



Provisional text

JUDGMENT OF THE COURT (First Chamber)
16 February 2017 (*)
(Reference for a preliminary ruling — Approximation of laws — Industrial policy — Directive 93/42/EEC — Checks on the conformity of medical devices — Notified body appointed by the manufacturer — Obligations of that body — Defective breast implants — Implants manufactured using silicone — Liability of the notified body)

In Case C-219/15,

REQUEST for a preliminary ruling under Article 267 TFEU from the Bundesgerichtshof (Federal Court of Justice, Germany), made by decision of 9 April 2015, received at the Court on 13 May 2015, in the proceedings

**Elisabeth Schmitt**

v

**TÜV Rheinland LGA Products GmbH,**

THE COURT (First Chamber),

composed of R. Silva de Lapuerta, President of the Chamber, E. Regan, J.-C. Bonichot, C.G. Fernlund (Rapporteur) and S. Rodin, Judges,
Advocate General : E. Sharpston,
Registrar: C. Strömholm, Administrator,
having regard to the written procedure and further to the hearing on 26 May 2016,
after considering the observations submitted on behalf of:
Mrs Schmitt, by R. Schultze-Zeu, Rechtsanwältin, and H. Riehn, Rechtsanwalt,
TÜV Rheinland LGA Products GmbH, by I. Brock, Rechtsanwältin, M. Schweiger, Rechtsanwalt, and D. Anderson QC,
the German Government, by T. Henze, J. Möller and K. Petersen, acting as Agents,
Ireland, by E. Creedon, L. Williams and A. Joyce, acting as Agents, and C. Toland, Barrister-at-Law,
the French Government, by G. de Bergues, D. Colas, F. Gloaguen and J. Traband, acting as Agents,
the European Commission, by M. Kellerbauer and P. Mihaylova, acting as Agents,
after hearing the Opinion of the Advocate General at the sitting on 15 September 2016,
gives the following

**Judgment**

This reference for a preliminary ruling concerns the interpretation of Article 11(1)(a) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1), as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ 2003 L 284, p. 1) ('Directive 93/42'), and sections 3.3, 4.3, 5.3 and 5.4 of Annex II to the directive.

The request has been made in proceedings between Mrs Elisabeth Schmitt and TÜV Rheinland LGA Products GmbH ('TÜV Rheinland') concerning the latter's liability, as notified body, for the harm caused to Mrs Schmitt by defective breast implants made of silicone.

**Legal context**

*EU law*

Directive 93/42

Directive 93/42 was amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ 2007 L 247, p. 21). However, those amendments relate to provisions that were to be applied from 21 March 2010 and are therefore irrelevant for the purpose of the present proceedings.

The third recital of Directive 93/42 states that 'national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonised in order to guarantee the free movement of such devices within the internal market'.

The fifth recital of Directive 93/42 states that 'medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; … therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive'.

Article 2 of Directive 93/42 provides that 'Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose'.

Article 11(1)(a) of Directive 93/42 sets out one of the alternatives for the conformity assessment procedure for Class III devices, other than custom-made devices and those intended for clinical investigations, which the manufacturer must choose in order to affix the CE marking. In practice, that alternative entails following the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance).

It is apparent from Article 11(9) of Directive 93/42 that, where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a body of its choice within the framework of the tasks for which the body has been notified. Article 11(10) provides that that body may require, where duly justified, any information or data which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

Article 16(6) of Directive 93/42 is worded as follows:

'Where a notified body finds that pertinent requirements of this Directive have not been met or are no longer met by the manufacturer or where a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the competent authority may become necessary, the notified body shall inform its competent authority thereof. The Member State shall inform the other Member States and the Commission.'

Annex II to Directive 93/42, headed 'EC declaration of conformity', provides in Section 1 thereof that 'the manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the products concerned, as specified in Section 3, and is subject to audit, as laid down in Sections 3.3 and 4, and to Community surveillance, as specified in Section 5.'

Section 3.2 of that annex states as follows:

'Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

…'

Section 3.3 of that annex is worded as follows:

'The notified body must audit the quality system to determine whether it meets the requirements referred to in section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team must include at least one number with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

The manufacturer shall be notified of the decision. It must contain the conclusions of the inspection and a reasoned assessment.'

