Product liability in the context of 3D printing – A Law and Economics Approach

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Nederlandse abstract

In deze bijdrage, die in het Engels is geschreven omdat een van de auteurs niet Nederlandstalig is, bespreken wij vanuit rechtseconomische optiek de vraag of de argumenten die bij traditionele massaproductie pleiten voor de regeling van risicoaansprakelijkheid voor defecte producten van art. 6:185 e.v. DCC nog wel opgaan bij 3D printen. Het gaat hierbij om argumenten betreffende informatieasymmetrie, activiteitenniveau, risicoaversie, schadespreiding en systeemkosten.
Bij de juridische regeling voor productaansprakelijkheid voor 3D-geprinte producten spelen in Nederland (maar ook daarbuiten) enkele bijzondere problemen. Zo is het de vraag of de partij die een defect CAD-bestand heeft gemaakt, wel via de regeling voor productaansprakelijkheid is aan te spreken, omdat het bestand wellicht niet kwalificeert als 'product' in de zin van art. 6:187 DCC. Vanuit rechtseconomische optiek kan dit juist precies de partij zijn die aansprakelijk zou moeten worden gesteld, omdat het de 'meest geschikte actor' is vanwege zijn invloed op de veiligheid van het uiteindelijke product. Ook is het bij 3D printen de vraag of er sprake is van een 'product' of van een 'dienst', zeker nu het uiteindelijke product vaak aan de wensen van de individuele consument is aangepast.
Wij maken onderscheid tussen twee modellen voor 3D printen. Het 'one stop model', waar één actor zowel het digitale CAD-bestand maakt als ook het printen voor zijn rekening neemt, verschilt zo weinig van traditionele massaproductie dat de huidige regeling van productaansprakelijkheid daarvoor nog steeds geschikt is. In het 'separation model' daarentegen is het gehele productieproces zo gefragmenteerd, dat dit niet langer zo is. Soms is de ontwerper van het CAD-bestand de meest geschikte actor die via aansprakelijkheid geprikkeld moet worden tot ander gedrag (een beter CAD-bestand ontwerpen) of die de schade het beste kan spreiden (via een hogere prijs voor zijn CAD-bestanden). In een ander geval is de meest geschikte actor degene die de uiteindelijke print maakt, of de leverancier van de grondstoffen, of de fabrikant van de printer, of juist de consument zelf.
De huidige regeling van productenaansprakelijkheid is onzes inziens dus niet geschikt voor gebruik in het separation model. Het valt buiten het bestek van onze bijdrage om mogelijke oplossingen voor dit probleem in detail uit te werken, maar wij menen wel dat vooral het contractenrecht een belangrijke rol kan spelen bij het verdelen van de risico's tussen de verschillende actoren in de keten. Bij die verdeling moet vooral worden gekeken naar wie de beste informatie heeft over de risico's, wie het beste de maatregelen kan treffen om de risico's te verkleinen en wie het beste in staat is om de schade te dragen en te spreiden. Bij traditionele

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massaproductie wijzen al die factoren in de richting van de producent zodat de regeling van productaansprakelijkheid daar goed werkt, maar bij het separation model is meer (contractueel) maatwerk vereist, want 'one size does not fit all'.

1. Introduction

Technically, 3D printing refers to a way of production that enables people to fabricate a physical object under the instruction of a digital format (the CAD file).[3] The wide application of 3D printing has transformed the conventional model of production in two fundamental ways. On the one side, the process of digital modeling becomes more critical for the performance and quality of the final product.[4] On the other side, activities related to production are no longer privileged to mass producers, which means that the threshold of engaging in relevant activities becomes lower and ordinary people thereby can be greatly involved.[5]

The disruptions caused by 3D printing create considerable value for the production sector. As the cost of shifting from one kind of product to another is no longer prohibitive, producers are able to capture the value in the niche market and the customized demand of consumers can be satisfied.[6] Therefore, a party, either being non-professional or professional or being an individual or an entity, can engage in production without the constraint of scale economies. To date, a variety of sectors, ranging from simple gadgets for household use to complex components for mechanic use, are witnessing an increasing adoption of 3D printing.[7]

At the same time, various new business models are established to facilitate the match between customized supplies and demands.[8] On the one hand, some firms are established to offer a one-stop solution for customers (hereinafter the 'one-stop model'). Since it still focuses on providing the final physical product to consumers, this business model does not deviate much from the traditional way of manufacturing, although the preference and customized demand of consumer may play a role in the process. On the other hand, other business models of 3D printing are completely different from the traditional way of production. A customer can make use of designing and printing process separately, meaning that he can firstly find a CAD file from one source and then have it printed from another source (hereinafter the 'separation model'). This separation

[3] I. Gibson, D. Rosen and B. Stucker, *Additive Manufacturing: 3D Printing, Rapid Prototyping, and Direct Manufacturing*, New York: Springer 2015, p. 2.

[4] J. Holmström et al., 'The direct digital manufacturing (r)evolution: definition of a research agenda', 9 *Operations Management Research* 2016, p. 1-10.

[5] I.J. Petrick and T.W. Simpson, '3D printing disrupts manufacturing: how economies of one create new rules of competition', 56(6) *Research-Technology Management* 2013, p. 12-16; M. Attaran, 'Additive manufacturing: the most promising technology to alter the supply chain and logistics', 10(3) *Journal of Service Science and Management* 2017, p. 189-205.

[6] B.P. Conner et al., 'Making sense of 3-D printing: Creating a map of additive manufacturing products and services', 1 *Additive Manufacturing* 2014, p. 64-76; C. Anderson, *Makers: The New Industrial Revolution*, New York: Crown Business 2014, p. 53-60.

