European product liability for AI-based clinical decision support systems

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Chapter 2
European Product Liability for AI-based Clinical Decision Support Systems

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Contents

Abstract Clinical decision support systems (CDSSs) are computer systems that support medical professionals in the clinical decision-making process. If a decision that involved the use of a CDSS has detrimental effects, the patient might seek compensation for the damage incurred. Here, the involvement of a CDSS, particularly if it is AI-based, could give rise to liability questions. On the one hand, the liability of

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the medical professional, which often depends on medical standards, raises questions on the type of behaviour on which these standards will require, particularly for AI-based CDSSs. On the other hand, questions arise on the liability of the manufacturer of the system. Product liability regimes such as those in the US and the EU do not require the claimant to prove fault, but instead require a product defect. For these regimes, AI-based CDSSs challenge the notions of defect and causation. This chapter focuses on EU product liability law, analysing whether and how it applies to AI-CDSSs. The three main questions discussed are (i) whether AI-CDSSs could fall within the scope of this regime, (ii) how the term 'defect' should be construed with respect to AI-CDSSs, arguing for a novel interpretation of AI manufacturing defects, and (iii) whether and how a causal link between defect and damage could be established.

Keywords Product liability · Artificial Intelligence · Defect · Causal link · Medical liability · Clinical Decision Support Systems

2.1 Introduction

2.1.1 Clinical Decision Support Systems, AI, and Liability

As is shown throughout this book, Artificial Intelligence (AI) technology has promising applications in many different fields. Medical practice is certainly one of these. Advances in machine learning have made it possible for clinical decision support systems (CDSSs), traditionally based on pre-programmed rules,[1] to infer these rules autonomously from large collections of clinical data or past experience, allowing for more powerful and flexible systems.[2]

Given the view in medicine that AI should aid, rather than replace, human professionals, and the related aspiration to keep a 'human in the loop', CDSSs could play a significant role in the clinical AI landscape.[3] At the same time, the opaque nature of AI-based CDSSs (hereafter simply referred to as 'CDSSs') is troublesome. If CDSSs malfunction, e.g. by erroneously recommending an unsuitable drug for a particular patient, their opaque nature not only makes it hard for the clinician to assess the validity of the given advice, but it also complicates the matter of determining if someone is liable for ensuing harm.[4]

[1] Berner 2007, pp. 3–8.

[2] Berner 2007, pp. 6–8; Schönberger 2019, pp. 174–175; Zikmundová 2023, pp. 284–385; Zech 2023, pp. 193–194. One example is a recently proposed system that assists GPs by analysing a patient's risk of developing cardiovascular diseases, see Van Os et al. 2023.

[3] Schönberger 2019, p. 193; Selbst 2020, pp. 1318–1319; Braun et al. 2021; Rajpurkar et al. 2022; Čartolovni et al. 2022.

[4] Smith and Fotheringham 2022, p. 34; Duffourc and Gerke 2024, p. 6.

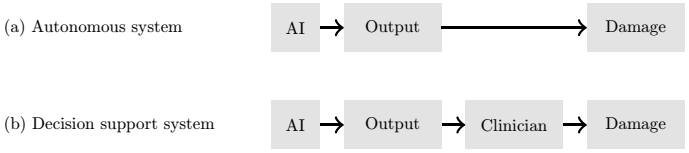

Fig. 2.1 Decision support systems can only cause damage indirectly

While this is true for AI systems in general, CDSSs pose specific challenges. In comparison to autonomous systems such as self-operating drug administration systems or self-driving cars, which directly impact their environment, CDSSs can only influence the environment through a human intermediary (see Fig. 2.1).[5] As for (strict) product liability of manufacturers,[6] the position of the clinician as an autonomous intermediary (‘*novus actus interveniens*’) creates difficulties in establishing a causal link.[7] However, the alternative, clinicians’ medical liability,[8] is based on negligence and thus only applies in cases of substandard performance.[9] The reality is that clinicians do not always bear full legal responsibility for the devices they use.[10] As CDSSs become more powerful, negligence standards will evolve and might even effectively *require* clinicians to use these systems without being able to fully comprehend how they work—reducing a clinician’s liability if it continues to be negligence-based.[11]

Although the general quality of healthcare might be improved with the widespread adoption of AI-based CDSSs, these observations show that their adoption may simultaneously leave injured patients without recourse.[12] Issues like these are referred to as ‘liability gaps’.[13] This chapter’s central objective is to analyse the aforementioned

[5] Cp. Wendehorst and Duller 2023, pp. 220–221.

[6] Smith and Fotheringham 2022, p. 50; Wagner 2022, p. 192 (although primarily on autonomous systems); Banja et al. 2022, p. 818.

[7] Smith and Fotheringham 2020, p. 145.

[8] As argued for by Selbst 2020, pp. 1319–1320 and 1322–1329. ‘Clinicians’ and other medical professionals will be used interchangeably throughout this chapter.

[9] Koch 2011, p. 628; Schönberger 2019, pp. 196–197; Zikmundová 2023, pp. 387–389; Buiten et al. 2023, para 3.2; Duffourc and Gerke 2023, p. 4; Duffourc and Gerke 2024, pp. 29–31.

[10] Cp. Smith 2021, p. 3; Smith and Fotheringham 2020; Smith and Fotheringham 2022, p. 49; Froomkin et al. 2019, pp. 61–62. This can differ between jurisdictions, as e.g. France (article 1142-1 Code de la santé publique) and The Netherlands (article 6:74 jo 6:77 Dutch Civil Code (DCC)) do have some form of strict liability for clinicians using (tangible) medical devices.

[11] Froomkin et al. 2019, pp. 61–63; Haftenberger 2023, pp. 263 and 265–267; Schneeberger et al. 2020, p. 219; Schönberger 2019, pp. 201–202; Kardasiadou 1998, p. 242. Cp. Selbst 2020, pp. 1338–1342.

[12] Cp. Schönberger 2019, pp. 185 and 199–202.

[13] Prifti et al. 2022; Buiten et al. 2023, para 3; Burton et al. 2020; Wendehorst 2023, p. 120; Borges 2023a, pp. 169–171; Duffourc and Gerke 2023. From a private law perspective, liability gaps might not be problematic *per se* (‘the loss lies where it falls’). See e.g. Selbst 2020, p. 1363 and Zerilli 2022, pp. 500–502.

gaps as they relate to EU product liability and propose how they can be bridged through existing legal mechanisms.

