BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [ ] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 6 June 2013

Case Number: T 0677/11 - 3.3.09

Application Number: 02725535.5

Publication Number: 1377280

IPC: A23L 1/236, A23L 1/308, A23L 1/29, A61P 3/04, A61K 31/716, A23C 9/13, A23L 1/09

Language of the proceedings: EN

Title of invention:
Use of bulking agents as satiety agents

Patent Proprietor:
DuPont Nutrition Biosciences ApS

Opponents:
COMPAGNIE GERVAIS DANONE
Tate & Lyle Ingredients Americas LLC
Unilever N.V.
Südzucker Aktiengesellschaft Mannheim/Ochsenfurt

Headword:
-

Relevant legal provisions:
EPC Art. 83
RPBA Art. 12(4)

Relevant legal provisions (EPC 1973):
EPC Art. 54(2), 54(5)

Keyword:
"Auxiliary request 2 (Novelty: no)"
"Auxiliary request 3 (Sufficiency: no)"

Decisions cited:
G 0005/83, G 0002/08, T 1063/06

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0677/11 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 6 June 2013

Appellant: (Patent Proprietor)
DuPont Nutrition Biosciences ApS
Langebrogade 1
Postboks 17
DK-1001 Copenhagen K. (DK)

Representative:
Alcock, David
D Young & Co LLP
120 Holborn
London EC1N 2DY (GB)

Respondent: (Opponent 1)
COMPAGNIE GERVAIS DANONE
17 Boulevard Haussmann
F-75009 Paris (FR)

Representative:
Regimbeau
20, rue de Chazelles
F-75847 Paris Cedex 17 (FR)

Respondent: (Opponent 2)
Tate & Lyle Ingredients Americas, LLC
5450 Prairie Stone Parkway
Hoffman Estates, IL 60192 (US)

Representative:
Nieuwenhuys, William Francis
Marks & Clerk LLP
90 Long Acre
London
WC2E 9RA (GB)

Respondent: (Opponent 3)
Unilever N.V.
Weena 455
NL-3013 AL Rotterdam (NL)

Representative:
Wurfbain, Gilles L.
Unilever Patent Group
P.O. Box 137
NL-3130 AC Vlaardingen (NL)

Respondent: (Opponent 4)	Südzucker Aktiengesellschaft Mannheim/Ochsenfurt Maximilianstrasse 10 D-68165 Mannheim (DE)
Representative:	Schrell, Andreas Gleiss Grosse Schrell & Partner Patentanwälte Rechtsanwälte Leitzstrasse 45 D-70469 Stuttgart (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 21 January 2011 revoking European patent No. 1377280 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: W. Sieber
Members: N. Perakis
R. Menapace

Summary of Facts and Submissions

I. Mention of the grant of European patent No. 1 377 280 to Danisco USA Inc (now DuPont Nutrition Biosciences ApS) was published on 18 July 2007 (Bulletin 2007/29).

II. Four oppositions were filed against the patent by:

- Compagnie Gervais Danone (opponent 1)
- Tate & Lyle Ingredients Americas Inc [now Tate & Lyle Ingredients Americas LLC](opponent 2)
- Unilever NV (opponent 3), and
- Südzucker AG (opponent 4).

The grounds for opposition relied upon by the opponents were lack of novelty and inventive step (Article 100(a) EPC), insufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

The documents filed with the notices of opposition included the following:

E1: WO 01/08505 A2;
E2: EP 0 749 697 A1;
E4: R.B. Shafer *et al*, "Effects of xylitol on gastric emptying and food intake", *Am J Clin Nutr*, 1987, 45, pp 744-747;
E8: N.W. Solomons *et al*, "Intestinal metabolism of a random-bonded polyglucose bulking agent in humans: In vitro and in vivo studies of hydrogen evolution", *J Lab Clin Med*, May 1985, 105 (5), pp 585-592;
E9: J.H. Giese, "Alternative Sweeteners and Bulking Agents", *Food Technology*, January 1993, pp 114, 115, 118, 120-122, 124-126;

E17: M. Yoshioka *et al*, "Effect of Polydextrose on Body Fat Accumulation in Rats", Bulletin of Institute of Health and Sport Sciences, University of Tsukuba, 1993 (16), pp 83-87 (English translation);

E30: J.H. Lavin *et al*, "The Effect on Hunger and Satiety of Slowing the Absorption of Glucose: Relationship with Gastric Emptying and Postprandial Blood Glucose and Insulin Responses", *Appetite*, 1995, 25, pp 89-96;

E32: E.M.R Kovacs *et al*, "The effect of addition of modified guar gum to a low-energy semisolid meal on appetite and body weight loss", *International Journal of Obesity*, 2001, 25, pp 307-315;

E35: US 3 843 786 A;

E38: GB 2 029 216 A;

E42: B. Burton-Freeman, "Dietary Fiber and Energy Regulation", *The Journal of Nutrition*, 1999 ASNS Symposium Proceedings, 130, 2S, pp 272S-275S;

E44: Human Nutrition & Dietetics 9E, Edited by J.S. Garrow, W.P.T. James, Churchill Livingstone, 1996, p 53;

