates powers with the ultimate goal 'towards socially desirable ends, and prevent social chaos and private oppression, immobilism, unaccountability, instability, and the ignorance and stupidity of politicians'?[167] Or is the Union moving towards a more fragmented structure in which domestic courts and governments will attempt to undermine the authority of the CJEU?[168]

The current crisis of the rule of law in some Member States of the EU, coupled with the restrictive measures in response to the pandemic, illustrates the complexity of the compound democratic orders such as the supranational structure of the EU. At the current moment, there are multiple pending infringement proceedings against Poland, for example. Moreover, the Commission has been criticised as being inactive in the lack of an urgent response to the backsliding of the rule of law in some EU Member States and even threatened with Article 265 TFEU proceedings by the European Parliament on several occasions.[169] It is noticeable that the Court of Justice of the EU has relied more heavily on foundational values of the Union in recent quintessential cases, directly relevant for the protection of the independence of the judiciary in EU Member States and effective judicial protection of fundamental rights. As

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[164] See Miguel Poiares Maduro, 'Three Claims of Constitutional Pluralism' in Matej Avbelj and Jan Komárek (eds) *Constitutional Pluralism in the European Union and beyond* (Hart Publishing 2012) 70.
[165] Miguel Poiares Maduro, 'Contrapunctual Law' in Neil Walker (ed), *Sovereignty in Transition* (Hart Publishing 2003) 523.
[166] Stoyan Panov, 'The EU's Trifecta Mechanisms: Analysis of EU's Response to the Challenges to the Rule of Law and Corruption' (2019) 5 Kyiv-Mohyla Law and Politics Journal 83, 89-91.
[167] Stephen Holmes, *Passions and Constraints. On the Theory of Liberal Democracy* (University of Chicago 1995) 51.
[168] Wojciech Kość and Lili Bayer, 'Battle of the courts: Contradictory rulings in Poland, EU raise specter of "Polexit"' (*Politico*, 14 July 2021) <https://www.politico.eu/article/contradictions-in-rulings-poland-eu-worries-polexit/> accessed 27 January 2023.
[169] European Parliament, 'Rule of Law: Parliament prepares to sue Commission for failure to act' (10 June 2021), < https://www.europarl.europa.eu/news/en/press-room/20210604IPR05528/rule-of-law-parliament-prepares-to-sue-commission-for-failure-to-act> accessed 27 January 2023.

the breaches of the foundational values may be characterised as political and ideological as in the case in Hungary and Poland, it is important to note that infringement proceedings or preliminary rulings may not be enough to deter Member States from continuous breaches. This paints a complex picture with respect to the constitutionalisation of the EU law and the relation and role of EU institutions, including the Court of Justice, with regard to domestic courts and governments.

Ultimately, the discourse will reach a junction at which the EU institutions and the Member States will need to decide where the Union stands on protecting, enforcing and abiding by the foundational value of the rule of law, enshrined in all constitutions in the EU Member States. It is time to echo the doctrine that the primary law of the EU functions 'to withdraw certain subjects from the vicissitudes of political controversy, to place them beyond the reach of majorities and officials and to establish them as legal principles to be applied by the courts'[170] if the Union wants to be governed by the rule of law, enshrined and reflected in common values and fundamental rights.

[170] *West Virginia Board of Education v Barnette* 319 US 624 (1943) 638.

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ONLY FAIR? THE RIGHT TO A FAIR TRIAL CHALLENGED IN CASE C-420/20 *HN (PROCÈS D'UN ACCUSÉ ÉLOIGNÉ DU TERRITOIRE)*

ANNEGRET ENGEL*

The right to a fair trial forms an integral part of the rule of law in the EU and is enshrined in Article 47 of the EU Charter of Fundamental Rights. It provides that

> *Everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal previously established by law. Everyone shall have the possibility of being advised, defended and represented.*

Further details, particularly on the right to be present as an essential element of the right to a fair trial, can be found in EU secondary legislation, such as Directive 2016/343.[1] *This came under scrutiny in the course of the criminal proceedings against HN.*[2]

1. IN A NUTSHELL – THE FACTS OF THE CASE

On 11 March 2020, HN, an Albanian citizen, was detained by the Bulgarian security control at Sofia airport for having presented forged documents of a falsified Greek identity in an attempt to board a plane to Bristol, the UK. While the criminal investigation procedure was initiated following his arrest, an administrative return decision was issued on 12 March 2020 together with an entry ban of five years. The latter was enforced on 16 June with the actual removal of HN from Bulgarian territory, however without prior communication to the criminal prosecutor.

