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Datasheet for the decision of 13 February 2023

Case Number: T 1656/20 - 3.3.09

Application Number: 11730513.6

Publication Number: 2584920

IPC: A61J15/00, A23L33/00

Language of the proceedings: EN

Title of invention:
HYPOCALORIC, HIGH PROTEIN NUTRITIONAL COMPOSITIONS AND METHODS OF USING SAME

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
N.V. Nutricia

Headword:
Hypocaloric, high protein nutritional compositions/NESTLÉ

Relevant legal provisions:
EPC Art. 100(a), 56
RPBA 2020 Art. 13(2)

Keyword:
Late-filed requests - main request and auxiliary requests 1 and 2 - admitted (no)
Inventive step - auxiliary requests 3 to 5 (no)

Decisions cited:
G 0003/14, T 1891/20, T 2563/17

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Case Number: T 1656/20 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 13 February 2023

Appellant: (Opponent)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Wohlfahrt, Jan Günther Gleiss Große Schrell und Partner mbB Patentanwälte Rechtsanwälte Leitzstraße 45 70469 Stuttgart (DE)
Respondent: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 28 May 2020 rejecting the opposition filed against European patent No. 2584920 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	C. Meiners
	N. Obrovski

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the opponent (appellant) against the decision of the opposition division to reject the opposition filed against the patent in suit ("the patent").

II. In its notice of opposition, the opponent had requested that the patent be revoked in its entirety based, *inter alia*, on the ground for opposition under Article 100(a) EPC in combination with Article 56 EPC (lack of inventive step).

III. The following documents are relevant for the decision:

D1 WO 2012/006074 A1

D6 A. Malone, "Enteral formula selection: a review of selected product categories", *Practical Gastroenterology*, June 2005, 44-74

D30 Excerpt of product catalogue "De beste voedingszorg voor uw patiënt", Nutricia 2006, 36-49

IV. In its decision, the opposition division found, *inter alia*, that the subject-matter of the claims as granted (main request) involved an inventive step in view of document D6 as the closest prior art.

V. With its reply to the statement of grounds of appeal, the patent proprietor (respondent) filed a first and a second auxiliary request.

VI. The board summoned the parties to oral proceedings and issued a communication under Article 15(1) RPBA 2020 in which it set out its preliminary opinion.

VII. By letter dated 11 January 2023, the respondent made substantive submissions on the case and filed a new main request and two auxiliary requests. The previous main request (claims as granted) and auxiliary requests 1 and 2 were re-numbered as auxiliary requests 3 to 5, respectively.

VIII. Wording of the relevant claims

Claim 1 of the main request reads as follows (amendments compared to claim 1 as granted being underlined):

"A complete daily feeding tube feed formulation for a tube fed human pediatric patient, having a caloric density from 0.5 to 0.8 kcal per ml, comprising:
a processed whole food component;
a source of vitamins or minerals; and
a source of protein that provides energy from protein in an amount from about 18% to about 35% of the total energy of the formulation, and having an osmolality that is less than or equal to 400 mOsm/kg water."

In claim 1 of auxiliary request 1, the complete daily feeding tube feed formulation is limited to those (suitable) "for a tube fed human pediatric patient having an underlying medical condition".

Compared to claim 1 of the main request, the osmolality is further limited to less than or equal to 380 mOsm/kg water in claim 1 of auxiliary request 2.

Claim 1 as granted of auxiliary request 3 (former main request, held allowable by the opposition division) reads as follows:

"A complete daily feeding tube feed formulation, having a caloric density from 0.5 to 0.8 kcal per ml, comprising:

a processed whole food component;

a source of vitamins or minerals; and

a source of protein that provides energy from protein in an amount from about 18% to about 35% of the total energy of the formulation, and having an osmolality that is less than or equal to 400 mOsm/kg water."

