PRODUCT LIABILITY INSURANCE NEW PATHS FOR SOFTWARE AND SYSTEMS OF ARTIFICIAL INTELLIGENCE FOLLOWING DIRECTIVE (EU) 2024/2853?

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Abstract

The recent EU Directive on liability for defective products (Directive 2024/2853) significantly expands liability to cover risks arising from digitalisation, including software and artificial intelligence (AI) systems. The purpose of this article is to examine the implications of these changes for product liability insurance, focusing on the need to adapt insurance models to address new risks such as cyber threats, machine-learning capabilities and data breaches. The analysis highlights the issues concerning whether certain risks can be insured, in particular systemic risks and non-material damages, while exploring potential solutions like risk pools and public compensation funds. There is also a critique of the EU's silence on compulsory EUwide liability insurance, arguing for sectoral mandates for high-risk products to balance innovation and victim protection. By comparing national approaches and referencing the German AVB BHV 2024 model contracts, the tension between harmonisation and Member State discretion in implementation is underscored.

Keywords

product liability insurance, artificial intelligence, Directive (EU) 2024/2853, Cyber Resilience Act, compulsory insurance, non-material damage, risk pools

[1] This article is a shortened, slightly modified and translated into English version of my article "Produkthaftpflichtversicherung – neue Wege nach der neuen Produkthaftungs-Richtlinie?" published in Ebers/Gsell/Mayrhofer/Danda (eds.), Neue europäische Produkthaftung (2025) 111 - 132.

1. INTRODUCTION

The recent Directive on liability for defective products (Directive (EU) 2024/2853, hereinafter "PLD 2024") was enacted on 23 October 2024. It was published in the Official Journal on 18 November 2024 and entered into force 20 days thereafter (Article 23 PLD 2024). Member States must transpose the Directive's provisions into national law by 9 December 2026 (Article 22(1) PLD 2024).

The Directive's transposition will require changes to be made to product liability insurance products in order to ensure cover for potentially liable parties. This is particularly relevant in respect of product liability risks associated with software and artificial intelligence systems.

The following analysis will highlight key aspects of these changes. Where reference is made to existing product liability insurance models, this refers to the model contracts provided by the German Insurance Association (https://www.gdv.de/gdv-en) – specifically to the *Allgemeine Versicherungsbedingungen für die Betriebs- und Berufshaftpflichtversicherung (AVB BHV) 2024* (hereinafter AVB BHV 2024).

2. THE PLD'S IMPACT ON THE DESIGN OF PRODUCT LIABILITY INSURANCE

2.1. New Insurance Requirements Due to New Liability for Software and Systems of Artificial Intelligence

The new Directive significantly extends liability to cover risks arising from digitalisation. The focus lies on the expanded product concept, which now encompasses software and digital design documentation alongside tangible products (Article 4(1) PLD 2024: for digital design documentation, see Article 4(2) PLD 2024). This also includes AI systems within the meaning of the Regulation on artificial intelligence (Regulation (EU) 2024/1689, hereinafter "AI Regulation"). Furthermore, when determining whether a product is defective, the requirements for cyber security (in particular under the "Cyber Resilience Act", i.e. the Cyber Resilience Regulation (Regulation (EU) 2024/2847)) and the consequences of a product's machine learning capability must also be taken into account (Article 7(2)(c) and (f) PLD 2024; see Recital 32 PLD 2024). The liability period has also been extended in particular for software, as liability now arises if the defect existed no later than at the time when the product was no longer under the manufacturer's control (see Article 7(2)(e) PLD 2024). The scope of recoverable losses has also been expanded: in addition to the right to compensation for personal injury and property damage, losses incurred through the destruction or falsification of private data are also recoverable (see Article 6(1)(c) PLD 2024).