Section 4.1 of Annex II to Directive 93/42 provides as follows:

'In addition to the obligations imposed by Section 3, the manufacturer must lodge with the notified body an application for examination of the design dossier relating to the product which he plans to manufacture …'

Section 4.2 of that annex states as follows:

'The application must describe the design, manufacture and performances of the product in question. It must include the documents needed to assess whether the product conforms to the requirements of this Directive …'

Section 4.3 of the annex provides as follows:

'The notified body must examine the application and, if the product conforms to the relevant provisions of this Directive, issue the application with an EC design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of the Directive. The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design and, where appropriate, a description of the intended purpose of the product.

…'

Section 5.1 of Annex II to Directive 93/42 is worded as follows:

‘The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.’

Section 5.2 of that annex provides as follows:

‘The manufacturer must authorise the notified body to carry out all the necessary inspections and supply it with all relevant information, in particular:

– the documentation on the quality system,

– the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculation, tests, etc.,

– the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.’

According to Section 5.3 of the annex, the notified body ‘must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and must supply the manufacturer with an assessment report’. In addition, Section 5.4 provides that that body ‘may pay unannounced visits to the manufacturer [during which it] may, where necessary, carry out or ask for tests in order to check that the quality system is working properly.’

Annex XI to Directive 93/42 lays down ‘Criteria to be met for the designation of notified bodies’, including those relating to greater independence and scientific expertise. In particular, it is apparent from Section 3 of the annex that a notified body must have ‘sufficient scientific staff … who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Directive’. Moreover, Section 6 of that annex states that such a body ‘must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.’

Directive 2003/12/EC

Under Article 1 of Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42 (OJ 2003 L 28, p. 43), such implants are to be classified as Class III medical devices.

That directive entered into force on 1 September 2003. It is apparent from Articles 2 and 3 of the directive that breast implants placed on the market before that date were to be subject to a conformity reassessment procedure as Class III medical devices before 1 March 2004.

*German law*

It is apparent from the order for reference that Directive 93/42 was transposed into German law by the Medizinproduktegesetz (Law on medical devices) (‘the MPG’) and the Medizinprodukt-Verordnung (the Order on medical devices).

In accordance with the first sentence of Paragraph 6(2) and Paragraph 37(1) of the MPG and point 1 of Paragraph 7(1) of the Order on medical devices, Class III medical devices may be placed on the market only if the requirements of the conformity assessment procedure laid down in Annex II to Directive 93/42 are met.

It is clear from various provisions of the Bürgereliches Gesetzbuch (German Civil Code), as interpreted in German case-law, first, that civil liability may be incurred for breach of a rule conferring legal protection and, second, that the scope of the duty to exercise due diligence and take all due care under a contract may, in certain cases, extend to third parties.

**The dispute in the main proceedings and the questions referred for a preliminary ruling**

On 1 December 2008, Mrs Schmitt had breast implants manufactured in France fitted in Germany.

The manufacturer of those implants, which became insolvent after that date, had appointed TÜV Rheinland to assess its quality system. It is apparent from the order for reference that, in the course of its involvement during the period 1998 to 2008, that notified body made eight visits to the manufacturer’s premises, all of which were announced in advance. During that period, TÜV Rheinland never inspected business records or ordered that the devices be inspected.

In 2010, the competent French authority established that the manufacturer in question had produced breast implants using industrial silicone which did not comply with quality standards. Accordingly, Mrs Schmitt had the implants removed in 2012.

Taking the view that TÜV Rheinland had not fulfilled its obligations satisfactorily, Mrs Schmitt claimed EUR 40 000 by way of compensation for non-material damage from that notified body before the German courts. She also sought a declaration that that body was liable for any future material damage. In support of her claims, Mrs Schmitt argued that an inspection of the delivery notes and invoices would have enabled TÜV Rheinland to ascertain that the manufacturer had not used an approved form of silicone.

Those claims were rejected at first instance and also by the appeal court.

First, the appeal court found that there could be no liability on the part of TÜV Rheinland for infringement of an obligation under a contract for the benefit of third parties, as the contract concluded between the notified body and the manufacturer fell to be assessed exclusively by reference to private law and did not include Mrs Schmitt. According to that court, it is neither the purpose nor the intention of TÜV Rheinland’s involvement to protect third parties, as the activities connected with certification serve only to ensure compliance with the requirements for placing medical devices on the market. The inclusion of a third party within the scope of the contract, contrary to the intention of the parties to the contract and in the absence of any legitimate interest in that regard, would have the effect of extending the notified body’s liability indefinitely.

