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Datasheet for the decision of 2 May 2024

Case Number: T 1396/22 - 3.3.09

Application Number: 08854301.2

Publication Number: 2224826

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Language of the proceedings: EN

Title of invention:
AGE-TAILORED NUTRITION SYSTEM FOR INFANTS

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
Fresenius Kabi Deutschland GmbH
N.V. Nutricia

Headword:
Age-tailored nutrition system for infants/NESTLÉ

Relevant legal provisions:
EPC Art. 54, 56, 100(a)
RPBA 2020 Art. 12(4), 13(1)

Keyword:
Novelty - main request and auxiliary requests 1 and 5 (no)
Inventive step - auxiliary requests 2 to 4 and 6 to 11 (no)
Amendment to case - evidence

Decisions cited:
T 0009/81, T 0468/11

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Case Number: T 1396/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 2 May 2024

Appellant: (Opponent 1)	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg (DE)
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Respondent: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Karlstraße 7 80333 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 31 March 2022 rejecting the opposition filed against European patent No. 2224826 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	C. Meiners
	R. Romandini

Summary of Facts and Submissions

I. This decision concerns the appeal filed by opponent 2 (appellant) against the opposition division's decision to reject the oppositions filed against the patent in suit (hereinafter "the patent"). Opponent 1 had also filed an appeal which it then withdrew. It is therefore party as of right under Article 107 EPC.

II. In its decision, the opposition division determined, *inter alia*, that the subject-matter of claims 1 and 13 as granted was novel over (among other things) documents D2 and D2a. Furthermore, the subject-matter of claims 1 and 13 was found to involve an inventive step in view of (among other things) document D14 as the closest prior art.

III. In their notices of opposition, opponents 1 and 2 had requested revocation of the patent on the basis of, *inter alia*, Article 100(a) EPC for lack of novelty and inventive step.

IV. Relevant documents/evidence filed by the parties

The following documents, filed in the opposition proceedings, are relevant to this decision:

D2 E. Riva *et al.*, "Closer to the Gold Standard: an Appraisal of Formulae Available in Italy for Use in Formula-fed Infants", *The Journal of International Medical Research*, 2005, 33, 595-611

D2a E. Riva *et al.*, "Comparison of the nutritional values of follow-on formulae available in Italy",

The Journal of International Medical Research, 2007, 20, 20-37

D8 C. Dupont, "Protein requirements during the first year of life", *Am J Clin Nutr*, 2003, 77(suppl), 1544S-9S

D14 S. J. Fomon, "Requirements and Recommended Dietary Intakes of Protein during Infancy", *Pediatric Research*, 1991, 30(5), 391-395

D16 Codex Alimentarius: Standard for infant formula and formulas for special medical purposes intended for infants; CODEX STAN 72-1981. Revised version 2007

D19 J. Spalinger *et al.*, American Academy of Pediatrics National Conference and Exhibition, October 24-27, 2017

D20 J. Spalinger *et al.*, "Growth of infants fed formula with evolving nutrition composition: a single-arm non-inferiority study", *Nutrients*, 2017, 9, 219; doi10.3390/nu9030219

Together with its statement of grounds of appeal, the appellant submitted the following documents and requested that they be admitted into the proceedings:

D29 Forum discussion, 27 January 2004, https://neonato.alfemminile.com/forum/latte-artificialehumana-e-puntini-rossi-fd1434746

D29a Forum discussion, 27 January 2004, Google machine translation of above link of D29.

D30 Humana 1 and Humana 2 product descriptions and product specification sheets, 8 May 2006, https://web.archive.org/web/20060508065924/https://www.humana.it/prodotti/index.asp?main=3&Lvl1=1&Lvl2=10&Lvl3=1&prod=5

https://web.archive.org/web/20060508065948/http://www.humana.it/pop/scheda_latti.asp?prod=5

https://web.archive.org/web/20060508070137/http://www.humana.it/prodotti/index.asp?main=3&Lvl1=1&Lvl2=10&Lvl3=3&prod=7

https://web.archive.org/web/20060508070204/http://www.humana.it/pop/scheda_latti.asp?prod=7