2.1.1.1 Scope and Contributions of this Chapter

This chapter examines the circumstances under which EU product liability for CDSSs could be established, specifically examining the central requirements of *defect* and *causality*. The EU product liability framework is currently undergoing revision. To incorporate the latest developments, notably the view that software can be regarded as a product, this chapter is based on the 2022 European Commission revision proposal, referred to here as the draft Product Liability Directive (DPLD).[14] However, given that the DPLD retains many elements of the current Product Liability Directive (PLD),[15] this chapter will also draw from, and connect with, existing discussions.

Its contributions are threefold:

(i) it analyses the possibility of, and concludes in favour of, applying the DPLD to CDSSs;
(ii) it considers how the term 'defect' could be applied to CDSSs, proposing to adopt an 'intentional stance' while arguing that the current focus on design defects is problematic and that AI defects should instead be regarded as manufacturing defects; and
(iii) it analyses whether and under which circumstances it could be possible to establish a causal link between the output of a defective CDSS and subsequent damage, proposing the adoption of a rebuttable presumption based on normative standards.

2.1.1.2 Structure of this Chapter

This chapter is structured as follows. First, it provides an outline of the DPLD (Sect. 2.2). Then, it analyses whether the DPLD could apply to CDSSs (Sect. 2.3), concluding in the affirmative. In proceeding to analyse the substantive topics of the DPLD, the notion of defect is explored (Sect. 2.4), after which the requirement for a causal link is analysed, first by investigating whether it could at all be possible to establish a causal link with CDSS output under the DPLD (Sect. 2.5)—concluding in the affirmative—and then by investigating under which circumstances such a causal link could be established in fact (Sect. 2.6). The findings are summarised in Sect. 2.7.

[14] Proposal for a Directive on liability for defective products (2022/0302(COD), COM(2022) 495 final) (DPLD).

[15] Directive 85/374/EEC of 25 July 1985 concerning liability for defective products (Product Liability Directive, PLD).

2.2 Navigating the Draft Product Liability Directive

The DPLD is part of a larger package of legislative measures that also includes the Artificial Intelligence Act (AIA)[16] and the AI Liability Directive (AILD).[17] The new product liability directive retains much of the structure, vocabulary and underlying principles of the existing PLD. Like the PLD, the DPLD prescribes a no-fault liability for damage caused by defective products incurred by natural persons. 'No-fault' means that the claimant does not have to prove that the manufacturer was at fault. The claimant bears the burden of proving that the product was defective, that they suffered damage, and that there is a causal link between the defect and the damage.[18]

EU product liability hinges on the requirement of defectiveness. The standard for defectiveness is that a product 'does not provide the safety which the public at large is entitled to expect, taking all circumstances into account'.[19] This standard is referred to as the consumer expectation test.[20] The test is both normative and objective in nature, as it is based on the legitimate expectations of the general public and not on the subjective expectations of a particular individual.[21] In contrast to the product liability regime in the US,[22] there is no formal role for the so-called risk-utility test,[23] and no distinction is made between different types of defects, i.e. manufacturing defects, design defects and instruction/warning defects.[24] Nonetheless, these concepts do play a role in the reasoning of (Member State) courts and in (academic) literature.[25]

While the consumer expectation test takes all circumstances into account, the DPLD mentions eight circumstances explicitly, five of which are new. One of the new circumstances, '(c) the effect on the product of any ability to continue to learn after deployment', targets AI systems specifically. However, not all AI systems continue to learn after deployment. This is only true for 'online learning' systems, which continue to learn in real time through interactions with their surroundings or the user.[26] Many systems instead use 'offline learning', in which the system is trained

[16] Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act).

[17] Proposal for a Directive on adapting non-contractual civil liability rules to artificial intelligence (2022/0303/COD, COM(2022) 496 final) (AI Liability Directive, AILD).

[18] Article 9 DPLD.

[19] Article 6-1 DPLD.

[20] Fairgrieve et al. 2016, pp. 50–61.

[21] Fairgrieve et al. 2016, p. 51, no 80; Verhoeven 2018, pp. 222–226.

[22] Duffourc and Gerke 2024, para II.A.1-3.

[23] The risk-utility test balances risks/costs and benefit of the product, i.e. an unsafe product could still be non-defective if it provides enough utility and alternative designs are either not available or prohibitively expensive.

[24] Fairgrieve et al. 2016, p. 53, no 82; High Court of Justice (UK), *A v National Blood Authority*, 26 March 2001, EWHC QB 446.

[25] Fairgrieve et al. 2016, pp. 51–53.

[26] Russell and Norvig 2021, pp. 702–704; Hacker 2023, p. 14; Wendehorst and Duller 2023, pp. 291–293.

and deployed iteratively.[27] Since this chapter aims to cover both online and offline learning systems, circumstance (c) will not be discussed any further, although it is a relevant and interesting addition.[28]

Another notable addition is circumstance (f), which establishes a relationship between product liability and product safety requirements. Previously, this link had been less clear.[29] It is important to note that compliance with relevant standards is not sufficient to avert liability.[30] After all, liability has a complementary role to safety standards, precisely because of its ability to 'regulate' uncertain risks that are hard to encapsulate in detailed *ex ante* rules.[31]

The DPLD includes several liability exemptions. The development risk defence, which was—although optional—already part of the PLD, shields the manufacturer from liability if the scientific and technical knowledge at the time the product was placed on the market or is out of the control of the manufacturer were such as not to allow for the discovery of the defect.[32]

2.3 Does the Scope of the DPLD Include CDSSs?

2.3.1 A Principal Question

In analysing the application of EU product liability law to CDSSs, the first question is whether the scope of the DPLD covers CDSS-induced damage at all. The DPLD does not explicitly declare these situations to be out of scope,[33] but some argue that the European Court of Justice's (ECJ) *Krone* judgment would exclude products that provide information.[34] The next section of this paragraph (Sect. 2.3.2) will discuss this case in detail, assert that this interpretation of the *Krone* judgment is too strict, and argue why these products could indeed fall within the scope of the DPLD.

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[27] Froomkin et al. 2019, pp. 60–61; Duffourc and Gerke 2023, p. 2.

[28] See more extensively Hacker 2023, p. 14; Spindler 2023, p. 53; De Bruyne et al. 2023, p. 13.

[29] Veldt 2020b, para 7.2.3.

[30] Veldt 2020b, para 7.2.2; Spindler 2023, p. 95.

[31] Veldt 2020a, para 3. See however Verhoeven 2018, pp. 99–104, who advocates equating product safety criteria with defectiveness; cp. Fairgrieve et al. 2016, pp. 100–103.