Second, the appeal court found that TÜV Rheinland was not liable under civil liability law either, as the purpose of that notified body’s activity was not to protect patients. Moreover, that court found that no fault could be established as TÜV Rheinland had made regular announced visits, which must be deemed sufficient in

the absence of any suspicion of improper production practices.

Mrs Schmitt brought an appeal on a point of law before the referring court.

In the view of the referring court, how the dispute will be resolved under German law depends, essentially, on the purpose of the involvement of a notified body in the conformity assessment procedure and on that body's obligations under that procedure.

The referring court has indicated that the answer to the question whether the first sentence of Paragraph 6(2) of the MPG is to be regarded as a provision conferring legal protection on individual interests depends essentially on the content and purpose of Directive 93/42 in general, and Annex II thereto in particular. Under German law, a provision should be regarded as conferring legal protection where, having regard to its purpose and content, it is intended to protect individuals or certain groups of persons against the infringement of a particular legal interest. It would be helpful in that regard to ascertain whether the legislature which adopted the provision in question specifically intended, if only as a secondary aim, to afford to certain groups of individuals the legal protection sought on account of the infringement alleged. It is also appropriate to ascertain, as part of a comprehensive assessment of the legislative context in which the provision in question applies, whether the legislature might have intended to make infringement of the protected interest result in the tortious liability of the party infringing that interest.

Furthermore, the referring court explains, with regard to any benefit that may accrue to a third party to the contract concluded between the manufacturer in question and TÜV Rheinland, that such benefits may arise where certain conditions are met, inter alia where the manufacturer has a protectable interest in the scope of the contractual obligations of the notified body being extended to a third party, such as Mrs Schmitt. In interpreting that contract in accordance with German law, the objectives pursued by Directive 93/42 in general through the conformity assessment procedure and, in particular, through the involvement of the notified body via that contract are of crucial importance.

In any event, in order for TÜV Rheinland to incur liability, that notified body must have infringed either a rule conferring legal protection or a contractual obligation. In order to establish whether there was such an infringement, the referring court would like to ascertain the specific content of the obligations arising under Sections 3.3, 4.3, 5.3 and 5.4 of Annex II to Directive 93/42. That court entertains doubts as to the precise nature of the obligations which a body such as TÜV Rheinland is under, in particular with regard to the level of supervision and scrutiny required of that body when it carries out inspection visits at the manufacturer's premises.

In those circumstances, the Bundesgerichtshof (Federal Court of Justice, Germany) decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

Is it the purpose and intention of Directive 93/42 that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance acts in order to protect all potential patients and may therefore, in the event of a culpable infringement of an obligation, have direct and unrestricted liability towards the patients concerned?

Does it follow from Sections [3.3, 4.3, 5.3 and 5.4] of Annex II to Directive 93/42 that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance is subject to a general obligation to examine devices, or at least to examine them where there is due cause?

Does it follow from the aforementioned sections of Annex II to Directive 93/42 that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance is subject to a general obligation to examine the manufacturer's business records and/or to carry out unannounced inspections, or at least to do so where there is due cause?'

**Consideration of the questions referred**

*The second and third questions*

By its second and third questions, which it is appropriate to answer first and together, the referring court seeks to ascertain, in essence, whether the provisions of Annex II to Directive 93/42 are to be interpreted as meaning that the notified body is required in general, or at least where there is due cause, to carry out unannounced inspections, to examine devices and/or to examine the manufacturer's business records.

It should be noted in that regard that some of the obligations the notified body is under pursuant to Annex II to Directive 93/42 are undoubtedly specific in terms of specific action to be taken. Thus, in auditing the manufacturer's quality system, the notified body is required to carry out an inspection on the manufacturer's premises, in accordance with Section 3.3 of that annex. Moreover, in carrying out 'surveillance' of the manufacturer's activities, the notified body must periodically undertake appropriate inspections and assessments, in accordance with Section 5.3 of the annex.

However, the provisions of Annex II to Directive 93/42 do not impose a general obligation on the notified body to carry out unannounced inspections, to examine devices and/or to examine the manufacturer's business records.