[7] For a detailed applications of 3D printing technology, see B. Redwood, F. Schoffer and B. Garret, *The 3D Printing Handbook: Technologies, Design and Applications*, Amsterdam: 3D Hubs 2017, p. 226-285.

[8] H. Rogers, N. Baricz and K.S. Pawar, '3D printing services: classification, supply chain implications and research agenda', 46(10) *International Journal of Physical Distribution & Logistics Management* 2016, p. 886-907.

model distinguishes 3D printing largely from traditional manufacturing, since the original supply chain has been greatly transformed.
Despite the added value, 3D printing exposes risk to the society, which generates the concern of allocation of the risk. If the digital designer and the physical fabricator in the separation model would be able to exchange information just as smoothly as different departments within a manufacturer under traditional mass production, allocation of risk would not be a problem. The parties could then decide between themselves who should bear the risk and via contracts channel liability to that party. However, in reality digital designers and fabricators in the separation model are strangers to each other and because economies of scale are no longer an obstacle to engage in production activities, many combinations of designers and fabricators are possible. Exchanging information between these parties, which may also be individual people instead of firms, is therefore very costly so that allocation of risk is problematic. In this sense, a key question to be asked is who is liable for harm caused by 3D printing according to the incumbent legal regime, and normatively, to whom the risk and liability *should be* allocated.[9]
This article focuses on the role of product liability law in the context of 3D printing. In Section 2 we give an overview of the risk-allocation in the scenario of traditional manufacturing and provide a Law and Economics perspective on product liability in this context. In Section 3, we shift to the context of 3D printing and analyze the extent to which relevant actors are subject to product liability there. In Section 4 we will conduct a Law and Economics analysis to discuss the extent to which the arguments in favor of strict product liability are applicable in the context of 3D printing. In Section 5 we conclude.

2. An overview of risk allocation in traditional manufacturing

2.1 Strict product liability

Mass production processes emerged during the Industrial Revolution. Supply chains became so complicated and remote that legal instruments other than contractual relationships were required. Tort liability, especially strict liability, was increasingly established around the world to regulate product safety. In the common law, strict liability was firstly developed in case law. In 1965, strict product liability was adopted in the United States in the Second Restatement of Torts U.S.[10] In Europe, strict product liability was established in 1985 in the European Product Liability Directive ('EPLD'),[11] after which Member States have adjusted their domestic laws accordingly.
In order to claim damage on the basis of product liability, the injured party has to prove four points, namely:

[9] See, for example, N.F. Engstrom, '3-D printing and product liability: identifying the obstacles.' 162 *University of Pennsylvania Law Review Online* 2013, p. 35; G. Howells, 'Protecting consumer protection values in the fourth industrial revolution.' *Journal of Consumer Policy* 2020, p. 1-31.
[10] American Law Institute, *Restatement (Second) of Torts* 1965, § 402A.
[11] The Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC). No L 210/29.

i. there is a producer;
ii. there is a product;
iii. the product is defective; and
iv. the damage is caused by the defective product.

In accordance with EPLD, a variety of parties are defined as the 'producer'. In Article 6:187 of the Dutch Civil Code (DCC), 'producer' means 'the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product, presents himself as its producer.' In practice, if a person suffers damage caused by a defective product, provided that he does not exactly know which party contributed to the defect, he tends to add all the identified 'producers' as the defendants before the court. However, the claim against specific producers may be declined if the requirement to impose strict liability on them is not met. Raw material providers and component manufacturers fall into the scope 'producer' under Article 6:187 DCC, as their 'products' are part of the final product. However, if the raw material producer and component manufacturer can prove that the materials or components offered by them are not defective *per se* or the damage is not caused by the materials or components, they will not be liable.

2.2. The prevailing strict product liability: A Law and Economics analysis

2.2.1. Product liability: information, deterrence and risk-spreading

In the Law and Economics literature, tort law is studied in its capacity to provide desirable behavioral incentives, both for deterrence purposes and for risk spreading. When analyzing product liability from this perspective, the starting point is the hypothetical situation where the consumer is fully informed about the risks of the products he is buying.[12] In such a situation of full information, the consumer does not only look at the market price of a product, but also at the expected losses that this product may cause and which are not covered by liability of the manufacturer. The consumer therefore looks at the 'perceived full price', which is determined by market price and expected losses.[13] Because of the assumption of complete information, the consumer exactly knows what this perceived full price is and he will choose the product with the lowest perceived full price. In such a situation, it is not relevant whether the producer can be held liable and whether there is strict liability or negligence.[14] After all, only if the producer takes the optimal precautionary measures the perceived full price will be minimal. A producer that takes inadequate care but is not liable for this can offer the product against a lower market price, but the consumer will add relatively high expected accident losses, so that the perceived full price will exceed that of a producer who took the desired measures.

[12] W.Y. Oi, 'The economics of product safety', 4(1) *Bell Journal of Economics* 1973, p. 3-28.
[13] A.M. Polinsky and S. Shavell, 'Mandatory versus voluntary disclosure of product risks', 28(2) *The Journal of Law, Economics, & Organization* 2010, p. 360-379.
[14] See e.g. S. Shavell, *Foundations of Economic Analysis of Law*, Boston, Massachusetts: Harvard University Press 2004, p. 212.