By extending liability to software, including artificial intelligence systems, the European legislature seeks to address the potential risks created by technical innovation without hampering innovation and research at the same time. In order to protect the latter, the PLD

2024 contains several restrictions and, in particular, excludes from the scope of product liability free and open-source software developed or supplied outside the scope of commercial activity (Article 2(2) PLD 2024; for the justification of the exception, see Recital 14). It is for the same reason that under Article 7(3) PLD 2024, it cannot be inferred that a product is defective solely on the basis that a better product has subsequently been placed on the market or put into service (with regard to the promotion of innovation and research as a contributing factor to this provision, see Recital 35 PLD 2024). In seeking to address new risks under liability law without hampering innovation, the new Directive is in line with the likewise recently adopted AI Regulation (see, in particular, Recital 8 AI Regulation). In general, the PLD 2024, with its focus on liability issues in the context of digitalisation, is part of a broad package of EU measures on digitalisation and, in particular, on the regulation of artificial intelligence (for more details, see Heiss, 2023, p. 245).

2.2. Impact on Product Liability Insurance

2.2.1. Reassessment of risk and possible limits to insurability

The developments in liability law outlined above, albeit in very rudimentary form only, will naturally have an impact on product liability insurance. It seems evident that extensions of liability will also necessitate an extension of insurance.

The primary task at hand is to get to grips with the new framework from an actuarial perspective. This initially concerns the fact that liability will also attach to software (including AI systems) in future, meaning that this risk must be recorded and assessed accordingly. Even if software is integrated into a tangible product, rapid technological developments give rise to new types of risk. The cyber security requirements recently laid down in the Cyber Resilience

Act (Regulation (EU) 2024/2847) must be met by such products (see at the end of Recital 32 PLD 2024). Artificial intelligence systems are also capable of learning, which means that they can change their behaviour. This risk is aptly described in Recital 32 PLD 2024:

> The effect on a product's safety of any ability to learn or acquire new features after it is placed on the market or put into service should also be taken into account to reflect the legitimate expectation that a product's software and underlying algorithms are designed in such a way as to prevent hazardous product behaviour. Consequently, a manufacturer that designs a product with the ability to develop unexpected behaviour should remain liable for behaviour that causes harm.

The actuarial assessment of this risk of change may, however, prove challenging.

Despite existing actuarial difficulties, these changes should not, in my opinion, call into question whether it is economically viable to provide insurance cover for such extended

liability (with regard to whether AI risks can be insured, see, for example, Reusch, 2020, paras. 346 ff.). If any doubts emerge as to whether these risks can be insured at all, then this, in my opinion, stems not from the extension of liability, but from the potential of software and AI systems to cause widespread damage in certain circumstances, in particular (but not limited to) through network effects (see, for example, Zech, 2020b, p. 51 with reference to Schneier, 2018, p. 3). Defective software deployed globally can also trigger damage worldwide, resulting in correspondingly high amounts of loss. The defective Crowdstrike software, which led to airport closures and disruptions in banks, hospitals and broadcasting stations worldwide, has already provided a real-life example (The damages are exorbitant and have been estimated at USD 15 billion – of which USD 1.5 to 3 billion are insured losses; see Jochum, 2024). Moreover, there are strong warnings about "systemic" cyber risks, in particular, though not exclusively, in the financial services sector (see, for example, European Systemic Risk Board, 2020, 24 ff.). As such horror scenarios cannot be ruled out, it necessitates ongoing monitoring by insurance companies. If it proves economically unviable to provide cover for such risks, they will have to be excluded from cover or alternatively secured through other means. This could be implemented, for example, through risk pools, similar to those established for terrorist risks in some countries (e.g. in Germany, terrorism risks are covered by the specialist insurer Extremus AG (www.extremus.de)).

