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Datasheet for the decision of 10 July 2015

Case Number: T 1580/13 - 3.3.09

Application Number: 06806927.7

Publication Number: 1940248

IPC: A23L1/29, A23L1/30, A61P3/02

Language of the proceedings: EN

Title of invention:
USE OF A NUTRITIONAL FORMULATION FOR PROMOTING CATCH-UP GROWTH

Patent Proprietor:
Nestec S.A.

Opponents:
THE IAMS COMPANY
ABBOTT LABORATORIES
N.V. NUTRICIA

Headword:

Relevant legal provisions:
EPC Art. 56, 83, 84
RPBA Art. 13(1)

Keyword:
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Catchword:

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Case Number: T 1580/13 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 10 July 2015

Appellant: (Opponent 1)	THE IAMS COMPANY 8060 South Mason-Montgomery Road Mason, OH 45040 (US)
Representative:	Jones, Helen M.M. Gill Jennings & Every LLP The Broadgate Tower 20 Primrose Street London EC2A 2ES (GB)
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Appellant: (Opponent 3)	N.V. NUTRICIA Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Schrell, Andreas Gleiss Große Schrell und Partner mbB Patentanwälte Rechtsanwälte Leitzstrasse 45 70469 Stuttgart (DE)
Respondent: (Patent Proprietor)	Nestec S.A. Avenue Nestlé 55 1800 Vevey (CH)
Representative:	Santarelli 49, avenue des Champs-Elysées 75008 Paris (FR)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 17 May 2013 concerning maintenance of the European Patent No. 1940248 in amended form.**

Composition of the Board:

Chairman W. Sieber
Members: M. O. Müller
F. Blumer

Summary of Facts and Submissions

I. This decision concerns the appeal filed by opponent 1 (The IAMS Company), opponent 2 (Abbott Laboratories) and opponent 3 (N.V. Nutricia) against the interlocutory decision of the opposition division that European patent No. 1 940 248 as amended meets the requirements of the EPC.

II. The opponents had requested revocation of the patent in its entirety on the grounds under Article 100(a) EPC (lack of novelty and inventive step), Article 100(b) EPC and Article 100(c) EPC.

The documents submitted during the opposition proceedings included:

D4: M. Fisberg et al, International Pediatrics, volume 17(4), 2002, pages 216 to 222;

D5: WO 2005/063050 A1;

D6: WO 2004/112509 A2;

D10: US 2004/0170668 A1;

D14: M. Rivero et al, Pediatric Gastroenterology 2004, Reports from the 2nd World Congress of Pediatric Gastroenterology, Hepatology and Nutrition, Paris (France), 3 to 7 July, 2004, 5 pages;

D16: J.D. Carver, Am. J. Clin. Nutr., volume 77 (suppl.), 2003, pages 1550S to 1554S;

D17: US 2002/0137796 A1;

D25: Data on example 1 of the opposed patent, 1 page;

D27: Experimental report, 5 pages;

D31: Commission Directive of 14 May 1991 on infant formulae and follow-on formulae (91/321/EEC), 27 pages; and

D33: Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae, 18 May 2003, 7 pages.

III. The opposition division's decision was based on a main request, with a single independent claim 1 reading as follows:

"1. Use of an n-3 long-chain polyunsaturated fatty acid (LC-PUFA), a prebiotic fibre and a probiotic bacterial strain for the manufacture of a nutritional formulation or medicament for promoting catch-up growth in sick and convalescent young mammals."

IV. As regards inventive step, the only issue relevant to the present decision, the opposition division reasoned essentially as follows:

The closest prior art D14 disclosed the use of a composition comprising LC-PUFAs but not necessarily n-3 LC-PUFAs as required by claim 1. The problem solved in view of D14 was the provision of a composition that promoted catch-up growth without promoting obesity. D14 resulted in promoted catch-up growth but together with a rapid recovery of appetite, and there was no disclosure in D14 of any catch-up growth without

increased risk of obesity. The claimed subject-matter was thus inventive in view of D14 considered alone. D5, D10 and D17 could not be combined with D14 since they related to a different patient group from D14. Hence, also in view of these documents, inventive step was to be acknowledged.