In reality, consumers do not possess full information.[15] If they overestimate the risks of the product, they overestimate the perceived full price, they buy too little of the product and they take too much care in handling the product (as compared to the socially optimal decisions which they would take if they had full information). If they underestimate the risks, the opposite situation occurs. If the manufacturer is held strictly liable for losses caused by the product, the market price equals the perceived full price, because the consumer who suffers losses due to the problem can recover them from the liable manufacturer. If the producer has the best information about the risks of the product, strict liability gives better incentives than no liability or negligence. Under strict liability, the producer takes all measures he finds worthwhile and includes the costs thereof in the price of the product. Therefore, the producer takes the desirable care measures and because the market price reflects the true costs, the buying level of the consumer is also optimal.[16] Under no liability, the manufacturer will take less than optimal care and the consumer will add his assessment of the non-compensated expected losses to the market price, but this assessment will be worse than that of the better-informed producer (which may result in too much care and a too low buying level of the consumer, or vice versa). And under negligence, the producers will take the care measures required by law, but if the producers were the best-informed parties, it would have been better that *they* would have decided which measures to take. After all, a better-informed producer can assess the optimal measures better than a less-informed court or legislator.[17]

Besides this argument regarding information about risks, a disadvantage of negligence vis-à-vis strict liability is that under negligence, if the victim cannot prove a breach of duty, the producer will not be liable, even if in reality he was negligent. It is likely that it is difficult for consumers to prove this breach of duty, given the fact that production processes can be complicated and that consumers do not have information about which measures were actually taken. Therefore, under negligence, producers will regularly escape liability, which is problematic for the deterrent incentives.

A third advantage of strict liability is that the producer can better spread the losses than the consumer.[18] The producer can spread the expected losses over all customers by simply including expected liability in the price of the product. In addition, because the manufacturer is a firm, risk aversion is less of a problem under strict liability (where the firm is liable) than under negligence (where the consumers bear the losses), because the assets of the producer in relation to the expected loss will be higher than those of the customer who suffers the loss.[19] If both parties can spread the losses via insurances, it becomes relevant whether (first party) loss insurance and (third party) liability insurance are available at fair premiums, and whether problems of moral hazard and adverse selection can be adequately tackled. According to Law and Economics literature, this may

[15] See e.g. V.P. Goldberg, 'Toward an expanded economic theory of contract', 10(1) *Journal of Economic Issues* 1976, p. 45-61.

[16] M.A. Geistfeld, *Principles of Product Liability*, 2nd Edition, New York: Thomson Reuters/Foundation Press 2011, p. 11.

[17] See e.g. Shavell 2004, p. 218.

[18] See e.g. G. Calabresi and J.T. Hirschoff, 'Toward a test for strict liability in torts', 81(6) *The Yale Law Journal* 1972, p. 1055-1085.

[19] This is not the case with 'scattered losses', where many consumers all suffer a small loss, but the total loss is large.

be an argument against strict liability, exactly because adverse selection and moral hazard are more problematic with third party insurances.[20]
A next issue is that some care measures which the manufacturer can take, are not observable for external parties. Under strict liability, the manufacturer also receives care incentives in those unobservable dimensions, because irrespective of which measures he takes, he is always liable.[21] He will therefore make a weighing between the cost and benefits of all care measures, whether observable or not. Under negligence, only the observable measures can be included in the behavioral norm, so that the producer does not get care incentives in the unobservable dimensions.[22] Given that in a production process not all measures are observable and monitorable to outside parties, providing care incentives also in unobservable dimensions is important.
Finally, Law and Economics literature argues that the costs of the legal system will be lower under strict liability than under negligence, because under negligence one has to establish a duty of care and, subsequently, one has to investigate whether this duty has been breached. This makes individual cases more complicated (and hence more expensive) and therefore the outcome of the cases is less predictable under negligence. This in turn reduces the likelihood of a settlement, which would have been cheaper than trial.[23]

So, summarizing, the traditional Law and Economics arguments in favor of strict liability for producers relate to the superior information of the manufacturer (so that he takes better care decisions than under negligence), the activity level, unobservable dimensions of care, loss spreading, risk aversion and system costs. Liability is regarded as an instrument to provide desirable behavioral incentives (deterrence) and to spread the losses which are not avoided.
In providing these desirable incentives, it is important not to forget the consumer. If the consumer can affect the accident probability and/or the size of the losses, a defense of comparative negligence, or a defense of assumption of risk[24] is required to provide incentives to the consumer as well. A consumer who misuses the product, does not act according to the instructions et cetera should receive no or less compensation, so that he is incentivized to act differently.[25]

[20] G.L. Priest, 'The current insurance crisis and modern tort law', 96 *Yale Law Journal* 1986, p. 1562.
[21] R.A. Posner, 'Strict liability: a comment', 2(1) *The Journal of Legal Studies* 1973, p. 205-221.
[22] R.A. Posner, 'A theory of negligence', 1(1) *The Journal of Legal Studies* 1972, p. 29-96.
[23] See e.g. G. Calabresi, *The Costs of Accidents. A Legal and Economic Analysis*, 5th Edition, New Haven, Connecticut: Yale University Press 1977, p. 28; Shavell 2004, p. 282, 283; J.M. Barendrecht et al., *Schadeclaims: kan het goedkoper en minder belastend? Opties om de transactiekosten van het aansprakelijkheidsrecht te verlagen*, Den Haag: Boom Juridische uitgevers 2004, p. 68.
[24] From a Law and Economics perspective it is not so important whether assumption of risk is regarded as a separate defense or as a form of comparative negligence.
[25] This also incentivizes producers to provide clear instructions, so that the consumer knows how to handle the product. It is therefore good that Article 6:186 DCC mentions the presentation of the product as a factor which is relevant in determining the safety the consumer was allowed to expect.