The pre-trial hearing for HN's criminal case was determined only after his removal took place, scheduled for 23 July 2020. The prosecuting court learned of HN's deportation on 16 July 2020 – an entire month after HN was forced to leave the country. As his whereabouts were unknown, it was not possible to properly inform HN of the scheduling of his proceedings before the court. While HN was informed about the opening of such proceedings and the possibility of a trial *in absentia* before his departure, the exact details thereof were specified only afterwards.

In the absence of being properly informed of the concrete details of and his options in the trial, while at the same time being unable to attend the trial regardless, the legality of

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[1] Directive (EU) 2016/343 of the European Parliament and of the Council of 9 March 2016 on the strengthening of certain aspects of the presumption of innocence and of the right to be present at the trial in criminal proceedings [2016] OJ L 65/1 (Directive 2016/343).

[2] Case C-420/20 *HN (Procès d'un accusé éloigné du territoire)* EU:C:2022:679. See also my Op-Ed on EU Law Live on this Judgment, Annegret Engel, 'The Court of Justice Strengthens the Rule of Law in Criminal Proceedings against *HN (Procès d'un accusé éloigné du territoire)*' (*EU Law Live*, 6 October 2022), <https://eulawlive.com/op-ed-the-court-of-justice-strengthens-the-rule-of-law-in-criminal-proceedings-against-hn-proces-dun-accuse-eloigne-du-territoire-by-annegret-engel/> accessed 27 January 2023.

HN's waiver of his rights was questioned. In addition, the entry ban was *per se* inhibiting a suspect's obligation to be present at the trial, as prescribed under Bulgarian law. The District Court in Sofia decided to stay the criminal proceedings against HN and make a preliminary reference to the European Court of Justice. The relevant issues shall be considered in the order presented in the court's judgment.

1.1. THE SCOPE OF THE RIGHT TO BE PRESENT AT THE TRIAL

In its judgment, the Court first considered the scope of the right to be present at the trial under EU law. According to Article 8(1) of Directive 2016/343, 'Member States *shall* ensure that suspects and accused persons have the right to be present at the trial.'[3] Further, subsection 2 of that provision states that 'Member States *may* provide that a trial which can result in a decision on the guilt or innocence of a suspect or accused person can be held in his or her absence'[4] under certain circumstances.

Ad verbum, the Court interpreted these provisions narrowly, finding that Member States are under an obligation to ensure the accused is able to exercise their right to be present, while exceptions to that right remain an option for Member States to allow for, if they wish. Consequently, Member States were under no requirement to provide for the possibility of a trial *in absentia*, the Court held.[5] In the absence of a Member State thus granting such exceptions to the right to be present at the trial, does this automatically turn the right into an obligation?

The court found no explicit answer in Article 8, which is silent as to whether an obligation to be present at the trial is to be allowed or rather prohibited. However, with regards to the overall purpose of the directive to lay down 'common minimum rules', as provided in Article 1, the Court noted that this rules out exhaustive harmonisation. As a result, the Court held that

> in the light of the limited scope of the harmonisation carried out by that directive and the fact that it does not govern the question whether the Member States may require the suspect or accused person to be present at the trial, such a question is a matter for national law alone.[6]

In other words, Member States have discretion in legislating beyond the minimum standards prescribed in the Directive, in this case imposing an obligation on the accused to be present at the trial. EU law effectively does not preclude such intergovernmental flexibility here.

1.2. THE CONDITIONS FOR A TRIAL IN ABSENTIA

In the second part of its judgment, the Court continued with the analysis of Articles 8(1) and (2) of Directive 2016/343, however with regards to the exceptions provided under the right to be present at the trial, ie the conditions for a trial *in absentia*. According to Article 8(2), one of the following conditions must be fulfilled:

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[3] Emphasis added.
[4] Emphasis added.
[5] *HN* (n 2), para 37.
[6] ibid para 42.

a) the suspect or accused person has been informed, in due time, of the trial and of the consequences of non-appearance; or
b) the suspect or accused person, having been informed of the trial, is represented by a mandated lawyer, who was appointed either by the suspect or accused person or by the State.

