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Defective Pharmaceuticals and Indeterminate Tortfeasors: A German Law Perspective on DES-Daughters Scenarios

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For centuries, pharmaceuticals in Germany were exclusively produced in small-scale pharmacies and had only to comply with the requirements set out in the pharmacy regulations. This picture changed in the 1950s and 1960s, when the manufacturing of pharmaceuticals by pharmacies shifted to mass production by the pharmaceutical industry. The German legislator responded to this shift by introducing the *Arzneimittelgesetz* (AMG) (Medicine Act),¹ which operates as special legislation in the field of the industrial production of pharmaceuticals, in 1961. The statute regulates all matters arising in the context of pharmaceutical production, including the requirement to register new drugs and wait for permission before distribution can begin. As a result of a revision in 1976, the statute also provides rules on no-fault liability in cases of personal injury caused by defective pharmaceuticals.² According to sections 84 *et seq.* AMG, any pharmaceutical manufacturer that makes a defective pharmaceutical product (due to errors in research, development, or manufacturing) available on the market that causes death or personal injury following the correct administration of the product is liable. The manufacturer is also liable when the harm results from a lack of technical information or from a lack of correct directions for usage.

The bases for liability for pharmaceuticals are not limited to the AMG.³ In addition, several other possible claims will be considered. Firstly – and very seldom, as the AMG is *lex specialis* – a claim based on the *Gesetz über die Haftung*

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1 *BGBI. (Bundesgesetzblatt (Federal Law Gazette))* I 1961, pp. 533 *et seq.*

2 On the legislative changes, see *BT-Drucks. (Bundestagsdrucksache (Official Records of the Parliament))*, 7th election period no. 5025, p. 65; 7th election period no. 3060, pp. 31 *et seq.*, 60 *et seq.*; and election period no. 5091, pp. 20 *et seq.*, all online available via <<http://druck.sachen.bundestag.de/drucksachen/>>; K. FEIDEN, *Die Neuordnung des Arzneimittelrechts*, GOVI, Frankfurt/Main 1978, p. 12; K.-J. HENNING, 'Der Nachweis der Wirksamkeit von Arzneimitteln', *NJW (Neue Juristische Wochenschrift)* 1978, p. 1671, at 1672; N. JENKE, *Haftung für fehlerhafte Arzneimittel und Medizinprodukte*, Springer, Heidelberg 2004, p. 23; G. SCHUBERT, 'Zur Einführung: Arzneimittelrecht', *JuS (Juristische Schulung)* 1983, pp. 748 *et seq.*

3 See sec. 91 *Arzneimittelgesetz* (AMG); for a full picture, see E. VON CAEMMERER, *Reform der Gefährdungshaftung*, Gesammelte Schriften III, Mohr Siebeck, Tübingen 1983, pp. 261 *et seq.*

für fehlerhafte Produkte (ProdHaftG) (Product Liability Act) could arise.⁴ Secondly, section 823 paragraph 1 *Bürgerliches Gesetzbuch* (BGB) (Civil Code) stipulates liability for any person who, intentionally or negligently, unlawfully injures the life, body, and health of another person. The cornerstone of such fault-based liability is the lack of diligence of the manufacturers as they failed to develop and manufacture a product made available on the market or did not provide information or warning on usage of the pharmaceutical in the manner that could be expected from a reasonable manufacturer in the circumstances of the case.⁵ Thirdly, a claim for damages could be based on breach of a statute under section 823 paragraph 2 BGB with section 5 AMG as the relevant statute prohibiting the distribution of any questionable pharmaceutical product.⁶

Any of these claims require a causal link between the conduct of the defendant pharmaceutical manufacturer (the relevant ‘conduct’ here will be the placing of a defective pharmaceutical on the market) and the violation of the protected rights under section 84 AMG and section 823 BGB (i.e., life, health, and bodily integrity).⁷ In determining such causation a but-for test is applied, and its results are subsequently limited to those events where the conduct of the defendant was generally apt to cause the result that has occurred and the injury sustained was within the scope of protection of the norm that was infringed.⁸ In the specific context of injuries caused by defective pharmaceuticals, German courts construed these combined criteria as a fourfold test. In the leading case regarding Thalidomide, it was generally accepted that proof of causation did not include evidence such as a clinical experiment or medically and epidemiologically-founded explanations of the mechanisms of Thalidomide and the injury sustained. For the court, epidemiological studies indicating a strong statistical correlation between the administering of Thalidomide and the Thalidomide-specific congenital malformations sufficed.⁹ In the later Impletol

4 Section 15 para. 1 *Gesetz über die Haftung für fehlerhafte Produkte* (Product Liability Act) provides for the exclusive application of the AMG.

