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**Datasheet for the decision  
of 27 May 2014**

**Case Number:** T 0605/11 - 3.3.06

**Application Number:** 03764038.0

**Publication Number:** 1534807

**IPC:** C11B3/14, C11B3/00

**Language of the proceedings:** EN

**Title of invention:**

A PROCESS FOR DECREASING THE AMOUNT OF CHOLESTEROL IN A MARINE  
OIL USING A VOLATILE WORKING FLUID

**Patent Proprietor:**

Pronova BioPharma Norge AS

**Opponents:**

Ocean Nutrition Canada Ltd.  
KNH PATENTANWÄLTE

**Headword:**

Cholesterol removal/PRONOVA

**Relevant legal provisions:**

RPBA Art. 12(4), 13(1), 13(3)  
EPC Art. 52(1), 56, 114(2)  
EPC R. 80

**Keyword:**

Late-

filed evidence admitted (yes; in part; very high relevance)

Compliance of claims set comprising a further independent claim with Rule 80 EPC (yes)

Remittal (yes)

**Decisions cited:**

T 0642/06, T 0263/05

**Catchword:**



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Case Number: T 0605/11 - 3.3.06

**D E C I S I O N  
of Technical Board of Appeal 3.3.06  
of 27 May 2014**

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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
18 January 2011 concerning maintenance of  
European Patent No. 1534807 in amended form.**

**Composition of the Board:**

**Chairman**            B. Czech  
**Members:**            P. Ammendola  
                              U. Lokys

## Summary of Facts and Submissions

I. The appeal by Opponent 1 is from the interlocutory decision of the Opposition Division concerning maintenance of European patent No. 1 534 807 in amended form.

II. Claims 1, 15 and 17 of the patent as granted read as follows:

"1. A process for decreasing the amount of cholesterol in a mixture comprising a marine oil, the marine oil containing the cholesterol, **characterized in that** the process comprises the steps of;

- adding a volatile working fluid to the mixture, where the volatile working fluid comprises at least one of a fatty acid ester, a fatty acid amide and a hydrocarbon, and
- subjecting the mixture with the added volatile working fluid to at least one stripping processing step, in which an amount of cholesterol present in the marine oil in free form is separated from the mixture together with the volatile working fluid."

"15. A process according to claim 1, wherein the stripping processing step is followed by the steps of;

- subjecting the stripped marine oil mixture to at least one trans-esterification reaction with a C<sub>1</sub>-C<sub>6</sub> alcohol under substantially anhydrous conditions, and thereafter
- subjecting the product obtained in the step above to at least one or more distillations, preferably one or more molecular distillations, to achieve a distillate fraction with reduced concentrations of both free and bound cholesterol

*from which product an amount of cholesterol in bound form has been separated in the residue fraction."*

*"17. Use of a volatile cholesterol decreasing working fluid comprising at least one of a fatty acid ester, a fatty acid amide and a hydrocarbon, or any combination thereof, in a process for decreasing the amount of cholesterol in a mixture comprising a marine oil, the marine oil containing the cholesterol, in which process the volatile working fluid is added to the mixture and then the mixture is subjected to at least one stripping processing step, preferably a thin-film evaporation process, a molecular distillation or a short-path distillation or any combination thereof, and in which process an amount of cholesterol present in the marine oil in free form is separated from the oil mixture together with the volatile working fluid."*

III. The patent in suit had been opposed by Opponents 1 and 2 on the grounds of added subject-matter, insufficient disclosure, lack of novelty and of inventive step.

IV. During the opposition proceedings the Opponents cited, *inter alia*, the following documents:

D3 = WO 95/24459 A1;

D5 = US 4,623,488 A;

D10 = GB 493,948 A;

D11 = GB 490,433 A;

D12 = US 2,146,894 A;

D13 = GB 476,134 A

and

D14 = GB 482,881 A.

Documents D10 to D14 are also collectively indicated below as **Hickman patents**.

The Patent Proprietor filed:

- with a letter of 28 July 2010 an experimental report (below **experiments of 2010**)

and

- at the oral proceedings before the Opposition Division an amended version of the patent in suit as Auxiliary Request 1.

V. In the set of twenty claims of this Auxiliary Request 1 (below **maintained claims**):

- claims 1, 3 and 16 differ respectively from claims 1, 3 and 17 as granted in that the feature

*"a fatty acid ester,"*

has been replaced with (emphasis added)

*"a fatty acid **methyl** ester, a fatty acid **ethyl** ester,";*

- claims 2, 4 to 15 and 17 to 19 are substantially identical to granted claims 2, 4, 6 to 16 and 18 to 20

respectively, renumbered where appropriate,

and

- claim 20 reads:

"20. A process for decreasing the amount of cholesterol in a mixture comprising a marine oil, the marine oil containing the cholesterol, characterized in that the process comprises the steps of;

- adding a volatile working fluid to the mixture, where the volatile working fluid comprises at least one of a fatty acid ester, a fatty acid amide and a hydrocarbon, and
- subjecting the mixture with the added volatile working fluid to at least one stripping processing step, in which an amount of cholesterol present in the marine oil in free form is separated from the mixture together with the volatile working fluid,
- subjecting the stripped marine oil mixture to at least one trans-esterification reaction with a C<sub>1</sub>-C<sub>6</sub> alcohol under substantially anhydrous conditions, and thereafter
- subjecting the product obtained in the step above to at least one or more distillations, preferably one or more molecular distillations, to achieve a distillate fraction with reduced concentrations of both free and bound cholesterol from which product an amount of cholesterol in bound form has been separated in the residue fraction."

VI. The Opposition Division in the interlocutory decision under appeal found, *inter alia*, that granted claim 1 lacked of novelty vis-à-vis document D5, but that the amended version of the patent in suit according to the



then pending Auxiliary Request 1 (point V *supra*) complied with the requirements of the EPC. In particular, the first paragraph on page 7 of the decision reads:

"As regards R. 80 EPC, the Opposition Division observes that new claim 20 encompasses the subject-matter of granted claim 15, which was dependent upon claim 1 found not novel. Thus, the Proprietor is justified to keep the corresponding scope of protection, which in the present case was done by drafting a separate independent claim. The requirements of R. 80 EPC are therefore not contravened."

