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Datasheet for the decision of 25 October 2023

Case Number: T 1876/21 - 3.3.09

Application Number: 13805304.6

Publication Number: 3082463

IPC: A23L33/00, A23C9/20, A23L33/17, A61P3/04

Language of the proceedings: EN

Title of invention:
USE OF NUTRITIONAL COMPOSITIONS HAVING A LOW PROTEIN AMOUNT

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
Reckitt Benckiser Health Limited
N.V. Nutricia

Headword:
Use of a nutritional composition having a low protein amount/ NESTLÉ

Relevant legal provisions:
EPC Art. 54

Keyword:
Novelty - main request and auxiliary requests (no) - novelty of use - second (or further) medical use

Decisions cited:
T 0019/86, T 0233/96, T 1399/04, T 0321/15, T 0694/16, T 0299/18

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Case Number: T 1876/21 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 25 October 2023

Appellant: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Plougmann Vingtoft a/s Strandvejen 70 2900 Hellerup (DK)
Respondent: (Opponent 1)	Reckitt Benckiser Health Limited 103-105 Bath Road Slough Berkshire SL1 3UH (GB)
Representative:	Carlin, Robert George Reckitt Benckiser Corporate Services Limited Legal Department - Patents Group Dansom Lane Hull HU8 7DS (GB)
Respondent: (Opponent 2)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 26 July 2021 revoking European patent No. 3082463 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. Ansorge
Members:	C. Meiners
	F. Blumer

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the patent proprietor (appellant) against the opposition division's decision to revoke the patent in suit (hereinafter "the patent").

II. In its notice of opposition, opponent 2 (respondent 2) had requested that the patent be revoked in its entirety, among other things on the ground for opposition under Article 100(a) EPC in conjunction with Article 54 EPC (lack of novelty).

III. In its decision, the opposition division found that the subject-matter of the main request and of auxiliary requests 1 to 11, filed on 18 February 2021, lacked novelty in view of document D7, *inter alia*. Moreover, it did not admit auxiliary request 12, filed during oral proceedings.

IV. The following documents, submitted by the parties in the opposition and appeal proceedings, are relevant to the present decision:

D1 B. Koletzko *et al.*, Am. J. Clin. Nutr. (2009), 89, 1836-1845

D7 WO 2008/071667 A1

D7a EP 2 096 941 B1

D12 M. F. Sewell *et al.*, American Journal of Obstetrics and Gynecology (2006), 195, 1100-1103

D13 H. R. Hull, American Journal of Obstetrics and Gynecology (2008), 198, 416.e1-416.e6

D14a O. Hansson *et al.*, Lancet Neurol. (2006), 5, 228-234 (D6 in decision T 694/16)

D17 Decision T 321/15

D18 Summons to attend oral proceedings pursuant to Rule 115(1) EPC relating to EP 3 082 463 & annex

D19 E. E. Ziegler et al., JPGN (2015), 61(5), 596-603

D19a *ibid.*, Supplementary Table S1

D19b *ibid.*, Supplementary Table S5

V. In preparation for oral proceedings, the board issued a communication pursuant to Article 15(1) RPBA 2020 (hereinafter "the communication") indicating its preliminary opinion that none of the claim requests on file was allowable due to a lack of novelty.

VI. Oral proceedings before the board were held by videoconference in the presence of the appellant and respondent 2. As announced in a letter dated 5 September 2023, opponent 1 (respondent 1) did not attend the oral proceedings.

VII. Claim 1 of the main request reads as follows:

"A synthetic nutritional composition comprising a protein source, a lipid source and a carbohydrate source, wherein the protein content is less than 1.8 g/100 kcal and wherein the energy density of the composition is from 600 to 680 kcal/litre, for use in reducing the risk of developing metabolic syndrome, obesity, insulin resistance, glucose intolerance or diabetes mellitus later in an infant's life, wherein said composition is administered to an infant born to a non-obese and non-overweight mother in the first year of the life of said infant."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the protein content is between 1.4 and 1.75 g/100 kcal.

