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**Datasheet for the decision
of 16 June 2011**

Case Number: T 1327/09 - 3.3.09

Application Number: 02737244.0

Publication Number: 1395132

IPC: A23L 1/29

Language of the proceedings: EN

Title of invention:

Dual viscosity fibre system and uses thereof

Patentee:

ABBOTT LABORATORIES

Opponent:

N.V. Nutricia

Headword:

-

Relevant legal provisions:

EPC Art. 84, 123(2)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Main request, auxiliary requests 1 to 4: Clarity (no)"

"Main request, auxiliary requests 1 to 4: Added subject-matter (yes)"

Decisions cited:

G 0001/99

Catchword:

-



Case Number: T 1327/09 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 16 June 2011

Appellant:
(Opponent)

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Representative:

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Respondent:
(Patent Proprietor)

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Decision under appeal:

Interlocutory decision of the Opposition
Division of the European Patent Office posted
3 April 1999 concerning maintenance of European
patent No. 1365132 in amended form.

Composition of the Board:

Chairman: W. Sieber
Members: W. Ehrenreich
F. Blumer

Summary of Facts and Submissions

I. Mention of the grant of European patent No. 1 395 132 in respect of European patent application No. 02 737 244.0, filed on 29 May 2002 as international application No. PCT/US2002/016875 in the name of *Abbott Laboratories*, was announced on 12 April 2006 in Bulletin 2006/15.

The patent was granted with 10 claims, claim 1 reading as follows:

"1. Use of a dual induced viscosity fiber system for manufacturing a meal replacement product for blunting the post-prandial glycemc response of an individual said fiber system comprises;

- a. an anionic soluble fiber source and a neutral soluble fiber source, each of which represents from 0,2% to 2,0% by weight of the meal replacement product;
- b. lightly hydrolized starch, having a DP (degree of polymerization) value in the range from 20 to 100 and which represents from 3% to 15% by weight of the meal replacement product; and
- c. water-insoluble, acid soluble, multivalent cation sources."

Claims 2 to 9 were dependent claims. Claim 10 was directed to a meal replacement product comprising a protein source, a fat source and a carbohydrate source, the latter including the dual induced viscosity fiber system as defined in claim 1.

II. An opposition against the patent was filed by *N.V. Nutricia* on 12 January 2007.

The opposition was based on the grounds according to Article 100(a) EPC that the claimed subject-matter was neither novel nor inventive, and on Article 100(b) EPC.

In support of its objections under Article 100(a) EPC the opponent cited a number of documents, *inter alia*

D2 US-A 5 470 839
D3 EP-A 0 898 900
D6 WO-A 01/67895
D8 WO-A 00/67592.

III. With its decision announced orally on 5 March 2009 and issued in writing on 3 April 2009 the opposition division maintained the patent in amended form on the basis of claims 1 to 9 according to the main request filed during oral proceedings. Claims 1 and 9 of the request were based on claims 1 and 10 as granted and additionally contained the following feature at the end:

"... wherein the induced viscosity fiber system generates an in vivo viscosity greater than 300 cps while generating a ready-to-feed viscosity of less than 200 cps."

It was the opposition division's position that the claims of the new main request met the requirements of Rule 80 EPC and Articles 83, 84 and 123(2)/(3) EPC, and that the claimed subject-matter was novel, in particular over D3 and D6 (the latter representing prior art according to Article 54(2) EPC because the

priority claimed was not valid), and was based on an inventive step vis-à-vis a combination of D2 with D8.

IV. Notice of appeal against the decision of the opposition division was filed by the opponent (hereinafter appellant) on 4 June 2009. The prescribed fee was paid on the same day. The statement setting out the grounds of appeal was submitted on 7 August 2009. In its grounds of appeal the appellant reiterated the objections in respect of insufficiency of disclosure, lack of novelty and lack of inventive step, and further raised the objection that the feature

"... wherein the induced viscosity fiber system generates an in vivo viscosity greater than 300 cps while generating a ready-to-feed viscosity of less than 200 cps"

introduced into claims 1 and 9 of the main request allowed by the opposition division, lacked clarity, and therefore infringed Article 84 EPC.

V. In its first statement dated 24 February 2010 the patent proprietor (hereinafter the respondent) defended the maintenance of the patent in amended form as allowed by the opposition division (main request).

VI. In preparation of the oral proceedings scheduled to take place on 16 June 2011 the board issued a communication dated 21 April 2011. Therein, the board made its provisional observations on essential issues of the case, *inter alia* concerning clarity, added subject-matter, sufficiency of disclosure, novelty and inventive step. The board's observations as to clarity

and added subject-matter in particular related to the above feature introduced into claims 1 and 9 of the main request (point IV above).

VII. In its letter dated 10 May 2011 the appellant confirmed its objections under clarity, sufficiency of disclosure, novelty and inventive step.

VIII. In reaction to the board's communication the respondent filed, with its letter dated 13 May 2011, five sets of claims as a new main request and first to fourth auxiliary requests. The independent claims of all requests (claims 1 and 9 of the main and first auxiliary requests; claims 1 and 8 of the second auxiliary request; claims 1 and 7 of the third and fourth auxiliary requests) contained an amended version of the feature relating to in vivo and ready-to-feed viscosity (hereinafter: "viscosity feature") which now reads as follows:

"... wherein the induced viscosity fiber system generates an in vivo viscosity of the meal replacement product of greater than 300 cps while generating a ready-to-feed viscosity of the meal replacement product of less than 200 cps."

The difference to the old feature in claims 1 and 9 of the former main request is that both the in vivo viscosity and the ready-to-feed viscosity are now related to the meal replacement product.

IX. In the oral proceedings held on 16 June 2011 the viscosity feature was discussed with reference to Articles 84 and 123(2) EPC. At the end of this

discussion the board concluded that the amendments were not allowable. In reaction thereto the respondent submitted further sets of claims as bases for fifth to eighth auxiliary requests where the viscosity feature was deleted from all independent claims.

X. The appellant's arguments relating to the viscosity feature may be summarised as follows:

(a) Main request, first to fourth auxiliary requests

Article 84 EPC

The feature "in vivo viscosity of the meal replacement product of greater than 300 cps" was not clear in respect of the description. On the one hand it was not indicated in paragraph [0055] of the patent specification that the viscosity range of greater than 300 cps was related to the meal replacement product. On the other hand, point "p" in paragraph [0024] did not clearly disclose at which stage of the simulated enzymatic digestion process - i.e. whether before or after the addition of 0.1N hydrochloric acid (HCl) - the in vivo viscosity was determined.

Article 123(2) EPC

The feature that the induced viscosity fiber system generated a ready-to-feed viscosity of less than 200 cps of the meal replacement product was not disclosed in the application as filed. It was disclosed on page 15 of the original description that the ready-to-feed viscosity range of less

than 200 cps was related to the induced fiber system as such. No disclosure was derivable therefrom that this viscosity range was the property of the meal replacement product which, in addition to the fiber system, contained further ingredients like fat, protein or minerals.

(b) Fifth to eighth auxiliary requests

The deletion of the feature concerning the in vivo and ready-to-feed viscosity of the meal replacement product at this late stage of the appeal proceedings led to problems in several aspects:

- extension of the scope beyond the scope of the claims according to the main request as allowed by the opposition division was a violation of the principle of prohibition of *reformatio in peius*;
- creation of a new situation, which would make a new evaluation of the cited documents necessary, in respect of the consideration of the question of inventive step;
- as regards the introduction into claim 1 of auxiliary request 5 of the feature that the level of free calcium in the meal replacement product was less than 40 ppm, a problem of inadmissible amendment under Article 123(2) EPC arose.

These amendments made for the first time in the oral proceedings were surprising for the appellant, which was therefore not in a position to consider

and discuss them thoroughly without adjournment of the oral proceedings. The fifth to eighth auxiliary requests should therefore not be admitted into the proceedings.

XI. The arguments of the respondent were as follows:

(a) Main request, first to fourth auxiliary requests

Article 84 EPC

The appellant's original clarity objections under Article 84 EPC had been removed by clarifying in the independent claims that the ranges for both the in vivo and ready-to-feed viscosity concerned the meal replacement product. As regards the in vivo viscosity of the meal replacement product it should be noted that a detailed method for measuring it on a model product was given under point "p" in paragraph [0024] of the patent specification. In this context reference was made to experiment 1 and figure 1 showing the influence of guar gum on the viscosity of several prototypes of a meal replacement product. In addition, experiment 2 in conjunction with figure 2 showed that the viscosity of one prototype taken from samples of experiment 1 increased from 200 cps (ready-to-feed viscosity - starting point of the graph) to over 19,000 cps (in vivo viscosity) after digestion with the enzyme alpha amylase and prior to addition of HCl (point marked with "After"). Figure 2 further showed that the viscosity of the prototype during the digestion process never dropped below the ready-to-feed

viscosity point. It was therefore clear for a skilled person that the maximum viscosity was the target for the *in vivo* viscosity.

Article 123(2) EPC

The application as originally filed related to two essential embodiments, namely the induced viscosity fiber system and the meal replacement product into which the fiber system as such was incorporated (page 1, second paragraph with the heading "Technical Field"). From original claims 1, 7, 8 and 10 in context it could be derived that the induced viscosity fiber system was an essential ingredient in a meal replacement product for the purpose of generating a ready-to-feed viscosity of less than 300 cps (claim 10) and an *in vivo* viscosity of greater than 300 cps (claim 7) of the meal replacement product.

In this context it was immediately understood by a skilled person that the passage on page 15 of the original description:

"The induced viscosity fiber system has been designed to generate optimal viscosity *in vivo* while minimizing the ready-to-feed viscosity. The ready-to-feed of the induced viscosity is less than about 300 cps, preferably less than about 200 cps ..."

related to the viscosity of the meal replacement product which was generated by the fiber system. Therefore, no deficiency under Article 123(2) EPC could be seen.

(b) Fifth to eighth auxiliary requests

According to G 1/99, limited exceptions to the rule of prohibition of *reformatio in peius* existed, in particular if an inadmissible amendment had been allowed by the opposition division. Because introduction of the viscosity feature was considered by the board to be an inadmissible amendment, deletion of the ready-to-feed and in vivo viscosity ranges from the independent claims of the fifth to eighth auxiliary requests was therefore such an exception, which would not negatively effect the opponent as the sole appellant.

Deletion of the viscosity feature would also not create a new scenario because the feature was not part of independent claims 1 and 10 as granted. Because the amendments made in the claims of the main request and the first to fourth auxiliary requests submitted on 13 May 2011 have been regarded as promising, submission of claims completely excluding the viscosity feature had not been contemplated at that time.

As regards the introduction of the level of calcium in the fifth auxiliary request, it should be noted that this feature was part of the first auxiliary request dated 13 May 2011, and it was not understood why the time period of one month up to the date of the oral proceedings should be too short for dealing with this feature. Moreover, the level of free calcium of less than 40 ppm was

disclosed on page 14 of the original description in relation to alginate. Therefore, no non-compliance with Article 123(2) EPC could be seen.

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

XIII. The respondent requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request as filed with letter dated 13 May 2011, or, alternatively, on the basis of any of the first, second, third or fourth auxiliary requests as filed with the letter dated 13 May 2011, or on the basis of any of the fifth, sixth, seventh or eighth auxiliary requests as filed during the oral proceedings before the board.

Reasons for the Decision

1. The appeal is admissible.
2. Main request, first to fourth auxiliary requests

As mentioned in point VIII above, the independent claims of the main request and the first to fourth auxiliary requests have the following amended feature (viscosity feature) in common:

"... ,wherein the induced viscosity fiber system generates an in vivo viscosity of the meal replacement product of greater than 300 cps while generating a ready-to-feed viscosity of the meal replacement product of less than 200 cps".

Because this feature was not part of the claims as granted, it has to be assessed whether this amendment meets the requirements of Articles 84 and 123(2) EPC.

2.1 Article 84 EPC

It is one requirement of the above feature that the induced viscosity fiber system generates an in vivo viscosity of the meal replacement product of greater than 300 cps. As indicated in the last paragraph on page 8 of the application as filed and in paragraph [0026] of the patent specification, a meal replacement product in the sense of the claimed invention contains a protein source, a lipid source, a carbohydrate source, and vitamins/minerals. This is also reflected by example 1 describing a typical nutritional product composed of a fiber in fat slurry (table 1), a protein in water slurry (table 2), a carbohydrate mineral slurry (table 3), a vitamin solution (table 4) and a guar gum solution (table 5).

- 2.1.1 According to point "p" in paragraph [0024] of the patent specification (paragraph bridging pages 7 and 8 of the application as filed) the "in vivo viscosity" refers to the viscosity measured by adding 20 μ L of bacterial alpha-amylase to 250 g of a sample, followed by shearing using a Glass-Col mixer for 30 minutes. The viscosity following shearing is measured using a Brookfield Viscometer (Model DV-II+) with a 62 spindle at room temperature. The enzyme-treated sample is then titrated with 0.1N HCl to determine "maximum viscosity". From this passage in the description it is not clear

whether the first or the second (maximum) viscosity is meant by the feature in the independent claims

"... wherein the induced viscosity fiber system generates an in vivo viscosity of the meal replacement product of greater than 300 cps ...".

2.1.2 Nor do figures 1 and 2 in conjunction with experiments 1 and 2 of the patent in suit help to clarify this issue.

Experiment 1 and corresponding figure 1 refer to initial experimentation evaluating the effect different levels of guar gum had on the initial viscosity of a **prototype**. This prototype contained 0.75% alginate, calcium carbonate and DE 1 maltodextrin, but apparently did not include further ingredients which are typical of a meal replacement product. Furthermore, the term "in vivo viscosity" is never used in the context of experiment 1 and figure 1.

Experiment 2/figure 2 describes the digestion of a certain sample taken from experiment 1 with alpha amylase. The induced viscosity increased from 200 cps to over 19,000 cps. Adding 0.1N HCl to the enzyme-treated product caused the viscosity of the simulated digesta to increase to over 30,000 cps. Again the term "in vivo viscosity" is not used in the context of experiment 2 and figure 2, and in particular it is not indicated which point of the graph of figure 2 represents the "in vivo viscosity".

Thus, the experiments relied upon by the respondent cannot clarify the issue relating to the "in vivo

viscosity". In fact, experiments 1 and 2 do not appear to describe a typical meal replacement product in the sense of the invention at all. As set out above, these experiments describe prototypes containing alginate, calcium carbonate and DE 1 maltodextrin. Essential ingredients like lipids, proteins, vitamins and/or minerals seem to be missing. Although it is mentioned in paragraph [0062] of the patent in suit that the product (i.e. the prototype containing alginate, calcium carbonate and DE 1 maltodextrin) was manufactured as described in example 1, this does not automatically mean, as alleged by the respondent, that all the other components of example 1 were contained in this prototype. On the other hand, example 1 and experiment 3, describing a typical meal replacement product and a study on the basis of this product and comparison products performed on adult male subjects, deal only with the satisfaction of the test person with regard to the feeling of fullness and satiety (tables 7 and 8) and hunger (table 9), but do not indicate any viscosity values before and after ingestion of the product.

2.1.3 Consequently, the independent claims of the main request and the first to fourth auxiliary requests are unclear, contrary to Article 84 EPC.

2.2 Article 123(2) EPC

2.2.1 A further requirement of the amended feature in the independent claims of the main and auxiliary requests 1 to 4 is that the induced viscosity fiber system generates

"... a ready-to-feed viscosity of the meal replacement product of less than 200 cps".

This feature unambiguously implies that the viscosity range of less than 200 cps represents the viscosity of the "complete" meal replacement product including, besides the above fiber system, other ingredients like lipids, protein vitamins and minerals, and is not the viscosity of the fiber system as such.

2.2.2 This, however, stands in contrast to the passage at page 15, lines 18 to 20 of the application as filed, which according to the opposition division and the respondent is the basis for the amendment. This passage states that

"The ready-to-feed viscosity of the induced viscosity fiber system is less than about 300 cps, preferably less than about 200 cps ..." (emphasis by the board).

This clearly means that the viscosity range of less than 200 cps represents the viscosity of the induced fiber system.

This is further supported by the fact that the application as filed, as pointed out by the respondent, describes two embodiments, namely the induced viscosity fiber system (addressed in original claims 1, 7 and 8) and a meal replacement product containing the induced viscosity fiber system (original claim 10). Thus, the induced fiber system as a first embodiment of the invention has to be clearly distinguished from the meal replacement product, including the above fiber system, as the second embodiment of the invention. Therefore,

disclosures of the viscosity ranges for the induced fiber system as such and those of the complete meal replacement product are not interchangeable and have to be strictly distinguished from each other. Therefore, the above passage in the original description cannot be considered to be a disclosure of a viscosity range relating to the meal replacement product.

Also, and contrary to the respondent's view, experiment 2 (page 16, lines 25 to 29) indicating that

"The induced viscosity increased from 200 cps to over 19,000 cps (Figure 2)"

cannot support the ready-to-feed viscosity range of less than 200 cps for the meal replacement product. First of all, a range of from 200 cps to over 19,000 cps cannot support a range of **less than** 200 cps. Secondly, this experiment relates to the in vivo viscosity of a prototype (see point 2.1.2 above) rather than the ready-to-feed viscosity of a meal replacement product.

2.2.3 Therefore the amended feature is in breach of Article 123(2) EPC.

2.3 Because the amendments to the independent claims of the main request and the first to fourth auxiliary requests do not meet the requirements of Articles 84 and 123(2) EPC, the requests are not allowable.

3. Admissibility of the fifth to eighth auxiliary requests

3.1.1 As mentioned in point IX above, the deletion of the viscosity feature ("wherein the induced viscosity fiber system generates an in vivo viscosity greater than 300 cps while generating a ready-to-feed viscosity of less than 200 cps") from the independent claims of the fifth to eighth auxiliary requests was made for the first time in the oral proceedings and was, according to the respondent, the consequence of the board's conclusion that including this feature in the independent claims of the main request and the first to fourth auxiliary requests was not in compliance with Articles 84 and 123(2) EPC. Although its deletion did not lead to an extension of the patent as granted and did not contravene Article 123(3) EPC, because the feature was not part of the granted independent claims 1 and 10, it extended the scope of the claims allowed by the opposition division.

3.1.2 As regards the deletion of the viscosity feature at this late stage of the appeal proceedings, it has to be considered that the feature relating to the ready-to-feed and in vivo viscosity as introduced into the claims allowed by the opposition division was already objected to under Article 84 EPC by the appellant with the statement of grounds of appeal. Furthermore, the board, in its communication dated 21 April 2011, pointed to problems under Articles 84 and 123(2) EPC with regard to this feature. In the board's judgment, deletion of the viscosity feature, as one option to overcome the objections under Articles 84 and 123(2) EPC, could therefore have been contemplated by the

respondent already in the written proceedings, i.e. at the latest in its letter dated 13 May 2011.

Deleting it instead for the first time in the oral proceedings enhances the complexity of the case at the very last stage of the proceedings. First of all, the question of *reformatio in peius* for the opponent as the sole appellant has to be dealt with. But even if the question whether the deletion of the viscosity feature constituted an exception to the principle of prohibition of *reformatio in peius* in the sense of G 1/99 - as submitted by the respondent - could have been answered in the affirmative, a new consideration of the issue of inventive step would have been necessary.

As can be concluded from the original application in its overall context, the viscosity of the fiber system and the meal replacement product is an essential feature of the claimed invention. This was also appreciated by the opposition division, which acknowledged inventive step for the subject-matter of claims, including the viscosity properties generated by the induced fiber system. Therefore, complete removal of this feature would lead to a situation in which the appellant might have to reconsider its inventive-step objection, which was previously based on claims including the viscosity properties of the fiber system. Thus the late filing of such requests is certainly not conclusive to procedural economy.

3.1.3 In the light of the above, the board exercised its discretion according to Article 13(1) of the Rules of Procedure of the Boards of Appeal and did not admit the fifth to eighth auxiliary requests into the proceedings.

4. In view of the above, there is no need to discuss the questions of sufficiency of disclosure, novelty and inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar

The Chairman

G. Röhn

W. Sieber