E45: J.E. Blundell *et al*, "Satiation, Satiety and the Action of Fibre on Food Intake", *International Journal of Obesity,* 1987 (11), Suppl. 1, pp 9-25;

E46: V.J. Burley *et al*, "Action of Dietary Fiber on the Satiety Cascade", in: Dietary Fiber. Chemistry, physiology and health effects, ed. D. Kritchevsky, C.B. Bonfield & J Anderson, New York, Plenum Press, 1990, pp 227-247;

E51: "Polydextrose pour les produits alimentaires allégés et diéthétiques modernes", Pfizer-France, Food Ingredient Europe, 1989;

E52: G. Livesey, "Tolerance of low-digestible carbohydrates: a general view", *British Journal of Nutrition*, 2001, 85, Suppl. 1, pp S7-S16; and

E57: J.E. Blundell *et al*, "Carbohydrates and human appetite", *Am J Clin Nutr*, 1994, 59 (suppl), pp 728S-734S.

The documents filed during the opposition proceedings included the following:

E61: Webster's New World Basic Dictionary of American English, 1996, p 37; and

E62: Annotated version of figures 4-6 of the patent in suit (Annex 8 of the minutes).

III. By a decision announced orally on 17 November 2010 and issued in writing on 21 January 2011, the opposition division revoked the patent because it considered that none of the requests on file met the requirements of the EPC. In particular it held that the main request and auxiliary requests 1, 2 and 5 lacked novelty and that auxiliary requests 3 and 4 lacked an inventive step.

For the present decision only auxiliary requests 2 and 4 are relevant, claims 1 and 2 of which read as follows:

Auxiliary request 2:

"1. Use of an enzyme resistant sugar polymer, wherein the enzyme resistant sugar polymer is polydextrose,

for manufacturing an appetite suppressing medicine, which comprises a food intake suppressing amount of said enzyme resistant sugar polymer."

"2. Non-therapeutic use of an enzyme resistant sugar polymer,
wherein the enzyme resistant sugar polymer is polydextrose,
for suppressing the appetite of a mammal."

Auxiliary request 4

"1. Use of an enzyme resistant sugar polymer,
wherein the enzyme resistant sugar polymer is polydextrose,
for manufacturing an appetite suppressing medicine, which comprises a food intake suppressing amount of said enzyme resistant sugar polymer, wherein a sugar alcohol or a polyol is additionally present in synergistically effective amounts, wherein the sugar alcohol is xylitol."

"2. Non-therapeutic use of an enzyme resistant sugar polymer,
wherein the enzyme resistant sugar polymer is polydextrose,
for suppressing the appetite of a mammal, wherein a sugar alcohol or a polyol is additionally present in synergistically effective amounts, wherein the sugar alcohol is xylitol."

As regards the disputed admission of certain documents into the proceedings, the opposition division decided:

(a) to admit E44, E51 and E61 into the proceedings because:

- E44 had been publicly available before the priority date of the patent in suit;
- E51 was legible;
- E61 was relevant for the interpretation of the term "appetite suppression";

(b) not to admit E46 and E62 into the proceedings because:

- the public availability of E46 before the priority date of the patent in suit had not been established beyond reasonable doubt;
- E62 was extremely late-filed and *prima facie* not relevant; it merely presented, in a different manner, the results depicted in figures 4-6 of the patent in suit.

IV. The patent proprietor (in the following: the appellant) filed an appeal against the decision of the opposition division on 21 March 2011 and paid the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 26 May 2011, including a main request and auxiliary requests 1 to 3.

The appellant also re-submitted E62 and argued that the annotated version of the figures of the patent in suit simply contained the facts already present in the original figures, but presented in a different way. Therefore it could not constitute late-filed evidence. The following additional documents were also filed:

E63: Affidavit of John E. Blundell of 19 May 2011 accompanied by five exhibits:

E63-Exh1: J.E. Blundell's curriculum vitae
E63-Exh2: identical to previously filed E45;
E63-Exh3: identical to previously filed E46;
E63-Exh4: J.E. Blundell *et al*, *Am J Clin Nutr*, 1994, 59(suppl), pp 728S-734S; and
E63-Exh5: J.E. Blundell *et al*, *Annu Rev Nutr*, 1996, 16, pp 285-319.

With letter of 29 August 2012 the appellant submitted further arguments.

With letter of 1 May 2013 the appellant withdrew the main request and auxiliary request 1. Therefore the requests relevant for the present decision are auxiliary requests 2 and 3.

Auxiliary request 2 corresponds to auxiliary request 2 before the opposition division, and auxiliary request 3 corresponds to auxiliary request 4 before the opposition division from which any reference to a "polyol" has been removed in the claims (see point III above).

V. Opponent 1 (in the following: respondent 1) filed observations on the appeal with letters of 7 October 2011 and 3 May 2013.

VI. Opponent 2 (in the following: respondent 2) filed observations on the appeal with letter of 5 October 2011. E46 was re-filed including a certification by the representative.

VII. Opponent 3 (in the following: respondent 3) did not file any requests or observations in the appeal proceedings. With letter of 25 February 2013 it informed the board that it would not be represented at the oral proceedings scheduled for 6 June 2013.

