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Datasheet for the decision of 20 June 2022

Case Number: T 3192/19 - 3.3.09

Application Number: 14800162.1

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IPC: A23L33/10, A23L33/17, A23L5/00, A23L33/00, C13K5/00

Language of the proceedings: EN

Title of invention:
POWDERED NUTRITIONAL COMPOSITION WITH LARGE LIPID GLOBULES

Patent Proprietor:
N.V. Nutricia

Opponent:
Société des Produits Nestlé S.A.

Headword:
Powdered nutritional composition/NUTRICIA

Relevant legal provisions:
EPC Art. 56, 83
RPBA 2020 Art. 12(4), 12(6) sentence 2

Keyword:

Inventive step - main request (yes)
Sufficiency of disclosure - main request (yes)
Late-filed evidence - admitted (no)

Decisions cited:

T 1772/09

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Beschwerdekammern

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Case Number: T 3192/19 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 20 June 2022

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Opponent)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Plougmann Vingtoft a/s Strandvejen 70 2900 Hellerup (DK)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 10 October 2019 concerning maintenance of the European Patent No. 3068239 in amended form.**

Composition of the Board:

Chairman	A. Haderlein
Members:	C. Meiners
	D. Rogers

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the patent proprietor (appellant) against the opposition division's interlocutory decision finding that European patent No. 3 068 239, as amended according to the fourth auxiliary request filed in the oral proceedings before the opposition division, met the requirements of the EPC.

II. After having found that the subject-matter of the main request met the requirements of Rule 80 EPC and Article 123(2) and (3) EPC; was sufficiently disclosed (Article 83 EPC); and complied with the requirement of novelty (Article 54(1) EPC), the opposition division held that the subject-matter of independent claims 1 and 10 to 14 of the main request and claim 1 of auxiliary requests 1 to 3 did not involve an inventive step (Article 56 EPC). The subject-matter of the then auxiliary request 4 was found to meet the requirements of the EPC.

III. In its notice of opposition, the opponent (respondent) had requested that the patent in suit ("the patent") be revoked in its entirety, *inter alia,* on the grounds for opposition under Article 100(a) EPC in combination with Article 56 EPC (lack of inventive step) and Article 100(b) EPC (insufficiency of disclosure).

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

D1	A. Rawle, Basic Principles of Particle Size Analysis, 2003, 1-8
D2	WO 2010/027259 A1
D3	EP 2 638 811 A1
D4	Product data sheet for Lactopure® lactose
D6a	Sieving particle size analysis of lactose product from Alpavit
D6	Laser diffraction particle size analysis of lactose product from Alpavit original file
D7	WO 2013/169097 A 1
D8	X.-M. Zeng et al., *J. Pharm. Sci.*, 2001, 90(9), 1424-34
D10	GB 987,934
D11	WO 2008/021858 A2
D14	WO 96/33619 A1
D17	Supplier information Lactochem® Microfine (10-10-2014)
D17b	Blown-up figure from D17
D18	DFE website: https://www.dfepharma.com/en/productfinder.aspx: Screenshot after selecting 'micronised lactose'
D18b	Screenshot of DFE website with information about Lactochem® Microfine II
D20a	Example of a narrow particle size distribution with D90 = 10 µm
D20b	Example of a broad particle size distribution with D50 = 6 µm
D21	WO 2006/079420 A1
D22	DFE Pharma – "Particle size measurement of lactose for dry powder inhalers"
D23	H. Adi *et al.*, *Powder Technology*, 2007, 179, 90-4

V. Claim 1 of the main request underlying the impugned decision, which is identical to the main request filed with the grounds of appeal, reads:
"A powdered nutritional composition comprising protein, carbohydrates and
a) lipid globules with a volume weighted mode diameter of 1 micrometer or above and/or at least 45 volume% based on total lipid with a diameter of 2 to 12 micrometer; and
b) micronized carbohydrates (iii) of which at least 90 volume% has a size less than 10 micrometer, and/or (iv) having a volume median particle size D50 below 6 micrometer, wherein said micronized carbohydrates preferably comprise one or more selected from the group consisting of micronized lactose, micronized glucose, micronized maltodextrin, micronized starch, micronized inulin and micronized sucrose, wherein said micronized carbohydrates are present in an amount of 2 - 10 wt %, based on total weight of the composition,
said nutritional composition being an infant formula, a follow on formula, and/or a growing up formula."

