Case C-10/24

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

9 January 2024

Referring court:

Bundesgerichtshof (Germany)

Date of the decision to refer:

21 December 2023

Applicant, appellant on a point of law and cross-respondent on a point of law:

Dürr Dental SE

Defendant, respondent in the appeal on a point of law and cross-appellant on a point of law:

Cattani Deutschland Helmes GmbH & Co. KG

Subject matter of the main proceedings

Regulation (EU) 2017/745 on medical devices – Competition law – CE marking as a medical device – Notified body identification number – Extent of distributor's obligation to verify

Subject matter and legal basis of the request

Interpretation of EU law, Article 267 TFEU

Questions referred for a preliminary ruling

1. Is a distributor obliged under Article 14(1) and point (a) of the first subparagraph of Article 14(2) of Regulation (EU) 2017/745 to verify whether the product which it makes available on the market is to be regarded as a medical device and therefore bears a CE marking as a

medical device and that an EU declaration of conformity of a medical device has been drawn up by the manufacturer?

2. Is it relevant for the answer to question 1 whether the product

   (a) has been CE marked by the manufacturer at all;

   (b) has been CE marked by the manufacturer as a medical device or an accessory for a medical device;

   (c) has been CE marked by the manufacturer not as a medical device or an accessory for a medical device, but with reference to Directive 2006/42/EC on machinery?

3. Do the verification obligations imposed on the distributor under point (a) of the first subparagraph of Article 14(2) in conjunction with Article 14(1) of Regulation (EU) 2017/745 also include verification of whether the device is to fall under risk class IIa within the meaning of Regulation (EU) 2017/745 and must therefore also be marked with a four-digit identification number of a notified body?

4. With respect to the question whether a distributor, under the third subparagraph of Article 14(2) in conjunction with Article 14(1) of Regulation (EU) 2017/745, has reason to believe that the device which it is making available on the market is not in conformity with the requirements of that regulation, is it relevant that the distributor is made aware by means of a letter of formal notice from a competitor of the latter's legal opinion that the article made available on the market by the distributor does not bear the requisite CE marking and an identification number of a notified body in accordance with the requirements of point (a) of the first subparagraph of Article 14(2) of Regulation (EU) 2017/745?

5. Is it relevant for the answer to question 4 whether

   (a) the letter of formal notice from a competitor contains a clear indication of an infringement, that is to say, it is worded so specifically that the distributor can easily identify the infringement without a detailed examination of the law or the facts;

   (b) the distributor, upon making an enquiry, has been informed by the manufacturer or by a public authority that the objections set out in the letter of formal notice are unfounded?

Provisions of European Union law relied on

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ 2017 L 117, p. 1), in particular Article 14(1) and point (a) of the first subparagraph and the third subparagraph of Article 14(2) thereof

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1) (no longer in force)

Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ 2006 L 157, p. 24)

Provisions of national law relied on

Gesetz gegen den unlauteren Wettbewerb (German Law against Unfair Competition; 'the UWG'), in particular the first sentence of Paragraph 8(1), Paragraph 3(1) and Paragraph 3a thereof

Gesetz über Medizinprodukte (German Law on Medical Devices; 'the MPG'), in particular the first sentence of Paragraph 6(1) thereof

Succinct presentation of the facts and procedure in the main proceedings

1 The applicant at first instance ('the applicant') manufactures compressors for the production of compressed air for dental treatment, which are class IIa medical devices within the meaning of Annex IX to Directive 93/42, as determined by decision of 23 January 2014 of the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices; BfArM).

2 As a legally independent German representative of the Italy-based firm Cattani S.p.A., the defendant at first instance ('the defendant') distributes, in Germany, what are known as oil-free dry air compressors for the production of compressed air.

