



Reports of Cases

JUDGMENT OF THE COURT (Seventh Chamber)

3 September 2015*

(Reference for a preliminary ruling — Approximation of laws — Cosmetic products — Consumer protection — Regulation (EC) No 1223/2009 — Scope — Non-corrective colour contact lenses featuring designs — Statement on the outer packaging describing the product in question as a cosmetic product — Consumer protection)

In Case C-321/14,

REQUEST for a preliminary ruling under Article 267 TFEU from the Landgericht Krefeld (Germany), made by decisions of 4 June and 4 August 2014, received at the Court on 4 July and 11 August 2014 respectively, in the proceedings

Colena AG

v

Karnevalservice Bastian GmbH,

THE COURT (Seventh Chamber),

composed of J.-C. Bonichot, President of the Chamber, A. Arabadjiev and C. Lycourgos (Rapporteur),
Judges,

Advocate General: N. Jääskinen,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

- Karnevalservice Bastian GmbH, by C. Ballke, Rechtsanwalt,
- the Czech Government, by M. Smolek and S. Šindelková, acting as Agents,
- the French Government, by F. Gloaguen and D. Colas, acting as Agents,
- the European Commission, by G. Wilms and P. Mihaylova, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

* Language of the case: German.

Judgment

- 1 This request for a preliminary ruling concerns the interpretation of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ 2009 L 342, p. 59).
- 2 The request has been made in proceedings between Colena AG ('Colena') and Karnevalservice Bastian GmbH ('Karnevalservice') concerning the marketing by the latter of non-corrective colour contact lenses featuring designs ('the lenses at issue').

EU law

- 3 Recital 6 in the preamble to Regulation No 1223/2009 reads as follows:

'This Regulation relates only to cosmetic products and not to medicinal products, medical devices or biocidal products. The delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use.'

- 4 Recital 7 in the preamble to that regulation states as follows:

'The assessment whether a product is a cosmetic product has to be made on the basis of a case by case assessment, taking into account all characteristics of the product. ...'

- 5 Article 1 of Regulation No 1223/2009, entitled 'Scope and objective', provides as follows:

'This Regulation establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health.'

- 6 Article 2 of Regulation No 1223/2009, entitled 'Definitions', provides in paragraph 1 thereof as follows:

'For the purposes of this Regulation, the following definitions shall apply:

- (a) "cosmetic product" means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;
- (b) "substance" means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- (c) "mixture" means a mixture or solution composed of two or more substances;

...'

- 7 Under the heading 'Labelling', Article 19 of Regulation No 1223/2009 provides in paragraph 1 thereof, in essence, that cosmetic products are to be made available on the market only where the container and packaging of such products provide various items of information in indelible, easily legible and visible lettering, including the name or registered name and the address of the responsible person, the nominal content at the time of packaging, the date until which the cosmetic product, stored under

appropriate conditions, will continue to fulfil its initial function, particular precautions to be observed in use, the batch number of manufacture or the reference for identifying the cosmetic product and a list of ingredients.

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

- 8 Karnevalservice markets the lenses at issue in Germany. The purpose of those products is not to remedy any kind of visual deficiency but, rather, to alter the user's appearance, especially on festive occasions. The outer packaging of the lenses at issue includes the following information: 'cosmetic eye accessory, subject to the EU Cosmetics Directive'.
- 9 On 24 October 2013, Colena brought proceedings before the Landgericht Krefeld (Regional Court, Krefeld) for an injunction to prevent Karnevalservice marketing the lenses at issue unless the packaging of the lenses provided certain information required under Article 19(1) of Regulation No 1223/2009. By decisions of 29 October 2013 and 11 December 2013, that court refused to grant the injunction, holding that the lenses at issue could not be classified as 'cosmetic products' within the meaning of that regulation and, as a consequence, the regulation was not applicable.
- 10 Colena brought an appeal against that decision before the Oberlandesgericht Düsseldorf (Düsseldorf Higher Regional Court). By decision of 9 January 2014, that court reversed the decision of the Landgericht Krefeld and granted the injunction sought, finding that, notwithstanding the fact that the lenses at issue could not be classified as 'cosmetic products' within the meaning of Regulation No 1223/2009, they must none the less be subject to the provisions of that regulation, in view of the statement on the outer packaging of the lenses that they are a 'cosmetic eye accessory, subject to the EU Cosmetics Directive', which will give to the 'average consumer, who is reasonably well informed and reasonably observant and circumspect' for the purpose of German law, the impression that the product is in fact a cosmetic product within the meaning of the regulation.
- 11 On 30 January 2014, Karnevalservice challenged the injunction before the referring court, which is required to decide whether the injunction granted by the Oberlandesgericht Düsseldorf is justified.
- 12 In the order for reference, the referring court expresses the view that the answer to the question whether a product which is not a cosmetic product within the meaning of Regulation No 1223/2009 must none the less satisfy the requirements laid down in that regulation because its packaging contains a statement describing it as a cosmetic product 'subject to the EU Cosmetics Regulation' is crucial to the resolution of the dispute before it. The decision given on appeal by the Oberlandesgericht Düsseldorf, reversing the conflicting decision of the referring court, and the existence of conflicting decisions by the Landgericht Essen (Regional Court, Essen) reflect the uncertainty that exists in national case-law concerning the scope of Regulation No 1223/2009.
- 13 Moreover, the referring court observes that conflicting judicial decisions exist in Germany concerning whether contact lenses such as those at issue in the main proceedings are covered by Regulation No 1223/2009. That court considers that the answer to that question is also crucial for the purpose of the decision in the case before it.
- 14 In those circumstances, the Landgericht Krefeld decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:
 - '(1) Must Regulation No 1223/2009 be interpreted as meaning that a product which does not come under Regulation No 1223/2009 must none the less comply with the requirements of that regulation solely by reason of a statement on the outer packaging that the product is a "cosmetic eye accessory, subject to the EU Cosmetics Directive"?

