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Datasheet for the decision of 23 February 2023

Case Number: T 1540/21 - 3.3.09

Application Number: 10189228.9

Publication Number: 2283736

IPC: A23L33/00, A23L33/105, A23L33/12

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 II/ABBOTT

Relevant legal provisions:
EPC Art. 54
RPBA 2020 Art. 12(4), 13(2)

Keyword:
Novelty - (no) - availability to the public - enabling disclosure
Amendment to case - amendment admitted (yes)
Amendment after summons - exceptional circumstances (yes)

Decisions cited:
G 0001/92, T 0952/92, T 2048/12

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Case Number: T 1540/21 - 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 Dept. 0377, Bldg. AP6A-1 100 Abbott Park Road Abbott Park IL 60064-6008 (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 25 May 2021 rejecting the opposition filed against European patent No. 2283736 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 had requested that the patent be revoked under Article 100(a) EPC for lack of novelty, among other grounds.

III. The following documents were cited during the opposition proceedings:

D1: 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

D3: Wyeth master formulation, product #6509 (MF#IRLBWB011)

D16: Declaration by Dan O'Callaghan (18 March 2020)

D17: Wyeth master formulation, product #6509 (MF#IRLBWB009)

D18: B. Koletzko *et al.*, "Long-Chain Polyunsaturated Fatty Acids in Diets for Infants: Choices for Recommending and Regulating Bodies and for Manufacturers of Dietary Products", Lipids, 34(2), 1999, 215-220

D21: SMA Low Birthweight 100 ml bottle label and Master labeling approval form (#IRLBWB009)

D22: SMA Low Birthweight 100 ml bottle label and internal label form (#IRLBWB011)

IV. On appeal, the appellant filed the following documents, among others:

D29: V. M. Sardesai, "Introduction to clinical nutrition", 2nd edn., New York: Marcel Dekkel, Inc., 2003, chapter 28 (10 pages)

D30: O. Sommerburg *et al.* "Fruits and vegetables that are sources for lutein and zeaxanthin: the macular pigment in human eyes", British Journal of Ophthalmology, 82, 1998, 907-910

D31: G. Aruna *et al.* "Lutein content of selected Indian vegetables and vegetable oils determined by HPLC", Journal of Food Composition and Analysis, 22, 2009, 632-636

D29 was filed with the statement setting out the grounds of appeal. D30 and D31 were filed with a letter dated 3 May 2022, one month after the board issued its communication under Article 15(1) RPBA 2020.

V. The only claim relevant to the decision is claim 1 of the patent as granted (i.e. of the main request), which reads:

"*A ready-to-feed liquid infant formula comprising fat, protein, carbohydrate, vitamins, minerals, at least 50 µg/liter of lutein, and from 72 to 360 mg/liter docosahexaenoic acid, 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.*"

VI. The appellant's arguments, where relevant to the decision, are summarised as follows.

- D29, D30 and D31 should be admitted into the proceedings. D29 was filed in reaction to the

opposition division's decision. D30 and D31 were filed in reply to the board's communication.

- Claim 1 lacked novelty over the infant formula SMA Low Birthweight (in the following also referred to as SMA LBW) as analysed in D1. Reference was made to evidence which included the scientific article D18 and documents from Wyeth, the manufacturer of the formula analysed in D1 (D17, D3, D21, D22 and D16).

VII. The arguments of the respondent (patent proprietor), where relevant to the decision, are summarised as follows.

- D29 to D31 should not be admitted into the proceedings. These documents were not relevant and could have been filed earlier.
- Claim 1 was novel over D1. The make-up of the formula SMA LBW as analysed in D1 was not made available to the public. The required standard of proof for the evidence provided ("up to the hilt") was not fulfilled. Furthermore, contrary to the condition stated in G 1/92, it was not possible to reproduce the formula as analysed in D1.

VIII. 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*

The patent relates to infant formulas containing combinations of lutein and docosahexaenoic acid. The formulas are stated to promote retinal health and vision development in infants (paragraph [0001]).

2. *Admittance of D29, D30 and D31*

2.1 D29

2.1.1 The appellant filed D29 with its statement setting out the grounds of appeal. In its view, the opposition division did not correctly assess the teaching in D1 that "[e]gg lipid is a rich source of lutein and to a lesser extent zeaxanthin ...". D29 confirmed that according to common general knowledge egg yolk contained relatively large amounts of zeaxanthin.