V. Opponents 1, 2 and 3 (hereinafter: appellants 1, 2 and 3, respectively) all filed an appeal. The statement of grounds of appeal of appellant 2 contained

D41: C. Beermann et al., Lipids in Health and Disease, volume 2, 2003, 10 pages.

VI. In its response to the statements of grounds of appeal, the proprietor (hereinafter: the respondent) filed a main request and first to sixth auxiliary requests, as well as

D42: Declaration of C. Garcia-Rodenas, signed on 3 February 2014; and

D43: Declaration of P. Steenhout, signed on 6 February 2014.

VII. With its communication dated 15 January 2015, the board communicated its preliminary opinion to the parties. As regards inventive step, the board observed that there appeared to be no evidence that the distinguishing feature over D14, i.e. the use of n-3 LC-PUFAs instead of other LC-PUFAs, led to any effect. The objective technical problem thus appeared to be the provision of an alternative composition to promote catch-up growth and this alternative appeared to be known from e.g. D5, D10 and D17.

VIII. In response to this communication, the parties filed

D44: Declaration of L. W. Williams, signed on 20 March 2015 (filed by appellant 2);

D45: Declaration of R. van Elburg, signed on 4 May 2015 (filed by appellant 03);

D46: Abstract of C.T. Collins et al, Br. J. Nutr., volume 105(11), 2011, pages 1635 to 1643 (filed by the respondent); and

D47: Second declaration of P. Steenhout, signed on 2 June 2015 (filed by the respondent).

IX. With its letter dated 8 July 2015, the respondent filed new first to fifth auxiliary requests to replace the auxiliary requests previously filed, the first and second auxiliary requests being identical to the previous third and fifth auxiliary requests.

X. With its letter dated 9 July 2015, appellant 1 announced that it would not be represented during the oral proceedings.

XI. On 10 July 2015, oral proceedings were held before the board, in the absence of appellant 1. The respondent requested that the following question be referred to the Enlarged Board of Appeal:

"In order to determine the objective technical problem of so-called "second medical use claims" (under Article 53(c) EPC), is it allowed to refer to statements mentioned in the description, or should the objective technical problem be determined from the sole use explicitly present in the claims?"

The appellants requested that the third to fifth auxiliary requests not be admitted into the proceedings.

XII. Claim 1 of the main request is identical to that before the opposition division (see point III above). Claim 1 of the first to fifth auxiliary requests reads as follows:

"1. Use of docosahexanoic acid, arachidonic acid, a prebiotic fibre and a probiotic bacterial strain for the manufacture of a nutritional formulation or medicament for promoting catch up growth in sick and convalescent young mammals" (first and second auxiliary requests).

"1. Use of an n-3 long-chain polyunsaturated fatty acid (LC-PUFA), a prebiotic fibre and a probiotic bacterial strain for the manufacture of a nutritional formulation or medicament for promoting catch-up growth in sick and convalescent young mammals without increasing the caloric intake, with equilibrated lean and fat body mass and without promoting obesity" (third auxiliary request).

"1. Use of docosahexanoic acid, arachidonic acid, a prebiotic fibre and a probiotic bacterial strain for the manufacture of a nutritional formulation or medicament for promoting catch-up growth in sick and convalescent young mammals, without increasing the caloric intake, with equilibrated lean and fat body mass and without promoting obesity" (fourth auxiliary request).

"1. Use of docosahexanoic acid, arachidonic acid, a prebiotic fibre and a probiotic bacterial strain for the manufacture of a nutritional formulation or medicament for promoting catch-up growth in sick and convalescent young mammals, with equilibrated lean and fat body mass and without promoting obesity" (fifth auxiliary request).

XIII. So far as relevant to the present decision, the appellants' arguments can be summarised as follows:

- The term "catch-up growth" in claim 1 implied that there was an increased velocity of growth after growth retardation but not necessarily that the acceleration of growth was such as to catch up with the growth curve the mammals would have been on without growth retardation (hereinafter "reference growth curve"). This was supported by paragraph [0002] as well as figure 1 in conjunction with paragraph [0037] of the patent. Figure 2, which was used by the respondent, was not relevant in this respect since it did not show any growth acceleration that led to a catch-up with the reference growth curve.

- The subject-matter of claim 1 lacked novelty over each of D6 and D14.