VII. Both Opponents filed an appeal against this decision.

In their respective statements of grounds of appeal, Opponent 1 (below **Appellant**) and **Opponent 2** held that the maintained claims were objectionable under Rule 80 and Articles 100(b)/83 EPC and that their subject-matter lacked novelty and inventive step. The Appellant additionally raised objections under Articles 84 and 100(c)/123(2) EPC.

In its statement of grounds, the Appellant also referred to two new documents, namely

D17 = "*Molecular Distillation*", P. Ridgway Watt;  
*Vacuum*, 1959, Vol.VI, CRC Press, Inc., Boca  
Raton, FL 1989, pages 113 to 160;

and

D18 = "*Vapour pressure and normal boiling point predictions of pure methyl esters and biodiesel fuels*", W. Yuan *et al.*; *Fuel*, Vol.84, 2005, pages 943 to 950;

and (on page 7 of the statement) to a figure showing the boiling point (volatility) of various free fatty acid methyl esters in comparison to that of cholesterol.

VIII. The Patent Proprietor (below **Respondent**) filed with its reply three sets of claims as main and auxiliary requests, said main request being identical to the set of maintained claims, and rebutted the objections raised by the adverse parties.

IX. In a further letter of 19 December 2012, the Appellant raised a novelty objection based on the newly filed document

D19 = US 3,082,228 A

and also filed further evidence that it considered relevant regarding inventive step, namely documents

D20 = "*Fractionation of fish oils and their fatty acids*", V.F. Stout *et al.* in "*Fish oil and Nutrition*", M.E. Stansby (ed.), van Nostrand Reinhold, New York, 1990, pages 73 to 88;

D21 = "*Processing of fish oils*", A.Bimbo in "*Fish oil and Nutrition*", M.E. Stansby (ed.), van Nostrand Reinhold, New York 1990, pages 181 to 225;

and

D22 = "*Biomedical test materials program: production methods and safety manual*", J.D. Joseph (ed.), NOAA Technical Memorandum NMFS SEFC - 234, 1989, pages 25-34.

- X. In a letter dated 16 April 2013 Opponent 2 stated:  
"Herewith our request for decision of the opposition/  
appeal division and our request for revocation of the  
European patent application before the European Patent  
Office are withdrawn."
- XI. With letter of 18 September 2013 the Respondent  
replaced the sets of claims filed with the reply to the  
grounds of appeal by four sets of amended claims as new  
main request and new auxiliary requests 1 to 3. It also  
requested not to admit into the proceedings the late  
filed documents D19 to D22.
- XII. The Board summoned the Parties to oral proceedings.
- XIII. Opponent 2 informed the Board with a letter of  
22 April 2014 that it was planning not to attend the  
forthcoming oral proceedings.
- XIV. In a communication (posted on 24 April 2014) issued in  
preparation for the oral proceedings, the Board  
indicated, *inter alia*,
- a possible discrepancy between claim 3 as maintained  
and some dependent claims of the main request and of  
the Auxiliary Request 3 filed with letter of  
18 September 2013
- and
- that Opponent 2 appeared "to have withdrawn (at  
least) its appeal with letter dated 16 April 2013 and  
expressly withdrew its request for revocation of the  
patent in suit".
- XV. In a letter of 25 April 2014 the Appellant extended its

novelty and inventive step objections to all pending requests of the Respondent. With the same letter, it filed new documents D23 to D25, the latter being:

D25 = An experimental report of A. McLachlan,  
dated 17 April 2014.

XVI. In a subsequent letter of 15 May 2014 the Appellant expressly stated that it no longer maintained its previously raised objections under Articles 83/100(b), 84 and 100(c)/123(2) EPC. It also acknowledged that: "Thin film distillation, molecular distillation and short path distillation are largely synonyms for a stripping process as claimed in the contested patent (molecular distillation being a subset of short path distillation). Such stripping process is well known to be applied to fish oil as a separation technique, and such separation technique belongs to the common general knowledge. Such a process can be implemented by the skilled person.

The volatile working fluid is equally well known to the skilled person, although it is generally named differently. A volatile working fluid will have a boiling point (or actually, a vapor pressure) at the reduced pressure "in the neighborhood of" a compound to be removed. Yet, the range of this boiling point can be broad."

XVII. The Respondent filed with letter of 15 May 2014 four sets of amended claims respectively labelled "Corrected Main Request" (below **Main Request**), "Corrected Auxiliary Request 1" (below **Auxiliary Request 1**), "Corrected Auxiliary Request 2" (below **Auxiliary Request 2**) and "Corrected Auxiliary Request 3" (below **Auxiliary Request 3**). In this letter the Respondent also requested the Board to adjourn the oral

proceedings in case the late filed additional experimental data D25 was regarded by the Board as relevant, and to apportion the costs incurred by the adjournment of oral proceedings such that they were borne entirely by Appellant for reasons of equity.

XVIII. The set of twenty claims according to this new **Main Request** only differs from the set of maintained claims (see above Section V) in that:

- the passage in maintained claims 1 and 16 reading

*"... ethyl ester, a fatty acid amide and a hydrocarbon,"*

is replaced in each of claims 1 and 16 of the Main Request by

*"... ethyl ester and a fatty acid amide,"*

and

- the passage in maintained claim 17 reading

*"a fatty acid ester"*

is replaced in claim 17 of the Main Request by

*"a fatty acid methyl ester, a fatty acid ethyl ester".*

In the new **Auxiliary Request 1**, claim 1 differs from claim 20 of the Main Request only in that the passage of this latter reading

*"... fatty acid ester, a fatty acid amide and a*

*hydrocarbon,"*

is replaced with

*"... fatty acid ester and a fatty acid amide,".*

Claim 3 of the Auxiliary Request 1 differs from claim 3 of the Main Request (and thus, also from claim 3 as maintained) in that the former comprises a passage reading

*"... said at least one of a fatty acid ester and a fatty acid amide"*

instead of the corresponding passage in claim 3 of the Main Request reading

*"... said at least one of a fatty acid methyl ester, fatty acid ethyl ester and a fatty acid amide".*

The remaining claims 2 and 4 to 18 of the Auxiliary Request 1 are respectively identical to claims 2, 4 to 13 and 15 to 19 of the Main Request, renumbered where appropriate.

