Case C-618/23

Request for a preliminary ruling

Date lodged:

6 October 2023

Referring court:

Oberlandesgericht Düsseldorf (Germany)

Date of the decision to refer:

28 September 2023

Defendant and appellant:

SALUS Haus Dr. med Otto Greither Nachf. GmbH & Co. KG

Applicant and respondent:

Astrid Twardy GmbH

[…]

OBERLANDESGERICHT DÜSSELDORF (Higher Regional Court, Düsseldorf)

ORDER

In the case of

SALUS Haus Dr. med Otto Greither Nachf. GmbH & Co. KG […]

Defendant and appellant,

[…]

v

Astrid Twardy GmbH […]

Applicant and respondent,

[…]

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the 20th Civil Chamber of the Higher Regional Court, Düsseldorf […] on 28 September 2023

made the following order:

I.

The proceedings are stayed.

II.

The Higher Regional Court, Düsseldorf refers the following questions to the Court of Justice of the European Union:

1.

Are herbal medicinal teas which are to be classified as 'traditional herbal medicinal products' within the meaning of point 29 of Article 1 and Article 16a of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311 p. 67), inserted by points (1) and (2) of Article 1 of Directive 2004/24 of the European Parliament and of the Council, ('the Community code') to be regarded as 'plant-based traditional herbal preparations' within the meaning of Article 2(1) of, in conjunction with Annex I to, Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ 2018 L 150, p. 1;'the Regulation on organic production' or 'the Regulation').

2.

If the first question is answered in the affirmative:

Can the labelling provided for in Chapter IV of the Regulation, in particular

– the official organic production logo of the European Union (Article 33 of, in conjunction with Annex V to, the Regulation),

– the company's own organic production logo (Article 33(5) of the Regulation),

– the code number of the control body (Article 32(1)(a) of the Regulation),

– the place of production 'EU Agriculture' or 'non-EU Agriculture' (Article 32(2) of the Regulation),

– the term 'bio' (Article 30(2) of the Regulation), and

– the reference 'from organic production' (Article 30(1) of the Regulation),

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be affixed on the outer packaging of a medicinal product without the conditions of Article 62 of the Community code having to be fulfilled?

3.

If the first or second question is answered in the negative:

Is the labelling that is specified in the second question labelling that is ‘useful for the patient’ and is not ‘of a promotional nature’?

G r o u n d s:

I.

1 The parties distribute, among other things, traditional herbal medicinal products. In addition to the herbal teas which are to be classified as food, the defendant’s product portfolio currently includes ‘Salus Arzneitee Salbeiblätter’ (Salus sage leaf medicinal tea) […]; it is also the intention to distribute ‘BioNerven-Beruhigungstee’ (organic nerve-calming tea) […] and ‘Frauenmantelkraut’ (Alchemilla) tea […]. All the products referred to are to be classified as traditional herbal medicinal products. The (outer) packaging of the ‘Salus Arzneitee Salbeiblätter’ medicinal tea bears the official logo of the European Union pursuant to Annex V to the Regulation, the control body’s code and the statement ‘non-EU Agriculture’. The ‘BioNerven-Beruhigungstee’ packaging is to bear the official logo, the defendant’s own organic production logo, the control body’s code as well as the statement ‘from organic production’, while the packaging of the ‘Frauenmantelkraut’ tea is to bear the official logo, the control body’s code and the statement ‘EU Agriculture’. The applicant considers this to be an infringement of the 5th sentence of Paragraph 10(1) of the Arzneimittelgesetz (German Law on Medicinal Products), which transposes Article 62 of the Community code and is worded as follows:

‘Additional information which is not prescribed by a Regulation of the European Community or European Union or is already permitted pursuant to such a Regulation shall be permitted in so far as it is linked to the use of the medicinal product, is useful for the patient’s health education and does not conflict with the information referred to under Paragraph 11a.’

The applicant therefore brought an action for an injunction, information, determination of the obligation to pay damages and for reimbursement of the pre-litigation costs. The defendant opposed this, referring to the provisions of the Regulation.

2 By the judgment under appeal, the Landgericht (Regional Court) ordered the defendant to refrain in the course of trade […]

1.