2.1.2 D29 adds no complexity to the case and clarifies that egg lipids comprise zeaxanthin. This helps to correctly interpret the statement under scrutiny in D1.

2.1.3 Therefore, D29 is admitted into the proceedings (Article 12(4) RPBA 2020).

2.2 D30 and D31

2.2.1 D30 and D31 were filed after notification of the summons to oral proceedings, approximately one month after the board issued its communication under Article 15(1) RPBA 2020.

2.2.2 In its communication (section 5.5.7), the board explained its interpretation of a passage of D1 ("*those milks with high concentrations of lutein and zeaxanthin, were found to contain egg lipid as a major fat source*", page 96, left-hand column). Moreover, in section 5.5.9 it noted that there seemed to be no explanation as to how the relatively high amounts of lutein found in SMA LBW came to be in the formula.

2.2.3 The board is satisfied that D30 and D31 specifically address points which it raised in its preliminary opinion. D30 teaches that whilst vegetables are a rich source of lutein, they do not necessarily contain zeaxanthin. Moreover, D30 shows that egg provides both lutein and zeaxanthin. Finally, D31 demonstrates that palm and soybean oil, which are allegedly used in the product analysed in D1, contain significant amounts of lutein and no detectable zeaxanthin.

2.2.4 Therefore, the filing of D30 and D31 is entirely justified under Article 13(2) RPBA 2020.

2.3 To conclude, D29 to D31 are admitted into the appeal proceedings.

3. *Article 100(a) EPC - Novelty*

3.1 The appellant argued that the subject-matter of claim 1 lacked novelty over the composition of SMA LBW as described and analysed in D1, in particular in Table 2.

3.2 D1 analyses and compares lutein and zeaxanthin concentrations in human milk samples and commercial milk formulas commonly used in hospitals. The analysis in D1 must have been carried out between 1998 and 2003.

One of the formulas analysed is the SMA LBW product of the company Wyeth, in Berks., UK. Based on the lutein concentration in the fat phase and the concentration of the fat phase in the formula, the lutein concentration in SMA LBW is calculated as being 100.1 µg/litre.

3.3 The respondent argued that according to its reading of D1, SMA LBW comprised egg phospholipids but apparently no docosahexaenoic acid.

3.4 The only issue in dispute here is the composition of SMA LBW. As evidence of the make-up of SMA LBW, the appellant filed internal documents from Wyeth setting out how the product was manufactured. According to the appellant, these documents are intended to show the concentration of docosahexaenoic acid in the product and the absence of egg phospholipids. Nevertheless, some information relevant to the make-up of SMA LBW was contained in publicly available documents at the time of priority of the contested patent.

3.5 These publicly available documents will be dealt with first (section 3.6). Then, the internal documents from Wyeth will be discussed (section 3.7). Finally, the respondent's argument that SMA LBW would not have been available to the skilled person because it could not be reproduced, i.e. a condition stated in G 1/92 was not fulfilled, will be addressed (section 3.8).

3.6 Information on SMA LBW in publicly available documents

3.6.1 As explained above (see section 3.2), D1 discloses the concentration of lutein found in commercial milk formulas. The six compositions analysed are classified into three groups of concentrations:

- Quite a large concentration of lutein (calculated as 157.7, 205.3 and 242.8 µg/litre) is found in three compositions. These are stated to have the highest concentrations of lutein identified. The values are approximately double the median concentration in human milk. All three compositions comprise zeaxanthin.
- An amount of lutein similar to that of human milk (calculated as 100.1 µg/litre) is found in SMA LBW. The composition contains no zeaxanthin.
- Very little or no lutein at all is found in two further compositions.

3.6.2 A further aspect of the study of D1 is how lutein is added to the compositions analysed.

"*As there is nothing to indicate that either lutein or zeaxanthin were added to any formula milk, they must be components of other ingredients in the milk. Subsequently, information on sources of fat in the milks was obtained from the manufacturers, and those milks with high concentrations of lutein and zeaxanthin, were found to contain egg lipid as a major fat source. Egg lipid is a rich source of lutein and to a lesser extent zeaxanthin, and therefore is the most likely source of these carotenoids in formula milks. Unpublished information from our laboratory shows the concentration of lutein plus zeaxanthin in egg yolk to range from 2 to 22 µg/g fat depending on the level of lutein supplied by the chicken feed*" (page 96, passage bridging the left- and right-hand columns).