Claim 15 as granted reads:

"A hypocaloric, complete daily feeding, tube feed formulation, having a caloric density from about 0.5 to about 0.8 kcal per ml, comprising a processed whole food component, a source of vitamins or minerals, and a source of protein that provides from about 18% to about 35% energy from protein, ,[sic] and having an osmolality that is less than or equal to 400 mOsm/kg water, for use in improving the overall health of a tube fed pediatric patient having an underlying medical condition."

Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 3 in that the "complete daily feeding tube feed formulation" is limited to those (suitable) "for a tube fed pediatric patient having an underlying medical condition".

Compared to claim 1 of auxiliary request 3, the osmolality is further limited to less than or equal to 380 mOsm/kg water in claim 1 of auxiliary request 5 (former auxiliary request 2).

IX. The appellant's arguments relevant to the decision can be summarised as follows.

- Starting from document D6 as the closest prior art, the subject-matter of claim 1 as granted lacked an inventive step. The disclosure of D6 implicitly anticipated osmolality values of below 400 mOsm/kg water and disclosed "complete" tube feed formulations. Assuming for the sake of completeness that these two features were not disclosed in D6 and thus represented the distinguishing features, the resulting objective technical problem was to provide alternative tube feed formulations. It was common general knowledge that it was desirable to have tube feeding formulations with an osmolality of at most 400 mOsm/kg water. In view of this knowledge, a skilled person would have tested the osmolality values of the formulations outlined in Table 16 of D6. Should the osmolality values have exceeded this value, they would have adapted the formulations accordingly. As claim 1 did not require a minimum amount of whole food comprised in the claimed composition, a skilled person could lower the amount of this whole food to reduce the osmolality of the composition or replace a part of the whole food component with another component. Thus, a skilled person would have arrived at the subject-matter of claim 1 in an obvious way.

- The new main request and auxiliary requests 1 and 2 should not be admitted and were not allowable

either. The subject-matter of the claims lacked clarity and went beyond the content of the application as filed.

The arguments of the respondent relevant to the decision can be summarised as follows.

- The new main request and auxiliary requests 1 and 2 had been filed in response to the board's preliminary opinion set out in its communication under Article 15(1) RPBA 2020. The introduction of a new point by the board qualified as exceptional circumstances within the meaning of Article 13(2) RPBA 2020. The limitation to human paediatric patients ensured that the restriction to complete daily feeding tube feed formulations was indeed a meaningful limitation.

- The amendments to the new requests had a basis in the original application documents and thus did not add subject-matter. The amendments were also clear and did not infringe the requirements of Article 84 EPC.

- As to inventive step, the subject-matter of all requests was not obvious to a skilled person in view of document D6 as the closest prior art. The compositions in Table 16 of D6 could not be taken as a "complete nutrition" within the meaning of paragraph [0040] of the patent. By contrast, D6 proposed *external* supplementation of nutrient components to ensure nutrient adequacy.

  The distinguishing features over the subject-matter of claim 1 as granted were *complete nutrition* and *low osmolality*. A skilled person would be aware

that the osmolality of physiological fluids was lower than 300 mOsm/kg water and that tube feeds with osmolality closer to this value would be better tolerated since the body had less of a differential to adjust to. Hence, it was clear to a skilled person that the advantage purported in paragraph [0033] of the patent was causally ascribable to the lower osmolality of the claimed compositions.

Thus, the objective technical problem was to provide a hypocaloric, high protein whole food composition with improved properties.

The solution to this problem was not obvious in view of D6 as diluting the compositions would lead the skilled person away from the scope of claim 1 of the main request. Furthermore, the appellant had not determined the osmolality of the compositions of D6 and thus had not corroborated that mere dilution could bring these compositions within the claimed osmolality range while remaining in the claimed range for caloric density.

X. Final requests

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

The respondent requested that the patent be maintained on the basis of the main request or one of auxiliary requests 1 and 2, all filed by letter of 11 January 2023, or on the basis of one of auxiliary requests 3 to 5 (corresponding to the previous main request and auxiliary requests 1 and 2 filed with the reply to the statement of grounds of appeal).