The Court interpreted these conditions narrowly in its judgment. In particular, and with regards to the information requirement, the person concerned must have been given a genuine opportunity to attend their trial and to have 'voluntarily and unequivocally' waived that right.[7] It follows that a mere informing of the person concerned who is otherwise prohibited from exercising their right to be present due to an entry ban imposed on them would not qualify as fulfilment of this condition. The Court found that this would otherwise 'deprive the conditions laid down in that provision of any practical effect'.[8]

It is clear from recitals 9 and 10 that the overall purpose of the Directive is to strengthen the right to a fair trial in criminal proceedings and, thus, build trust between Member States in each other's criminal justice systems with the aim to facilitate mutual recognition of decisions in criminal matters. Along this line, the Court recalled Articles 47 and 48 of the EU Charter of Fundamental Rights, which established the right to be present as an essential element of the right to a fair trial. It was therefore necessary for the Court to also consider the necessity of the entry ban imposed on the individual and the possibility for Member States to withdraw or suspend any such decision under EU law for the purpose of ensuring the right to a fair trial.

The procedural rules for Member States to return illegally residing third-country nationals are regulated in Directive 2008/115/EC.[9] Article 11 of that Directive, which lays down the conditions for an entry ban, provides in subsection 3 that Member States shall consider withdrawing or suspending such an entry ban under certain circumstances. The Court found that this option must be interpreted widely in order to allow the proper attainment of other rights. As a result, the Court held that Article 8(2) of Directive 2016/343

> must be interpreted as precluding legislation of a Member State which permits a trial to be held in the absence of the suspect or accused person, where that person is outside that Member State and is unable to enter its territory because of an entry ban imposed on him or her by the competent authorities of that Member State.[10]

The Court thus found the relevant criminal procedural laws to prevail over the administrative aspects of migration law in this case in order to guarantee a fair trial.

2. ANALYSIS – THE JUDGMENT IN CONTEXT

Varying standards of fundamental rights protection in criminal proceedings between Member States have caused numerous legal challenges in the past. As a result, harmonising

[7] *HN* (n 2), para 58.
[8] ibid para 59.
[9] Directive 2008/115/EC of the European Parliament and of the Council of 16 December 2008 on common standards and procedures in Member States for returning illegally staying third-country nationals [2008] OJ L348/98.
[10] *HN* (n 2), para 66.

those standards across the national legal systems by raising them to a minimum level of protection has often been the chosen method of the EU legislator. Once harmonising legislation is in place, Member States can deviate from the prescribed standard only to the extent that they are left with a regulatory margin and – in case of minimum harmonisation – and only if they provide for higher standards of protection.[11]

2.1. HIGHER OR LOWER – WHICH STANDARD OF FUNDAMENTAL RIGHTS PROTECTION IN CRIMINAL PROCEEDINGS?

Indeed, in the *criminal proceedings against HN*, the Court ruled that minimum harmonisation was at stake.[12] While the relevant EU legislation sets the minimum standard of a right to be present at the trial, Bulgarian national laws impose an obligation on the accused to be present at their trial. The court found that such an obligation was neither required nor prohibited under EU law and consequently fell within the margin of appreciation of the national legislator. But does an obligation indeed constitute a higher standard of protection than a mere right to be present? Would such an obligation perhaps pose an unreasonable burden on the accused if there is no possibility for a waiver?

The Advocate General (AG) de la Tour argued in his opinion that such an obligation imposed on the accused does not constitute a higher level of protection, but, to the contrary, would be rather restrictive by depriving the accused of the possibility to waive their right to be present at the trial. Thus, the AG claimed, such an obligation would conversely lower the standard of protection provided for in the Directive.[13] De la Tour compared this with the right not to give testimony before a court under certain circumstances, in particular concerning cases in which suspects would incriminate themselves.[14] This reasoning is however flawed, as presence in a trial would not automatically lead to self-incrimination and therefore does not necessitate the existence of a waiver as an essential guarantor of fundamental rights protection in the same way as is the case with testimonies.