[32] Article 6-1-c DPLD. See Stapleton 1994, pp. 49–52; Fairgrieve et al. 2016, pp. 75–79; Fairgrieve and Goldberg 2020, para 13.33–13.125; Borghetti 2023b, pp. 32–35. The defence tempers the no-fault character of EU product liability, in which Wendehorst describes it as 'mov[ing] it into the vicinity of fault liability', Wendehorst 2020, p. 158 (see also Howells 2020, pp. 92–93).

[33] Other than the AILD, which does so in recital 15. See criticism by Hacker 2023, pp. 13–14 and Spindler 2023, pp. 76–77.

[34] Borges 2023b, p. 39 (no. 49) and Borges 2022, p. 2652; opposed by Spindler 2023, p. 47. See earlier Triaille 1993, pp. 222–223.

There are other products, notably alarm systems, to which the DPLD applies, even though their main function is to provide output as a basis for a human decision. Section 2.3.3 analyses how these products compare to CDSSs. Section 2.3.4 concludes by clarifying that, while it is admittedly not clear whether all CDSS-induced damage could fall within the scope of the DPLD, a blanket rejection cannot hold either, paving the way for the substantive analysis in Sect. 2.4 onwards.

2.3.2 *The Krone Case—Can Output Render a Product Defective?*

On 31 December 2016, the Austrian newspaper *Kronen-Zeitung* published a column written by 'herbal medicine expert' 'Kräuterpfarrer Benedikt', who suggested to apply freshly grated horseradish to alleviate rheumatic pain and to leave it on the affected bodily area for two to five hours. As one reader found out after experiencing 'severe pain due to a toxic skin reaction', the advice should have read minutes instead of hours. She claimed compensation from the newspaper, which ultimately brought the ECJ to rule whether a newspaper containing incorrect health advice could qualify as a defective product.[35]

The ECJ concluded it could not. First, it expressed that the PLD only applies to products, not to services.[36] However, it then proceeded to analyse whether 'health advice which, by its nature, constitutes a service, can, when incorporated into a physical item—in this case, a printed newspaper—result, on account of the fact that it proved to be inaccurate, in the newspaper itself being defective in nature'.[37] Since in this case the service (provision of—incorrect—advice) was unrelated to the medium (the newspaper), it was not 'part of the inherent characteristics of the printed newspaper' and as such could not render the newspaper defective.[38]

What does this mean for CDSSs? The output of these systems would undoubtedly also qualify as a service, which means the output is not covered by the DPLD *per se*. However, as Haftenberger points out, the reasoning of the Court compels us to focus not on the output being a service, but on its potential to render the *system* defective.[39] If a CDSS itself qualifies as a product, as did the copy of the *Kronen-Zeitung*, its AI-mediated output is evidently more related to it than the health advice in the newspaper: the CDSS is not merely a carrier, but the source of the advice, since it is created or modified by the system.[40] Therefore, it is quite possible that

[35] ECJ, *Krone,* 1 June 2021, C-65/20, ECLI:EU:C:2021:471.

[36] ECJ, *Krone,* 1 June 2021, C-65/20, ECLI:EU:C:2021:471; Van der Putt and Westerdijk 2023, para 4.2; Veldt 2022, para 3; Wuyts 2014, pp. 5–7.

[37] ECJ, *Krone,* 1 June 2021, C-65/20, ECLI:EU:C:2021:471, para 32.

[38] ECJ, *Krone,* 1 June 2021, C-65/20, ECLI:EU:C:2021:471, para 36; see also Twigg-Flesner 2021.

[39] Haftenberger 2023, pp. 85–89.

[40] Wendehorst and Duller 2023, pp. 221–222; Haftenberger 2023, pp. 87–89; cp. Westerdijk 1995, pp. 242–243 and (in a different context) 208–210.

the output which is generated by these systems should be viewed as part of their 'inherent characteristics', implying that the DPLD could indeed apply to CDSSs.

2.3.3 Are CDSSs like Alarm Systems?

There is little doubt that the DPLD, like its predecessor, applies to alarm systems, even though their main function is also to provide information to a user. It is assumed here that a product failing to provide any signals is equally non-functioning as a product that provides incorrect signals, given that this is equivalent from a safety perspective.[41] Examples from literature and EU documents include medical smartwatch apps[42] and smoke detectors.[43] While alarm systems may intuitively seem different from CDSSs, the distinction is not easily justified using product liability rhetoric. This can be shown by analysing three arguments that might support this distinction: (i) the fact that CDSSs are used to provide services, (ii) the doctrine of the 'learned intermediary' and (iii) the exclusion of indirect risks in interpreting the term 'safety'.

The first proposition alludes to the notorious product-service dichotomy. The product liability directive applies to products, not to services, as the ECJ asserted in the *Dutrueux* case.[44] At the same time, it does apply to products being used for services, as noted in the *Veedfald* case.[45] This case law should be interpreted in line with the new directive. Under the new directive, software is clearly regarded as a product and not as a service (*Dutrueux*) and as such falls within the scope of the directive, even if it is used in the provision of services (*Veedfald*).[46] This renders the product-service discussion obsolete,[47] while raising the aforementioned question (Sect. 2.3.2) of whether information originating from AI software can indeed be inherent to it (*Krone*).

As for the second proposition, the learned intermediary docrine found in common law suggests that 'the manufacturer can discharge of [its] duty to warn by providing

[41] Compare recital 44 of Directive (EU) 2019/770 on certain aspects concerning contracts for the supply of digital content and digital services – although the perspective there is not that of safety risks, but of contractual performance.

[42] The DPLD impact assessment notes: '[S]oftware itself may also cause personal injury or property damage. For example, a medically-approved smartwatch app intended to send an alarm notification to the user or doctor when it recognises irregular heartbeats could defectively fail to do so, leading to injury, or a defective app or computer programs could cause a computer battery to overheat or explode', DPLD impact assessment, SWD(2022) 316 final, 28 September 2022.

[43] See AG Hogan in his Opinion for the Krone judgment, C-65/20, ECLI:EU:C:2021:298, para 28; Kardasiadou 1998, pp. 231–232 on medical warning systems.

[44] ECJ, *Dutrueux*, 21 December 2011, C-495/10, ECLI:EU:C:2011:869, para 18–39.

[45] ECJ, *Veedfald*, 10 May 2001, C-203/99, ECLI:EU:C:2001:258, para 12. See the dissenting Opinion, ECLI:EU:C:2001:697, para. 15.

[46] Cp. Liivak 2018, pp. 181–182; Rott 2020, p. 642.

