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Datasheet for the decision of 13 January 2015

Case Number: T 2540/12 - 3.3.09

Application Number: 04709282.0

Publication Number: 1605780

IPC: A23L1/29, A23C9/20

Language of the proceedings: EN

Title of invention:
BABY FEEDING SYSTEM

Patent Proprietor:
UNIVERSITY COLLEGE LONDON

Opponent:
NESTEC S.A.

Headword:

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

Keyword:
Inventive step - main request (no)
Auxiliary request filed during the oral proceedings after with drawal of previous auxiliary requests - procedural economy

Decisions cited:
T 1790/06

Catchword:

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Case Number: T 2540/12 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 13 January 2015

Appellant: (Opponent)	NESTEC S.A. Avenue Nestlé 55 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Sonnenstraße 33 80331 München (DE)
Respondent: (Patent Proprietor)	UNIVERSITY COLLEGE LONDON Institute of Child Health, 30 Guilford Street London WC1N 1EH (GB)
Representative:	Lucas, Phillip Brian Lucas & Co. 135 Westhall Road Warlingham, Surrey CR6 9HJ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 November 2012 rejecting the opposition filed against European patent No. 1605780 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	W. Sieber
Members:	M. O. Müller
	K. Garnett

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the opponent against the decision of the opposition division to reject the opposition against European patent No. EP 1 605 780.

II. The opponent had requested revocation of the patent in its entirety on the grounds that the claimed subject-matter was not inventive (Article 100(a) EPC), that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC) and that the patent contained subject-matter which extended beyond the content of the application as filed (Article 100(c) EPC).

The documents submitted during the opposition proceedings included:

D1: A. Singhal et al, "Early nutrition and leptin concentrations in later life", Am J Clin Nutr, volume 75, 2002, pages 993 to 999;

D2: A. Lucas et al, "Randomised trial of early diet in preterm babies and later intelligence quotient", BMJ, volume 317, 1998, pages 1481 to 1487;

D4: K. K. Ong et al, "Perinatal growth failure: the road to obesity, insulin resistance and cardiovascular disease in adults", Best Practice & Research Clinical Endocrinology and Metabolism, volume 16(2), 2002, pages 191 to 207;

D22: A. C. J. Ravelli et al, "Infant feeding and adult glucose tolerance, lipid profile, blood pressure, and obesity", Arch Dis Child, volume 82, 2000, pages 248 to 252; and

D23: "Human energy requirements", report of a Joint FAO/WHO/UNU Expert Consultation, Rome 17 to 24 October 2001, pages v, vii, ix, and pages 2 to 96 (even pages only).

III. The opposition division's decision was based on the claims as granted, of which claim 1 reads as follows:

"1. Use of nutrient in the manufacture of a feeding formula for feeding to human infants in the period up to 2 months of age to avoid long-term adverse health effects consequent upon excessive weight gain in that period, wherein said feeding formula comprises 0.5 to 1.00 grams of protein and 25-50 kilocalories per 100 ml."

Claims 2 to 7 were dependent claims.

The opposition division did not admit D23 into the proceedings. The opposition division was furthermore satisfied that the claims as granted met the requirements of Articles 56, 83 and 123(2) EPC. As regards Article 56 EPC, the opposition division essentially reasoned as follows:

The subject-matter of claim 1 differed from the closest prior art document D1 in that a feeding formula was used comprising 0.5 to 1.00 grams of protein and 25 to 50 kilocalories per 100 ml. The objective technical