Claim 1 of auxiliary request 2 corresponds to claim 1 of the main request, save for the additional limitation: "[,] and wherein said infant will be fed said nutritional composition from the age of 3 months".

Claim 1 of auxiliary request 3 is the result of the combination of the features of claim 1 of auxiliary requests 1 and 2.

Claim 1 of auxiliary requests 4 to 7 differs from claim 1 of the main request and auxiliary requests 1 to 3, respectively, in that it comprises the additional indications of reducing the risk of developing "increased weight gain", "increased fat deposition" and "overweight".

Claim 1 of auxiliary request 8 corresponds to claim 1 of the patent as granted:

"A synthetic nutritional composition comprising a protein source, a lipid source and a carbohydrate source, wherein the protein content is less than 1.8 g/100 kcal and wherein the energy density of the composition is from 600 to 680 kcal/litre, for use in administration to an infant born to a non-obese and non-overweight mother, in the first year of the life of said infant for the reduction of the risk of developing metabolic syndrome, increased weight gain, increased fat deposition, overweight, obesity, insulin resistance, glucose intolerance or diabetes mellitus later in said infant's life."

Claim 1 of auxiliary requests 9 to 11 corresponds to claim 1 of auxiliary request 8, save for the restriction of the protein content to a range of between 1.4 and 1.75 g/100 kcal in auxiliary request 9, the feature "[,] wherein said infant will be fed said nutritional composition from the age of 3 months" in auxiliary request 10, or the combination of both of said limitations in auxiliary request 11.

VIII. The appellant's arguments, where relevant to the present decision, can be summarised as follows.

The claimed subject-matter was *novel* over D7. This applied to the main request and to auxiliary requests 1 to 11, in particular for the following reasons.

(a) - Unlike what was held by the opposition division, "an infant born to a non-obese and non-overweight mother" constituted a new group of subjects which was *distinguished* from those previously treated infants, described in D7, by its physiological or pathological status. It followed from documents D12 and D13 that the infants born to mothers having a body mass index (BMI) below 25 were distinguished from infants born to overweight mothers or obese mothers. The former group of infants had *on average* a lower fat mass and percentage of body fat than the latter group. Moreover, the infants born to non-overweight and non-obese mothers had been purposively selected and could be identified either by retrieving information about the mother's pre-pregnancy BMI and/or by measuring the neonate's fat mass or content.

- Decision T 694/16 set out that the criterion specified in T 233/96 that a group of patients was not novel if the known groups and the new groups overlapped did not apply when the group of patients to be treated could be distinguished by "clearly defined testable criteria". As was derivable from T 1399/04, the size of the target group was not a criterion for denying its novelty over the prior art either.

(b) - Likewise, the opposition division's conclusion that the claimed group of infants was *arbitrarily* selected and that no functional relationship existed between the physiological or pathological status and the obtained effect *was wrong*.

- The data in the patent demonstrated that the reduction in weight gain was much greater for the infants born to non-overweight and non-obese mothers fed with the low-protein nutritional composition from claim 1. This finding opened up targeted prophylactic treatment of this particular group of infants.

- Whilst the data in the patent did not contain indications of their statistical relevance, the difference in weight gain between the infant groups provided sufficient evidence that the claimed group benefited most from the claimed nutritional composition. Moreover, additional indications provided by the patentee demonstrated that the data in Table 3 of the patent relating to the claimed target group were indeed *statistically significant*.

(c) Since claim 1 of the main request concerned infants born to mothers having a BMI below 25 prior to

pregnancy, it followed from the reasoning in decision T 321/15 that claim 1 of the main request was novel over D7.

Respondent 2's arguments, where relevant to the present decision, can be summarised as follows.

The subject-matter claimed in the main request (as well as that of auxiliary requests 1 to 11) *lacked novelty* in view of D7, in particular for the following reasons.

(a) - Infants born to a non-obese and non-overweight mother did not constitute a new group of treated subjects which is distinguished from infants disclosed in D7 by its physiological or pathological status. D7 *as a whole* related to a group of treated infants born to overweight *or* obese mothers. Hence, D7 already anticipated the group of treated infants born to overweight mothers as well. Consequently, the main request lacked novelty over document D7.

- *In utero* there were *risks* for adiposity *other* than the mother's BMI. Hence, measuring an infant's adiposity in the first month of life was not a suitable testable criterion for identifying infants born to non-overweight/non-obese mothers.

(b) The patent did not provide enough information to conclude that there was a *difference* in weight gain between the *groups of infants* fed with the low-protein nutritional composition claimed in the patent. The same applied with regard to the levels of IGF-1 measured in the infants. Hence, the group of patients defined in claim 1 was *arbitrary*.

(c) T 321/15 did not state whether infants born to *non-overweight mothers* were physiologically different from *overweight* mothers.

IX. Final requests

The appellant requested that the decision under appeal be set aside and that the Board acknowledge the novelty of the claims of the main request or any of auxiliary requests 1 to 11, filed on 18 February 2021 and re-filed with the statement setting out the grounds of appeal, and that the case be remitted to the opposition division for examination of inventive step. Alternatively, the appellant requested that the opposition division's decision be set aside and that the patent be maintained on the basis of the main request or any of auxiliary requests 1 to 11.

Respondent 2 requested that the appeal be dismissed.

Respondent 1 has not submitted any requests.

Reasons for the Decision

1. Novelty (Article 54 EPC) - main request

1.1 Independent claim 1 is drafted in the format of a second medical use in accordance with Article 54(5) EPC.

1.2 It is common ground that document D7 discloses nutritional compositions (for infants) having the same composition as recited in claim 1. It is also undisputed that the claimed therapeutic (preventive) effect is disclosed in document D7. The nutritional

compositions in claim 1 and D7 contain a reduced protein content compared with "standard" infant formulas. The purported effect is the prevention of obesity and related medical conditions later in the life of the infant fed with such compositions in the first year of its life. Hence, there was no dispute between the parties that the remaining features of claim 1, besides the treated group of subjects, are already disclosed in D7. The disclosure of those features in D7 is correctly described in section 4.4.2 of the decision under appeal (see claims 1 to 3 and 13 to 15 and page 4, lines 8 to 9 of D7).

1.3 The only point of dispute between the parties was whether the patient/subject population as specified in claim 1 constituted a new group of treated subjects in the context of an otherwise known second medical use of a compound or composition (Article 54(5) EPC).

1.4 Interpretation of claim 1

The board agrees with the opposition division's assessment that, when interpreting the claim in the light of the description, the reduction of the risk referred to in claim 1 has to be assessed *in comparison* with a subject population fed with a corresponding infant formula with a higher protein content (see paragraphs [0006], [0114] and [0115] of the patent; cf. point 3.4 of the decision under appeal).

Likewise, it follows from paragraphs [0036] to [0039] of the patent that the terms "non-obese mother" and "non-overweight mother" refer to mothers having a body mass index (BMI) of below 30 or below 25, respectively, *prior to establishment of pregnancy*. Consequently, the

following assessment of novelty will be based on this interpretation.

1.5 According to established case law of the boards of appeal, the use of the same compound in the treatment of the same disease for a particular group of subjects, can nevertheless constitute a novel therapeutic application, provided that
i) it is carried out on a new group of subjects which is *distinguished* from the former by its *physiological or pathological status* (see Case Law of the Boards of Appeal, tenth edition, 2022, I.C.7.2.4.b; cf. T 19/86, OJ 1989, 24; T 233/96).
In decision T 233/96, as a further requirement for establishing such an aforementioned novel therapeutic application, it was held that ii) the establishment of the novel group must not be *arbitrary*. This requires that there is a *functional relationship* between said status and the therapeutic effect obtained (see e.g. T 233/96, point 8.7 of the Reasons; cf. T 694/16, point 5.20 of the Reasons). The opposition division based its decision regarding novelty on said criteria i) and ii) (see point 4.4.3 of the decision under appeal).

1.6 With regard to the first point to be elucidated, point i), the board makes the following observations.

1.6.1 D7 is directed to nutritional compositions for infants at risk of developing obesity later in life. The compositions comprise a protein source, a lipid source and a carbohydrate source and have a protein content of less than 1.8 g/100 kcal and an energy density of less than 650 kcal/litre (see e.g. claim 1).

1.6.2 At the same time, D7 already discloses two groups of subjects *expressly*, namely infants born to obese

mothers and infants born to overweight mothers (see the paragraph bridging pages 2 and 3). In this document, it is also mentioned that for these groups it may be possible to reduce the risk of future obesity by feeding the at-risk infant with the nutritional compositions. The remaining third group, i.e. infants born to mothers who are not overweight and not obese at establishment of pregnancy ("lean mothers"), is also mentioned in D7 on page 1, lines 25 to 27.

1.6.3 D7 states that the administration of the formulas is *particularly* (and hence not exclusively) proposed for infants at risk of developing obesity later in life. The following is stated in the corresponding passage of D7 on page 3, last paragraph: "Without wishing to be bound by theory, the inventors believe that for infants at risk of developing obesity *in particular*, feeding a nutritional composition with a controlled protein and energy content which is moreover preferably relatively rich in the satiety-inducing protein casein could counteract any tendency on the part of the infant to *overfeed*, *particularly as regards protein intake*, whilst supplying sufficient quantities of nutrients essential for growth and development and *resulting in a growth pattern similar to that observed in breast fed infants*" (emphasis added by the board).

1.6.4 Whilst the aforementioned third group of subjects (mothers' BMI < 25) is mentioned in the introductory part of D7, it seems that D7 does not directly and unambiguously disclose that the nutritional compositions in D7 are administered to said third group of subjects, i.e. infants born to non-overweight and non-obese mothers.

1.6.5 However, the board concurs with respondent 2 that neither the patent nor documents D12 and D13 corroborate that the groups of infants born to non-obese and non-overweight mothers (i.e. having a BMI < 25 prior to establishment of pregnancy) exhibit a physiological status that could be discerned from that of an infant born to an *overweight* mother, which is unambiguously disclosed in D7 as an infant at risk of developing obesity later in life.

1.6.6 This lack of distinction between the physiological status of the known treatment group "infants born to overweight mothers" and the group recited in claim 1 is *aggravated by the fact that claim 1 encompasses children born to mothers having developed gestational diabetes mellitus (GDM) and/or gestational overweight during pregnancy*. These conditions are further factors that influence the pathophysiological/endocrinological status and in particular fat mass in infants. This is derivable from the first full paragraph, left-hand column, on page 1101 of D12 and section 2.1 of decision T 321/15 (D17).

1.6.7 With regard to the latter point, the appellant argued that GDM was a *rare event*. GDM only occurred in 3 out of 1000 lean mothers during pregnancy. The appellant stated in the oral proceedings before the board that this had been reported in a clinical study in 2010. GDM thus had no bearing on the conclusion that it could be said with high certainty whether an infant had been born to a non-obese and non-overweight mother.

However, no evidence of this assertion of fact has been presented. Even assuming that this argument were correct, it would not be persuasive. It cannot undermine the conclusion that more than just a few

individuals are exposed to *other risk factors for developing increased fat mass in the first month of life in utero* besides the mother's BMI at conception.

1.6.8 The appellant also stated that it was clear that the obese mothers in D12 and D13 did not make up 90% of mothers having a BMI ≥ 25 at establishment of pregnancy. This was not the way in which clinical studies were designed. This expectation is reasonable; however, it cannot invalidate the conclusion that the *larger* group of infants born to mothers having a BMI ≥ 25 at conception already *greatly overlaps* with the subject group in claim 1 in terms of their relative fat mass.

This is clear from the data presented in Table II in D12 and in Table 2 in D13. It thus has to be expected that the corresponding distribution curves obtained for the infant groups as characterised by "mother's BMI < 25" vs. "mother's BMI ≥ 25 < 30" would *converge even further.* This would mean excising the group of the infants born to obese mothers, having a BMI of at least 30. No data for the group of infants born to overweight mothers only are provided in D12 or D13. Therefore, D12 and D13 fail to demonstrate that there is a distinction in the physiological or pathological status between an infant born to a non-obese and non-overweight mother and an infant born to an overweight mother as disclosed in D7.

1.6.9 At the same time, the relative fat content and absolute body fat mass have been invoked by the appellant as *markers* for the infant's physiological status (a pathological status does not appear to apply to healthy children).

1.6.10 The appellant's line of argument is that the group of infants born to mothers having a BMI < 25 prior to establishment of pregnancy can be taken as a new group of (treated) subjects over document D7. It was also stated on page 1, lines 25 to 27 of D7 that infants born to overweight and obese mothers had a greater risk of becoming overweight and obese later in life than infants born to lean mothers. This greater risk existed because they were thus somehow different.

1.6.11 D7 already individualises the treatment of the *remaining* groups of infants in relation to the mothers' BMI. The infants recited in claim 1 are first and foremost characterised by a characteristic of *their mother* prior to establishment of pregnancy, rather than by parameters that would render the individual *infants* discernible from infants forming part of said two remaining infant groups. As mentioned above, however, the group of infants born to lean mothers includes sub-collectives that have an increased risk of adiposity later in life. It is therefore not a homogeneous group of patients.

1.6.12 In view of the above, and in particular the greatly overlapping distribution curves for absolute and relative fat mass of the infants, the board sees no invoked physiological parameter that could distinguish the collective of infants born to mothers having a BMI < 25 prior to establishment of pregnancy from the remaining groups, in particular from infants born to mothers having a BMI between ≥ 25 and < 30 prior to establishment of pregnancy (overweight mothers). In view of the heterogeneity of the target group, it is considered impossible to establish whether a given infant fulfils the criterion "born to a non-obese and non-overweight mother", corresponding to a mother's BMI

< 25 *prior to establishment of pregnancy*. The board thus shares the opposition division's corresponding concerns.

1.6.13 The situation underlying the patent on the relevant date differs markedly from the scenario encountered in decision T 321/15, which was cited by the appellant on appeal. In decision T 321/15 (based on European patent D7a as counterpart to D7), the deciding board held that infants born to *obese* mothers were distinct from infants *in general*. The deciding board's conclusion was, *inter alia*, that the group of infants born to obese mothers exhibited a pathophysiological status which differed from that of infants born to *non-obese mothers* (i.e. having a BMI < 30 prior to the establishment of pregnancy). No conclusion with regard to the establishment of a new group of treated subjects was drawn with regard to infants born to overweight mothers or mothers having a BMI < 25 prior to conception. In the present case, document D7 forms part of the prior art under Article 54(2) EPC. The implication of this is that, in the present case, e.g. the treated patient/subject collective "infants born to mothers having a BMI ≥ 25 < 30" was explicitly disclosed in the prior art. For these reasons, the reference to T 321/15 cannot support the appellant's case.

1.6.14 The case underlying decision T 694/16 is based on claimed subject-matter involving two specific biological markers and a patient population that can be determined using established criteria based on cognitive and functional tests (see points 5.5 and 5.20 of the Reasons). The patient groups considered in that decision thus do *not overlap* other than the claimed group having been considered to be encompassed/embedded

in the larger (more generic) patient group treated in the prior art. Hence, the appellant's discussion of the overlap of the values for the clinical markers relied on in T 694/16 in the light of Figure 1c of D14a, referred to in that decision, is without merit. Moreover, the relevant marker concentration ranges appear in the *claims* of the relevant claim request in that case, unlike in the current case.

1.6.15 In the case underlying T 1399/04, the members of the group of subjects in question could be *distinguished* from all other chronic hepatitis C patients by a specific virus genotype and viral load, which can be easily determined and constitute clear biological parameters. This made it possible to *differentiate members of the target group from all other chronic hepatitis C patients*. This conclusion from T 1399/04 was explicitly cited by the appellant in its statement of grounds of appeal. In the present case, however, the group of subjects is determined by characteristics of the *mothers* prior to establishment of pregnancy. Whether or not the infants born to lean mothers constitute the largest group of subjects (as possibly the target patient group in T 1399/04) is not relevant to the board's conclusion on novelty in the current case.

1.6.16 Similarly, in the oral proceedings before the board, the appellant referred to decisions by the Boards of Appeal that dealt with infants delivered by Caesarean section as a treated patient/subject group. That group had a specific intestinal microbiome that differed from that of infants delivered by vaginal birth. The appellant argued that exactly the same scenario applied as in the current case: a physiologically different sub-group of infants was defined by the way in which

they had been delivered by their mothers. There were also infants that had a microbiome that differed from that typically observed in the aforementioned group born by Caesarean section.

The board observes that the feature relied upon was not comparable as the infants could be distinguished in that case. First, the status of the infant at birth should be known and is not characterised by an event that typically occurs nine months prior to birth. By contrast, in the current case, the relevant event is the mother's BMI *prior to establishment of pregnancy*. Secondly, the infant's microbiome is characteristic and associated with delivery by Caesarean section. The infant's microbiome is considered a marker suitable for distinguishing between infants delivered by Caesarean section and vaginal birth, unlike absolute and relative body fat mass, which is argued to distinguish the target group in the case in hand by its average value at largely overlapping distribution curves. Therefore, this line of argument does not support the appellant's case.

1.6.17 In view of the above, novelty of the subject-matter of claim 1 has to be denied over D7 for a lack of a distinct physiological status of the group of subjects recited in claim 1.

1.7 Apart from these considerations, the aforementioned criterion ii) for establishing novelty for a known substance or composition by a second or further medical use by a new treated group of subjects is not met either. This criterion requires a *functional relationship* between the established new group of subjects and the effect relied upon.

1.7.1 In its grounds of appeal, the appellant underlines that it had been well established on the priority date of the patent that formula-fed infants gained more weight than breast-fed infants. Rapid weight gain during infancy was also associated with an increased risk of obesity later in life. This was stated in paragraph [0006] of the patent and in D1, page 1836, left-hand column, first paragraph of text section "Introduction". Moreover, high protein intake during infancy was associated with rapid weight gain and hence an increased risk of obesity later in life. This was demonstrated in D1 (see abstract of this document and paragraph [0009] of the patent under appeal). Surprisingly, the reduction in weight gain, observed in the clinical study underlying the patent, was much more pronounced in infants born to mothers as specified in claim 1. This was also apparent from Table 3 of the patent. In view of the above, these mothers are defined in the patent as those having a BMI < 25 prior to establishment of pregnancy.

1.7.2 However, the board notes that no data comparing the two *sub-groups* "mothers having a BMI < 25" and "mothers having a BMI ≥ 25 < 30" prior to establishment of pregnancy have been provided. Even the data presented in the patent including *both* groups of infants, born to obese or overweight mothers, do not include relevant statistical indications (such as the P-values and standard deviations measured in the clinical trial reported).

The appellant argued in this context that the difference in weight gain between all infants receiving either "low-protein" formula or "high-protein" formula was close to being statistically significant (see P-value of about 0.07 in Table 1 of D19, to which the

appellant referred in the oral proceedings). However, no data comparing the aforementioned *sub-groups* are provided in the patent (or in the description of the clinical trial reported in D19; see below). This would mean comparing data sets obtained for said sub-groups of infants, born to mothers having BMIs prior to conception of < 25 and $\geq 25 < 30$, respectively. Therefore, the appellant's argument that it was highly likely that the effect of reduced weight gain for the infants of lean mothers vs. those born to obese *and* overweight mothers was significant, even without providing *statistical* significance, is not convincing.

1.7.3 In view of the indications provided in the patent and in post-published documents D19 and D19a, the board agrees with the respondent that it is reasonable to assume that D19 describes the clinical trial underlying the data presented in the patent. The data disclosed in D19/D19b for the serum concentrations of IGF-1 (insulin-like growth factor 1), determined at an age of 6 and 12 months, are not statistically significant. In addition, these data were not broken down to consider sub-groups classified according to the BMIs of the mothers prior to pregnancy (see Table S5 in D19b). As confirmed by the appellant, the study was not designed in terms of sample size to demonstrate statistically significant differences between sub-groups established by the mothers' BMIs.

In the same way, data sets for the individual sub-groups established by the mothers' BMIs are not provided in Table 4 of the patent either. In the patent and in D19, the growth hormone IGF-1 seems to have been monitored as a *predictive marker for the risk of developing obesity later in life and for infants' weight gain (see e.g. paragraph [0098] of the patent,*

referred to by the respondent at the oral proceedings before the board). Therefore, no relative reduction in the risk of developing the diseases recited in claim 1 has been corroborated by the appellant for the group claimed.

1.7.4 Whilst the appellant argued in favour of statistical considerations in relation to the distinction of infants by their absolute and relative fat mass, it argued that statistical significance was not necessary in relation to the aforementioned second criterion for establishing a new patient group in a second medical use.

At the same time, however, the appellant held that the purported effect of reduced weight gain in children born to lean mothers was *surprising* in the patent and in the statement of grounds of appeal (page 5, lines 4 to 6 and page 22, lines 9 to 11). In the latter, it is stated that, if anything, a skilled person would have expected that infants born to obese and overweight mothers would benefit most from the low-protein diet.

In view of the principle of free evaluation of evidence, the board is not bound to a specific methodology when evaluating evidence adduced. In the current case, the board observes that the purported effect of reduced weight gain in infants born to "lean" mothers vs. those born to overweight mothers on feeding a protein-reduced diet has not been supported by other convincing evidence. In view of the lack of a comparison of the relevant sub-groups, the data provided in Table 3 of the patent do not render convincing an effect that would be associated with the sub-group of infants born to lean mothers, let alone data that would be statistically relevant. There is

thus no "clear trend to the naked eye in the current case", referred to in point 3.6.7 of the reasons for the decision of T 299/18 in the context of different data relating to an unrelated scenario. Hence, the appellant's reference to decision T 299/18 at the oral proceedings before the board does not support its case. Similarly, the reference to point 5.10.1 of a board's communication in a different case (T 1863/21, concerning European patent EP 2 575 508) can merely serve as a reminder that statistical significance is a concept that bears the risk of unjustly disregarding experimental results; however, as correctly pointed out by the respondent, in the current case, there is no experimental evidence comparing the target group of subjects with the infants born to mothers having a BMI ≥ 25 < 30.

Hence, it is also not relevant for the present decision that the opposition division had held in their *preliminary* opinion (D18, point 6.4), rather than in their decision, that a reduction in weight gain in the clinical trial with the protein-reduced diet was more pronounced in infants born to mothers having a BMI < 25. The opposition division referred to Table 3 of the patent in this context.

1.8 It is for these reasons that the board considers that the aforementioned criteria for establishing a new group of subjects treated have not been met. Resuming this point, it has first not been demonstrated that there is a difference between the physiological status of the known group of infants as characterised by "mother's BMI ≥ 25 < 30" and that of the known group recited in claim 1 ("infants born to mothers with BMI < 25"). Second, a functional relationship between the respective physiological status and the alleged

therapeutic effect has not been corroborated by the appellant.

1.9 Due to the finding that the compositions and their use as specified in claim 1 are disclosed in D7 for the above-indicated reasons, the board concludes that the subject-matter of claim 1 lacks novelty over document D7 (Article 54 EPC).

2. Novelty - auxiliary requests 1 to 11

The appellant did not present any further arguments with regard to the novelty of the subject-matter of the auxiliary requests at the oral proceedings. Hence, the board's negative assessment of the novelty of these requests, outlined in its communication, is essentially repeated in the following.

The remarks made in section 1 above apply equally to the analysis of novelty of claim 1 of each of auxiliary requests 1 to 11. With regard to the additional features contained in each claim 1, the board endorses the conclusions provided in sections 5 to 9 of the Reasons of the decision under appeal. Furthermore, document D7 also discloses the feeding period from 3 to 12 months (see lines 2 to 5 on page 9; page 3, line 1; page 4, line 6), as required in claim 1 of auxiliary request 2. Hence, none of the auxiliary claim requests meets the requirement of Article 54 EPC either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

K. Götz-Wein M. Ansorge

Decision electronically authenticated