3 In November 2020, the applicant ordered from the defendant a compressor manufactured by Cattani S.p.A., as a test purchase. This was CE marked. The accompanying declaration of conformity drawn up by the manufacturer did not refer to Directive 93/42 or Regulation 2017/745, but to Directive 2006/42. The compressor delivered by the defendant did not have a four-digit identification number of the notified body responsible for the conformity assessment procedure, which must follow the CE marking of a class IIa medical device in accordance with Directive 93/42 and Regulation 2017/745. The machine was accompanied by

an instruction manual for the manufacturer's 'oil-free dry air compressors 1-2-3 cylinders'.

4 Further information on the area of application of the compressors was available on the manufacturer's website.

5 The applicant requested that the defendant make a declaration of intention to desist, which the defendant refused to do.

6 At the beginning of 2021, the applicant made another test purchase from the defendant for a compressor, which was delivered on 9 February 2021. The machine was marked in the same way as the first order. An instruction manual was included.

7 By its main application for injunctive relief, the applicant sought to prohibit the making available of the defendant's compressors where those compressors do not bear a CE marking as a medical device and a four-digit identification number of a notified body or, in the alternative, to prohibit such making available where the compressors do not bear a CE marking as a medical device.

8 Furthermore, with respect to the act to be prohibited, the applicant sought an order obliging the defendant to pay compensation for damages and requested the provision of information, reimbursement of the costs incurred in issuing the formal notice in the amount of EUR 2 305.40, plus interest, as well as reimbursement of the costs of the (first) test purchase of November 2020, plus interest.

9 The Landgericht (Regional Court, Germany) upheld the claim for reimbursement of the costs relating to the first test purchase in the amount of EUR 2 241.78, plus interest, and dismissed the action as to the remainder. The appellate court revised the judgment of the Regional Court in part and, in accordance with the alternative claim, ordered the defendant to cease and desist, ruled that the defendant was liable to pay damages and ordered the defendant to provide information and to pay the costs associated with the formal notice, plus interest.

10 By its appeal on a point of law, which was permitted by the appellate court, the applicant is pursuing its main application for injunctive relief and its related application for a court order. By its cross-appeal, the defendant is seeking to have the judgment on appeal set aside in so far as it goes beyond the order at first instance concerning reimbursement of the costs of the first test purchase, plus interest, and to have the appeal brought by the applicant dismissed.

The essential arguments of the parties in the main proceedings

11 The applicant submits that it is apparent from the information in the instruction manual and on the manufacturer's website that the defendant's compressors are accessories for medical devices which must fall under class IIa within the meaning

of Directive 93/42 and Regulation 2017/745, and that therefore they must bear a CE marking and a four-digit identification number of the notified body responsible for the conformity assessment procedure. It maintains that the defendant, as a distributor, is under an obligation to verify and ensure compliance with those provisions.

12 The defendant argues that the obligations arising from Regulation 2017/745 concern only devices expressly placed on the market by the manufacturer as medical devices, which is not the case with the compressor in question, since it was made available on the market as a technical machine. Furthermore, it maintains that only the manufacturer, with the knowledge available to it, would be able to resolve the complex legal question of whether a product is a medical device and assign it to class IIa under Directive 93/42. According to the defendant, such an assessment does not arise for the distributor under Regulation 2017/745. In addition, it claims that, following the applicant's letter of formal notice outlining the supposedly incorrect CE marking, the distributor did everything within its power, namely it asked the manufacturer whether the product was a medical device and the supervisory authority whether official measures were necessary, receiving a response in the negative in both cases.

Succinct presentation of the reasoning in the request for a preliminary ruling

13 The success of the appeal depends on the interpretation of Article 14(1) and point (a) of the first subparagraph and the first sentence of the third subparagraph of Article 14(2) of Regulation 2017/745.

14 The applicant's claim to injunctive relief based on the risk of repetition pursuant to the first sentence of Paragraph 8(1) of the UWG exists only if the defendant's conduct that is being challenged was unlawful both at the time it was carried out (first and second test purchase) and is unlawful at the time of the appeal hearing. Given that the legal situation changed after the test purchases, both the provisions of the MPG, in force until 25 May 2021, and of the Order on Medical Devices, as well as the underlying provisions of Directive 93/42 and those currently in force under Regulation 2017/745, are relevant for the legal assessment.