D30a Humana 1 and Humana 2 product descriptions and product specification sheets, 8 May 2006, Google machine translations of above links of D30

D31 Humana plus product description and product specification sheet, 8 May 2006,

https://web.archive.org/web/20060508070213/http://www.humana.it/prodotti/index.asp?main=3&Lvl1=1&Lvl2=10&Lvl3=2&prod=6

https://web.archive.org/web/20060508070226/http://www.humana.it/pop/scheda_latti.asp?prod=6

D31a Humana plus product description and product specification sheet, 8 May 2006, Google machine translation of above links of D31

With its letter dated 17 August 2023, the patent proprietor (respondent) filed document D32:

D32 WayBack Machine Extracts from May 8, 2006 for Humana 1, Plus, 2 and 3, and from March 22, 2010 for Humana 1

V. *Wording of the relevant claims*

Claim 1 of the main request (claim 1 as granted) reads:

"Use of a protein source comprising whey and casein proteins for providing an age-tailored nutrition system for an infant which system comprises two infant formulas each appropriate to an infant of a different age and each comprising the protein source wherein the whey:casein ratio of each formula is chosen in the range from 100:0 to 40:60 and decreases according to the age of the infant and the protein content of each formula is chosen in the range from 1.5 to 3.0g protein/100 kcal and decreases according to the age of the infant."

Claim 13 as granted reads:
"An age-tailored nutrition system comprising two infant formulas each appropriate to an infant of a different age and each comprising a protein source wherein the whey:casein ratio of each formula is chosen in the range from 100:0 to 40:60 and decreases according to the age of the infant and the protein content of each formula is chosen in the range from 1.5 to 3.0 g protein/100kcal and decreases according to the age of the infant."

Claim 1 of auxiliary request 1 reads (amendments with respect to claim 1 as granted highlighted):
"Use of a protein source comprising whey and casein proteins for providing an age-tailored nutrition system for an infant from birth to two months which system comprises a first infant formula having a protein source comprising whey and optionally casein proteins and having a whey:casein ratio between 100:0 and 60:40 and a protein content between 2.0 and 3.0g protein/100

kcal and a second infant formula having a protein source comprising whey and casein proteins and having a whey:casein ratio between 70:30 and 50:50 and a protein content between 1.8 and 2.0g protein/100 kcal, ~~two infant formulas each appropriate to an infant of a different age and each comprising the protein source~~ wherein the whey:casein ratio of each formula ~~is chosen in the range from 100:0 to 40:60 and~~ decreases according to the age of the infant and the protein content of each formula ~~is chosen in the range from 1.5 to 3.0g protein/100 kcal and~~ decreases according to the age of the infant."

Claim 11 of that request reads:
"An age-tailored nutrition system for an infant from birth to two months comprising a first infant formula having a protein source comprising whey and optionally casein proteins and having a whey:casein ratio between 100:0 and 60:40 and a protein content between 2.0 and 3.0g protein/100 kcal and a second infant formula having a protein source comprising whey and casein proteins and having a whey:casein ratio between 70:30 and 50:50 and a protein content between 1.8 and 2.0g protein/100 kcal, ~~two infant formulas each appropriate to an infant of a different age and each comprising a protein source~~ wherein the whey:casein ratio of each formula ~~is chosen in the range from 100:0 to 40:60 and~~ decreases according to the age of the infant and the protein content of each formula ~~is chosen in the range from 1.5 to 3.0 g protein/100kcal and~~ decreases according to the age of the infant."

Claim 1 and claim 10 of auxiliary request 2 correspond to claim 1 and claim 11 of the first auxiliary request but contain the additional limitation "[,] and wherein the infant formulas additionally comprise a lipid

source and the lipid content of each formula is chosen in the range from 4.5 to 6.0g lipid/100kcal generally decreasing with increasing age of the infant".

Compared to the aforementioned corresponding claims of the second auxiliary request, claims 1 and 9 of auxiliary request 3 contain the further restriction "[,] and wherein the infant formulas additionally comprise a carbohydrate source and the carbohydrate content of each formula is chosen in the range from 9.0 to 12.0g carbohydrate/100kcal generally increasing with increasing age of the infant".

Claim 1 of auxiliary request 4 is identical to that of auxiliary request 3.

Claim 1 of each of auxiliary requests 5 to 7 is identical to the respective *product* claim of auxiliary requests 1 to 3.

Claim 1 of each of auxiliary requests 8 and 9 reads: "Use of a protein source comprising whey and casein proteins for providing an age-tailored nutrition system for an infant which system comprises ~~two infant formulas each appropriate to an infant of a different age and each comprising the protein source~~
- a first infant formula for the first two to four weeks of life having a protein source with a whey:casein ratio between 80:20 and 60:40 and a protein content between 2.0 and 3.0 g protein/100 kcal,
- a second infant formula from the age of two to four weeks to the age of two months having a whey:casein ratio between 70:30 and 50:50 and a protein content between 1.8 and 2.0g protein/100 kcal, and
- a third infant formula from the third to sixth months of life having a whey:casein ratio between 70:30 and

50:50 and a protein content between 1.8 and 2.0g protein/100 kcal, wherein both the protein content and the whey:casein ratio of the third formula are lower than for the second formula~~wherein the whey:casein ratio of each formula is chosen in the range from 100:0 to 40:60 and decreases according to the age of the infant and the protein content of each formula is chosen in the range from 1.5 to 3.0g protein/100 kcal and decreases according to the age of the infant~~."

Claim 1 of auxiliary request 10 reads:
"An age-tailored nutrition system comprising
- a first infant formula with a whey:casein ratio of 70:30 and a protein content of 2.5g protein/100 kcal for an infant in the first two weeks of life,
- a second infant formula with a whey:casein ratio of 60:40 and a protein content of 2.0g protein/100 kcal for an infant in the next six weeks of life and
- a third infant formula with whey:casein ratio of 60:40 and a protein content of 1.8g protein/100 kcal for an infant in the third to sixth months of life,
wherein both the whey: casein ratio and the protein content decrease with increasing age of the infant."

Claim 1 of auxiliary request 11 corresponds to claim 1 of auxiliary request 10 but contains the additional limitation "and
- a fourth infant formula having a whey:casein ratio of 50:50 and a protein content of 1.8g protein/100 kcal for an infant in the second six months of life[,]".

VI. The appellant's arguments relevant to the present decision can be summarised as follows:

(a) Documents D29 to D31 and D29a to D31a should be admitted into the appeal proceedings.

(b) The "nutrition system" claimed encompassed two infant formulas provided as a compilation, a set or product line where there was a commercial link between the sale of the products. A non-therapeutic use indication for a product had to be ignored for the purpose of examining novelty and inventive step. It was sufficient for the product to be suitable for that use. Consequently, the subject-matter of claims 1 and 13 as granted lacked *novelty* over each of, *inter alia*, document D2 alone, documents D2 plus D2a and D30/D30a alone.

(c) The main request lacked *inventive step* in view of, *inter alia*, document D14 in combination with, *inter alia*, document D8. No effect had been demonstrated that could be causally associated with whey to casein ratios as claimed in claims 1 and 13 as granted.

(d) The arguments in relation to novelty and inventive step also applied to each of auxiliary requests 1 to 11.

VII. The respondent's arguments relevant to the present decision can be summarised as follows:

(a) Documents D29/29a to D31/D31a should not be admitted into the appeal proceedings since they had been filed late.

(b) As to *claim interpretation*, claims 1 and 13 as granted were directed towards a kit of parts, wherein in both claims the kits were provided so as to allow a common technical effect to be achieved on an infant that was fed in a timely staggered

manner. The order of decreasing protein and whey to casein ratio according to the age of the infant and their functional unity were features in claims 1 and 13 that had to be taken into account for the purposes of assessment of novelty.

(c) Concerning *novelty*, the subject-matter claimed was novel over each of the documents cited against the novelty of granted claims 1 and 13. In particular, Humana 1 and Humana Plus could not be considered as related pairs.