- The subject-matter of claim 1 of the main request was furthermore not inventive. The closest prior-art document D14 differed from claim 1, if at all, in that it disclosed LC-PUFAs in general while claim 1 required the LC-PUFA to be an n-3 LC-PUFA. Contrary to the respondent's assertion, the patient group did not constitute a further distinguishing feature.

The respondent's assertion that the problem solved in view of D14 was a more efficient promotion of catch-up growth was not supported by D46, on which the respondent relied. Furthermore, the respondent's assertion that the problem solved over D14 was the promotion of catch-up growth without increasing caloric intake, with equilibrated lean and fat body mass and without promotion of obesity was not supported by any of figures 3 to 5 of the patent, D25 and D27. In fact there was no evidence at all that this problem was solved, let alone that it was solved over D14.

The objective technical problem was therefore the promotion of catch-up growth by an alternative composition. The solution was obvious in view of any of D5, D6, D10, D16, D17, D31 or D33. It was not correct that the skilled person would not have combined D14 with these documents on the ground that they did not refer to follow-on formulae (the relevant formula of D14 is a follow-on formula) since the formulae of e.g. D5, D10 and D17 included follow-on formulae. Furthermore, contrary to the respondent's assertion, these documents did not teach away from the claimed subject-matter but clearly taught the skilled person to use a combination of DHA and AA in D14. By doing so, the skilled person would have arrived at the subject-matter of claim 1.

- For the same reasons as given with regard to the main request, the first and second auxiliary requests lacked inventive step.

- The third to fifth auxiliary requests should not be admitted into the proceedings. They had been announced and filed extremely late and furthermore were not *prima facie* allowable under Articles 83 and 84 EPC. Firstly, for the same reasons that the main request lacked inventive step, the third to fifth auxiliary requests lacked sufficiency of disclosure. Secondly, the amendments rendered claim 1 unclear.

XIV. So far as relevant to the present decision, the respondent's arguments can be summarised as follows:

- The term catch-up growth in claim 1 implied an accelerated growth after growth retardation, with the acceleration of growth being such that the growth curve was brought on and thus caught up with the reference growth curve. This was supported by figure 2 of the patent as well as the definitions of catch-up growth in D4.

- The claimed subject-matter was inventive in view of D14 as the closest prior art. The problem solved in view of D14 was to promote catch-up growth more efficiently, as evidenced by D46, or to promote it without an increase in caloric intake, with equilibrated lean and fat body mass and without promoting obesity, as evidenced in figures 3 to 5 of the patent, figure B of D25 and figure 2 of D27.

- As regards the first and second auxiliary requests, the respondent essentially reiterated its arguments made with regard to the main request.

- The third to fifth auxiliary requests should be admitted into the proceedings since these requests constituted a reaction to the board's preliminary opinion and had already been announced previously. The problem that now formed part of claim 1 was credibly solved, so that there was no insufficiency of disclosure. Furthermore, the features added to claim 1 did not render it unclear. More specifically, it was clear that the caloric intake had not to be increased compared to a person with no need for catch-up growth, and that the avoidance of obesity referred to the avoidance of obesity in later life. The claim requests were thus *prima facie* allowable.

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

XVI. The respondent requested that

- the appeals be dismissed, implying maintenance of the patent on the basis of the main request maintained by the opposition division, re-filed with letter of 6 February 2014, or, alternatively, that

- the patent be maintained on the basis of any of the first to fifth auxiliary requests filed with letter dated 8 July 2015.

The respondent further requested that the question set out in point XI above be referred to the Enlarged Board of Appeal.

Reasons for the Decision

Main request

1. The claimed subject-matter

1.1 Claim 1 is a Swiss-type claim referring to the use of an n-3 LC-PUFA, a prebiotic fibre and a probiotic bacterial strain for the manufacture of a nutritional formulation or medicament for promoting catch-up growth in sick and convalescent young mammals.

1.2 All parties agreed that the term "catch-up growth" implied an acceleration of the rate of growth after a prior retardation. However, it was a point of dispute whether this in itself was already catch-up growth (as argued by the appellants) or whether, to qualify as catch-up growth, the rate of growth had to fulfill the additional criterion of being high enough to bring the mammal up to the growth curve it would have been on if its growth had not been retarded (hereinafter "reference growth curve").