15 The conduct being challenged by the applicant was unlawful when it was carried out. By delivering the test purchases to the applicant, the defendant infringed the prohibition laid down in the first sentence of Paragraph 6(1) of the MPG because the medical devices did not bear the relevant CE marking.

16 Whether the defendant's conduct that is being challenged by the applicant was also in breach of Article 14(1) and point (a) of the first subparagraph and the first sentence of the third subparagraph of Article 14(2) of Regulation 2017/745 under the law in force at the time of the appeal hearing depends on the interpretation of those EU law provisions. It is necessary to examine whether the defendant, as a distributor, had reason to believe that the compressors delivered to the defendant were not in conformity with the requirements of that Regulation because, first,

they did not bear a CE marking as a medical device and, second, they did not bear the identification number of a notified body. In this respect, a distinction has to be made between the first and the second test purchases because the question arises as to whether, because of the formal notice given after the first test purchase, the defendant had reason to believe this. Questions 1, 2, 4 and 5 referred for a preliminary ruling are intended to clarify the issues concerning interpretation of EU law that arise in this respect.

Possible infringement due to the absence of a CE marking as a medical device

First test purchase

17 The question arises whether the defendant, as a distributor, was required, when making the product available, to verify whether it is a medical device, which must therefore bear a corresponding CE marking as a medical device and for which an EU declaration of conformity as a medical device would have to be drawn up by the manufacturer (question 1), and whether it is relevant that only a CE marking with respect to Directive 2006/42 was present (question 2). That question is to be determined by way of interpretation.

18 The wording of Article 14(1) and (2) of Regulation 2017/745 does not expressly impose an obligation on the distributor to verify that the device has been assessed to be a medical device or an accessory for such by the manufacturer, nor does it expressly indicate that such an assessment is to be verified as part of the distributor's verification obligations. However, this does not mean that the verification obligation on the part of the distributor is unlimited. On the contrary, the distributor's verification obligation is limited by the fact that the distributor is required to take into account the applicable requirements only within the context of its activities and must act with due care. As the manufacturer is responsible for proper CE marking (Article 2(43) of Regulation 2017/745), Article 14(1) of that regulation could be interpreted as meaning that the distributor is required to comply with the requirements of that regulation for medical devices only where the manufacturer has assessed the product to be a medical device or as an accessory for such a device.

19 Recitals 27 and 36 of Regulation 2017/745, which mention the aspect of creating legal certainty as regards the obligations incumbent on the respective economic operators, could also be seen as supporting such an interpretation.

20 By contrast, the meaning and purpose of Article 14 of Regulation 2017/745 could militate in favour of a verification obligation on the distributor, given that, according to recitals 1 and 2 of that regulation, a high level of safety and protection of health for patients and users is to be ensured, which is all the more effective if the distributor's verification obligations are more comprehensive. However, the interests of small and medium-sized enterprises that are active in the medical devices sector must also be taken into account (recital 2 of Regulation 2017/745). That verification can be carried out on the basis of the intended

purpose documented by the manufacturer in the instruction manual or in the promotional and sales material, which is to be available to the distributor and is to be comprehensible.

21 Similarly, it is not clear from the legislative context that the product's assessment as a medical device or as an accessory for a medical device forms no part of the distributor's verification obligation. It is true that Article 16 of Regulation 2017/745 sets out the conditions under which the distributor is to assume all of the manufacturer's obligations. However, the relevant question in the present case, namely the extent to which the distributor is obliged to verify the CE marking, which must originally be carried out by the manufacturer, is to be determined solely under Article 14 of that regulation, which is subject to the 'multiple-eyes rule' in the interest of increasing product safety and protection of health. The case-law resulting from the judgment of 8 September 2005, *Yonemoto* (C-40/04, EU:C:2005:519), is not relevant in the present case, since that judgment was given in relation to Directive 98/37/EC on machinery, which does not impose any inherent verification obligations on the distributor as regards CE marking.