- (2) Must Regulation No 1223/2009 be interpreted as meaning that “non-corrective contact lenses featuring designs” come within the scope of that regulation?

Consideration of the questions referred

- 15 By its questions, which it is appropriate to examine together, the Landgericht Krefeld seeks to ascertain, in essence, whether Regulation No 1223/2009 must be interpreted as meaning that the contact lenses at issue fall within the scope of that regulation on the ground either that they satisfy the requirements laid down for so doing or, if that is not the case, that their outer packaging bears the statement ‘cosmetic eye accessory, subject to the EU Cosmetics Directive’.
- 16 In order to determine whether a product falls within the scope of Regulation No 1223/2009, it is necessary to refer to Article 1 of the regulation, which provides that its objective is to establish rules to be complied with by ‘any cosmetic product made available on the market’. That article is supplemented by a definition of ‘cosmetic products’ in Article 2(1)(a) of the regulation.
- 17 It follows from a combined reading of those two provisions that Regulation No 1223/2009 is applicable to all products which satisfy the definition given in Article 2(1)(a) of the regulation, and only those products. By stating that the objective of the regulation is to establish a regulatory framework applicable to all cosmetic products, Article 1 limits the scope of the regulation to such products alone, and the detailed definition of ‘cosmetic product’ subsequently given in Article 2 of the regulation makes that limitation clear.
- 18 That conclusion is confirmed by recital 6 of Regulation No 1223/2009, which, while specifically making a distinction between cosmetic products on the one hand and medicinal products, medical devices or biocidal products on the other, states that the regulation relates ‘only to cosmetic products’.
- 19 It is therefore necessary to examine whether the lenses at issue meet all the criteria set out in the definition of ‘cosmetic product’ in Article 2(1)(a) of Regulation No 1223/2009. As is apparent from that provision, that definition is based on three cumulative criteria: (i) the nature of the product in question (substance or mixture); (ii) the part of the human body with which it is intended to be placed in contact; and (iii) the purpose of its use.
- 20 With regard to the first criterion, relating to the nature of the product in question, Article 2(1)(b) of Regulation No 1223/2009 defines ‘substance’ as ‘a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition’. Article 2(1)(c) of the regulation states that the word ‘mixture’ means ‘a mixture or solution composed of two or more substances’. In the light of the objective characteristics of the lenses at issue, on the basis of which they may be classified as ‘objects’, they cannot be regarded as a ‘substance’ or a ‘mixture’ within the meaning of that provision.
- 21 With regard to the second criterion, Article 2(1)(a) of Regulation No 1223/2009 sets out, in the definition of ‘cosmetic product’, the parts of the human body with which such a product is intended to be placed in contact. It gives an exhaustive list, as is abundantly clear from the detailed, precise wording of that provision, and from the fact that the EU legislature refrained in the drafting of that provision from adding any terms such as ‘as’, ‘for example’, ‘including’ or ‘etc.’, which would have indicated that the items listed were given merely by way of example. The lenses at issue are placed on the eye’s cornea, which is not referred to in that exhaustive list and does not appear in any other provision of Regulation No 1223/2009. It follows that the lenses at issue do not satisfy the second criterion.

- 22 With regard to the third criterion, which relates to the purpose of using the product, it should be noted that, as the function of the lenses at issue is to change the appearance of the eye's cornea, on which they are placed, their sole or main function is not to clean, perfume, change the appearance of, protect or keep in good condition any of the parts of the body listed in Article 2(1)(a) of Regulation No 1223/2009, or to correct body odours. Accordingly, the third criterion is not met.
- 23 It follows from an assessment which, in accordance with recital 7 of Regulation No 1223/2009, takes into account all the characteristics of the lenses at issue, that such lenses do not satisfy any of the three cumulative criteria that need to be met in order to fall within the definition of 'cosmetic product' in Article 2(1)(a) of the regulation. Accordingly, the Court finds that the lenses at issue cannot be classified as 'cosmetic products' as defined in that regulation and therefore fall outside the scope of the regulation.
- 24 That conclusion is not affected by the fact that it is stated on the outer packaging of the lenses at issue that they are a 'cosmetic eye accessory, subject to the EU Cosmetics Directive'.
- 25 Unlike the choice made by the EU legislature for other products, in particular medicinal products, the definition in Article 2(1)(a) of Regulation No 1223/2009 does not contain a category of cosmetic products defined by reference to their 'presentation', whereby it is possible to categorise a product as a 'cosmetic product' as a matter of law for the sole reason that it is presented as such.
- 26 That assessment is, however, without prejudice to the application, where appropriate, of rules enabling the competent authorities to verify whether or not the statement on the outer packaging of the lenses at issue that the product is a 'cosmetic eye accessory, subject to the EU Cosmetics Directive' constitutes misleading commercial practice.
- 27 In the light of the foregoing considerations, the answer to the questions referred is that Regulation No 1223/2009 must be interpreted as meaning that the lenses at issue do not fall within the scope of that regulation, notwithstanding the fact that their outer packaging bears the statement 'cosmetic eye accessory, subject to the EU Cosmetics Directive'.

Costs

- 28 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 (Seventh Chamber) hereby rules:

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products must be interpreted as meaning that non-corrective colour contact lenses featuring designs do not fall within the scope of that regulation, notwithstanding the fact that their outer packaging bears the statement 'cosmetic eye accessory, subject to the EU Cosmetics Directive'.

[Signatures]