2.2.2. Spotlight: Revision of the product definition in the AVB BHV 2024

Under section A3-1 AVB BHV 2024, insurance cover is provided for liability for losses caused by "products". The term "product" itself is flexible enough to include intangible products such as software and artificial intelligence systems. However, this approach cannot apply to existing contracts as the term "product" must be interpreted based on its meaning at the time of contract conclusion. Under this interpretation, only physical objects within the meaning of § 90 of the German Civil Code (BGB) are classified as products (Bruck/Möller-*Koch*, 2023, Ziff. 1, ProdHM 2008/2015, no. 9). Following this approach, software only counts as a product when it is stored on a physical medium (Bruck/Möller-*Koch*, 2023, Ziff. 1, ProdHM 2008/2015, no. 10). Consequently, an amendment to the provision in section A3-1 AVB BHV 2024 is to be expected.

2.2.3. Spotlight: Pure economic loss and "purely" non-material damage

In Article 6(1) of the new PLD, the recoverable losses are limited to death or bodily injury, including medically recognised damage to psychological health, property damage ("damage to, or destruction of, any property") and the destruction or falsification of private data. For such types of damage, compensation may be claimed for the resulting economic loss and nonmaterial damage, the latter in accordance with national liability law (Article 6(2) PLD 2024).

However, this does not include events resulting solely in pure economic loss or exclusively in "purely" non-material damage. Yet, it is precisely due to the extension of the product concept to software and artificial intelligence systems that both types of damage are much more likely to occur in the future than under the old Directive on product liability (Council Directive 85/374/EEC). For one, defective software may provide incorrect data, causing users to make unfavourable investment decisions and suffer pure economic loss. For another, a biased AI system, for example, may violate personal rights through discriminatory treatment, which solely results in non-material damage without any economic loss whatsoever. The failure to address such damage in the PLD merely means that, while these damages are not recoverable under the specific product liability provisions in the Directive, they may be recoverable under other national liability regimes pursuant to Art. 6(3) PLD. There is therefore a need for insurance cover and, consequently, a need to amend the AVB BHV 2024.

Insurance cover is governed in section A3-3.1 of the AVB BHV 2024, under which cover is limited to personal injury, property damage or economic loss resulting therefrom. Insofar as personal injury also gives rise to claims for non-material damage, these are included in "personal injury" and are therefore also covered (see Bruck/Möller-*Koch*, 2023, Ziff. 1 AHB 2016, no. 17; the same concept of personal injury also applies in the context of product liability insurance). In legal literature, there is no clear answer to the question of whether a violation of personal rights also constitutes personal injury within the meaning of the AVB BHV 2024 in the various sub-sectors of liability insurance. It is clear that violations of personal rights cannot be classified under the terms used in the PLD 2024, namely "death or bodily injury, including medically recognised impairment of mental health" (Article 6(1)(a) PLD 2024). However, the term "personal injury" as employed in the AVB BHV 2024 for various sub-sectors of liability insurance is drafted more broadly, thereby allowing for an interpretation that in principle could include violations of personal rights (on this point, see Bruck/Möller-*Koch*, 2023, Ziff. 1 AHB 2016, m.n. 15). However, the prevailing scholarly opinion rejects the classification of pure violations of personal rights as personal injury (see only the literature cited in Bruck/Möller*Koch*, 2023, Ziff. 1 AHB 2016, m.n. 15 in footnote 16; also Langheid/Wandt-*Littbarski*, 2023, m.n. 133 f.). According to prevailing opinion, economic loss stemming from personal rights' violations are to be regarded, from an insurance law perspective, as "pure economic loss" and intangible losses as "pure non-material losses" and neither are therefore insured under section A3-3.1 of the AVB BHV 2024.

If claims for such "purely non-material damage" and/or "pure economic loss" are made, it would be logical to not regard these cases as product liability cases at all and consequently to subject them to the general first part of the AVB BHV 2024. However, the same applies in this context: only "personal injury, property damage or economic loss resulting therefrom" is

insured (translated by the author). Furthermore, the special exclusion of cover in section A17.9 of the general part makes it clear that damage resulting from violations of personal rights are not covered. This exclusion of economic loss resulting from personal rights' violations is stated expressly in section A1-6.12.1, which also contains an exclusion of liability arising from defective products.