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from distributing or causing to be distributed the medicinal tea ‘Salbeiblätter’ if the following details are contained on the outer packaging:

a) the organic production logo of the European Union pursuant to Annex V to Regulation (EU) 2018/848:

and/or

b) the control body’s code:

DE-ÖKO-003

and/or

c) ‘non-EU Agriculture’,

as on the outer packaging of the medicinal tea ‘Salbeiblätter’ […];

and/or

2.

from distributing and/or causing to be distributed the medicinal tea ‘Bio Nerven-Beruhigungs-Tee’ if the following details are contained on the outer packaging:

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a) the organic production logo of the European Union pursuant to Annex V to Regulation (EU) 2018/848:

and/or

d) the Salus company's own organic production logo

and/or

e) the control body's code:

DE-ÖKO-003

and/or

f) 'Bio Nerven- und Beruhigungs-Tee'

and/or

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g) ‘from organic production’,

as on the outer packaging of the medicinal tea ‘Bio Nerven Beruhigungs-Tee im Filterbeutel’ (organic nerve-calming tea in tea bags) […];

and/or

3.

from distributing and/or causing to be distributed the medicinal tea ‘Frauenmantelkraut’ (Alchemilla) if the following details are contained on the outer packaging:

a) the organic production logo of the European Union pursuant to Annex V to Regulation (EU) 2018/848:

and/or

b) the control body’s code:

DE-ÖKO-003

and/or

c) ‘EU Agriculture’,

as on the outer packaging of the medicinal tea ‘Frauenmantelkraut’ […];

3 Furthermore, the Regional Court ordered the defendant to pay the pre-litigation costs and to provide information as regards the medicinal tea ‘Salbeiblätter’ […] and to that extent determined an obligation to pay damages. As to the grounds, the Regional Court stated that all of the disputed information was unlawful pursuant to the fifth sentence of Paragraph 10(1) of the German Law on Medicinal Products. ‘Regulation of the European Community or European Union’ as referred to in the first alternative of the provision, covers, as is apparent from the explanatory memorandum, only regulations relating to medicinal products, which is not the case for the Regulation on organic production. The question of whether the Regulation on organic production is applicable here could remain open, since the labelling provisions of the legislation on medicinal products take precedence, especially since the information is not mandatory under the Regulation. The second alternative in the fifth sentence of Paragraph 10(1) of the German Law on

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Medicinal Products could not be relied on by the defendant as the information referred to in the Regulation was not directly connected with the taking of the medicinal product by the patient and was therefore not useful for the patient's health.

4 The defendant's appeal is directed against that judgment. The defendant alleges that, as a result of the extension of the material scope of the Regulation by comparison with its predecessor, Regulation (EC) No 834/2007, to cover certain non-food or feed, namely 'plant-based traditional herbal preparations' as 'other products closely linked to agriculture' in Article 2(1) of, in conjunction with Annex 1 to, the Regulation, the medicinal teas in question were now also included. That extension would be pointless if it then had no consequences. On the contrary, it argues, the provisions on labelling pursuant to the Regulation and the Arzneimittelkodex (Medicinal Products Code) apply in parallel. In any event, Article 62 of the Community code and, by interpretation in line with that directive, consequently also the fifth sentence of Paragraph 10(1) of the Law on Medicinal Products implementing that provision should be interpreted as meaning that the labelling approved under the Regulation is 'useful for the patient'. The defendant therefore requests

that the action be dismissed, amending the judgment under appeal.

5 The applicant requests

that the appeal be dismissed.

The applicant claims that, even if the material scope of the Regulation also extends to 'plant-based traditional herbal preparations' which are to be classified as medicinal products, Article 62 of the Community code and the provision of the fifth sentence of Paragraph 10(1) of the Law on Medicinal products based thereon take precedence. The derogating provision should be interpreted narrowly to protect the customer against excessive information on the outer packaging and advertising, especially since there is no obligation to disclose the organic origin.

II.