2.2.2. Defects

Product liability does not imply strict liability for *all* losses caused by products, but only for losses caused by *defective* products. According to Article 6:186 DCC, a product is defective if it does not offer the safety one is entitled to expect, in other words if the product was not 'safe enough'. From a Law and Economics perspective, this question resembles a negligence test: were the additional costs of more safety higher or lower than the additional benefits? Product liability hence is different from pure strict liability (because there is no strict liability for *all* losses caused by products) but it is also different from pure negligence (because the manufacturer is also liable if he was not to blame for the fact that the product was not safe enough). So even if the care level of the producer is, in general terms, high enough to be regarded as due care (so that he is not negligent), the producer will be liable if an occasional product is not safe enough.

The restriction of strict liability to only defective products can be defended on the basis of economic arguments. The impact consumers have on the expected losses caused by non-defective products is larger than with defective products. So, with non-defective products the consumer will often be the 'least cost accident avoider'. The fact that strict liability does not apply in such cases indeed provides incentives to the consumer to use the product prudently.[26] Non-defective products can still cause losses (e.g. dropping a pan on one's foot). Liability for the manufacturer for such losses cannot provide desirable incentives to the producer but would entail costs of using the tort system anyway. Liability in such cases is therefore undesirable. However, if the product is defective (e.g. the pan handle breaks off so that the pan falls on one's foot), the manufacturer should receive incentives to prevent such accidents, so that liability makes sense there. And even if it would be too costly for the manufacturer to avoid an occasional accident due to a defect, strict liability results in loss spreading via the price, which is desirable in itself.

In addition, if the costs for consumers to become informed about the risks of a product are low so that the consumer can take well-informed decisions, the situation resembles the starting point of the fully informed consumer which was mentioned above. There it was explained that tort liability is not required to provide the desirable incentives. In such a situation, where the product satisfies the expectations the consumer has about the safety, the requirement of a defect indeed avoids tort claims, because a product that offers the safety the consumer was allowed to expect, is not deemed defective.[27] On the other hand, if the consumer does not possess enough information about the risks of the product and the product is not as safe as the fully informed consumer would have wanted it to be, it should be regarded as defective and product liability is triggered. Hence, the defect requirement allows differentiating between the situation where the consumer can adequately assess the risks and act accordingly (where product liability is not needed to provide the desirable incentives to the manufacturer) and the situation where the consumer does not possess that information (so that product liability *is* needed).

Warning defects can be assessed in the same light: the warning provides information to the consumer, who can now make better decisions. But for this, the warning needs to be adequate, in

[26] S. Shavell, *Economic Analysis of Accident Law*, Boston, Massachusetts: Harvard University Press 1987, p. 60.
[27] M.A. Geistfeld, 'Products Liability', in: M. Faure (Ed.), *Tort Law and Economics. Encyclopedia of Law and Economics, second edition*, Cheltenham: Edward Elgar 2009, p. 309.

other words, it should provide the information which allows the consumer to make a well-informed choice.[28] If it does not do so, it is defective. This resembles a negligence test, because it asks the question whether the warning was 'good enough'. The costs of consumers to read and understand the warnings should be included in this test, to avoid over warning.

3. A positive legal analysis of product liability for 3D printing

3.1. One-stop shop model and separation model

3D printing can be distinguished into various business models, and not all of them result in sharp disruptions compared with traditional manufacturing. In the one-stop model, the complete process of production is still accomplished within a single entity, which is largely hidden from the consumer side. Therefore, the criteria from Section 2 that justify strict product liability are still valid in this case.

In addition, liability for specific actors in the supply chain would not change in the setting of 3D printing. For example, raw material providers and 3D printer manufacturers are indispensable. However, consistently with the traditional paradigm, they are liable only if the raw materials or 3D printers provided by them are defective *per se* and damage is caused by the defective raw materials and 3D printers. As a result, in the context of 3D printing, raw material producers, component producers as well as 3D printer producers will not bear liability as long as they can prove that their 'products' (i.e. raw materials, components and 3D printer) work well.

Controversies over the liability of actors in the context of 3D printing arise when digital designing and physical fabrication are accomplished by different parties.[29] Unlike traditional mass production where the manufacturer takes control of the whole production process without the intervention of consumers and where information is distributed among different departments within the entity, 3D printing that adopts a separation model is characterized as a way of production that is carried out by multiple strangers and the consumer plays a crucial role in organizing the agile supply chain. In this regard, it is the consumer that can choose to acquire a CAD file from one source and then decides to have it printed out by another entity/person. Hence, the key question from a positive legal perspective is what kind of liability rule applies to the CAD file designer and final object fabricator within the separation model. The following discussion in this section will focus on this issue.

[28] Geistfeld 2009, p. 313.

[29] For example, scholars reached quite different conclusions on the issue of whether CAD file designers should be strictly liable for the harm caused by the final product. While some scholars hesitate to apply strict liability to digital designers (e.g. Engstrom 2013), some others are inclined to pose strict liability. See E. Lindenfeld, '3D printing of medical devices: CAD designers as the most realistic target for strict, product liability lawsuits', 85 *University of Missouri-Kansas City Law Review* 2016, p. 79. Also see European Commission, *Evaluation of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products*, SWD(2018) 157 final, p. 53ff.

3.2. The controversy over the tangible/intangible dichotomy

According to Article 6:187 DCC, 'product' only refers to movable things. In this sense, at first glance, any intangible goods are literally excluded from the scope of the 'product', as a result of which the developer of an intangible good is not regarded as the 'producer' and is thus excluded from product liability.

