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**Datasheet for the decision
of 23 April 2024**

Case Number: T 0815/22 - 3.3.09

Application Number: 16781491.2

Publication Number: 3361885

IPC: A23L33/17, A23L33/115

Language of the proceedings: EN

Title of invention:

INFANT FORMULA WITH SPECIAL LIPID ARCHITECTURE FOR PROMOTING
HEALTHY GROWTH

Patent Proprietor:

N.V. Nutricia

Opponents:

Société des Produits Nestlé S.A.
Fresenius Kabi Deutschland GmbH

Headword:

Infant formula promoting growth/NUTRICIA

Relevant legal provisions:

EPC Art. 53(c), 54(5)

Keyword:

Method of treatment excluded from patentability under Article 53(c) EPC - (No)

Purpose-limited product claim under Article 54(5) EPC - (No)

Novelty over the cited prior art documents - (No)

Decisions cited:

G 0005/83, G 0001/07, G 0002/08, T 0135/98, T 0182/16,

T 1186/16, T 0586/16

Catchword:

The use of an infant formula for promoting, in an infant, a postnatal growth trajectory or body development towards a growth trajectory or body development similar to those observed in human milk fed infants, does not qualify as a method of treatment by therapy under Article 53(c) EPC (Reasons 1.7 to 1.39).



Beschwerdekammern
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Case Number: T 0815/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 23 April 2024

Appellant: Société des Produits Nestlé S.A.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
14 February 2022 concerning maintenance of the
European Patent No. 3361885 in amended form.

Composition of the Board:

Chairman A. Haderlein
Members: A. Veronese
 N. Obrovski

Summary of Facts and Submissions

I. The opponents (appellants) filed appeals against the opposition division's decision finding that the European patent as amended according to the main request filed by letter dated 28 July 2020 met the requirements of the EPC.

II. Claim 1 of the main request reads:

"1. A nutritional composition selected from an infant formula and a follow on formula comprising 3 to 7 g lipid/100 kcal, 1.25 to 5 g protein/100 kcal and 6 to 18 g digestible carbohydrate/100 kcal and comprising lipid globules having

a) mode diameter, based on volume of at least 1.0 μm and/or having a diameter of 2 to 12 μm in an amount of at least 45 volume % based on total lipid, and

b) on the surface at least partly a coating of phospholipids

for use in promoting a postnatal growth trajectory or body development in an infant towards a growth trajectory or body development which is similar to the growth trajectory or body development observed in human milk fed infants."

III. The documents submitted during the opposition proceedings included:

D2: WO 2010/027258 A1

D3: WO 2010/027259 A1

D8: WO 2012/173486 A1

- D16: Bulletin of the World Health Organization
2011; vol. 89(4), p. 250-251. doi:10.2471/BLT.
11.040411 "New WHO child growth standards
catch on"
- D17: Young et al., Advanced Nutrition, 2012;
vol. 3, p. 675-686

- IV. The opposition division found, *inter alia*, that the claims related to therapeutic uses of the claimed infant formula and that they had to be construed as purpose-limited product claims under Article 54(5) EPC. It then considered that none of the cited documents disclosed those uses and that, consequently, the claimed subject-matter was novel.
- V. In reply to the appellants' statements setting out the grounds of appeal, the patent proprietor (respondent) filed a main request, corresponding to the request considered allowable by the opposition division, and auxiliary requests 1 to 19. With a letter dated 18 April 2024 the respondent withdrew auxiliary requests 4 to 7, 12 to 15, 18 and 19.
- VI. Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the lipid in the composition:

"comprises triglycerides that comprise at least 10 wt.% palmitic acid based on total fatty acids, and wherein at least 15 % of the palmitic acid is present at the sn-2 position of the triglycerides"
- VII. Claim 1 of auxiliary request 2 differs from claim 1 of the main request on account of the following feature:

"... wherein the growth trajectory or body development is the growth trajectory or body development of the first 12 months of life of the infant."