[47] Even for 'software as a service' (SaaS), see Borghetti 2023a, p. 138.

the relevant information to a responsible intermediary',[48] i.e. the clinician. In medical situations, its (perceived but possibly overstated) effect is to block a product liability claim when a learned intermediary is involved, as it is the clinician's duty to correctly inform and warn the patient about risks (and possible defects), not the manufacturer's.[49] The status of this rule is debated.[50] In the absence of consensus, it could be argued that the existence of a learned intermediary, although it 'does not provide a complete or automatic defence for a producer',[51] precludes the application of the DPLD to CDSSs.[52] However, given the case law's narrow focus on the manufacturer's duty to warn, it seems likely that the rule is relevant solely from an information perspective, where for warning defects, the information in possession of the intermediary can influence the level of safety the consumer is entitled to expect. However, a product can be unsafe even if one considers both the knowledge of the patient and that of the intermediary clinician and therefore this rule would probably not preclude defective CDSSs as a matter of principle.

Considering the third proposition, it might be true that alarm signals should usually be heeded without much thought, whereas CDSS output might require more deliberation.[53] However, as described in Sect. 2.1.1, it is not implausible that clinicians (rightly) come to depend on CDSSs to interpret certain symptoms. A clinician should be able to have a certain level of trust in the fidelity of the output. As we know from the ECJ's *Boston* judgment, the public is entitled to expect a high level of safety from medical systems.[54] This would justify a broad interpretation of the term 'safety' which includes unsafe situations that indirectly result in damage.[55]

[48] Fairgrieve and Goldberg 2020, para 12.55. See for a US perspective Duffourc and Gerke 2024, p. 22.

[49] See e.g. Sullivan and Schweikart p. 162; Pasquale 2022, p. 205; Duffourc and Giovanniello 2023, pp. 222–223.

[50] Fairgrieve and Goldberg 2020, para 12.55.

[51] High Court of Justice (UK), *Wilkes v Depuy International Ltd*, 6 December 2016, EWHC QB 3096, para 108.

[52] In *Wilkes* at para 108, Hickinbottom J appears to place some emphasis on the agency of the intermediary in noting that it was the intermediary who '[had] chosen a particular prosthesis for a particular patient'.

[53] Wendehorst and Duller 2023, pp. 220–221. See also, although with regard to causation, Taeger 1995, pp. 206–209.

[54] At least where it can result in serious injury or death: ECJ, *Boston Scientific Medizintechnik*, 5 March 2015, C-503/13, ECLI:EU:C:2015:148; Fairgrieve et al. 2016, pp. 53–56; Verhoeven 2018, pp. 225–226; Triaille 1993, p. 221. However, this is not equal to *perfect* performance, see Kardasiadou 1998, pp. 174–175. Cp. Cayol 2021, p. 25.

[55] Wendehorst and Duller 2023, pp. 220–221; cp. Fairgrieve and Goldberg 2020, para 17.87: 'The general rule in English law as in the United States remains that he who creates a situation of danger must expect a third party carelessly (though not consciously) to activate its potential for harm.'

2.3.4 Conclusion

This section discussed whether the application of the DPLD to CDSSs should be ruled out as a matter of principle. A positive answer would end the discussion regarding CDSSs at this juncture. However, the view adopted here is that it is not that simple.

Given that software is considered a product under the DPLD, the question is no longer whether a CDSS would qualify as a product, but rather whether its output can render it defective. First, it was suggested that unlike the newspaper in the Krone case, a CDSS is not merely a medium for its advice but its source, and hence we should regard its output as 'inherent to it'. Second, it was suggested that it might be hard to distinguish between CDSSs and alarm systems, which do fall within the scope of the DPLD.

It does not seem unreasonable to conclude that the DPLD could apply to CDSSs. In the next sections, we will examine two specific DPLD requirements: defect (Sect. 2.4) and causation (Sects. 2.5 and 2.6).

2.4 AI Product Defects

2.4.1 Establishing a Defect

A product is defective if it does not provide the safety which the public at large is entitled to expect (the 'consumer expectations test'). Borghetti describes four 'usual' methods through which this is assessed (and explains why they are hard to apply to AI systems):[56] (i) *res ipsa loquitur*,[57] (ii) violations of relevant safety requirements,[58] (iii) risk-benefit analysis,[59] and (iv) product comparison.[60] These methods all have their specific drawbacks. To an extent, this is related to the open-ended nature of the consumer expectation test, limited by the development risk defence, which allows for a spectrum of possible defects that is hard to describe *ex ante*.[61] Specifically

[56] Borghetti 2019, pp. 67–68.

[57] Can be difficult to apply in medical cases, since the right treatment can still produce negative results. Holm et al. 2021, pp. 180–181; Zikmundová 2023, p. 390; Borges 2023a, pp. 183–184 and Wendehorst 2023, p. 108.

[58] See Hacker 2023, p. 16; Wendehorst 2023, pp. 112–114.

[59] Also Borghetti 2023a, p. 153; Wagner 2022, pp. 204–205; Santos Silva et al. 2021, pp. 127–131; Verhoeven 2018, pp. 119–131.

[60] Patti 2020, pp. 116–120; Holm et al. 2021, pp. 182–183; Borges 2021, pp. 35–37; Hacker 2023, pp. 15–16; Buiten et al. 2023, p. 16 on comparing AI and human performance; Verhoeven 2018, pp. 191–192.

[61] Veldt 2020a, para 3. Verhoeven 2018, pp. 99–104 advocates equating product safety criteria with defectiveness; cp. Fairgrieve et al. 2016, pp. 100–103.

for AI systems, they are hard to apply, given that these methods have been developed for traditional, mass-manufactured products.[62] They need to be adjusted to apply to AI systems.[63] The next paragraph offers a possible approach. Most of all, it provides a theoretical basis to counter the criticism that the *res ipsa loquitur* approach inappropriately takes AI output as the sole object of analysis.[64]

2.4.2 *The Intentional Stance, or: Why AI Defects are Manufacturing Defects*

One possible explanation for the abovementioned four methods being hard to apply to AI systems can be illustrated through Dennett's theory on 'stances'.[65] Traditionally, this chapter submits, products are judged through adopting a *design stance*, which means that their behaviour and associated level of safety are based on their intended function.[66] However, for AI systems, the *intentional stance* could sometimes be more appropriate. This stance assumes that AI systems possess internal (non-emotional) beliefs, desires, and the ability to respond and adapt to their environment. This more accurate view of AI systems may in fact correspond with how the general public regards AI systems.[67] Therefore, the adoption of the intentional stance can be seen as an interpretation of the consumer expectations test itself and thus permissible within the existing DPLD framework.