This interpretation was reasonable in the context of traditional mass production, since the products that are placed into circulation are mostly movable in nature and digital goods only played a role of delivering information.[30] However, as intangibles are playing an increasingly important role in finalising a product, in recent years damage has been substantially linked with intangible goods. An intangible good is gradually regarded as the product, on the condition that it can be *materialized* on a tangible medium.[31] In contrast, book contents and pure electronic data are not regarded as products, since they are considered as 'pure information' in traditional production. They only serve as a channel for conveying the information and hence cannot directly result in a materialized effect.[32]

A more complicated question is whether a *digital good that further could be executed* would be categorized as a product. When computer software was initially linked with damage, it was not regarded as the product.[33] Even to date, software without a material carrier is not defined as the 'product' under Dutch law.[34] However, as intangible smart technologies, especially the non-embedded software or intelligent systems, are becoming the main driver of production in recent years, the function and performance of the final product turn to increasingly rest on them. Recently, some countries have gradually expanded strict liability to non-embedded software in practice. For example, computer software is explicitly defined as a movable in the Law of Obligations Act in Estonia.[35] Likewise, courts in Germany also imply that online software, which is not embedded in the material medium, is a 'product' under the German Product Liability Act.[36] A similar trend is also observed on the other side of the Atlantic. According to the Reporters of the Product Liability Restatement, when a court decides whether strict liability applies to software, it 'draw[s] an analogy between the treatment of software under the Uniform Commercial Code and under

[30] J.L. Reutiman, 'Defective information: Should information be a product subject to products liability claims', 22 *Cornell Journal of Law and Public Policy* 2012, p. 181.

[31] J.M. Beck and M.D. Jacobson, '3D printing: what could happen to products liability when users (and everyone else in between) become manufacturers', 18 *Minnesota Journal of Law, Science & Technology* 2017, p. 143.

[32] G. Howells, C. Twigg-Flesner and C. Willett, 'Product liability and digital products', in: T.-E. Synodinou, P. Jougleux and T. Prastitou (Eds.), *EU Internet Law*, Cham: Springer 2017, p. 183-195.

[33] See Written Question No 706/88 by Mr Gijs de Vries to the Commission: Product Liability for Computer Programs [1989] OJ C114/42.

[34] A.L.C. Keirse, 'Product liability in the Netherlands', in: P. Machnikowski (Ed.), *European product liability: An analysis of the state of the art in the era of new technologies*, Antwerp: Intersentia 2016, p. 318.

[35] § 1063 (under Division 3 'Liability for Defective Product' of the Chapter 53 'Unlawful causing of damage') states that 'Any movable is deemed to be a product, even if the movable constitutes a part of another movable or if the movable has become a part of an immovable, and electricity and computer software are also deemed to be movables.'

[36] See U. Magnus, 'Product liability in Germany', in: P. Machnikowski (Ed.), *European product liability: An analysis of the state of the art in the era of new technologies*, Antwerp: Intersentia 2016, p. 245. There are also cases with opposite opinions, see Erman/Schiemann §2 ProdHaftG.

products liability law'. In the US Uniform Commercial Code, 'software that is mass-marketed is considered a good.'[37]
At the current stage, no explicit clue has been offered in the Dutch Civil Code or in case law upon the issue of whether CAD file can be defined as a product in the Netherlands. According to the analysis above, the answer to this question rests on the issue of whether the CAD file is simply regarded as a medium to store and deliver the instruction for further fabrication, or if instead closer attention is paid to the substantial impact of the CAD file on the performance of the final product. If the latter case is considered in a serious way, CAD file makers may be regarded as producer.

To conclude this part, the controversy of the tangible/intangible dichotomy serves as ambiguity in assessing the application of liability rules. Specifically, it is still an open question whether the designer of the CAD file is subject to strict liability. Further (normative) analysis is required to offer an answer.

3.3. The controversy over the production/service dichotomy

Besides the controversy over the tangible/intangible dichotomy used for assessing product liability, another criterion is also relevant. Traditionally, the production/service dichotomy is used to determine the scope of the concept of 'product'. According to Recital 3 of the EPLD, 'liability without fault should apply only to movables which have been *industrially produced*'. Therefore, any product that is offered outside industrial production seems to be excluded from the scope of 'product'.
Despite the wording of Recital 3 of the EPLD, Member States show different approaches. For example, in *Henning Veedfald v. Arhus Amtskommune*, the application of strict product liability to a product that is not industrially manufactured was confirmed by the European Court of Justice (ECJ), which explained that 'it is sufficient to observe that the case involved the defectiveness of a product – used in the course of providing a service – and not any defect in the service as such.'[38]
This interpretation is also adopted in the Netherlands. However, it does not necessarily mean that products obtained from any type of service can be defined as the 'product' under Article 6:187 DCC. An item will fall outside the scope of 'product', provided that it is *customized* at the requirement of the consumer.[39] As analyzed before, we find that the issue whether the service is oriented through a customized way is essential to determine the liability of the relevant parties.
One feature that differentiates 3D printing from traditional mass production is that most of the digital designers and fabricators do not produce any final products before receiving the orders from customers. Under this background, the criterion of production/service has significant implications in the context of 3D printing. Firstly, the designers of CAD files, whose designing activities are customized according to the requirement of customers, are not subject to strict liability due to the customized service essence of their activities. Secondly, considering the tendency to regard the goods obtained in the process of service as the 'product', many fabricators whose business it is to

[37] See Restatement (Third) of Torts: Products Liability § 19 comment d, 1998.
[38] See Case C-203/99, Veedfald v Arhus Amtskommune [2001] ECR I-3569, recital 12.
[39] Keirse 2016, p. 317.

transform the CAD file offered by customers into the final product, may be at the risk of bearing strict liability.

3.4. A brief summary of the positive legal analysis

Some findings with regard to the 'separation model' of 3D printing can be briefly concluded according to the positive legal analysis. Firstly, fabricators would be subject to strict liability in the context of 3D printing as their business is not driven by customized service. On the one hand, for the fabricators who receive the CAD files from their customers and are responsible for printing out the physical object, although the final product is delivered in a service context, according to the positive legal analysis above, the incumbent Dutch product liability regime tends to impose strict liability in this scenario.[40] As a consequence, strict liability may be indifferently applied to any fabricator that engages in 3D printing for sale.
Secondly, the CAD file makers might not be subject to strict liability in the context of 3D printing, considering the essence of their business. Pursuant to the incumbent regime, it is not clear whether the CAD file makers who offer standardized CAD files are subject to strict liability. This is the core dispute under the tangible/intangible dichotomy. On the other hand, constrained by both the tangible/intangible and production/service dichotomy, the designer of the CAD file who offers a customized digital file may not be strictly liable for the damage caused by its defective CAD files.

To conclude, the positive legal analysis in this section answered the question of whether strict product liability applies to the designer of the CAD file and the fabricator of the final product. We found that fabricators that offer printing services are largely at the risk of bearing strict liability. In contrast, CAD file makers, whether they offer standardized services or customized services, currently probably cannot be held strictly liable. However, what the positive legal analysis fails to tell us is whether this allocation of liability is efficient. In the next section, we will explore the efficiency of the incumbent allocation of liability from the perspective of economic analysis.

4. Economic analysis of product liability in the context of 3D printing

4.1 Introduction

From a Law and Economics perspective, the criteria to evaluate the issue of whether a specific liability rule is efficient is to examine the social welfare resulting from a specific liability rule.[41] In order to examine the efficiency of liability rules in a specific context, we want to allocate the liability to the 'most suitable actor'. To find out the most suitable actor in a particular scenario,

[40] E.N. Spijkerman, '3D-printen: het nieuwe doe-het-zelven Een eerste verkenning van de aansprakelijkheids- en verzekeringsaspecten', *AV&S* 2015, p. 166ff.
[41] Shavell 2004, p. 2.

economists specifically ask whether the rules can incentivize parties to behave appropriately and whether the risk-averse parties can avoid bearing the risk.[42]

The extent to which the arguments in favor of strict liability which we have sketched in Section 2.2 still hold, crucially depends on the exact way in which the production process is organized. The more the different activities are executed by one and the same party, the more it resembles traditional production and the more the arguments still hold. From this perspective, we may firstly conclude that strict liability still is desirable for the one-stop business model. The reasons are, briefly speaking, that in a one-stop model, parties organize all activities in such a way that they still hold more information than consumers and they can reduce risk at a lower price. In comparison, in the separation model where every actor in a sense is independent, the arguments in favor of strict liability are weaker.

The following analysis in this section will explore the extent to which strict liability may not be favored under the separation models in the context of 3D printing. As we argued in Section 3, according to Dutch law the CAD file designer may not be subject to strict liability, while the fabricator of the final product is. In this section, we will apply a Law and Economics analysis to explore whether allocating product risk in this way is efficient.

4.2. Deterrence and information perspective

According to Law and Economics, liability rules provide an incentive to the relevant parties to behave in a socially desirable manner. As analyzed, strict product liability is superior to negligence from the perspective of deterrence, according to the reasons we have provided in Section 2.2. Therefore, the producer is considered as the 'most suitable actor' to reduce the expected accident losses caused by defective products. However, the preference for strict liability from this dimension could be diluted in the context of 3D printing.[43]

Unlike the traditional mass production, in which information is collected and transferred within one entity, under the separation model in the context of 3D printing, information is possessed by various actors from different modules. Therefore, we can by no means simply conclude that it is the CAD file designer or the final fabricator that serves as the 'most suitable actor', because the activities under this business model are bilateral, meaning that the safety of the final product is determined by multiple parties.

It is important to distinguish between various types of situations. In one situation, the consumer may download the CAD file from a designer on the open-source platform (such as Thingiverse.com), and then ask a professional fabricating company (such as Imaterilise.com) to print it out. In this case, while the fabricator is a professional that is supposed to be more knowledgeable than any other actor along the supply chain, it faces an information asymmetry regarding the safety of the CAD file. In other words, under a business model where the CAD file

[42] As Shavell articulated, 'it should be emphasized that the allocation of risk is in principle just as important a determinant of social welfare as (…) the reduction of accident losses'. Shavell 1987, p. 192.

[43] Also see K. Heine and S. Li, 'What Shall we do with the Drunken Sailor? Product Safety in the Aftermath of 3D Printing', *European Journal of Risk Regulation* 2019, p. 34ff.

designer and the fabricator do not belong to the same entity, the role of a non-professional designer may be even more substantial than a professional fabricator, since the former actor may possess more concrete safety information than the latter one.

In another situation, the activities of the final fabricator may be much more important for the final risk. This is the case when a consumer purchases a high-quality CAD file from a certified professional but then has it printed out by a non-professional using the most basic desktop 3D printer (e.g. a nearby printer found on Treatstock.com). Since the non-professional may be inexperienced with the activities of converting the digital formats into the physical object, his activities may pose more risks than the other parties along the chain. In such a situation, strict liability of the CAD file designer does not make economic sense. It would, for example, be very difficult or impossible for the CAD file designer to make an accurate assessment of the risk that the (high-quality) design would still result in a defective product due to (low-quality) printing. However, if the CAD file designer would be strictly liable, this is exactly what he would have to do in order to include the expected liability in the price. Due to information problems, the best he can do is to include an assessment of the 'average costs' in the price. This in turn may result in the well-known problem of adverse selection, because the price set by the CAD file designer cannot differentiate between low-quality and high-quality printing.

Besides the CAD file designer and fabricator, the behavior of the consumer may also be very important in the separation model. Under traditional mass production, the designing department and the manufacturing department can exchange information at a relatively low transaction cost. In contrast, in 3D printing, it is the consumer himself that has to make the choice among different service providers. If the consumer could distinguish the competent actors from the incompetent ones, there would not be a problem to start with, because as we explained in Section 2.2, the consumer then chooses the product with the lowest perceived full price. However, if the consumer misperceives the risk of various solutions, he may choose a product which actually causes more risk than expected, and also more risks than other available products. The safer products are likely more expensive, but if the consumer cannot distinguish products on the basis of their quality, he may choose on the basis of price, so that more dangerous products would be produced.

The choice of a consumer is determined by a variety of factors, ranging from his experience on the relevant market and the reputation of related seller to certificates endorsed by authorities. In an emerging market like 3D printing, consumers may need more time to collect and evaluate information appropriately.

To summarize, in the context of 3D printing especially for the separation models, it may be extremely difficult to generalize the 'most suitable actor', who can best deal with product risk via their activities. This reduces the applicability of the concept of 'strict liability for the producer', because (1) it is not always clear who the producer is, and (2) it is not always clear whether that producer is also the actor who has most impact on the product risk.

4.3. Risk-bearing perspective[44]

As analyzed before, deciding the 'most suitable actor' also depends upon the issue of which party has the best capacity to spread and shift risk. Adopting strict liability in mass production can also be justified from this perspective.[45] On the one hand, producers are considered less risk-averse than injured parties. On the other hand, compared to consumers, producers are better able to spread the risk. Therefore, compared to the rule of negligence, applying strict liability in the context of traditional manufacturing is concerned to result in a higher level of social welfare from the perspective of risk-bearing.

Things change when it comes to the context of 3D printing. 3D printing democratizes the way of production, meaning that ordinary people as well as small business can substantially engage in the activities of digital designing as well as physical fabrication. Compared to traditional mass producers, who are often enterprises and hold assets in response to risk, participants in the context of 3D printing may be less capable of bearing the risk. For example, in a separation-model where the consumer acquires a CAD file from an individual designer and then has it printed out by an individual printer nearby, since all the involved parties are ordinary individuals without significant differences with the consumer, we can hardly distinguish which party is more capable of bearing the risk than the other. In other words, in the context of 3D printing, it is very likely that the designer of the CAD file and the fabricator of the final product are not necessarily less risk-averse than injured parties.

In addition, risk-spreading could be problematic. Under traditional manufacturing, as a standard product can be accessed by a large group of consumers, the risk generated by the product is expected to be spread among them. In this sense, the manufacturer turns to be the 'most suitable actor' to aggregate the total risk, because he can spread the loss over all consumers by including a mark-up in the product price (also if the producer is insured, he will increase the product price to reflect the insurance premium). In comparison, as 3D printing in the separation model is characterized by customization, a fabricator can hardly organize a risk-pool consisting of homogenous consumers to spread the risk. More importantly, for insurers, many uncertainties arise for the evaluation of the risk to be insured. Compared with mass producers, the activities of the decentralized CAD file makers and final fabricators are less predictable to insurers. It is not easy to differentiate the risk among different insured parties so as to narrow the risk pools. Also, monitoring the activities of insured parties could be difficult in the new era. Concerning the potential increasing adverse selection and moral hazard problems, liability insurance may not be a

[44] Also see M. Faure and S. Li, 'Risk shifting in the context of 3D printing: an insurability perspective', *The Geneva Papers on Risk and Insurance - Issues and Practice* 2020.

[45] For example, in the case Escola v. Coca Cola Bottling Co, Justice Traynor argued that the producer situated in the best position to distribute the product risk, and they had the capacity to afford it. He further explained his argument. 'Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business.' See 150 P.2d 436, 441 (Cal. 1944) Later in the case Henningsen v. Bloomfield Motors, the same opinion was repeated by Justice Francis. He reasoned that '[The consumer] has the least individual ability to bear the disastrous consequences [of product risks].' See 161 A.2d 69, 87 (N.J. 1960).

good choice for risk-spreading. Therefore, the superiority of strict liability may decrease in the context of 3D printing unless new methods of risk-differentiation and monitoring are developed.

4.4. A brief summary of the Law and Economic analysis

To conclude this part, we argue that the issue of whether to apply strict liability to CAD file designers and final fabricators lies in the answer to the question whether either or both of them turn to be the 'most suitable actor'. According to Law and Economics theory, the determination of this 'most suitable actor' is highly related to the assessment of deterrence and risk-spreading. We found that while this 'most suitable actor' points to the producer under mass production with potent justification, it generates considerable controversy in the context of 3D printing, especially under the separation model when the CAD file designer and final fabricator do not come from the same entity. Since neither the digital designer nor the physical fabricator are undoubtfully deemed as the 'most suitable actor', strict liability may not result in the desirable outcome regarding deterrence and risk-spreading in the context of 3D printing. Therefore, the analysis in this section implies that we should be very cautious when applying strict liability toward CAD file makers and fabricators: one size does not fit all!

5. Concluding remarks and further considerations

Based on the positive legal analysis of Dutch liability regime, we found that the designer of the CAD file for sale likely will be not subject to strict liability, while the fabricator of the final product for sale like will be. We analyzed whether allocating risk in this way is desirable. To answer this question, we applied a Law and Economics analysis. In order to efficiently allocate product risk generated in the separation model, we need to attach the liability to the 'most suitable actor', who is either the party at the best position to take measures to reduce product risk or the one having the best capacity to spread the risk. Our analysis argues that it is difficult to identify this 'most suitable actor' in the separation models. As a result, adopting strict product liability in this new era may not provide incentives to the actors who are best positioned to reduce product risk and/or spread it over a larger group.

The difficulty of identifying the 'most suitable actor' in the context of 3D printing indicates that strict product liability tends to be less attractive in terms of offering incentives and spreading risk. Therefore, the next key issue that scholars should think about would be what other complementary instruments could be used to provide relevant parties with the appropriate incentives and to spread the loss. Giving a definitive answer to this question is beyond the scope of our paper. However, we will make some preliminary remarks in this respect.

Firstly, it should be studied whether the current legal landscape is already able to deal with the challenges posed by 3D printing, or that a new regime is required.[46] For example, if it would be possible to identify the party who did not take adequate precautionary measures (e.g. in designing the CAD file, or in printing the product), the current legal regime of product liability can provide the desirable care incentives by labelling this actor as producer. But this might not also be the party who has the best information, can best spread the losses, et cetera. If it is the consumer who should have acted differently (e.g. by not simply downloading a CAD file, making changes to it and then having it printed), the current legal framework may indeed incentivize him by e.g. not labelling one of the other actors as producers, or by not regarding the product as defective. After all, in such a situation the consumer will have to bear his own losses (because he cannot use Article 6:185 DCC and he also will not be able to establish tortious behavior ex Article 6:162 DCC) and hence is incentivized to act differently. But again, whether this is also the actor with the best information and the best ability to bear or spread the losses, remains to be seen. And, obviously, if it is not clear who the 'best suitable actor' is, it is also not possible to determine which actor the legal system should incentivize to act differently. Hence, answering the question whether the current legal system is able to provide the desirable solutions or that we need different instruments, requires more research.[47]

Secondly, also due to the above-mentioned challenges, contractual relationships might play an increasing role, since we can reasonably imagine that various parties along the chain in the separation model are willing and able to bargain over the allocation of potential risks. The contractual party that assumes the liability will ask a price for this. If parties themselves, in their contractual negotiations, are able to identify which of them in their particular shackle in the whole production chain is best able to reduce the risk, bear it or spread it, they can allocate liability to that party and hence create the desirable incentives contractually. This way, tort liability for losses of the victim could be channeled through the contractual chain until it reaches the 'most suitable actor'. Who that actor is may differ per chain, but is determined contractually. In other words, because in the separation model the various parties (i.e. CAD file designers, printers and consumers) are strangers to each other, the current system of product liability is not able to reach the desirable outcome, exactly because the various parties are not part of the same entity (i.e. 'the producer'). We instead need to find ways to reduce bargaining difficulties and information asymmetry between the parties so that they can make the desirable agreements. In practice, intermediaries such as online platforms are proving to become more crucial to achieve this goal. We have witnessed that some platforms are transforming their business model from simply serving as the online marketplace to becoming a party that take proactive roles in helping exchanging

[46] In the evaluation of the product liability Directive, producers stated that 'at this stage, the directive is fit for purpose' because 'in terms of liability effects there is no difference between using a 3D printer to produce product parts or finished products, and using other more traditional machinery or manufacturing methods'. On the other hand, 'the majority of consumers believe that the current rules are not fit for new technological developments.' See European Commission 2018, p. 34.

[47] Also see Heine and Li 2018, p. 38ff.

safety information between actors and consumers.[48] Whether such contractual relationships are indeed able to provide a good solution, again is subject for more research.

Thirdly, we may rely more on first party insurance to spread the risk and to compensate the victims who suffer a loss from the accident. If applying strict liability fails to generate appropriate deterrence incentives to relevant parties, the advantage of the tort system over insurance may disappear. This hold even more if one considers that tort law is a much more expensive system for compensation than insurances.

To conclude, the disruption of the supply chain by 3D printing indicates that we may no long find a 'one-size fits all' regime to deal with deterrence as well as risk spreading issues. Complementary regimes are desirable in this era to achieve the goals of deterrence and risk spreading. For one shop stop models of 3D printing, the regime of strict product liability may still work well, because this model resembles traditional mass production. For the separation model, this is different. We have argued that strict product liability is a too crude instrument to provide the desirable incentives there. We believe that especially contract law should be used to enable parties in the production chain to make welfare enhancing arrangements regarding risk taking and risk spreading, which are tailored to their specific situation.

[48] For example, 3D Hubs used to serve as an online marketplace, where consumers with CAD files were free to contact with fabricators. Since 2017, 3D Hubs started to transform its role from an online marketplace to an intermediary, which exchange information between producers and consumers. In specific, it sets up a particular software to evaluate the potential risk of the CAD file offered by the consumer. On the other hand, it declines some fabricators from developing business on the platform unless they meet particular requirements, such as being certified by standard bodies and proving their 3D printers are advanced.