- VIII. Claim 1 of auxiliary request 3 differs from claim 1 of the main request in that it contains the additional features characterising claim 1 of both auxiliary requests 1 and 2.
- IX. Claim 1 of auxiliary request 8 corresponds to claim 1 of the main request.
- X. Claim 1 of auxiliary request 9 corresponds to claim 1 of auxiliary request 1.
- XI. Claim 1 of auxiliary request 10 corresponds to claim 1 of auxiliary request 2.
- XII. Claim 1 of auxiliary request 11 corresponds to claim 1 of auxiliary request 3.
- XIII. Claim 1 of auxiliary request 16 differs from claim 1 of the main request on account of the following additional feature:

"wherein at 12 months the infant has a weight and/or BMI and/or weight for length that is approximate to the weight and/or BMI and/or weight for length at 12 months of human milk fed infants"
- XIV. Claim 1 of auxiliary request 17 differs from claim 1 of the main request in that it contains the aforementioned additional features of claim 1 of both auxiliary requests 1 and 16.

XV. The appellants' arguments relevant for the decision can be summarised as follows.

- The claims did not relate to a therapeutic method of treatment. Promoting a postnatal growth trajectory or body development similar to that observed in human milk-fed infants was not a therapeutic use. The tests in the patent did not provide evidence of any therapeutic effects. The risk of obesity in infants fed with compositions according to the invention was the same as that observed with compositions of the prior art. Thus, the claims were not purpose-limited product claims under Article 54(5) EPC; they merely defined infant formulas suitable for promoting the claimed growth and body development.
- Several documents, including D2, D3 and D8, disclosed infant formulas comprising all the ingredients specified in the claims, including lipid globules having the claimed lipid architecture. These infant formulas were suitable for the uses mentioned in the claims. Therefore, the claimed subject-matter lacked novelty.
- These arguments applied to the main request as well as to the auxiliary requests.

XVI. The respondent's arguments relevant for the decision are summarised as follows.

- The claims related to a therapeutic method of treatment and were purpose-limited under Article 54(5) EPC. The skilled person understood that the claims related to formula-fed infants and that these infants were at risk of developing

metabolic diseases such as diabetes. By providing a growth trajectory similar to that observed in breastfed infants, these diseases could be prevented in formula-fed infants. Thus, the claimed uses were therapeutic and the claims were limited to therapeutic uses. Since none of the cited prior art documents disclosed these uses, the claimed subject-matter was novel.

- These arguments applied to the main request as well as to the auxiliary requests. The auxiliary requests addressed the objections of lack of sufficiency and inventive step raised by the appellants.

The requests

- XVII. The appellants requested that the decision under appeal be set aside and that the patent be revoked.
- XVIII. The respondent requested that the appeals be dismissed (main request) or, alternatively, that the patent be maintained on the basis of auxiliary requests 1 to 3, 8 to 11, 16 and 17 as filed with the reply to the statements setting out the grounds of appeal.

Reasons for the Decision

Main request

1. *Claim construction*

1.1 Claim 1 relates to:

- an infant formula or follow-on formula comprising lipid globules having a certain lipid architecture,

defined by a specific minimum globule size and the presence of a phospholipid coating

- the formula being for use in promoting a postnatal growth trajectory or body development in an infant towards a growth trajectory or body development similar to that observed in human milk-fed infants

1.2 According to the respondent, the invention related and was limited to a therapeutic use of the nutritional composition. Referring to D16 and D17 the respondent argued that the benefits of breastfeeding on growth and long-term health were well known and that formula-fed infants, i.e. infants who were non-breastfed, were known to be at risk of developing metabolic diseases such as obesity. It also argued that by inducing a growth trajectory or body development similar to that observed in breastfed infants, the risk of those diseases was diminished. Hence, the claimed composition had a prophylactic therapeutic effect.

1.3 It submitted in particular that attaining a postnatal growth trajectory or body development comparable with breastfed infants reduced the risk of metabolic disturbances in the "at-risk" group of infants fed with the claimed infant or follow-on formula as defined in the claims, rather than a "regular" infant formula.

1.4 Therefore, in its opinion, claim 1 did not merely relate to feeding an infant to promote growth, but to the use of the claimed infant formula in an "at-risk" group of formula-fed infants to promote a growth pattern or body development which prevented the occurrence of metabolic diseases such as diabetes.