The intentional stance helps to conceptualise AI defects. Traditionally, since software production is seen as invulnerable to manufacturing defects, errors and bugs are approached as *design defects* (not to be confused with the unrelated design *stance*).[68] This focus on design defects is problematic, especially with AI, because it undermines the no-fault character of the DPLD by placing emphasis on its elements of negligence.[69]

For traditional software, the design defects-based approach might be reasonable given the idea that errors can in some way be traced back to a human who made a

[62] Cp. Froomkin et al. 2019, p. 80.

[63] Cp. Duffourc and Gerke 2024, pp. 56–57.

[64] Borges 2021, p. 35; Borges 2023b, p. 35 (no. 15). See also Froomkin et al. 2019, p. 66; Mazeau 2018, p. 8; Verhoeven 2018, p. 187; Borghetti 2023b, p. 34.

[65] Dennett 2017, p. 37.

[66] Dennett 2017, p. 37; Crilly et al. 2008, para 3.1–2 ; cp. Sartor 2009, pp. 257–260.

[67] See in a broader context Gröndahl 2008, pp. 89–92; Sartor 2009, pp. 260–263; Voulon 2010, pp. 30–35; Beckers and Teubner 2021, pp. 34–37. It is important to express that this does not entail an anthropomorphisation of AI: 'beliefs' and 'desires' as used here only refer to internally stored models of reality and objectives.

[68] Westerdijk 1995, pp. 223–224; Kardasiadou 1998, pp. 196–197; Ruesen 2017, para 2.2; Buiten et al. 2021, p. 54; Knetsch 2022, p. 111; Duffourc and Gerke 2023, p. 4.

[69] See e.g. Duffourc and Gerke 2023, p. 4; Werro et al. 2004, pp. 436–441; Wagner 2010, pp. 136–138 and 145; Giesen 2010, pp. 154–155; Patti 2020, pp. 116–120; Wendehorst and Duller 2023, pp. 272–273; Hacker 2023, pp. 29–30. Cp. Howells 2020, pp. 92–93.

design decision.[70] However, manufacturing AI software is different, since machine learning processes are not entirely within a programmer's control.[71] Manufacturing defects can be described either as 'a failure to screen out or eliminate something which is naturally within a product',[72] or as deviating from what the manufacturer intended to produce.[73] It is submitted here that similar to e.g. contaminated shellfish or a batch of horsemeat infected with a bacterium,[74] AI systems can autonomously develop manufacturing defects, namely when they learn statistical patterns from training data or develop behavioural patterns or model characteristics that defy safety expectations.[75] An AI system partly 'designs itself',[76] and where it fails, this is a manufacturing defect, not a design defect.

In essence, it comes down to this: typically, the goal of machine learning is to acquire an imperfect but representative model of (a part of) reality.[77] Adopting an intentional stance, it is the safety risk associated with these imperfections which should inform the consumer expectations test. If the imperfections in the trained model raise safety risks that exceed consumer expectations, it is fair to say the system contains a (manufacturing) defect. This has the advantage that the claimant can challenge the *result* of the machine learning process, instead of merely arguing that certain (procedural) design standards were not met.[78]

The approach proposed here should appeal to those who advocate a more manufacturer-focused liability scheme for medical AI systems,[79] as it places less emphasis on the manufacturer's level of care than a design defects-based perspective.[80] At the same time, it aligns with Borges' point that the incorrectness of the output should not, by itself, render an AI system defective.[81] EU product liability indeed does not require flawless output and therefore necessitates an evaluation of the AI system's (internal) properties—both 'AI model' and encompassing 'non-AI'

[70] Cp. Wendehorst 2020, p. 159.

[71] Tjong Tjin Tai 2022a, p. 117.

[72] Fairgrieve and Goldberg 2020, para 11.05.

[73] Kardasiadou 1998, pp. 170–171; Verhoeven 2018, pp. 132–136; Selbst 2020, p. 1323; Price et al. 2022, para III.A; Borghetti 2023b, p. 33.

[74] Examples borrowed from Fairgrieve and Goldberg 2020, p. 381 (n. 26) and Wuyts 2014, p. 32.

[75] Hacker 2023, p. 15 instead uses a wider definition of 'design defects', with which I respectfully disagree, given that the term 'design' implies a certain intent, although it is admittedly true that these defects, like design defects, affect the entire product 'series' (cp. Kardasiadou 1998, pp. 170–171; Fairgrieve and Goldberg 2020, para 11.05).

[76] Duffourc and Gerke 2024, p. 40: '[The] AI responded to vast amounts of data during the training process and, to some extent, *designed itself* using deep learning.' Cp. Patti 2020, pp. 108–110.

[77] Russell and Norvig 2021, pp. 651–656; Goodfellow et al. 2016, p. 8; cp. Tjong Tjin Tai 2022a, p. 117.

[78] Cp. Duffourc and Gerke 2023, p. 4; Duffourc and Giovanniello 2023, pp. 222–223. Similarly Liivak 2018, p. 183.

[79] See Sect. 2.1.1.

[80] Van Dam 2013, pp. 428; Fairgrieve et al. 2016, p. 53; See also Parasidis 2018, pp. 224–225. Cp. Froomkin et al. 2019, p. 80.

[81] Borges 2023b, p. 35 (no. 15). See also Froomkin et al. 2019, p. 66.

software—that brought it to produce the output.[82] However, it is worth noting that (internal) properties and (external) output are not disconnected, especially for less stochastic AI systems that operate in well-defined spheres of application. Hence, while output or behaviour should not form the *basis* for a defect, it can be a *strong indicator* for one.

It might not be an easy task for a claimant to prove such a defect. For some types of AI models, e.g. generative or reinforcement learning models, this approach is less realistic than for others, such as the GP's risk assessment model referenced in Sect. 2.1.1. At the same time, this should not prevent adopting this line of reasoning where it *is* possible. Additionally, it is not necessary to understand every aspect of the AI system in detail, since proving defectiveness does not require the highest possible technical precision.[83] A preliminary indication of a model's characteristics and built-in 'guard rails' could therefore be sufficient. Furthermore, the claimant might be aided by the new presumptions in article 9 of the DPLD (see Sect. 2.6.6), especially article 9-4 DPLD.

2.4.3 The Development Risk Defence and XAI

The development risk defence prevents the manufacturer from being liable for model characteristics they could not have discovered (article 10-1-e DPLD), for which the manufacturer bears the burden of proof.[84] The criterion for discoverability is objective and takes into account all scientific and technical knowledge available at the time of placing the product on the market, but also during the time in which it was within the manufacturer's control, regardless of whether the manufacturer was aware of it.[85] If we follow the line of reasoning outlined in the previous section, this mechanism could actually stimulate the manufacturer to keep up to date with 'explainable artificial intelligence' (XAI) techniques.[86] It requires the manufacturer to be able to argue in detail why the defence should apply, in other words: why the defect was indiscoverable, given the XAI methods available at the time—that is, if the courts set a sufficiently high bar for the substantiation of the defence.[87]

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[82] Borges 2021, p. 35; Borges 2023b, p. 35 (no. 15).