Reasons for the Decision

1. Admittance of the new main request and auxiliary requests 1 and 2

1.1 Under Article 13(2) RPBA 2020, any amendment to a party's appeal case made after the expiry of a period specified by the board in a communication under Rule 100(2) EPC or, where such a communication is not issued, after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

1.2 The admittance of such an amendment is at the discretion of the board entrusted with the case. At the third level of the convergent approach, the board may also rely on criteria applicable at the second level of the convergent approach, i.e. as set out in Article 13(1) RPBA 2020. This is confirmed by the explanatory remarks on Article 13(2) RPBA 2020, which also contain the following guidance: "At the third level of the convergent approach, the Board may also rely on criteria applicable at the second level of the convergent approach, i.e. as set out in proposed new paragraph 1 of Article 13." (Document CA/3/19, section VI, explanatory remarks on Article 13(2), fourth paragraph).

1.3 A clear and detailed preliminary opinion provided by a board is predominantly intended to give the parties an opportunity to thoroughly prepare their arguments in response to it but not to file new submissions, such as

new sets of claims. Amendments submitted in response to a preliminary opinion cannot *per se* give rise to "exceptional circumstances" within the meaning of Article 13(2) RPBA 2020.

1.4 In the case in hand, the decision under appeal and the statement of grounds of appeal refer to paragraph [0040] of the patent, where it is stated: "As used herein, 'complete nutrition' includes nutritional products and compositions that contain sufficient types and levels of macronutrients (protein, fats and carbohydrates) and micronutrients to be sufficient to be a sole source of nutrition for the animal to which it is being administered to."

1.5 According to the respondent, the board's argument that claim 1 did not specify the kind of animal to which the daily feeding tube feed formulation was administered was new. In contrast, the appellant had only relied on paragraph [0040] to show what contributed to complete nutrition, namely macronutrients and micronutrients but not water. Consequently, the respondent had been taken by surprise by this development. Such an unforeseeable development, not dealt with in the decision under appeal, justified amendments which addressed such a development. The respondent referred to the Case Law of the Boards of Appeal, 10th edition 2022, section V.A.5.12.4, which concerns amendments made in response to objections made by a board.

1.6 The board takes the view that, in the case in hand, the amendments in claim 1 of the main request and the first and second auxiliary requests are:
i) not justified as a response to the board's considerations in its preliminary opinion
ii) not suitable to overcome the conclusion that

"complete" as used in claim 1 cannot serve as a distinguishing feature
iii) detrimental to procedural economy because they give rise to new issues

1.6.1 As to aspect i), the board notes that the appellant had considered the subject-matter of auxiliary requests 3 to 5 not to be novel in view of document D6 in its statement of grounds of appeal. The line of argument developed in section 5.1 a) of its grounds of appeal is clearly an auxiliary argument for if the board did not accept the argument on lack of novelty vis-à-vis D6; it was not a recognition of the feature "complete nutrition" being a distinguishing feature.

The exact meaning of this feature "complete" and whether it was anticipated in D6 was always contentious, and the opposition division and the appellant referred to paragraph [0040] for its interpretation. In section 4.2 of the grounds of appeal, the appellant also mentioned that the tube feed formulations of D6 were "complete" since footnote 3 in Table 16 of D6 only referred to an *average* need for *adults* and since vitamins and minerals could be supplemented to provide nutrient adequacy for *any kind of person*. It can be inferred from this statement that the nutritional adequacy (and thus whether a given formulation can be considered "complete") depends on the patient considered and is thus *relative*. The board merely refined this argument by a *prima facie* consideration of the reflections outlined in the first two paragraphs of paragraph 4.2 of the statement of grounds of appeal, which state, *inter alia*: "The OD defines a complete formulation according to paragraph [0040] of the contested patent, i.e. a complete nutrition is defined as containing sufficient types of

macronutrients and micronutrients to be a sole source of nutrition *for the animal to be administered to*." (emphasis added by the board). The following paragraph refers to the *average* need for adults. Thus, the board's remark in section 7.2.1 of its communication ties in with the appellant's conclusion that the nutrient requirements are person-specific and therefore *relative*. It thus cannot be argued that the board brought up the aspect that the exact "patient collective" is not specified in claim 1 and that therefore "complete" cannot delimit against the prior art.