That being so, it should be recalled that the notified body is under an obligation, pursuant to Sections 3.2, 3.3 and 4.1 to 4.3 of Annex II to Directive 93/42, first, to analyse the application for examination of the design dossier lodged by the manufacturer, which must describe the design, manufacture and performance of the product in question and, second, to ascertain whether the application of the quality system contemplated by the manufacturer ensures that the products fulfil the relevant requirements under that directive. Moreover, it is apparent from Section 5.1 of that annex that the notified body must satisfy itself that the manufacturer duly fulfils the obligations imposed by the approved quality system.

Annex II to Directive 93/42 expressly lays down various measures enabling the notified body to fulfil its surveillance obligations. It is apparent from Section 5.4 of the annex that the notified body may pay unannounced visits to the manufacturer during which it may, where necessary, carry out or ask for tests in order to check that the quality system is working properly.

Moreover, it is clear from Article 11(10) of Directive 93/42 that the notified body may require, where duly justified, any information or data which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure. Accordingly, in the procedure relating to the EC declaration of conformity, the manufacturer must allow that body to carry out all the inspections necessary and provide it with all relevant information, in accordance with Section 5.2 of Annex II to the directive.

Several of the interested parties which have submitted observations to the Court have argued that it follows from the wording and overall scheme of Directive 93/42 that all the above measures are optional and that notified bodies should be allowed a broad degree of discretion in that regard.

It is true, as the Advocate General observed in point 44 of her Opinion, that those bodies must be allowed an appropriate degree of discretion, in view of the stringent requirements which they must satisfy under Annex IX to Directive 93/42 as regards their independence and scientific expertise. However, the obligations laid down in Article 16(6) of the directive and those set out in paragraph 41 above would be a dead letter if the degree of discretion knew no limits. The notified body would not be able to fulfil its function under the procedure relating to the EC declaration of conformity if it were free not to take any steps in the face of evidence indicating that a medical device might not comply with the requirements laid down in Directive 93/42.

Consequently, as they are required to establish whether EU certification may be maintained pursuant to Article 16(6) of Directive 93/42, notified bodies are under a general obligation to act with all due diligence when engaged in a procedure relating to the EC declaration of conformity.

It follows, as the Advocate General observed in point 54 of her Opinion, that a notified body is under a duty to be alert, with the result that, in the face of evidence indicating that a medical device may not comply with the requirements laid down in Directive 93/42, that body must take all steps necessary to ensure that it fulfils its obligations under Article 16(6) of the directive, as well as those set out in paragraph 41 above.

In the light of the foregoing considerations, the answer to the second and third questions is that the provisions of Annex II to Directive 93/42, read in the light of Article 11(1) and (10) and Article 16(6) of the directive, are to be interpreted as meaning that the notified body is not under a general obligation to carry out unannounced inspections, to examine devices and/or to examine the manufacturer's business records. However, in the face of evidence indicating that a medical device may not comply with the requirements laid down in Directive 93/42, the notified body must take all the steps necessary to ensure that it fulfils its obligations under Article 16(6) of the directive and Sections 3.2, 3.3, 4.1 to 4.3 and 5.1 of Annex II to the directive.

*The first question*

By its first question, the referring court seeks to ascertain, in essence, whether Directive 93/42 is to be interpreted as meaning, first, that in the procedure relating to the EC declaration of conformity, the purpose of the notified body's involvement is to protect the end users of medical devices and, second, that a culpable failure by that body to comply with its obligations is therefore liable to give rise to liability on its part vis-à-vis such users.

It should be observed that the Court has previously held, on the basis of, inter alia, the third and fifth recitals of Directive 93/42, that the aim of the directive is not only the protection of health *stricto sensu*, but also the safety of persons and that it does not concern only patients and users of medical devices but, more generally, 'third parties' or 'other persons' (judgment of 19 November 2009, *Nordiska Dental*, C-288/08, EU:C:2009:718, paragraph 29). It follows that the actual aim of that directive is to protect the end users of medical devices.

While it is incumbent on the manufacturer, in the first place, to ensure that the medical device complies with the requirements laid down in Directive 93/42, it is clear that that directive also imposes obligations to that end on the Member States and notified bodies.

In that regard, it should be noted, first, that in addition to the obligation on Member States under Article 2 of Directive 93/42 to take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in the directive, the latter imposes specific obligations on the Member States as regards surveillance of the market. As the Court held in paragraphs 35 to 38 of its judgment of 24 November 2016, *Lohmann & Rauscher International* (C-662/15, EU:C:2016:903), the combination of those obligations in connection with the procedures for safeguarding, vigilance and health surveillance, all of which are laid down by the directive, ensures protection for the health and safety of persons.

