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Datasheet for the decision of 10 May 2011

Case Number: T 2111/08 - 3.3.09

Application Number: 01948924.4

Publication Number: 1251750

IPC: A23L 1/305

Language of the proceedings: EN

Title of invention:
Improved pediatric formula and methods for providing nutrition and improving tolerance

Patent Proprietor:
ABBOTT LABORATORIES

Opponent:
N.V. Nutricia

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 84, 111(1), 123(2), 123(3)
RPBA Art. 13(1)

Relevant legal provisions (EPC 1973):
EPC Art. 54(5)

Keyword:
"Main request - clarity (no)"
"First and second auxiliary requests - Article 123(3) (no)"
"Third auxiliary request - inventive step (no)"
"Fourth auxiliary request - admissibility (no)"

Decisions cited:
G 0002/83, G 0001/99, T 1129/97, T 1048/98, T 0381/02, T 0830/08

Catchword:
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Case Number: T 2111/08 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 10 May 2011

Appellant: (Opponent)	N.V. Nutricia Eerste Stationsstraat 186 NL-2712 HM Zoetermeer (NL)
Representative:	Kremer, Simon Mark Mewburn Ellis LLP 33 Gutter Lane London EC2V 8AS (GB)
Respondent: (Patent Proprietor)	ABBOTT LABORATORIES CHAD 0377/AP6D-2 100 Abbott Park Road Abbott Park IL 60064-3500 (US)
Representative:	Modiano, Micaela Nadia Modiano Josif Pisanty & Staub Ltd Thierschstrasse 11 D-80538 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted 1 August 2008 concerning maintenance of European patent No. 1251750 in amended form.**

Composition of the Board:

Chairman: W. Sieber
Members: N. Perakis
K. Garnett

Summary of Facts and Submissions

I. Mention of the grant of European patent No. 1 251 750 in respect of European patent application No 01948924.4 in the name of ABBOTT LABORATORIES, which had been filed as international application No. PCT/US2001/001295 on 16 January 2001, was published on 29 March 2006 (Bulletin 2006/13). The patent was granted with 22 claims, independent Claims 1, 7, 21 and 22 reading as follows:

"1. A pediatric formula comprising per liter from 53 to 107 grams carbohydrate, 22 to 40 grams lipid, 12 to 22 grams protein, and a tolerance improver comprising 250 to 2500 milligrams xanthan gum."

"7. A pediatric formula in a powdered form which comprises, based on 100 grams of powder, 30 to 90 grams carbohydrate, 15 to 30 grams lipid, 8 to 17 grams protein, and 188 to 1880 milligrams xanthan gum."

"21. Use of a formula according to any of claims 1-20 in the manufacture of a formula for providing nutrition to a pediatric patient."

"22. Use of a formula according to any of claims 1-20 in the manufacture of a formula for improving tolerance in a pediatric patient."

II. The opponent, N.V. Nutricia, requested revocation of the patent in its entirety on the grounds that the claimed subject-matter was neither novel nor 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 subject-matter of the claims as granted extended beyond the content of the application as filed (Article 100(c) EPC).

Together with the notice of opposition, the opponent filed *inter alia* the following documents:

D1A: Statutory Instruments, 1999, No. 1136, "The Miscellaneous Food Additives (Amendments) Regulations 1999", pages 1-28;

D1B: Statutory Instruments, 1995, No 3187, "The Miscellaneous Food Additives Regulations 1995,", pages 1-67; and

D5: US 4 670 268.

III. In its interlocutory decision posted on 1 August 2008 the opposition division held that the subject-matter of Claims 1-14 of Auxiliary Request 2 filed during the oral proceedings of 10 June 2008 met the requirements of the EPC.

Claim 1 of this request, which derives from granted Claim 7, reads as follows:

"1. A pediatric formula in a powdered form which comprises, based on 100 grams of powder, 30 to 90 grams carbohydrate, 15 to 30 grams lipid, 8 to 17 grams protein, and 188 to 1880 milligrams xanthan gum **for improving tolerance of pediatric patients fed the formula**." *(amendment vis-à-vis granted Claim 7 in bold)*

IV. The opponent (appellant) filed an appeal against the decision of the opposition division on 8 October 2008 and paid the appeal fee on the same day.

The statement setting out the grounds of appeal was filed on 10 December 2008. The appellant argued that the claims upheld by the opposition division did not satisfy the requirements of Articles 54, 56, 83, 84 and 123(2) EPC and requested revocation of the patent.

V. In its reply dated 15 April 2009 the patent proprietor (respondent) requested rejection of the appeal, i.e. to maintain the patent with the claims allowed by the opposition division (main request), and filed an auxiliary request.

By letters dated 10 March 2011 and 27 April 2011 the respondent filed further auxiliary requests which were eventually replaced by the auxiliary requests filed during the oral proceedings before the board.

VI. With letters dated 5 April 2011 and 4 May 2011, the appellant filed further arguments against the main request and raised various objections against the auxiliary requests. It also filed the following document with the letter dated 4 May 2011:

D6: Extract from "The Food Labelling Regulations 1996", No 1499, Schedule 7, from www.legislation.gov.uk.

VII. Oral proceedings before the board were held on 10 May 2011. During these proceedings the respondent stood by its main request and presented the following first, second, third and fourth auxiliary requests:

The **first auxiliary request** corresponded to the auxiliary request filed with letter dated 15 April 2009. Claim 1 reads as follows:

"1. Use of xanthan gum in a pediatric formula for enhancing tolerance of pediatric patients fed the formula, wherein the formula comprises in a powdered form based on 100 grams of powder, 30 to 90 grams of carbohydrate, 15 to 30 grams lipid, 8 to 17 grams protein, and 188 to 1880 milligrams xanthan gum."

The **second auxiliary request** did not correspond to any previous request. Claim 1 reads as follows:

"1. Use of xanthan gum in a pediatric formula for enhancing tolerance of pediatric patients fed the formula **such as to change one or more characteristics selected from the group consisting of stool pattern, vomiting, spit up, acceptance of formula, fussing or crying**, wherein the formula comprises in a powdered form based on 100 grams of powder, 30 to 90 grams of carbohydrate, 15 to 30 grams lipid, 8 to 17 grams protein, and 188 to 1880 milligrams xanthan gum." *(amendment vis-à-vis Claim 1 of the first auxiliary request in bold)*.

The **third auxiliary request** corresponded to the second auxiliary request filed with the letter dated 10 March 2011. Claim 1 reads as follows:

"1. Use of a pediatric formula in a powdered form which comprises, based on 100 grams of powder, 30 to 90 grams of carbohydrate, 15 to 30 grams lipid, 8 to 17 grams protein, and 188 to 1880 milligrams xanthan gum, in the manufacture of a formula for improving tolerance in a pediatric patient."

The **fourth auxiliary request** did not correspond to any previous request. Claim 1 reads as follows:

"1. Use of a pediatric formula in a powdered form which comprises, based on 100 grams of powder, 30 to 90 grams of carbohydrate, 15 to 30 grams lipid, 8 to 17 grams protein, and 188 to 1880 milligrams xanthan gum, in the manufacture of a formula for improving **non-immune system associated** tolerance in a pediatric patient **such as to change one or more characteristics selected from the group consisting of stool pattern, vomiting, spit up, acceptance of formula, fussing or crying**." *(amendment vis-à-vis Claim 1 of the third auxiliary request in bold)*

VIII. The appellant (opponent) requested that the decision under appeal be set aside and that the European patent No. 1 251 750 be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed, alternatively that the decision under appeal be set aside and the patent be maintained on the basis of the first, second, third or fourth auxiliary requests filed during the oral proceedings.

IX. The relevant arguments put forward by the appellant in its written submissions and at the oral proceedings may be summarised as follows:

– The subject-matter of Claim 1 of the **main request,** lacked clarity. It derived from granted Claim 7 with the following further feature taken from the description "for improving tolerance of pediatric patients fed the formula". Firstly, this feature introduced ambiguity regarding the category of the claim since it could be interpreted as relating to a product defined as a first medical indication or to concern simply a purposive use of the product. Secondly, this feature lacked clarity per se in view of the unclear terms "improving" and "tolerance".

– The subject-matter of Claim 1 of the **first and second auxiliary requests**, which related to the use of xanthan gum, did not fulfil the requirements of Article 123(3) EPC. All granted claims related to a formula made out of at least four ingredients and none of them allowed the individualisation of xanthan gum out of the four-ingredients combination.

– The subject-matter of Claim 1 of the **third auxiliary request** lacked novelty in view of the disclosure of D5. Although D5 did not disclose the amount of xanthan gum in the formula, this amount would be seriously contemplated by the skilled person in view of the specific disclosure of Table I of D5 (relating to the amount of the equivalent ingredient, carrageenan) or his general background knowledge as set out in D1A/D1B (UK food regulations establishing the highest limit of xanthan gum in pediatric formulas).

– Furthermore, the subject-matter of Claim 1 of the **third auxiliary request** lacked an inventive step. The contested patent did not provide technical evidence of an improvement over the closest state of the art, namely D5. Therefore the technical problem in view of D5 could only be seen in the provision of an alternative formula to be fed to pediatric patients. The claimed formula would have been obvious to the skilled person. On the one hand the amount of xanthan gum in the specific range was an arbitrary modification of the formula of D5. On the other hand a value falling within the claimed range was disclosed in D5 for a stabilizer equivalent to xanthan gum. Furthermore values falling within the claimed range were disclosed in the Food Regulations set out in D1A/D1B, which belonged to the general technical knowledge of the skilled person in the art.

– The **fourth auxiliary request** should not be admitted into the proceedings. It was late-filed without any reasonable excuse, it resulted from the modification of the third auxiliary request by introducing features from the description which surprised the appellant and

it gave rise to *prima facie* objections of lack of clarity and added subject-matter.

X. The arguments put forward by the respondent in its written submissions and at the oral proceedings can be summarised as follows:

– The subject-matter of Claim 1 of the **main request** fulfilled the clarity requirement. The claimed subject-matter was a pediatric formula drafted in the format of the first medical indication. The medical indication was the tolerance of pediatric patients to a food formula comprising xanthan gum. The meaning of tolerance was defined in the patent in suit and no objection on the meaning of this term could be raised. Finally the improvement in tolerance of a formula comprising xanthan gum compared with a formula not comprising xanthan gum was illustrated in the experimental part of the patent specification.

– The subject-matter of Claim 1 of the **first and second auxiliary requests** fulfilled the requirements of Article 123(3) EPC. The product claim of the main request, which related to a pediatric formula, was converted in these requests into a use claim for the preparation of the pediatric formula. The individualisation of xanthan gum did not extend the scope of protection offered by the granted claims because it found a basis in granted Claim 1.

– The subject-matter of Claim 1 of the **third auxiliary request** was novel over D5, which did not disclose the combination of all the claimed features. The allegations of the appellant were wrong on this issue because the novelty objection could not be based on the unjustified extrapolation from the disclosure of D5, namely that the amount for carrageenan would be used for the amount of xanthan gum, nor from the combination of documents, namely D5 with D1A/D1B.

– The subject-matter of Claim 1 of the **third auxiliary request** also involved an inventive step. The skilled person starting from D5, considered as the closest state of the art, would not consider xanthan gum as an ingredient of the pediatric formula for the improvement of tolerance because according to the disclosure of D5 xanthan gum was only used as stabilizer. Surprisingly, the experimental technical evidence of the contested patent showed the *in vivo* improvement in tolerance when the pediatric formula comprised xanthan gum over a formula without it. This was not obvious in the light of the available state of the art.

– The **fourth auxiliary request** should be admitted into the proceedings. It represented the heart of the

extensive study carried out *in vivo* by the respondent patent proprietor. This request had not been filed previously because the respondent had considered that, on the basis of the positive prospects for the subject-matter upheld by the opposition division, such an amended subject-matter was not appropriate. Though this subject-matter might be surprising to the appellant, it should be admitted on the basis of procedural symmetry, namely because the respondent did not contest the admissibility of the late-filed document D6.

Reasons for the Decision

1. The appeal is admissible.

Main Request

2. Clarity

2.1 Claim 1 of the main request (points III and V above) is not a granted claim. It results from the combination of granted Claim 7 with the feature "for improving tolerance of pediatric patients fed the formula", which is disclosed in the description, namely page 1, lines 7-8 of the originally filed application and paragraph [0001] of the patent specification, respectively. Therefore the amendment has to fulfil the clarity requirements under Article 84 EPC.

2.2 The board agrees with the appellant that the insertion of the above recited feature into granted Claim 7 introduces uncertainties with regard to the category of the claim and the interpretation of the claimed subject-matter.

2.2.1 According to the respondent, Claim 1 of the main request is a purpose-limited composition under Article 54(5) EPC 1973, i.e. a so-called "1st medical use" claim (see point 2.2 of the letter dated 15 April 2009). However there are number of problems with this.

Article 54(5) EPC 1973 concerns compositions "comprised in the state of the art" which, according to the opposition division and the respondent, is not the case here (see point 4.3 of the decision of the opposition division). Therefore, it is not clear that the statement at the end of Claim 1 (i.e., "for improving tolerance of pediatric patients fed the formula") should be anything more than a functional limitation, i.e., a limitation that the formula is "suitable for" the stated purpose. Thus, the subject-matter for which protection is sought is rendered ambiguous by the amendment, contrary to Article 84 EPC.

2.2.2 But even if "improved tolerance" is intended to define a medical indication (whether in a purpose-limited or mere

functional sense) it does not do so clearly (in an Article 84 EPC sense) because it is inherently unclear.

Firstly, the claim is apparently directed to the "formula" for improving tolerance to 'something'. But what does the "formula" improve tolerance to? The simplest interpretation is that "the formula" is to be used to "improve tolerance" to 'itself'. However there is nothing in the specification to suggest that children who are intolerant to a formula will somehow be 'cured' of that condition by being fed that **same** formula. Thus such an interpretation would give rise to lack of support or enablement. Conversely if that is not what is meant, then how can the claim be interpreted?

Secondly, if "improved tolerance" is really intended to be the central characterising feature of the claim, the term "tolerance" is far too broad and vague to clearly define a therapeutic application. As pointed out by the appellant there appears to be no generally accepted definition for the term "tolerance". Paragraph [0020] defines improved tolerance "as an improvement (change towards normal patterns) of one or more of the following symptoms or characteristics: stool pattern, vomiting, spit up, acceptance of formula, fussing, crying, or exits for intolerance (clinical setting)". While the board accepts that to some extent a patentee can define terms in the specification, nevertheless the claims must be clear as they stand. According to the consistent case law of the boards of appeals of the EPO, clarity is a requirement of the claims and cannot be substituted by the disclosure in the description (cf. T 1129/97, OJ EPO 2001, 273, point 2.1.2 of the reasons). Thus, also for this reason, the amendment does not meet the requirement of Article 84 EPC.

Finally, even if improving tolerance is an essential feature of the claim, the present claim seemingly allows for any of the xanthan, lipid, protein and carbohydrate constituents to play a role in the tolerance improvement. Such a wide range of possibilities is not supported by the description, which typically compares formulas differing only in xanthan gum, i.e. attributes the tolerance improving effect only to xanthan gum. Thus, the amendment also lacks support from the description in the sense of Article 84 EPC.

2.3 In view of the above, the amendment to Claim 1 of the main request does not meet the requirements of Article 84 EPC.

3. Amendments

3.1 The appellant argued that the wording "for improving tolerance of pediatric patients fed **the** formula" introduced into Claim 1 of the main request required that the formula is fed to pediatric patients **in a powdered form**, since the word "the" in the introduced wording can only refer to the preceding "pediatric formula in powdered form". There was,

however, no basis in the application for the concept of feeding patients the formula in powdered form. On the contrary, page 5, lines 14-16 of the application as filed makes it clear that, before feeding, water is added to the powdered formula.

3.2 The board does not consider it appropriate to elaborate on this point at length since the main request has already been found to be not allowable for clarity reasons (point 2 above). However for the sake of completeness, the board is of the opinion that the skilled reader would not interpret the claim in the restrictive manner suggested by the appellant, since from a realistic point of view it makes no sense to feed the powdered formula directly to a pediatric patient. The skilled person reading the claim would immediately understand that the pediatric formula in powdered form will have to be mixed with water before it is fed to pediatric patients. Thus the board considers that this amendment fulfils the requirements of Article 123(2) EPC.

First auxiliary request

4. Amendments under Article 123(3) EPC

4.1 Claim 1 of the first auxiliary request (point VII above) is directed to the use of xanthan gum in a pediatric formula for enhancing tolerance of pediatric patients fed the formula.

However, as the appellant correctly pointed out, Claim 1 is directed to a particular use of xanthan gum alone, this specific use of an individual component not having been in the granted claims. Also, no claim to xanthan gum *per se* existed in the patent as granted, whether as a product or anything else. Thus, acts relating to use of xanthan gum alone could well be covered by the claims as amended, whereas previously only compositions of a number of ingredients were referred to. Therefore the individualisation of xanthan gum out of the granted subject-matter extends protection and does not fulfil the requirement of Article 123(3) EPC.

4.2 The respondent argued that such an individualisation of xanthan gum found support in granted Claim 1. The board acknowledges that said claim recites the feature of "a tolerance improver comprising 250 to 2500 milligrams xanthan gum". However, as set out above, granted Claim 1 is directed to a formula comprising xanthan gum and not to xanthan gum alone. Therefore, the respondent's argument is not accepted.

Second auxiliary request

5. Claim 1 of the second auxiliary request (point VII above) relates, as does Claim 1 of the first auxiliary request, to

the use of xanthan gum in a pediatric formula for enhancing tolerance of pediatric patients fed the formula (with the tolerance further specified). The reasoning set out in point 4 above applies *mutatis mutandis* to this claim with the consequence that Claim 1 of the second auxiliary request also does not fulfil the requirements of Article 123(3) EPC.

Third auxiliary Request

6. Admissibility

6.1 The appellant contested the admissibility of the third auxiliary request on the ground of procedural abuse. The alleged abuse consisted in the reintroduction of this request into the proceedings, which had been expressly withdrawn by the patent proprietor during the proceedings before the opposition division.

The board cannot agree with the appellant. As correctly pointed out by the respondent during the oral proceedings before the board, this request was filed with the letter dated 10 March 2011 in response to objections raised by the appellant against the claims upheld by the opposition division and against the claims of the auxiliary request filed with the letter of 15 April 2009. Furthermore, the appellant had already commented on the subject-matter of the third auxiliary request in its letter of 5 April 2011 (page 6, point 3) but without raising the issue of procedural abuse. Raising this serious issue for the first time at the oral proceedings before the board was not only something of an ambush but also unfair to the respondent for a further reason, namely that the representative was not in a position to say on the spot why this request had been withdrawn before the opposition. In view of these considerations the board concludes that the filing of the third auxiliary request was not an abuse.

6.2 Furthermore, the appellant contested the admissibility of this request on the basis of the legal principle of prohibition of *reformatio in peius*. In Claim 1 of the third auxiliary request a feature has been deleted from the claims upheld by the opposition division. According to the appellant, Claim 1 no longer requires that the powdered formula be fed to the pediatric patient. Thus it now provides for a use of a powdered formula for the manufacture of "a formula", which presumably could be a liquid, reconstituted one. Thus, a liquid formula was once again covered, whereas it was not in the claims as upheld by the opposition division (which were limited to administration in the form of a powder).

This argument is, however, not persuasive. The claims upheld by the opposition division refer to a "pediatric formula in a powdered formula … for improving tolerance of pediatric patients fed the formula". In principle, a product claim

covers any possible use. Furthermore, as already pointed in point 3.2 above, the skilled reader would understand from the terminology in the claims upheld by the opposition division that the powdered formula will have to be mixed with water before it is fed to pediatric patients. Therefore it is doubtful that the third auxiliary request offends the principle of the prohibition of *reformatio in peius*. But even it the appellant's assumption were correct, the board finds that the specific circumstances of the present case justify an exception to the rule in accordance with G 1/99 (OJ EPO 2001, 381, Headnote) because the third auxiliary request appears to be the respondent's only remaining way to overcome the objections raised against the claims upheld by the opposition division.

6.3 In view of the above considerations the board admitted the third auxiliary request into the proceedings.

7. Remittal

The appellant requested that if the board admitted the third auxiliary request into the proceedings the case should be remitted to the opposition division for further prosecution. The board, however, did not see this as being appropriate, as the appellant had in the written appeal phase already raised formal and substantive objections against the subject-matter of the third auxiliary request. This in fact demonstrated that the appellant was familiar with all patentability issues concerning the subject-matter of this request. Under these circumstances the board exercised its discretion under Article 111(1) EPC and decided not to remit the case to the opposition division for further prosecution.

8. Amendments

8.1 Claim 1 of the third auxiliary request (point VII above) relates to the use of a pediatric formula in a powdered form in the manufacture of a formula for improving tolerance in a pediatric patient. Its language is based on Claims 15 and 71 as originally filed (cf. Claims 7 and 22 as granted, see point I above). Though a slightly different wording was used in Claim 71 as originally filed ("… administering an effective amount of a pediatric formula reconstituted from a powdered composition …"), the wording of Claim 1 of the third auxiliary is considered to be equivalent to the original text. Therefore, Claim 1 meets the requirements of Article 123(2) EPC.

No further objections under Article 123(2) EPC were raised by the appellant against the remaining claims. The board is also satisfied that these claims meet the requirements of Article 123(2) EPC.

Likewise, no objections under Article 123(3) arise.

8.2 The clarity objection raised against Claim 1 of the main request can no longer be invoked against Claim 1 of the third auxiliary request, since this claim is based on a combination of granted claims. Normally, any lack of clarity arising from a mere combination of granted claims cannot be attacked under Article 84 EPC in opposition proceedings (e.g. T 381/02, point 2 of the reasons).

9. Interpretation of Claim 1

Claim 1 relates to the use of a pediatric formula in powdered form in the manufacture of a formula for improving tolerance in a pediatric patient. This claim is evidently drafted in the form of a second medical use claim, following G 2/83 (Swiss-type claim). Nevertheless the board considers that no disease is recited in the claimed subject-matter. As set out in point 2.2.2 above, the terms "tolerance" and "improving tolerance" are far too broad and vague to clearly define a therapeutic application. Especially in a claim directed to a second medical use, the disease to be treated and the therapeutic application must each be clearly defined (see for example T 830/08, point 4 of the reasons, and T 1048/98, points 2.1 to 2.5 of the reasons). Consequently Claim 1 of the third auxiliary request is not to be interpreted as having the improved tolerance as a limiting feature. Rather Claim 1 is directed to the use of a pediatric formula in the manufacture of a formula suitable for improving tolerance in a pediatric patient.

10. Novelty

10.1 The appellant argued that the subject-matter of Claim 1 lacks novelty in view of D5. This document discloses hypoallergenic formulas for pediatric patients (Claim 1; column 1, lines 32-37). These formulas contain the same macronutrients as required in the claim and in comparable amounts, and it can be manufactured in powdered form (Claims 1 and 8; column 7, lines 20-26). The disclosed formulas also contain a stabiliser such as lambda carrageenan or xanthan gum (Claim 11; column 4, lines 21-27). Such formulas are suitable to enhance patient acceptability (column 6, lines 12-16).

However, D5 does not disclose, explicitly or implicitly, the combination of all the individual ingredients of the claimed formula or that these ingredients are combined in a formula in powdered form. Although some of the claimed features largely overlap with those disclosed in D5, such as the ranges of macronutrients, one would have to make multiple selections in order to arrive at the claimed subject-matter, namely the physical state of the formula, the chemical nature of the stabilizer, the amount of the stabilizer xanthan gum and the amount of the macronutrients, in particular protein. Under these circumstances the board

considers that the claimed subject-matter is novel over the disclosure of D5.

11. Inventive step

11.1 With regard to the issue of inventive step the board concurs with the appellant that D5 has to be considered to represent the closest state of the art since this document belongs, as explained above, to the same technical field as the patent in suit, namely hypoallergenic formulas for pediatric patients.

11.2 Regarding the technical problem to be solved, the patent in suit repeatedly recites that its aim is the provision of a formula for the enhancement/improvement of the tolerance of pediatric patients fed the formula (paragraphs [0001], [0016] and [0019]).

11.2.1 Tolerance is understood to mean that intolerance is avoided, the latter being defined in paragraph [0003] of the contested patent as follows:

"*Intolerance is a non-immune system associated reaction and may be evidenced by behavior or stool or feeding pattern changes such as increased spit-up or vomiting, an increased number of stools, or more watery stools, and increased fussiness as compared to normal infants who tolerate the formula*".

Similarly paragraph [0020] states:

"*Intolerance (formula intolerance) in infants is often indicated by gastrointestinal symptoms (e.g. emesis, stool pattern, and gas) as well as behavioral characteristics (e.g. acceptance of formula, fussing, and crying). For purposes of this invention, improved tolerance (or reduced intolerance) is defined as an improvement (change towards normal patterns) of one or more of the following symptoms or characteristic: stool pattern, vomiting, spit up, acceptance of formula, fussing, crying, or exits for intolerance (clinical settings)*".

11.2.2 Regarding the improvement/enhancement of tolerance reported in the patent in suit (page 3, lines 43-44 and example 1), this improvement relates to the positive change in tolerance of children fed the formula containing xanthan gum compared with the tolerance when the children are fed a formula which does not contain any xanthan gum.

However, this comparison is immaterial since it does not reflect the comparison with the above identified closest state of the art D5, which already contains xanthan gum, although labelled as stabilizer. Thus, with respect to D5, the patent specification does not contain any comparative data. Nor has the respondent provided evidence which would

illustrate an improvement in tolerance over D5. Under these circumstances, no improvement of tolerance has been established over the formula of D5, which leads the board to conclude that the concept of an improvement cannot be part of the technical problem to be solved.

11.2.3 Furthermore the definition of "tolerance" of a formula given in the patent in suit overlaps with the "acceptability" of a formula disclosed in D5 (column 6, lines 11-21). Under "acceptability" D5 discloses avoidance of acid stool, gas, diarrhoea, water and electrolyte loss (compare the definition of tolerance recited above, point 11.2.1). Hence, the formulas prepared in D5 provide already "tolerance".

11.2.4 Consequently the technical problem has to be redefined in a less ambitious manner. The objective technical problem should thus be to provide for the use of a hypoallergenic formula for pediatric patients which is an alternative to the formula known from D5.

11.3 Regarding the question of obviousness, the board considers that the person skilled in the art, starting from the disclosure of D5 and seeking an alternative hypoallergenic formula to be fed to pediatric patients, would obviously consider the claimed formula without exercising any inventive step, for the following reasons.

11.3.1 Concerning the macronutrients of the formula, the board notes that D5 already discloses that proteins, lipids and carbohydrates are the essential ingredients. The concentration ranges disclosed in D5 for these ingredients largely overlap with those required in Claim 1 and the board considers that the skilled person in his every day work would seriously contemplate working in the specified ranges. Furthermore, there is no evidence on file for any particular technical advantage associated with these ranges.

11.3.2 As regards the amount of xanthan gum, it has not been shown that this amount is linked to a particular effect, with the consequence that the claimed range merely amounts to an arbitrary selection which thus does not involve any inventiveness.

Independently of the above, the claimed xanthan amount is in fact obvious from D5 itself. Table I of D5 lists all ingredients for a specific hypoallergenic formula, in particular 0.52 g of carrageenan (lamda type). This amount falls within the claimed range. As pointed out by the appellant, 520 mg per 676.3 Kcal according to Table I corresponds to 77 mg per 100 Kcal, which in turn corresponds to at least 374 mg of carrageenan per 100 g powder (based on Table II of the patent in suit). The skilled person would be motivated to use xanthan gum in a similar amount because D5 discloses both carrageenan and xanthan gum as equally suitable stabilisers (Claim 11 and in particular column 4,

lines 21-27: *"Xanthan gum may also be used in hypoallergenic formula as a stabilizer in the same fashion as lambda carrageenan.*"). In fact, D5 discloses only these two stabilisers explicitly.

11.3.3 Finally the powdered form of the claimed formula is an obvious alternative out of the three equivalent forms disclosed in D5 (column 7, lines 20-26) which the skilled person would select in accordance to conventional technical or commercial requirements, such as a convenient form for transport and/or long shelf-life, without the exercise of an inventive step.

11.4 In view of these considerations the board comes to the conclusion that the claimed formula is an obvious arbitrary modification of the formula of D5 and that its use in hypoallergenic powered formula for pediatric patients in order to manufacture a formula does not involve any inventive merit.

Fourth auxiliary request

12. Admissibility

12.1 This request is based on the hierarchically higher third auxiliary request including a more detailed definition of improved tolerance in Claim 1 as set out in paragraph [0020] of the patent specification (point VII above). This was done in an attempt to more clearly define the medical indication, which according to the respondent was the central point of the claimed invention.

12.2 This request was filed at a very late stage of the proceedings, namely during the oral proceedings before the board after the main request and three auxiliary requests had been discussed and rejected by the board as not patentable.

No plausible explanation was provided by the respondent for the late filing of this request. Even if the specific medical use is indeed the crucial point of the claimed invention, the respondent should have filed a claim addressing this issue much earlier, in particular because the issue of medical or non-medical aspect of the intended use was raised by the appellant at the beginning of the appeal proceedings and was maintained throughout the whole appeal procedure.

Furthermore, the respondent had not indicated any intention to make the newly introduced amendment at an earlier stage. The board therefore concurred with the appellant that taking features from the description at this late stage was surprising and put the appellant in an unfairly difficult position. Further the proposed amendment in Claim 1 of the fourth auxiliary request *prima facie* gave rise to objections

under Article 84 EPC. In this context the appellant in particular pointed out that "improving non-immune system associated tolerance" was still broad and it was not clear whether or not this term described a disease. In addition, it was not clear how this limitation to the improvement of the non-immune system associated tolerance could be compatible with the statement in paragraph [0042] of the patent specification which states that "*… the improved tolerance results achieved here should also be experienced by infants with allergies or sensitivities to intact proteins ….*".

12.3 The respondent argued that there was no need for an earlier filing of the now-claimed subject-matter because the decision of the opposition division had been favourable to it and that the board had not issued a preliminary opinion raising an objection in that direction. However, first, the whole point of appeal proceedings is that the first instance decision may be reversed: it cannot be assumed by a respondent that it will be upheld until told otherwise. Secondly, in the present case the board did not find it necessary to issue a communication since the medical/non-medical issue of the claimed invention had been raised by the appellant from the beginning and the arguments provided in writing by the parties were sufficient to reach a reasoned decision. Therefore this argument of the patent proprietor was not persuasive.

Nor does the board accept the argument of the respondent that the objected request should be admitted on the basis of "procedural symmetry", since it had not raised any objection against the admissibility of appellant's late-filed document D6. The board stresses that admissibility of a late-filed document or a late-filed request is a matter of discretion under Article 13 of the Rules of Procedure of the Boards of Appeal (PRBA), and each admissibility issue has to be evaluated on its own merits. Thus, it is quite wrong to think that the admission of a document or a request of one party will automatically lead to the admission of a request or document of the other party on the basis of some kind of mutual reciprocity. In any event, the admissibility of D6 was never discussed because the appellant did not rely on this document in the oral proceedings.

12.4 In view of the above considerations the board in exercise of its discretion under Article 13(1) RPBA decided not to admit the fourth auxiliary request into the proceedings.

13. Consequently none of the respondent's requests can be allowed.

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:

G. Röhn W. Sieber