(d) As to *inventive step*, the subject-matter claimed was not obvious in view of the prior art. In particular, the objective technical problem underlying claims 1 and 13 in view of D14 was to provide infant nutrition that as far as possible replicated human milk in terms of its nutritional properties. The solution was not obvious. Document D8 did not teach towards the claimed subject-matter either.

(e) Similarly, the subject-matter of auxiliary requests 1 to 11 met, *inter alia*, the requirements of Articles 54 and 56 EPC.

VIII. Final requests

The appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent requested as its main request that the appeal be dismissed. As an auxiliary measure, the respondent requested that the patent be maintained on the basis of any of auxiliary requests 1 to 11 filed with the reply to the statement of grounds of appeal.

Reasons for the Decision

1. Admittance of documents D29 to D32

1.1 The appellant requested that documents D29 to D31a be admitted into the appeal proceedings. The opposition division's decision is not based on them, and the documents were submitted for the first time in the appeal proceedings. Consequently, their filing constitutes an amendment within the meaning of Article 12(4) RPBA. Any such amendment may be admitted only at the discretion of the Board (Article 12(4) RPBA, second sentence).

1.2 The question as to whether Humana 1, Humana plus and Humana 2 can be regarded as forming part of the *same* nutrition system arose for the first time in the opposition division's decision (see page 13, third paragraph and page 16, third paragraph). Consequently, the filing of the aforementioned documents can be considered a direct response to that decision. Moreover, the documents address issues that had already been discussed in the first-instance proceedings and are not complex. As outlined below, the documents are also relevant to the case. Consequently, the board admitted these documents into the appeal proceedings.

1.3 In the same way, the respondent's filing of document D32 was occasioned by the submission of documents D29 to D31a. The document addresses the same topic, namely the question of whether or not Humana 1, Humana plus and Humana 2 belong to the same nutrition system. The filing of D32 had already been referred to in the respondent's reply to the statement of grounds of

appeal. Whilst the provisions of Article 13(1) RPBA formally apply, the board saw no reason not to admit D32 into the proceedings. D32 provides further pertinent information about Humana's range of infant formula products in Italy prior to the priority date of the patent and does not add to the complexity of the case. Hence, the board admitted document D32 into the appeal proceedings.

Main request

2. Novelty

2.1 Interpretation of independent claims 1 and 13

2.1.1 According to one line of argument of the respondent, the term "nutrition system" should be construed so as to refer to a kit of parts.

2.1.2 The board does not agree. There is no basis for limiting the meaning of the term "nutrition system" as used in the claims to a kit of parts comprising at least two - albeit separate, but still physically/ spatially closely related - infant formulas in a kit. Independent claims 1 and 13 do not call for a "kit of parts". Similarly, the description refers to a "nutrition system" in the context of the examples.

2.1.3 The respondent argued in the oral proceedings before the board that in the case in hand there was also a spatial juxtaposition of the nutritional formulas in the nutrition system. This spatial juxtaposition occurred when the products were available on the market and usually provided close to each other. It could also be concluded from claim 14 as granted that claims 1 and 13 related to a kit of parts. The disposable capsules

made it possible to provide the individual formulas together according to the age of the infant. The system was a set and not a product line. This was also in line with the corresponding indications in paragraph [0005] of the patent.

2.1.4 With regard to this line of argument, the board considers that it is not apparent that the individual formulas that make up the two "systems" described in examples 1 and 2 would constitute a pack or kit. The term "nutrition system" also extends to a product line where such infant formulas are provided together or separately. The appellant also pointed to the fact that it made no sense to offer, for instance, a nutritional system in the form of a set or kit of two formulas for infants in their first and twelfth month of life because the consumer would not buy an infant nutrition product and store it for about a year. The description of the patent also does not refer to a "set" or "kit" either. In the same way, the nutrition system of claim 13 is not limited to those used in disposable capsules as taught in claim 14. Paragraph [0005] of the patent does not support the respondent's view either.

Consequently, the board agrees with the appellant that the meaning of the term "nutrition system", referred to in claims 1 and 13, also encompasses a product line of infant formulas.

The opposition division also appears to have adopted this interpretation in the decision under appeal. It nevertheless concluded that it had not been shown that the prior art disclosed a set of infant formulas belonging to the *same* "system". The latter required the disclosure of "[t]heir suitability for administration to an infant at different ages in a given order, which

order determines their protein and whey:casein ratio [...]" (see last sentence on page 12 of the decision under appeal). The board disagrees for the following reasons.

2.1.5 Firstly, there seems to be common ground between the parties that claims 1 and 13 are directed to *non-medical uses*. Consequently, the discussion between the parties about the correct format for claiming a kit of parts for *therapeutic uses* is not relevant to the case in hand. Likewise, any assessment of whether the conclusions in T 9/81, referred to by the appellant and relating to a kit of parts, also apply to non-therapeutic composition claims directed to kits of parts (T 468/11 was invoked in this context) does not have a bearing on the decision that had to be taken either. In view of the above, any product line or disclosed combination of infant formulas *suitable for* the purpose indications in claims 1 or 13 would fall within the scope of these claims (cf. Case Law of the Boards of Appeal, 10th edition, 2022, I.C.8.1.5, in particular fifth paragraph).

2.1.6 Secondly, claim 1 requires the *use of a protein source for providing an age-tailored nutrition system* rather than feeding the nutrition system to an infant. The respondent's argument that the purpose indications relating to the decreasing protein content and whey to casein ratio according to the age of the infant had to be taken into account as process features of claim 1 is not persuasive. The system *comprises* i) two infant formulas which both have to meet the additional *structural* limitations: ii) each having a whey to casein ratio and a protein content falling within the ranges specified in claim 1 (or claim 13, see below), iii) wherein said ratio and protein content of one of

the formulas are lower than in the other formula, and iv) the formula having the lower protein content and whey to casein ratio must be *suitable for* feeding the infant at an older age and *vice versa*. Such a nutrient system would be "age-tailored" and each formula would be "appropriate to an infant of a different age". Claim 1 defines the nutrient system as such in *structural* terms. Meeting these structural limitations does not require any specific point in time for feeding the infant according to its age.

2.1.7 Concerning claim 13, considering that it does not relate to a medical use format under Articles 54(4) or (5) EPC, any indications as to specific purposes/uses in the claims again do not limit the claimed subject-matter to the uses specified. Such indications merely require the *suitability* of the claimed nutrition system for the indicated purposes. Claim 13 does not call for a kit of parts either. Consequently, the remarks made in relation to claim 1 apply *mutatis mutandis*, and only limitations i) to iv) apply to product claim 13.

2.1.8 The board also observes that the claims as granted relate to a nutrition system "comprising" the two formulas. It is clear from e.g. claims 4 and 5 as granted that additional infant formulas do not necessarily have to meet the limitations of claim 1 (or claim 13). A third or fourth formula can for instance have *either* a lower whey to casein ratio *or* a lower protein content than *either/any* of the two (or three) other infant formulas.

2.2 Application of the conclusions regarding claim interpretation to the prior art

2.2.1 As established by the appellant by reference to documents D30/D30a and D31/D31a, at the relevant date the Humana product range/series of infant formulas marketed in Italy included Humana 1 as a starter formula, Humana Plus, and additionally Humana 2 as a follow-on formula. D30 mentions that Humana 2 is the "natural continuation of Humana 1 and Humana plus".

2.2.2 As to this point, the respondent argued that this did not mean that Humana Plus and Humana 1 or Humana Plus and Humana 2 could be regarded as related pairs (in the sense of functionally matched products). Otherwise, Humana Plus would also have to be considered the natural continuation of Humana 1 but there was no suggestion that Humana Plus could be considered as such.

2.2.3 For the reasons set out under point 2.1.6, this line of argument is not persuasive. Whether the prior art, and in particular D32, suggests a particular order of administration of the different formulas, as argued by the respondent, is thus irrelevant.

2.2.4 Document D2 discloses in table 2 Humana 1 (formula 1) and Humana Plus (formula 1A) as members of a nutrition system/product line falling within the scope of claims 1 and 13. Table 2 of D2 shows for Humana 1 a protein content of 2.5 g/100 kcal and a whey to casein ratio of 60:40 and for Humana Plus about 1.94 g/100 kcal protein in combination with a whey to casein ratio of 50:50. Taking into account the above conclusions in points 2.1.5 to 2.1.7, the subject-matter of claims 1 and 13 lacks novelty in view of D2 for these reasons alone.

2.2.5 It is for these reasons that the subject-matter of independent claims 1 and 13 lacks novelty over document D2 (Article 54(1) EPC).

Auxiliary requests

3. *Auxiliary requests 1 and 5 - novelty*

The above conclusions as to lack of novelty apply equally to claim 1 of each of auxiliary requests 1 and 5. The Humana 1 and Humana Plus formulas, disclosed in table 2 of D2, meet the limitations in relation to decreasing protein content and whey to casein ratio as stipulated in each claim 1. The first and fifth auxiliary requests thus do not meet the requirement of novelty, as stipulated by Article 54(1) EPC, either.

4. Auxiliary request 2 - inventive step

4.1 Closest prior art and its teaching

4.1.1 The appellant put forward arguments against the inventive merit of the main request, starting, *inter alia*, from document D14 as the closest prior art. The decision under appeal is likewise based, *inter alia*, on that document as the starting point for the assessment of inventive step. D14 is also concerned with milk-based infant formulas, taking into account the nutritional requirements according to the age of the infant. The conversion of dietary protein (*from cow milk or whey-fortified cow milk*) to body protein is assumed to be *90% efficient* in D14. Based on this, D14 estimated the age-dependent protein requirements of *formula-fed* male infants from 0 to 12 months of life (see table 1). These are compared with the estimated

protein-intake of male breast-fed infants. Consequently, D14 is also directed to providing age-tailored nutrition to infants and thus to the same or similar purpose as the patent and qualifies as the closest prior art.

4.1.2 Table 3 of D14 shows the (changing) estimated mean energy and protein requirements during infancy, and table 4 displays the resulting derived recommended dietary intake (RDI) values for protein. The protein requirement is derived from the estimated incremental increase in body protein, the resulting estimated protein demand for *growth* and protein losses and referenced against the estimated protein intake of breast-fed infants. The resulting protein requirement is also influenced by the efficiency of conversion of nutritional protein to body protein. The resulting recommended dietary protein intake values per age group are *lower* than those proposed by the WHO (see abstract of D14). This RDI should be sufficient to meet the needs of nearly *all* infants (taking into account individual variability of protein requirement for growth), see first paragraph of the left-hand column on page 391.

4.1.3 According to D14, during the *first two months of life*, the protein intake of breast-fed infants does not differ much from the estimated protein requirement of formula-fed infants in view of the data provided in tables 1 and 2. The age-dependent RDIs in table 4 *transform into different infant formulas* comprising 2.2 g/100 kcal, 2.0 g/100 kcal and 1.8 g/100 kcal protein in the first, second and third months of life, respectively. In the 9 to 12 month age interval, the RDI is 1.5 g/100 kcal. The appellant correctly pointed out at the oral proceedings that the last paragraph on

page 395 of D14 associates the RDI values in table 4 with infant formulas.

4.2 Distinguishing features

The *distinguishing features* between the subject-matter of claims 1 and 10 of auxiliary request 2 and D14 thus are i) the whey to protein ratios of 100:0 to 60:40 for a first infant formula and between 70:30 and 50:50 for a second formula (having a protein level of 2.0 g/ 100 kcal for the second month of life); and ii) a lipid level between 4.5 and 6.0 g per 100 kcal and which is "generally decreasing with increasing age of the infant".

4.3 Technical effect and objective technical problem

4.3.1 No technical effect has been demonstrated that could be observed as a causal consequence of these differences. In this context, the appellant correctly argued that the whey to casein ratio is not varied in the first 6 months of life in the clinical trial described in D19/ D20. Said ratio corresponds to 70:30 in the first six months (and is reduced to 50:50 for the seventh to twelfth months).

