

**Case C-418/21**

**Request for a preliminary ruling**

**Date lodged:**

9 July 2021

**Referring court:**

Oberlandesgericht Düsseldorf (Germany)

**Date of the decision to refer:**

28 June 2021

**Defendant and appellant:**

Orthomol pharmazeutische Vertriebs GmbH

**Applicant and respondent:**

Verband Sozialer Wettbewerb e. V.

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[...]

OBERLANDESGERICHT DÜSSELDORF (HIGHER REGIONAL COURT,  
DÜSSELDORF)

ORDER

In the case of

Orthomol pharmazeutische Vertriebs GmbH [...]

[...] Langenfeld,

defendant and appellant,

– [...]

v

Verband Sozialer Wettbewerb e. V., [...] Berlin,

applicant and respondent,

– [...]

the 20th Civil Chamber of the Higher Regional Court, Düsseldorf made, on 28 June 2021, the following

o r d e r:

I.

The proceedings are stayed.

II.

The Higher Regional Court, Düsseldorf refers the following questions on the interpretation of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 [...] (OJ 2013 L 185, p. 35) ('the FSG Regulation') and in relation to Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes (OJ 2016 L 25, p. 30) ('the Delegated Regulation') to the Court of Justice of the European Union

for a preliminary ruling:

1.

Under what circumstances are there other medical nutrient requirements pursuant to the second alternative in Article 2(2)(g) of the FSG Regulation, namely:

do they require – in addition to the limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food, as referred to in the first alternative – that there is an increased nutrient requirement brought about by illness, which is to be covered by the food,

or is it sufficient if the patient [...] generally benefits from the intake of that food because substances contained therein counteract the disorder or alleviate its symptoms?

2.

In the event that the first question is answered in accordance with the latter alternative:

Does ‘generally accepted scientific data’ within the meaning of Article 2(2) of the Delegated Regulation in any event presuppose a randomised, placebo-controlled double-blind study which, although not related to the product in question itself, at least provides starting points for the claimed effects?

Grounds:

- 1 The applicant is a registered association, one of the statutory duties of which is to protect the commercial interests of its members, in particular compliance with the rules of fair competition. It has standing to bring proceedings under German law.
- 2 The defendant is a pharmaceutical company and markets, in particular, foodstuffs in the form of food supplements and products which it regards as food for special medical purposes.
- 3 By the present action, the applicant challenges the marketing and advertising of ‘Orthomol Immun’ and ‘Orthomol AMD extra’ as food for special medical purposes. It takes the view that those products do not meet the requirements for classification as ‘food for special medical purposes’. It submits that such foodstuffs must be distinguished from medicinal products. ‘Orthomol Immun’ is intended to be used for cases of nutritionally acquired immunodeficiency – a disease – and, according to the defendant, to strengthen the immune system.

‘Orthomol AMD’ is intended to be used to counter the progression of a disease, namely age-related macular degeneration. They are not diseases which lead to a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites. The second alternative in Article 2(1)(g) of the FSG Regulation (‘patients ... with other medically determined nutrient requirements’) concerns only diseases or conditions that lead to special energy and nutrient requirements on the part of the patient, such as mucoviscidosis (increased salt and calorie requirements), cancer cachexia (higher quantities of nutrients) or severe wounds/burns/pressure necrosis (increased requirement for proteins and glutamine), but does not concern substances that serve to treat the disease or condition itself.

- 4 The defendant contended that the second alternative in Article 2(1)(g) of the FSG Regulation must be interpreted broadly. According to the defendant, it also concerns foodstuffs that contain substances that can be used to compensate for the consequences of a disease or to prevent the progression of the disease. ‘Orthomol Immun’ strengthens the immune system; in that respect, there is a study on the ‘Dietary efficacy of a micronutrient combination in patients with recurrent upper respiratory tract infections’ in patients susceptible to infections. The defendant submits that ‘Orthomol AMD Extra’ slows down the progression of age-related macular degeneration; this is proven by studies.

5 The Landgericht (Regional Court) shared the view taken by the applicant and prohibited the defendant, in accordance with the form of order sought, from doing the following in the course of trade

1.

placing on the market and/or distributing the product ‘Orthomol Immun’ for the dietary management of nutrition-related immune deficiencies.

2.

advertising the product ‘Orthomol Immun’ as follows:

2.1

‘Common cold? Not for me thanks!’<sup>1</sup>;

2.2

‘Using nutritional science to support the immune system’;

2.3

‘Orthomol Immun is a dietary food for special medical purposes (balanced diet), Orthomol immune for the dietary management of nutrition-related immune deficiencies (e.g. recurrent respiratory infections)’;

2.4

‘Immunocompetent cells have an increased need for micronutrients compared to other body cells due to their increased metabolic turnover. In particular folic acid, vitamin B12, zinc and iron are involved in the growth of immune cells’;

3.

placing on the market and/or distributing the product ‘Orthomol AMD extra’ for the dietary management of advanced age-related macular degeneration;

4.

advertising the product ‘Orthomol AMD extra’ as follows:

4.1

‘Restricted? Losing sight of life? I have good support’;

<sup>1</sup> The German includes the verb ‘husten’ (to cough), thereby creating a pun.

4.2

‘Using nutritional science to support advanced AMD’;

4.3

‘Orthomol AMD extra is a food for special medical purposes (balanced diet). It is suitable for the dietary management of patients with advanced age-related macular degeneration’;

4.4

Micronutrients for the dietary management of advanced macular degeneration;

4.4.1

‘The retina is characterised by high metabolic activity and light exposure.