However, two extensions of liability must be noted in this context: firstly, the extension of liability in section A1-6.13, which governs cover for damage resulting from violations of data protection laws and from the transfer of electronic data (however, it should also be noted that section A1-6.13.3(b) AVB BHV 2024 specifically excludes software development from the scope of the cover); secondly, the extension of cover in section 4 (section A4-1 ff.), which provides cover for claims arising from discrimination. This should, in my view, also apply to prohibitions on discrimination arising from personal rights. While this covers important aspects of personal rights, possible violations of these rights go far beyond data protection violations and discrimination. In this respect, digitalisation and, in particular, the use of AI create a further need for cover.

2.3. "Transition phase": Covering the risk of legal changes

The implementation of the new PLD 2024 will incorporate the aforementioned extensions of liability. The Directive must be implemented by no later than 9 December 2026 (Article 22(1) PLD 2024), though implementation may take place earlier. It is therefore advisable to amend product liability insurance – and thus the AVB BHV of March 2024 – as soon as possible. This amendment would ensure that the new liability risks are covered in new contracts.

The extension of liability introduced in the PLD raises the question of the extent to which this legislative development may be construed as an increase in risk within the meaning of § 23 of the German Insurance Contract Act (dVVG) for contracts concluded prior to its implementation (see Prölss/Martin-*Armbrüster* (2024) no. 24 regarding the amendment of liability law as an increase in risk). However, existing customers need not be concerned, as the risk of a change in the law is expressly covered under the AVB BHV 2024. The relevant provision in section A1-8.2 AVB BHV 2024 also applies in principle to product liability insurance by virtue of section A3-9 AVB BHV 2024. Where the insurance agreement incorporates cover for special product liability risks within the meaning of section A3-7 AVB BHV 2024, the provision set out in section A3-9.2 AVB BHV 2024, which is substantively identical yet more specific, will apply. However, under these provisions, the insurer is granted the option of terminating the contract with one month's notice. The period commences when the insurer becomes aware of the increase in the insured risk as a result of a change in the law.

2.4. Exhaustive harmonisation and European policies

When recalculating risks, it is important to note that the new PLD 2024 represents both a minimum and a maximum standard (Article 3 PLD 2024). This should, at least in theory, eliminate relevant differences in the level of liability across Member States. This is beneficial for insurance companies that offer (or wish to offer) product liability insurance in several Member States or throughout the entire internal market. The exhaustive harmonisation provided by the Directive is therefore likely to facilitate the development of "European policies".

On closer inspection, however, potential for significant differences remain: under Article 18

PLD 2024, Member States may derogate from Article 11(1)(e) and govern liability for development damage differently, in particular to maintain or introduce such liability. It appears particularly relevant to me that the calculation of damages is not governed by Directive. There is also a reference in the second sentence of Article 6(2) to national law for compensation for non-material damage (see Piovano & Hess, 2024, § 5 m.n. 57 f.). Finally, pursuant to Article 6(3), damages not covered by the Directive may be recovered under other liability regimes established in national law.

3. INSURANCE-RELATED PROVISIONS OF THE NEW PLD

3.1. Reporting obligation of the Commission under Article 20 of the PLD 2024

The new PLD 2024 does not govern product liability insurance. (However, see section 2.2 below on compensation schemes, which may also be insurance solutions.) In particular, it does not impose any insurance obligation, although this had been proposed during the legislative process (for more details, see section 3 below; cf. generally Heiss, 2023, 253 ff).

Yet, product liability insurance is at least mentioned in Article 20. This provision requires the Commission to evaluate the application of the new PLD 2024 at regular intervals. To this end, the Commission must submit a report, which must, in particular, also provide information on the availability of product liability insurance. Beyond this reference, however, product liability insurance remains *invisible* in the PLD 2024.