Criteria iii) and/or iv) as specified in claim 1 are also recited in independent claims 10 and 14 of the main request.

VI. With its statement setting out the grounds of appeal, the appellant filed a main request and auxiliary requests 1 to 14. The main request corresponds to the main request underlying the decision appealed.

VII. In its reply to the statement setting out the grounds of appeal, the respondent argued, *inter alia*, why the main request was not allowable. The respondent also requested that oral proceedings before the board be

held in accordance with Article 116 EPC as an auxiliary measure if the board was not inclined to grant the respondent's main request.

VIII. The board summoned the parties to oral proceedings. Moreover, the board issued a communication pursuant to Article 15(1) RPBA 2020 ("the board's communication") in which it set out its preliminary opinion. The preliminary finding of the board was that the claimed subject-matter of the main request was sufficiently disclosed and involved an inventive step.

IX. The respondent withdrew its request for oral proceedings. It did not reply in substance to the preliminary opinion set out in the communication pursuant to Article 15(1) RPBA 2020.

X. The board cancelled the oral proceedings.

XI. The appellant's arguments relevant to the decision may be summarised as follows.

(a) Document D23 should not be admitted into the appeal proceedings. There was no reason why the opponent had not submitted the document in the opposition proceedings. What is more, the admission of D23 would give rise to new issues (de-agglomeration and storage effects on lactose), and thus a fresh discussion would be initiated for the first time in appeal proceedings.

A skilled person was aware that laser diffraction was the most appropriate method for determining the particle size for lactose manufacturing and lactose applications. In this area of technology, the volume distribution of particle sizes was commonly

used. The primary result obtained from laser diffraction measurements was a volume distribution, which was typically referred to as D50 instead of Dv50. Malvern laser diffraction analysers were the only type of measurement tool mentioned for determining particle sizes in the original application. Hence, it followed that a skilled person would use Malvern laser diffraction technology to determine the size of micronised carbohydrates. There was thus no undue burden for a skilled person to reproduce the invention. The opponent had not provided any substantiation why a micronised carbohydrate with a particle size within the claimed ranges would not result in free flowing properties, even when allowing for some margin in determining the actual particle size.

(b) As to inventive step, it was credible that either criterion iii) or iv) sufficed for achieving the desired technical effect. Small carbohydrate particles prevented the bigger formula particles with protein, carbohydrates and lipid globules from gluing together. What is more, the claims should be read with a mind willing to understand. This meant that the claims of the main request could only be construed to mean that there was a formula, comprising, *inter alia,* carbohydrates, to which micronised carbohydrates were added. The technical difference over documents D2 and D3 was the presence of micronised carbohydrates with the particle size distribution as required in claim 1. The resulting technical effect was improved flowability of powdered nutritional compositions comprising large lipid globules. On the basis of documents D2 or D3 as the closest prior art, a skilled person would not be motivated to search for

compositions with reduced caking, lumping and flowability. Hence, an inventive step was to be acknowledged for the subject-matter of claim 1.

XII. The respondent's arguments relevant to the decision may be summarised as follows.

(a) The claimed subject-matter was insufficiently disclosed because how to measure and determine the size of the micronised carbohydrates in a reliable manner was not disclosed. In the absence of such disclosure, the skilled person would have no way of knowing if the problem of improving the flow properties (of powdered nutritional compositions) had been solved.

The patent was completely silent on the measuring method to be employed. In paragraph [0020], no particle size was indicated for the commercially available Lactochem® Microfine lactose product either. However, different measurement methods for determining particle sizes existed that gave different results. This was because the methods used different detection principles and properties of the particles.

Even if assuming, *arguendo*, that a skilled person realised that the particle size referred to in claim 1 of all requests should be measured by laser diffraction, the obtained particle size distribution depended, *inter alia*, strongly on the sample pretreatment and the choice of dispersant. This was convincingly demonstrated in document D23.

Moreover, the deficiencies relating to sufficiency of disclosure could not be overcome by using Lactochem® Microfine lactose as a calibration tool.

(b) Regarding the requirement of inventive step, the subject-matter of claim 1 of the main request did not require that both criteria iii) and iv) be fulfilled by the micronised carbohydrates. It had not credibly been demonstrated that micronised carbohydrates having a particle size distribution very different from the exemplified micronised lactose would have the same advantageous impact on flow properties (of powdered nutritional compositions containing lipid globules).

It was furthermore stated in paragraph [0009] of the patent that the addition of the micronised carbohydrates to a powder containing the remaining nutritional ingredients was essential to obtain the desired effect and solve the problem of improving flow properties. This structural feature was obtained by preparing the powdered nutritional compositions as described in example 1, which involved the blending of the micronised lactose with a spray-dried powder. In contrast, claim 1 included variants in which the micronised carbohydrates were incorporated into spray-dried particles containing protein, carbohydrates and lipid globules of a certain size. Likewise, claim 1 also covered powdered nutritional compositions where all the ingredients were dry-mixed with each other. This would yield a simple powder mixture. There was no evidence that the addition of micronised carbohydrates to such a simple powder mixture would have any effect on the flow properties.

Consequently, the objective technical problem to be formulated in view of D2 or D3 as the closest prior art was merely to create alternative powdered nutritional compositions containing large lipid globules.

The solution to this very problem, however, was obvious in view of the state of the art.

XIII. Requests

The appellant (patent proprietor) requests that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or alternatively upon the basis of one of auxiliary requests 1 to 14, all filed with the statement setting out the grounds of appeal.

The respondent (opponent) requests that the appeal be dismissed.

Reasons for the Decision

1. Admissibility of document D23

1.1 As regards the admissibility of document D23 into the appeal proceedings, the board's communication sets out the following in point 6:

"The appellant requests that this document not be admitted into the proceedings.

The board preliminarily concurs with the appellant that

document D23 could have been filed in the opposition proceedings, also in view of the opposition division's positive preliminary opinion on sufficiency of disclosure. Moreover, the board agrees with the appellant that the question of agglomerate formation in different solvents gives rise to new issues to be discussed in relation to sufficiency of disclosure. Consequently, the board intends not to admit D23 into the proceedings (Article 12(4) RPBA 2020)."

1.2 The respondent has not provided any counter-arguments. In view of these considerations, the board decides not to admit document D23 into the appeal proceedings (Article 12(4) and (6) RPBA 2020).

2. Sufficiency of disclosure - main request

2.1 As regards the question of sufficiency of disclosure, the board's communication sets out as follows in points 7.1.1 to 7.1.12:

"7.1.1 The first argument put forward by the respondent in respect of sufficiency of disclosure is that there was technical information missing in the patent in suit for reliably determining the particle size of the micronised carbohydrates. However, as was derivable from document D1, different methods of measurement would lead to different results.

Whilst this conclusion may hold true, the board agrees with the appellant's argument that D1 sets out on page 7 that laser diffraction is the preferred standard in many industries and that the output of the laser diffraction particle size measurement is the volume distribution of particle diameters.

7.1.2 The board also agrees with the opposition division's conclusion that claim 1 characterises the particle sizes of the micronised carbohydrates in criteria (iii) and (iv) in terms of the volume median particle size D_V50 and the D_V90 diameter, respectively. Both values can be directly obtained from the cumulative volume distribution function as determined by laser scattering. Volume distribution equals the weight distribution if the density of the material under scrutiny is constant. This appears to be the preferred distribution in the technical field in question (see third full paragraph of the second column on page 8 of D1). Malvern laser diffraction measurements are the only technique for measuring particle sizes applied in the patent, and such measurements also directly yield D50 and D90 particle sizes.

7.1.3 In contrast, the skilled person would not use sieving because, as is stated in D1, particle size determination by sieving is difficult for dry powders. The respondent argued in this context that wet sieving was said to solve this problem. However, D1 mentions that results from this technique give very poor reproducibility and are difficult to carry out. What is more, cohesive and agglomerated materials are difficult to measure by this technique. Additionally, D1 mentions that a true weight-distribution is not obtained when applying this technique [...] (see second column on page 5 of D1). This conclusion is not invalidated by document D6a, which relates to much coarser lactose powders (the D50 as determined by sieving analysis is 156 micrometres). It has not even been demonstrated by the respondent that powders having a D50 of 6 micrometres, let alone D50 values which are significantly lower than this threshold value called

for in claim 1, can be analysed by sieve analysis at all. D22 does not set out what should be taken as 'finer lactose grades' and can thus apparently not support that a skilled person would have (and could have) employed sieve analysis for analysing particle size distributions as required in claim 1 either.

7.1.4 By contrast, D1 also sets out that laser diffraction yields the volume equivalent spherical diameter, as conceded by the respondent. This representation of the particle diameter hinges on the scattering volume and not on the particle geometry (e.g. spherical or needle-shaped geometry). The method is moreover applicable in a range from 0.1 to 3000 micrometres (see e.g. the first full paragraph in the second column on page 7).

7.1.5 Thus, the board preliminarily concurs with the appellant and the opposition division's decision that laser diffraction is the standard method for determining the particle size in the low-micron range. This technique yields volume distributions of particle sizes which are apparently not susceptible to any potential form-anisotropy of the measured particles.

7.1.6 This method is the only measurement method explicitly disclosed in the cited documents for micronised lactose/carbohydrates having a D90 of less than 10 micrometres and/or a D50 below 6 micrometres.

7.1.7 In view of this preliminary conclusion, any reference by the respondent to the potential influence of form-anisotropy of particles on the result of the reading values for the particle size when applying different measurement techniques is without merit.

7.1.8 As the output of the laser diffraction measurement is the volume distribution function, from which the D50 and D90 can be directly determined from the cumulative distribution curve, the case at hand appears to differ significantly from the scenario under scrutiny in T 1772/09. In that decision, cited by the respondent, the mean particle diameter (which had not been specified further) had to be determined and not the D50 value. Moreover, in that case the particle size characterised a single chemical compound claimed and not a composition characterised by per se known components.

7.1.9 What is more, D1 sets out that the full Mie theory can be applied by the latest instruments such as Malvern Instruments when determining and calculating the particle size by laser diffraction. According to D1, this allows completely accurate results over a large size range (see right-hand column on page 7 of D1, published in 2003). D1 also sets out that laser diffraction is an absolute method which does not require calibration (see page 8, left-hand column, first text section).

7.1.10 The board preliminarily takes the view that the difference of about 28% between the D90 value estimated by the respondent from the graph in figure 3 of D7 and the value reported in D18/D18b could also be ascribable to inter-batch fluctuations of particle size distribution. It should also be noted that the figure 3 of D7 does not allow for an accurate determination of the D90. Values of 7 microns (D18b) and 9 microns (D7) are close so that this figure might as well be read so as to arrive at a value of about 7 microns.

The board considers that there is no information at hand supporting a finding that a skilled person would have been faced with an undue burden when using suitable laser diffraction instruments at the priority date of the patent.

7.1.11 Even assuming that a skilled person would not infer from the patent and their common general knowledge that laser diffraction should be used as the method of choice for determining the D50 and D90 values called for in claim 1, the criticality of an exact determination of the reading values for carrying out the invention described in the patent has not been demonstrated.

Even assuming arguendo that a difference between reading values of about 23% could be observed when using different methods of measurement, as observed for markedly coarser lactose particles by comparing the results described in D6 vs. D6a, it has not been shown or rendered plausible that such a fluctuation of the particle size of the micronised carbohydrate particles would not prevent the larger powdered fat-containing nutritional material from cohesion (cf. paragraph [0009] of the patent). This cohesion appears to be ascribable to the presence of greater amounts of free oil on the surface of the particles of the nutritional material comprising larger lipid globules (cf. example 1 and paragraphs [0006] and [0009] of the patent). It is not apparent that a skilled person would be unable to adjust the particle size of the micronised carbohydrate particles, e.g. by further milling, if a first particle size measurement resulted in too low D50 and D90 values. This would mean that the particles would be coarser than suggested by the measurement.

In view of these considerations, any kind of 'calibration' using Lactochem® Microfine for concluding whether a useful measuring method for determining the particle size of the micronised carbohydrates is employed is not needed for working the invention. As argued by the respondent, the particle size distribution of this trade product could vary and/or change over time.

7.1.12 The board therefore preliminarily concludes for these reasons that the claimed subject-matter of the main request is sufficiently disclosed (Article 83 EPC)."

2.2 No counter-arguments were provided by the respondent. Thus, the board has no reason to review its preliminary opinion. Therefore, the board comes to the conclusion that the claimed subject-matter of the main request is sufficiently disclosed and meets the requirements of Article 83 EPC.

3. Inventive step - main request

3.1 Interpretation of claim 1

3.1.1 The board does not agree with the respondent's view that the wording of claim 1 should be construed to allow for the integration of the micronised carbohydrates in the powdered material comprising protein, carbohydrates and lipid globules.

3.1.2 Firstly, the indication of specific amounts for component (b) in claim 1 suggests that those should be a separate entity, apart from the carbohydrates mentioned in line 1 of claim 1.

3.1.3 Secondly, such an integration of the micronised carbohydrates, having according to claim 1 a particle size distribution as characterised by criteria (iii) and/or (iv), would mean that such a particle size distribution would be absent in the final claimed powdered nutritional composition. Given that carbohydrates typically have melting points below spray-drying temperatures (and are typically dissolved in the aqueous phase during emulsification), it has to be expected that component (b) would not be present in the final powdered material as discrete particles meeting the limitations imposed by claim 1 (i.e. criteria (iii) and/or (iv)). Such compositions would thus apparently not comprise "micronised carbohydrates" as in claim 1.

3.1.4 In line with this interpretation of claim 1, paragraph [0009] of the patent sets out: "The micronized carbohydrates are present in particulate form distributed alongside the larger powdered nutritional material comprising lipid globules, thus preventing these larger powdered fat-containing nutritional compositions from cohesion."

3.1.5 Similarly, it has to be expected that blowing micronised carbohydrate particles, as in D21, into the product stream of a spray-drying nutritional composition would lead to the (at least partial) melting and agglomeration of the carbohydrate particles in the spray-drying process. This is expressly described and intended in D21 (see page 4, lines 6 to 8). They would thus not be present in the powdered compositions required in claim 1 in their initial form any longer.

3.1.6 Likewise, in view of the typical preparation process of powdered nutritional compositions (involving the dissolution of the carbohydrates and proteins in water prior to the emulsification step with the lipid phase), relying on the particle size distribution of the pristine carbohydrates, prior to the nutrient powder preparation process and their dissolution in the aqueous phase, makes no technical sense. In the dried powder, the carbohydrates could have any particle size (assuming that they would form discrete particles).

3.1.7 The respondent's new argument that claim 1 of the main request covers a powdered nutritional composition where all the ingredients are dry mixed with each other was not put forward in the first-instance proceedings. Nor has it been substantiated that such compositions of claim 1, stipulating, *inter alia*, the presence of lipid globules with a specific particle size distribution, would be obtainable by a dry mixing process. In contrast, the patent mentions spray-drying for obtaining the compositions of claim 1.

3.1.8 Consequently, when trying to interpret claim 1 in a way which makes technical sense, the claim implicitly requires the presence of non-integrated micronised carbohydrates which have been blended with the powdered nutritional material after a completed spray-drying process (see paragraph [0009], lines 11 to 15 of the patent). However, the board would arrive at the same conclusion on inventive step even if the broader interpretation as submitted by the respondent were adopted (see below).

3.2 Closest prior art

The board accepts the respondent's and opposition division's conclusion that either document D2 or document D3 could be taken as the closest prior art for the subject-matter of claim 1 of the main request. Both documents at least pertain to the same technical field as the impugned patent, namely powdered nutritional compositions comprising lipid globules.

3.3 Distinguishing feature and associated objective technical problem

3.3.1 The difference between the subject-matter of claim 1 and the disclosure of D2 or D3 resides in the presence of micronised carbohydrates as specified in claim 1, characterised by criteria iii) and/or iv) in amounts of 2 to 10 wt% based on the total weight of the composition.

3.3.2 The opposition division held that an effect had only been substantiated by example 1 of the patent for a particular morphology of the micronised carbohydrates and when a certain amount was present in the claimed compositions. The latter morphology involved the simultaneous fulfilment of criteria (iii) and (iv) in claim 1 of the main request (see point 2.5.3.3 of the impugned decision).

3.3.3 However, the board does not agree with the opposition division's finding that the purported technical effect of improved flowability had not been demonstrated across the full breadth of claim 1. The board takes the view that the appellant has principally demonstrated that embodiments falling within the scope of claim 1 exhibit the technical effect of improved flowability of

powdered nutritional compositions comprising protein, carbohydrates and large lipid globules. As set out in paragraph [0009] of the patent and explained by the appellant, small (i.e. micronised) carbohydrate particles prevent the bigger particles comprising protein, carbohydrates and lipid globules from gluing together (the alternative term "cohesion" is used in line 13 on page 3 of the patent).

3.3.4 As explained in the patent, larger lipid globules appear to lead to an increased amount of free fat on the surface of the powdered particles of the nutritional composition comprising protein, carbohydrates and lipid globules. However, (free) fat present in powdered infant formulas potentially contributes to caking (see lines 29 to 30 in paragraph [0004] and lines 17 to 20 of paragraph [0024] of the patent). The micronised carbohydrates according to the patent improve flowability and reduce the stickiness of powdered nutritional compositions comprising large lipid (globules), as outlined in paragraph [0032] of the patent. According to paragraph [0058], increased flowability is indicative of a decreased cohesiveness of the powdered compositions.

3.3.5 The board observes that the criticality of an upper threshold particle size of 10 µm of the micronised carbohydrates for achieving the desired technical effect is not derivable from the patent.

The opponent/respondent has filed particle size distribution curves displaying a narrow particle size distribution curve with a D90 of 10 µm and a D50 greater than 6 µm (designated as D20a) and one with a broad particle size distribution with a D50 of 6 µm and a D90 exceeding 10 µm (D20b). The respondent argued

that the importance of specifying both the D50 and the D90 values was illustrated in D20a and D20b, which are based on D17b. The particle size distribution shown in D20a was covered by claim 1. Likewise, the particle size distribution displayed in D20b was encompassed by claim 1. The consequence of only including criterion iii) or iv) in claim 1 was that the claim encompassed micronised carbohydrate particles where a considerable fraction of the particles were much larger than what had been demonstrated experimentally (in the patent).

However, even in the scenario depicted in document D20b, about 70% of the carbohydrate particles have a particle size below 10 µm.

The same holds true for an alleged critical minimum amount of the micronised carbohydrate particles as argued by the opposition division (see item 2.5.3.3 of the impugned decision). Hence, the board considers it credible that the technical effect of achieving improved flowability of a powdered nutritional composition as characterised in claim 1 is obtained essentially across the full breadth of claim 1.

3.3.6 The board observes that the above considerations also apply to the conclusion that the improved flowability would also be obtained when the micronised carbohydrates were blended with the remaining components of claim 1 by dry blending (which the respondent contends was covered by claim 1).

3.3.7 Hence, the board considers that the objective technical problem underlying the subject-matter of claim 1 is to provide powdered nutritional compositions with large lipid globules having improved flowability.

3.4 Obviousness

3.4.1 According to the respondent, the subject-matter of claim 1 lacked an inventive step in view of D2 or D3 alone or in combination with D8, D10, D11 and D14.

3.4.2 Neither D2 nor D3 gives any incentive or prompting to a skilled person to look for the improvement of flow properties of powdered nutritional compositions comprising protein, carbohydrates and large lipid globules. Likewise, D4 (to which the respondent referred in this respect), does not contain any such teaching.

3.4.3 As to D8, the respondent criticised the approach of the opposition division (holding that D8 makes no direct link between the improvement of flow properties and the addition of micronised lactose as defined in part b) of claim 1) to take the improvement of flow properties into account when assessing whether a skilled person would combine D8 with the closest prior art. The respondent referred to point 2.5.4, last sentence of the decision of the opposition division. It is, however, not apparent from the line of argument put forward by the respondent how it can be concluded that a skilled person could infer from D8 that the flow properties of the resulting composition would in fact be improved, let alone of nutritional compositions as specified in claim 1 or D2 or D3 which comprise large lipid globules. The passage on page 1425, left-hand column, lines 15 to 19 of D8 cited by the respondent discloses that *drug aerosolisation* is improved by adding a small amount of a fine carrier.

Consequently, the board holds that the arguments put forward by the respondent why a skilled person would

infer from D8 that micronised lactose can improve the flow properties of powdered nutritional compositions comprising large lipid globules (as featured in D2 or D3) and why the corresponding conclusions made in point 2.5.4, last sentence of the opposition division's decision were wrong are not convincing.

3.4.4 Document D10 discloses a free-flowing particulate product containing 20 to 45 wt% lactulose and 45 to 70 wt% lactose (see page 3, lines 19 to 22). The particles have a size from 2 to 50 µm (page 3, lines 6 to 8). There is, in the view of the board, no teaching in D10 that such particulate products (having a particle size of e.g. 2 µm) are useful for improving the flow properties of powdered nutritional compositions containing large lipid globules, such as those disclosed in D2 or D3.

3.4.5 D11 focuses on a completely different application area, namely to provide crystalline lactose suitable for use as a carrier material in inhalation therapy. As to the effect obtainable by the addition of small lactose particles, D11 describes on page 15, lines 5 to 9 that the flow properties of the DCL ("directly crystallized lactose") formulation itself are less affected by the addition of another component (cellobiose octa-acetate) than corresponding conventional fine lactose formulations. The passage does thus not teach that micronised lactose can improve flowability (of a composition) and that it affected the flowability of the other ingredient(s). D11 is, thus, not relevant to a skilled person faced in view of D2 or D3 with the objective technical problem of improving the flowability of a powdered nutritional composition comprising large lipid globules.

3.4.6 D14 teaches edible lactose-containing compositions containing microcrystals of lactose (page 1, lines 4 to 5). Such compositions can be "milk-based products" (see page 16, lines 10 to 11). The lactose particles can have a particle size in the range of about 0.5 to about 10 µm (page 4, lines 7 to 12 of D14). D14 does not suggest using lactose microcrystals to improve the flow properties of powdered nutritional compositions containing large lipid globules, such as those of D2 or D3. D14 does thus not lead to something falling within the scope of claim 1 in an obvious manner either.

3.5 For these reasons, the subject-matter of claim 1 of the main request involves an inventive step (Article 56 EPC). The same applies *mutatis mutandis* to claims 2 to 14.

Order

For these reasons it is decided that:

1. The decision appealed is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the main request filed with the statement setting out the grounds of appeal and a description to be adapted.

The Registrar: The Chairman:

A. Nielsen-Hannerup A. Haderlein

Decision electronically authenticated