In addition, this argumentation could be misused by Member States as a loophole to avoid compliance with their own obligations imposed on them by EU law, especially if the requirements for a trial *in absentia* can be watered down by lowering the threshold for a possible waiver of rights to merely informing the accused. Indeed, maintaining a high threshold for the exceptions to apply might be costly and time consuming and it might place an additional administrative burden on the Member State to ensure that any suspect would have a genuine possibility to attend their trial. De la Tour's reasoning would have thus sent the wrong message to Member States, effectively lowering the standards for a fair trial and incentivising trials *in absentia*.

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[11] Article 53 of the EU Charter of Fundamental Rights provides that 'Nothing in this Charter shall be interpreted as restricting or adversely affecting human rights and fundamental freedoms as recognized […] by Union law and international law […] and by the Member States' constitutions'.

[12] See also point 48 of the preamble of Directive (EU) 2016/343 (n 1) which provides that 'Member States should be able to extend the rights laid down in this Directive in order to provide a higher level of protection'.

[13] Opinion of the Advocate General Jean Richard de la Tour in Case C-420/20 *HN (Procès d'un accusé éloigné du territoire)* EU:C:2022:157, para 116.

[14] Interestingly, while the AG seemed apprehensive about the compliance with the minimum requirements of an accused person's rights on this issue, he was rather unconcerned about the waiver of rights after merely informing the accused on the second issue.

It is therefore unsurprising that the Court did not follow the AG's opinion, but instead found that a Member State's obligation imposed on the accused to be present at their trial would in fact constitute a higher standard of protection and a strengthening of the rule of law and effectiveness of a fair trial, which therefore could not be invalidated. A higher standard of fundamental rights protection at national level would only be problematic if a conflict occurred with some equally important EU principle or legal norm. The *Melloni* case[15] serves as perfect illustration of this – a similar legal setting, yet with some key differences – to be distinguished from the case at hand.

2.2. COMPARING APPLES AND ORANGES – HN DISTINGUISHED FROM THE MELLONI-SAGA

Looking at the facts of both cases and the issues under scrutiny therein, most legal experts in the field would point out the undeniable resemblance of *HN* and *Melloni* . Both concern the right to a fair trial, and, particularly, the conditions for a trial *in absentia* under EU law. However, it seems they have received different appraisals concerning the protection of fundamental rights standards in criminal proceedings at their respective national level. Can this be merited based on differences in the facts? Or has the Court changed its approach over the course of time?

Mr Melloni, an Italian citizen was residing in Spain when a European Arrest Warrant was issued by the competent Italian authorities for his involvement in bankruptcy fraud. While his surrender was authorised by the Spanish authorities, Mr Melloni escaped during his release on bail; his trial in Italy was subsequently held *in absentia*. When finally being arrested again years thereafter, Mr Melloni contended the execution of his surrender based on the fact that under Italian procedural law a judgment *in absentia* cannot be appealed against; such a right to appeal was however protected under Spanish constitutional law.[16]

Thus, the higher standard of fundamental rights protection under Spanish law in *Melloni* had to be balanced against the lower level of protection under Italian procedural law, the latter of which nevertheless complied with the minimum standards required at EU level. Unlike the circumstances at stake in *HN*, the higher standards under Spanish law cannot be viewed in isolation as they impact on another Member State and on the proper function of intergovernmental cooperation in criminal matters. While Spain would certainly have discretion to impose higher standards of fundamental rights protection with regards to its own affairs[17] – just as in *HN* – the same cannot be expected from other Member States.

In addition, this feeds into the principle of primacy of EU law. Insisting on a higher standard of fundamental rights protection across Member States in *Melloni* would have also impeded the effectiveness and proper functioning of the European Arrest Warrant according

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[15] Case C-399/11 *Stefano Melloni v Ministerio Fiscal* EU:C:2013:107. See eg case discussion by Vanessa Franssen, 'Melloni as a Wake-up Call – Setting Limits to Higher National Standards of Fundamental Rights' Protection' (*European Law Blog*, 10 March 2014) <https://europeanlawblog.eu/2014/03/10/melloni-as-a-wake-up-call-setting-limits-to-higher-national-standards-of-fundamental-rights-protection/> accessed 27 January 2023.