1.3 From the disclosure of the patent, the appellants' definition is the correct one.

1.3.1 The patent describes a study in which one group of rat pups stayed with their mothers until post-natal day 21. This group is denoted "non-stressed group" or "NS" in the patent. Since these rat pups were not subjected to any stress till post-natal day 21, they did not experience any growth retardation and thus, until postnatal day 21, their growth curve corresponded to the reference growth curve. A second group of pups was separated 3 hours daily from their mothers (denoted "stressed group" or "MS" in the patent) and one sub-

group of these stressed pups was fed with a diet as required by claim 1 containing the probiotics L. paracasei and B. longum, the prebiotics gum arabic, FOS and inulin and the n-3 LC-PUFA docosahexaenoic acid (DHA) and the n-6 LC-PUFA arachidonic acid (AA) ("Supplemented 1" or "Stress cocktail" in the patent), three sub-groups were fed with diets containing only one of the three ingredients as required by claim 1 (probiotics, prebiotics or n-3 LC-PUFAs) and a last sub-group was fed with a diet not containing any of the three ingredients.

In figure 1 of the patent, the growth curves of the non-stressed pups (reference growth curve) and the stressed pups fed with the various diets are shown from post-natal day 15 to 21. From day 15 to 17, all stressed pups show a decrease in body weight, corresponding to growth retardation. From day 17 onwards, the body weight of these pups increases, with the increase becoming more prominent over time. Since body weight gain is equated in the patent with growth, this corresponds to an accelerated growth. The curve that shows the most prominent acceleration of growth is that of the pups fed the diet according to claim 1 (curve with white triangles). This curve is qualified in paragraph [0037] as the "most efficient catch-up growth". This curve does not however catch up with the reference growth curve of the non-stressed pups in figure 1. Hence, figure 1 in conjunction with paragraph [0037] of the patent supports the appellant's understanding of the term "catch-up growth" as meaning an acceleration of growth after growth retardation, without this necessarily leading to catch-up with the reference growth curve.

The respondent argued that figure 1 had to be interpreted in conjunction with figure 2, which showed the growth curves for subsequent post-natal days 21 to 35 and where the curve of the stressed pups fed the diet according to claim 1 showed a catch-up with the reference growth curve of the non-stressed pups. The board acknowledges that on post-natal day 23 in figure 2 the growth curve of the pups fed the diet according to claim 1 does indeed catch up with the growth curve of the non-stressed pubs. However, this is due to the fact that the "non-stressed" animals had in fact been stressed by being separated from their mothers on post-natal day 21 (third line of paragraph [0034]), so that their growth velocity decreased. So what is seen in figure 2 is actually not a catch-up of the pups fed the diet according to claim 1 with the reference growth curve of the "non-stressed" pups but a falling-behind of the latter.

Hence, figure 2 does not invalidate the above finding that catch-up growth implies an accelerated growth after growth retardation, without this necessarily leading to a catch-up with the reference growth curve.

1.3.2 That a catch-up with the reference growth curve is not needed for the growth to qualify as catch-up growth is furthermore confirmed by paragraph [0002] of the patent. In this passage, where catch-up growth is defined as a sudden spurt of growth, it is explicitly stated that in severe cases it may be that the mammal never attains the physical state that it would have reached had the stress not been suffered.

1.4 The board acknowledges in this respect that there may be other definitions of catch-up growth, e.g. those given in D4. However in view of the clear definition

being derivable from the patent itself, there is no need, and it is actually not permissible, to use a different definition as possibly present in D4.

2. Novelty

The appellants argued that the subject-matter of claim 1 lacked novelty over each of D6 and D14. At the oral proceedings, the board came to the conclusion that the subject-matter of claim 1 of the main request was novel over these documents. However, in view of the board's finding that inventive step has to be denied over D14 as the closest prior art (point 3 below), there is no need to elaborate on the issue of novelty in more detail.

3. Inventive step

3.1 The patent concerns the use of formulations to promote catch-up growth in young mammals whose growth has been retarded as a result of physical or mental stress (page 2, lines 5 to 7).

3.2 D14 was used by all parties as the closest prior art. This document describes a study evaluating the effect of new infant formulae on weight recovery after an infection (first sentence of the summary on page 81 and the text above figure 3 on page 84). D14 is thus in the same technical field and deals with the same problem as the opposed patent. Therefore, D14 can indeed be considered to represent the closest prior art.