problem was seen as how to find a feeding routine for early postnatal nutrition that reduced the risk of long-term adverse health effects consequent upon excessive weight gain caused by using infant formulae. It was credible that the technical effect of reducing long-term adverse health effects upon excessive weight gain was achieved by the feeding formula as required in granted claim 1. D1 acknowledged a relationship between nutrient-enriched diets given to neonates and obesity in later life. There was however no teaching in D1 to modify existing feeding formulae according to claim 1. D1 merely suggested that breastfeeding was preferable for obtaining the long-term benefit on adiposity. The opponent's argument that the experimental data in D1 would lead the skilled person in an obvious way to the claimed solution in the same way as the experimental data of the opposed patent was not considered to be convincing as this reasoning would be based on hindsight knowledge of the invention. The subject-matter of claim 1, formulated as a plausible prediction on the basis of the experimental data in the contested patent, indeed appeared logical *a posteriori*. However in the absence of a pointer in D1 to reconsider the energy and protein requirements of commercial feeding formulae in order to solve the above-mentioned objective technical problem, the skilled person would not have arrived at the claimed solution in an obvious way.

IV. On 6 December 2012, the opponent (hereinafter "the appellant") filed an appeal and, on the same day, paid the prescribed fee. The statement setting out the grounds of appeal was filed on 25 March 2013. The appellant requested that the decision under appeal be set aside and the patent be revoked and that D23 be admitted into the proceedings.

V. A response was filed by the proprietor (hereinafter "the respondent") with its letter of 31 July 2013. The respondent requested that the appeal be dismissed and the patent be maintained as granted.

VI. Further observations were filed with the appellant's letter of 5 December 2013.

VII. On 15 July 2014, the parties were summoned to oral proceedings. The summons contained the board's preliminary opinion on *inter alia* inventive step, starting from D1 as the closest prior art.

VIII. With letter of 12 December 2014, the appellant filed a response to the preliminary opinion of the board together with pages 11 to 18 of D23.

IX. With letter of 17 December 2014, the respondent filed two auxiliary requests headed "AUXILIARY REQUEST" and "AUXILIARY REQUEST 2".

Claim 1 of the AUXILIARY REQUEST read as follows:

"1. Use of nutrient in the manufacture of a feeding formula for feeding to human infants in the period up to 2 months of age to avoid long-term adverse health effects consequent upon excessive weight gain in that period which are development of atherosclerosis or insulin resistance and non-insulin resistant diabetes (NIDBM) *[sic]*, wherein said feeding formula comprises 0.5 to 1.00 grams of protein and 25-50 kilocalories per 100 ml."

X. With letter of 29 December 2014, the respondent filed

D25: Internet excerpt "Early nutrition", 3 pages.

XI. On 13 January 2015, oral proceedings were held before the board. The appellant maintained its request made during the written proceedings that the decision under appeal be set aside and the patent be revoked, but withdrew its previous request to admit D23 into the proceedings. The respondent's main request (dismissal of the appeal, i.e. maintenance of the patent as granted) was discussed as regards the grounds for opposition under Articles 100(c), 100(b) and 100(a) EPC (lack of inventive step). After the board had announced its opinion on the grounds under Article 100(c) and (a) EPC, the respondent withdrew its AUXILIARY REQUEST, filed with letter of 17 December 2014. After discussing the admissibility of its AUXILIARY REQUEST 2, filed with the same letter, the respondent also withdrew this auxiliary request and filed new auxiliary requests 2 and 3 which were later in the oral proceedings also withdrawn. Finally, it filed a new auxiliary request (see also point 4.2 below). The respondent's final requests were thus that the appeal be dismissed (main request), alternatively that the patent be maintained on the basis of the new auxiliary request filed during the oral proceedings.

Claim 1 of this new auxiliary request read as follows:

"1. Use of nutrient in the manufacture of a feeding formula for feeding to human infants in the period up to 2 months of age to avoid long-term adverse health effects consequent upon excessive weight gain in that period, wherein said feeding formula comprises 0.5 to 1.00 grams of protein and 25-50 kilocalories per 100 ml wherein said long-term adverse health effects are vascular, and are development of atherosclerosis or

wherein said long-term adverse health effects are insulin resistance and non-insulin dependent diabetes (NIDDM)."

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

- Main request

The claims of the main request were not based on the application as filed and the invention defined in these claims was not sufficiently disclosed.