Nevertheless, precisely because insurance is mentioned in Article 20 PLD 2024, it is reasonable to conclude that the European legislature took into account the anticipated availability of insurance cover for potentially liable persons when redesigning the product liability rules. This is the only way to explain why the availability of product liability insurance is a mandatory assessment criterion for the Commission's reports. In this respect, insurance or rather the views of insurance providers may have served as an (albeit not sole) "*invisible* hand" guiding the European legislature. Through its reports, the Commission's actions will likely continue to be influenced by the availability of adequate product liability insurance cover.

3.2. Insurance as an alternative to or safety net for liability regimes

3.2.1. Compensation schemes "outside the context of liability regimes" (Recital 11 PLD 2024)

Further references to insurance can also be found in Recital 11 PLD 2024. This clarifies that compensation schemes "outside the context of liability regimes" (English version) or "*en dehors du cadre des régimes de responsabilité*" (French version) are neither governed nor therefore excluded by the Directive. As examples, "national health systems, social security schemes or insurance schemes" are cited in Recital 11. In my view, these are social or private insurance schemes or systems that provide compensation directly to victims of defective products and subsequently seek recourse against the party liable. Hence, these systems do not replace the liability of the manufacturer or other liable parties and therefore do not fall within the "context of liability regimes". Nor does the example cited in Recital 11, namely that some Member States have compensation schemes for damage caused by "pharmaceutical products that cause harm without being defective", represent any contradiction to the Directive. This is because these systems relate to pharmaceutical products that are not defective within the meaning of the PLD 2024, so that no liability can arise under PLD 2024.

It is not entirely clear to me whether such systems would also be permissible if they replaced the liability of the manufacturer or other liable persons, i.e. if insurance cover were to operate in lieu of liability claims, thereby precluding the compensation scheme from taking recourse against the manufacturer or other liable persons. For instance, in line with the opinion of several commentators in the literature, Zech (2020a) has contemplated the introduction of statutory insurance, modelled on statutory accident insurance for accidents at work in Germany, in relation to liability arising from decisions made by autonomous digital artificial intelligence systems (A105 ff. with further references, in particular in footnote 267). However, indemnity insurance for individual artificial intelligence systems (see also Zech, 2020a, A105 ff. with further references, in particular in footnote 267; cf. Heiss, 2023, 265 ff.) and the establishment of public compensation funds are also possible options. Such compensation schemes appear questionable in light of the phrase "outside the context of liability regimes". This is because, by eliminating liability, these systems could be regarded as falling "within the scope of liability regimes". At the very least, this creates legal uncertainty. By contrast, the financing of a compensation scheme by potentially liable parties, whether voluntarily or by legal mandate, does not appear to be problematic, provided that any actual compensation paid can be offset against the claim for damages under the Directive by way of benefit set-off. This is because these systems would base any set-off against liability claims on the compensation actually provided by the compensation scheme, without inherently limiting victims to seeking redress solely through the compensation scheme.

Irrespective of whether a compensation scheme substituting liability under national law would be contrary to the Directive, the introduction of a compensation scheme substituting liability at the level of Union law would still be possible. These schemes are often credited with the advantage of promoting innovation in the field of artificial intelligence while ensuring adequate compensation for victims. Costs would also be reduced because compensation schemes would incur lower litigation costs than liability systems (see Borges, 2019, p. 160; cf. Bertolini & Episcopo, 2021, 657 f.). Despite these advantages, this system could create the problem of a *moral hazard*: in the absence of liability, manufacturers would be more likely to act carelessly (see von Bar, 1998, A 73; such a "moral hazard" is, of course, also seen in traditional liability insurance, see Wagner, 1999, 1441 with further references). This misplaced incentive found in models of liability substitution using compensation schemes would therefore have to be effectively countered. The introduction of a right of recourse is only one conceivable approach. An even subtler approach would be to tie the right of recourse to risk prevention duties on the part of the manufacturer, limiting recourse to cases where certain duties of care have been breached (Heiss, 2023, 269 f.). In addition to possible misplaced incentives, the costs of such systems would also have to be taken into account, as they do not always appear to be costeffective.