The four claims of **Auxiliary Request 2** are identical to the use claims 16 to 19 of the Main Request, renumbered.

The **Auxiliary Request 3** only differs from the Auxiliary Request 2 only in that in claim 1 the wordings "*... in a process for decreasing ...*" and "*... in which process ...*" are respectively replaced by "*... for decreasing ...*" and "*... wherein ...*".

XIX. At the oral proceedings held before the Board on

27 May 2014 (in the announced absence of the duly summoned Opponent 2):

i) the **Respondent**

- withdrew its request for apportionment of costs as well as the sets of claims according to the requests filed with letter of 18 September 2013 and conceded that it belonged to common general knowledge that marine oils contained **cholesterol** in both **free** and **bound** form (below also **FC** and **BC**).

ii) the **Appellant** explicitly stated:

- that it did not object to the admission into the proceedings of the Respondent's requests filed with letter of 15 May 2014;

- to have no objection against the pending sets of claims under Articles 83/100(b), 84 or 100(c)/123(2) EPC;

- but that it maintained that the Main Request and Auxiliary Request 1 did not comply with the provisions of Rule 80 EPC;

- that it no longer maintained against the now pending sets of claims any of the novelty objections based on documents already on file before the filing of D19;

- but that it (still) considered that the subject-matter of claim 1 of the Main Request did not involve an inventive step vis-à-vis the prior art disclosed in the documents already on file before the filing of D19;

- that documents D19 to D22 and D25 should be admitted

because of their high relevance regarding novelty and of inventive step with respect to all the Respondent's requests;

- that it no longer requested, however, the admission into the proceedings of documents D23 and D24;

and

- to have no objection against the remittal of the case to the Opposition Division in case any of documents D19 to D22 and D25 were allowed into the proceedings.

Thus, the debate at the hearing focused on:

- the compliance of the Respondent's Main Request and Auxiliary Request 1 with the provisions of Rule 80 EPC;

- the Appellant's inventive step objection to the process of claim 1 of the Main Request on the basis of documents already on file before the filing of D19

and, finally,

- the admissibility into the proceedings of documents D19 to D22 and D25.

XX. Final requests submitted at the oral proceedings

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

The Respondent requested that the patent be maintained in amended form on the basis of the claims according to the Main Request or one of the Auxiliary Requests 1 to 3 filed with letter dated 15 May 2014 and,



in case one of the documents D19 to D25 were admitted into the proceedings, that the case be remitted to the Opposition Division for further prosecution.

XXI. The Parties' submissions may be summarized as follows.

The **Appellant** argued that the Main Request and the Auxiliary Request 1 did not comply with Rule 80 EPC for the following reasons:

i) The patent as granted comprised an independent process claim 1 and an independent use claim 17 relating to **processes** and **uses** defined only by means of features relating to the step of **stripping FC** together with a **volatile working fluid** (below **VWF, FC-VWF stripping processes** and **VWF uses**), as well as a process claim 15 dependent on claim 1 and directed to a variant of the FC-VWF stripping processes defined in claim 1, in which the marine oil residue (the product remaining after the stripping of the FC together with the VWF) is additionally subjected to trans-esterification and distillation(s) so as to isolate a marine oil (fraction) with a **reduced** amount of both **FC** and **BC** (below the **process** according to granted claim 15 is referred to as the **FBC reducing process**).

ii) However, the Respondent's Main Request and Auxiliary Request 1 both contained at least two different independent claims based on two different kinds of amendments of the originally granted independent claims, namely:

a) limitations in respect of the nature of the VWF used; see independent claims 1 and 16 of the Main Request and claims 1 and 15 of the Auxiliary Request 1

and

b) limitations to a FBC reducing process; see claim 20 of the Main Request and Claim 1 of Auxiliary Request 1.

The Appellant referred in particular to the reasons given in decision T 0642/06 of 17 March 2009, point 4.2 of the reasons.

Concerning the issue of inventive step with regard to claim 1 of the Main Request in the light of the prior art documents already on file before the filing of D19, the Appellant held that the claimed FC-VWF process represented an obvious alternative to the stripping processing step for removing cholesterol from marine oil disclosed in Example 2 of document D5, during which FC was necessarily also distilled off together with BC and the used fatty acid ester (i.e. oleyl monoglyceride) having a boiling point close to that of the BC.

The Appellant rejected as contrary to the claim's wording and to the content of paragraph [0014] of the patent in suit the Respondent's allegation that the process defined in claim 1 of the Main Request solved the technical problem of selectively removing exclusively the FC, i.e. a technical problem different from that addressed in the closest prior art D5.

In the opinion of the Appellant, also the allegation made by the Respondent as to the advantage possibly deriving from the fact that methyl or ethyl esters of fatty acids might have lower melting temperatures in comparison to the monoglyceride esters used in the prior art, had to be rejected as unproved and not mentioned or implied in the patent in suit.

The Appellant argued that the skilled person searching for an alternative to the stripping processing step disclosed in Example 2 of document D5 would find e.g. in Example 2 of document D3 a pointer to the possibility of using ethyl esters (albeit generated *in situ*) of fatty acids as VWF.

Alternatively, the skilled person starting from Example 2 of document D5, and aware of the common general knowledge apparent from the Hickman patents, would consider obvious to replace the fatty acid ester used in document D5 by any other fatty acid ester having a vapour pressure similar to that of cholesterol under stripping processing conditions. The skilled person would then also find in document D11 a pointer to the possibility of using fatty acid methyl esters.

The Appellant requested the Board to admit documents D19 to D22 and D25 because of their high relevance regarding novelty and inventive step with respect to all claims requests at issue. It stated that the filing of documents D19 to D22 only with letter of 20 December 2012 was due to the fact that the Appellant, while preparing for the opposition oral proceedings held on 7 November 2012 in respect of another European patent, had:

a) become aware of the existence of document D19

and

b) realized the relevance of documents D20 to D22.

As to the particular relevance of these documents, the Appellant pointed out the following:

- The specific teachings of documents D19 and D20 were more relevant than those disclosed in the documents already on file, because document D19 disclosed in example 5 the stripping in a molecular still of methyl esters of fatty acids previously added to a marine oil, and document D20 disclosed the use as VWF of a fatty acid whose boiling point was closer to those of the methyl or ethyl fatty acid esters than e.g. the boiling points of the monoglyceride of document D5 was.
  