5 *Bundesgerichtshof* (BGH) (Federal Court of Justice) 26 Nov. 1968, *BGHZ (Entscheidungen des Bundesgerichtshof in Zivilsachen)* 51, 91 = *NJW* 1969, 269 (note U. DIEDERICHSEN); BGH 19 Jun. 1973, *NJW* 1602; BGH 3 Jun. 1975, *NJW* 1975, 1827; C. VON BAR, *Verkehrspflichten*, Heymann, Köln 1980, pp. 52 *et seq.*; J. ESSER & H.-L. WEYERS, *Schuldrecht*, vol. II/2, 8th edn, C.F. Müller, Heidelberg 2000, sec. 55 II 3, V, and sec. 55a.

6 See BGH 26 Nov. 1969, *BGHZ* 51, 91 at 103.

7 See sec. 84 para. 1 sent. 1 AMG: ‘infolge der Anwendung eines Arzneimittels’ (as a result of the administration of a pharmaceutical); C. GRÜNEBERG, in *Palandt, Bürgerliches Gesetzbuch*, 72th edn, C.H. Beck, München 2013, Vorb v § 249, no. 24 *et seq.*

8 C. VON BAR, *Gemeineuropäisches Deliktsrecht*, vol. II, C.H. Beck, München 1999, no. 437; G. BRÜGGEMEIER, *Haftungsrecht*, Springer, Berlin/Heidelberg 2006, p. 28; C. VAN DAM, *European Tort Law*, OUP, Oxford 2006, pp. 286 *et seq.*; W.B. SCHÜNEMANN, ‘Kausalität in der Gefährdungshaftung’, *NJW* 1981, pp. 2796 *et seq.*

9 Landgericht (LG) (County Court) Aachen 18 Dec. 1970, *JZ (Juristenzeitung)* 1971, pp. 507 *et seq.*

case, where the claimant suffered death after taking the pharmaceutical, the *Oberlandesgericht* (OLG) (Higher Regional Court) Stuttgart approved this approach but added that two additional conditions have to be met. As it was unclear whether the claimant had died as a result of the usage of Impletol or simply suffered a heart attack, the court required evidence of any scientific knowledge or experience to prove such a link (analogous experiences) and, moreover, evidence that no alternative cause of the particular injury sustained existed.¹⁰ The final condition was provided by the OLG Celle in a case where the claimant suffered personal injury due to a rare precondition after being vaccinated against TBC. The court held that the plaintiff would have to prove not only the specific causal link in his case but also general causation, that is, evidence that the pharmaceutical product was generally apt to cause injury.¹¹ As a result, the proof of such a causal link was one of the most difficult tasks a claimant (and his legal and medical counsel) could possibly embark on as it is good law that any compensation is awarded only when it is established to the practically certain personal conviction of the judge that all conditions of liability – including the causal link – are present; a significant degree of probability or an overwhelming likelihood does not suffice.¹² In contrast, the claimant lacks specific medical, pharmacological, or epidemiological knowledge if this exists at all: for some pharmaceuticals, for instance in neuroleptics and antidepressants, the exact biochemical mechanisms of action are only partially understood.¹³ Additionally, it seems rather odd to require evidence that there could have been no other possible cause of the injury.

