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**Datasheet for the decision
of 20 April 2006**

Case Number: T 0424/02 - 3.3.09

Application Number: 96201526.9

Publication Number: 0745330

IPC: A23L 1/0522

Language of the proceedings: EN

Title of invention:
Anti-regurgitation infant formula

Patentee:
BRISTOL-MYERS SQUIBB COMPANY

Opponents:
Nestec S.A.
Wyeth

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 107, 108
EPC R. 64, 65

Keyword:
"Admissibility of Proprietor's appeal (no) - not adversely
affected by the appealed decision"
"Admissibility of Opponents' appeals (yes)"
"Novelty (yes) - alleged prior public use not proven"
"Inventive step (no)"

Decisions cited:
T 0073/88, T 0631/91, T 0273/92, T 0298/97, T 0098/01
T 0084/02

Catchword:
-



Case Number: T 0424/02 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 20 April 2006

Appellant:
(Opponent 01)

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Respondent:
(Patent Proprietor)

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Decision under appeal:

Decision of the Opposition Division of the
European Patent Office orally announced on
15 November 2001 and posted 1 March 2002
rejecting the oppositions filed against
European Patent No. 0745330 pursuant to Article
102(2) EPC.

Composition of the Board:

Chairman: P. Kitzmantel
Members: W. Ehrenreich
M.-B. Tardo-Dino

Summary of Facts and Submissions

I. Mention of the grant of European patent No. 0 745 330 in respect of European patent application no. 96 201 526.9 in the name of *Bristol-Myers Squibb Company* filed on 31 May 1996 and claiming the priority US 457699 of 1 June 1995 was announced on 7 October 1998.

The patent, entitled "*Anti-regurgitation infant formula*" was granted with twenty eight claims, independent Claims 1 and 18 reading as follows:

"1. An infant formula having calories from protein, fat and carbohydrate in proportions similar to human milk, characterised in that it comprises a thickening agent which comprises potato starch, waxy grain starch, or a mixture thereof, in an amount effective to ameliorate regurgitation in infants."

"18. Use of waxy grain starch, potato starch, or a mixture thereof, in the manufacture of an infant formula for use in the treatment of regurgitation in infants."

Claims 2 to 17 were dependent on Claim 1 and Claims 19 to 28 were dependent on Claim 18.

II. Notices of opposition requesting revocation of the patent in its entirety on the grounds of Articles 100(a) and 100(b) EPC were filed by

Nestec SA - Opponent I - on 8 July 1999

and

American Home Products Corporation, now Wyeth, -
Opponent II - on 7 July 1999.

Under the Article 100(a) opposition grounds the Opponents submitted that the claimed subject-matter was not new and did not involve an inventive step.

With regard to the issue of novelty, Opponent I argued that the claimed subject-matter was not new over the infant formula Nestlé Beba H.A.2, which was available on the market in 1994, i.e. before the priority date. Opponent II submitted that the claimed subject-matter was not new in view of the prior public use of the modified maize starch thickener Thixo-D in infant formulae for the purpose of amelioration of regurgitation or treatment of infants suffering from simple gastro-esophageal reflux (regurgitation).

In support of their alleged prior public uses the Opponents, *inter alia*, cited the following documents within the opposition period:

- D12 Nestlé Beba H.A.: "Das allergenarme Säuglingsnahrungskonzept von Nestlé - Jetzt als Stufensystem" together with a copy of a list dated December 1993, indicating the composition of the product Nestlé Beba H.A.2;
- D13 A copy of the package for the product "Nestlé Beba H.A.2" Hypoallergene Folgenahrung;
- D21 Whistler, R. et al. "Starch: Chemistry and Technology", Academic Press, Inc. (1984), pages 575 to 591;

- D25 Declaration of Bhupinder Kaur Sandhu dated
16 October 1998;
- D212 Official Journal of the European Communities;
Commission Directives 91/321/EEC and 96/4/EC,
Annexes inclusive.

After the expiry of the opposition period, further documents were cited in support of the alleged prior public use by Nestlé Beba H.A.2, inter alia:

- D16 Affidavit of Robert Aderbauer.

Concerning the question of inventive step, the Opponents cited, inter alia, the documents:

- D110 US-A 3 950 547
D24 US-A 4 428 972
D27 EP-A 0 611 525.

D110 was filed after the expiry of the opposition period.

Under Article 100(b) EPC the Opponent II argued that the claimed invention lacked sufficiency of disclosure in so far as it related to the use of potato starch because no examples were given in this respect and no information was available in the patent specification as to the type of potato starch which would overcome the problem posed.

- III. With the decision orally announced on 15 November 2001 and issued in writing on 1 March 2002 the Opposition Division rejected the oppositions.

In the decision it was held that the opposition ground according to Article 100(b) EPC was not applicable because it would be routine for a skilled person to determine the percentage of potato or waxy grain starch effective to reduce regurgitation.

Concerning the issue of novelty, while admitting the documents filed by the Opponents after the opposition period, the Opposition Division nevertheless found that the alleged prior public uses of the Nestlé product Beba H.A.2 and of the starch thickener Thixo-D in infant formulae had not been established.

With regard to the issue of inventive step, the Opposition Division considered document D27 representative of the closest prior art as it concerned ready-to-use infant milk formulations for the treatment of regurgitation comprising thickening agents like carob, guar gum or pectin.

The Division argued that there was no incentive for a skilled person to replace the thickeners mentioned in D27 by waxy grain starch or potato starch. In particular, the skilled person would not combine D27 with D110, the latter disclosing high amylose waxy grain starch, because this document related to the different problem of improving the emulsion stability of dietary compositions.

IV. Appeals against the decision of the Opposition Division were lodged by all three parties.

The Patent Proprietor filed a notice of appeal on 1 May 2002. In this notice the Proprietor indicated that appeal was filed against part of the decision [emphasis

added] to the extent that the Opposition Division admitted into the opposition proceedings any evidence of the alleged prior use filed after the nine month opposition period.

The Statement of the Grounds of Appeal was submitted on 9 July 2002.

Notice of appeal was filed by Opponent I on 30 April 2002 on behalf of Nestec SA. The Statement of the Grounds of Appeal, in which objections were raised under Articles 100(a) (lack of novelty and lack of inventive step) and 100(b), was submitted on 10 July 2002 on behalf of Société des Produits Nestlé.

Opponent II filed a notice of appeal *"against the decision of the Opposition Division in respect of EP 745 330"* on 26 April 2002. The Statement of the Grounds of Appeal was submitted on 10 July 2002. It was stated therein that the claimed invention lacked both novelty and inventive step and was insufficiently disclosed. This appeal was considered inadmissible by the Patent Proprietor who alleged in its letter dated 8 July 2002 that the notice of appeal did not indicate the extent to which amendment or cancellation of the decision was required and, therefore, did not meet the minimum requirements for an admissible appeal set out in Article 108 and Rule 64 EPC.

- V. In support of the alleged prior public use of the infant formula Nestlé Beba H.A.2 described in D12 and D13, the Appellant/Opponent I (hereinafter "Appellant I") introduced further documents into the appeal proceedings, inter alia:

- D111 Allergie-Vorsorge in Stufen" in "Rundschau 5/94,
page 74;
- D112 "Nestlé-Alete Folgekost" in "Industrie-
Mitteilungen", SB-Artikel 3-4/94, page 47;
- D113 "Neue Trends bei der Säuglingsernährung" in
"Ernährungsrundschau 41, Heft 5 (1994), page 207";
- D16 New affidavit of Robert Aderbauer dated 8 July
2002.

The Appellant/Opponent II (hereinafter "Appellant II")
introduced for the first time into the appeal
proceedings the document:

- D222 V.Shaw & M.Lawson in "*Clinical Paediatric
Dietetics*" Chapter 6, pages 63 and 64, published
in 1994.

VI. In response to the Statement of the Grounds of Appeal
of Appellants I and II the Patent Proprietor filed,
with a letter dated 16 May 2003, a new main request
consisting of 27 claims. Claim 1 of this request reads
as follows:

"1. An infant formula having calories from protein, fat
and carbohydrate in proportions similar to human milk,
characterised in that it comprises a thickening agent
which comprises potato starch, waxy grain starch, or a
mixture thereof, in an amount effective to ameliorate
regurgitation in infants, wherein the formula comprises,
per 100 kcal of total formula, 1.8g to 4.59g protein,
3.3g to 6g lipid, and 7g to 14g carbohydrate."

VII. A communication with provisional comments of the Board
was issued on 2 February 2006.

In section I of this communication the Board indicated that the Patent Proprietor was not entitled to appeal because the Opposition Division had maintained the patent as granted and the Proprietor was therefore not adversely affected by the decision within the meaning of Article 107 EPC.

The Board considered the appeal of the Appellant II admissible pursuant to Article 108 in combination with Rule 64 EPC, and having regard to the case law T 631/91 and T 273/92.

It was furthermore indicated by the Board that the identity of Appellant I was not clear because the notice of appeal was filed on behalf of Nestec SA and the Statement of the Grounds of Appeal was submitted on behalf of the Société des Produits Nestlé.

In section III of the communication the Board took the position that the documents D111, D112, D113 and D16 should be admitted into the appeal proceedings because they were relevant for the assessment whether the product Nestlé Beba H.A.2 described in D12 and D13 was available to the public. In the Board's view the document D222 should also be admitted because of its relevance in combination with the EEC Directives set out in D212.

VIII. In response to the Board's communication the Proprietor submitted auxiliary requests 1 to 8 with a letter dated 20 March 2006, which requests were argued by the Appellants to be late filed and therefore inadmissible.

During the oral proceedings held on 20 April 2006, the auxiliary requests 1 to 5 were withdrawn.

Claims 1 of the auxiliary requests 6 to 8 read as follows:

Auxiliary request 6

"1. An infant formula having calories from protein, fat and carbohydrate in proportions similar to human milk, characterised in that it comprises a thickening agent which comprises potato starch, waxy rice starch, or a mixture thereof, in an amount effective to ameliorate regurgitation in infants, wherein the formula comprises, per 100 kcal of total formula, 1.8g to 4.59g protein, 3.3g to 6g lipid, and 7g to 14g carbohydrate."

This claim differs from Claim 1 of the main request in that the waxy grain starch is replaced by waxy rice starch.

Auxiliary request 7

"1. An infant formula having calories from protein, fat and carbohydrate in proportions similar to human milk, characterised in that it comprises a thickening agent which comprises waxy rice starch in an amount effective to ameliorate regurgitation in infants, wherein the formula comprises, per 100 kcal of total formula, 1.8g to 4.59g protein, 3.3g to 6g lipid, and 7g to 14g carbohydrate."

In comparison to Claim 1 of the auxiliary request 6, potato starch has been deleted.

Auxiliary request 8

Claim 1 of this request is identical with Claim 1 of the auxiliary request 7.

IX. The written and oral arguments of the Patent Proprietor may be summarised as follows:

(a) *Admissibility of the appeals*

- The Proprietor's appeal was admissible in view of the admittance of the late filed documents by the Opposition Division, in support of the alleged public prior uses.

Because the evidence of the alleged public prior use lay solely within the hands of the Opponent, the Patentee was never able to adopt a final position on that issue in case further evidence, submitted after the nine-month opposition period, was admitted.

Therefore, the Opposition Division should not have extended the framework of the proceedings by the admittance of this new evidence, and thus the Patent proprietor was adversely affected by the appealed decision.

- The appeal of the Opponent I was inadmissible because the Notice of Appeal and the Statement of the Grounds of Appeal were filed under different names (Nestec SA and Société des Produits Nestlé, respectively). Because of this inconsistent identification of the Appellant, the requirements of Rule 64(a) EPC were not met. Hence, the appeal

should be rejected as inadmissible in accordance with Rule 65(2) EPC.

- Because the Opponent II had not specified in its notice of appeal the extent to which reversal of the decision was requested, a situation could be constructed - to the disadvantage of a third party - where the objections of the Appellant in the appeal proceedings had been changed vis à vis those raised as Opponent in the opposition proceedings.

Therefore, the appeal of the Opponent II did not meet the requirement of Article 108 in conjunction with Rule 64(b) EPC and should also be rejected as inadmissible.

(b) *Novelty*

The alleged public prior use of the product Nestlé Beba H.A.2 had not been proven up to the hilt in line with the standards developed in the case law of the Boards of Appeal.

In particular, the documents D12 and D13 could not be combined because of lack of any cross-reference between them. There was no suggestion that the starch ("Stärke") mentioned in the list of ingredients for Beba H.A.2 enumerated in D12 (bearing the date 12/93) corresponded to the potato starch ("Kartoffelstärke") indicated in D13. Because there was no date on D13 and, according to the affidavit of Dr. Aderbauer, the product Nestlé Beba H.A.2 was only "launched" in Germany in 1994, it could have been that the product had been launched solely for advertising purposes. It was

therefore not proven that Beba H.A.2 with the composition indicated in D13 was commercially available in 1994. Confirmation of this was to be found in the fact that the warning on the package: *"Nur unter medizinischer Kontrolle verwenden. Bei einer bereits bestehenden Kuhmilcheiweiß-Allergie oder dem Verdacht auf eine solche darf Nestlé Beba H.A.2 nicht verwendet werden"*

was prescribed for the first time in Annex IV of the Commission Directive 96/4, point 5, i.e. in 1996 and thus after the priority date.

In document D222 it was not explained what was meant by the term *"usual infant's milk feeds"* disclosed in the left column of page 63, which term could either relate to (a) commercial infant formulae, (b) pre-term infant formulae or (c) breast milk.

Moreover, there was no link in D222 to the EEC Directives D212, which also only prescribed the composition of infant formulae for the European market and not for countries outside Europe for which possibly different requirements had to be met in respect to their composition.

Furthermore, Thixo-D was only one alternative thickener out of the number of thickeners mentioned in D222.

Therefore, multiple selections had to be made from D222 in order to arrive at the claimed infant formula.

(c) *Inventive step*

Starting from D222 as the closest prior art, the problem to be solved by the claimed invention consisted in the provision of ready-to-use infant formulae for treating regurgitation with the best nutritional profile for infants.

By the use of potato starch or waxy grain starch as thickener, the claimed formula was not hypercaloric because much less starch could be used to achieve anti-regurgitation effects than with prior art starches, like non-waxy starches: see the patent specification, page 2, lines 38 to 41; page 3, lines 24 to 26 and lines 31 to 36 and the example 7.

A skilled person, however, reading Table 6.1 of D222, which indicated in a footnote that the energy content of products like Thixo-D should be considered when being fed to infants, would anticipate that the thickener Thixo-D would upset the energy balance when added as an additive to calorifically balanced infant formulae. Therefore, in order to avoid the risk of overfeeding the infants, he would select other thickeners, like gums (Nestargel, Carobel), which, according to D222 (left column of page 63), did not add any nutritional value to the feed.

Therefore, a skilled person was not encouraged by D222 to use waxy grain starch thickeners for preparing the calorifically balanced infant formulae according to the claimed invention.

X. Appellants I and II provided the following written and oral arguments:

(a) *Admissibility of the appeals*

Appellant I referred to its written submissions dated 20 March 2006 and argued that both the notice of opposition and the notice of appeal had been filed in the name of Nestec SA, i.e. that the identity of the Opponent/Appellant was clear by the end of the time limit for filing an appeal. This fact reflected the intention of the Opponent/Appellant to continue the proceedings by way of appeal.

The erroneous reference in the Statement of the Grounds of Appeal to "Société des Produits Nestlé" (a sister company to Nestec SA) as being the Opponent/Appellant would not have prevented the Patentee from recognising that the Opponent in the first instance proceedings and the Appellant were identical. In particular, due to the indication of the case number of the appeal and the fact that the representative acting on the filing of the appeal on behalf of Nestec SA was the same as that acting during the opposition, it was obvious that an error had occurred which should be corrected under Rule 88 EPC.

The Appellant II referred to the front page of the decision of the Opposition Division where it was stated that the oppositions were rejected and argued that it was clear from the wording of the notice of appeal, which stated that it was filed "against the decision of the Opposition Division",

that the appeal was directed against the decision as a whole.

(b) *Novelty*

The infant formula Nestlé Beba H.A.2, which fulfilled all requirements set out in the Annexes of the EEC Directives 91/321/EEC (D212), was on the market from 1994 onwards as could be seen from the journal articles D111 to D113 published in 1994. D12 was printed in December 1993 and indicated a list of ingredients of Beba H.A.2 which corresponded to the composition given on the label of the package D13, which was sold in 1994. The link between D12 and D13 (the latter bearing no date) was made by the affidavit of Mr. Aderbauer, the marketing manager for Nestlé Beba, who was involved in the development of Beba H.A.2 from the very beginning. Mr. Aderbauer's declaration that the product had always contained a potato starch thickener and was sold in 1994 with the composition according to D13 was wholly credible. Therefore, the starch ("Stärke") referred to in D12 was identical with potato starch ("Kartoffelstärke") referred to on the label of the box depicted in D13. Nestlé Beba H.A.2 was therefore citable prior art which was prejudicial to the novelty of the claimed subject-matter as far as potato starch as thickener was concerned.

The document D222 was part of the book "Clinical Paediatric Dietetics" published in 1994 and was therefore citable prior art. D222 expressly

disclosed infants' usual milk feeds thickened with Thixo-D, a waxy maize starch thickener, for the management of GOR (Gastro Oesophageal Reflux = regurgitation).

This book was edited for the Paediatric Group of the *British Dietetic Association*. Hence, the requirements of the EEC Directives D212 - prescribing in the Annexes I and II amounts of protein, lipid and carbohydrate per 100 kcal of total formula, which were identical with the respective ranges claimed - had to be applied as a matter of course for the infants' usual milk feeds mentioned in D222. Consequently, D222 anticipated the subject-matter of the main request as far as waxy grain starch was concerned.

In this context, it was irrelevant that Table 6.1 of D222 proposed the addition of Thixo-D to the feed from 1% up to the high amount of 3% because, as could be deduced from column 10 in Table 2 at page 10 of the written submissions dated 20 March 2006, the energy balance would not change much by the addition of such high amounts and would exceed the upper limit prescribed in the EEC Directives only in extreme cases. Moreover, a skilled person knew that the addition of 2g thickener was the upper limit.

(c) *Inventive Step*

D222, which described thickening of infants' usual milk feeds with the waxy maize starch thickener Thixo-D for the amelioration of regurgitation, was representative of the closest prior art. Because the composition of the formula with respect to

protein, lipid and carbohydrate was not expressly mentioned in this document, the skilled person was faced with the problem of providing an infant formula with the optimum nutritional composition meeting the standards of the European Communities.

In order to solve this problem, the skilled person would take note of the EEC Directives D212 and as a matter of course compose the "infant's usual milk feeds" mentioned in D222 such that they would inevitably conform to Claim 1 of the main request. The infant formula according to the main request, as far as a waxy grain starch thickener was concerned, therefore lacked an inventive step over a combination of D222 with D212.

Nor, in this respect, could an inventive step be seen in using a potato starch and/or waxy rice starch thickener according to the Claims 1 of auxiliary requests 6 to 8, because the high thickening ability of potato starch was known from D21 (pages 579/580, point 4.) and because the thickening and stabilising properties of waxy starches, like waxy rice starch, and their aptitude for thickening baby food were mentioned in D24 (column 1, lines 13 to 19 and column 3, lines 11 to 15).

A skilled person could therefore arrive at the invention claimed in the auxiliary requests 6 to 8 with a reasonable expectation of success.

XI. The Patent Proprietor requested that both Opponent's appeals be declared inadmissible and that the patent be maintained on the basis of the main request filed with

the letter dated 16 May 2003, alternatively on one of the sets of claims of auxiliary requests 6 to 8 filed with the letter dated 20 March 2006.

- XII. The Appellants requested that the decision under appeal be set aside and the patent be revoked.

In the oral proceedings the Appellants further requested that the Proprietor's auxiliary requests be not admitted into the proceedings.

Reasons for the Decision

1. *Admissibility of the Appeals*

1.1 Appeal lodged by the Patent Proprietor

The Patent Proprietor contends that its appeal is admissible because it is concerned with the decision of the opposition division solely to the extent that this decision admitted into the proceedings each Opponent's evidence of alleged prior use, which evidence was filed after the nine month opposition period and which was also not referred to in the notices of opposition.

Pursuant to Article 107 EPC a party entitled to appeal is any party **adversely affected** by a decision.

According to the established case law of the boards of appeal (see in particular T 0073/88 OJ 1992, 557; T 0084/02 and T 0098/01, both not published in the OJ EPO), the requirement of being adversely affected is narrowly understood and restricted to the case where the decision does not allow one or more of the final

requests of the party concerned. If its final main request is allowed (as was the position in the present case, where the main request was for the maintenance of the patent as granted), the party is not entitled to appeal, whatever the reasoning in the decision.

For these reasons the appeal filed by the Patent Proprietor is not admissible.

Notwithstanding this, the Proprietor, acting as Respondent, has the right to fully contest the allegation of prior public use and this right is not limited by the fact that it is not an Appellant.

1.2 Appeal of the Opponent I

In its communication, the Board pointed out that, while the notice of appeal had been filed in the name of NESTEC SA, the Statement of Grounds was filed in the name of Société des Produits Nestlé.

Appellant I explained the erroneous reference to Société Nestlé in the heading of the Statement of Grounds by the intimate relationship between the two sister companies, as is apparent from the use of the same letter paper carrying the Nestlé logo and the common "general" company name "Nestlé".

The Board concurs with Appellant I and regards the reference to "Société des Produits Nestlé" in the Statement of Grounds as a clerical error without any consequences for the identification of the true appellant. From the beginning it has been clear that the opposition and then the ensuing appeal was filed on

behalf of Nestec SA. The simple fact that another denomination appeared on the Statements of Grounds - and only on the Statement of Grounds, since the Appellant's subsequent submissions were again in the name of Nestec SA - does not amount to a procedural deficiency under Article 108 and Rule 65 EPC leading to the inadmissibility of the appeal, as alleged by the Patent Proprietor.

In particular the case T 298/97 referred to by the Patent Proprietor is of no relevance in this case, given the very different circumstances and factual framework which led the Board in that case to conclude that the appeal was inadmissible.

Thus, the request that the name on the Statement of Grounds of Appeal be corrected is allowed - which in turn leads to the conclusion that the Statement of Grounds is considered to be filed on behalf Nesctec SA. As a consequence the appeal is admissible.

1.3 Appeal of the Opponent II

As far as the Board understood the arguments of the Patent Proprietor on this issue, the fact that the Appellant did not specify in its notice of appeal the extent to which amendment or cancellation of the appealed decision was required, in contravention of Rule 64 EPC, would have been confusing for third parties who for instance would not know precisely the prior art to be considered.

The requirements of Rule 64 EPC referred to by the Patent Proprietor according to the contents of the

notice of appeal relate to the extent to which this decision is challenged and not to the reasons why it is challenged. It is only at the stage of filing the Statement of Grounds that reasons must be supplied. In a case where an Opponent/Appellant files a notice of appeal against a decision which has rejected its opposition, merely identifying the decision and the case number, under the established case law the Appellant/Opponent is nevertheless regarded as seeking the revocation of the patent (see as example T 631/91; T 273/92 not published).

Thus there was no violation of Rule 64 EPC and accordingly the appeal is admissible.

As to the alleged interference with the interests of third parties, the Board notes that the particular procedural issue addressed in Rule 64 EPC is restricted to the formal requirements of the EPC for filing an appeal within a limited time period. These requirements are not concerned with any theoretical interests of third parties.

2. *Admittance of the auxiliary requests 6 to 8 into the appeal proceedings*

The auxiliary requests 6 to 8, in which respectively the waxy grain starch has been restricted to waxy rice starch and the potato starch thickener has been deleted (auxiliary requests 7 and 8), are admitted into the proceedings.

The Board has no objection to this amendment, which was part of the Proprietor's legitimate defence against the Appellants' objections under the Articles 54 and 56.

3. *Novelty*

3.1 Alleged public prior use of the infant formula Nestlé Beba H.A.2

This issue was comprehensively discussed in the oral proceedings. The Board came to the conclusion that Appellant I had not proved that the product Nestlé Beba H.A.2 was available to the public in the composition according to the label on the packaging box D13. The alleged public prior use does therefore not constitute citable prior art.

Because this issue is irrelevant for the outcome of the appeal proceedings, the Board does not propose to give detailed reasons.

3.2 Novelty over D222

It is disclosed in this document that infants' usual milk feeds can be thickened inter alia with Thixo-D (which it is not in dispute consists of waxy maize starch) for the dietary management of infants with GOR (regurgitation).

In this context, the Patent Proprietor argued that Thixo-D was only one alternative of numerous other thickeners mentioned in D222 (Thick and Easy, Vitaquick, Instant Carobel, Nestargel) and that the term "infant's usual milk feeds" not only represented an infant formula based on cow milk in the sense of the invention, but also, with respect to the disclosure in the right-hand column at page 63, breast milk or juice or water as part of the infant's fluid intake. Therefore, a

selection from two lists had to be made in order to arrive at an infant formula thickened with Thixo-D.

This argument, however, is not convincing. In the Board's judgment, a clear difference is made at page 63 of D222 between an infant's usual milk feeds on the one hand (which alternatively can be thickened with Thixo-D - cf. left column, second paragraph to right column, first paragraph), and a breast-fed infant (who can be fed with a gel of Instant Carobel or Nestargel before and after a feed - cf. right column, second paragraph), or juice or water as part of the infant's fluid intake (which can also be thickened - cf. last sentence in the third paragraph of the right column), on the other. Therefore, an unambiguous link exists in D222 between an infant's usual milk feeds, representing an infant formula in the sense of the invention, and Thixo-D.

However, in the absence of a definition of the composition of the infant's usual milk feed and of a clear reference to the EEC-Directives concerning its composition, the Board concludes that D222 does not expressly disclose, in a novelty-anticipating manner, the subject-matter according to the main request.

Because D222 mentions neither potato starch nor waxy rice starch, it cannot anticipate the novelty of the subject-matter of the auxiliary requests 6 to 8.

4. *Inventive step*

4.1 The subject-matter of the patent in suit

- 4.1.1 The patent in suit concerns an infant formula thickened with potato and/or waxy (ie high amylopectin) starches and having calories from protein, fat and carbohydrate. The amounts of protein, lipid and carbohydrate per 100 kcal of total formula are defined in the Claims 1 of all requests. The waxy starches can either be waxy grain starch (main request) or waxy rice starch (auxiliary requests 6 to 8).

In the description of the patent specification, the problem of regurgitation of infant formulae by infants and the reduction of the incidence and/or severity of regurgitation in the prior art by adding certain thickening agents (rice cereals or seed gums like carob bean gum) to infant formulae is discussed (page 2, lines 13 to 17). According to the invention it was found that the use of potato starch or certain high amylopectin grain starches (waxy grain starches) as thickeners provided advantages in treating regurgitation (patent specification, page 2, lines 32 to 35 and lines 43/44). As a further advantage it is stated that the infant formulae of the invention are not hypercaloric and have excellent storage stability (page 3, lines 24 to 26).

- 4.1.2 In the examples 1 to 6 the preparation of anti-regurgitation formulae according to the invention is described. In example 7 infant formulae according to the invention are compared with prior art formulae with

respect to their storage stability (cf. the tables at pages 9 and 10 of the patent specification). However, none of the examples demonstrate that the formulae according to the invention are more effective in the treatment of regurgitation than those of the prior art.

4.2 The closest prior art

The document D222 is representative of the closest prior art. As already mentioned under point 3.2, it is disclosed in D222 that infants' usual milk feeds, which correspond to infant formulae in the sense of the invention, are thickened with Thixo-D, a waxy maize starch thickener, in order to treat regurgitation of infants. The further disclosure in D222 (page 63, second paragraph in the left column) that *"the infant's usual milk intake should be checked to ensure that he [ie the infant] is not simply being overfed"* implies that the infant formula should also be provided and applied in a non-hypercaloric form.

4.3 Inventive step of the subject-matter according to the main request

The infant formula according to the main request differs from the closest prior art in that certain defined amounts of protein, lipid and carbohydrate per 100 kcal formula are present.

4.3.1 Problem and Solution

The problem to be solved by the claimed invention is therefore seen in the provision of an infant formula

with an optimised balance between protein, lipid and carbohydrate.

4.3.2 Obviousness

A skilled person is aware of the fact that infant formulae may be marketed only if they meet certain compositional requirements. Therefore, when proposing to provide the infant formulae disclosed in D222 for the European market, he would automatically apply the Commission Directive 91/321/EEC (D212), which requires in Article 4, points 1 and 2, that infant formulae/follow-on formulae must comply with the compositional criteria specified in the Annexes I/II. In these Annexes the following amounts for protein, lipid and carbohydrate, per 100 kcal of formula, are laid down:

Infant formula (Annex I)

Protein (unmodified cow milk protein):

2.25 g Minimum; 3 g Maximum

Lipid: 3.3 g Minimum; 6.5 g Maximum

Carbohydrate: 7 g Minimum; 14 g Maximum

Follow-on formula (Annex II)

Protein (cow milk):

2.25 g Minimum; 4.5 g Maximum

Lipid: 3.3 g Minimum; 6.5 g Maximum

Carbohydrate: 7 g Minimum; 14 g Maximum

These amounts broadly overlap with the respective amounts of protein, lipid and carbohydrate as defined in Claim 1.

Therefore, a skilled person starting from D222 and applying the above EEC Directives in order to solve the problem posed would directly arrive at the subject-matter claimed.

This conclusion is not changed by the argument of the Patent Proprietor that a skilled person would not select Thixo-D because this thickener could destroy the energy balance when added to a ready-to-use infant formula and would therefore be less preferred. It is clear that formulae meeting the requirements of the EEC Directives with respect to the ranges of amounts of protein, lipid and carbohydrate are calorifically balanced. Thus, a skilled person using Thixo-D, which adds energy to the feed as mentioned in D222, would take care that he did not exceed the maximum amount of 14 g carbohydrate per 100 kcal formula as prescribed in D212 and would accordingly adapt the amounts of protein and lipid.

4.3.3 Therefore, the subject-matter of Claim 1 does not meet the requirements of Article 56 EPC.
The main request is not allowable.

4.4 Inventive step of the subject-matter according to the auxiliary requests 6 to 8

4.4.1 Problem and solution

In Claims 1 of the auxiliary requests 6 to 8 the general term "waxy grain starch" - which embraces the waxy maize starch thickener Thixo-D used in D222 - is replaced by waxy rice starch.

In the absence of any experimental evidence showing an unexpected technical effect of waxy rice starch over waxy maize starch, the problem to be solved by this embodiment is seen in the provision of an infant formula with an alternative waxy starch thickener.

4.4.2 Obviousness

The use of waxy rice starch as a thickener for foodstuff, inter alia baby food, is disclosed in D24 (cf. column 1, lines 13 to 19, in conjunction with column 3, lines 11 to 15). The skilled person could therefore anticipate that Thixo-D of D222 can be replaced by waxy rice starch, which also belongs to the class of high amylopectin starches, without hampering the anti-regurgitation properties of the infant formula.

4.4.3 Essentially the same obviousness considerations as in points 4.4.1 and 4.4.2 apply to the embodiment of Claim 1 of auxiliary request 6 concerning the use of a potato starch thickener, especially in view of the exceptionally high thickening ability of potato starch mentioned in part II, point 4 of D21.

4.4.4 Thus the subject-matter of Claims 1 of the auxiliary requests 6 to 8 is also considered obvious.

The requests are not allowable.

5. Under these circumstances it is not necessary to discuss the objections raised by the Appellants under the opposition ground according to Article 100(b) EPC.

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

P. Kitzmantel