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**Datasheet for the decision
of 12 June 2008**

Case Number: T 0541/05 - 3.3.09

Application Number: 97902529.3

Publication Number: 0902624

IPC: A23L 1/305

Language of the proceedings: EN

Title of invention:

Composition and its use as a food supplement or for lowering lipids in serum

Patentee:

Nutri Pharma ASA

Opponent:

Solae, LLC

Relevant legal provisions:

EPC Art. 54, 56
RPBA Art. 13(1)

Relevant legal provisions (EPC 1973):

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Keyword:

"Main request - novelty" - no"
"Auxiliary request 1 - inventive step - no"
"Auxiliary request 2 - late filed - not admitted"

Decisions cited:

-

Catchword:

-



Case Number: T 0541/05 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 12 June 2008

Appellant: Solae, LLC
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
2 March 2005 concerning maintenance of European
patent No. 0902624 in amended form.

Composition of the Board:

Chairman: P. Kitzmantel
Members: J. Jardón Álvarez
W. Sekretaruk

Summary of Facts and Submissions

I. The grant of European patent No. 0 902 624 in respect of European patent application No 97902529.3 in the name of Nutri Pharma ASA, which had been filed on 12 February 1997 as International application PCT/IB97/00152 (WO - 97/31546), was announced on 3 January 2001 (Bulletin 2001/01) on the basis of 55 claims. Claim 1 read as follows:

"1. A composition on basis of soybean ingredients comprising:

(a) isolated soy protein

(b) soybean fibres,

wherein

i) the protein content provides at least 15 percent of the total energy content of the composition,

ii) the weight ratio between (a) and (b) is at least 2,

iii) the isolated soy protein is present in an amount of at least 75 weight percent of the total protein content of the composition."

II. A Notice of Opposition, requesting the revocation of the patent in its entirety on the grounds of Articles 100(a) and (c) EPC was filed against the

patent by Protein Technology International (now Solae, LLC) on 28 September 2001.

During the opposition proceedings *inter alia* the following documents were cited:

- D2: S.M. Potter *et al.*, "Depression of plasma cholesterol in men by consumption of baked products containing soy protein." *Am. J. Clin. Nutr.* 1993; 58, pages 501 - 506,
- D8: R.M. Bakhit *et al.* "Intake of 25 g of Soybean Protein with or without Soybean Fiber Alters Plasma Lipids in Men with Elevated Cholesterol Concentrations." *J. Nutr.* 1994; 124, pages 213 - 222, and
- D13: J.W. Anderson *et al.*, "Meta-analysis of the effects of soy protein intake on serum lipids." *The New England Journal of Medicine*, 1995, 333, pages 276 - 282.

III. By its interlocutory decision announced orally on 21 January 2005 and issued in writing on 2 March 2005, the Opposition Division held that the grounds for opposition raised by the Opponent did not prejudice the maintenance of the patent in amended form.

This decision was based on an amended set of claims filed by the Patent Proprietor during the oral proceedings held on 21 January 2005. Claim 1 was identical to the granted claim (see above).

The Opposition Division in its decision acknowledged the novelty of Claim 1 over document D2 because in the ISP (isolated soy protein)/SCF (soy cotyledon fibre) composition of Table 2 of D2 the isolated soy protein was not present in an amount of at least 75 weight percent of the total protein content of the composition.

Concerning inventive step, the Opposition Division was of the opinion that D13 represented the closest prior art document. The problem to be solved by the invention with regard to this document, which taught that soy protein can reduce serum cholesterol in patients with elevated as well as with low initial cholesterol levels, was seen in modifying the compositions of D13 such that the serum cholesterol depressing effect was enhanced. In its opinion, the solution to this problem, namely the claimed compositions, was not obvious because D13 did not mention any cholesterol reducing effect of soybean fibres. In fact, D13 was silent about isolated soy protein compositions comprising soy fibres. In the Opposition Division's view, D8 gave no incentive to add soybean fibres to the isolated soy protein. On the contrary, D8 taught away from such addition, because it disclosed that the addition of soybean fibre (a) offsets the effects of the isolated soybean protein as far as cholesterol reduction in subjects with normal initial cholesterol concentrations was concerned and (b) had no additional effects in subjects with enhanced initial cholesterol levels. Consequently, the claimed subject-matter was seen as inventive.

IV. On 27 April 2005 the Opponent (Appellant) lodged an appeal against the decision of the Opposition Division and paid the appeal fee on the same day.

In the Statement of Grounds of Appeal filed on 11 July 2005, the Appellant requested the revocation of the patent in its entirety. It also filed the following further documents:

- D18: O. Bosello *et al.* "Short and Long-Term Effect of Hypocaloric Diets Containing Proteins of Different Sources on Plasma Lipids and Apoproteins of Obese Subjects." *Ann. Nutr. Metab.* 1988, 32, pages 206 - 214,
- D19: K.M. Widhalm *et al.* "Lipids and lipoproteins in obese adolescents during a very low calorie diet (VLCD)." *International Journal of Obesity*, 1983, 7, pages 599 - 600,
- D20: O. Bosello *et al.* "High Density Lipoprotein Subfractions during Semistarvation in Obese Women." *Ann. Nutr. Metab.* 1985, 29, pages 381 - 386,
- D21: K.K. Carroll *et al.* "Hypocholesterolemic effect of substituting soybean protein for animal protein in the diet of healthy young women." *The American Journal of Clinical Nutrition* 1978, 31, pages 1312 - 1321, and
- D22: J.G. Wechsler *et al.* "Lipids and lipoproteins during a very-low-calorie diet." *International Journal of Obesity* 1981, 5, pages 325 - 331.

V. The Respondent (Patent Proprietor) presented its counterstatement by letter dated 14 November 2005. It

disputed all the arguments submitted by the Appellant and requested that the appeal be dismissed and the patent be maintained with the claims in accordance with the decision of the Opposition Division.

VI. On 14 February 2008 the Board dispatched the summons to attend oral proceedings. In the annexed communication the Board drew the attention of the parties to the points to be discussed during the oral proceedings.

VII. By letter dated 21 April 2008, the Respondent filed an amended version of the claims upheld by the Opposition Division wherein only the dependency of some of the claims was corrected. It filed further sets of claims for six auxiliary requests.

Claim 1 of the first auxiliary request was based on Claim 1 of the main request wherein the weight ratio between isolated soy protein (a) and soybean fibres (b) was amended to read "3 to 4".

VIII. On 7 May 2008 the Appellant filed a further document:

D23: EP - A - 0 425 423

and requested its admittance into the proceedings due to its relevance.

IX. On 12 May 2008 the Respondent replied to the new submissions made by the Respondent.

X. During the oral proceedings held before the Board on 12 June 2008, after the discussion on inventive step of the first auxiliary request, the Respondent withdrew

its previous auxiliary requests 2 to 6 and filed a new second auxiliary request. The only claim of this request read as follows:

"The use of a composition on basis of soybean ingredients for the preparation of a medicament for lowering the cholesterol level and the triglyceride level and for increasing the HDL/LDL-cholesterol ratio in serum, said composition comprising:

(a) isolated soy protein

(b) soybean fibres,

wherein

i) the protein content provides at least 15 percent of the total energy content of the composition,

ii) the weight ratio between (a) and (b) is 3 to 4,

iii) the isolated soy protein is present in an amount of at least 75 weight percent of the total protein content of the composition."

XI. The arguments presented by the Appellant in writing and at the oral proceedings held on 12 June 2008 may be summarized as follows:

- The subject-matter of Claim 1 of the main request, which was directed to a composition comprising soy protein and soybean fibres in certain proportions, independently of how these ingredients were brought

into the composition, lacked novelty having regard to the disclosures of D2, D23 and soy beans as such. It argued that the term "isolated soy protein" as used in the patent in suit should be understood as the major proteinaceous fraction of soybeans, that is to say, the protein to be found in natural soybeans and also in the soy concentrate described in D23. It argued that the preparation method for "isolated" soy protein did not qualitatively make the protein portion of the resulting ISP product different from the protein portion in a soybean concentrate. Consequently, the concentrate disclosed in D23 contained qualitatively the same soy protein (as well as soybean fibres) as used according to the present invention. Moreover, the concentrate used in the example of D23 included these components in amounts and a weight ratio anticipating all the features of Claim 1 of the main request.

- The subject-matter of Claim 1 of the first auxiliary requests also lacked novelty having regard to the disclosures of D23 and D2. The Appellant acknowledged that the compositions of D23 did not have a weight ratio of soy protein to soybean fibres in the range of 3 to 4 but argued that this value was an arbitrary selection within the general teaching of D23. Such selection did not fulfil the requirements of a selection invention. Additionally, the composition ISP/SCF according to Table 2 of D2 was also novelty destroying, when account was taken of the fact that the amounts given in the table for soy cotyledon fibres relate to a product whose fibre content is only 75%. When thus corrected from the indicated content of 20 g to the "true" fibre

content of 15 g the weight ratio soy protein to soybean fibres in the ISP/SCF diet would be >3 (50/15) and not <3 (50/20).

- The Appellant acknowledged that Claim 1 of the auxiliary request fulfilled the requirements of Articles 123(2) and (3) EPC but argued that the dependent claims did not fulfil the requirements of these articles due to the fact that the feature incorporated into Claim 1 was disclosed in granted Claim 27 which referred back only to Claim 1 and not to the other dependent claims.

- Concerning inventive step of the first auxiliary request it submitted that the claimed compositions for lowering cholesterol were an obvious alternative to the compositions known from, for instance, D2 and/or D8. It argued that the examples in the patent did not show any unexpected effect in lowering the cholesterol levels. The results were the logical consequence of the use of an increased amount of protein and the use of a very low caloric diet. The reduction of the cholesterol level in the examples of the patent was due to the mere addition of both effects. The claimed compositions therefore lacked an inventive step.

- The Appellant further maintained that the second auxiliary request should not be admitted into the proceedings as it had been filed at a very late stage of the proceedings.

XII. The arguments presented by the Respondent may be summarized as follows:

- The subject-matter of Claim 1 of the main request was not anticipated by D23, essentially because this document did not use "isolated" soy protein. The operations involved in the production of isolated soy protein were fundamentally different from those appropriate for making the concentrates. The process steps would result in significant physico-chemical changes in the end-product material. During the preparation of the isolated protein the globular structure of the protein was denatured, while this was not the case for the concentrate. It further pointed out that it was possible analytically to distinguish, for instance by electrophoresis, between a protein coming from a concentrate and from an isolate.

- Concerning the first auxiliary request it pointed out that the generic disclosure of D23 did not anticipate the specific range now claimed. Moreover, the compositions according to Table 2 of D2 showed a weight ratio between isolated soy protein and fibres of 2.5, outside the range claimed. This could be concluded from the information in the table, which information did not necessitate any interpretation with regard to the components or their amounts used, because these should be understood in the way they are designated therein.

- The Respondent, starting from D8 as the closest prior art document, saw the objective technical problem to be solved as being to provide a composition for lowering cholesterol levels for a long period of time, even for subjects with a

moderate starting cholesterol serum level. This problem was solved by the claimed compositions formed by taking isolated soy protein and adding back soy fibre. The examples in the patent showed that compositions according to the patent in suit were better than the commercially available product according to D23 used for comparison. It pointed out that in every group of subjects an improvement was achieved, even with compositions which are not hypocaloric. It pointed out that the mechanism of lowering cholesterol levels was still not fully understood and criticized calculations made by the Appellant according to which any enhancement of serum cholesterol depression resulted proportionally from the use of a diet having an increased content of soy protein and a decreased caloric value. In summary, the long term improvement achieved by the claimed compositions was a quite unexpected finding that could not be derived from the available prior art.

- The second auxiliary request should be admitted into the proceedings, as the sole claim of this request did not raise any new issue. Its subject-matter was further limited to the purposes of lowering the triglyceride level and increasing the HDL/LDL-cholesterol ratio in which respect the claimed compositions were more effective than any prior art composition. Its late filing was due to the negative conclusions drawn by the Board with regard to the previous requests.

XIII. The Appellant requested that the decision under appeal be set aside and that the European patent No. 0 902 624 be revoked.

The Respondent requested that the appeal be dismissed or the European patent be maintained on the basis of the set of claims of the first auxiliary request filed with letter dated 21 April 2008 or on the basis of the second auxiliary request filed on 12 June 2008 during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

MAIN REQUEST

2. *Novelty (Article 54 EPC)*

2.1 The subject-matter of Claim 1 of the main request is directed to a composition based on soybean ingredients showing the following features:

- a) isolated soy protein (ISP), and
- b) soybean fibres (SF), wherein
- c) the protein content provides at least 15 percent of the total energy content of the composition,
- d) the weight ratio ISP/SF is at least 2, and
- e) the ISP is in an amount of at least 75 weight % of the total protein content of the composition.

2.2 The novelty of this claim was contested by the Appellant having regard *inter alia* to the disclosure of D23.

2.2.1 Document D23, a late filed document admitted into the proceedings by the Board due to its relevance, discloses in column 3, lines 40 - 51 a low-calorie nutritional composition consisting of 60 parts by weight of soy protein concentrate, 25 parts by weight of agglomerated skimmed milk powder, 2 parts by weight of soy phospholipid, 12.5 parts by weight of lecithinated cocoa and 0.2 parts by weight of vanillin. The composition of Example 1 of D23 includes a soy protein concentrate comprising soy protein (feature (a)) and soy fibre (feature (b)) in a weight ratio of 16.2 (feature (d)), in which concentrate the isolated soy protein represents 77.3 weight % of the total protein content (feature (e)) and provides more than 15% of the total energy content (feature (c)). Thus it discloses all the features of the subject-matter of Claim 1 of the main request.

2.2.2 The Respondent does not dispute that the compositions of D23 anticipate features (b) to (e) of Claim 1 but maintains that the soy protein contained in the concentrate used in D23 is a different material, a soy protein having a different structure than the isolated soy protein of Claim 1. Thus, in its view, feature (a) was a distinguishing feature.

2.2.3 The Board cannot accept this argument of the Respondent. Soy protein isolates and soy protein concentrates are two products derived from soybean which differ mainly in the concentration of protein and the fibre content.

The soy protein concentrates comprise about 70% soy protein (on dry weight) and are made from de-fatted soy flakes by removing most of the carbohydrates but keeping the soy fibre. The soy protein isolates comprise about 90% soy protein (on dry weight) and are also made from de-fatted soy flakes *inter alia* by extracting the carbohydrate and precipitating and drying the protein.

Thus the soy protein in both cases originates from the same starting material. The additional processing steps for the preparation of the isolates (washing steps to remove fibre and soluble compounds, precipitation of the protein by adjusting the pH) are carried out under conditions to avoid any denaturation/destruction of the protein which would damage its genuine characteristics (required for its later nutritional use). The soy protein present in the isolate is thus the same soy protein present in the concentrate; therefore the use of the term "isolated soy protein" cannot render the protein component therein distinguishable from the one present in a soy concentrate.

This interpretation is confirmed by paragraph [0015] of the specification wherein the isolated soy protein is defined "as the major proteinaceous fraction of soybeans" and its preparation takes place through a series of steps in which the soybean protein is said to be "separated from the rest of soybean".

No denaturation of the protein is said to occur during this separation (isolation) of the protein. In any case, there is no evidence on file showing that it would be possible to differentiate between a soy protein

originating from an isolate and a soy protein originating from a concentrate.

- 2.3 For these reasons the subject-matter of Claim 1 of the main request lacks novelty.

FIRST AUXILIARY REQUEST

3. *Amendments (Article 123 EPC)*

- 3.1 The subject-matter of Claim 1 of the first auxiliary has been amended to read that the weight ratio between isolated soy protein and soybean fibres is "3 to 4". This feature is supported by Claim 4 of the application as originally filed (see also page 6, lines 19 - 20). The amended claim thus fulfils the requirements of Article 123(2) EPC.

- 3.2 By limiting the weight ratio from "at least 2" to "between 3 and 4", the amended claim is clearly restricted over the granted claim. The requirements of Article 123(3) EPC are thus also fulfilled.

- 3.3 The Appellant admitted that the subject-matter of Claim 1 was limited over the granted patent but argued that the dependent claims could include embodiments extending the protection beyond the granted claims, although it could not point to any embodiment covered by the amended claims that would not be embraced by the granted claims.

The Board cannot accept this objection of the Appellant. Dependent claims relate by definition to preferred, limited, embodiments of the independent claim on which

they depend and their scope is thus always restricted with respect to this independent claim. Any limitation of an independent claim leads to an identical limitation of the claims dependent thereupon. This is also the case here.

3.4 The Board is therefore satisfied that the amendments made to the claims fulfil the requirements of Articles 123(2) and (3) EPC.

4. *Novelty (Article 54 EPC)*

4.1 The novelty of Claim 1 of this request was also contested by the Appellant having regard to the disclosures of D23 and D2.

4.1.1 Concerning D23 it is observed that there is no composition in D23 wherein the weight ratio between isolated soy protein and soybean fibres lies within the values of 3 to 4. As explained above (see 2.2.1) the only composition exemplified in D23 has a ratio of 16.2 and is well outside the now claimed range.

The Appellant does not dispute that there is no specific disclosure of a novelty destroying composition in D23 but it argues that the range "3 to 4" represents an arbitrary selection within the teaching of D23 and this selection did not fulfil the criteria for selection inventions.

The Board cannot accept this argument of the Appellant. The compositions disclosed in D23 are made using soy protein concentrates having a very different isolated soy protein/soybean fibre weight ratio. D23 does not

contemplate any source of soy protein/soybean fibre compositions other than a soy concentrate. D23 does not therefore disclose a range of the soy protein/soybean fibre weight ratio from which a "selection" could be envisaged. Consequently, application of the so-called "criteria for selection inventions" misses the point.

- 4.1.2 There is also no novelty-destroying composition in D2. D2 describes the effect of soy-protein consumption with and without soy fibre on plasma lipids using a diet including 50 g protein and 20 g dietary fibre (see abstract). The composition in Table 2 designated ISP/SCF comprises, among other things, 50 g isolated soybean protein and 20 g soybean fibre. The ratio ISP/SCF is thus 2.5 and outside the range covered by Claim 1 of the first auxiliary request.

The Board cannot accept the argument of the Appellant that the amount of soy cotyledon fibre (SCF) indicated in Table 2 of D2 to be 20 g for the ISP/SCF treatment group should be corrected to 15 g taking account of the "dietary fibre content" of (only) 75% of the soy cotyledon fibre Fibrin as indicated in the footnote of that table, a correction which would lead to a weight ratio of isolated soy protein/soybean fibre of above 3 (50/15). The Board agrees with the interpretation of the Respondent that the values given in Table 2 are already "corrected" values, taking account of the effective fibre (and protein) content of each of the components used. This has been done in order to allow a sensible comparison of the different experiments which otherwise would not be possible because then the contribution of the fibre to the effect of the diet would be distorted in view of the quite different fibre

"purity" of the other dietary fibres used in Table 2 (soy fibre SF: 19%; cellulose: 99-100%).

4.2 For these reasons the subject-matter of Claim 1 of the first auxiliary request is novel.

5. *Inventive step (Article 56 EPC)*

5.1 Closest prior art

5.1.1 The patent in suit relates to compositions based on soybean ingredients, namely soy protein and soybean fibres, for lowering serum lipid levels.

5.1.2 Most of the documents cited in the present proceedings (D2, D8, D13, D18, D23, etc) relate to the beneficial effects achieved in decreasing serum cholesterol levels when animal protein is replaced by soy protein in the diet. In the Board's opinion D13 and D8 are the closest documents.

5.1.3 D13 is a paper review which summarizes the results of 38 previously conducted clinical trials including several of the further documents cited in the present proceedings (D2, D8, D21). This document concludes that the consumption of soy protein significantly decreases serum concentrations of total cholesterol, LDL cholesterol, and triglycerides (see last paragraph of the Abstract).

According to D13 the amount of soy protein ingested has a significant effect on serum cholesterol concentrations. From the analysis of the previous studies, the authors of D13 conclude that the ingestion

of 25 or 50 g of soy protein per day is estimated to decrease serum cholesterol concentration by 0.23 mmol/l (8.9 mg/dl) or 0.45 mmol/l (17.4 mg/dl), respectively. Moreover persons with moderate or severe hypercholesterolemia should have even larger decreases in serum cholesterol concentrations when soy protein replaces animal protein in the diet (see D13, pages 280 - 281, especially the paragraph bridging the left and right columns on page 280). Document D13 is silent about the effect of soybean fibres on serum lipids.

- 5.1.4 D8 emphasizes the value of soy protein as part of a low cholesterol diet in the achievement of low cholesterol levels. The aim of the study of D8 was to evaluate the effectiveness of decreasing the plasma lipid concentration of a typical low lipid diet comprising relatively low levels of soy protein (25 g/day) together with soybean fibre (20 g/day) or without such fibre (see Abstract).

The authors of D8 concluded that individuals with elevated (6.20 mmol/l) starting cholesterol levels may benefit by incorporation of small amounts of soy protein into their diets. However, they did not observe a reduction of cholesterol levels in subjects with moderate (5.74 mmol/l) starting cholesterol levels (see Table 5).

Furthermore the authors of the article did not observe any additional effect of the simultaneous ingestion of soy protein and soybean fibre. Considering that other authors describe a blood lipid lowering effect of soybean fibres (page 213, last paragraph, right column) they postulate that this could be either an indication

that the cholesterol-lowering effect of soy protein is stronger and overrides effects of soybean fibre or be due to different modes of action of soybean protein and soybean fibre (see last two paragraphs of the article).

5.1.5 The Board regards D8 as the closest prior art document essentially because it also discusses the influence of soybean fibre in the diet compositions therein studied. Moreover, it was considered by the Respondent as closest prior art. In any case the Board would arrive at the same inventive step conclusions if D13 were to be considered as the closest prior art document.

5.2 The objective problem to be solved and its solution.

5.2.1 The technical problem to be solved by the patent in relation to said closest prior art can be formulated as the provision of further soy compositions which provide a significant reduction of cholesterol levels after a long period of time even for subjects with a moderate starting cholesterol level.

5.2.2 This problem is solved by the compositions according to Claim 1 which differ from the compositions of D8 essentially by an increased amount of isolated soy protein in order to give a higher isolated soy protein/soybean fibre ratio (between 3 and 4 while in D8 the ratio is of 1.25 (25/20)).

5.2.3 The results of example 3 in the patent specification demonstrate that, by using the compositions called VLCD/530 having an ISP/SF weight ratio of 3 and LCD/880 having an ISP/SF weight ratio of 3.5, a cholesterol reduction of over 25% in six weeks is obtained.

Moreover the results in example 4 demonstrate that the claimed compositions are more effective than a commercial composition including soy protein concentrate (NUTRILETT®VLCD 420).

5.2.4 In the light of this experimental evidence, the Board is satisfied that the above-defined technical problem is plausibly solved. This finding was not contested by the Appellant.

5.3 *Obviousness*

5.3.1 It remains to be decided whether, in view of the available prior art documents; it would have been obvious for the skilled person to solve this technical problem by the means claimed.

5.3.2 The "inventive" compositions VLCD/530 and LCD/880 of the patent in suit differ from the composition "ISP + SCF" of D8 essentially by:

- i) the use of a higher amount of soy protein (60 g or 75 g vs. 25 g in D8), and
- ii) a lower calorie content (530Kcal or 880Kcal vs. 2340 Kcal in D8).

- Concerning the use of a higher amount of soy protein, D13 teaches that "the amount of soy protein ingested had a significant effect on serum cholesterol concentrations" (page 280 left column, lines 34 - 38), the effect being larger in persons with moderate or severe hypercholesterolemia. According to D13, the ingestion of 25 or 50 g of soy protein is estimated to decrease serum concentration levels by 0.23 mmol/L or 0.45 mmol/l, respectively (see

point 5.1.3 above). It would be clear for the skilled person from this teaching that the compositions used in the examples of the specification would have an increased cholesterol lowering effect merely due to the higher content of soy protein.

- Concerning the use of a diet with a much reduced calorie content, reference is made for instance to D19 and D20. In D19 obese adolescents were treated with a very low calorie diet without soy protein. The cholesterol levels in these subjects dropped from 180 mg/dl (4.65 mmol/l) to 125 mg/dl (3.23 mmol/l) in 21 days (see Table 2). Similar results are obtained in D20, in which a very low calorie diet reduced cholesterol levels from 204.3 (5.28 mmol/l) to 154.6 mg/dl (4.0 mmol/l) after 15 days (see Table I). Thus, it would be clear for the skilled person that the use of a diet with a low content of calories accounts for a further reduction of the serum cholesterol level.

5.3.3 In summary, the lowering effect of the claimed compositions is the logical consequence of the measures taken according to the claimed subject-matter (increased amount of soy protein and lowering of calorie intake).

Consequently, the skilled person would arrive at the claimed subject-matter by applying the teaching of D13 and D19 (or D20) to the compositions of D8; the subject-matter of Claim 1 of the first auxiliary request therefore lacks an inventive step.

5.3.4 It was argued by the Respondent that the long term lowering of cholesterol levels achieved by the claimed compositions was unexpected in view of the teaching of the prior art. It pointed out in particular:

- i) that the comparison of example 4 of the patent using the commercially available product Nutrilett® VLCD 420 showed in every tested subject an improvement,
- ii) that the lowering of cholesterol levels in subjects with a moderate starting cholesterol level could not be predicted in view of the results in D8 for the same subjects, and
- iii) that although a part of the cholesterol reducing effect of the claimed compositions could be due to the use of low calorie diets, the examples showed that the effect achieved with the compositions of the invention was distinct from this calorie reduction effect. The finding that the compositions as claimed formed by adding back soy fibre to isolated soy protein were much better than unrefined soy product containing soy protein could not have been expected or predicted in view of the cited prior art.

5.3.5 The Board finds these arguments unconvincing. While it is correct that the claimed compositions show a certain improvement when compared with the commercially available composition Nutrilett® VLCD 420, no true comparison can be made between these compositions as the exact nature of Nutrilett® VLCD 420 is not known. It is said to contain 61.5 g protein as a combination

of soy protein concentrate and skimmed milk powder but the amount of soy protein is not given in the specification and the Respondent's representative stated during the oral proceedings that he didn't know it. Thus, the improved results could just as well be explained by the use of a higher amount of soy protein in the compositions of the patent. In any case an unexpected effect of the weight ratio range of isolated soy protein to soybean fibre between 3 and 4 cannot be deduced from the experimental evidence on file.

Concerning the absence of a cholesterol lowering effect on subjects with a moderate starting level of cholesterol (5.74 mmol/l) according to D8 (Table 2), it is noted that the amount of soy protein used in the diet of D8 is also well below the one used in the examples in the patent and that in such cases a higher amount of soy protein may be necessary to reduce the cholesterol level as taught in D13 (see 5.1.3 above or D13 pages 280 - 281).

Lastly, the Board agrees with the Respondent that it is not possible to predict quantitatively the cholesterol reducing effect of a low calorie diet, the mechanisms responsible for the serum cholesterol reduction being not yet entirely understood. The fact is, however, that the results in the patent are qualitatively explained by the combined use of calorie intake reduction and the increase of the soy protein amount, and that no effect of the claimed compositions beyond what the skilled person would expect has been established by the Respondent.

5.4 Hence, the Board concludes that, in the light of the cited prior art, it would have been obvious to a person skilled in the art to arrive at the claimed compositions.

SECOND AUXILIARY REQUEST

6. The Respondent filed this request towards the end of the oral proceedings, after the Board had deliberated on the allowability of the first auxiliary request, that is to say, at the very last moment. The Respondent justified the late filing as resulting from the discussion during the oral proceedings and the negative decision made by the Board on the previous requests. The only claim of the request clearly fulfilled the formal requirements of the EPC and it was further limited to the medical use of the compositions.

6.1 According to Article 13(1) of the Rules of Procedure of the Boards of Appeal any amendment to a party's case after it has filed its grounds of appeal may be admitted and considered at the Board's discretion. The discretion has to be exercised in view of *inter alia* the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy. Auxiliary requests filed at the end of the oral proceedings are admitted into the appeal proceedings only under exceptional circumstances.

6.2 In the present case the Board decided not to admit the extremely late-filed second auxiliary request into the proceedings essentially because *prima facie* it does not overcome the inventive step objection raised against the first auxiliary request.

As explained in detail for the first auxiliary request the beneficial effect of soy protein for lowering the cholesterol level in serum was already well known, this being one of the reasons for the finding that the subject-matter of Claim 1 of the first auxiliary request lacks an inventive step. Its use for lowering the triglyceride level and the low-density lipoprotein (which implies an increase of the HDL/LDL ratio) is also known from, for instance, D13 (see abstract). Once these effects are known, including the known potential contribution thereto by soybean fibres (cf. D8, last paragraph of right column), a possibly enhanced degree of such effect could not be regarded as inventive.

For these reasons the second auxiliary request is not admitted into the proceedings.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The European patent is revoked.

The Registrar

The Chairman

G. Röhn

P. Kitzmantel