In the wake of the scandal surrounding HIV-contaminated blood products, it became obvious that claimants were unable to prove the causal link between

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- 10 *Oberlandesgericht* (OLG) Stuttgart 23 Feb. 1989, *VersR* (*Zeitschrift für Versicherungsrecht, Haftungs- und Schadensrecht*) 1990, 631 *et seq.*; see also LG Traunstein, *MedR* (*Medizinrecht*) 1995, p. 241, at 242; BGH 24 Jan. 1989, *BGHZ* 106, 273 = *VersR* 1989, pp. 399 *et seq.*
- 11 OLG Celle 27 Jun. 1983, *VersR* 1983, pp. 1143 *et seq.*
- 12 See sec. 286 *Zivilprozessordnung* (ZPO) (Code of Civil Procedure), and for this standard, see F. BIEN, ‘Schadensrechtliches Alles-oder-Nichts-Prinzip und Beweislastumkehr’, *ERPL* (*European Review of Private Law*) 2008, pp. 1083, 1089; MünchKommZPO/H. PRÜTTING, § 402 ZPO, 3rd edn, Beck, München 2008, no. 1; S. STEEL, ‘Exceptional Doctrines of Natural Causation’, 2 *JETL* (*Journal of European Tort Law*) 2011, p. 294, at 304; J. TAUPITZ, ‘Proportionalhaftung zur Lösung von Kausalitätsproblemen’, in FS Canaris, Beck, München 2007, p. 1231, at 1235; G. WAGNER, ‘Proportionalhaftung’, in FS Hirsch, de Gruyter, Berlin/Boston 2008, p. 453.
- 13 See E. MUTSCHLER, G. GEISLINGER, H.K. KROEMER, P. RUTH & M. SCHÄFER-KORTING, *Mutschler Arzneimittelwirkungen*, 9th edn, Wissenschaftliche Verlagsgesellschaft, Stuttgart 2008, pp. 162, 173.

their HIV-infection and the contaminated blood products¹⁴ as the products themselves were disposed; it was unclear which products were contaminated and, thus, who was the actual pharmaceutical manufacturer of the contaminated product. The German legislator reacted and implemented a presumption of a causal connection between the defective pharmaceutical and the injury sustained by the claimant in the circumstances of the individual case.¹⁵ The claimant will now have to submit information relating to the manufacturer, the dosage, and the composition of the pharmaceutical product, as well as medical studies indicating a causal link between the pharmaceutical and, generally, that the type of injury is caused by that defective product.¹⁶

That said, and with a view to diethylstilbestrol (DES)-daughters cases, it is arguable whether such relaxation of the burden of proof meets the injured claimant's needs in cases of multiple, indeterminate tortfeasors. Both section 93 AMG and section 830 BGB specify corresponding rules under which several defendants may be responsible for a single injury. The norms provide that potential tortfeasors are each responsible for the full damage and that the same applies where it is certain that one of a number of defendants caused the injury but it is impossible for the plaintiff to identify the defendant who did in fact commit the wrong.¹⁷ For the latter extension of liability of multiple tortfeasors, it is good law that some additional conditions must be fulfilled. First, each of the tortfeasors must have committed a tort with all the requirements necessary to establish liability (excluding the causal link) having been provided by the claimant in court.¹⁸ Second, there must be no doubt that one of the tortfeasors in fact

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- 14 OLG Düsseldorf 22 Jun. 1995, *NJW* 1995, pp. 3060 *et seq.*; OLG Hamm 23 Oct. 1996, *NJWRR* (*Neue Juristische Wochenschrift-Rechtsprechungsreport*) 1997, 217 *et seq.*; OLG Celle 12. Jun. 1996, *VersR* 1998, 1023 *et seq.*; BGH 30. Apr. 1991, *NJW* 1991, 1948 *et seq.*
- 15 See sec. 84 para. 2 AMG, implemented by the *Zweites Gesetz zur Änderung schadensersatzrechtlicher Vorschriften*, BGBl. I 2002, pp. 2674 *et seq.*, available online at <<http://www.bundesanzeiger-verlag.de/evidenzzentrale/>>.
- 16 See H.-J. KULLMANN, 'Erleichterung der Beweisführung aus § 84 AMG', in FS Gerda Müller, Carl Heymanns, Köln 2009, p. 253, at 256.
- 17 For a comparative and historical analysis, see R. ZIMMERMANN & J. KLEINSCHMIDT, in B. Winiger, H. Koziol, B.A. Koch, R. Zimmermann (eds.), *Digest of European Tort Law*, vol 1: *Essential Cases on Causation*, 2007 6a/2, nos. 1 *et seq.*; U. MAGNUS, 'Germany', in I. Gilead, M.D. Green & B.A. Koch (eds.), *Proportional Liability: Analytical and Comparative Perspectives* (forthcoming).
- 18 BGH 24 Jan. 1984, *BGHZ* 89, 383, at 399 = *NJW* 1984, 1226, at 1230; Staudinger/C. EBERL-BORGES, § 830 BGB, Sellier/de Gruyter, Berlin/Boston 2008, no. 11; H.-J. KULLMANN, 'Arzneimittelhaftung bei Blutpräparaten', in R. Damm, D. Hart (eds.), *Regulierung von Gesundheitsrisiken*, Nomos, Baden-Baden 1993, p. 133, at 147; MünchKommBGB/G. WAGNER, § 830 BGB, 5th edn, Beck, München 2009, nos. 47 *et seq.*