- Document D21 and document D22, which was also referred to in document D21, had instead only been filed to prove that it belonged to common general knowledge that stripping processing steps (without VWFs) had been known since long as a way to remove cholesterol from fats and oils, such as marine oil, and that fatty acids and cholesterol were removed together.

The Appellant stressed that document D25 was just further evidence of a fact that was already evident to the skilled reader of document D19 *per se*, i.e. that under the stripping processing conditions used in the examples of D19 at least some FC was also necessarily distilled off together with the previously added VWFs. Since this fact had been disputed by the Respondent in its letter of 18 September 2013, the Appellant had only considered necessary to provide supporting experimental evidence after having received that letter. Due to difficulties in importing one of the ingredients needed to rework the stripping steps of examples 5 and 6 of document D19, it had only been able to file these experimental data with letter of 25 April 2014.

The **Respondent** argued that in the present case, the

simultaneous presence of three or two different independent claims in the Main Request and in Auxiliary Request 1 complied with Rule 80 EPC, since the amended sets of claims had been filed in order to overcome a novelty objection that had been raised during the opposition proceedings against the granted claims on the basis of document D5. In this connection the Respondent referred to decision T 0263/05 (OJ 2008, 239), insofar as it addresses issues under Rule 57(a) EPC 1973 (corresponding to Rule 80 EPC).

The Respondent rebutted the inventive step objections raised by the Appellant with respect to claim 1 of the Main Request that were based on the references already on file before the filing of document D19, arguing that the claimed FC-VWF stripping process did not represent a mere alternative to the process disclosed in document D5 based on the use of a different VWF. Indeed, the claimed process was directed to the selective removal of the FC. This was not only the sole reasonable interpretation of the claim wording, but was also proved by the experiments of 2010. The content of paragraph [0014] of the description of the patent as granted was not referring specifically to the case of using fatty acid methyl or ethyl esters, but rather to other, no longer claimed, VWF options.

In document D5 instead it was only the cholesterol in the form of fatty acid ester (i.e. BC) that was certainly distilled together with the monooleyl glyceride previously added to the marine oil.

Moreover, the claimed FC-VWF stripping process permitted to set the temperature on the condenser surface during the stripping to a value that was lower than that required in the prior art, because the

melting points of methyl and ethyl esters were lower than those of monoglyceride esters.

In any case, the inventive step attacks of the Appellant were both unconvincing for the following reasons:

i) Document D3 was silent as to the presence of cholesterol in any form in any of the fractions separated by means of stripping processing steps, not to mention its presence in those distilled-off fractions in which the fatty acid ethyl esters were present. Moreover, the initial degassing and stripping processing step disclosed e.g. in Example 2 of document D3, was carried out with the aim to remove volatile substances, i.e. used conditions possibly too mild in comparison to those required for removing the FC. The possible influence of differing stripping processing conditions was also apparent e.g. from the differences in temperature in Example 2 of document D5 between the first stripping processing step only aiming at deodorizing, and the subsequent stripping processing steps.

ii) The Hickman patents were very old references in which the molecular distillation (i.e. a stripping processing step) of marine oil associated with the use of certain low or high boiling fluids only aimed at isolating the vitamins contained in the condensed fraction, and not (as in the present invention) at obtaining a residue fraction with a reduced amount of cholesterol, not to mention of a reduced amount of FC.

iii) Document D11 only mentioned the addition of methyl esters of fatty acids as high boiling diluents that had to remain in the distilland, and not as volatile

ingredient that had to distill off together with a component of marine oil.

iv) Finally, the Appellant's assumption that the common general knowledge allegedly proved by the Hickman patents would render obvious to use as VWF any fatty acid ester having a volatility similar to that of cholesterol, was contrary to the expectation of the skilled person that also the reactivity or the similarity in chemical nature might result in that only some of the compounds belonging to the classes disclosed in general in these patents as possible VWFs, were actually suitable for separating certain marine oil ingredients.

Hence, the prior art filed before the filing of document D19 contained not even a pointer to the possibility of using ethyl or methyl esters of fatty acids for stripping BC from marine oil. As the process of claim 1 of the Main Request was rather directed to the selective stripping of FC, these prior art teachings could not possibly render obvious the claimed FC-VWF stripping process.

The Respondent objected to the admission into the appeal proceedings of the documents D19 to D22 and D25.

It stressed that document D19 was cited on the cover sheets of the US patent corresponding to the patent in suit and that documents D20 to D22 had been cited during the other opposition case referred to by the Appellant, well before the limit date for filing the statement of grounds of appeal in the present case. Hence, D19 to D22 could and should have been filed at latest at the beginning of the present appeal proceedings.

The Respondent additionally considered that none of the late filed documents D19 to D22 and D25 was of high relevance for the now pending sets of claims in view of the following:

i) Document D19 was silent as to the possible presence of cholesterol in any fraction obtained by molecular distillation (i.e. a stripping process), in particular example 5 only briefly referred to the addition of methyl esters of fatty acids to marine oil prior to molecular distillation for removing odorous substances, without even specifying the conditions used, thus there was no reason to presume that in this prior art example also some FC had to distill together with the methyl esters of fatty acids.

ii) Document D20 was cited for its disclosure of a single specific example of cholesterol stripping with a specific fatty acid that the Appellant had alleged, but not proved, to possess a vapour pressure that was closer to the vapour pressure of the fatty acid methyl or ethyl esters, than the vapour pressure of e.g. the monooleyl glyceride was.

iii) Document D21 failed to provide any details suggesting the use in the prior art of VWFs for that aim of removing cholesterol from marine oil.

iv) Document D22 was a safety manual of the U.S. Department of Commerce dealing with vacuum deodorization (i.e. a stripping processing step) of fish oil, thus it was *per se* insufficient to establish common general knowledge. Moreover, it did not disclose the same process as disclosed in document D21 (with reference to a possibly different publication of the same Department of Commerce that produced D22) since



document D21 referred to the vacuum stripping of mixture not containing fatty acids.

v) Finally, document D25 was an attempt to carry out an arbitrarily selected hypothetical version of example 5 of document D19, based on the unjustified assumption that the used distillation temperatures were the same used in example 6 of document D19.