Likewise, no technical effect has been demonstrated that could be causally related to the specific lipid level per 100 kcal called for in claims 1 and 10 or to the requirement that it (generally) decreases according to the age of the infant. The lipid levels are indicated per a constant energy content of 100 kcal in the infant formulas in claims 1 and 10.

4.3.2 The resulting *objective technical problem* is thus to provide a first and a second alternative infant formula for feeding an infant from birth to two months.

4.4 Obviousness

4.4.1 The RDI values for proteins in table 4 of D14 are calculated, and indeed various assumptions are made in D14 for the greater estimated protein requirements (of formula-fed infants) than the estimated protein intake of breast-fed infants. This fact was stressed by the respondent. Nevertheless, the RDI values in table 4 are the result of the considerations of the factorial approach applied in D14 and form the starting point for the problem-solution approach. As correctly argued by the respondent, D14 proposed in 1991 that the lower limit of protein level in infant formulas seemed to merit revision and that this lower limit had still not been revised in the Codex Alimentarius in 2007 (see D16) or even in 2016. However, this does not call into question working above this legislative threshold protein level and D14's attempt to estimate protein levels that come closer to the required level. As correctly stated by the appellant, a skilled person implementing D14 would have to remain within the boundaries set in the Codex Alimentarius valid at that time (see D16) and thus remain at a minimum protein level of 1.8 g/100 kcal to be able to sell the formulas.

4.4.2 Further, D14 even mentions "whey-fortified cow milk" as a protein source (see page 391, right-hand column, first full paragraph). In this context, reference is made to document D8, which discloses that the whey to casein ratio decreases in human milk from 80:20 to 60:40 (and even lower) during lactation (first full

paragraph of the right-hand column on page 1554S). The board acknowledges that, as correctly stated by the respondent, there is thus variability in the composition of human milk and that D8 sets out that the quality of the protein in infant formulas is to be assessed on the basis of casein as a reference protein. However, this does not mean that the protein in a formula must contain at least 70% casein, merely that when the protein efficiency rate (PER) is lower than that of casein, the total amount of protein must be increased in a reciprocal manner. The respondent's other arguments, according to which D8 would lead the skilled person away from the claimed subject-matter, are not convincing either. In particular, the respondent's argument that D8 would at most have prompted a skilled person to reduce the protein content in infant formulas is not persuasive.

4.4.3 Likewise, the lipid levels called for in claims 1 and 10 merely reflect usual levels for lipids required in infant formulas. In this context, the appellant referred, *inter alia*, to the Codex Alimentarius (D16) and the lipid levels in Humana 1 and Humana 2. Documents D2 and D2a likewise disclose these lipid levels of Humana 1 and Humana 2. The specific lipid level and a decreasing lipid level with increasing age of the infant have not been demonstrated as being of any significance. No causal relationship between lipid levels of the formulas as distinguishing feature ii) and any corresponding technical effect is derivable from documents D19/D20 either.

4.4.4 Consequently, implementing the whey to casein ratios and lipid levels as stipulated in claims 1 and 10, both decreasing with increasing age of the infant, would have been obvious to a skilled person in view of D14,

who would thus have arrived at the subject-matter of claims 1 and 10 without inventive effort. Thus, the subject-matter of claims 1 and 10 does not meet the requirement of Article 56 EPC.

5. Auxiliary request 3 - inventive step

5.1 Starting from D14, and in particular table 4, as the closest prior art, in addition to differences i) and ii) referred to above, the carbohydrate level of each formula chosen in the range from 9.0 to 12.0 g/ 100 kcal, increasing with increasing age of the infant, was established as a third difference iii) by the board.

5.2 The respondent argued that D20 showed that increasing carbohydrate content and decreasing protein level in the infant formulas with increasing age in the claimed age period and amounts achieved good growth that was unexpectedly close to the WHO standard (for breastfed infants).

5.3 This is not persuasive. As argued by the appellant, these measures are arbitrary. The carbohydrate levels required in claims 1 and 9 fall safely within the range stipulated in the Codex Alimentarius (see D16, page 4). It was obvious that, when decreasing the level of two of three energy sources (proteins and lipids), the third source (carbohydrates) had to be increased complementarily to maintain the necessary energy content ("per 100 kcal").