22 Moreover, the relevance of questions 1 and 2 for the purposes of adjudication is not precluded by the fact that the defendant 'did everything within its power'. The application for injunctive relief may be well founded merely because the defendant did not verify, prior to the formal notice provided by the applicant, whether the product had be marked as an accessory for a medical device. If the answer to questions 1 and 2 reveals an inherent obligation on the distributor to carry out verification, the defendant would have breached that obligation and there would be a risk of repetition triggering the claim for injunctive relief, which can only be eliminated by the issuing of a declaration of intention to desist coupled with a penalty clause.

Second test purchase

23 Due to the formal notice provided to the defendant after the first test purchase and the resulting notification of the applicant's legal opinion, the second test purchase raises the question of the extent of the defendant's verification obligation (question 4), whether it is relevant if the formal notice contains a clear indication of an infringement (question 5a) and if the distributor was informed upon its enquiry by the manufacturer or a public authority that the objections raised by means of the formal notice were unfounded (question 5b).

24 Whether the second delivery of the compressor, which was carried out in the same way despite the formal notice having been given by the applicant beforehand, constitutes a separate infringement of the defendant's verification obligation depends on whether a distributor such as the defendant in a case like the present one has reason to believe, within the meaning of the third subparagraph of Article 14(2) in conjunction with Article 14(1) of Regulation 2017/745, that the product which it makes available on the market is not in conformity with the requirements of Regulation 2017/745. There is no clear answer to that question.

25 The wording of the third subparagraph of Article 14(2) of Regulation 2017/745 does not expressly indicate whether such a reason is present. However, based on the natural meaning of the term ‘reason to believe’ and the general standard of due care within the meaning of Article 14(1) of Regulation 2017/745, this could include any aspect that a reasonable distributor acting with ordinary prudence and making reasonable efforts to prevent harm to others, taking into account the circumstances, will take as grounds for verifying the question of product marking in accordance with the requirements of Regulation 2017/745.

26 According to those standards, a distributor must take a competitor’s formal notice as grounds for verifying the marking if the notice indicates a clear and specific infringement. The meaning and purpose of Regulation 2017/745 in general, and of the distributor obligation provisions under Article 14 of that regulation in particular, namely to ensure product safety and protection of health, support that view.

27 An enquiry to the manufacturer or a public authority does nothing to change this, as the first sentence of the third subparagraph of Article 14(2) of Regulation 2017/745 also states that a distributor who has reason to believe that a device is not in conformity with the requirements of that regulation is not only obliged to inform the manufacturer and, where applicable, the manufacturer’s authorised representative and the importer, but is also not to make the device in question available on the market until it has been brought into conformity.

Possible infringement due to the absence of an identification number of a notified body

28 In the appeal on a point of law, it is necessary to assume that the requirements of Regulation 2017/745 were not met in the present case also because, according to the findings of the appellate court, the compressor delivered by the defendant was not accompanied by the identification number of the notified body competent for the conformity assessment procedures referred to in Article 52 of Regulation 2017/745.

29 According to Article 20(5) of Regulation 2017/745, the CE marking is, where applicable, to be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 52 of Regulation 2017/745. Pursuant to Article 52(1) of Regulation 2017/745, prior to placing a device on the market, manufacturers are to undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI thereto. According to Article 51(1) of Regulation 2017/745, devices are to be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks, and classification is to be carried out in accordance with Annex VIII to that regulation.

30 Given the findings of the appellate court that, according to the manufacturer's instruction manual, the compressor is an accessory for a medical device, it is necessary, for the purposes of the appeal on a point of law, to proceed on the basis that the compressors at issue fall within class IIa, in accordance with Rule 9 of Annex VIII to Regulation 2017/745.