3.2.2. "Add-on" or subsidiary compensation systems (Article 8(5) PLD 2024)

Compensation schemes that only intervene subsidiarily to liability ("*add-on* compensation funds") are specifically permitted under Article 8(5) PLD 2024. Such compensation funds would therefore become active in cases where there is no liability (first alternative of Article 8(5) PLD 2024) or it cannot be enforced despite its existence (second and third alternatives of Article 8(5) PLD 2024). The latter would be the case if the liable party is insolvent or no longer exists (second and third alternatives of Article 8(5) PLD 2024 and

Recital 41 PLD 2024).

This provision is reminiscent of the compensation schemes relating to motor vehicle liability insurance for various situations provided for in EU directives (Directive on motor vehicle liability insurance (Directive 2009/103/EC), in particular (but not exclusively) Articles 10 and 25, which govern compensation for accident victims for damage caused by an unidentifiable or uninsured vehicle or by a vehicle insured by an unidentifiable insurer; cf. by virtue of Directive (EU) 2021/2118, in particular Articles 10a and 25a, these compensation schemes are extended to cover cases in which the motor vehicle liability insurance company has become insolvent). If, for example, motor vehicle liability damage is caused by an uninsured or unidentifiable vehicle, a compensation fund steps in instead of the liability insurance of the party responsible for the damage. In this regard, the Expert Group on Liability and New Technologies had called for compensation funds to also be introduced at EU level for liability for AI (European Commission, 2019, p. 62). Article 10 of Directive 2009/103/EC is explicitly cited as a model.

However, under the PLD 2024, it has now been left up to the Member States to create such systems. Furthermore, the PLD 2024 does not provide for compulsory insurance (see section 3 below). Insofar as the Member States do not make liability insurance compulsory, the compensation schemes permitted under Article 8(5) PLD 2024 take the place of the liable party and not – as is the case with the compensation funds under Directive 2009/103/EC – the place of the missing liability insurance.

4. THE MISSING PROVISION: COMPULSORY LIABILITY INSURANCE[2]

4.1. Silence on the part of the European legislature

The PLD 2024 does not provide for any EU-wide insurance obligation, although during the legislative process the European Law Institute had suggested that the introduction of compulsory liability insurance be examined. For example, in Guiding Principle 3 of the Guiding Principles for Updating the Product Liability Directive for the Digital Age published by the European Law Institute (2021), there is a reference to the need to align the rules on liability in the PLD with insurance and other compensation schemes: "The PLD must be aligned with measures in related areas of law, as well as with non-legal measures such as insurance or compensation schemes" (p. 4). In view of these considerations, there is also a call in Guiding Principle 3 for an assessment of whether mandatory insurance should be introduced.

The report written by the Commission's Expert Group on Liability and New Technologies goes into even greater detail, though its scope is limited to liability frameworks for artificial intelligence systems (European Commission, 2019, pp. 61 f.). This report first examines possible insurance solutions in national legal systems (pp. 30 f.) before considering the introduction of mandatory insurance at EU level. In this regard, it provides a carefully balanced analysis (pp. 61 f.):

> 17. Insurance
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> ... compulsory liability insurance should not be introduced without a careful analysis of whether it is really needed, rather than automatically linked to a certain activity. After all, the tortfeasor may be able to compensate victims of her activities out of her own funds if the overall losses to be expected can be covered even without insurance. Also, the market may simply not offer insurance cover for a certain risk, particularly if it is difficult to calculate due to a lack of experience, which is quite likely with new technologies (and may therefore also be a problem with emerging digital technologies). Requiring insurance in the latter situation may effectively prevent the deployment of the technology if this requires proof of insurance despite the fact that no one on the market is willing to underwrite such as yet unknown risks.

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[2] On the following (with regard to liability for artificial intelligence) Heiss, 2023, pp. 256 ff.