caused the harm in question;¹⁹ this will not be the case where it cannot be ruled out that the injury was caused by an ‘innocent’ source such as the natural development of the condition from an underlying illness of the claimant. Third, it must be unclear who, in the group of potential tortfeasors, actually caused the injury. Finally, each of the contributions of several tortfeasors must, on its own, have been sufficient to cause the injury.²⁰ Particularly the first and second conditions may prove burdensome to most prospective claimants as they could have used comparable pharmaceutical products of different manufacturers or they simply do not know which of a number of possible pharmaceuticals in what dosage were administered to them.²¹ These problems are aggravated by the fact that any solidary liability will be rejected in all cases where one of the manufacturers can prove that his product was without defect.²² It is well accepted that whenever it is possible to identify a causal link, allowing for the attribution of a distinct part of the damage to a single tortfeasor, the principle of partial liability takes priority over the rule of solidary liability.²³

Without a doubt, there is an intense debate among academics focusing on concepts such as market share liability and proportional liability in general.²⁴ Some suggest that the narrow limits of the above-mentioned solidary liability should be abandoned in favour of a wider scope of application of joint and several

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- 19 BGH 24 Jan. 1984, *BGHZ* 89, 383, at 399 = *NJW* 1984, 1226; R. ZIMMERMANN & J. KLEINSCHMIDT, n. 17, 6a/2, no. 11.
- 20 *Reichsgericht* (RG) (Supreme Court of the German Reich) 30 Jun. 1904, *RGZ* (*Entscheidungen des Reichsgerichts*) 58, 357, 361; BGH 15 Dec. 1970, *BGHZ* 55, 86, at 92 *et seq.*, 95; BGH 7 Nov. 1978, *BGHZ* 72, 355, at 358; BGH 27 May 1987, *BGHZ* 101, 108 = *NJW* 1987, 2810; MünchKommBGB/G. WAGNER, n. 18, nos. 36 *et seq.*
- 21 See BGH 11 Jan. 1994, *NJW* 1994, 932, at 934; C. VON BAR, ‘Empfehlen sich gesetzgeberische Maßnahmen zur rechtlichen Bewältigung der Haftung für Massenschäden?’, in Gutachten zum 62. Deutschen Juristentag (DJT), Beck, München 1998, pp. A 57 *et seq.*; C. EBERL-BORGES, ‘§ 830 BGB und die Gefährdungshaftung’, 196 *AcP* (*Archiv für die civilistische Praxis*) 1996, p. 491, at 536; MünchKommBGB/G. WAGNER, n. 18, nos. 56, 51.
- 22 BGH, 2 Feb. 1962, *VersR* 1962, 430; BGH 24 Jan. 1984, *BGHZ* 89, 383, at 399 = *NJW* 1984, 1226, at 1230; Staudinger/C. EBERL-BORGES, n. 18, no. 115; E. REINELT, ‘Zur Haftung des Arzneimittelherstellers für die Übertragung von Viren durch Blutprodukte’, *VersR* 1990, p. 565, 567; MünchKommBGB/G. WAGNER, n. 18, no. 47.
- 23 BGH 13 Feb. 1976, *BGHZ* 66, 70, at 75 *et seq.* = *NJW* 1976, 797, at 798 *et seq.*; BGH 26 Oct. 1978, *BGHZ* 72, 289, at 297 *et seq.* = *NJW* 1979, 164, at 165 *et seq.*; BGH 27 May 1987, *BGHZ* 101, 106, at 113 = *VersR* 1987, 1193, at 1194 = *NJW* 1987, 2810, at 2812; BGH 31 Jan. 1995, *NJW* 1995, 1286, at 1288; MünchKommBGB/G. WAGNER, n. 18, no. 44; G. WAGNER, ‘Aggregation and Divisibility of Damage in Germany’, in K. Oliphant (ed.), *Aggregation and Divisibility of Damage*, Springer, Wien/New York 2009, no. 59.
- 24 T. BODEWIG, ‘Probleme alternativer Kausalität bei Massenschäden’, 185 *AcP* 1985, p. 505, at 548; G. WAGNER, ‘Schadensersatz - Zwecke, Inhalte, Grenzen’, in E. Lorenz (ed.), *Karlsruher Forum* 2006, Verlag Versicherungswirtschaft, Karlsruhe 2006, pp. 80 *et seq.*, and reference in n. 12.