The initial statement of grounds of appeal of **Opponent 2** concerned the maintained claims. Subsequently, Opponent 2 withdrew its request for revocation of the patent in suit and submitted no substantial or formal objection directed against any of the Respondent's requests filed during the appeal proceedings including those now on file.

## **Reasons for the Decision**

### *Status of Opponent 2*

1. As indicated in the communication dated 24 April 2014, the Board understands the letter of Opponent 2 dated 16 April 2013 as a withdrawal of its appeal (see VII *supra*). No comment on this point was provided in writing or orally by any of the parties.

Thus, the Board concludes that Opponent 2 is a Party as of right to these appeal proceedings (Article 107 EPC).

### *Admissibility of the Respondent's requests*

2. The Respondent's Main Request and Auxiliary Requests 1 to 3 at issue were only filed a few days before the day

of the oral proceedings.

2.1 The Board accepts, however, that they were filed in response to an objection raised in its communication of 24 April 2014 (see XIV *supra*). Moreover, their filing did not raise new issues of particular complexity. Finally, their admissibility was not disputed by the Appellant despite their late filing.

2.2 The Board therefore decided to admit into the proceedings the Respondent's Main Request and Auxiliary Requests 1 to 3 despite their late filing (Articles 114(2) EPC and 13(3) RPBA).

*Admissibility of documents D17 and D18*

3. These two citations were both filed together with the statement of grounds of appeal.

3.1 They manifestly constitute evidence of common general knowledge, and their admissibility was not disputed by the Respondent despite their late filing.

3.2 Thus the Board decided to admit Documents D17 and D18 into the appeal proceedings pursuant to Article 12(4) RPBA.

*Compliance of Respondent's Main request and Auxiliary request 1 with the provisions of Rule 80 EPC*

4. Rule 80 EPC stipulates that the claims of a granted European patent may be amended "provided that the amendments are occasioned by a ground for opposition under Article 100, even if that ground has not been invoked by the opponent".

4.1 Rule 80 EPC does not prohibit an amendment to a granted patent initially containing one independent claim whereby this latter is replaced by a plurality of independent claims, if this amendment is a necessary and appropriate response to a ground for opposition (see e.g. decision T 0263/05, Reasons 4.8).

4.2 The Appellant considered that the present Main Request and the Auxiliary Request 1 did not comply with Rule 80 because these Requests contained, respectively, three and two independent claims deriving from two different categories of amendments of the granted claims (see X *supra*).

In particular, it pointed out that according to the Main Request:

- claims 1 and 17 were directed to the FC-VWF stripping process and the VWF use resulting from the amendment of the corresponding granted claims 1 and 17 in respect of the kind of compounds to be used as VWF,

whereas

- claim 20 was directed to the same FBC reducing process as claim 15 as granted (which was a claim dependent on claim 1 as granted), according to which the marine oil residue resulting from the FC-VWF stripping is additionally subjected to trans-esterification and distillation(s).

Similarly, according to Auxiliary Request 1:

- claim 1 was directed to substantially the same FBC reducing process as claim 20 of the Main Request,

whereas

- claim 15 was directed to the same VWF use as claim 17 of the Main Request.

The Appellant considered both these claims Requests comparable to the set of amended claims rejected by another Board of Appeal in case T 0642/06, for the reasons given at point 4.2 of that decision.

- 4.3 The Board notes preliminarily that the factual situation underlying T 0642/06 is substantially different from that of the present case. Indeed, it is apparent from point 4.2 of T 0642/06 that the set of amended claims considered in that case comprised three independent product claims originating from alternative combinations of granted claim 1 with different dependent claims, none of which was exclusively dependent on granted claim 1. In the present Main Request and Auxiliary Request 1, instead, there are only process and use claims whereby the FBC reducing process (i.e. that claimed in claim 20 of the Main Request and in claim 1 of the Auxiliary Request 1) results from the combination of granted claim 1 with granted claim 15 which was only dependent on claim 1. Thus, the findings in T 0642/06 are not immediately applicable to the present case.

- 4.4 The Board notes further that each of the two different kinds of amendment identified by the Appellant, results in amended independent claims whose subject-matter is restricted compared to that of the corresponding independent process or use claims as granted. Hence, the two kinds of amendment made, being both substantial restrictions of the claimed subject-matter, can both be considered as being occasioned by, and as being an

appropriate response to, a ground for opposition under Article 100(a) EPC.

Accordingly, the Board sees no reason for reversing the finding of the Opposition Division (see VI above), undisputed by the Appellant, that these two kinds of amendment manifestly delimit the patented subject-matter in response to a novelty-objection invoked in the opposition proceedings (on the basis of document D5).

4.5 For the Board, the Appellant's argument that the two kinds of amendment of the granted claims resulting in the (three) independent claims now present in the Main Request, focus onto two different aspects of the patented invention, does not *ipso facto* imply that these amendments are inappropriate, still less when considering that in the present case, granted dependent claim 15 was directed to a process which, due to its additional processing steps, resulted in different products in comparison to those directly resulting from the processing steps defined in granted claim 1.

4.6 Hence, in the Board's judgement, the Respondent's Main Request and Auxiliary Request 1 both comply with Rule 80 EPC.

*Objections no longer maintained (all requests)*

5. Taking into consideration the findings of the Opposition Division in the decision under appeal and the arguments provided by the Respondent in the course of the appeal proceedings, the Board is satisfied that the claims of the Main Request and those of the Auxiliary Requests 1 to 3 comply with the requirements of Articles 100(b)/83, 84 and 100(c)/123(2) EPC.

Considering that the Appellant has explicitly stated at the hearing (see XIX *supra*) to have no corresponding objections against the sets of claims at issue, and that Opponent 2 withdrew its request for revocation and refrained from submitting any comments regarding the requests at issue, further details need not be given in this respect.

*Novelty - Main request - Claim 1*

6. Herein, the issue of novelty is dealt with regarding the subject-matter of claim 1 according to the Main Request and the prior art documents which were already on file before the filing of document D19.
- 6.1 The Board is satisfied that the subject-matter of claim 1 at issue is not anticipated by the prior art disclosed in these documents. The Board notes, in particular, that document D5, which was initially held to be novelty-destroying according to the two statements of grounds of appeal, does not disclose the use of a VWF complying with the definition given in claim 1 of the present Main Request, i.e. comprising at least one of a fatty acid methyl ester, a fatty acid ethyl ester and a fatty acid amide (see also point 7.2.2 below).
- 6.2 Further details on this issue need not to be given, since the Appellant has explicitly stated at the hearing (see XIX above) that it no longer maintained any of the novelty objections previously raised in view of the documents already on file before the filing of D19.

*Inventive step - Main request - Claim 1*

7. In the following, the issue of inventive step is only dealt with having regard the subject-matter of claim 1 according to the Main Request at issue and the prior art documents already on file before the filing of D19.

7.1 The invention

The invention as defined in claim 1 concerns a "*process for decreasing the amount of cholesterol in a mixture comprising a marine oil*" wherein the mixture is added with a VWF, and then subjected to a stripping processing step in which VWF is separated from the mixture together with FC.

7.2 Closest prior art

7.2.1 The Appellant considered document D5, and in particular Example 2 thereof, as the closest prior art, and the Respondent did not dispute that this prior art represented a suitable starting point for the assessment of inventive step. Considering the similarity of the process disclosed in D5 Example 2 and the issues addressed in this document, the Board has no reason to take a different stance.

7.2.2 Indeed, Example 2 of D5 discloses a process in which interesterified sardine oil, i.e. a "*marine oil*" in the broadest sense of claim 1, is initially added with monooleyl glyceride, then deodorized in a first stripping processing step and subsequently subjected to further stripping processing steps at higher temperatures (see document D5, from column 6, lines 33 to column 7, line 4). It is apparent from column 3, lines 45 to 49, that the added monoglyceride "also acts

the role of removing cholesterol", i.e. as a VWF in the sense of claim 1, in (at least one of) the stripping processing step(s), since it "has a boiling point near that of cholesterol". It is undisputed that the mixtures distilled off during (at least one of) the stripping processing steps, comprise (at least) "fatty acid ester of cholesterol" (i.e. a BC) "accompanied with the monoglyceride" (see column 4, lines 24 to 34). The Board notes that this latter passage is the only part of document D5 explicitly mentioning a BC, all other previously cited passages of this citation, as well as the Table 2, just mention "cholesterol" without specifying its form (bound or free).

Hence, this prior art is found to be explicitly directed to the removal of cholesterol - and in particular to the removal of BC - from marine oils, by means of a stripping processing step requiring a monoglyceride VWF.

7.2.3 Moreover, taking into consideration that BC has a higher boiling point than FC (as implicitly acknowledged in paragraph [0014], last sentence, of the patent in suit), the Board is convinced that during the stripping process step of Example 2 of document D5 - in which the monooleyl glyceride acts as VWF promoting the removal of BC - also at least some of the FC present is inevitably distilled off together with the monooleyl glyceride and the BC.

Thus, for the Board, the process disclosed in Example 2 of document D5 implies also the removal of some FC during the stripping processing step(s) in which the monooleyl glyceride is distilled off.



7.3 Technical problem according to the Respondent

The Respondent argued (see XXI above) that in the light of the closest prior art, the technical problem solved by the process of claim 1, when properly construed, was not merely to be seen in the the provision of an alternative process, but consisted in the provision of a process resulting in the selective removal of FC only, as proved by the experiments of 2010.

7.4 The solution

As the solution to this technical problem the patent in suit proposes the process for decreasing the amount of cholesterol in (a mixture comprising) a marine oil according to claim 1, which is characterised in particular in that it comprises the steps of (emphasis added)

**"- adding a volatile working fluid to the mixture, where the volatile working fluid comprises at least one of a fatty acid methyl ester, a fatty acid ethyl ester, and a fatty acid amide, and**  
**- subjecting the mixture with the added volatile working fluid to at least one stripping processing step, in which an amount of cholesterol present in the marine oil in free form is separated from the mixture together with the volatile working fluid."**

7.5 Alleged success of the solution

7.5.1 The Board notes preliminarily that claim 1 at issue is directed to a "process for decreasing the amount of **cholesterol**" in a marine oil and neither explicitly requires the selective removal of exclusively the FC, nor indicates any process parameter of the stripping processing step (e.g. the temperature and vacuum/

pressure to be applied) which could possibly render plausible that only the FC is distilled off.

For the Board, the requirement of claim 1 that "*an amount of cholesterol in free form*" must distill off together with the VWF, does not (literally or logically) exclude the simultaneous separation together with the mentioned FC and VWF, of substantial amounts of BC, or of some other ingredients.

Nor is the Respondent's restrictive interpretation of claim 1 at issue justified or implied in some way by the contents of the description of the patent in suit. Indeed only paragraph [0014] of the patent in suit (also present in the maintained version of the patent) provides relevant technical information, by indicating that the preferential, i.e. not necessarily exclusive, removal of the FC may be favoured when using VWFs that have boiling points lower than that of the BC.

However, claim 1 at issue imposes no direct or indirect limitation as to the VWFs' boiling points, let alone a limitation to VWFs having boiling points which are substantially lower than those of any BC. On the contrary, the boiling points of the compounds that claim 1 defines as VWF are known, or can be expected to, vary over broad ranges. This is evident when considering, for instance, the number of commercially available compounds that fall under the expression "*fatty acid amide*" and have chemical residues of substantially different dimensions (and, possibly even substantially different polarity) on both sides of the amide bond. The same is also evident in respect of the more restricted (due to the limitation to just methyl or ethyl esters) definition of the fatty acid ester VWFs. Already the methyl esters of e.g. the naturally

occurring C10 to C22 fatty acids (i.e. those indicated as preferred VWF in paragraph [0073] of the patent in suit) show quite different boiling points as evident from the figure reported on page 7 of the statement of grounds of appeal of the Appellant.

Whether or not the experiments of 2010, using as VWF a "*fatty acid ethyl ester mixture*" (which is not further specified), show that the selective removal of FC may actually be obtained in some very specific embodiments of the claimed process, has no particular bearing on the validity of the above considerations.

Hence, the Board does not accept that the FC-VWF process of claim 1 successfully solves, across the full breadth of the claim, the problem of providing providing a process for selective and exclusive removal of FC from the mixture comprising marine oil.

- 7.5.2 The Respondent additionally argued (see XXI above) that the use of methyl and ethyl esters in FC - VWF stripping processing step instead of monoglyceride esters resulted in a further technical advantage: due to the lower melting point of the methyl and ethyl esters as compared to monoglyceride esters, the claimed process permitted to set the temperature on the condenser surface of the stripping processing apparatus to a lower value.

The Board finds this argument (which in any case does not apply to the claimed VWF's option "*fatty acid amides*") unconvincing for the following reasons:

- firstly, this alleged advantage is not even indirectly foreshadowed in the patent in suit;

and

- secondly, it is based on an unsupported, very general and, hence, questionable allegation implying lower melting points of (any) methyl/ethyl esters in comparison to those of (any) monoglyceride esters, allegation that has been disputed by the Appellant.

7.5.3 Hence, the Appellant did not convince the Board that the FC-VWF process of claim 1 of the Main Request provides some technical advantage over the process of D5/Example 2, let alone across the full breadth of claim 1.

7.6 Reformulation of the technical problem

Accordingly, the technical problem solved in the light of the closest prior D5 must be formulated in a less ambitious manner and can be seen in the mere provision of a further process for reducing the amount of cholesterol, including FC, present in marine oils.

7.7 Success of the solution according to claim 1

It is undisputed among the Parties that the claimed FC-VWF process allows to reduce the amount of cholesterol in marine oils. The Board also considers it technically plausible that the intended result is achieved by the claimed process.

7.8 Non-obviousness of the solution

7.8.1 The Appellant argued (see XXI above) that the proposed solution was obvious in view of a combination of document D5 with either document D3 or common general knowledge apparent from the Hickman patents and D11.

In the opinion of this Party the skilled person starting from the teaching in document D5 that stripping processing steps allow to distill off cholesterol together with certain fatty acid ester VWFs (i.e. monoglycerides) having a boiling point close to that of the cholesterol, would consider obvious to replace these fatty acid ester VWFs either

- by the fatty acid ethyl esters (albeit generated *in situ*) already used according to document D3 (see e.g. Example 2a) as VWF for stripping marine oils,

or

- by the fatty acid methyl esters already used according to document D11 (see page 4, lines 67 to 75) for the same purpose.

In the Appellant's opinion the relevance of this latter disclosure would be all the more evident for a skilled person, who was also certainly aware of the common general teaching of the Hickman patents and, thus, considered obvious in general to replace any VWF previously used in a stripping processing step, by any fatty acid ester having a similar vapour pressure.

7.8.2 As regards the combination with D3, the Board notes, however, that this document (and in particular Example 2 thereof) is totally silent on the presence of cholesterol (in any form) in any of the fractions separated by means of stripping processing, let alone on the presence of FC in those collected fractions in which the fatty acid ethyl esters were present.

Hence, the Board finds that it is not apparent from Example 2 and the remainder of the description of

document D3 that under the specific stripping conditions described some cholesterol was removed from the marine oil together with the fatty acid ethyl esters (generated in situ). Indeed, as correctly observed by the Respondent, and not disputed by the Appellant, a stripping processing with VWF may also be used for removing volatile odorous substances only. This is confirmed by e.g. Example 2 of D5, wherein the initial stripping processing step described at column 6, lines 38 to 46, is described as a mere deodorization, and is carried out at substantially lower temperature than the subsequent stripping processing steps.

Thus, for the Board, D3 contains no clear pointer to the possibility of using fatty acid ethyl ester as VWF in a stripping processing step for distilling off cholesterol (in any form) from marine oil.

- 7.8.3 Also the Hickman patents, including D11, do not appear to contain any pointers to fatty acid methyl or ethyl esters as possible VWFs that can be distilled off together with cholesterol when stripping processing marine oils.

The Appellant's reasoning appears to be implicitly based on the assumption that the Hickman patents can be considered to prove that common general knowledge at the effective filing date of the patent in suit encompassed the knowledge that e.g. any fatty acid ester compound (regardless of its structure/nature) can represent a VWF suitable for separating any compound present in a marine oil, as long as the boiling points of these two compounds were sufficiently close to each other.

For the following reasons, the Board does not accept, however, that such a common generic knowledge or teaching can be extracted from the said bundle of patents without *ex post facto* considerations, let alone that it can be considered to constitute common general knowledge. For instance, as pointed out by the Respondent, a skilled person would reasonably expect other factors (chemical and physical properties due to specific structure) to have a bearing on the suitability of a given fatty acid ester as VWF for certain marine oil ingredients, but not for others. This is also (at least in part) confirmed e.g. in the passage at page 1, right column, lines 39 to 49, of document D12 reading (emphasis added by the Board): "The materials to be added **may be selected** from widely different types of compounds or mixtures thereof. Any material may be used as long as it has a boiling point in the neighborhood of the distillate desired, under molecular distillation conditions **and has no adverse effect on the material undergoing treatment**. Thus, fatty acids, esters, mineral oil fractions, terpenes, essential oils and the like have been found to give useful results. Of course, a compound which is subject to material decomposition **should not be selected**."

Thus, in the Board's judgement,

- the Hickman patents at most render plausible the existence of a teaching generally accepted at the time of their publication only in respect of the correlation that exists between the boiling points of the ingredients that are actually disclosed as suitable VWFs, and the marine oil ingredients that are actually disclosed as distilled off (during the stripping processing steps) using such VWFs,

and

- hence, the Appellant's allegation as to a generally known and accepted teaching in respect of the stripping of any ingredient of marine oil with any fatty acid ester having the appropriate boiling point, is not established by the contents of the Hickman patents.

The Board additionally notes the there is no mention in the Hickman patents of a stripping precessing step resulting in a distilled-off fraction comprising cholesterol (in any form), let alone of any specific example or class of ingredients that is qualified as suitable VWF for stripping cholesterol.

The Board notes, last but not least, that in all the Hickman patents the only mention of fatty acid methyl esters is that contained in lines 66 to 75 of page 4 of D11. However, in this passage the cited "methyl oleate and stearate" are clearly added as high boiling "diluent of the distilland" that have to remain in the residue of the stripping processing step. Since these fatty acid methyl esters are not used as compounds to be distilled off, they are not suggested (in D11 or in any other of documents from the whole group of Hickman patents) as VWFs in the sense of claim 1 at issue, let alone as VWFs for cholesterol removal.