3.6.3 This is the only passage in D1 discussing the source of lutein in the compositions analysed. The "milks with high concentrations of lutein and zeaxanthin" refer manifestly to the first group of compositions, with the

highest concentration of lutein and some zeaxanthin. SMA LBW is not described as having a high or very large concentration of lutein. Instead, the amount is similar to that of human milk. Moreover, SMA LBW does not comprise any detectable amount of zeaxanthin. In contrast, in D1 egg lipids are discussed only in the context of compositions that contain high concentrations of both lutein and zeaxanthin.

3.6.4 In view of this, there is nothing in D1 to support the respondent's allegation that SMA LBW comprises egg phospholipids. The same holds true for the other documents on file. D29 and D30 confirm that egg phospholipids comprise both lutein and zeaxanthin. The precise ratio of these two carotenoids depends of course on the feed of the chicken. However, if a composition comprises lutein and no zeaxanthin, as in the case of SMA LBW, there is no reason to conclude that it comprises egg phospholipids.

3.6.5 This is also supported by D18, a scientific article published in 1999. The study relates to amounts of polyunsaturated fatty acids, such as docosahexaenoic acid, found in infant formula compositions and the raw materials used for adding these fatty acids.

3.6.6 D18 examines several nutritional products suitable for healthy term infants (Table 2) or low-birthweight infants (Table 1). SMA LBW is one of the products suitable for low-birthweight infants. According to the manufacturer's data, SMA LBW contains single-cell oils as the raw material for adding the polyunsaturated fatty acids. Although about half of the products examined include egg lipids as the source of these fatty acids, SMA LBW does not.

3.6.7 Therefore, D18 - a publication unrelated to and independent from D1 - provides confirmation that SMA LBW does not contain egg phospholipids.

3.6.8 There is no reason to believe that the manufacturer of SMA LBW passed on incorrect information to the authors of D18. On the contrary, egg ingredients are potentially allergenic, which is why they receive particular attention in research. As its title implies, D18 has gathered knowledge on polyunsaturated fatty acids in infant diets, with the aim of providing this information to recommending and regulatory bodies.

3.6.9 As an intermediate conclusion, based on the evidence publicly available in printed documents on the date of priority of the patent, there is no reason to assume that SMA LBW comprises egg phospholipids. On the contrary, the opposite is more likely. Therefore, in accordance with general principles governing the evaluation of evidence according to the case law (Case Law of the Boards of Appeal, 10th edition, 2022, III.G.4.3), this must be considered true for the purpose of the decision to be made by the board.

3.6.10 At this juncture it is noted that even the concentration of docosahexaenoic acid in SMA LBW can be derived from D18 and D1. D18 discloses the amount of docosahexaenoic acid present in SMA LBW as a percentage of fat (0.4%). D1 states that SMA LBW contains fat in a concentration of 44 g/litre. From these values, the appellant calculated a concentration of docosahexaenoic acid of about 170 mg/litre.

3.7 Internal documents relating to SMA LBW

3.7.1 To demonstrate that SMA LBW as analysed in D1 was free of egg phospholipids and comprised the amount of docosahexaenoic acid stipulated in claim 1, the opponent (now the appellant) filed additional evidence.

3.7.2 The evidence concerns the following documents:

- D17: Master formulation (#IRLBWB009), in use as of May 1997
- D3: Master formulation (#IRLBWB011), in use as of October 2002
- D21: Label for a 100 ml bottle of "SMA Low Birthweight", and an internal label form for SMA LBW RTF (#IRLBWB009)
- D22: Label for a 100 ml bottle of "SMA Low Birthweight", and an internal label form for SMA LBW (#IRLBWB011)
- D16: Declaration by Dan O'Callaghan, Head of the Nestlé Development Centre (R&D) at Wyeth Nutrition’s facility in Askeaton, Ireland

3.7.3 All these documents were issued by Wyeth, the manufacturer of SMA LBW. Although D3 and D17 are documents drafted in 2003 and 1997, respectively, as such they were not available to the public at the time of priority of the patent. However, the information in D3 and D17 concerning the label claims (i.e. page LC-1 in both documents) would have been available to the public. Similarly, the labels in D21 and D22 are intended to be accessible by the public and to inform the consumer about the product, whereas the internal label forms are manifestly not. Finally, D16 is a declaration that was drafted in 2020.

3.7.4 The appellant acquired Wyeth in 2012. Therefore, these documents are considered to be within the sphere of the appellant.

3.7.5 The respondent argued that it did not have access to these documents. The case genuinely related to an instance of public prior use and therefore a high burden of proof applied to the evidence, namely "up to the hilt".

3.7.6 However, the prior art publicly available before the priority date of the patent points towards the conclusion that SMA LBW is free of egg phospholipids and comprises docosahexaenoic acid in the amounts stipulated in claim 1. This is explained in section 3.6 above.

3.7.7 As already mentioned (see section 3.6.9 above), the standard of proof which generally applies when answering the question of whether a fact may be considered to be true is the balance of probability. Exceptions may apply only where the relevant evidence lies entirely within the sphere of a specific party alleging the fact in dispute. In the case in hand, however, where relevant evidence is in part in the public domain and in part not, there is no reason to depart from this standard.

3.7.8 The analysis below will explain why the internal documents

- confirms the conclusion which the board has reached on the basis of the publicly available documents regarding the absence of egg phospholipids in SMA LBW

- supports the further conclusion that the SMA LBW analysed in D1 contained the amount of docosahexaenoic acid recited in claim 1 of the main and sole request

3.7.9 D17 relates to the master formulation #IRLBWB009 for manufacturing a liquid product at Wyeth. SMA LBW is not mentioned. Among other things, D17 discloses the amounts of the oils used for making the fat blend of the product, including palm and soybean oil, and the amount of docosahexaenoic acid. Egg phospholipids are not mentioned anywhere. D17 discloses labelling information (page LC-1) applicable in various regions of the world, such as Australia and the UK.

3.7.10 D21 shows an internal label form (#IRLBWB009) relating to the product SMA LBW RTF. RTF stands for ready-to-feed, i.e. a liquid composition. D21 also shows a sample of a label with the product name, i.e. "SMA Low Birthweight", as well as the ingredients and nutritional information. Egg, a potentially allergenic ingredient, is not mentioned, nor are egg phospholipids. The address on the label reads:

"SMA Nutrition
Huntercombe Lane South
Taplow, Maidenhead, Berks., SL6 0PH
In Republic of Ireland ..."

3.7.11 D3 relates to the master formulation #IRLBWB011 for manufacturing a liquid product at Wyeth. SMA LBW is not mentioned. It is explicitly stated that as of 8 October 2002, D3 replaces master formulation #IRLBWB011. Although revisions have been carried out (e.g. on 20 June 2003), these relate to a change in

documentation or labelling instructions relevant to some regions of the world. The revisions do not concern any relevant change in the make-up of the formula. Like D17, D3 discloses the amounts of docosahexaenoic acid and oils used for making the fat blend of the product, and also labelling information applicable in various regions of the world (page LC-1). Egg phospholipids are not mentioned anywhere.

3.7.12 D22 shows an internal label form (#IRLBWB011) for the product SMA LBW, and a sample of a label. The disclosure of the label of D22 is similar to that of D21 but with an updated design and address in the Republic of Ireland.

3.7.13 Based on these documents, the following intermediate conclusions can be drawn:

- D21 shows that the product with the master formulation #IRLBWB009 of D17 is SMA LBW in use as of 1997.

- D22 shows that the product with the master formulation #IRLBWB011 of D3 is SMA LBW in use as of October 2002, when it replaced the product of D21 and D17.

- From D3 and D17, the concentration of docosahexaenoic acid can be calculated. The concentration is essentially the same as that which can be derived from D18 and D1 (see section 3.6.10 above). Thus, there is no reason to assume that the amount of docosahexaenoic acid varied throughout the time during which the experiments in D1 were carried out. In this context it is observed that SMA LBW is intended for use in hospitals and for

preterm infants. Fluctuations beyond minimal ones in the amounts of the components would not have occurred. In any case, it is inconceivable that a potential fluctuation would be so sizeable that the concentration of docosahexaenoic acid and the weight ratio according to claim 1 would no longer be achieved.