liability.²⁵ It is argued that the placing of the defective pharmaceutical on the market in itself suffices as basis for liability due to the increased risk of harm occurring.²⁶ And indeed, no innocent manufacturer would be liable as in sum the total amount of liability remains the same.²⁷ Accordingly, the manufacturer ought to be liable for the extent to which his actions exposed the victim to the risk of harm.²⁸ In addition, it is fundamentally understood in German tort law that the main purpose of tort law is the (full) compensation of damage (*restitutio in integrum*).²⁹ This objective would not be achieved where, in spite of the fact that all conditions of liability are met, a victim who is unable to satisfy the standard of proof as to whether it was the defendant's pharmaceutical that caused the injury – despite the high probability – goes uncompensated. Furthermore, it is generally agreed that prevention is an additional aim of tort law since having to compensate is basically assumed to have some measure of deterrent effect.³⁰ Any such deterrent effect must then surely fail if a manufacturer is not held liable for his undoubtedly defective product.

The courts and a majority of legal scholars have been unwilling to seriously take up any of these proposals: proportional liability is rejected as it contradicts the statutory framework of German tort law in equating the creation of a risk of injury with harm itself.³¹ Some argue, any extension of liability to potential tortfeasors would violate the most fundamental principle of German tort law: in contrast to, for example, French tort law,³² it is understood that any injured

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- 25 J. BRAUN, 'Haftung für Massenschäden', *NJW* 1998, p. 2318, at 2330.
- 26 T. BODEWIG, n. 24, p. 523; J. BRAUN, n. 25, p. 2330; C. SEYFERT, *Mass Toxic Torts*, Duncker & Humblot, Berlin 2004, pp. 238 *et seq.*; see also J. HAGER, 'Die Kausalität bei Massenschäden' in FS Canaris, fn. 12, p. 403, at 413.
- 27 T. BODEWIG, n. 24, pp. 528 *et seq.*; F. BYDLINSKI, 'Aktuelle Streitfragen um die alternative Kausalität', in FS Beitzke, de Gruyter, Berlin/New York 1979, p. 6, at 30. This is of course no solace to an individual manufacturer who was in fact not responsible for the injury sustained.
- 28 T. BODEWIG, n. 24, p. 548.
- 29 F. BYDLINSKI, *System und Prinzipien des Privatrechts*, Springer, Wien/New York 1996, pp. 187 *et seq.*; H. KOZIOL, *Grundfragen des Schadenersatzrechts*, Jan Sramek Verlag, Wien 2010, pp. 75 *et seq.*; U. MAGNUS, 'Comparative Report', in U. Magnus (ed.), *Unification of Tort Law: Damages*, Springer, Wien/New York 2001, p. 185; MünchKommBGB/G. WAGNER, Vor § 823 BGB, 5th edn, Beck, München 2009, nos. 38 *et seq.*, all with extensive further reference.
- 30 U. MAGNUS, 'Comparative Report', in U. Magnus (ed.), *Unification of Tort Law: Damages*, Sp2001, p. 187; F. BYDLINSKI, *System und Prinzipien*, pp. 190 *et seq.*; M. FAURE, 'Economic Analysis', in B.A. Koch & H. Koziol (eds.), *Unification of Tort Law: Strict Liability*, Springer, Wien/New York 2002, pp. 364 *et seq.*
- 31 G. MÜLLER, Bericht zum 66. DJT, vol. II/1, Beck, München 2006, p. L 28; J. TAUPITZ, n. 12, pp. 1234 *et seq.*
- 32 C. QUÉZEL-AMBRUNAZ, 'Fault, Damage and the Equivalence Principle in French Law', 1 *JETL* 2012, pp. 21 *et seq.*