3.2.1 In the study described in D14, infants between 0 and 12 months of age affected by a non-severe digestive or respiratory infectious disease were randomly allocated to one of two feeding groups: one group received a

standard formula and the other received an infant formula from 0 to 4 months of age and a follow-on formula from 5 to 12 months of age. The follow-on formula comprised galacto oligosaccharides, corresponding to the prebiotic fibre of claim 1, L. rhamnosus and B. infantis, corresponding to the probiotic bacterial strain of claim 1 and LC-PUFAs (chapter "Materials and methods" on pages 82 and 83). It was found that weight was recovered more rapidly by infants who received the infant and follow-on formula than by those who received the standard formula, and that about 95% of children fed the infant and follow-on formula recovered the initial weight, whereas in the control group the percentage was only 69% (page 84).

D14 thus discloses the claimed therapeutic effect of promoting catch-up growth. This was in fact not disputed by any of the parties.

3.2.2 The respondent argued, however, that it was not clear whether the infants in D14 had experienced any growth retardation and thus whether the patient group in D14 was the same as in claim 1.

The board does not find this argument persuasive. Firstly, it is reported in D14 (text above figure 3) that the weight of the infants was recovered, which implies that, contrary to the respondent's assertion, there had been growth retardation before. Secondly, since the infants in D14 are affected by a non-severe digestive or respiratory infectious disease, they are sick young mammals and thus are as specified in claim 1. There is thus no difference in terms of the patient group between D14 and claim 1.

3.2.3 The board however shares the respondent's view that a difference exists with regard to the type of LC-PUFAs. More specifically, D14 just refers to "long chain polyunsaturated fatty acids (LC-PUFAs)" (bottom of page 82) without specifying the type of LC-PUFA. These might thus be of the n-3 type as required by claim 1, or of a different type, namely n-6 or n-9 LC-PUFAs.

3.3 The objective technical problem solved by Swiss-type claims is normally defined as the achievement of the therapeutic effect defined in this claim. In the present case, the objective technical problem would thus be the promotion of catch-up growth in sick and convalescent young mammals. However, as set out above (point 3.2.1), this therapeutic effect is already obtained in D14. The therapeutic effect defined in claim 1 can therefore not constitute the objective technical problem. This problem has thus to be formulated less ambitiously as the promotion of catch-up growth by alternative means.

3.4 In order to avoid this less ambitious definition of the objective technical problem, the respondent argued that the problem solved by the claimed subject-matter in view of D14 was to promote catch-up growth more efficiently. The respondent in this respect referred to the post-published document D46 as evidence that this problem was indeed solved.

However, D46 does not contain any comparison with other LC-PUFAs, and thus does not prove that growth is more efficient than in D14. Furthermore, according to D46, only high doses of DHA (1%, standard feeding is 0.2 to 0.3%) lead to increased growth. Claim 1 does however not limit the amount of DHA, so that D46 cannot prove that a more efficient catch-up growth, if any, is

obtained over the entire scope claimed. In view of this, D46 does not support the respondent's assertion that the use of diets as covered by claim 1 leads to more efficient catch-up growth than the diet disclosed in D14.

3.5 In an alternative attempt to avoid a less ambitious definition of the objective technical problem, the respondent argued that the problem solved over D14 was the promotion of catch-up growth without an increase in caloric intake, with equilibrated lean and fat body mass and without promoting obesity. In this context, the respondent relied upon figures 3 to 5 in the patent, D25 and D27. It was a matter of dispute whether there was evidence that this problem had been credibly solved.

3.5.1 According to the respondent, figure 3 of the patent proved that the problem of catch-up growth without increased caloric intake had been solved.

As can be deduced from this figure, except for the formula with prebiotic fibres (FOS/GOS), the caloric intake of the diet according to claim 1 (stress control diet) is on almost all post-natal days higher than that of the other diets and even higher than that of the non-stressed pups. Hence, the respondent's assertion that the patent provides evidence for catch-up growth without increasing the caloric intake is not correct.

3.5.2 Figure 4 of the patent allegedly provided evidence for catch-up growth associated with an equilibrated lean and fat body mass.