- The labels in D21 and D22 and the master formulations D17 and D3 confirm that no egg phospholipids were used to prepare SMA LBW. This is entirely in line with the disclosure in D1 and D18 as discussed in section 3.6 above.

- The products referred to in D1 and D18 were made for the UK market. D21 and D22 confirm that the locations of the distributor of SMA LBW in the UK as mentioned in D18 (Taplow) and in D1 (Berks.) relate to the identical postal address (see section 3.7.10 above: D21 and D22 refer to "Taplow, ... Berks.").

- The master formulation D3 directly replaced the earlier formulation D17. There is no reason to assume that there might have been a product with a master formulation #IRLBWB010. The respondent's allegation that there might have been such a product are speculative.

3.7.14 D16, the declaration by Mr O'Callaghan, confirms the conclusions made above. According to his own submissions, since 1994 Mr O'Callaghan had managed the R&D department at Wyeth in Askeaton, Ireland. The declaration that egg phospholipids were never added to any Wyeth Nutrition product is confirmed by D1 and D18 and in addition by the master formulations D17 and D3.

The same applies to the concentration of docosahexaenoic acid mentioned in the declaration.

3.7.15 The labels D21 and D22 show that SMA LBW was made for the UK and the Republic of Ireland at the same location. But it is correct that there is no further, separate evidence corroborating the statement in D16 that since 1997 the only manufacturing facility producing SMA LBW had been Wyeth Nutrition's facility in Askeaton (Ireland).

3.7.16 However, the relevant point is not whether there were different production sites for SMA LBW. What has to be ascertained is the composition of the product analysed in D1, in particular whether the product had the required amount of docosahexaenoic acid and no egg phospholipids. Based on what is set out above, the board has no doubt about this.

3.7.17 The issue of whether there were different production sites is relevant only in the context of the respondent's speculative argument that there might have been a further SMA LBW product made somewhere in the world but marketed with an address in the UK, with a different composition and in powder form, and that precisely such a product was the one analysed in D1. None of these speculations is based on verifiable evidence, apart from one specific allegation.

3.7.18 The respondent referred to the passage in the right-hand column on page 91 of D1, which stated that "milks were premixed and vacuum-sealed and stored ... until analysis". From this passage the respondent inferred that the compositions examined in D1, and in particular SMA LBW, must have been a powder, not a liquid. This was in contradiction to D17, D3, D21, D22 and D16,

which all showed that SMA LBW was a liquid formula. The respondent drew the conclusion that no link had been established between D1 and the remaining evidence also for this reason.

3.7.19 Contrary to the respondent's allegation, D1 contains no explicit or even implicit disclosure that SMA LBW as analysed in the study was a powder. On the contrary, the most straightforward reading of the passage on page 91 is simply that the samples, in particular milk expressed using a breast pump, i.e. samples in liquid form, were premixed before storage.

3.7.20 Therefore, the respondent's allegation that the analysis in D1 must have been based on a speculative product, i.e. SMA LBW in powder form, has to be rejected. As a consequence of this, there is nothing to break the link between D1 and the remaining evidence cited, in particular the documents from Wyeth.

3.7.21 To conclude, the board is convinced that SMA LBW as analysed in D1 comprised all of the features of claim 1, in particular the concentrations of lutein and docosahexaenoic acid, the weight ratio of these two substances and no egg phospholipids.

3.8 Was SMA LBW fully reproducible?

3.8.1 The respondent contested that the make-up of SMA LBW had been made available to the public. Its arguments were as follows.

- According to opinion G 1/92, the chemical composition of a product was considered to be prior art when the product could be analysed and reproduced by a skilled person.

- However, the information given in D1 for SMA LBW was insufficient. The protein, carbohydrate and fat sources were not mentioned. These natural products were inevitably subject to variation from batch to batch. The fat source typically involved a mixture of fats and oils from different sources.

- The lutein concentration analysed in D1 had to be regarded as similar to an impurity. Lutein was not considered during the preparation process described e.g. in D17 and was not deliberately added to SMA LBW. Instead, it was added as an intrinsic part of other components.