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> Nevertheless, as experience in at least some fields (mostly motorised traffic) has shown, mandatory liability insurance can work well and is indeed appropriate under certain conditions.
>
> From an insurance perspective, certain sectors are the most suited to compulsory insurance schemes, including transportation, industries with a high potential for personal injury and/or environmental harm, hazardous activities and certain professional sectors.
>
> Therefore, it may indeed be advisable to make liability insurance cover compulsory for certain emerging digital technologies. This is particularly true for highly significant risks (which may either lead to substantial harm and/or cause frequent losses), where it seems unlikely that potential injurers will be capable of compensating all victims themselves (either out of their own funds, with the help of alternative financial securities, or through voluntary self-insurance).
>
> If compulsory liability insurance is introduced, the insurer should have a recourse claim against the tortfeasor. In risk scenarios comparable to those of motorised traffic, direct action by victims against the insurer may also be advisable.

In cases where compulsory insurance is appropriate, the report continues, it must be supplemented by *compensation funds* that compensate victims for damage arising from unidentified or uninsured technology, based on the model provided by Article 10 Directive 2009/103/EC (European Commission, 2019, p. 62).

The European Parliament largely adopted these proposals in a resolution dated 20 October 2020 (European Parliament Resolution, 2020).

Despite these clear developments, the European legislature has not made use of the instrument of compulsory liability insurance. As far as can be seen, the Commission, for example, has not even commented on the question of compulsory insurance. This means that the question of whether compulsory insurance should be introduced is left within the competence of the Member States for the time being as well as unanswered at the level of Union law.

4.2. Justifications for compulsory product liability insurance?

Several arguments may support the introduction of compulsory liability insurance. Firstly, insurance obligations can serve to protect potentially liable parties from misjudging the risk due to a lack of or insufficient information (Faure, 2016). Motor vehicle liability insurance is a good example of this (Faure, 2016). Where product liability is concerned, however, this argument rarely applies. Secondly, the protection of the injured party is a very important justification. This protective concept always applies when an effective liability claim would be prevented due to the lack of liquidity on the part of the tortfeasor, because in this case the

injured party would remain encumbered with the costs of the damage. An insurance obligation, on the other hand, would prevent such externalisation of damage costs (Faure, 2016, p. 321). This second point is a particularly compelling argument in favour of imposing an insurance obligation (see Wagner, 2020, p. 737 on liability in the field of artificial intelligence). Naturally, the PLD 2024 applies to all products, regardless of their potential to cause damage and of the risk of externalising damage costs in the event of the liability holder's insolvency. Compulsory insurance can therefore only be justified on a sectoral basis, limited to specific high-risk products. There is a third, preventive reason favouring compulsory liability insurance that has already been pursued, for example, by the Directive on insurance for shipowners (Directive 2009/20/EC), which introduced compulsory insurance for ships. Without such insurance, ships flying the flag of a third country are not allowed to enter ports in the Union (Article 4(2) Directive 2009/20/EC). According to the first sentence of Recital 4, this compulsory insurance is intended to protect the injured party. According to the second sentence of Recital 4, the insurance obligation is also intended to help to "eliminate substandard ships and make it possible to reestablish competition between operators." In this context, insurance becomes an instrument of prevention and of creating a level playing field (the topic of "prevention through insurance" is, of course, much broader and has gained momentum under the influence of new digital possibilities; see, for example, Malinowska, 2024). This additional aspect cannot be applied across the board to all products, yet it could well be relevant for certain products. Again, this aspect can only be used as the basis for sectoral regulation; it cannot support the imposition of a horizontal insurance obligation applicable to all products. In this context, it should of course be remembered that the European legislature is careful not to hamper innovation (see under section 2.1 above). It is therefore altogether doubtful whether the legislature intended to pursue the preventive purpose as described above.