Furthermore, the subject-matter of claim 1 was not inventive in view of D1 as the closest prior art. The formula of claim 1 differed from those disclosed in D1 in that the protein and energy content was slightly lower. No data were contained in the opposed patent as to the claimed formula and no effect had been attributed to the slight reduction in protein and energy content. Hence it had to be assumed that the formula of D1 provided the same effect as that of claim 1. Therefore the objective technical problem solved in the light of D1 was the provision of an alternative composition to achieve the same therapeutic effect. D1 already pointed at lowering the protein and energy content since lower protein and energy contents let to lower leptin concentrations and hence less risk of obesity in later life. In this respect, trial 2 of D1 was relevant, in which the use of a non-enriched standard term formula instead of the preterm formula led to a reduction in the leptin concentration of 29%. In view of the respondent's arguments made during the discussion of sufficiency of disclosure (see point 2.5 below),

it had to be assumed that the skilled person would extrapolate the trend observed in this trial towards even lower protein and energy contents, such that he would arrive at the subject-matter of claim 1.

- New auxiliary request

The new auxiliary request should not be admitted into the proceedings. This request was essentially the same as the previously withdrawn auxiliary request. Hence hours had been lost during the oral proceedings in discussing the admissibility of auxiliary requests that were later withdrawn. Former auxiliary request 2, which for the first time contained an amended time period in claim 1, was only filed with letter dated 17 December 2014. Taking the Christmas holidays into account, this left very little time to the appellant to consider this amendment, such that the earliest possible opportunity to react to this amendment was at the oral proceedings before the board. By amending its claims so late, the respondent had therefore to accept the risk that it would be confronted with new objections for the first time during the oral proceedings. The fact that these objections were new thus did not justify the respondent's actions.

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

- Main request

D1 was the closest prior art, from which the claimed formula differed in terms of the protein and energy content. The objective technical

problem was how to avoid in formula-fed infants the risk of creating long-term adverse health effects. There was no significant difference in D1 between formula-fed infants and infants that had received breast milk, and between infants having received the preterm formula and those having been fed banked breast milk. The skilled person would thus not have been motivated to change the composition of the preterm and term formulae in D1. Furthermore, it was commonly known that breast milk was the "gold standard". Therefore, the fact that the preterm formula in D1 was less beneficial than mother's own expressed breast milk would not induce the skilled person to modify the preterm formula. Also the authors of D22 had realised that formula-fed infants had a higher fasting insulin concentration than breastfed infants but had not suggested modifying the formulae. Finally, there was nothing about insulin resistance in D1 and the skilled person would thus not have been motivated to choose the claimed formula to avoid insulin resistance.

- New auxiliary request

The new auxiliary request should be admitted into the proceedings. Proceedings before the boards of appeal were about giving justice to the parties and it was therefore right that the oral proceedings should be conducted so as to find out whether the new auxiliary request was allowable. Furthermore, the objections against the amended time period in the former and new auxiliary requests 2 and new auxiliary request 3 were new to the respondent, which was why it was only at a late stage during the oral proceedings that the

respondent realised that it should continue with the previously withdrawn auxiliary request. Moreover, the claims of the new auxiliary request represented merely a combination of granted claims and thus did not raise any new issues. Even if this auxiliary request had been filed for the first time during the oral proceedings, the board would have been obliged to admit this request into the proceedings. Finally, the various auxiliary requests had been filed and then withdrawn for the purposes of procedural economy, rather than by way of procedural trickery.

Reasons for the Decision

1. The appeal is admissible.

Main request (patent as granted)

2. Inventive step

2.1 The invention underlying the opposed patent relates to the use of infant formulae to avoid long-term adverse health effects consequent upon excessive weight gain (paragraphs [0006], [0007] and [0010] and claim 1 of the patent).