- According to T 2048/12, in which the principles of G 1/92 were applied, the mere commercial availability of a product did not amount to a disclosure of all of the impurities it contained. This was all the more so if such impurities were not mentioned in the context of the product's commercialisation.

3.8.2 The respondent's arguments have failed to convince the board.

3.8.3 According to Headnote 1 of opinion G 1/92, the

"*chemical composition of a product is state of the art when the product as such is available to the public and can be analysed and reproduced by the skilled person, irrespective of whether or not particular reasons can be identified for analysing the composition.*"

3.8.4 Clearly, at the time of priority of the contested patent it was possible to analyse the SMA LBW to such

an extent that even lutein and zeaxanthin were quantified. D1 constitutes evidence that these components, which are present at a microgram level, were identified and quantified. Furthermore, not only was the naked (but analysable) product in the hands of the public but so was the label of the commercial product, i.e. the label shown in D21 or D22.

3.8.5 Therefore, the question to be answered is what is meant in G 1/92 by the condition that the contentious product must be analysed and reproduced by the skilled person (Headnote 1 and Reasons 1.4) when applied to the case in hand? Does it have to be fully reproduced down to the exact nature of the vegetable oil mixture, in particular the sources of oils, as suggested by the respondent? Or is it sufficient for something that falls within the scope of the claim under examination to be produced, as argued the appellant?

3.8.6 G 1/92 itself does not give any indication as to the extent to which the condition of analysing and reproducing the product is to be fulfilled.

3.8.7 However, T 952/92 (Reasons 2.3) addresses in detail the question of whether

"*if the composition of a prior used product is to be 'made available', a complete analysis of such product must be possible, so that, as submitted by the patent Proprietor, such product could have been exactly reproduced*."

3.8.8 The competent board first explained that such a strict and literal interpretation of G 1/92 would not have been intended by the Enlarged Board. It then stated the following:

"*According to the established jurisprudence of the Boards of Appeal, the novelty of a claimed invention is destroyed by the prior disclosure (by whatever means) of an embodiment which falls within the claim. Thus in the Board's view, the novelty of a claimed invention is destroyed by the prior use of a product, for example, sale of a product, if an analysis of a product using available analytical techniques is such as to inform the skilled person of an embodiment of the product which falls within the claim of the patent. The Board therefore does not accept the patent proprietor's submissions to the effect that a* ***complete*** *analysis of a prior used product must be possible, so as to enable an* ***exact*** *reproduction of such product, in order to destroy the novelty of the claimed product*" (emphasis in the original).

3.8.9 This says it all. In the case in hand, the board has no doubt that the product SMA LBW as analysed in D1 was made available to the skilled person by the standards required in G 1/92, as interpreted in T 952/92.

3.8.10 As to T 2048/12, which was cited by the respondent, the following observations are made. In the case underlying the cited decision, a commercially available catalyst, which was a single catalytic chemical compound, contained a minor amount of an impurity, the component TMAEE. Conventional chemical analysis of the commercially available catalyst allowed TMAEE to be identified therein. The question was whether the catalyst with its impurity was made available to the public. The competent board established that the traces of impurities had no relevance on the intended application of the catalyst. Based on this, it decided that a skilled person who got hold of the catalyst

would have had no reason to perform an analysis thereon with the aim of identifying the amount of impurities therein.

3.8.11 However, T 2048/12 is not relevant for the case in hand. In the cited decision, the issue was essentially whether the skilled person would have had a motivation to analyse the catalyst and identify the impurity. In the current case, however, lutein is not an impurity. It is a recognised constituent of human milk and infant formula compositions. It is acknowledged in the art that lutein has a function in the protection and development of the infant eye. There is also no need to consider whether there was any reason to analyse SMA LBW and determine the amount of lutein because this was already done in D1.

3.9 To conclude, it has been shown to the conviction of board that SMA LBW, as analysed in D1, was made available to the public and that it discloses all of the features of claim 1.

3.10 Therefore, SMA LBW, as analysed in D1, anticipates the subject-matter of claim 1 of the patent as granted. The ground for opposition under Articles 100(a) and 54 EPC prejudices the maintenance of the patent as granted.

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