[16] Article 24(2) of the Spanish Constitution.

[17] cf Case C-617/10 *Åkerberg Fransson* EU:C:2013:105. See also discussion in Laurens Ankersmit 'Casting the net of fundamental rights protection: C-617/10 Åkerberg Fransson' (European Law Blog, 26 February 2013) <https://europeanlawblog.eu/2013/02/26/casting-the-net-of-fundamental-rights-protection-c-61710-akerberg-fransson/> accessed 27 January 2023.

to Framework Decision 2002/584/JHA.[18] For this to work, Member States cannot oblige each other to comply with the highest standards of protection, which would defeat the whole purpose of the European Arrest Warrant as a mechanism of mutual trust and recognition of the different national judiciaries.[19] Such mutual trust is based on the minimum requirements set at EU level, and therefore, Member States have to accept a potentially lower standard of protection in such intergovernmental cooperation.

Hence, the court's decision in *Melloni* has to be distinguished from the criminal proceedings against *HN*. While the former concerned a triangle situation in which the Spanish laws had to be evaluated, the latter merely affected the direct relationship between a national legal setting vis-à-vis EU norms. It is thus unsurprising that the higher level of protection was ruled down in *Melloni*, whereas it was upheld in *HN*. Crucially, a different result in *HN* would have required Member States to lower their fundamental rights standards in criminal proceedings without any direct conflict with other national or European legislation. Perhaps this would have led to another *Solange* moment in EU litigation,[20] with the effect of Member States refusing to apply EU legal standards as long as they provide for a lower level of protection, with the inevitable constitutional battle between national and European courts.[21]

3. CONCLUDING REMARKS

In conclusion, the *HN* judgment strengthens the rule of law and the right to be present as an essential element of a fair trial. An obligation to be present in criminal proceedings constitutes a higher standard of fundamental rights protection, which is within the discretion of the national legislator, where EU law provides for minimum harmonisation only. A Member State can go beyond the required minimum standards if no other conflict occurs, with EU legislation otherwise taking precedence. In addition, a trial *in absentia* has to meet certain minimum thresholds in order to avoid misuse at national level and circumvention through non-essential administrative provisions, such as migration law, as was the case here.

The judgment also provides guidance for subsequent cases already pending before the European courts. For example, in the criminal proceedings against *VB*,[22] the Bulgarian criminal court requested another preliminary ruling in relation to Directive 2016/343 and certain aspects of the right to appeal against a trial *in absentia*. As such, *HN* might well have laid the foundations and provided a direction for a series of judgments to come in this area.

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[18] Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States [2002] OJ L190/1, as amended by Council Framework Decision 2009/299/JHA of 26 February 2009 amending Framework Decisions 2002/584/JHA, 2005/214/JHA, 2006/783/JHA, 2008/909/JHA and 2008/947/JHA, thereby enhancing the procedural rights of persons and fostering the application of the principle of mutual recognition to decisions rendered in the absence of the person concerned at the trial [2009] OJ L81/24.

[19] See also Consolidated Version of the Treaty on European Union [2012] OJ C 326/13 (TEU), art 4(2). A discussion on these issues can be found in Costanza di Francesco Maesa, 'Effectiveness and Primacy of EU Law v. Higher National Protection of Fundamental Rights and National Identity' (2018) 1 The European Criminal Law Associations' Forum.

[20] Case C-11/70 *Internationale Handelsgesellschaft mbH v Einfuhr- und Vorratsstelle für Getreide und Futtermittel (Solange I)* EU:C:1970:114.

[21] The German Federal Constitutional Court, with reference to the *Åkerberg Fransson* judgment (n 17), already raised concerns of *ultra vires* action on the part of the European courts, 1 BvR 1215/07, para 91.

[22] Case C-468/22 *VB*, pending.

While it is too early to call it a landmark judgment, *HN*'s significance for the strengthening of the rule of law in criminal proceedings and the conditions for a fair trial in the EU are already undeniable.

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