The first question

6 In order to resolve the dispute, it is relevant, first of all, whether 'plant-based traditional herbal preparations' within the meaning of Article 2(1) of, in conjunction with Annex I to, the Regulation also include those which are to be classified as medicinal products. This category is new and has no equivalent in the predecessor regulation, Regulation (EC) No 834/2007. As is evident from recital 10, the material scope was also to be extended to include certain products other than food and feed, without, however, these being defined or justified in more detail. There is no intended purpose 'as food or feed' in that category, unlike points (b) and (c) of the first sentence of Article 2(1) and some products in Annex I. In any event, the wording is such that medicinal products could also be

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covered. Doubts might arise, however, from the fact that obvious problems with the labelling (see the second and third questions) are not explicitly addressed. The scope of the Regulation in that field would then still include cosmetic products within the meaning of Regulation (EC) No 1223/2009, for which these problems do not arise.

The second question:

7 Should the Court answer the first question in the affirmative, the question then arises as to the relationship between the labelling rules pursuant to the Regulation on the one hand and pursuant to the Community code on the other hand. While the Community code contains a generally exhaustive list of particulars which may appear on the packaging, a list on which, subject to Article 62 (see the third question), the labelling approved under the Regulation is not mentioned, the Regulation permits a wide variety of particulars, some of which are mandatory where the product is regarded as bearing terms referring to organic production (Articles 30, 32 of the Regulation). However, the Regulation also permits a large number of other forms of labelling in Article 33(5).

8 Under Article 2(4), the Regulation applies ‘without prejudice to related … legislation’, except where otherwise provided. The Community code is not among the legal provisions referred to ‘in particular’. The precedence of the Community code is demonstrated by the fact that it regulates the specific risks and necessities of information on the packaging of medicinal products, and in so doing undertakes the necessary balancing exercise. The patient should be protected against excessive information and advertising. On the other hand, it might be argued that a narrower interpretation of Article 62 of the Community code would practically eliminate any application of the Regulation to medicinal products which had been specifically rendered possible by Annex I. However, it could be argued that an appropriate application of Article 62 of the Community code could take that into account. In particular Article 33(5) of the Regulation would allow a wide variety of information.

The third question:

9 Should the second question be answered to the effect that the labelling provisions of the Community code take precedence, a further question arises as to the interpretation of Article 62 of the Community code.

10 The question is not rendered irrelevant by the fact that, under national law, information is also permitted if it is declared permissible by EU regulations and the defendant could rely on it despite any non-conformity of that exception with EU law. As the Regional Court rightly points out, that provision is applied only to EU regulations relating to medicinal products, which do not include the Regulation on organic production.

11 As regards the second alternative in the fifth sentence of Paragraph 10(1) of the Law on Medicinal Products, it is evident that the wording is closer to the original

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version of Article 62 of the Community code, according to which only information 'which is useful for health education' was permitted, whereas the new version allows any and all information 'which is useful for the patient'. In so far as the wording of the German provision may be too narrow in relation to the Community code, that could not be relied on against the defendant.

12 In so far as can be ascertained, there is no established case-law of the Court of Justice as to what information 'is useful for the patient'. This therefore requires clarification. The amendment to Article 62 of the Community code referred to in paragraph 11 might militate in favour of the argument that it does not refer solely to information that is useful for the patient's health education. The previous interpretation by the German courts, according to which only information that is directly useful for the health of the patient, which does not include information on the method of manufacture, in particular the origin of herbal substances from organic production, may therefore be too narrow. Given the importance that EU law assigns to organic origin through the revision of the Regulation, this too could be 'useful for the patient'. It should be noted that, in point 8a of the first sentence of Paragraph 10(1) of the Law on Medicinal Products, the national legislature requires further information for medicinal products obtained by means of genetic engineering, and therefore in that case attaches importance to the method of production.

13 It would then also be possible to differentiate between mandatory information (Article 32 of the Regulation) and other information as referred to in Article 33(5) of the Regulation.

In the case of the latter, the greatest risk is that it may be 'of a promotional nature', whereas that is not likely to be the case in the case of mandatory information.

14 The third question also arises if the first question were to be answered in the negative, since Article 62 of the Community code would also be relevant in that case […]. However, a different weighting might then present itself. It is then unlikely that the advertiser could extend the material scope of the Regulation on its own initiative. One might well ask, however, whether reference could not be made to the origin of the plants from which the substances are extracted (statement: 'EU Agriculture' or 'non-EU Agriculture'), since that might be of interest to patients, just as in the case of food derived from plants.

[…]

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