Here, for example, vitamin C, vitamin E and zinc, with their nutritional and physiological properties, make a significant contribution to the dietary treatment of advanced age-related macular degeneration’;

4.4.2

‘The carotenoids lutein and zeaxanthin are selectively enriched in the macula and their concentration is particularly high in the macula lutea. The composition of Orthomol AMD extra is carefully tailored to the nutritional needs of AMD patients’;

in each case in so far as they occur as reproduced in a specific annex.

- 6 The defendant’s appeal is directed against that decision. It takes the view that food does not have to serve nutritional purposes, at least not exclusively. It submits that the case-law to date is still applicable. It therefore requests that the court dismiss the action, altering the contested judgment.
- 7 The applicant requests that the appeal be dismissed. It considers that the view taken by the Regional Court, which is also shared by other courts, is correct, and it argues that it is not sufficient that a nutrient being supplied has positive effects on the development of a disease in the sense that it helps to prevent, alleviate or cure it.

*The first question:*

- 8 The outcome of the dispute depends first of all on whether the contested products are a ‘food for special medical purposes’. Should this not be the case, as the applicant claims, the action would be well-founded from the outset. Under

German law, the applicant could then have the distribution and advertising prohibited by a court.

Such food is defined as follows in Article 2(2)(g) of the FSG Regulation:

food specially processed or formulated and intended for the dietary management of patients ...., to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone.

- 9 That provision replaces the definitions in Article 1(2)(b) of Directive 1999/21

foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two.

and in Article 1(2) of Directive 2009/39/EC

foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.

The Bundesgerichtshof (Federal Court of Justice) (IZR 100/06 – judgment of 4 December 2008 – *Erfokol-Kapseln*, paragraph 16 et seq.) interpreted those provisions as meaning that a particular nutritional purpose exists not only where there is a medically determined nutrient deficiency, but also where the nutrient intake is intended to counteract illnesses in other ways and the consumer can derive particular benefits from the controlled intake of certain nutrients ('broad concept of nutrition'). Commentary on that case-law expresses the view that such foodstuffs have thereby been categorised as a 'small medicinal product'.

- 10 Recently, however, there has been discussion as to whether that case-law can continue to be applicable following the entry into force of the FSG Regulation and, at the latest, since the entry into force of the Delegated Regulation. The case-law of the higher regional courts (most recently the Higher Regional Court, Frankfurt am Main – 6 U 38/20 – judgment of 16 July 2020; Higher Regional Court, Karlsruhe – 4 U 125/20 – judgment of 26 February 2021; Higher Regional Court, Schleswig – 6 U 6/20 – judgment of 25 March 2021; there is not yet any such case-law from the Court of Justice or the Federal Court of Justice) and the

published opinion of the authorities proceed on the assumption [...] that a ‘narrow concept of nutrition’ now applies in any event. According to that opinion, under the law as it stands, foods for special medical purposes require that they are developed, intended and suitable for patients whose nutritional needs cannot be met by the consumption of ordinary food because of specific diseases, disorders or medical conditions.

- 11 That view is derived, in particular, from recitals 10 et seq. of the FSG Regulation, recital 3 of the Delegated Regulation and the Commission Notice on the classification of Food for Special Medical Purposes (2017/C 401/01). The FSG Regulation was adopted precisely for the purpose of regulating the ‘uncontrolled proliferation’ that had arisen in Germany as a result of the case-law, and the resulting difficulties in establishing a distinction from medicinal products.
- 12 Against that, however, it is contended in the legal literature that the wording of the provision has not changed significantly compared to that of the previous provisions. The category of persons ‘with other medically determined nutrient requirements’ continues to exist.
- 13 The prevailing view (see paragraph 9) seems to the Chamber to stand to reason, especially against the background of the legislative history of the FSG Regulation. However, as this question arises in a large number of proceedings, the Chamber considers that it would be appropriate to obtain clarification from the Court.
- 14 The question is also material to the resolution of the dispute [...]. Nutrition-related immune deficiencies and age-related macular degeneration (AMD) are diseases. It is common ground that the foods in question do not fall within the scope of the first alternative in Article 2(2)(g) of the FSG Regulation. Nor do they serve to meet a patient’s increased nutrient requirements brought about by illness.

*The second question:*

- 15 The second question arises only if the Court answers the first question in accordance with the ‘broad concept of nutrition’ (paragraph 6). This is because, with regard to that eventuality, the parties are in dispute as to whether the documents submitted by the defendant in respect of the claimed effects of ‘Orthomol Immun’ are sufficient.
- 16 Article 2(2) of the Delegated Regulation provides that ‘food for special medical purposes shall be based on sound medical and nutritional principles’.
- 17 With regard to the efficacy of ‘Orthomol Immun’, the defendant submits a placebo-controlled, randomised double-blind study on the ‘Dietary efficacy of a micronutrient combination in patients with recurrent upper respiratory tract infections’ [...], a study on the ‘Effects of nutritional supplements on health’ [...], a study on ‘Nutritional Formula Enhanced Immune Function and Reduced Days of Symptoms of Upper Respiratory Tract Infection in Seniors’ [...] as well as

studies on ‘Immunobiological effects of micronutrients’ [...]. It follows from those studies that the addition of certain micronutrients strengthens the immune system in people with recurrent respiratory infections and thereby counteracts those infections. The applicant contends that those studies cover only patients with recurrent respiratory infections, particularly of the upper respiratory tract, and do not relate to the advertised range of applications in its entirety. In that respect, it must be stated that the studies do in fact relate only to that specific group of patients and that, for other patients, they contain at best only indications of positive effects.

WORKING DOCUMENT