In view of these considerations, it is apparent that the board did not make a new objection but merely refined an existing argument (see T 1891/20, Reasons 4.1.4 and T 2563/17, Reasons 1.4). This cannot be taken as exceptional circumstances which justify the admittance of the main request and auxiliary requests 1 and 2.

The board also notes that a similar request, aimed at narrowing the patient collective to which the tube feed formulations should be administered, had already been submitted in the form of auxiliary request 4 (former auxiliary request 1, filed with the reply to the statement of grounds of appeal). The respondent thus obviously considered right at the start of the appeal proceedings that the patient collective might have to be narrowed.

1.6.2 As to aspect ii), the board holds that the amendments are not suitable for implementing a clear limitation in claim 1. They merely require that the formulations be suitable for a tube-fed human paediatric patient (with new auxiliary request 1 further stipulating that the

patient have an underlying medical condition). As discussed in the oral proceedings, the term "pediatric" is vague and refers to persons up to 18 or even 21 years of age. It is thus not clear how this term could delimit the respective claim 1 vis-à-vis the disclosure of D6 and its reference to the nutritional demand (DRI) of an average adult in footnote 3. Furthermore, depending on the exact definition of the term, a given patient could be considered a "pediatric patient" or not. In this context, the appellant referred to paragraph [0093] of the application as filed (corresponding to paragraph [0087] of the patent).

1.6.3 As to aspect iii), in view of the remarks in section 1.6.2, the amendments to the main and auxiliary requests 1 and 2 are also considered to give rise to new objections and are thus also detrimental to procedural economy (stipulated in Article 13(1) RPBA 2020, the criteria of which are applicable). Inserting a vague and relative feature "for a tube fed human pediatric patient" may give rise to a clarity objection under Article 84 EPC. The amendments were not found in claim 1 as granted. Independent granted claim 15, the only granted claim comprising the feature "pediatric patient", comprises the feature "for use in improving the overall health", which is not found in the claim 1 under scrutiny. Furthermore, granted claim 15 does not mention the expression "for a tube fed *human* pediatric patient" (emphasis added by the board). The term "human" is directly and unambiguously only disclosed in the description (see e.g. paragraph [0042] of the patent and the application as filed; see the WO PCT publication pamphlet D1). For these reasons, the amendments to claim 1 can be assessed as to their compliance with the requirements of Article 84 EPC (G 3/14).

Furthermore, the board concurs with the appellant that the insertion of "for a tube fed human pediatric patient" or "for a tube fed human pediatric patient having an underlying medical condition" in claim 1 gives rise to the question of whether the claimed subject-matter is directly and unambiguously disclosed in the original application documents (Article 123(2) EPC). At least two independent selections from different passages of the description are necessary firstly for restricting the patient collective to human paediatric patients (see e.g. paragraph [0093] as filed, assuming to the benefit of the respondent that paediatric patients are necessarily human paediatric patients) and secondly for specifying the osmolality value in view of paragraph [0125] as filed. Hence, a new issue could *prima facie* also arise from this aspect.

1.7 It is for these reasons that the board decided not to admit the main request and auxiliary requests 1 and 2 under Article 13(2) RPBA 2020.

2. Inventive step - auxiliary request 3

2.1 The patent

The patent is concerned with providing hypocaloric, complete daily feeding tube feed formulations which comprise processed whole food components (see paragraph [0001] of the patent).