5.4 Whilst in D20 an increase in the carbohydrate content and a decrease in protein content were implemented in the first two formulas, no (unexpected) technical effect has been shown to be causally related to this

specific feature either. Hence, in addition to the reasoning for asserting the obviousness of the second auxiliary request, it would have been obvious, when decreasing the protein and lipid content with increasing age, to increase the carbohydrate level to maintain the required energy content in the formulas. The board therefore agrees with the appellant that implementing usual carbohydrate levels as called for in claims 1 and 9 in infant formulas does not confer any inventive merit. Thus, the subject-matter of claims 1 and 9 of the third auxiliary request is also obvious to a skilled person and accordingly does not meet the requirement of Article 56 EPC either.

6. In view of the above findings, claim 1 of each of auxiliary requests 4, 6 and 7 likewise fails to meet the requirement of inventive step in view of D14, with the above reasons given for the second and third auxiliary requests applying *mutatis mutandis*.

7. *Auxiliary requests 8 and 9 - inventive step*

The different RDIs proposed in table 4 according to age transform into different infant formulas comprising 2.2 g/100 kcal, 2.0 g/100 kcal and 1.8 g/100 kcal protein in the first, second and third months of life, respectively (see point 4.1.3 above). As outlined above for the second auxiliary request, no technical effect has been demonstrated that could be related to whey to casein ratios as claimed, which ratios are thus arbitrary. Hence, implementation of the whey to casein ratios as the distinguishing feature is again obvious in view of D14 and in particular table 4 in combination with e.g. document D8 as a secondary information source. As convincingly argued by the appellant, D14 even mentions on page 395 that regulations require a

minimum protein level of 1.8 g/100 kcal in infant formulas. Maintaining that protein level after the third month of life in order to be able to sell such a product would also be obvious, rather than conferring any inventive merit. Consequently, the subject-matter of claim 1 does not meet the requirement of Article 56 EPC.

8. Auxiliary requests 10 and 11 - inventive step

8.1 As conceded by the respondent at the oral proceedings, the feature "wherein both the whey:casein ratio and the protein content decrease with increasing age of the infant" in claim 1 of each of auxiliary requests 10 and 11 does not provide any further restriction.

8.2 Thus, as a first difference, table 4 of D14 does not disclose an infant formula having a protein content of 2.5 g/100 kcal, as required in each claim 1. The highest protein content indicated in table 4 for the first month of life is 2.2 g/100 kcal. The infant formulas tested in the clinical trial described in D20 likewise have a maximum protein level of 2.25 g/100 kcal and thus likewise for this reason do not fall within the scope of claim 1 of each of auxiliary requests 10 and 11. It follows that any unexpected technical effect that might be causally related to this distinguishing feature has not been demonstrated. It is thus arbitrary. However, D14 does not teach against increasing the protein level to e.g. 2.5 g/100 kcal for feeding infants either and in this respect, the appellant correctly mentioned that D14 does not teach against exceeding a protein level of 2.2 g/100 kcal. A protein level of 2.5 g/100 kcal for a first infant formula would safely fall within the range stipulated in the Codex Alimentarius (D16), referred to by the

appellant in this context, which permits up to 3.0 g of protein per 100 kcal.

8.3 Moreover, the implementation of a whey to casein ratio as required in each claim 1 as a second distinguishing feature vis-à-vis D14 is rendered obvious in view of document D8 as a secondary information source (see above).

8.4 With regard to claim 1 of auxiliary request 11, maintaining the protein level in a *fourth* formula at the minimum level required by legislation, namely 1.8 g/100 kcal, as a third distinguishing feature for that request, does not lead to any demonstrated effect either.

8.5 Thus, the subject-matter of each claim 1 is obvious to a skilled person in view of the combined teaching of documents D14 and D8. It therefore does not meet the requirement of Article 56 EPC.

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:

L. Stridde A. Haderlein

Decision electronically authenticated