31 With regard to the prohibition on making available sought by the main application for injunctive relief, it is again necessary, pursuant to the third subparagraph of Article 14(2) of Regulation 2017/745, for the defendant to have had reason to believe that the dry air compressors delivered to the applicant were not in conformity with the requirements of that regulation because they did not bear an identification number of a notified body. The defendant would have had a reason for this belief if it had been obliged under Article 14(1) and point (a) of the first subparagraph of Article 14(2) of Regulation 2017/745 to verify, prior to making the devices available on the market, whether the devices are to be classified in class IIa within the meaning of Regulation 2017/745 and must therefore also be provided with a four-digit identification number of a notified body. In order to ascertain whether the defendant failed to fulfil that obligation, it is again necessary to distinguish between the first and the second test purchases. Question 3 referred for a preliminary ruling (in conjunction with questions 1, 2, 4 and 5) is intended to clarify these issues.

First test purchase

32 The wording of Article 14(1) and point (a) of the first subparagraph of Article 14(2) of Regulation 2017/745 does not provide a clear rule in this regard. According to those provisions, the requirements to be verified by the distributor include only the fact that the device bears the CE marking and that an EU declaration of conformity has been drawn up. The need to add the identification number is laid down in Article 20(5) of Regulation 2017/745. The aforementioned objective of that regulation to ensure legal certainty as regards the obligations of the respective economic operators could therefore militate in favour of the view that the distributor must verify only those marking elements referred to in point (a) of the first subparagraph of Article 14(2) of that regulation.

33 An interpretation based on the purpose of Article 14 of Regulation 2017/745 also does not lead to an unambiguous conclusion. Here again, the aim of that regulation to ensure a high level of safety and protection of health for patients and users, on the one hand, is set against the interests of small and medium-sized companies operating in the medical devices sector, on the other.

34 When assessing the 'whether' and the 'how' of classification of medical devices and accessories for medical devices, it must be taken into account that this raises questions in law and in fact that are significantly more complex than those raised when assessing a product as a medical device or accessory for a medical device, which cannot be answered by looking at the instruction manual or the intended purpose documented in promotional and sales materials.

35 On the contrary, classification must normally be carried out not by the manufacturer alone, but with the participation of the notified body, and any dispute between the manufacturer and the notified body concerned arising from the application of Annex VIII to Regulation 2017/745 is to be referred for a decision to the competent authority of the Member State in which the manufacturer has its registered place of business (Article 51(2) of Regulation 2017/745). It is already clear from those procedural provisions that the classification of medical devices and accessories for a medical device according to the regulatory system chosen by the legislature requires an examination of issues that are often complex in law and in fact. There are, however, devices which do not have to bear an identification number of a notified body because they fall within class I, where the manufacturer draws up the declaration of conformity without the involvement of a notified body and there is no identification number (see recital 60, Article 20(5) and Article 52(7) of Regulation 2017/745), and therefore the distributor's obligation cannot be limited to verifying whether that device has an identification number of a notified body.

36 The fact that the due care expected of the distributor is restricted in this respect is also consistent with the Commission's assessment. Accordingly, the distributor has only to know what is a 'clear' indication of the product being non-compliant (Commission Notice, The 'Blue Guide' on the implementation of EU product rules 2022 (OJ 2022 C 247, p. 1) ('Blue Guide'), p. 41 under 3.4, and p. 151). The question whether the product bears the required conformity marking(s) would have to be verified as a 'formal' requirement by the distributor only prior to the making available on the market (Blue Guide, p. 42), and the distributor would have to have 'basic knowledge' of the legal requirements for CE marking (Blue Guide, p. 151).

Second test purchase

37 Since the defendant delivered another compressor bearing the corresponding marking to the applicant after the letter of formal notice on the basis of the second test purchase, the question also arises whether notification of the applicant's legal opinion, associated with the formal notice, has an impact on the extent of the defendant's verification obligation. Questions 4 and 5 in turn are intended to clarify this.

38 In this respect, the considerations already set out in relation to questions 1 and 2 in conjunction with questions 4 and 5 are likely to be relevant. Once again, the fact that the classification of medical devices and accessories for medical devices will often be more complex in law and in fact than the assessment of a product as a medical device or accessory for a medical device must be taken into account.