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Datasheet for the decision of 3 July 2018

Case Number: T 1972/14 - 3.3.09

Application Number: 05819164.4

Publication Number: 1841330

IPC: A23L1/29, A23L1/305

Language of the proceedings: EN

Title of invention:
USE OF INFANT FORMULA WITH REDUCED PROTEIN CONTENT

Patent Proprietor:
Nestec S.A.

Opponents:
ABBOTT LABORATORIES
Semper AB
N.V. Nutricia

Headword:

Relevant legal provisions:
EPC Art. 54

Keyword:
Novelty - (no)

Decisions cited:

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 1972/14 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 3 July 2018

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 16 July 2014 revoking European patent No. 1841330 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

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

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the proprietor of European patent No. 1 841 330 against the decision of the opposition division to revoke it.

II. With their notices of opposition, opponents 1 to 3 had requested revocation of the patent in its entirety on the grounds under Article 100(a) (lack of novelty, lack of inventive step and non-patentable subject-matter under Article 52 EPC) and Article 100(b) EPC.

The documents submitted during the opposition proceedings included:

D2: I. Gunnarsdottir et al., International Journal of Obesity, volume 27, 2003, pages 1523 to 1527;

D8: C. Hoppe et al., Am. J. Clin. Nutr., volume 79, 2004, pages 494 to 501;

D30: E.E. Ziegler et al., Monatsschrift Kinderheilk., volume 151 (Suppl. 1), 2003, pages S65 to S71;

D38: P.M. Karlsland Åkeson et al., Journal of Pediatric Gastroenterology and Nutrition, volume 26, 1998, pages 1 to 8; and

D42: C.G. Metges, The Journal of Nutrition, 2001, pages 2062 to 2066.

III. The opposition division's decision was based *inter alia* on auxiliary request 8, claim 1 of which read as

follows (higher-ranking requests are not relevant to the present decision):

> "The use of whey, casein and mixtures thereof from cow's milk as a source of proteins for the preparation of an infant formula for administration to a human infant so as to continuously reduce the circulating level of IGF-1 in the first few months of the life of the infant and thereby reduce the risk of development of obesity later in life wherein the infant formula contains less than 2.25 g of protein per 100 kcal."

The opposition division held that claim 1 met the requirements of Articles 123(2), 123(3), 52(2)(a) and 53(c) EPC and that the invention defined in claim 1 was sufficiently disclosed and novel but not inventive on the basis of D30 as the closest prior art. As regards novelty over D30, the opposition division acknowledged that this document suggested that high protein intake during early childhood might be linked to the development of obesity. For the acceptance of lack of novelty, however, the claimed subject-matter had to be directly and unambiguously disclosed in the prior art. A mere suggestion as formulated in D30 was not an unambiguous disclosure, and thus this document was not novelty-destroying.

IV. This decision was appealed by the proprietor (hereinafter: the appellant). The statement setting out the grounds of appeal (letter dated 26 November 2014) contained a main request and auxiliary requests 1 to 7.

V. Responses were filed by opponents 1 and 3 (hereinafter: respondents 1 and 3).

VI. With its communication dated 9 November 2017, the board issued its preliminary opinion.

VII. With its letter dated 15 February 2018, respondent 1 provided further written submissions.

VIII. With its letter dated 31 May 2018, the appellant filed auxiliary requests 8 to 11.

IX. With its letter dated 12 April 2018, opponent 2 (hereinafter: respondent 2) announced that it would not be present at the oral proceedings.

X. On 3 July 2018, oral proceedings were held before the board in respondent 2's absence. All parties present maintained their requests made during the written proceedings.

XI. Claim 1 of the main request is identical to claim 1 of auxiliary request 8 before the opposition division (see point III above).

Claim 1 of auxiliary requests 1 and 2 reads as follows (amendments made with regard to the main request are highlighted by the board):

> Auxiliary request 1: "1. The use of whey, casein and mixtures thereof from cow's milk as a source of proteins for the preparation of an infant formula for administration to a human infant **during the first four to six months of the life of the infant** so as to continuously reduce the circulating level of IGF-1 in the first few months of the life of the infant and thereby reduce the risk of development of obesity later in life wherein the infant formula contains less than 2.25 g of protein per 100 kcal."

Auxiliary request 2: "1. The use of whey, casein and mixtures thereof from cow's milk as a source of proteins for the preparation of an infant formula for administration to a human infant so as to continuously reduce the circulating level of IGF-1 in the first few months of the life of the infant and thereby reduce the risk of development of obesity later in life wherein the infant formula ~~contains less than 2.25 g~~ **comprises between 1.8 and 2.0 g** of protein per 100 kcal."

Auxiliary request 3 is a combination of auxiliary requests 1 and 2.

Claim 1 of auxiliary request 4 reads as follows (amendments made with regard to the main request are highlighted by the board):

"The use of ~~whey, casein and mixtures thereof from cow's milk~~ **sweet whey protein from which caseino-glycomacropeptide has been removed** as a source of proteins for the preparation of an infant formula for administration to a human infant so as to continuously reduce the circulating level of IGF-1 in the first few months of the life of the infant and thereby reduce the risk of development of obesity later in life wherein the infant formula contains less than 2.25 g of protein per 100 kcal."

Auxiliary requests 5 to 7 are a combination of auxiliary requests 1 and 4, 2 and 4 and 3 and 4, respectively.

Claim 1 of auxiliary request 8 reads as follows (amendments made with regard to the main request are highlighted by the board):

"The use of ~~whey, casein and mixtures thereof from cow's milk as~~ a source of proteins for the preparation of ~~an infant formula~~ **nutritional composition** for administration to a human infant so as to continuously reduce the circulating level of IGF-1 in the first few months of the life of the infant and thereby reduce the risk of development of obesity later in life wherein the ~~infant formula~~ **composition** contains less than 2.25 g of protein per 100 kcal, **wherein the source of proteins is sweet whey protein from which caseino-glycomacropeptide has been removed, and wherein the nutritional composition is an infant formula.**"

Auxiliary requests 9 to 11 are a combination of auxiliary requests 1 and 8, 2 and 8 and 3 and 8, respectively.

XII. Where relevant to the present decision, the appellant's arguments may be summarised as follows:

Main request

The appellant conceded that reducing the risk of developing obesity later in life represented the therapeutic effect to be achieved by claim 1, while the continuous reduction of the circulating level of IGF-1 represented the mechanism underlying that effect. It also acknowledged that the formula as used in the study of D30 was as required by claim 1. However, it argued that the subject-matter of claim 1 was still novel over D30, since that document merely speculated and thus did

not directly and unambiguously disclose the link between use and therapeutic effect as defined in claim 1. In the prior art there was also doubt as to whether a link between feeding high protein contents early in life and obesity later in life was present. Lastly, in the prior art, the effect on obesity later in life had been investigated only for infants that had been fed high-protein formulae after six months of age. This was different from claim 1, which required feeding in the first few months of life.

Auxiliary requests 1 to 11

The appellant conceded that the additional features introduced into the claims of the auxiliary requests did not lead to any distinction with regard to D30.

XIII. Where relevant to the present decision, the arguments of respondents 1 and 3 may be summarised as follows:

Main request

The subject-matter of claim 1 lacked novelty over D30, which disclosed that the protein content of infant formulae should exceed protein needs only by the smallest possible margin and that excessive protein intake should be avoided because of the possibility that a high protein intake in early life might predispose to obesity later in life. Starting from this premise, D30 disclosed a study showing that normal growth of infants could also be achieved with low protein contents. The link between high protein content and obesity later in life was not pure speculation in D30, since otherwise it would not have made sense to perform a study on low protein contents. In fact, claim 1 did not talk about reducing obesity later in

life, but only about reducing the risk thereof, which was equivalent to what was disclosed in D30. There was also no teaching in the further prior art that this link was not present, and in any case what mattered was whether D30 as such rather than further prior art anticipated the claimed subject-matter. The same applied to the appellant's argument that the prior art only looked at feeding low protein contents beyond the age of six months. Again, what mattered was the disclosure of D30, in which the low-protein formula was administered until an age of 112 days, i.e. during roughly the first four months of life only.

The subject-matter of claim 1 furthermore lacked novelty over D38. Apart from that, the main request did not fulfil the requirements of Articles 123(2) and (3), 56 and 83 EPC.

Auxiliary requests 1 to 11

The auxiliary requests should not be admitted into the proceedings and, if admitted, did not introduce any feature that distinguished the claimed subject-matter from D30.

XIV. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or one of auxiliary requests 1 to 7, all requests as filed with a letter dated 26 November 2014, or on the basis of one of auxiliary requests 8 to 11 as filed with the letter dated 31 May 2018.

XV. Respondents 1 and 3 requested that the appeal be dismissed.

Respondent 1 further requested that none of auxiliary requests 1 to 11 be admitted into the proceedings.

Respondent 2 did not submit any requests.

Reasons for the Decision

Main request

1. Novelty

1.1 Claim 1 is a Swiss-type claim directed to the preparation of a certain infant formula so as to continuously reduce the circulating level of IGF-1 in the first few months of the life of an infant and thereby reduce the risk of development of obesity later in life. As was common ground between the parties, reducing the risk of developing obesity later in life represents the therapeutic effect to be achieved by claim 1, while the continuous reduction of the circulating level of IGF-1 represents the mechanism underlying this effect. A Swiss-type claim can derive novelty from the claimed therapeutic effect, but not from the mechanism underlying it.

1.2 Respondents 1 and 3 attacked novelty on the basis *inter alia* of D30.

1.3 D30 is a scientific article which deals with infant formulae with reduced protein content (see e.g. the title of D30).

1.3.1 In the first sentence of the introductory section (page S65), D30 states:

> "The protein of infant formulas must meet the protein needs of infants, yet should exceed protein needs by the smallest possible margin."

Still in the same section, namely in the last sentence of the first paragraph of the right-hand column of page S65, D30 adds:

> "Excessive protein intake should be avoided also because of the possibility that a high protein intake in early life may predispose to obesity later in life [12]".

Directly thereafter it states that

> "The present study asked the question whether a formula with a protein-energy ratio of 1.90 g/100 kcal meets the protein requirements of normal infants."

To answer this question, a study was carried out in which three groups of infants were fed until the age of 112 days with (i) a reduced protein formula RP with a protein content of 1.92 g/100 kcal, (ii) a reduced protein formula plus probiotic RP+P with a protein content of 1.89 g/100 kcal and (iii) a comparative formula C with a protein content of 2.39 g/100 kcal (table 1 on page S66). In all formulae, the protein consisted of partially hydrolysed whey proteins (second sentence in the right-hand column on page S66).

Based on the results obtained in this study, in particular the weight and length of the infants and the level of albumin, urea nitrogen and certain amino acids found in the infants' blood, D30 (first sentence of the "Discussion" section on page S70) answers the question

asked in the introductory section in the affirmative, stating namely that:

> "The present study demonstrated that a formula with a protein-energy ratio of 1.90 g/100 kcal met the protein requirements of normal infants.

and that (last sentence on page S71):

> "In summary, the present study has demonstrated that a formula with a protein-energy ratio of 1.90 g/100 kcal from modified, partially hydrolyzed whey proteins supports normal growth in term infants."

1.3.2 It was acknowledged by the appellant that the formula as used in the study of D30 was as required by claim 1.

1.3.3 As set out above, D30 teaches to avoid excessive protein intake in early life in order to exclude the possibility of predisposition to obesity later in life. D30 thus discloses the claimed therapeutic effect of reducing the risk of development of obesity later in life.

1.3.4 The appellant argued that the link between a reduced protein content and the avoidance of a predisposition to obesity later in life as referred to in D30 was mere speculation, and thus not directly and unambiguously disclosed.

1.3.5 The board does not agree. As set out above, just after addressing predisposition to obesity caused by excessive amounts of protein, D30 presents a study that investigates a formula with reduced protein content. D30 thus does not merely speculate about whether there

may be a link between reduced protein content and obesity later in life. On the contrary, it starts from the very premise that this link is present. In fact, otherwise the study disclosed in D30 on formulae with reduced protein contents would not make sense.

This conclusion is not changed by the fact that D30 only discloses that a high protein intake in early life may - and hence not necessarily must - predispose to obesity later in life. Nothing else is required by claim 1, which merely stipulates that the risk of developing obesity later in life is reduced. Referring to a risk does not rule out the possibility of some of the infants fed the formula as defined in claim 1 becoming obese later in life; hence an infant fed this formula may, but not necessarily must, be free of obesity later in life.

1.4 The appellant argued that, if not in D30 itself, there was doubt in the prior art as to whether there really was a link between feeding high protein contents early in life and obesity later in life. The appellant in this respect referred to D2, D8 and D42.

This argument is not convincing. What matters is what D30 discloses, rather than other prior-art documents. And as set out above, the skilled reader deduces from D30 that such a link is present. Incidentally, it is noted that the review article D42 referenced in the introductory section of D30 and referred to by the appellant acknowledges epidemiological evidence, albeit weak, for a link between high protein intake during early childhood and the development of obesity in adults (second sentence of the last full paragraph in the right-hand column of page 2064). There is thus no

general doubt in the prior art as regards the presence of this link.

1.5 The appellant also argued that in the prior art, e.g. D2 and D8, the effect on obesity later in life had been investigated only for infants that had been fed formulae with high protein contents after six months of age. This was different from claim 1, which required feeding to take place in the first few months of life.

This argument is not convincing either. The study in D30 was carried out during the first 112 days of life ("Study design" section on page S66), i.e. until roughly four months of age, rather than beyond the age of six months. Thus, the study in D30 was conducted in the same time range as required by claim 1. In fact, the time range in D30 has been acknowledged by the appellant to be identical to that applied in the example of the opposed patent. That other documents such as D2 and D8 relate to different time intervals is of no relevance. What matters is whether D30 itself anticipates the claimed subject-matter, not D2 or D8.

1.6 In view of the above, the subject-matter of claim 1 of the main request lacks novelty over D30.

1.7 Respondents 1 and 3 had attacked novelty on the basis of document D38 as well. During the oral proceedings, the board came to the conclusion that the subject-matter of claim 1 also lacked novelty over that document. Since novelty over D30 however is denied, there is no need to elaborate on this point in the present decision.

2. Considering that the claimed subject-matter lacked novelty, the board during the oral proceedings saw no

reason to decide on respondent 1 and 3's further objections under Articles 123(2) and (3), 56 and 83 EPC.

Auxiliary requests 1 to 11

3. Admittance

3.1 Respondent 1 requested that auxiliary requests 1 to 11 not be admitted into the proceedings.

3.2 The board decided to reject this request and to admit all auxiliary requests into the appeal proceedings. Given that none of these auxiliary requests meets the requirement of novelty (see point 4 below), there is no need to give detailed reasons in the present decision for admitting these requests.

4. Novelty

4.1 The appellant conceded during the oral proceedings that the additional features introduced into the claims of the auxiliary requests did not lead to any distinction with regard to D30. The board fully shares this view and thus considers the subject-matter as claimed in the auxiliary requests to lack novelty over D30.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

T. Buschek W. Sieber

Decision electronically authenticated