2.1.1 The opposed patent describes on pages 3 to 15 a study in which the effects of early diet on later life was tested. In this study, 926 infants being born preterm between 1982 and 1985 and having below 1850g in birthweight were recruited in 5 centres (Norwich, Cambridge, Sheffield, Ipswich and King's Lynn). At birth, these infants were randomly assigned, in two randomised trials, different diets, namely:

(a) a preterm formula containing 2.0 g/100ml protein, 4.9 g/100ml fat and 7.0 g/100ml carbohydrate;

(b) a term formula containing 1.5 g/100ml protein, 3.8 g/100ml fat and 7.0 g/100ml carbohydrate;

(c) banked donated milk containing 1.1 g/100ml protein, 2.0 g/100ml fat and 7.0 g/100ml carbohydrate; and

(d) mothers' own expressed milk containing 1.5 g/100ml protein, 3.0 g/100ml fat and 7.0 g/100ml carbohydrate.

The term formula had an energy content of 68 kcal/100ml (see the term formula in table 1 of D2, which has the same composition as the term formula in the patent).

In a follow up at an age of thirteen to sixteen years, the 32-33 split proinsulin concentration, as a measure of insulin resistance, and the flow-mediated endothelial dependent dilation (FMD), as an indicator of endothelial dysfunction relevant to the atherosclerotic process, were determined.

It was found (paragraph [0060]) that infants fed with the term formula (lower nutrient diet) had a lower fasting 32-33 split proinsulin concentration in the follow-up than those that had received the preterm formula (nutrient enriched). According to the opposed patent (paragraph [0060]), this suggested that a reduced early growth rate as a consequence of relative under-nutrition programs a lower insulin resistance. In the same way it was found that early under-nutrition had a positive effect on FMD (paragraph [0044]).

2.1.2 It is important at this junction to note that the formulae used in the experiments of the opposed patent are not as required by claim 1. More specifically, the protein and energy contents in the formulae used in the study described in the opposed patent are slightly higher than those of the formula according to claim 1. For instance, the term formula used in the study of the opposed patent has a protein content of 1.5 g/100ml and an energy content of 68 kcal/100ml, compared to upper limits of 1.00 g /100 ml and 50 kcal/100ml for the protein and energy content in claim 1.

2.2 D1 is a scientific paper published by a group of authors including the two inventors of the opposed patent. In the same way as in the patent, this paper is dealing with the effects of early diet on later life. The study described in D1 is exactly that disclosed in the patent, i.e. the infant group, study design and formulae (a) to (d) applied in the study of the patent are used in D1 as well (as regards infants and study design of feeding the infants, see paragraph bridging left- and right-hand column on page 994; as regards formulae, see the first full paragraph on the right-hand column of page 994; as regards the study design of the follow up, see the first paragraph on the left-hand column on page 995). The only difference between the study in D1 and that in the opposed patent is that in D1 the relative leptin concentrations indicative for obesity in later life are measured in the follow up (abstract on page 993 and conclusions on page 998), rather than the 32-33 split proinsulin concentration and the flow-mediated endothelial dependent dilation (FMD) in the patent.

D1 is thus in the same technical field and aims at the same objective as the opposed patent. As acknowledged

by both parties, D1 therefore can be considered to represent the closest prior art.

In the same way as the diets used for the examples in the opposed patent, the diets used in D1 are different from the formula defined in claim 1 of the opposed patent in that the protein and energy contents in D1 are slightly higher than those of the formula according to claim 1.

2.3 According to the respondent, the problem solved by the patent was how to avoid, in the case of formula-fed infants, the risk of creating long-term adverse health effects.

2.4 As a solution to this problem, the patent proposes the use according to claim 1, characterised in that an infant formula is applied with a slightly lower protein and energy content than that present in the term formula of D1, namely 0.5-1.00 g/100ml of protein and 25-50 kcal/100ml.

2.5 It needs to be examined whether this problem has been credibly solved by the claimed subject-matter, i.e. by the lower protein and energy contents required by claim 1.

During the discussion of sufficiency of disclosure during the oral proceedings before the board, the respondent explained that the skilled person looking at the experiments in the study described in the opposed patent would have reasonably expected that the trend observed in this study, namely that lower protein and energy contents led to lower insulin resistance and endothelial dysfunction, could be extrapolated to the even lower protein and energy contents required by

claim 1. In other words, the skilled person would have expected that at these even lower protein and energy contents, insulin resistance and endothelial dysfunction would be avoided.

The board accepts this argument and therefore considers it to be credible that the above problem (point 2.3) is solved by the subject-matter of claim 1. This problem thus represents the objective technical problem.

2.6 It needs finally to be examined whether in view of this problem, the claimed solution is obvious.

2.6.1 In trial 2 of D1, children fed the term formula were compared to children fed the preterm formula (figure 1 on page 994). It was found that children who had received the term formula (with a lower protein and energy content, see point 2.1.1 above) had a leptin concentration at the age of 13 to 16 years that was 29.0% lower than children who had received the preterm formula (trial 2 in table 3 on page 997 and lines 10 to 16 of the left-hand column on page 998 of D1), and this correlated to a lower risk of obesity in later life (lines 4 to 6 of the right-hand column on page 997 of D1).

Hence, exactly the same trend is described in D1 as in the patent, namely that a lower protein and energy content of the term formula reduces adverse health effects in later life (obesity in D1 and insulin resistance and endothelial dysfunction in the opposed patent).

2.6.2 Accepting the respondent's argument that in the patent this trend can be extrapolated to lower protein and energy contents as required by claim 1, which the board

does (point 2.5 above), the same must be assumed for D1. More specifically, in the same way as for the study described in the patent, it must be assumed that the skilled person reading D1 would expect that by reducing the protein and energy content of the term formula in D1 even further, the risk of obesity in later life would be avoided. The skilled person seeking to achieve this avoidance would thus reduce the protein and energy content of the term formula of D1 and would thereby arrive at the subject-matter of claim 1. This subject-matter is therefore obvious in view of D1.

2.7 The respondent's arguments made as regards inventive step are in this respect not convincing:

2.7.1 The respondent argued that there was no significant difference in D1 between formula-fed infants and infants that had received breast milk and between infants having received the preterm formula and those having been fed banked breast milk. The skilled person would thus not have been motivated to change the composition of the preterm or term formulae in D1.

However, this argument is not relevant since D1 contains a comparison of infants fed with a term formula and those fed with a preterm formula and since, as has been set out above, in view of this comparison the claimed subject-matter is obvious.

2.7.2 The respondent also argued that it was commonly known that breast milk was the "gold standard". Therefore, the fact that the preterm formula in D1 was less beneficial than mother's own expressed breast milk would not induce the skilled person to modify the preterm formula. Also the authors of D22 had realised that formula-fed infants had a higher fasting insulin

concentration than breastfed infants but did not suggest modifying the formula.

However, in the same way as for the respondent's first argument, this argument disregards the fact that D1 contains a comparison between a preterm and a term formula and that, on the basis of this comparison, the claimed subject-matter is obvious.

2.7.3 The respondent further argued that there was nothing about insulin resistance in D1.

This argument is not relevant either since claim 1 is not restricted to the avoidance of insulin resistance but covers the avoidance of adverse health effects in general.

2.8 The subject-matter of claim 1 therefore lacks inventive step in view of D1.

3. Since the main request is thus not allowable, there is no need to address the further grounds of opposition under Articles 100(b) and 100(c) EPC that were invoked against the main request.

Auxiliary request

4. Admissibility

4.1 The auxiliary request (hereinafter "new auxiliary request") was filed at approximately 2.50 pm during the oral proceedings before the board. Pursuant to Article 13(1) RPBA, it is at the board's discretion to admit or not to admit the new auxiliary request. This discretion shall be exercised in view of *inter alia* the need for procedural economy. When exercising this

discretion, the board has to take into account the respondent's behaviour during the oral proceedings (T 1790/06, point 16). To decide on the admissibility of the new auxiliary request, it is therefore necessary to reiterate the course of the present oral proceedings, including the respondent's latest written submissions.

4.2 With letter dated 17 December 2014, the respondent had filed two auxiliary requests, namely an AUXILIARY REQUEST and an AUXILIARY REQUEST 2 (see point IX above). Oral proceedings were held on 13 January 2015 and started with the discussion of the respondent's main request. After the board had announced its opinion that the main request was not inventive, the respondent withdrew its AUXILIARY REQUEST filed with letter of 17 December 2014. Subsequently, the admissibility of AUXILIARY REQUEST 2 was discussed, focusing on problems arising due to the amendment of the time period defined in claim 1. This AUXILIARY REQUEST 2 was again withdrawn and new auxiliary requests 2 and 3 were filed. The admissibility of these two requests was then discussed, again focusing on problems concerning the now differently amended time period in claim 1. Also these auxiliary requests were subsequently withdrawn and at approximately 2.50 pm the new auxiliary request was filed.

The new auxiliary request is in essence identical to the AUXILIARY REQUEST filed with letter of 17 December 2014 but then withdrawn in the oral proceedings. The filing of the new auxiliary request thus essentially represents a re-introduction of the withdrawn AUXILIARY REQUEST, after several hours of discussion on several other also later withdrawn auxiliary requests. Because of the way in which the requests were filed and later

withdrawn, the discussion during the oral proceedings went in circles, such that the conduct of the oral proceedings became very inefficient. The respondent thereby did not comply with its duty as regards the efficient conduct of the oral proceedings (T 1790/06, point 16).

4.3 The respondent argued that proceedings before the boards of appeal were about giving justice to all parties and the oral proceedings should therefore be conducted so as to find out whether the new auxiliary request was allowable.

The board does not find this argument convincing. Justice is also about procedural fairness to the parties and the board does not consider it to be fair to confront an appellant repeatedly with new requests, to withdraw them and then to come back at a later stage of the oral proceedings with a request that essentially had been withdrawn hours before during the oral proceedings.

The respondent also argued that the objections against the amended time period in AUXILIARY REQUEST 2 filed with letter of 17 December 2014 had not been known to it before, which was why, only at a late stage during the oral proceedings, it realised that it should continue essentially with the withdrawn AUXILIARY REQUEST, such request not containing any amendment with regard to this time period.

However, the respondent chose to amend this time period for the first time with its AUXILIARY REQUEST 2 filed with letter dated 17 December 2014. Taking the Christmas holidays into account, this left very little time to the appellant to consider this amendment, such

that the earliest possible opportunity to react to this amendment was at the oral proceedings before the board. The respondent had therefore to take the risk that it would be confronted with new objections against this amendment for the first time during the oral proceedings.

The respondent additionally argued that the claims of the new auxiliary request represented merely a combination of granted claims and thus did not raise any new issues. It was said that even if this auxiliary request had been filed for the first time during the oral proceedings, the board would therefore have been obliged to admit this request into the proceedings.

It is, however, not correct that a claim request containing only a combination of granted claims must automatically be admitted into the proceedings. On the contrary, it is at the board's discretion to admit or not to admit such a claim request and, as set out above, one of the criteria to be applied is the need for procedural economy.

The respondent finally argued that the way the auxiliary requests had been filed and withdrawn had been done with a view to procedural economy, rather than by way of procedural trickery.

The board accepts that the way the respondent acted during the oral proceedings did not entail any devious intent. Nevertheless, as set out above, the respondent's behaviour impaired the efficient conduct of the oral proceedings and this in itself was sufficient reason not to admit the new auxiliary request.

4.4 The board therefore decided not to admit the new auxiliary request into the proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated