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Datasheet for the decision of 23 February 2023

Case Number: T 0703/18 - 3.3.09

Application Number: 06826479.5

Publication Number: 1945045

IPC: A23L1/30, A23L1/29

Language of the proceedings: EN

Title of invention:
INFANT FORMULAS CONTAINING DOCOSAHEXAENOIC ACID AND LUTEIN

Patent Proprietor:
ABBOTT LABORATORIES

Opponent:
Société des Produits Nestlé S.A.

Headword:
Infant formulas containing DHA and lutein/ABBOTT

Relevant legal provisions:
EPC Art. 56, 100(a)

Keyword:
Inventive step - problem invention (no)

Decisions cited:
T 0002/83

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0703/18 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 23 February 2023

Appellant: (Opponent)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Respondent: (Patent Proprietor)	ABBOTT LABORATORIES 100 Abbott Park Road Abbott Park, IL 60064-3500 (US)
Representative:	Boult Wade Tennant LLP Salisbury Square House 8 Salisbury Square London EC4Y 8AP (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 10 January 2018 rejecting the opposition filed against European patent No. 1945045 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	F. Rinaldi
	R. Romandini

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the opponent (appellant) against the opposition division's decision to reject the opposition.

II. In the notice of opposition, the opponent requested that the patent be revoked under Article 100(a) EPC due to lack of inventive step, among other things.

III. The documents relevant to this decision are:

D16: US 2003/0228392 A1

D18: V. C. Jewell *et al.*, "A comparison of lutein and zeaxanthin concentrations in formula and human milk samples from Northern Ireland mothers", European Journal of Clinical Nutrition, 58, 2004, 90-97

IV. The only claim relevant to the decision is claim 1 of the patent as granted (main request). It reads:

"*A ready-to-feed liquid infant formula comprising fat, protein, carbohydrate, vitamin, and minerals, including docosahexaenoic acid and at least 75 µg/liter of lutein, wherein the weight ratio of lutein (µg) to docosahexaenoic acid (mg) is from 1:2 to 10:1 and the formula is free of egg phospholipids*."

V. The appellant argued that claim 1 lacked inventive step over D16 as closest prior art. The distinguishing feature was the concentration of lutein. The problem solved was to provide an infant formula suitable for

newborn infants. The solution would have been obvious in view of the disclosure of D18.

VI. The respondent (patent proprietor) argued that claim 1 involved an inventive step. D16 was the closest prior art. The claimed subject-matter differed from example 1 of D16 by a higher concentration of lutein (at least 75 µg/liter in claim 1; 25 µg/liter in example 1). The invention was a "problem invention" and resided in recognising that bioavailability of lutein from infant formula was low. None of the prior art documents addressed this problem. The solution would not have been obvious to the skilled person.

VII. Final requests

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

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. *Patent*

1.1 The patent relates to an infant formula containing combinations of lutein and docosahexaenoic acid. The composition is stated to promote retinal health and vision development in infants (paragraph [0001]).

1.2 Paragraph [0007] discloses that infant formulas typically contain less than 20 µg/liter of lutein, most of which is inherently added with fats and oils.

According to the patent, the invention resides in recognising that bioavailability of lutein from infant formula is low. The lutein concentration in an infant formula has been higher than that found in human milk to achieve the same plasma lutein concentration as in breast-fed infants.

2. *Article 100(a) EPC - Inventive step*

2.1 In the decision under review, the opposition division concluded that claim 1 involved an inventive step. The reasoning was as follows.

- D16 was the closest prior art. The distinguishing feature of claim 1 over example 1 of D16 was the higher concentration of lutein.

- None of the cited documents referred to bioavailability of lutein but rather to that of trace elements and lipids. The problem was to provide an infant formula that led to the same plasma lutein concentration as in breast-fed infants. In such a case, "identifying the problem in itself leads to an inventive step (problem invention)" (decision, page 6).

- The prior art did not teach the problem identified. There would have been no motivation to increase the amount of lutein.

2.2 The appellant argued that the opposition division's formulation of the problem and finding on obviousness was incorrect.

2.3 Closest prior art D16

2.3.1 The parties agreed to use D16 as the closest prior art.

2.3.2 D16 discloses infant formulas containing lutein and zeaxanthin. Paragraph [0016] reports a study in which the total lutein and zeaxanthin content of human milk samples from 450 women in nine countries was analysed. The individual concentration of the two carotenoids was between 6 µg/liter and 230 µg/liter. Dependent claim 2 is directed to an infant formula composition comprising these concentrations of lutein and zeaxanthin.

2.3.3 Example 1 of D16 discloses a nutritional infant formula having a concentration of lutein and zeaxanthin of 25 µg/liter. The concentration of docosahexaenoic acid is calculated to be 75.6 mg/liter.

2.3.4 The parties agree that example 1 of D16 does not disclose the lutein concentration set out in claim 1 (i.e. 75 µg/liter).

2.3.5 As correctly pointed out by the respondent, a direct consequence of the low concentration of lutein in example 1 is that the weight ratio of lutein (µg) to docosahexaenoic acid (mg) of claim 1 is also not disclosed in D16.

2.4 The problem to be solved proved to be a contentious issue.

2.4.1 The appellant argued that the technical problem was to provide an infant formula suitable for newborn infants.

2.4.2 For the respondent, however, the correct technical problem was the one identified in the decision under appeal. In its view, the patent involved one of the rare cases of a "problem invention". It had not been recognised in the art that bioavailability of lutein from formula milk was lower than that achieved by human milk. Once this was known, the solution would have been obvious.

2.4.3 As the respondent acknowledged, "problem inventions" are rare. One reason for this may be that they are somewhat at odds with the problem-solution approach. It is generally accepted that the formulation of the technical problem should not contain pointers to the solution or partially anticipate the solution. In contrast to this, "problem inventions" tend to do both.

2.4.4 A relevant decision dealing with "problem inventions" is T 2/83. In point 6 of the Reasons, the following is stated.

"*The discovery of a yet unrecognised problem may, in certain circumstances, give rise to patentable subject-matter in spite of the fact that the claimed solution is retrospectively trivial and in itself obvious ('problem inventions') ... It appears however, that whenever the modification of a known device involves no real choice in the direction of a clearly desired improvement, i.e the skilled man is in an inevitable 'one-way-street' situation, the additional provision of a yet unsuspected 'bonus' or side effect, which may be interpreted as a solution of a yet unknown problem, should not necessarily be decisive for patentability.*"

2.4.5 Although this passage of T 2/83 refers to a device, it is not apparent why the reasoning in it would not apply also to claims directed to compositions.

2.4.6 The decision T 2/83 concedes that the discovery of an unrecognised problem may in certain circumstances give rise to patentable subject-matter. This may be so even though once the formulation of the problem is accepted, the question of whether the solution was obvious becomes irrelevant. A situation may arise in which, if a subject-matter claimed is assessed as a "problem invention", an attack based on lack of inventive step can be successfully directed only against the recognition of the problem, not against the claimed solution. At the same time, T 2/83 makes it clear that in the context of a clearly desired improvement, side effects which may be interpreted as a solution of a yet unknown problem shall not be decisive for patentability.

2.4.7 In the case in hand, the following has to be taken into account when formulating the technical problem.

2.4.8 First, while the issue with bioavailability of lutein is new information, bioavailability of trace elements and lipids from infant milk has been well investigated. This was thoroughly discussed in the oral proceedings before the opposition division (minutes, points 7.1 and 7.2) and in the decision under appeal (e.g. pages 5 and 6).

2.4.9 Second, the "gold standard" for preparing an infant formula is and remains human milk. Therefore, when formulating the problem to be solved, one must draw closely on the teaching available in the art on human milk. D16 itself discloses that the individual

concentration of lutein and zeaxanthin in human milk is distributed over a wide range (6 µg/liter to 230 µg/liter) and teaches the use of these concentrations in an infant formula (claim 2).

2.4.10 Third, the patent in suit relates to preparing an infant formula. The target group for the formula is not restricted in claim 1, but preterm infants are explicitly mentioned throughout the patent. Moreover, the patent also makes reference to newborns, i.e. infants of 0 months of age (paragraph [0013]). In other words, the formula of the patent in suit has to be suitable for newborns and infants born prematurely.

2.4.11 Considering all this, it is not justified to accept the formulation of a "problem invention", as suggested by the respondent. Instead, the technical problem has to be regarded as that of providing a nutritional formula (with lutein) suitable for infants, including newborns.

2.5 Obviousness

2.5.1 The skilled person tasked with solving the problem would turn to D18. This document relates to a study in which lutein and zeaxanthin concentrations in commercial infant formulas and human milk samples are investigated. Lutein and zeaxanthin are described as important protective factors in retinal pigment epithelium of newborn infants (page 91, left column).

2.5.2 Among the results discussed in D18, the following are highlighted.

- The milk of mothers of newborn infants contains much higher levels of lutein than those found after

several days of lactation in the milk of the same mother (figures 1 and 2).

- The median concentration of lutein found in expressed human milk is calculated as 109 µg/liter. This value is 8 to 9 times greater than the concentration of zeaxanthin, which is calculated as 12.5 µg/liter (table 1). These values are obtained over a period longer than just the first days of lactation. In other words, the relatively high concentration of lutein is found not only in the first days of lactation.

- The highest lutein concentrations found in commercial infant formula (e.g. calculated as 205.3 and 157.7 µg/liter) are found in milks formulated for preterm infants. They potentially require a higher concentration for protection against oxidative damage to the eye (page 96, right column).

2.5.3 In short, D18 shows that the concentration of lutein found in human milk, and especially in milk of mothers of newborn infants, is considerably higher than that disclosed by example 1 of D16. In view of this, the solution that the skilled person would have provided is to increase the concentration of lutein. This has the inevitable side effect that the bioavailability of lutein is increased. Increasing the amount of lutein in an infant formula is a straightforward exercise. D16 suggests the addition of a commercially available ingredient (paragraph [0014]).

2.5.4 The appellant argued that the skilled person would have chosen a concentration of 75 µg/liter or higher. The board has no reason to doubt that this is a value that

the skilled person would consider. This value is within the range suggested in claim 2 of D16.

2.5.5 Be that as it may, irrespective of whether the amount of lutein selected is 75 µg/liter, 109 µg/liter (as discussed in D18, see point 2.5.2 above) or even as high as 230 µg/liter (the highest amount suggested in D16), with any of these concentrations the weight ratio of lutein (µg) to docosahexaenoic acid (mg) called for in claim 1 would be fulfilled.

2.6 Therefore, claim 1 as granted lacks inventive step. The ground for opposition under Article 100(a) and 56 EPC is prejudicial to maintenance of the patent.

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. Schalow A. Haderlein

Decision electronically authenticated