Figure 4 shows the body mass index expressed as

grams/cm^2 obtained with the various diets. However, it is not clear what is meant by an equilibrated lean and fat body mass and whether this corresponds to the body mass index shown in figure 4. Furthermore, it is questionable whether any conclusion can be drawn as to the body mass index or lean and fat body mass due to the large error bars in figure 4. Hence, the respondent's assertion that the patent provides evidence for catch-up growth associated with equilibrated lean and fat body mass is not correct.

3.5.3 According to the respondent, figure 5 of the patent provided evidence that catch-up growth occurred without promoting obesity.

As is apparent from paragraph [0003] of the patent, and as acknowledged by the respondent, the problem of promoting obesity actually refers to the avoidance of obesity later in life (see the reference to the "risk of future obesity" at the end of paragraph [0003]). Figure 5 does not however refer to any obesity later in life but just to the weight of the pups at the end of the experiment, i.e. at post-natal day 35. Furthermore, due to the large error bars in this figure, it is questionable whether any conclusion can be drawn as to the weight, let alone obesity, of the pups. Thus this figure cannot provide evidence of catch-up growth occurring without promoting obesity.

3.5.4 The respondent argued that also figure B of D25 and figure 2 of D27 provided evidence that catch-up growth was promoted while achieving an equilibrated lean and fat body mass without any promotion of obesity later in life.

In the two figures, the ratio of body weight gain to food intake is shown for various diets and this ratio is highest for the diet according to claim 1. However, it is not clear whether and, if so, how this ratio is linked to an equilibrated lean and fat body mass or obesity later in life.

3.5.5 In conclusion, neither the patent nor either D25 or D27 supports the respondent's assertion that the problem of catch-up growth without an increase in caloric intake, with equilibrated lean and fat body mass and without promoting obesity has been solved.

3.5.6 Furthermore, and even more importantly, the patent does not contain any comparison of a diet according to claim 1, which contains an n-3 LC-PUFA, with a diet according to D14, which is identical except that it contains a different type of LC-PUFA. Consequently, the patent not only lacks any evidence that the problem relied upon by the respondent has been solved, but it also in particular lacks any evidence that this problem has been solved over D14. It can therefore not constitute the objective technical problem.

3.5.7 The respondent argued in this respect that the burden of proof as regards whether or not this problem was solved over D14 rested on the appellants and they had not provided any data. However, in view of the fact that the patent does not even render it plausible that this problem has been solved at all, let alone that it has been solved over D14, the burden of proof to show with at least some degree of plausibility that this problem has been solved rested on the respondent.

3.6 In view of the above, the objective technical problem remains the promotion of catch-up growth by alternative means.

3.7 It needs to be examined whether the solution according to claim 1, i.e. the use of a composition comprising a prebiotic fibre, a probiotic bacterial strain and LC-PUFA characterised in that the LC-PUFA is or includes an n-3 LC-PUFA, is obvious in view of the prior art.

3.7.1 It is already known from D17 (paragraph [0010]) that administering a combination of the n-3 LC-PUFA DHA together with the n-6 LC-PUFA AA results in enhanced growth of both infants and pre-term infants. A similar disclosure is present in paragraph [0013] of D10. Furthermore, an infant formula containing DHA and AA is known from D5 (first three lines of page 1 and last two paragraphs of page 2).

3.7.2 The respondent argued that D5, D10 and D17 were not relevant since they did not refer to follow-on formulae as used in D14. However, this argument is not persuasive. D5 defines the term "infant" including infants from 8 to 12 months corrected age (fourth paragraph from the bottom of page 3), which implies that the formula described in this document can be a follow-on formula. D10 and D17 refer to an infant formula and the term "infant formula" includes a follow-on formula. The skilled person looking for an alternative to the follow-on formula of D14 would thus have consulted these documents.

The respondent furthermore argued that D17 taught away from the claimed subject-matter since it mentioned in paragraph [0010] the negative effect of DHA on growth. However, D17 teaches the use of DHA in combination with

AA to enhance growth, and by applying this combination in D14 the skilled person would arrive at the subject-matter of claim 1.

3.8 Consequently, the subject-matter of claim 1 lacks inventive step in view of D14 in combination with any of D5, D10 or D17. The main request is thus not allowable.

4. Request for referral to the Enlarged Board of Appeal

The respondent requested that a question be referred to the Enlarged Board of Appeal (see point XI above), if the board decided that the problem relied upon by the respondent in the context of a second medical use claim (point 3.5 above) could not be taken into account for inventive step, since it was mentioned only in the description of the patent, not in the claim.

As set out above, this problem cannot be taken into account for a different reason, namely that it has not been credibly solved. Thus, the respondent's referral question would not have had any impact on the present case. The board therefore decided to refuse the respondent's request for referral.

First auxiliary request

5. Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the LC-PUFA has been specified to be DHA and AA.

In the same way as for the main request, D14 constitutes the closest prior art and, in the same way as for this request, the subject-matter of claim 1 differs from D14 in terms of the LC-PUFAs. More

specifically, claim 1 requires the LC-PUFAs to be DHA and AA while D14 refers to LC-PUFAs in general. For the same reasons as given above with regard to the main request, the objective technical problem is thus the promotion of catch-up growth by an alternative means. As set out above (point 3.7.1), the skilled person taking, for example, D17 into account would have applied a combination of DHA and AA in D14. He would thus have arrived at the subject-matter of claim 1 of the first auxiliary request, so that the subject-matter of this claim is obvious.

Second auxiliary request

6. Claim 1 of the second auxiliary request is identical to claim 1 of the first auxiliary request. Consequently, for the same reasons as given above with regard to the first auxiliary request, the subject-matter of claim 1 of the second auxiliary request is obvious.

Third to fifth auxiliary requests

7. Admissibility

7.1 In claim 1 of both the third and fourth auxiliary requests the wording "without increasing the caloric intake, with equilibrated lean and fat body mass and without promoting obesity" has been added at the end. Similarly, at the end of claim 1 of the fifth auxiliary request the wording "with equilibrated lean and fat body mass and without promoting obesity" has been added (for the exact wording of claim 1, see point XII above).

7.2 The appellants requested that these claim requests not be admitted into the proceedings.

7.3 These claim requests were filed very late, namely two days before the oral proceedings before the board.

The respondent argued that the new claim requests were a reaction to the board's preliminary opinion and should therefore be admitted. However, this reaction (if it is one) occurred only about six months after the board's preliminary opinion had been issued, and thus was not timely.

The respondent furthermore argued that the amendments had been announced in its letter of 9 June 2015. However, this announcement too was made late, namely about 5 months after the board's preliminary opinion had been issued. In addition, only an example of how claim 1 might then read was given. The exact wording of a possible claim 1 remained open.

7.4 Furthermore, the claim requests are not *prima facie* allowable under Articles 83 and 84 EPC.

7.4.1 The wording inserted into claim 1 of the third to fifth auxiliary requests corresponds to (part of) the more ambitious problem referred to by the respondent when discussing inventive step of the main request. Accordingly, this problem now forms a functional feature of claim 1. The finding for the main request that this problem has not been credibly solved thus translates into the finding, for the third to fifth auxiliary requests, that it is not credible that this functional feature of claim 1 can be put into practice. Hence, what led to the denial of inventive step for the main request leads, by way of amendment of claim 1, to an insufficiency objection for the third to fifth auxiliary requests with regard to the added feature.

7.4.2 Further, the inserted wording, which was not present in any of the granted claims, renders claim 1 of each of the third to fifth auxiliary requests unclear. Firstly, it is not clear with regard to what the caloric intake must not be increased. Secondly, it is not clear what is meant by a lean and fat body mass that is "equilibrated". Thirdly, it is not clear whether "with equilibrated lean and fat body mass" refers to the feature of promoting catch-up growth or whether it refers to and thus characterises the patient group of sick and convalescent young mammals. Fourthly, as set out above, the feature "without promoting obesity" actually refers to the avoidance of obesity later in life. It is not clear how it can be determined whether a specific use occurring at a certain point in time meets this requirement, since this can be verified only at some unspecified point in time in the future.

7.5 The board therefore decided not to admit the third to fifth auxiliary requests into the proceedings (Article 13(1) RPBA).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The request for a referral to the Enlarged Board of Appeal is refused.

3. The patent is revoked.

The Registrar: The Chairman:

D. Hampe W. Sieber

Decision electronically authenticated