2.2 Closest prior art

It is common ground between the parties that document D6, and in particular the formulations

featured in Table 16, can be taken as a suitable starting point for the assessment of whether the subject-matter of independent claim 1 involves an inventive step. D6 was also considered to represent the closest prior art in the decision under appeal.

2.3 Distinguishing feature

2.3.1 According to the impugned decision and the respondent, the subject-matter of claim 1 differs from D6, Table 16 in that the tube feed formulations are i) "complete" and ii) have osmolalities of at most 400 mOsm/kg water.

2.3.2 By contrast, the appellant argued that the formulations of Table 16 inherently disclosed limitations i) and ii).

The board, however, notes that the appellant has not adduced any proof of the alleged common general knowledge that tube feeding formulations (and particularly tube feeding formulations comprising whole food components) inherently and inevitably have osmolality values of at most 400 mOsm/kg water.

However, as concerns the feature "complete daily tube feeding composition" i), the board concludes that this feature is not limiting in view of D6. This feature relates to humans and animals alike (see paragraphs [0038], [0047], [0065]), the animal in need of nutrition not being specified, let alone its exact age. As to the latter point, even "pediatric" (human) patients as featured in the patent include (as discussed in the oral proceedings before the board) a patient collective including persons up to an age of 21 years (see also the pertinent indications provided in paragraph [0096] as filed to which the appellant

referred, corresponding to paragraph [0087] of the patent). In view of this, the board agrees with the appellant that even in light of the explanations provided in this passage of the description, no clear limitations which could characterise the claimed formulations can be associated with the term "complete". Also, the feeding formulations in Table 16 of D6 generally comply with the definition in paragraph [0040] of the patent. While the formulae designated "800" and "1200" in Table 16 could be "complete" for certain animals/patients, they may be insufficient as a sole source of nutrition for others under specific conditions and physiological requirements (such as an average adult). As correctly observed by the appellant, the RDI (recommended dietary intake) values displayed in Table 16 of D6 relate to the average daily dietary intake level sufficient to meet the nutrient requirements of an *average adult*. It follows from these considerations that the feature "complete" cannot serve as a distinguishing feature over the prior art (such as document D6). In conclusion, the sole distinguishing feature over D6 is the claimed osmolality value.

2.4 Technical effect and objective technical problem

2.4.1 In the decision under appeal, it was concluded that the objective technical problem was to provide an alternative daily feeding tube feed formulation suitable to be used as a sole source of nutrition for an individual and that the proposed solution would not be obvious.

2.4.2 The board observes that no examples are on file which show that the alleged effect (namely the prevention of feeding intolerance) is causally associated with osmolality values of 400 mOsm/kg water or lower.

Similarly, the opposition division held that paragraph [0033] of the patent, which refers to improvement and prevention of feeding intolerance with tube feeding, did not teach which feature of the formulation was responsible for the alleged technical effect of preventing feeding intolerance. Therefore, it was not clear which effect was caused by the distinguishing feature of a certain osmolality.

2.4.3 It is common ground between the parties that it was common general knowledge before the priority date that physiological fluids are isotonic and have osmolalities of about 300 mOsm/kg water. The respondent argued that tube feed formulations having osmolalities below 400 mOsm/kg water and thus closer to the osmolality of physiological fluids would be better tolerated because the body had less of a differential to adjust to. To the board, this line of argument is persuasive.

2.4.4 As elucidated in the oral proceedings before the board, it is common ground between the parties and was common general knowledge before the priority date that lower molecular weight components contribute to a higher extent to the osmolality of a composition than higher molecular weight components at a given mass fraction of the respective component in the composition. In this context, the effect of the molecular weight of carbohydrates was discussed for a polysaccharide comprising e.g. 50 glucose units versus e.g. a monomeric saccharide.

2.4.5 Therefore, in the board's view, the objective technical problem to be solved was to provide hypocaloric, high protein content tube feeding compositions with improved feeding tolerance. In view of the above remarks in

sections 2.4.3 and 2.4.4, the board has no doubt that this problem has credibly been solved over the full scope of claim 1.

2.5 Obviousness

2.5.1 Starting from D6 as the closest prior art, a skilled person wishing to provide a daily feeding tube feed formulation suitable as a sole source of nutrition would have contemplated lowering the osmolality to 400 mOsm/kg water or below while maintaining caloric density in a range from 0.5 to 0.8 kcal per ml and a source of protein at levels that provide from about 18% to about 35% of the total energy of the formulation.

2.5.2 Assuming that, for instance, the osmolality of the composition having 1200 kcal would have been higher than 400 mOsm/kg water, a skilled person would have contemplated reducing the osmolality when wishing to provide a formulation better tolerated by patients. In view of common general knowledge that human body fluids have an osmolality of about 300 mOsm/kg water, a skilled person would have expected to improve food tolerance by adjusting the osmolality to a value closer to that of physiological fluids. This expectation alone, based on the common general knowledge of the skilled person, was the basis for the above mentioned formulation of the objective problem posed.

2.5.3 In the view of the board, it was obvious to reduce the osmolality of formulations as featured in Table 16 of D6 by diluting (or "watering down") the compositions known from D6. Dilution with water is proposed in footnote 2 of Table 16 and would not change the relative contribution of protein relative to the total energy content of the composition.

2.5.4 With regard to the statement in the decision under appeal, point 54 that the addition of water would reduce the caloric value of the formulations so that the formulations may comprise less than 0.5 kcal per ml, the board notes that this does not necessarily have to be the case. Based on the composition having e.g. 1200 kcal energy content, there would have been a substantial margin to keep energy density at 0.5 kcal per ml or above when watering down this formulation. While the board agrees that this dilution would have limits, the board does not concur with the respondent that e.g. doubling the volume of the formulation from about 1.5 l to about 3 l would raise the question of whether such a composition would still be suitable for tube feeding. Watering down the formulation would (also in view of footnote 3 of Table 16) instead lead towards a more "complete" formulation in terms of hydration needs. There are no specific restrictions on the viscosity of the formulations in claim 1 either (as long as they are suitable for use as tube feed formulations). Hence, contrary to the respondent's argument, the fact that no viscosity measurements are given in D6 does not lead away from the subject-matter of claim 1.

2.5.5 The board also agrees with the appellant that the content of the processed whole food component in the claimed formulations is not restricted and can be rather low. Furthermore, a skilled person would have considered fully or partially replacing components with (corresponding) components having a lower osmolality if mere dilution did not suffice to reach osmolality values of 400 mOsm/kg water or below while keeping energy density at levels of at least 0.5 kcal per ml. When necessary, this could have been accomplished by

fully or partially exchanging low molecular weight components, such as sugar, for ingredients having a higher molecular weight (see point 2.4.4 above).

2.5.6 The respondent also argued that watering down the formulations of Table 16 would further reduce their concentration of micronutrients. The board, however, notes again that the RDI values indicated in Table 16 are *average* recommended values for adults but that the patient collective is not specified in claim 1. Even assuming for the sake of argument that the patient collective was restricted to e.g. paediatric patients and assuming that the resulting formulation was deficient in micronutrients and thus could not serve as a "complete" sole source of nutrition, a skilled person would have been prompted to adjust the level of micronutrients by either supplementation in the formulation or optimisation of the nutrients without departing from keeping osmolality at the desired low levels closer to those of physiological fluids. D6 mentions that a few of the lower calorie formulations do not provide 100% of the RDIs (for average adults) and that supplementation of vitamins/ minerals might be needed to ensure nutrient adequacy (see third paragraph of the left-hand column on page 73). Adding such supplements into the formulations would thus be straightforward rather than far-fetched.

Likewise, the board holds that a skilled person could compensate for any potential deficiency of macronutrients by adjusting the composition of the formulation. Keeping the caloric density within a range of from 0.5 to 0.8 kcal per ml to meet the caloric demands of the target patient group would have been an obvious measure. In the same way, keeping the protein source at a level meeting the patient's protein

demands, as in the first and third formulation in Table 16, likewise would have been obvious to a skilled person having such a patient group in mind.

2.5.7 D6 prompts the skilled person to vary foods in blenderised tube feed formulations (see page 73, left-hand column). Hence, D6 *does* propose reformulating the exemplary recipes featured in Table 16. There, it is also stated that a commercially prepared blenderised product designated "Compleat" had already been on the market (before the priority date of the patent). Furthermore, D6 mentions a strong desire of some patients and caregivers to provide "home-made" nutrition. It follows that D6 fosters the expectation of a skilled person that such nutritional products would be sought after.

2.5.8 The respondent's argument that D6 states that most nutrition support clinicians discourage the use of homemade formulas (see first paragraph of the section "Homemade/Blenderized Enteral Feedings" on page 70) does not convince the board. D6 addresses the skilled person in the field concerned and not persons/ laypersons providing homemade recipes. Hence, any concerns about nutritional adequacy (and/or potential food-borne illnesses) could be tackled by pertinent measures.

2.5.9 In view of the remarks in section 2.5.6 above, even when considering the feature "complete" in claim 1 as being a second distinguishing feature over D6, the above conclusions on the obviousness of the subject-matter of claim 1 do not differ. As outlined under point 2.5.6, a skilled person would have been prompted by the teaching of D6 to provide "complete" tube feed compositions and to adjust the compositions to meet the

complete nutritional demand of a given patient collective. For the above indicated reasons, it is not apparent that such an adaptation would require an inventive effort.

2.5.10 It follows from these considerations that the subject-matter of claim 1, having regard to the state of the art, is obvious to a skilled person and does therefore not meet the requirement of Article 56 EPC.

3. *Inventive step - auxiliary request 4*

3.1 The additional limitation inserted in claim 1 of auxiliary request 4 does not alter the problem-solution approach outlined in section 2 above. D6 also describes complete daily feeding tube feed formulations (suitable) for paediatric patients. In this context, the appellant referred, *inter alia*, to Table 10. There, a complete tube feed formulation designated "EleCare" for paediatric patients is featured. Hence, the respondent's argument that D6 was not a realistic starting point for this patient group is not convincing. By contrast, Table 16 features several exemplary formulations meeting different caloric requirements, including formulations having rather low energy densities. It follows from the above considerations (as outlined in particular in points 2.5.5 to 2.5.7) that varying the exact composition of the exemplary formulations discussed in Table 16 of D6 to meet the nutritional demand of the target patient (collective), here paediatric patients, would not involve an inventive effort and would have been implemented by a skilled person when having this patient group in mind. Furthermore, as discussed in the oral proceedings before the board, the definition of the term "pediatric patient" as used in the patent is

rather broad. It can also be assumed that tube-fed paediatric patients implicitly have an underlying medical condition.

3.2 Consequently, the subject-matter of claim 1 of auxiliary request 4 is obvious to a skilled person in view of D6 and common general knowledge and does not, therefore, meet the requirement of Article 56 EPC either.

4. *Inventive step - auxiliary request 5*

4.1 The additional limitation imposed in claim 1 merely limits the osmolality of the formulation to values of less than or equal to 380 mOsm/kg water.

4.2 Claim 1 of auxiliary request 3 includes this value of 380 mOsm/kg water for the osmolality. Consequently, the limitation to this threshold value does not alter the problem-solution approach outlined in point 2 above. Consequently, the considerations on a lack of inventive step apply *mutatis mutandis* to the subject-matter of claim 1 of auxiliary request 5. It does not, therefore, meet the requirement of Article 56 EPC either.

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:

M. Schalow A. Haderlein

Decision electronically authenticated