VIII. Opponent 4 (in the following: respondent 4) filed observations on the appeal with letters of 30 September 2011 and 2 April 2013. In support of its arguments it also filed the following additional documents:

E64: Burley *et al*, "Influence of high-fibre food (myco-protein*) on appetite: effects on satiation (within meals) and satiety (following meals)", *Europ J Clin Nutr*, 1993, 47, pp 409-418; and

E65: Halford *et al*, "Pharmacology of appetite suppression", Progress in Drug Research, vol. 54, 2000, pp 54, 25-58.

IX. In preparation for the oral proceedings the board issued a communication on 3 May 2013.

X. Oral proceedings before the board were held on 6 June 2013 in the absence of respondent 3. During the oral proceedings the appellant proposed the deletion of claim 2 of auxiliary request 2 if this established novelty. Nevertheless, this was not considered necessary, as the subject-matter of claim 1 was also found to lack novelty.

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

Interpretation of the term "appetite suppression"

- The skilled person in the art, i.e., a practitioner in the field of nutrition of mammals, in particular humans, would interpret the meaning of the term "appetite suppression" on the basis of his technical background knowledge. In the present case, Prof. Blundell should be considered as the skilled person and his eminent opinion should be taken into account (see E63 and the accompanying exhibits).

- Thus, the term "appetite suppression" should be given the meaning that it affected simultaneously satiation and satiety (i.e. a narrow interpretation of the term).

- The broad interpretation given by the opposition division, whereby at least satiation or satiety was affected, did not correspond to the skilled person's understanding of effective appetite suppression.

- At the priority date it was commonly accepted that satiety and satiation were distinct phenomena. The one did not necessarily affect the other and they were thus independent. Contrary to the respondents' assertion, satiation was not considered to be another form of satiety.

Novelty of claims 1 and 2 of auxiliary request 2

- None of the cited documents E8, E17, E45, E51 or E52 disclosed the subject-matter of claims 1 and 2 of auxiliary request 2.

– In particular, E17 did not disclose that polydextrose (PDX) had a specific effect on satiety or satiation. Furthermore, E17 did not disclose that the amount of PDX had a food intake suppressing effect. The presence of this feature in claim 1 defined in fact the dosage regime of PDX and established novelty under G2/08. Moreover, the disclosure of E17 was not relevant since the effect of PDX resulted from its comparison with other dietary fibres and not from a comparison with a control.

Sufficiency of disclosure of the invention of claim 1 of auxiliary request 3

– The invention of claim 1 of auxiliary request 3 was sufficiently disclosed since the patent contained an example for carrying out the invention which involved PDX and xylitol in 50:50 percent amounts. The patent thus gave the skilled person sufficient guidance on at least one way of how to carry out the invention and at least one ingredients ratio, so that he could carry out the invention without undue burden.

– The synergy requirement of claim 1 related to the appetite suppression and not to the food intake suppression. This was supported by the content of the application as filed and was clear from dependent claim 7 which additionally required synergy for the suppression of food intake. Therefore, figures 1 and 2 of the patent specification, which related to food intake suppression, were irrelevant for the issue of the

synergistic effect on appetite suppression required by claim 1.

- In contrast, figures 3 to 6 showed that mixing PDX and xylitol had a synergistic effect on suppression of satiety (figures 3, 4) or satiation (figures 5, 6), and thus on appetite suppression. The respondents, who had the burden of proof, had not filed any technical evidence to contradict the evidence of the appellant.

- Furthermore, the respondents were wrong to require from the appellant experiments involving an admixture of 25g of PDX and 25g of xylitol in order to measure the level of fullness. The administration of double the control amounts made no sense since this would require the fullness response also to be double. When a subject was full, the maximum had been attained and it could not be "more full". It would have been more accurate to carry out experiments with reduced amounts for PDX and xylitol and measure the feeling of fullness.

- In this context, E62 showed that the "expected" cumulative effect based on the effect of half the amount of PDX and xylitol, i.e. 12,5g, was smaller than the effect obtained in reality (annotated figures 3 to 6).

- The respondents' assertions that the effect of PDX and xylitol did not linearly depend on the amount of each of these constituents had not been technically demonstrated. Their reference to E4 and E38 was irrelevant since E4 concerned another effect, namely

the suppression of food intake, but not the suppression of appetite, and E38 concerned another sugar, namely xanthan gum. In the present case the appellant should be given the benefit of doubt.

XII. The relevant arguments put forward by the respondents in their written submissions and at the oral proceedings may be summarised as follows:

Interpretation of the term "appetite suppression"

- The description did not define the term "appetite suppression". Therefore this term should be interpreted on the basis of the general technical knowledge of the skilled person at the priority date of the patent in suit.

- There was no doubt that satiety and satiation were parameters which controlled the appetite. However, there was no common understanding/agreement in the art at the priority date of the patent in suit regarding the meaning of the term "appetite suppression".

- The natural meaning of the term "appetite" was to be found in E61 (a dictionary) where it was defined as the desire to eat. Thus, "appetite suppression" could only mean suppression of this desire, whatever the mechanism involved for suppressing the appetite, and irrespective of the extent and duration of the suppression. Deviation from this natural meaning could be accepted only if the patent defined "appetite suppression" differently, which it did not.

- It was wrong to consider Prof. Blundell as the skilled person in the art since he was an eminent expert in this field with extraordinary technical knowledge. Moreover, the affidavit of Prof. Blundell disclosed his personal opinion on 19 May 2011, i.e. ten years after the priority date of the patent in suit. Furthermore, Prof. Blundell stated that the combination of satiety and satiation was required for an "effective control" of the appetite. Such a requirement was absent from the independent claims.

- The contested expression was not understood at the priority date of the patent by a person skilled in the art to correspond to a "narrow concept" requiring that both satiety and satiation were positively affected. On the basis of the available state of the art, it was clear that a "broad concept" applied, which involved measurement of either the satiety effect, the satiation effect or both.

- The appellant's narrow interpretation, i.e. that both mechanisms needed to be addressed at the same time, was an arbitrary and completely unsupported assertion made "a posteriori" long after the filing of the contested patent.

Novelty of claims 1 and 2 of auxiliary request 2

- The subject-matter of claims 1 and 2 of auxiliary request 2 lacked novelty in view of the disclosure of documents E8, E17, E45, E51 and E52.

– In particular, E17 (abstract; page 2, right column, last full sentence to page 3, left column, first paragraph) disclosed the use of PDX as an appetite suppressing agent in amounts which also reduced the food intake. The effect of the PDX was shown on the basis of comparisons with other dietary fibers without the use of a control. However, this was not a deficiency since no genuine control had been used in the patent in suit.

Sufficiency of disclosure of the invention of claim 1 of auxiliary request 3

– The invention of claim 1 of auxiliary request 3 was not sufficiently disclosed because the claim did not specify whether the synergy had an impact on the appetite suppression, the food intake suppression or both. Furthermore, the patent did not disclose by which means, which methodology and which amounts a synergistic effect could be obtained.

– It was clear from figures 1 and 2 that mixing PDX and xylitol had no synergistic effect on food intake suppression. The results of the individual compounds were better than those of their mixture. This was also admitted by the appellant.

– Figures 4 and 6 showed that the addition of xylitol to PDX did not have any synergistic effect on appetite suppression in terms of satiety or satiation. On the contrary, the results on test day 1 were better when PDX was used alone than the results when xylitol was added to PDX.

- The additional bars present in E62 (compared to figures 3-6 of the patent), which according to the appellant showed an unexpected synergy, did not rely on any technical fact. They were based on the incorrect assumption that the appetite suppression depended linearly on the amount of xylitol or PDX. The skilled person would however have expected this dependency to be rather in an S-form going through a plateau value for the appetite suppression. This was a realistic expectation which derived from E4 (bridging paragraph of pages 745 and 746) and E38 (page 1, left column, lines 40-45).

- Moreover, since no synergy had been technically demonstrated by the appellant, the respondents had no reason to provide any experimental counter-evidence. It was enough to provide arguments against the plausibility of the arguments of the appellant.

- The tests illustrated in figures 3 to 6 were based on subjective ratings which made the validity of their results questionable. The necessity of rigour ratings and test protocols had been disclosed in the state of the art (E45: page 15, first full paragraph: page 23, first paragraph under the title "Satiation and satiety - experimental designs"). Thus the results on figures 3 and 6 could not be used to convincingly demonstrate a synergistic effect.

XIII. The appellant (patent proprietor) requested that the decision be set aside and that the patent be maintained on the basis of the claims according to auxiliary requests 2 or 3 submitted with the statement setting out the grounds of appeal.

XIV. Respondents 1, 2 and 4 (opponents 1, 2 and 4) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Admission of documents

2.1 E46 had been filed by respondent 2 with its notice of opposition, but was not admitted into the proceedings by the opposition division, because the public availability of the document had not been established beyond reasonable doubt. In the appeal proceedings E46 was re-filed by respondent 2 (including proof of its availability) and even relied upon by the appellant (E63, Exhibit 3). In view of the adversary parties' wishes, the board admitted this document into the proceedings on the basis of Article 12(4) RPBA.

2.2 E62 had been submitted by the appellant during the oral proceedings before the opposition division, but had not been admitted at that late stage. The document, an annotated version of figures 4 to 6 of the patent in suit, was re-filed with the statement of grounds of appeal. The board agrees with the appellant that this document does not contain any new facts not already present in the original figures, and simply presents the facts in a different way. Actually, it is nothing more than a visual illustration of the appellant's argument concerning the issue of synergy based on the information presented in figures 4 to 6 of the patent

in suit. Thus the technical content of E62 was always present in the proceedings and does not constitute late-filed evidence. Therefore the board admitted E62 into the proceedings on the basis of Article 12(4) RPBA.

3. Interpretation of the term "appetite suppression"

3.1 The subject-matter of claims 1 and 2 of auxiliary requests 2 and 3 is directed to the appetite suppressing effect of an enzyme resistant sugar polymer, namely polydextrose (PDX). Since the claims do not explicitly require that the appetite suppressing effect be on satiation, on satiety or on both, it is necessary to define the meaning of the terms "appetite suppressing medicine" as used in claim 1 and "for suppressing the appetite" as used in claim 2. In the following these terms will be examined together by reference to the term "appetite suppression". The interpretation of this term - be it narrow and concerning the combined effect on satiation and satiety, or be it broad and concerning each of them independently or in combination - has been at the core of the dispute between the appellant and the respondents.

Regarding the definition of the terms "satiation" and "satiety", reference is made to E63-Exh1, the affidavit of Prof. Blundell, an eminent expert in the field of nutrition:

"9. **Satiation** develops during the course of eating and eventually brings the period of eating to a close. Accordingly, satiation can be defined by the measured size of the eating episode." (emphasis added)

"10. **Satiety** is the state in which further eating is inhibited and follows the end of an eating episode. I am aware that a procedure used to assess the action of a food on satiety is the preload strategy, where precisely prepared foods are consumed in a "preload". Effects on later food consumption are then measured over varying periods of time by visual analogue scales, and sometimes by additional eating tests, if appropriate." (emphasis added)

These definitions confirm what the two terms were generally considered to mean in this field at the priority date of the patent in suit (in this context reference can be made to E45: page 16, lines 10-19; E46: pages 229-231, section 3, "Measuring the satiating power of food: the satiety cascade"; E63-Exh5: pages 293-294, "The Satiety Cascade").

3.2 Interpretation of the term in the light of the patent itself

3.2.1 The respondents have pointed out that the patent specification does not contain any explicit narrow definition of the disputed term and the appellant has not contested this fact during the oral proceedings. The board acknowledges that the patent uses interchangeably a number of terms related to appetite suppression without attaching particular meaning to any one of them and without any consistency or precision. Terms employed include: suppress appetite, reduce appetite, control appetite, control food intake, reduce food intake, suppress food intake, provide a feeling of fullness, control hunger, provide fullness sensation,

suppress hunger, reduce hunger, induce fullness, appetite is depressed, curb the appetite, decrease the intake of food, provide feeling of satiation, give a significant calorie reduction, reduce caloric intake.

All these terms are neither necessarily correlated nor necessarily combined. Therefore there is no basis in the patent for a narrow construction of the term "appetite suppressing" requiring an obligatory cumulative effect on satiation **and** satiety as alleged by the appellant.

3.2.2 In fact the contrary is true. The patent specification (paragraphs [0035], [0052] and [0070]) provides ample evidence that the term "appetite suppression" as used in the claims means a suppression of hunger (satiety induction) or induced fullness (induction of satiation).

Paragraph [0035]:

"By taking the satiety agent, … before a meal or snack for a sufficient time for the satiety agent to be effective in suppressing hunger and/or inducing fullness, the animal, e.g. mammal, will be ingesting less food between meals and/or during meals" (lines 15-17);
"...as the satiety agent … will act to curb the appetite" (lines 22-23);
"Typically, then the satiety agent, … will be taken sometime in a period prior to a meal or at the time a usual meal is eaten, and this will serve to decrease the intake of food at a meal or may even eliminate the meal altogether, as the satiety agent, e.g. polydextrose, … may provide a sufficient feeling of

satiation to eliminate some normally eaten meals or snacks" (lines 23-27).

Paragraph [0052]:

"… it was possible to determine the satiating effect (i.e. suppression of hunger, or increase in fullness) …".

Paragraph [0070]:

"Furthermore, the sugar polymer, including the hydrogenated polymer, either alone or in combination, act with xylitol or other sugar alcohol in synergism to control the appetite of the animal and/or provide fullness".

Thus the patent itself discloses that either an effect on satiation or an effect on satiety or both is to be considered as being an effect on appetite suppression.

3.3 Interpretation of the term in the light of the common general knowledge of the person skilled in the art at the priority date of the patent in suit

3.3.1 The appellant did not dispute that the patent in suit allowed the term "appetite suppression" to be broadly interpreted. Rather, it argued that it was in the "mental furniture" of the average skilled person that when using the term "appetite suppression" he understood that both satiety and satiation must be affected. In other words, despite the broad meaning given to the term "appetite suppression" in the patent

in suit, the skilled person would nevertheless give it a narrow interpretation.

Thus the interpretation of the term "appetite suppression" boils down to the question of what interpretation the average skilled person in the art would have given to this term at the priority date of the patent in suit, which is incontestably 9 April 2001. Regarding the average skilled person in the art, the board concurs with the appellant that he should be the practitioner in the field of nutrition of mammals, in particular humans. Regarding the question as to whether Prof. Blundell should be considered as the average skilled person in the art, the board considers that Prof. Blundell is an eminent specialist with an extraordinary technical knowledge in this field and cannot represent the average skilled person. According to his curriculum vitae (E63-Exh1) he has spent many years working in the field of nutrition and has extensively studied the effects of various foodstuffs on human appetite. Thus the statements in his affidavit (E63):

"19. It is my opinion that it is not satisfactory to assume that because a particular food has an effect on satiety it necessarily also has an effect on satiation. As a consequence and in the absence of an inevitable link between the two both must be independently affected in order to exert an effect on appetite control."

"21. In summary, it is my opinion that the understanding of a claim about appetite suppression

requires an affect on both the satiety and satiation of a subject."

cannot be considered to represent the general technical knowledge of the average practitioner at the priority date of the patent in suit. Furthermore, E63 expresses a personal opinion on the date of 19 May 2011, i.e. ten years after the priority date of the patent in suit.

3.3.2 Thus the board agrees with the respondents that the skilled person trying to assign a meaning to the term "appetite suppression" would start from the natural meaning to the term "appetite", which is to be found in E61 (a dictionary). According to E61 the term "appetite" as used in everyday language expresses *"the desire or wish for food"*. Naturally "appetite suppression" can only mean suppression of this desire, whatever the mechanism involved is, irrespective of the extent and duration of appetite suppression. This is the literal and clear meaning of the claims for the skilled person and there is no reason to deviate from this definition, in particular as the patent specification does not attribute a different meaning to the term "appetite".

On this basis the term "appetite suppression" would be understood by the skilled person as "the suppression of the desire or wish for food", regardless how this effect is achieved, be it by acting on satiation or satiety or even on both.

It has not been disputed that two different mechanisms were known at the priority date of the patent which influence the appetite of a subject, namely satiation

and satiety which, whilst closely related, can operate independently of each other (E45: page 16, lines 17-19; E46: pages 229-231, section 3. Measuring the satiating power of food: the satiety cascade; E63-Exh5: pages 293-294, "The Satiety Cascade").

Nevertheless, an appetite suppressing effect of a compound could be evaluated by measuring of either its satiation effect or its satiety effect, with the combination of both satiation and satiety being the most effective alternative. Indeed the prior art uses interchangeably a plethora of different terms to designate the same concept: reduction of satiation, satiety, food intake suppression, satiating effect, satiation, energy intake suppression, and appetite suppression. The interchangeable use of "satiety" and "satiation" indicates that the interpretation of the term "appetite suppression" as only a combination of both satiation and satiety, as alleged by the appellant, was not well established in the state of the art at the priority date of the patent in suit. For illustration, reference is made to the following documents:

- E1 (page 6, lines 14-22) discloses the use of carbohydrates for suppressing appetite, whereas only the low decrease of the insulin peak was monitored, thus revealing an effect on satiety (i.e. less hunger between meals and less snacking);

- E2 discloses a method to retard the food's digestion resulting in glucose being released into the bloodstream at a slower rate over a long period of time (page 5, lines 28-29) providing a feeling of prolonged satiety and helping to prevent snacking

between meals (sentence bridging pages 7 and 8) and finally leading to the suppression of appetite (page 5, line 17).

- E32, page 310, discloses real appetite-suppressant compositions and recites under the title "Satiety" that
"Perception of satiety (hunger, satiety, fullness, desire to eat, appetite estimation of how much one could eat, and thirst) was scored on anchored 100 mm visual analogue scales at day 4 during baseline and day 11 during each intervention period. ... To characterize the development of satiation during a meal, questions on hunger, satiety and pleasantness of taste were answered on 100 mm visual analogue scales every 2 min during dinner consumed on the same day." (emphasis added);

- E35 (column 1, lines 58-62) mentions that
"… the [xanthan] gum per se taken well before meals and without food will act to suppress the appetite, perhaps through a bulking phenomenon which possibly causes a signal of satiety, diminishing the desire for further food intake." (emphasis added);

- E64 discloses that Quorn® (a high protein, dietary fibre combination) has an appetite suppressing effect by having a strong impact on late satiety (abstract, lines 14-16; page 410, left column, lines 23-33; page 413, right column, second paragraph under "Results" and table 5).

- E65 (page 27, lines 27-30 and page 35, lines 32-34) discloses that the modulation of appetite involves

quite a variety of alternative possibilities (enhancing satiety and or inhibiting hunger or altering food selection) which do not have to be present in a cumulative way.

3.3.3 Certainly, the state of the art at the priority date of the patent in suit discloses also the cumulative effect of satiation and satiety for the control of appetite. Reference is made to E63-Exh5 (page 309, lines 16-18; page 312, lines 5-7), and the affidavit of Prof. Blundell (E63: point 11) confirms this fact. Nevertheless, the cumulative effect concerns the "optimum situation" for the suppression of appetite. The patent in suit (paragraph [009]) incidentally defines the "effective" appetite suppression as a 20 to 30% reduction of food intake, although the highest exemplified reduction in food intake is only 16.8% (table III). The fact that there is an optimum situation does not cast doubt on the fact that the state of the art cited above discloses also a less ideal suppression of appetite by affecting either satiation or satiety. The technical evidence of the patent in suit discloses in tables II and III values for food intake reduction such as 7.2%, 9.9%, 16.8% and 10.9%, which are much lower than the effectively reduced appetite suppression of 20-30% (page 2, line 44).

3.4 The board thus concurs with the respondents that the appellant's narrow interpretation of the term "appetite suppression" to require both satiety and satiation is an assertion made *"a posteriori"*, that is, in view of the respondents' various objections during the opposition and appeal proceedings before the EPO. The

appellant cannot be permitted to fill in the blanks after the priority date and provide now, when the granted patent is challenged, a new and completely unsupported interpretation of the patent language and maintain that this narrow interpretation is the only interpretation that the person skilled in the art would contemplate upon reading the patent.

3.5 In summary, the contested term has to be interpreted as deriving from the control of satiation or satiety or both.

Auxiliary request 2

4. Novelty

In view of the above interpretation of the term "appetite suppression" the board in agreement with the respondents considers that the disclosure of E17 anticipates the subject-matter of claims 1 and 2 of auxiliary request 2.

4.1 Claim 2 (non-therapeutic use - Article 54(2) EPC 1973)

The non-therapeutic use of claim 2 is anticipated by the disclosure of E17 (abstract) which discloses the effect of dietary polydextrose (PDX) on body fat accumulation in rats and therefore the non-therapeutic use of PDX on mammals. PDX reduces food intake (abstract, last two lines). Furthermore, E17 discloses that PDX enhances the feeling of satiety after a meal and decreases food intake (paragraph bridging pages 84 and 85), which amounts to suppressing the appetite of a mammal by PDX. The board thus concludes that the

subject-matter of claim 2 lacks novelty over the disclosure of E17.

4.2 Claim 1 (second medical use - Article 54(5) EPC 1973)

4.2.1 Claim 1 is drafted as a "Swiss-type claim", a format allowed pursuant to a line of case law first set out in decision G 5/83 (OJ 1985, 64) in order to provide protection for a further medical application under Article 54(5) EPC 1973. Basically, claim 1 is directed to the use of polydextrose for manufacturing an appetite suppressing medicine, which comprises a food intake suppressing amount of the polydextrose.

4.2.2 The second medical use of claim 1 is anticipated by the disclosure of E17 (abstract) which teaches the use of PDX as a dietary component for the control of fat accumulation in rats. This is a clear disclosure of the preventive use of PDX in order to avoid the accumulation of surplus fat, which according to the common general knowledge - as also acknowledged by the patent in suit (see paragraph [0003]) - leads to obesity and contributes to the development of various illnesses. The diet of E17 containing PDX, therefore, relates also to a medical use of PDX in mammals.

4.2.3 As already discussed in point 4.1 above with regard to the novelty of claim 2, E17 discloses the use of PDX for the suppression of appetite in a mammal. Consequently the diet comprising PDX is an appetite suppressing medicine.

4.2.4 With regard to the feature of a food intake suppression amount of PDX present in the medicine, it is self-

evident that such an amount was used in E17 as the diet reduced food intake (abstract, lines 4-6 and 8-9).

4.2.5 The board takes the opportunity to remark that contrary to the assertions of the appellant, this feature expresses "wishful thinking" / "result to be achieved" and does not correspond to a dosage regime in the sense of G 2/08 (OJ 2010, 456), which requires concrete measures for its implementation. Furthermore, it is self-evident that a sufficient amount of PDX is necessary in the medicine so that it has the medical function of appetite suppression.

4.2.6 The board does not agree with the appellant's criticism that E17 does not convincingly illustrate the effect of PDX on satiety. It is true that this effect is compared to the effect of three other dietary fibres, namely cellulose, indigestible dextrine and galactomannan derivatives (see tables 1 and 2). This effect is, however, not invalidated because there is no comparison with a control. The board in agreement with the respondents observes that even the patent in suit does not use such a control. The sucrose used in the control yoghurt (see paragraph [0044]) is another sugar and not a valid control in this type of experiment. Following E4, water is a valid control for the evaluation of the effect on energy intake (see page 745, right column, table 1).

4.3 Since the subject-matter of claims 1 and 2 lacks novelty over E17, auxiliary request 2 is not allowable.

Auxiliary request 3

5. Sufficiency of disclosure

5.1 The issue of sufficiency essentially concerns the synergy between the food intake suppressing amount of polydextrose and the synergistically effective amount of xylitol. According to the patent in suit (paragraph [0062] lines 35-37), " *… when the xylitol and h-polydextrose were used in synergistic effective amounts, the combination resulted in greater suppression of hunger and enhancement of fullness*".

The respondents argued that according to the wording of claim 1 the synergy concerned the appetite suppression effect or/and the food intake suppressing effect and thus related to three alternatives. The appellant argued that it concerned exclusively the appetite suppressing effect.

5.2 The board in agreement with the respondents considers that the invention as defined by the wording of claim 1 allows the interpretation that the synergy of the respective amounts of polydextrose and xylitol leads either to the suppression of appetite or of food intake or of both. This interpretation is fully supported by the patent specification, as can be seen from the following passages:

- "the synergistic combination of h-polydextrose and xylitol in effecting appetite suppression **and/or** reducing caloric intake" (paragraph [0062]);
- "the synergistic effect of polydextrose … and xylitol in suppressing the appetite of the animal e.g., mammal, **and/or** in reducing food intake" (paragraph [0064]);

– "sugar polymer … act with xylitol … in synergism to control the appetite of the animal **and/or** provide fullness" (paragraph [0070]).

The board is also not convinced by the appellant's argument that in view of the synergistic effect directed to the suppression of food intake mentioned in dependent claim 7 ("The use according to any of claims 1 to 6, wherein said sugar polymer and sugar alcohol are present in an amount having a synergistic effect on the suppression of food intake"), the synergistic effect of claim 1 concerns only the suppression of appetite. In the board's view the synergistic effect of claim 7 does not necessarily concern an additional synergistic effect but could also be interpreted as relating to the most preferred synergistic effect, limiting the three alternatives of claim 1 to only one, namely the synergistic effect on food intake suppression.

5.3 Concerning the synergistic effect of the effective amounts of polydextrose and xylitol in order to obtain a greater suppression of food intake, the board does not find any information in the patent in suit as to how this greater suppression can be achieved. The workable examples of the patent in suit, tables II and III and figures 1 and 2, show that the combination of polydextrose and xylitol in equal amounts does not improve (i.e. reduce) the energy intake compared to the use of the same total amount of each of the components, PDX or xylitol. This deficiency was also acknowledged by the appellant during the oral proceedings before the board. Thus, there is no teaching in the patent in suit

as to how to achieve a synergistic effect having regard to the suppression of food intake.

5.4 As regards the appetite suppression relied upon by the appellant as the relevant synergy, the skilled person would still not find the necessary information in the patent in suit as to how this specific type of synergy could be obtained. Figures 3 and 4 in the patent in suit illustrate the suppression of appetite in terms of satiety and figures 5 and 6 the suppression of appetite in terms of satiation. However, the results of these figures are based on subjective ratings (see patent in suit, paragraph [0047] and [0052]) which render the validity of these results questionable. The necessity of rigorous ratings and test protocols was already pointed out in the state of the art (E45: page 15, first full paragraph: page 23, first paragraph under the title "Satiation and satiety - experimental designs"). The conclusion is that the results of figures 3 to 6 cannot be used to convincingly demonstrate a synergistic effect.

5.5 But apart from the subjective character of these ratings, the results for test day 1 for both satiety and satiation as given in figure 4 (relative suppression of hunger/satiety) and figure 6 (relative increase in fullness/satiation) show that the combination of 50:50% of hydrogenated polydextrose (PDXh) and xylitol provides worse results than 100% of PDXh. Thus no synergy is shown for test day 1. Consequently, even when adopting the interpretation of the appellant for the meaning of synergy, and disregarding the subjective aspect of the ratings, the skilled person does not find in the patent in suit the

necessary information for obtaining the required synergy.

5.6 The board, contrary to the appellant's assertions, does not acknowledge that the synergistic effect is illustrated by the annotated figures in E62.

5.6.1 The figures of E62 are a reproduction of figures 3 to 6 of the patent in suit where the bars relating to xylitol and polydextrose are chopped in half to produce the "Expected XylPDXh". The appellant's procedure of chopping the bars is based on the assumption that the appetite suppressing effect depends linearly on the amount of the sugar and the alcohol. There is, however, no convincing evidence in the patent itself, nor has the appellant submitted any proof in this context.

5.6.2 Moreover, the respondents showed by reference to E4 and E38 that the skilled person would legitimately have expected this dependency to be non-linear:

- E4 (page 745, right column, last five lines; page 746, table 2) discloses that 25 g of xylitol reduced *ad libitum* food intake by 25%, whereas lower doses [i.e. 15g or 5g] failed to reduce food intake. Under the study of E4 the effect of xylitol was not linear and it was not possible that half the dose had half of the effect of the full dose.

- Although directed to a different appetite suppressant, namely xanthan gum, E38 (page 1, left column, lines 40-47) teaches in a similar way that administration of less than 100 mg of xanthan gum per day to human subjects is not effective.

The board, in agreement with the respondents, accepts that E4 and E38 (E38 at least in a corroborative way) plausibly show that the skilled person would consider that the appetite suppression effect would not depend linearly on the amount of PDX or xylitol.

In view of the above there is no expectation that the relationship between appetite and the amount ingested is linear, and the appellant's procedure of chopping the bars in half is fundamentally flawed.

5.6.3 In this context the board considers that it is the appellant who carries the burden of proof. By choosing not to submit any technical evidence, it has failed to discharge this burden and to overcome the serious doubt cast on the alleged linear dependency of the appetite suppression effect on the amount of polydextrose and xylitol.

5.7 In summary, claim 1 merely defines the appropriate amount of xylitol in functional terms ("synergistically effective amounts"). As outlined above, the skilled person does not find in the patent in suit any teaching as to how to determine the amounts which provide the synergistic effect in appetite suppression and/or food intake suppression. All that the opposed patent thus provides is an invitation to carry out a research programme and to find out by trial and error which amounts provide the synergy, whereby the parties even disagreed about the type of synergy to be looked at (point 5.2 above). This amounts to an undue burden, and sufficiency of disclosure must therefore be denied (in

this context see for instance T 1063/06, OJ EPO 2009, 516, headnote II).

Consequently, auxiliary request 3 is not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber