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Datasheet for the decision of 2 May 2016

Case Number: T 0178/13 - 3.3.07

Application Number: 05702139.6

Publication Number: 1755565

IPC: A61K9/48, A61P35/00, A61P3/06, A61P11/06, A61P25/18, A61P29/00

Language of the proceedings: EN

Title of invention:
SOFT GELATIN CAPSULE COMPRISING OMEGA-3 POLYUNSATURATED FATTY ACID

Patent Proprietor:
Chrysalis Pharma AG

Opponents:
Catalent Pharma Solutions, Inc.
S P A SOCIETA' PRODOTTI ANTIBIOTICI S.p.A.
Pronova Biopharma Norge AS

Relevant legal provisions:
EPC Art. 54(3), 123(2), 100(b), 54(2), 56

Keyword:

Novelty - main request (no) - auxiliary request (yes)
Amendments - auxiliary request, added subject-matter (no)
Sufficiency of disclosure - auxiliary request (yes)
Inventive step - auxiliary request (yes)

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European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0178/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 2 May 2016

Appellant: (Opponent 3)	Pronova Biopharma Norge AS P.O.Box 420 1327 Lysaker (NO)
Representative:	Weickmann, Hans Weickmann & Weickmann Patentanwälte PartmbB Richard-Strauss-Straße 80 81679 München (DE)
Respondent: (Patent Proprietor)	Chrysalis Pharma AG Chilchgasse 8 6072 Sachseln (CH)
Representative:	Beck Greener Fulwood House 12 Fulwood Place London WC1V 6HR (GB)
Party as of right: (Opponent 2)	S P A SOCIETA' PRODOTTI ANTIBIOTICI S.p.A. Via Biella, 8 20143 Milano (IT
Representative:	Minoja, Fabrizio Bianchetti Bracco Minoja S.r.l. Via Plinio, 63 20129 Milano (IT)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 4 December 2012 concerning maintenance of the European Patent No. 1755565 in amended form.**

Composition of the Board:

Chairman	J. Riolo
Members:	A. Usuelli
	D. T. Keeling

Summary of Facts and Submissions

I. European patent No. 1 755 565 is based on European patent application No. 05702139.6, which was filed as international application PCT/GB2005/000415 on 7 February 2005 claiming a priority date of 13 February 2004. The patent was granted on the basis of twenty claims.

II. Three oppositions were filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as filed. The opposition by opponent 1 was withdrawn before the opposition division took its decision.

The following documents were among those cited during the first-instance proceedings:

D2: WO 2004/091317
D3: GB 2223943
D4: Fax from RP Scherer SpA dated 19 November 1998
D7: Affidavit of Mr Rowe
D11: Quality report for Batch 05502KL
D26: Martindale, 33 Edition 2002, page 737
D28: Declaration of Mr Buser
D29: Report of Dr Henry Wu
D30: Declaration of Mr Thorstad
D31: Declaration of Mr Breivik
D38: Excerpt from Informatore Farmaceutico 1997 concerning the product Seacor®
D39: Excerpt from Informatore Farmaceutico 1998 concerning the product Seacor®
D41: GB 836,082

III. By an interlocutory decision posted on 4 December 2012 , the opposition division maintained the patent in amended form. The decision was based on a set of claims filed with letter dated 13 September 2012 as main request.

Independent claims 1 and 17 of the main request allowed by the opposition division read respectively as follows:

"1. A soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form characterised in that the capsule comprises porcine Type A gelatin".

"17. Use of porcine Type A gelatin in a soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form to improve shelf life of the soft gelatin capsule, wherein said shelf life is greater than that for a soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form in which the gelatin consists essentially of Type B gelatin".

IV. The decision of the opposition division can be summarised as follows:

(a) The main request complied with the requirements of Article 123(2) EPC and was sufficiently disclosed.

(b) Document D2 was prior art pursuant to Article 54(3) EPC 1973. This document did not unambiguously disclose capsules comprising gelatin A of porcine

origin and did not unambiguously disclose the presence of 4,7,10,13,16,19-docosahexaenoic acid (DHA) in free acid form. For this reason D2 was not novelty-destroying under Article 54(3) EPC.

(c) The commercial product Seacor® contained succinylated gelatin which was not the same product as the Type A porcine gelatin. The product Maxepa® did not appear to contain ω-3 polyunsaturated fatty acid in free acid form. Thus, the subject-matter of claim 1 was not anticipated by the prior uses of the products Seacor® and Maxepa®.

(d) Document D3 was the closest prior art for the assessment of inventive step. The soft capsules defined in claim 1 differed from the capsules disclosed in this document on account of the presence of type A porcine gelatin. The technical problem was to be seen in the provision of gelatin capsules comprising ω-3 polyunsaturated fatty acid in free acid form having improved storage stability. The prior art did not suggest using type A porcine gelatin in order to obtain this improvement. The subject-matter of the main request therefore complied with the requirements of Article 56 EPC.

V. Opponents 2 and 3 lodged an appeal against that decision.

With the statement setting out the grounds of appeal appellant-opponent 3 (hereinafter appellant) submitted *inter alia* the following items of evidence:

D45: Declaration by Dr. Piccardi
D48: Thesis of Pascal Georges Felix

D49: Confirmation of the publication date of D48.

VI. By a letter dated 7 May 2013 the Board informed opponent 2 that it had to expect a rejection of the appeal as inadmissible pursuant to Article 108 EPC since it did not submit the written statement of grounds of appeal.

VII. The patent proprietor (hereinafter respondent) replied to the grounds of appeal by a letter dated 5 November 2013. With the same letter the respondent submitted eighteen sets of claims consisting of a main request and seventeen auxiliary requests.

The main request was identical to the request allowed by the opposition division.

The following document was also submitted with the reply to the grounds of appeal:

D52: E-mail exchange between Mr Choski and Dr Harries

VIII. On 9 February 2016, the Board issued a communication pursuant to Article 15(1) RPBA in which, *inter alia*, the following observations were made:

(a) The subject-matter of the main request appeared to comply with the requirements of Article 123(2) EPC and sufficiency of disclosure
(b) The post-published document D2 was considered to anticipate the subject-matter of claim 1 of the main request and of auxiliary requests 1 to 3.
(c) Claim 1 of auxiliary request 4 appeared novel over the disclosure of D2 at least on account of the mandatory presence of 5,8,11,14,17-eicosapentaenoic

acid (EPA). All the requests appeared novel over the prior uses of the products Maxepa® and Seacor®.

(d) Document D3 was the closest prior art for the assessment of inventive step of all the requests. The capsules of the requests of the opposed patent differed from the capsules of D3 mainly on account of the use of porcine type A gelatin. The technical problem was to be seen in the provision of soft capsules containing omega-3 polyunsaturated fatty acid having an increased shelf life.

(e) The evidence on file did not convincingly show that document D48, relied upon by the respondent in relation to the assessment of inventive step, was published before the priority date of the patent in suit.

IX. By letter dated 7 March 2016 the respondent filed auxiliary requests 1 to 18 in replacement of the auxiliary requests filed on 5 November 2013.

Claim 1 of auxiliary request 1 read as follows:

"1. A soft gelatin capsule containing a pharmaceutical formulation comprising 5,8,11,14,17-eicosapentaenoic acid (or "EPA") in free acid form characterised in that the capsule comprises porcine Type A gelatin".

Independent claim 16 of auxiliary request 1 was identical to claim 17 of the main request (see points II and VII above).

Auxiliary requests 2 to 18 were identical to auxiliary requests 1 to 17 submitted on 5 November 2013.

X. With letter of 22 April 2016 the appellant informed the Board on its decision not not attend the oral proceedings.

XI. The oral proceedings held on 2 May 2016 were attended only be the respondent.

XII. The appellant's arguments, as far as they are relevant for the present decision, can be summarised as follows:

Article 123(2) EPC

Claim 1 of the original application related to a gelatin capsule comprising gelatin extracted by an extraction process comprising acid pre-treatment of collagen source. The replacement of this functional definition of the gelatin by the feature "Type A gelatin" had no basis in the original application. Furthermore, the combination of the features that the active ingredient was in free acid form and the gelatin was porcine type A gelatin could not be directly and unambiguously derived from te application as filed. Thus, independent claims 1 and 17 of the main request and the corresponding claims of the auxiliary requests did not comply with Article 123(2) EPC.

Sufficiency of disclosure

Claim 17 of the main request was a use claim directed to a technical effect, namely the improvement of shelf life. The subject-matter of this claim was not sufficiently disclosed in that the patent in suit did not contain any evidence to show that capsules comprising less than 100% porcine type A gelatin had an improved shelf life. The conclusions drawn by Dr Wu in document D29 were merely based on statistical data and

started from the assumption that different types of gelatin would provide a linear contribution to the shelf life of the capsules. However, this assumption was in contradiction with the observations made by Dr Buser in paragraph 6 of its declaration (D28). Furthermore, the patent did not specify under which conditions the shelf life of the capsules was determined and which type of gelatin B was used. These objections applied also to claim 16 of auxiliary request 1 which was identical to claim 17 of the main request.

The subject-matter of all the claims also covered compositions comprising mixtures of types A and type B gelatin. However, the patent did not sufficiently describe the preparation of such mixtures. Document D41 reported problems of incompatibility in mixing the two tapes of gelatin.

Novelty

Document D2 disclosed on page 14 a gelatin-based composition comprising *inter alia* docosahexaenoic acid (DHA), i.e a long-chain fatty acid. As disclosed on page 6, the gelatin was preferably type A gelatin of porcine origin. This disclosure anticipated claim 1 the main request.

The subject-matter of claim 1 of the main request and of auxiliary request 1 was not novel also in view of the public prior use in Italy of the product Seacor®, as evidenced by the excerpts of 1997 and 1998 from the "Informatore Farmaceutico" (documents D38 and D39). Documents D4 and D43 indicated that the gelatin used for the manufacture of Seacor® was succinylated gelatin of type A derived from skin. The definition "Type A

gelatin" used in the patent encompassed also the type A succinylated gelatin. Furthermore, as supported by document D45, before 1996 the product was manufactured with a different gelatin, namely a mixture of gelatin A and B of porcine origin. As indicated in D38 and D38 the active ingredients of Seacor® were ethyl esters of the fatty acids EPA and DHA. However, the product contained also minor amounts of the free acids EPA and DHA. This was demonstrated by the experimental report D11 and by the declarations of Mr Thorstad (D30) and Mr Breivik (D31).

The product Maxepa® was on the market before the priority date of the patent. As reported in exhibit 6 of document D7 this product contained fatty acids in the triglyceride form. As explained in document D31, the triglycerides also contained some minor amounts of free fatty acids. Thus, the gelatin capsules of the patent in suit were anticipated also by the prior use of the product Maxepa®.

Inventive step

Document D3 was the closest prior art. The capsules defined in claim 1 of the main request and claim 1 of auxiliary request 1 differed from the capsules of D3 in the use of porcine gelatin type A. The patent did not provide any evidence for the presence of an unexpected effect over the whole scope of the claim. In particular the comparative test in example 1 of the patent did not convincingly show that the alleged advantage had its origin in the distinguishing feature. Moreover, there were no data relating to capsules containing only minor amounts of porcine type A gelatin. Starting from document D3 the skilled person would have considered to use for the preparation of the capsules disclosed

therein porcine type A gelatin. This was suggested by D48 which indicated that the type A gelatin was more resistant to cross-linking than the type B gelatin.

Document D48 was published on 18 November 2003, i.e. before the priority date of the opposed patent. The publication date was confirmed by the statement of Dr Harries (D49).

XIII. The respondent's arguments, as far as they are relevant for the present decision, can be summarised as follows:

Article 123(2) EPC

Page 4 of the original application (lines 31 and 32) provided a basis for introducing in claim 1 the feature "Type A gelatin" without offending Article 123(2) EPC. The combination of the feature that the fatty acid was in free acid form with the feature that the gelatin was type A of porcine origin had a basis in original claims 12 and 13.

Sufficiency of disclosure

The data disclosed in the patent showed that capsules containing only type A gelatin were more stable than capsules containing only type B gelatin. Furthermore document D29 confirmed that even small amounts of type A gelatin in a mixture with type B resulted in an improvement of the shelf life of the capsules. The objection against claim 17 of the main request was therefore not justified.

The skilled person would have been able to prepare compositions containing mixtures of type A and type B gelatin. Indeed, document D26 referred to mixtures of

gelatin A and B without reporting problems of incompatibility.

Novelty

Document D2 did not directly and unambiguously disclose the information that the DHA used in the composition of example 1 was in free acid form. The term "DHA" was commonly used in the technical field of the patent to indicate not only the free acid form of the docosahexaenoic acid but also its esters, such as the triglycerides. Furthermore, various references acknowledged in D2 related to products containing DHA and EPA derived from fish oil. It was well known that these substances were present in the fish oil in the form of triglycerides. This was an additional indication that the term "DHA" was not necessarily used in D2 to designate the free acid form of the docosahexaenoic acid. Claim 1 of the main request was novel over the composition disclosed in example 1 of D2 also on account of the requirement that it contained type A gelatin from a porcine source. Example 1 was silent with regard to the specific type of gelatin used for preparing the capsules. According to page 6 of the description, the gelatin could be of type A or B. The reference on page 5 to gelatin of porcine origin could not be considered as a disclosure of porcine type A gelatin. Claim 1 of the main request was therefore novel over the disclosure of D2.

The product Seacor® contained succinylated gelatin type A which was different from type A gelatin. Already for this reason this product did not anticipate the capsules defined in claim 1 of all the requests. Additionally, there was no evidence that Seacor® contained the fatty acids in free acid form as required

by claim 1 of all the requests. As to the composition of the Seacor® capsules before 1996, document D45 did not establish beyond doubt that they contained porcine type A gelatin. Moreover, also in respect to these capsules it was not proved that they contained free fatty acids.

The appellant did not identify the batch of Maxepa® that was made available to the public before the priority date. In any case there was no evidence that this product contained EPA and DHA in free acid form.

Inventive step

The capsules of the invention were distinguished over the capsules of D3 by virtue of the use of porcine type A gelatin. The technical effect arising from the use of this type of gelatin was the inhibition of the hardening of the capsule shell resulting in the prolongation of the period of time that the capsule may be stored. This effect was not suggested in any of the prior art documents. Document D52 showed that document D48 was not made available to the public before the priority date of the patent. Hence, this document could not be used for the assessment of inventive step. In an case this document was not relevant since it did not relate to capsules containing fatty acids. The requirements of inventive step were therefore met.

XIV. Opponent 2 did not file any submission during the appeal proceedings.

XV. The appellant requested in writing that the decision under appeal be set aside and that the patent be revoked.

XVI. The respondent requested that the appeal be dismissed (Main Request) or, in the alternative, that the patent be maintained on the basis of the claims of one of the auxiliary requests 1 to 18, filed on 7 March 2016.

Reasons for the Decision

Admissibility of the appeal of opponent 2

1. As no written statement setting out the grounds of appeal has been filed, the appeal of opponent 2 is rejected as inadmissible (Article 108 EPC, third sentence, in conjunction with Rule 101(1) EPC).

Main request

2. Novelty

The appellant's objections under Article 54 EPC are based *inter alia* on the disclosure of document D2.

D2 was published on 28 October 2004, i.e. between the priority date and the filing date of the patent in suit. It claims a priority date of 17 April 2003, which is earlier than the priority date of the opposed patent namely, 13 February 2004. The parties agree that document D2 is prior art pursuant to Article 54(3) EPC 1973.

2.1 Document D2 relates to pharmaceutical or dietary compositions containing DHA as active ingredient (page 4, lines 19 to 25). The compositions may be formulated in various forms including soft gelatin capsules (page 6, lines 19 to 23). Example 1 discloses the preparation of soft gelatin capsules comprising DHA as DHA oil.

It is disputed by the parties whether, as required by claim 1 of the main request, DHA is a fatty acid in free acid form and whether the capsules of example 1 contains porcine type A gelatin.

2.2 On page 12 of D2 (line 15) it is explained that the term DHA refers to docosahexaenoic acid, i.e. a long-chain fatty acid. In the respondent's view, in the absence of an explicit indication that the DHA is in free acid form, it cannot be concluded whether in the capsules of example 1 this substance is present as a free acid or whether is in the form of an ester such as a triglyceride. In this context the respondent refers to various prior art documents to argue that the term "DHA" is used to designate not only the free acid but also its esters.

2.3 The Board's does not share this view. The definition on page 12 of D2, clearly indicates that the term "DHA" is used in the context of this document to designate docosahexaenoic acid. This chemical name unambiguously defines an acid. The absence of the adjective "free" is irrelevant because the feature that the acid function is free, i.e. is not in the form of an acid derivative such as an ester, is incorporated in the chemical name itself. In other words, the skilled person would unambiguously read the definition "docosahexaenoic acid" as referring to a free acid even in the absence of term "free".

In the Board's view, equally immaterial is the fact that in some prior art documents the term "DHA" is used to refer to esters. Since document D2 provides on page 12 an unambiguous definition of this term which is not in conflict with other information disclosed in this

document, the skilled person would have no reason to consider other possible meanings given to this term in other documents.

In this respect the Board also notes that when the term DHA is used to designate esters of docosahexaenoic acid, there is usually an explicit indication in this sense. This occurs for instance in D12 (see example 1) and D5 (claims 1 and 8). However, document D2 does not include any reference to esters or other derivatives of of docosahexaenoic acid.

2.4 As a further argument, the respondent observes that various prior art documents discussed in the "Background information" section of D2, relate to products containing DHA and EPA derived from fish oil, which is known to contain these fatty acids in the form of triglycerides. This would support the conclusion that the term DHA used in D2 may also be used in relation to triglycerides.

The Board sees however no reason to derive the meaning of the term "DHA" from the content of the documents referenced in D2, when D2 itself provides an unambiguous definition of this term. In this respect the Board observes that a document concerning an acid may well refer to a prior art document concerning an ester of this acid as part of the relevant background art. In any case, the fact that the source of the DHA and EPA in the prior art documents discussed in D2 is fish oil does not imply that these products are used as triglycerides in the final formulations. Indeed it appears that the triglycerides could be hydrolysed to provide the free acids before the manufacture of the final pharmaceutical products.

In the light of the above, the Board concludes that the DHA contained in the capsules of example 1 of D2 is a fatty acid in free acid form.

2.5 Example 1 of D2 does not provide any information as to the type of gelatin used. Therefore, it needs to be investigated whether this information can be derived from other parts of document D2.

The Board notes in this respect that on page 5 (line 31) it is reported that gelatin may have various origins such as bovine, porcine and vegetable. In the first full paragraph of page 6, it is explained that gelatin material can be classified in types A and B depending on the process of preparation. Concerning type A, D2 indicates that this is obtained by acid-processing of porcine skin (page 6, line 8). No other origin is reported for this type of gelatin. The opposition division considered that two selections were necessary in order to arrive at the porcine type-A gelatin, namely the origin and the type. However, the fact of classifying the types of gelatin according to different criteria, for a better understanding, does not imply that a multiple selection is required in order arrive at the porcine type-A gelatin. The types of gelatin useful for the formulations of D2 represent a single group of elements. Hence, selecting the porcine type-A gelatin does not involve a twofold selection.

Independently from the above, the Board notes that in relation to the preparation of soft gelatin capsules, D2 mentions only mixtures of gelatin type-A and type-B (page 6, lines 22 and 23). Since porcine gelatin is the sole example of gelatin type-A considered in D2 (page 6, line 8), the mixture of gelatin type-A and type-B

referred to on page 6 is comprised in the definition of gelatin covered by claim 1 of the main request.

Thus, the description of D2 unambiguously discloses the use of porcine type-A gelatin for the preparation of the capsules of example 1.

2.6 In the light of the considerations made above, the Board concludes that document D2 anticipates claim 1 of the main request.

Auxiliary request 1

3. Article 123(2) EPC

The objections raised by the appellant under Article 123(2) EPC apply to claims 1 and 16 of auxiliary request 1 (see point XII above).

3.1 Claim 1 of the originally filed application relates to capsules comprising at least one omega-3-fatty acid. Claim 2 of the original application depends on claim 1 and specifies that the fatty acid is 5,8,11,14,17-eicosapentaenoic acid ("EPA"). Claim 1 of auxiliary request 1 is therefore based on original claim 2.

The replacement of the feature "gelatin extracted by an extraction process comprising acid pre-treatment of a collagen source", included in original claims 1, by the feature "type A gelatin", finds support, for instance, on page 4 (lines 31 and 32) of the original application.

The porcine origin of gelatin finds support, for instance, on page 4 of the description, line 32. In the

Board's view, the combination of the feature "porcine type A gelatin" with the requirement that the active ingredient is in free acid form, reflects a preferred embodiment of the invention which finds support, for instance, in the first paragraph of page 10. Thus, the appellant's argument that this combination is not unambiguously disclosed in the original application is not convincing.

3.2 The use claim 16 is based on the combination of original claims 28 and 29. The feature "type A gelatin" and the indication that the gelatin is of porcine origin find support on page 4, as discussed above in respect of claim 1. The replacement of the feature "gelatin extracted by an extraction process comprising alkali pre-treatment of a collagen source", included in original claim 29, by "type B gelatin" is supported by page 1 of the description, line 29.

3.3 Hence, the amendments in claims 1 and 16 do not introduce subject-matter which extends beyond the content of the application as filed.

The Board is satisfied that also the remaining claims of auxiliary request 1 find support in the original disclosure. The requirements of Article 123(2) EPC are therefore met.

4. Sufficiency of disclosure

4.1 The appellant considers that the subject-matter of claim 16 is not sufficiently disclosed in that the patent in suit does not contain any evidence to show that capsules comprising less than 100% porcine type A gelatin have an improved shelf life.

The Board notes in this respect that Dr Wu affirms in the conclusions of its statistical study (document D29, page 13) that also small percentages of porcine type A gelatin (0.5%) are effective in extending the shelf life of the capsules. The appellant contests the validity of these conclusions, arguing that Dr Wu's study is based on the erroneous assumption that different types of gelatin would provide a linear contribution to the shelf life of the capsules.

However, it does not provide any evidence or convincing argument to demonstrate that this assumption is so erroneous as to invalidate the conclusions of Dr Wu. The appellant refers to the conclusions set out by Dr Buser in point 6 of his declaration (D28), according to which a hardening was observed with various types of gelatin, different from porcine type A, which caused a reduction of the shelf life. In the Board's view this observation does not contradict the fact that different types of gelatin provide a linear contribution to the shelf life of the capsules. On the contrary, it appears that the considerations of Dr Buser would support the conclusion that reducing the relative amount of the types of gelatin different from porcine type A would reduce the hardening of the capsules and therefore increase the shelf life.

As to the argument that the patent does not specify under which conditions the shelf life of the capsules should be determined and which type of gelatin B should be used, the Board observes that information in this respect is provided in paragraph [0036] and Table 1 of the patent in suit.

4.2 The appellant also considers that the patent in suit does not sufficiently describe the preparation of

mixtures of type A and B gelatin. In this respect it refers to document D41 which reports problems of incompatibility when mixing these types of gelatin.

The Board observes that D41 indicates that problems of incompatibility exist when the types A and B of gelatin are mixed in certain ratios and in a specific pH range to form dilute solutions (1.5%). The Board considers that the skilled person would be able to avoid conditions which are known to result in the formation of mixtures which are not suitable for preparing soft gelatin capsules. Furthermore, as observed by the respondent, D26 refers to mixtures of gelatin A and B without indicating problems of incompatibility.

4.3 Thus, the objections put forward by the appellant are not persuasive. Accordingly, the Board concludes that the subject-matter of auxiliary request 1 is sufficiently disclosed.

5. Novelty

5.1 The appellant has based its objections of lack of novelty of claim 1 on the post-published document D2 and on the prior uses of the products Seacor® and Maxepa®.

5.2 Documents D2 relates to pharmaceutical compositions containing DHA as active ingredient. No mention at all is made in this document of the fatty acid EPA. Hence, claim 1 is novel over D2 on account of the mandatory presence of EPA in the capsules.

5.3 In relation to the prior use of the product Seacor®, the appellant raised two distinct objections based on

two different formulations available in Italy before the priority date of the patent.

5.3.1 The first objection concerns the formulation of Seacor® available since 1997. Documents D38 and D39 indicate that this product comprises ester of the fatty acids DHA and EPA and succinylated gelatin. The objection of the appellant is based on the argument that the esters of the fatty acids inevitably contain also minor amounts of free acids and that the expression "porcine type A gelatin" used in the claims of the patent in suit also covers succinylated gelatin of porcine origin.

In the communication of 9 February 2016, the Board indicated that the appellant's arguments were not convincing. In particular, it was observed that the extracts from the European Pharmacopoeia referred to by the appellant (D8 and D9) simply established the maximum amount of acid that can be present in the omega-3-ester products. However, these documents did not indicate that the omega-3-esters necessarily also contain the corresponding acids. In relation to the experimental report D11, which indicated that a product comprising triglycerides of DHA and EPA also contained the free acid form of these substances in an amount of 0.85%, and in relation to the declarations of Mr Thorstad (D30) and Mr Breivik (D31) which referred to D11, the Board remarked that there was no clear evidence to show that the composition analysed in D11 was a batch of the product Seacor® marketed before the priority date of the patent in suit. In this respect the Board also observed that D11 bore the date 16 November 2010, which was more than six years after the priority date of the patent.

Concerning the issue as to whether the expression "porcine type A gelatin" used in claim 1 of the opposed patent also covered the succinylated gelatin contained in the product Seacor®, the Board observed that it was clear from Table I of document D41 that the unmodified type A gelatin derived from porkskin and the succinylated gelatin were distinct products with different characteristics. Accordingly, a skilled person would have not considered the definition "type A gelatin" as covering also the succinylated form. It was furthermore observed that the patent in suit did not contain any reference to chemically modified gelatin products.

The appellant did not submit any reply to the communication of 9 February 2016. Hence, the Board confirms the conclusions drawn in this communication, namely that there is no evidence that the product Seacor® available in Italy since 1997 contained fatty acid in free acid form and that the feature "type A gelatin" does not cover also the succinylated form of gelatin.

5.3.2 The second objection in relation to the product Seacor® relates to the formulation which was used until 1996. In the statement setting out the grounds of appeal the appellant referred to document D45 to argue that this formulation contained a mixture of type A and type B gelatin derived from various animals including pigs.

Document D45 is a declaration from the manufacturer of the capsules Seacor®. It indicates that the mixture of type A and B gelatin used before 1996 was derived from a blend of bovines bones, bovine hide split and pigskin. In its response to the appeal, the respondent remarked that this declaration does not establish

beyond doubt that the earlier capsules contained porcine type A gelatin. The Board concurs with the respondent's remark since D45 does not unambiguously indicate that the part of gelatin of porcine origin was extracted by a process comprising an acid pre-treatment, i.e. is of type A. The appellant did not submit any remark in this respect. The Board concludes from the above that there is no evidence that before 1996 the capsules Seacor® contained porcine type A gelatin.

Moreover, the considerations set out in 5.3.1 above in relation to the active ingredients contained in the capsules Seacor® apply also here, with the consequence that also in respect of the product sold before 1996 it must be concluded that there is no proof that it contained EPA and DHA in free acid form.

5.3.3 Therefore, the novelty objection based on the prior use of the product Seacor® in two different formulations is not successful.

5.3.4 The appellant's objection concerning the prior use of the product Maxepa® is based on the affidavit of Mr Rowe (D7) according to which this product was sold before the priority date of the patent in the United Kingdom and in France.

Exhibit 6 annexed to D7 indicates that Maxepa® contains fatty acids from the omega-3 series in their natural form as triglycerides. The appellant reiterated the argument submitted also in relation to the product Seacor® that the esters of the fatty acids inevitably contain also minor amounts of free acids.

In the Board's view this argument is not persuasive since there is no evidence that samples of Maxepa® available to the public before the priority date of the opposed patent actually contained some amount of EPA in free acid form. The data reported in exhibits 5 and 7 of D7 indicate the presence of EPA and DHA in free acid form in samples of Maxepa®. There is however no proof that the samples analysed were actually available to the public.

In the communication issued on 9 February 2016 the Board expressed the opinion that there was no convincing evidence showing that samples of Maxepa® containing omega-3 fatty acids in free acid form were available to the public before the priority date of the patent in suit. As indicated above, the appellant did not file any submission in reply to this communication.

Thus, the appellant's objection of lack of novelty of claim 1 based on the prior use of the product Maxepa® fails to convince the Board.

5.4 It follows from the above, that the objections of lack of novelty raised against the subject-matter of auxiliary request 1 are not successful.

6. Publication date of document D48

6.1 During the appeal proceedings the appellant relied upon the teaching of document D48 to argue that the requirement of inventive step was not met. The publication date of this document was disputed by the parties.

6.2 D48 is a thesis for the degree of Master of Science in Biomedical Engineering at the University of South

Florida. The cover sheet of this document bears the information "Date of Approval: November, 18 2003", which according to the appellant corresponds also to the publication date of the document. To corroborate this conclusion, the appellant refers to the e-mail of 20 November 2012 of Professor Harries of the University of South Florida (document D49), according to which the University establishes the publication date of a thesis as the date the document was approved by the thesis committee.

6.3 Also the respondent enquired with Professor Harries about the publication date of document D48. This is attested by a series of e-mails exchanged in July 2013 (D52). According to the information that the respondent obtained from Professor Harries, the thesis was approved by the thesis committee on 18 November 2003. However, it was not approved for publication until 16 November 2004, because the author of the thesis did not graduate until fall 2004. Thus, in the e-mails sent to the respondent, Professor Harries appears to retract the information that he himself gave to the appellant.

6.4 A further aspect to be considered in deciding on the publication date of D48, is the fact that the year of the copyright notice on the front page of the document is 2004. This date clearly supports the respondent's position that D48 was not published on 18 November 2003 as maintained by the appellant.

6.5 In its communication of 9 February 2016 the Board expressed the opinion that the evidence available did not convincingly prove that document D48 was published before the priority date of the patent in suit. Since no reply was submitted by the appellant, the Board confirms its preliminary opinion.

Accordingly, document D48 is not prior art pursuant to Article 54(2) EPC and cannot be used to assess inventive step.

7. Inventive step

7.1 Closest prior art

It is not disputed by the parties that document D3 represents the closest prior art. The single example of this document relates to hard gelatin capsules containing EPA and DHA. No information is provided in D3 as to the type of gelatin used for the capsules.

Therefore, the capsules of claim 1 differ from the capsules of D3 by virtue of the use of porcine type A gelatin. Also this point is not disputed by the parties.

7.2 Technical problem

7.2.1 The invention addresses the problem of providing a soft gelatin capsule containing omega-3 polyunsaturated fatty acid that displays a reduced hardening rate and thereby has an increased shelf life (see [0011]).

7.2.2 The description of the patent (paragraphs [0035] to [0039] of and table 1) illustrates an experiment comparing the stability of capsules containing porcine type-A gelatin and capsules containing bovine type B gelatin. The results indicate that the disintegration time of the capsules containing bovine type B gelatin increases by increasing the storage time. In some cases the capsules are insoluble. In contrast, the

disintegration time of the capsules with porcine type-A gelatin does not substantially increase.

7.2.3 Similar experiments are disclosed in appendix I of D29. In this case capsules according to claim 1 are compared with capsules containing type A fish gelatin, type A bovine gelatin and type B bovine gelatin. The results disclosed in section 9.3 indicate that the capsules containing porcine type A gelatin are the most stable in that the disintegration time does not substantially increase by increasing the storage time.

As discussed also in point 4.1 above, document D29 describes also a statistical study made by Dr Wu. Based on the shelf life estimations, Dr Wu concludes that also small percentages of porcine type A gelatin (0.5%) are effective in extending the shelf life of the capsules.

7.2.4 Further experimental data concerning the disintegration time of capsules containing different types of gelatin are disclosed in document D28. These data are substantially identical to those disclosed in the appendix of D29.

7.2.5 In the Board's view, the experimental data illustrated above make it credible that capsules containing porcine type A gelatin maintain a constant disintegration time upon storage. In contrast, capsules containing other types of gelatin show an increase of the disintegration time as the storage time increases. This effect indicates a better stability of the capsules containing porcine type A gelatin and therefore an increased shelf life.

7.2.6 On the basis of the above experimental results, the technical problem in view of D3 is seen in the provision of soft gelatin capsules containing EPA having an increased shelf life.

7.3 Obviousness

The appellant did not point to any prior art document hinting at the use of porcine type A gelatin for manufacturing capsules having an extended shelf life. Nor is the Board aware of any document suggesting the beneficial effects of this specific type of gelatin in the manufacture of capsules containing fatty acids.

The subject-matter of claim 1 of the main request is therefore considered to comply with the requirements of Article 56 EPC.

7.4 The appellant did not submit any argument concerning the inventive step of the other independent claims of auxiliary request 1. The Board is satisfied that these claims also comply with the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of the claims of new auxiliary request 1, filed on 7 March 2016, and a description to be adapted thereto.

The Registrar: The Chairman:

G. Rauh J. Riolo

Decision electronically authenticated