1.5 Thus, the claim related to a therapeutic effect and had to be construed as a purpose-limited product claim under Article 54(5) EPC limited to this effect.

1.6 The board does not agree with the respondent's view.

Therapeutic methods under Article 53(c) EPC and purpose-limited product claims under Article 54(5) EPC

1.7 By virtue of a legal fiction, Article 54(5) EPC acknowledges the notional novelty of substances or compositions even when they are already comprised in the state of the art, provided they are claimed for a new use in a therapeutic method practised on the human or animal body which Article 53(c) EPC excludes from patent protection. In such cases the notional novelty is derived not from the substance or composition as such but from its intended therapeutic use (see G 2/08, Reasons 5.10.9, second and third paragraphs).

1.8 Articles 53(c) and 54(5) EPC are complementary (see G 2/08, Reasons 5.10.9, first paragraph). Article 53(c), first clause, EPC excludes, *inter alia*, therapeutic methods from patentability. The reasons for excluding such methods from patent protection are socio-ethical and public health considerations. Medical and veterinary practitioners should be free to use their skills and knowledge of the best available treatments to achieve the utmost benefit for their patients uninhibited by any worry that a therapeutic method might be covered by a patent (see G 1/07, Reasons 3.3.6). The concept of "therapy" includes treatment with chemical substances or compositions (see G 5/83, Reasons 10).

- 1.9 Whereas method claims directed to therapy are absolutely forbidden in order to leave the physician free to act unfettered, product claims are allowable under Article 53(c), second clause, EPC provided their subject-matter is new and inventive (see G 2/08, Reasons 5.7). Moreover, Article 54(5) EPC expressly allows patent protection of substances or compositions already known as medicines provided their use in a method under Article 53(c) EPC is specific and not comprised in the state of the art (see G 2/08, Reasons 5.9).
- 1.10 Article 54(5) EPC explicitly refers to a substance or composition for any specific use in a method referred to in Article 53(c) EPC. Hence, "the special approach to the derivation of novelty" under these provisions can be applied only to claims relating to the use of substances or compositions in methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body which are excluded from patent protection by Article 53(c) EPC (see in that regard also G 2/08, Reasons 7.1.1, first and second paragraphs, and G 5/83, Reasons 21, last sentence).
- 1.11 In G 1/07 the Enlarged Board stated that the exclusion under Article 53(c) EPC served "the purpose of, in the interests of public health and of patients, specifically freeing the medical profession from constraints which would be imposed on them by patents granted on methods for surgical or therapeutic treatment", thereby explicitly including therapeutic treatments in the statement. It further stated that the exception under Article 53(c) EPC concerning surgical methods must cover the kind of interventions which represent the core of the medical profession's

activities, i.e. the kind of interventions for which the members of the medical profession are specifically trained and for which they assume a particular responsibility (see G 1/07, Reasons 3.4.2.3, first paragraph). In addition, the Enlarged Board held that the exclusion from patentability under Article 53(c) EPC should not be applied to methods in respect of which the interests of public health, of protection of patients and as a counterpart to that of the freedom of the medical profession to apply the treatment of choice to their patients do not call for their exclusion from patentability (see G 1/07, Reasons 3.4.2.4, third paragraph).

1.12 The present board considers that similar considerations apply to the exception under Article 53(c) EPC concerning therapeutic methods.

1.13 It is established case law that both curative and prophylactic methods of treating disease are covered by the word therapy, since both are directed to the maintenance or restoration of health (Case Law of the Boards of Appeal, 10th edition, 2022, I.B.4.5.1(b)). It is, however, important not to dilute the concept of treatment by therapy within the meaning of Article 53(c) EPC. Taking into account the rationale underlying this article as set out above, this concept must be understood as the curative or prophylactic treatment of a pathological condition which is part of the core of the medical profession's activities.

1.14 Malnutrition occurs when a human or animal gets either too few or too many of certain nutrients (by ingesting too little, too much or the wrong kind of food). A malnourished subject may develop a variety of diet-related diseases.

- 1.15 However, it would go against the rationale underlying Article 53(c) EPC as set out above if the ordinary provision of food (i.e. of a substance containing nutrients) in order to provide nourishment - and without any further qualification - were considered a prophylactic therapeutic method within the meaning of this provision.
- 1.16 Furthermore, not every deviation from what is considered an optimum diet results in a pathological condition the treatment of which is part of the core of the medical profession's activities.
- 1.17 As stated before, the exception under Article 53(c) EPC and the special approach to the derivation of novelty under Article 54(5) EPC are complementary. Hence, if a certain method does not qualify as a therapeutic method under Article 53(c) EPC, a claim directed to the substance or composition for a further use in such a method cannot qualify as a medical use claim under Article 54(5) EPC either. The board considers that this is the situation in this case. The board reaches this conclusion by taking into account the rationale underlying Article 53(c) EPC as set out above, as well as earlier relevant case law and the specific circumstances of the case in hand, which will be discussed in the following.

Earlier case law on nutritional compositions allegedly falling under Article 54(5) EPC

- 1.18 In T 586/16, the board, acknowledging that ordinary nutrition is needed for maintaining the body's principal functions, held that it would take the definition of therapeutic treatment too far if every

parent feeding their newborn baby with an infant formula were considered to be carrying out a therapeutic step. The board further stated that not even the provision of nutritional support to malnourished individuals was necessarily a therapeutic treatment, since it may merely include the normal process of eating.

- 1.19 In T 182/16 the claims were directed to an infant composition for use in "improving body composition", the improvement being selected from an "increase in lean body mass and increased muscle mass". According to the patent proprietor in this case, an increase in the lean body mass and muscle mass in the infant reduced the risk of developing obesity and associated secondary disorders. Thus, in its opinion, the claims fell under Article 54(5) EPC and were intrinsically limited to those prophylactic benefits.
- 1.20 The board did not agree. It considered that the claimed improvements of body composition "were typically non-therapeutic and in any case covered non-therapeutic improvements". Consequently, the board refuted the proprietor's argument that a claim directed at obtaining an effect, e.g. at increasing lean body mass, which can induce therapeutic benefits, e.g. reduce the risk of developing obesity, is "intrinsically" purpose-limited to those therapeutic benefits, under Article 54(5) EPC.
- 1.21 The board also explained that the wording "composition for use" adopted in the claims did as such not imply that these related to a method referred to in Article 53(c) EPC, because there was "nothing in the claim to indicate that its scope is intended to be

restricted to uses which are prophylactic against medical conditions or therapeutic in other ways".

- 1.22 In T 1186/16 the claims related to a food material comprising palatinose for reducing the postprandial increase of blood glucose levels induced by the ingestion of foods comprising, e.g. carbohydrates.
- 1.23 The patent proprietor in this case did not dispute that the patent mentioned neither the term "therapy" nor the treatment of any disease associated with a dysfunction of the glucose metabolism, e.g. diabetes. Nor did it dispute that the studies in the patent were conducted with healthy patients. It argued, however, that the skilled person would have recognised that the claims concerned exclusively individuals vulnerable to hyperglycaemia requiring a therapeutic control of blood glucose levels. Thus, the claims were purpose-limited under Article 54(5) EPC.
- 1.24 The board did not find these arguments convincing. It noted that fluctuations of glucose blood levels were physiological and that glycaemia typically increased after consumption of carbohydrates. This natural phenomenon occurred in healthy individuals, without being associated with any pathological condition. Furthermore, a reduction in postprandial glucose levels induced non-therapeutic benefits in healthy individuals. For example, it increased the endurance performance in athletes. Thus, the claims were not limited to a therapeutic method of treatment. To the extent that they encompassed non-therapeutic uses, they did not fall under Article 54(5) EPC and could not derive their novelty from the allegedly newly discovered effect of reducing postprandial blood glucose levels.

1.25 Thus, in T 1186/16 the board confirmed that a claim directed at obtaining an effect - reducing postprandial glycaemia - which may result in a therapeutic benefit in subjects requiring control of glucose levels was not "intrinsically" purpose-limited to those therapeutic benefits under Article 54(5) EPC.

1.26 In decision T 135/98, the relevant claim related to a fish-feed containing certain ingredients "for use in obtaining a prophylactic effect on diseases or improved health and growth for fish fed with said feed". According to the proprietor, this use was limited to a medical treatment of the animal body.

1.27 The board did not agree in this case either. It noted that the claim did not specify either the pathological conditions to be prevented or any detail of the alleged improvement, in terms of the health and growth achieved by feeding fish with the claimed diet. The board then considered that any prophylactic effect on an unspecified disease and any unspecified improvement in health and growth had to be regarded as the natural function or direct consequence of properly feeding the fish with the claimed feed. Thus, the use indicated in the claim was the optimal satisfaction of the nutritional requirements of farmed fish. This use was not therapeutic and the claim was not limited to a medical use.

The case in hand: infant formula for promoting the growth trajectory observed in breastfed infants

1.28 Like the boards in the aforementioned cases, the board in this case considers that the use indicated in claim 1 is not therapeutic and that, for this reason,

the claim cannot be considered a purpose-limited product claim falling under Article 54(5) EPC.

- 1.29 The idea underlying the claimed invention is to administer a nutritional composition for infants which is similar to human milk, in order to promote a postnatal growth trajectory or body development which is similar to that observed in infants fed with human milk.
- 1.30 It is uncontested that breastfeeding is the natural way and the "gold standard" to provide nourishment and promote normal healthy growth in an infant. It is also uncontested that even if breastfeeding does induce optimal growth and prevent the development of metabolic disturbances which may occur in sub-optimally nourished infants, it is not a therapeutic method or intervention.
- 1.31 The purpose of feeding an infant with an infant formula or follow-on formula instead of breastfeeding is the same as that of breastfeeding, namely to provide nourishment and to promote the normal growth of the infant. For all infants, receiving nourishment is a prerequisite for healthy development and for preventing disorders which could arise if an infant is malnourished or fed with a food which does not promote normal growth. Hence, feeding an infant with a formula promoting normal growth and body development is, as such, not therapeutic.
- 1.32 The board further notes that claim 1 does not refer to infants who are affected by or at risk of any disorder. Furthermore, paragraph [0009] of the patent explicitly states that all the infants concerned (i.e. the infants

in both of the groups compared in the study) are healthy.

- 1.33 It must also be considered that the manufacture and commercialisation of infant formulas are subject to strict regulations which require the formulas to provide adequate nourishment, promote normal growth and fulfil safety requirements. However, if these regulations are complied with, infant formulas can be put on the market and purchased in a non-medical, commercial environment. Moreover, their use is left to the caregivers' responsibility and is not considered a medical intervention undertaken by members of the medical profession.
- 1.34 Considering all of the above, excluding from patentability, under Article 53(c) EPC, the use of infant formulas for providing nourishment and promoting the normal growth trajectory and body development observed in breastfed infants would not serve the purpose of excluding therapeutic treatments from patentability in the interest of public health. For the same reason, the use of such infant formulas does not qualify as a medical use under Article 54(5) EPC either.
- 1.35 The respondent further argued that infant formulas which do not contain lipid globules having the claimed lipid architecture do not promote the growth trajectory observed in breastfed infants and, as a result, increase the risk of metabolic disorders. In its opinion, since these diseases are prevented using infant formulas comprising lipid globules having the claimed lipid architecture instead of those not containing them, the claimed use is therapeutic.

- 1.36 These arguments are not convincing either. It is beside the point whether or not there are infant formulas that induce a sub-optimal growth trajectory and, possibly, an increase in the risk of metabolic disorders. What matters is that feeding an infant with an infant formula promoting normal growth and body development is not therapeutic. This follows from the rationale underlying Article 53(c) EPC as set out above.
- 1.37 Furthermore, the assumptions on which the respondent's arguments are based are contradicted by the results observed in the infants involved in the study described in the patent. Irrespective of whether they were fed with the formula of the invention or a reference one comprising smaller globules and inducing a different growth trajectory, all the infants were found to be healthy and not at risk of obesity; see example 3 and in particular paragraph [0101] of the patent.
- 1.38 For these reasons, the board concludes that the use of the formula specified in claim 1 to promote a "growth trajectory" and "body development" similar to those observed in breastfed infants is not a therapeutic method of treatment under Article 53(c) EPC. Accordingly, claim 1 does not qualify as a purpose-limited product claim falling under Article 54(5) EPC. The claimed subject-matter merely defines an infant or follow-on formula suitable for the claimed uses.
- 1.39 Generally speaking, the assessment of whether an intended use can be considered therapeutic under Article 53(c) EPC and whether a claim referring to that use can be construed as falling under Article 54(5) EPC depends on the specific circumstances of each case.

- 1.40 A claim referring explicitly to the curative or prophylactic treatment of a pathological disease will usually be understood as being related to a therapeutic use.
- 1.41 In certain circumstances, in order to obtain broad patent protection for their invention, parties may consider it desirable to draft purpose-limited product claims without explicitly mentioning any specific diseases in the claim and to refer instead, for example, to the attainment of a biological effect which allegedly plays a beneficial role in the treatment or prevention of an entire class of diseases.
- 1.42 However, when such claims are drafted, there is the risk, which materialised in the case in hand, that the intended use will not be considered therapeutic and that the claims will therefore not be construed as falling under Article 54(5) EPC.
- 1.43 For completeness, the board notes that, as stated in T 182/16, Reasons 2.3.3, the mere choice of the wording "composition for use" is not sufficient for a claim to qualify as a medical use claim under Article 54(5) EPC. Rather, the claimed use must be understood, from the perspective of the person skilled in the art, as being therapeutic, including with regard to the pathological condition(s) intended to be treated or prevented.

2. *Novelty*

- 2.1 The appellants argued that the subject-matter of claim 1 was not novel over, *inter alia*, the teaching of D2, D3 and D8. In particular, the appellants referred to the infant formulas comprising lipid globules having the claimed lipid architecture disclosed in:

- D2, example 4 and page 11, lines 1-24
- D3, example 4 and page 9, lines 16-26
- D8, example 4 on pages 33 and 34

2.2 The respondent did not dispute that these documents disclosed infant formulas containing all the ingredients specified in claim 1, including the lipid globules. It argued, however, that claim 1 was purpose-limited under Article 54(5) EPC and that the specified uses distinguished the claimed subject-matter from the teaching of the prior art documents.

2.3 This argument fails to persuade. As already mentioned above, the uses specified in claim 1 are not therapeutic and do not limit the claimed subject-matter to a therapeutic treatment under Article 54(5) EPC, let alone to the prevention of metabolic disorders.

2.4 Since the infant formulas disclosed in D2, D3 and D8 comprise all the ingredients specified in claim 1, they are suitable to promote a postnatal growth trajectory and body development similar to those observed in human milk-fed infants. Accordingly, the subject-matter of claim 1 lacks novelty over the teaching of these documents.

Auxiliary request 1

3. *Novelty*

3.1 Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the composition comprises triglycerides containing a certain amount of palmitic acid and in that a certain amount of the palmitic acid is in position sn-2 of the triglycerides.

3.2 It was not contested that the infant formula of example 4 of D8 fulfils this additional requirement. Therefore, for the same reasons already discussed above when dealing with the main request, the subject-matter of claim 1 of auxiliary request 1 is not novel either.

Auxiliary request 2

4. *Novelty*

4.1 Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the use is further characterised by the growth trajectory or body development being that of the first 12 months of the infant's life. However, it was not contested that the compositions of the prior art are suitable for this use. Hence, the subject-matter of claim 1 is not novel for the same reasons discussed when dealing with the main request.

Auxiliary requests 3, 8 to 11, 16 and 17

5. *Novelty*

5.1 Claim 1 of auxiliary requests 3 and 8 to 11 is characterised by the same features characterising claim 1 of the main request and/or of auxiliary requests 1 and 2. The use defined in claim 1 of auxiliary requests 16 and 17 is further characterised by features relating to the infant's weight or BMI at 12 months. However, it was not contested that the compositions of the prior art are suitable for the claimed use. The claimed subject-matter is thus not novel for the same reasons already discussed when dealing with the previous requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



K. Götz-Wein

A. Haderlein

Decision electronically authenticated