[83] Rott 2020, pp. 655–656.

[84] ECJ, *Commission v United Kingdom*, 29 May 1997, C-300/95, ECLI:EU:C:1997:255, para 34; cp. Borges 2021, p. 37; this might be difficult to prove, see Triaille 1993, p. 221.

[85] Smith and Fotheringham 2022, p. 42; Patti 2020, pp. 115–116. Note, however, that the applicability of the development risk defence for manufacturing defects has been disputed, see Verhoeven 2018, pp. 277–280; Fairgrieve and Goldberg 2020, para 13.110–13.124; Borghetti 2023b, pp. 37–39. Compare in particular Knetsch 2021, pp. 175–177 on Cour de Cassation, 5 May 2021, No. 19-25102, ECLI:FR:CCASS:2021:C100330 with Chibanguza et al. 2022, p. 837 on Bundesgerichtshof (BGH), NJW 1995, 1094 and BGH, NJW 1995, 2162. See also Brun 2023, pp. 552–553.

[86] Russell and Norvig 2021, pp. 710–712.

[87] Cp. Borges 2021, p. 37; note that failing to comply with the prospective 'explainability requirements' in the AIA could also itself result in defectiveness through article 6-1-f DPLD.

2.5 Could a Causal Link Exist?

2.5.1 The Factual and the Normative Phase

If a CDSS is considered defective, the next question would be whether there is a causal link between the output resulting from this defect and the subsequent damage.[88] Some would argue that such a link is generally not possible. Taeger, for example, argued that the causal chain between CDSS output and damage is broken, since the intermediary—the clinician—ultimately bears the responsibility over the correctness of the medical decision.[89] However, from a legal point of view, clinicians are not strictly responsible for the devices they use.[90] Additionally, this view conflicts with the fact that clinicians are supposed to be influenced by the output of diagnostic systems.[91]

Under EU product liability law, the requirement of a causal link is a matter of national law.[92] The interpretation of this requirement differs between Member States. It is, however, common to distinguish two phases: (i) a 'factual' phase of testing for a *sine qua non* ('but for') link, and (ii) a subsequent 'normative' phase that eliminates some or all of the causes nominated in the first phase on normative grounds, e.g. because damages are too remote or result from the own fault of the party suffering damage.[93]

The first phase is of a factual nature. Most differences between Member States arise in the second, normative phase, where considerations such as 'foreseeability' and 'responsibility' come in.[94] In jurisdictions where the normative phase is more permissive,[95] the oft-cited AI liability hurdle of 'foreseeability' might pose a less difficult challenge.[96]

Hereafter, we focus on the first phase's challenge of establishing a *sine qua non* link between a CDSS defect and damage, as it can be encountered across all EU jurisdictions. The question of what would have happened in absence of the CDSS defect is hard to answer, since the occurrence of damage partly depends on the actions of the intermediary.[97] The next section (Sect. 2.5.2) will argue why there are

[88] A link between defect and output is also required.

[89] Taeger 1995, pp. 207–208; cp. Haftenberger 2023, p. 263.

[90] See n. 10 infra.

[91] Haftenberger 2023, p. 263.

[92] ECJ, *Sanofi Pasteur*, 21 June 2017, C-621/15, ECLI:EU:C:2017:484, para 18–43.

[93] Fairgrieve et al. 2016, p. 86; Fairgrieve and Goldberg 2020, p. 674.

[94] Fairgrieve et al. 2016, p. 86, although note that the standard of proof for the *sine qua non* link can differ across jurisdictions; Wuyts 2014, pp. 25–28; Verhoeven 2018, pp. 239–240 (BE); Van Dam 2020, pp. 533–561 (NL).

[95] This might be the case in jurisdictions where the 'theory of equivalence' plays a role, such as France (Brun 2023, para 237–248 and 249) and Belgium (Verhoeven 2018, pp. 239–240; Van Quickenborne 2007, pp. 13–43). See also Askeland 2016, p. 369 on Norway.

[96] See Selbst 2020, pp. 1344–1346, also for arguments why foreseeability might not be problematic.

[97] The importance of which seems to be underappreciated in Kardasiadou 1998, pp. 236–243.

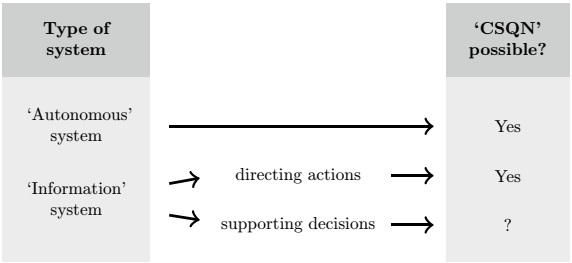

Fig. 2.2 Westerdijk's model separates directive and supportive information systems

no principal objections to the establishment of a *sine qua non* link, after which the following section (Sect. 2.6) will discuss several approaches for establishing a causal link in fact.

2.5.2 Sine Qua Non Link: No Principal Objections

A *sine qua non* link can be assumed if in the absence of the product defect the (same) damage would not have occurred.[98] Inevitably this theoretical exercise requires a certain appreciation of the expected actions of the intermediary: what would they have done if provided with the 'correct' output?

In 1995, Westerdijk described a model distinguishing between software-based information systems that *direct* the user towards certain decisions or actions (*beslissingssturend*), and systems that merely *support* the decision-making process of the user (*beslissingsondersteunend*).[99] For directive systems such as a pilot's flight instruments, a causal link, he argues, can exist both in the factual and normative sense between the output and the subsequent human action. This is not the case for supportive systems such as medical information systems, due to the larger role and autonomy of the intervening actor (see Fig. 2.2). In these situations, he argues, the requirements set by Dutch law for the normative phase are not met. While this distinction will be challenged in Sect. 2.6, accepting the possibility of a causal link for at least directive information systems would be a first step towards answering this section's main question.

Unfortunately, a search for case law in which EU product liability law is applied to such malfunctions did not return any instructive results. A case that nonetheless deserves mentioning is the Spanish Supreme Court's *Überlingen* judgment, in which it ruled that the (directive) Traffic alert and Collision Avoidance System (TCAS), which provides pilots with suggested route adjustments to avoid collisions, was defective, resulting in liability for the manufacturer under New Jersey/Arizona

[98] Fairgrieve et al. 2016, p. 86; Fairgrieve and Goldberg 2020, p. 684.