Second, with regard to the involvement of the notified body in the procedure relating to the EC declaration of conformity, it is apparent from the wording and overall scheme of Directive 93/42 that the purpose of that procedure is to ensure protection for the health and safety of persons.

In the light of the foregoing, it is necessary to determine whether, under Directive 93/42, a culpable infringement of its obligations by a notified body in the course of its involvement in the procedure in question may render it liable vis-à-vis the end users of medical devices.

It should be noted at the outset that the Court has previously stated that it does not necessarily follow from the fact that a directive imposes surveillance obligations on certain bodies or the fact that one of the objectives of the directive is to protect injured parties that the directive seeks to confer rights on such parties in the event that those bodies fail to fulfil their obligations, and that is the case especially if the directive does not contain any express rule granting such rights (see, to that effect, judgment of 12 October 2004, *Paul and Others*, C-222/02, EU:C:2004:606, paragraphs 38 to 40).

Similarly, it should be noted that, in the absence of any mention in Directive 93/42 of the manner in which the civil liability of notified bodies may be incurred, it cannot be maintained that the purpose of the directive is to govern the conditions under which the end users of medical devices may be able to obtain compensation for culpable failure by those bodies to fulfil their obligations.

In any event, the mere fact that Section 6 of Annex XI to Directive 93/42 requires notified bodies to take out civil liability insurance is not sufficient, in the absence of any further detail in that regard, for it to be concluded that the directive requires Member States to confer on the end users of medical devices who have suffered injury as a result of culpable failure on the part of notified bodies to fulfil their obligations a right to look to those bodies for compensation.

It is established case-law that the system of rules put in place by 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 (OJ 1985 L 210, p. 29) does not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as fault (see, to that effect, judgment of 10 January 2006, *Skov and Bilka*, C-402/03, EU:C:2006:6, paragraph 47).

It follows that, under EU law as it currently stands, the conditions under which culpable failure on the part of a notified body to fulfil its obligations under the procedure relating to the EC declaration of conformity laid down by Directive 93/42 may give rise to liability on its part vis-à-vis the end users of medical devices are governed by national law, subject to the principles of equivalence and effectiveness.

In the light of the foregoing considerations, the answer to the first question is that Directive 93/42 is to be interpreted as meaning that in the procedure relating to the EC declaration of conformity, the purpose of the notified body's involvement is to protect the end users of medical devices. The conditions under which culpable failure by that body to fulfil its obligations under the directive in connection with that procedure may give rise to liability on its part vis-à-vis those end users are governed by national law, subject to the principles of equivalence and effectiveness.

*The request that the effects of the present judgment be limited in time*

In its observations, Ireland has requested the Court to limit the temporal effects of the present judgment, if the Court were to conclude that Directive 93/42 provides that, in the event of culpable failure to comply with its obligations in connection with a Class III medical device, the notified body has direct and unrestricted liability towards the users of the device.

It is sufficient to observe that it follows from the answer to the first question that Directive 93/42 does not impose such liability.

Accordingly, there is no need to limit the temporal effects of the present judgment.

**Costs**

Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (First Chamber) hereby rules:

**The provisions of Annex II to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003, read in the light of Article 11(1) and (10) and Article 16(6) of the directive, are to be interpreted as meaning that the notified body is not under a general obligation to carry out unannounced inspections, to examine devices and/or to examine the manufacturer's business records. However, in the face of evidence indicating that a medical device may not comply with the requirements laid down in Directive 93/42, as amended by Regulation No 1882/2003, the notified body must take all the steps necessary to ensure that it fulfils its obligations under Article 16(6) of the directive and Sections 3.2, 3.3, 4.1 to 4.3 and 5.1 of Annex II to the directive.**

**Directive 93/42, as amended, is to be interpreted as meaning that, in the procedure relating to the EC declaration of conformity, the purpose of the notified body's involvement is to protect the end users of medical devices. The conditions under which culpable failure by that body to fulfil its obligations under the directive in connection with that procedure may give rise to liability on its part vis-à-vis those end users are governed by national law, subject to the principles of equivalence and effectiveness.**

[Signatures]

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* Language of the case: German.