- 7.8.4 From the above, the Board concludes that starting from D5/Example 2 as the closest prior art, the subject-matter of claim 1 of the Main Request involves an inventive step (Article 52(1) and 56 EPC) in the light of the prior art invoked by the Appellant, i.e. D3, D11 or any general common teaching that may be derivable from the Hickman patents.



*Admissibility of documents D19, D21 and D25*

8. Document D19

8.1 D19 was filed, together with documents D20 to D22, at a late stage of the written appeal procedure (with letter of 19 December 2012), but long before the parties were summoned (in 2014) to oral proceedings.

8.2 The Appellant submitted that the belated filing of D19 to D22 was due to the fact that it had only become aware of the these documents and their relevance when preparing for the oral proceedings in another opposition case.

8.3 In the present case, the Board had no reason to disbelieve this explanation. Moreover, for the Board, the fact stressed by the Respondent and undisputed by the Appellant that this document could in principle have been considered and invoked by the Appellant well before the limit date for filing the statement of grounds of appeal, does not permit to conclude that that the late filing of this document amounted *ipso facto* to an intentional abuse of the proceedings.

8.4 As to the relevance of document D19 the Board notes the following

8.4.1 As pointed out by the Appellant, it was not disputed that the amended sets of claims filed by the Respondent with letter of 18 September 2013 manifestly aimed to overcome a novelty objection based on (Example 6 of) document D19. The filing of these amended claims can thus be regarded as an implicit acknowledgement by the Respondent of the very high relevance of this document.

8.4.2 Moreover, this document, although also being silent on the removal of cholesterol, appears to potentially disclose one of the features of the claimed FC-VWF stripping processes and/or VWF uses that is not disclosed in any of the documents already on file. Indeed, Example 5 of document D19 discloses the stripping processing of marine oil previously added with methyl esters of fatty acids, whereby "simple esters" (i.e. possibly also the added methyl esters) were collected as distillate, unlike in the process of document D11, according to which, as discussed above, the mentioned methyl esters of fatty acids are explicitly qualified as high-boiling diluents that remain in the distilland.

8.4.3 Thus the Board concludes that disclosure of document D19 is *prima facie* of very high relevance in the sense that there is a high likelihood that it could prejudice the maintenance of the patent. Moreover, it is more relevant than that of the previously filed documents as regards the claimed use of methyl esters of fatty acids.

9. Document D21

9.1 D21 was filed together with D19.

9.2 Nevertheless, it is common ground between the Parties that this document (with particular references to pages 218 and 219) only constituted further evidence of the common general knowledge referred to by the Appellant since the beginning of the opposition proceedings, i.e. regarding the known use of stripping processing steps to, *inter alia*, remove cholesterol from fats or oils including marine oils.

10. Document D25

10.1 This document was only filed with letter of 15 Mai 2014, i.e. a few days before the oral proceedings.

10.2 According to the Appellant's, it was filed so very late for two reasons:

i) The Respondent had, on the one hand, only disputed the occurrence of FC removal (during the stripping of the methyl esters of fatty acid or the Nujol added to the marine oils) in Examples 5 and 6 of document D19 with letter of 18 September 2013, i.e. it had disputed something that was, in the Appellant's understanding of D19, implicit and self-evident just upon reading document D19.

ii) On the other hand, it had been difficult for the Appellant to obtain and import one of the ingredients needed to rework the stripping steps of these two prior art examples.

The Board notes that this was not disputed by the Respondent. Hence, the Board has no reason to consider that the late filing of document D25 amounted to an intentional abuse of the proceedings.

Moreover, it is apparent to the Board that this experimental evidence is an attempt to rework the same Examples disclosed in document D19, whose relevance has been discussed above. Thus, the same degree of relevance is acknowledged also for the experimental data in document D25, for the same reasons.

11. In view of the above, and taking also into account the provisions of Article 114(2) EPC and Articles 13(1)

RPBA decided to admit documents D19 and D21, into the proceedings despite their late filing.

Since D25 is complementary evidence concerning the disclosure of the admitted document D19, and was filed in response to arguments calling into question some aspects of the disclosure of D19 without apparently intended delay, the Board decided to also admit D25 into the proceedings despite its very late filing (Article 13(3) RPBA).

*Non-admissibility of documents D20 and D22*

12. Documents D20 and D22 were also filed with letter of 19 December 2012.

12.1 As regards D20, it is apparent that this document has not been cited to prove the existence of common general knowledge, but rather for the disclosure of a specific example on page 88.

As regards D22, the Appellant has provided no reason rendering credible its allegation, disputed by the Respondent, that the disclosure of this citation, which is neither a textbook nor a handbook, belonged to common general knowledge in this field.

12.2 Thus, to be potentially considered as admissible (pursuant to Article 114(2) and 12(4)/13(1) RPBA), D20 and D22 would have to be prima facie more relevant (at least under some aspects) than the documents already in the proceedings. In the Board's judgement, this is not the case for the following reasons:

12.2.1 Regarding D20, the Appellant argued that it was relevant because it disclosed a cholesterol stripping

processing step based on a VWF ingredient (i.e. linoleic acid, see page 88 of document D20, section "3") whose boiling point was closer to the boiling points of the fatty acid methyl or ethyl esters than e.g. the boiling point of the mono-oleyl glyceride (used in Example 2 of document D5).

For the Board, this argument on the proximity of boiling points is, however, an unsupported allegation that was disputed by the Respondent.

12.2.2 The specific disclosure of D22 undisputedly does not relate to any stripping processing steps requiring VWFs.

12.3 If alone for these reasons, the Board, in the exercise of its discretion under the provisions of Article 114(2) EPC and Articles 12(4) and 13(1) RPBA, decided not to admit documents D20 and D22 into the proceedings.

*Remittal of the case*

13. Taking into account that patentability issues arising from the admission of documents D19, D21 and D25 into the proceedings have not been addressed before the department of first instance, the Board considers it appropriate to remit the case to the Opposition Division in accordance with the Respondent's request to this end (Article 111(1) EPC).

## Order

### For these reasons it is decided that:

The case is remitted to the Opposition Division for further prosecution on the basis of the claims according to the requests filed with the letter of 15 May 2014.

The Registrar:

The Chairman:



D. Magliano

B. Czech

Decision electronically authenticated