[99] Westerdijk 1995, pp. 242–243 and 270–271; Alheit 2001, pp. 205–208. Cp. Taeger 1995, p. 207.

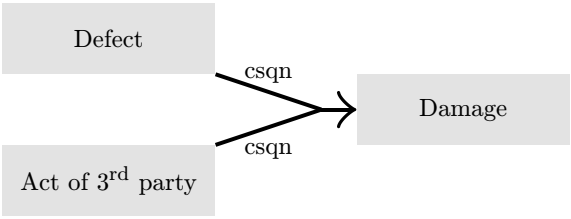

Fig. 2.3 Article 12-1 DPLD requires a sine qua non link for every cumulative cause

product liability law.[100] The Court did suggest, by way of *obiter dictum*, that this was an example of cumulative causation which, if Spanish law would have applied, would have seen the application of article 8-1 PLD (article 12-1 DPLD), suggesting that a causal link could be established.[101]

We can, however, use the examples discussed earlier in Sect. 2.3.3 to determine to the validity of both Westerdijk's and the Spanish Supreme Court's viewpoint. If it can be concluded that the alarm systems fall within the scope of the DPLD, this implies that it should be possible to establish causality for those systems. Based on the arguments provided in Sect. 2.3.3, this should arguably extend to (at least some) CDSSs. This section's question is therefore answered, tentatively, in the affirmative.

2.6 How to Establish a Causal Link in Fact

2.6.1 Introduction

The next question is how we can establish a causal link in fact. While Westerdijk's dichotomy provides a useful conceptual framework, its practical use is limited due to the lack of a clear test to distinguish between his two categories of systems, namely 'directive' and 'supportive' systems. After all, both directive and supportive systems provide information to the user upon which the user decides to act. In reality, these categories exist on a continuous spectrum. To separate them, we need to establish a suitable decision boundary. This section discusses several approaches.

First, it will discuss a rule in the directive (article 12-1 DPLD) that might seem to solve this problem and show why it does not (Sect. 2.6.2). Then, it analyses and criticises the approach taken by Haftenberger, who uses legitimate consumer expectations as a central concept to establish or reject a causal link (Sect. 2.6.3). As an alternative, the approach used under Dutch law in informed consent cases is described (Sect. 2.6.4), which is taken as a basis for a proposal for a rebuttable

[100] Spanish Supreme Court, *Überlingen*, 13 January 2015, STS 181/2015, ECLI:ES:TS:2015:181; discussed in Contissa 2017, para 7 and Schebesta 2017.

[101] Spanish Supreme Court, *Überlingen*, 13 January 2015, STS 181/2015, ECLI:ES:TS:2015:181, p. 46. See also Sect. 2.6.2 below.

presumption based on normative standards (Sect. 2.6.5), before briefly discussing the DPLD's article 9 presumptions (Sect. 2.6.6).

2.6.2 *Article 12-1 DPLD (Cumulative Causation) Does Not Apply*

While the DPLD does not provide a standard for causation, it does contain a rule on concurrent causes. According to article 12-1 DPLD, previously article 8-1 PLD, the liability of the manufacturer 'is not reduced when the damage is caused both by the defectiveness of a product and by an act or omission of a third party'. This rule applies to situations of cumulative causation, where the product defect and the actions of the third-party intermediary contributed independently and in parallel to the occurrence of the damage.[102] Through this rule, manufacturers cannot escape liability by claiming their product was only one of multiple contributing factors.[103]

However, to be able to successfully apply article 12-1, the *sine qua non* test with regard to the defective product must still be met (see Fig. 2.3).[104] Otherwise, the AI output cannot be said to have contributed to the damage, in which case it is not a—cumulative—cause of the damage. Article 12-1 DPLD is, therefore, not able to close this causality gap.[105]

2.6.3 *The Consumer Expectation Test Does Not Apply*

Haftenberger rightly states that the impact of human actions on the causal link between medical (software) product defects and damage is to be decided on a case-by-case basis.[106] As she also remarks, it could still be possible to propose a number of general rules through distinguishing certain categories of cases.

However, her categorisation focuses on the extent to which the user may rely on the output, given the legitimate safety expectations (as used in the consumer expectation test) regarding the software.[107] This could lead to an unjustified conflation of defectiveness and causality. Unlike defectiveness, establishing causality is currently

[102] Rolland 1990, pp. 220–221; Foerste and Graf von Westphalen 2012, para 51 (no. 10); Ehring and Taeger 2022, para 6 (no. 14–15); Lenz 2022, para 3 (no. 422); Ehring and Taeger 2022, para 6 (no. 15).

[103] This can be important when multiple software systems are used in conjunction to treat a patient.

[104] Van Empel and Ritsema 1991, p. 73; Foerste and Graf von Westphalen 2012, para 51 (no. 10); Kardasiadou 1998, p. 233.

[105] Similarly Kardasiadou 1998, p. 233, although Haftenberger 2023, p. 263 seems to disagree.

[106] Haftenberger 2023, p. 264.

[107] Haftenberger 2023, p. 264.

a matter of national law.[108] Applying the consumer expectation test for causation, therefore, has no basis. Aside from this formal criticism, there is also an objection of a substantive nature. In the first phase of causation (see Sect. 2.5.1), establishing a *sine qua non* link entails predicting the behaviour of the intermediary. This expected behaviour can indeed be influenced by (abstract) safety expectations, but other factors that are not related to the product, such as (abnormal) patient-specific circumstances, can also play a role. Such subtleties are lost when causation is viewed exclusively through the lens of legitimate safety expectations.[109]

2.6.4 Causality in Dutch Informed Consent Cases

The *sine qua non* test essentially inquires whether the intermediary would have chosen a different action if they were instead provided with the correct information.[110] An interesting parallel exists with a line of Dutch case law regarding informed consent.[111] In these cases, patients complain that their decision to agree to a certain treatment was based on incorrect information. If they had been given the correct information, they would purportedly not have agreed to this treatment, thus avoiding the harm they incurred. Unlike in several other jurisdictions, under Dutch law the patient bears the burden of proof with regard to the lack of consent and the causal link between it and the damage.[112]

For the causal link, the substantive *sine qua non* test requires patients to prove that, had they been given the correct information, they would have made a different decision. Dutch law has seen the development of a mostly objective test to answer the question: what would a 'reasonable patient' have decided, when given the correct information, under those circumstances? If this fictional reasonable patient would have been presented with the *correct* information, would they still have made the same decision? If so, the information cannot be said to have 'caused' the decision and thereby the damage. However, if a reasonable patient would have made a different decision when provided with the correct information, the court can assume the existence of a causal link between the (incorrect) information and the chosen treatment.[113]

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[108] As discussed in Sect. 2.5.1.