person should have to bear his losses himself unless the injury is attributable to another person. Such imputation can, however, only operate if the tortfeasors are known and demonstrated to be such.³³ Finally, attention was drawn to the legislator as the DES-daughters cases became known well before the last revision of both the AMG and the BGB. It is felt that a market share or proportional liability was rejected due to substantial problems in determining such share at a given time and the simple fact that some manufacturers no longer exist.³⁴ Under present German law, the problem at hand may thus be understood not as the causal link between the pharmaceutical product and the injury sustained but the inability to determine the actual wrongdoer with certainty; in this latter case, however, the solidary liability mentioned above cannot apply.³⁵

In conclusion, a claim in a DES-daughters scenario would most probably be denied in spite of recent reforms. However, as reality is the antithesis of expectation, any fears for the injured claimants may well be misplaced. Any difficulty with gathering evidence in the German Public Health Insurance system will be – unlike in the USA – less pressing as German doctors prescribe specific pharmaceuticals and pharmacies are only allowed to substitute them to a limited extent.³⁶ Any information as regards prescription and substitution is documented and retained for a long period of time. Thus, any pharmaceutical manufacturer can be determined easily.³⁷ Additionally, in specific cases (such as the Thalidomide and HIV cases, above), where the defendants could not be held liable for reasons such as those outlined here, manufacturers are subject to specific statutory schemes³⁸ established by central government to provide financial help for victims of these defective pharmaceuticals. Finally, the widespread and long-standing availability of social insurance in Germany lightens the burden of people injured in such a scenario as discussed here; they will be able to recover pecuniary loss as normal via the machinery of social insurance with tort law being relegated to deal with non-pecuniary loss only.

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- 33 E. DEUTSCH, 'Das Arzneimittelrecht im Haftungssystem', *VersR* 1979, p. 685, at 689; O. DE LOUSANOFF, 'Market Share Liability', *RIW (Recht der internationalen Wirtschaft)* 1983, pp. 151 *et seq.*; E. REINELT, n. 22, p. 567; H. STOLL, *Haftungsfolgen im bürgerlichen Recht*, C.F. Müller, Heidelberg 1999, p. 116; J. TAUPITZ, n. 12, p. 1235.
- 34 C. VON BAR, n. 21, p. 71; L. RÖCKRATH, *Kausalität, Wahrscheinlichkeit und Haftung*, Beck, München 2001, pp. 174 *et seq.*; Staudinger/C. EBERL-BORGES, n. 18, no. 111.
- 35 C. VON BAR, n. 21, p. 69; C. EBERL-BORGES, n. 21; G. MÜLLER, n. 31, L 28 *et seq.*
- 36 C.R. BARTRAM, Bericht zum 62. DJT, vol. II/1, Beck, München 1998, pp. I 123 *et seq.*
- 37 C.R. BARTRAM, n. 36.
- 38 See *Gesetz über die humanitäre Hilfe für durch Blutprodukte HIV-infizierte Personen* BGBl. I 1995, p. 972; 'Gesetz über die Errichtung einer Stiftung "Hilfswerk für behinderte Kinder"' 1971, BGBl. I 1971, p. 2018, available online <<http://www.bundesanzeiger-verlag.de/evidenzzentrale/>>.