4.3. Justification for compulsory insurance at Union level

Differences in the Member States' rules on compulsory liability insurance can hinder the functioning of the internal market (Case C-518/06 *Commission v Italy*, p. 71). At the same time, the ECJ's existing case law demonstrates that this impediment to the functioning of the internal market is justified by public interest considerations and therefore cannot be contested under EU law (Case C-518/06 *Commission v Italy*; Perner, 2016, pp. 294 f.; Case C-546/07 *Commission v Austria*). This means that the "negative" approximation of laws proves ineffective, leaving the restrictions in place (in respect of "negative" harmonisation through fundamental freedoms, see e.g. Basedow, 2021a, pp. 75 ff.). In this regard, Member States may also maintain national insurance obligations under specific provisions of directives. Such provisions are contained, for example, in the Directive to facilitate practice of lawyers (Directive 98/5/EC) and the Directive on services (Directive 2006/123/EC). Both Directives allow the Member State in which the

activity is carried out to require the provider of a regulated service to comply with compulsory insurance requirements (Article 6(3) Directive 98/5/EC; Article 23 Directive 2006/123/EC; on the Commission's competence to define dangerous services and appropriate insurance in more detail, see Article 23 Directive 2006/123/EC; paragraph 4 of the same provision defines the terms "direct and particular risk", "health and safety", "financial security" and "professional liability insurance"; on the whole, Member States are encouraged under the Directive to exercise restraint, see Recital 99 in this regard).

Another argument in favour of imposing EU insurance obligations is the experience that national insurance obligations leave gaps in protection from the perspective of the internal market. The ECJ ruling of 11 June 2020 in Case C-581/18 demonstrates this problem in detail (Case C-581/18 *RB v TÜV Rheinland LGA Products GmbH, Allianz IARD SA*). The German claimant had been fitted with defective breast implants manufactured in France. She therefore claimed damages (para. 21). However, the manufacturer's French compulsory liability insurer refused to pay any compensation on the grounds that the relevant insurance policy only covered damage occurring within French territory (para. 22). The ECJ therefore had to specifically determine whether the territorial restriction of cover violated the prohibition on discrimination under EU law pursuant to Article 18(1) TFEU. The ECJ found no violation (in detail, paras. 28 ff.). Providers of liability insurance mandated under the law of a Member State are therefore not required by EU law to protect injured parties from other Member States (as already emphatically highlighted by Basedow, 2021b, p. 1). Anyone who wants this protection must call for harmonisation of the rules on compulsory insurance, as has been done, for example, in Directive 2009/103/EC in the field of motor vehicle liability insurance. In Directive 2009/103/EC, the so-called single premium principle enshrined in Article 14 ensures that the territorial scope of every insurance contract covers the entire EU.

4.4. Problem: "Bare" EU insurance obligations

Union insurance obligations, however, have the problem that they often come in "naked" form (with regard to the problem of "bare" insurance obligations, Basedow, 2021b, p. 1). Clothes make people, and "clothes" therefore also make compulsory insurance. What does this mean? – Under Article 31(9) of the AI Regulation, for example, so-called notified bodies are obliged to take out "appropriate" liability insurance. The Regulation does not contain a definition of what "appropriate" means. In specific terms, liability insurance is considered appropriate in the literature if, for example, "it can satisfy the liability risks typically foreseeable in connection with the conformity assessment." (English translation of Roth-Isigkeit, 2024, para. 22). Despite this clarification, each national legislature retains broad discretion in implementation. Different national approaches may emerge with regard to, for example, minimum insured sums, the right of direct action, permitted exclusions of cover or waivers of objections in the event of

breaches of duty (in particular non-payment of the premium or breach of an obligation). In short, and without going into detail here (see Heiss, 2022, p. 209): if the European legislature makes liability insurance mandatory, it should also ensure that these insurance obligations are adequately "attired". The legislature should therefore – in line with the model presented in §§ 113 to 124 of the German Insurance Contract Act (dVVG) – create general rules for compulsory insurance that apply to all of the different types of compulsory liability insurance required by the EU. National legislatures could also (optionally) subject insurance required under national law to the general provisions of EU law.

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