[109] Although the patient-friendly way in which Haftenberger interprets these expectations could admittedly produce similar results, see Haftenberger 2023, pp. 265–267. See similarly Kardasiadou 1998, pp. 242–243. It may be true that consumer expectations also play a role in the 'second' phase of causation, but that depends on how this aspect is regulated in national law.

[110] Fairgrieve et al. 2016, p. 86; Fairgrieve and Goldberg 2020, p. 674.

[111] Dutch Supreme Court (HR), 23 November 2001, ECLI:NL:HR:2001:AB2737, NJ 2002/386, para 3.5.6; HR, 23 November 2001, ECLI:NL:HR:2001:AD3963, NJ 2002/387, para 3.5.5; HR, 23 April 2010, ECLI:NL:HR:2010:BL4882, JA 2010/97.

[112] Koch 2011, pp. 630–637; Wijne 2021b, para 25.4; Tjong Tjin Tai 2022b, para 453–454.

[113] De Tavernier 2010, para 2; Tjong Tjin Tai 2022b, para 454; Wijne 2021b, para 25.4; Wijne 2021a, pp. 665–670.

Let us consider a different context, that of liability arising out of misleading information in a prospectus. A similar question arises, specifically whether the claimant would have made the same investment decision if the information in the prospectus had been accurate. In a 2008 ruling, the Dutch Supreme Court concluded that in the absence of proof to the contrary, a causal link between the misleading prospectus and the subsequent investment decision can be presumed, in order to ensure effective protection under Directive 2003/71/EG (Prospectus Directive).[114] It considered that 'while it is, in principle, for the investor to prove the existence of a *sine qua non* link, this proof is problematic, given the fact that an investors will generally base investment decisions on a multitude of factors, while it will often not be possible to establish whether they actually received the misleading information, let alone that they were actually influenced by it'.[115]

2.6.5 Normative Standards as a Basis for a Rebuttable Presumption

There is a similarity between these lines of Dutch case law and establishing the DPLD's causal link for CDSS defects. The question is essentially the same: is it possible to establish a *sine qua non* link between the (incorrect) information provided to the decision-maker and the decision they have made?

Although it would go too far to adopt a general presumption of a causal link such as in the prospectus judgment, it would be appropriate to follow a similar approach as in the Dutch case law on informed consent. That approach entails that the question of what the *intermediary* (i.e. the decision-maker) would have done in fact can be approximated through answering the question of what normative expectations (the 'reasonable decision-maker') would require them to do in that specific situation.

Essentially, this boils down to the same test as for medical negligence. Unlike the test based on the product-related safety expectations (Sect. 2.6.3), this test allows the consideration of patient-specific circumstances. Expert reports can be used to answer the question what the intermediary should have done, similar to how courts approach the test for medical negligence. The established practice of using expert reports in medical liability cases makes this a viable approach for product liability related to specifically *clinical* decision support systems.

However, it is important to recognise that while what intermediaries *should* have done might be a reasonable estimation of what they *would* have done, these are not to be equated. The proposed approach can, therefore, not be accepted as a rule. It

[114] HR, *World Online*, 27 November 2009, ECLI:NL:HR:2009:BH2162, NJ 2014/201. See Pijls 2022, pp. 283–287 and Pijls 2023.

[115] HR, *World Online*, 27 November 2009, ECLI:NL:HR:2009:BH2162, NJ 2014/201, para 4.11.1–3.

can, however, play a role as a rebuttable presumption in the absence of superior information.[116]

Given the fact that causation is a matter of national law, the decision to adopt such a presumption is up to national courts and/or legislators.[117] Notably, this presumption would not change the fact that the claimant bears the burden of proving the causal link, since it is still up to them to show what a reasonable intermediary would have done, and is therefore not contradictory to article 9-1 DPLD.

2.6.6 The DPLD's Own Presumptions Regarding Causality (Article 9)

The DPLD itself contains, in article 9, several rebuttable presumptions alleviating the claimant's burden of proof. Given the provisional nature of the draft, this provision will only be described briefly here, referring to other works for a more in-depth discussion.[118]

Article 9 of the DPLD contains three 'alleviation mechanisms': (i) a presumption of defectiveness (article 9-2), (ii) a presumption of a causal link (article 9-3), and (iii) a presumption of both defectiveness and causal link for 'excessively difficult cases' (article 9-4). The presumption in article 9-3 applies when it has been established that the product is defective and the damage caused is of a kind typically consistent with the defect in question. The presumption in article 9-4 applies when the 'technical or scientific complexity' makes it excessively difficult for the claimant to prove defect, causal link or both.

The presumption in article 9-4 appears to target situations where the causal chain is obfuscated by the technical complexity of the product instead of the complexity within the causal chain itself (i.e. the presence of an intermediary), although it seems fit to resolve latter situations as well. It would therefore be valuable to observe how these rules evolve during the drafting process. However, it should be remembered that these presumptions are also *procedural* in nature. The importance of establishing a thorough understanding of the substantive aspects of causation, such as discussed in Sects. 2.6.2 and 2.6.3, should not be overlooked.

[116] See critically Kardasiadou 1998, p. 240.

[117] See also the presumptions in article 9 of the DPLD (Sect. 2.6.6).

[118] Hacker 2023, pp. 25–28; De Bruyne et al. 2023, para 3.5; Borges 2023b, para 4; Sormunen and Havu 2022, para III.2.b; Veldt 2023, para V; Borghetti 2023a, pp. 161–163; Spindler 2023, pp. 64–71; Zech 2023, pp. 198–199; Wagner 2022, pp. 217–218; Buiten et al. 2023, para 5.1.3.

2.7 Conclusions

This chapter focused on the application of EU product liability law to AI-based clinical decision support systems (CDSSs). The chapter claims that in some cases it should be possible to establish a causal link between incorrect information provided by the CDSS and damage caused by the intermediary acting on that information, and that the scope of the DPLD includes these situations.

Regarding the requirement of a product defect, this chapter argued for the adoption of the intentional stance in construing customer expectations for AI systems, rather than the more traditional design stance. A reinterpretation of the manufacturing defect allows us to retain the no-fault character of EU product liability, whereas design defects risk emphasising its elements of negligence.

With respect to establishing causality, this chapter argued that the *sine qua non* link between damage and CDSS output cannot be established through art 12-1 DPLD or through the consumer expectation test. Instead, this chapter proposed to adopt a rebuttable presumption in which the presence of a *sine qua non* link between output and damage is assumed in cases where a 'reasonable clinician' would have followed the system's advice.

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