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Datasheet for the decision of 25 November 2009

Case Number: T 0502/07 - 3.3.01

Application Number: 97930494.6

Publication Number: 0914329

IPC: C07J 9/00

Language of the proceedings: EN

Title of invention:
Method of manufacturing an ester mixture

Patentees:
Unilever N.V., Unilever PLC

Opponent:
RAISIO BENECOL LTD.

Headword:
Sterol fatty acid esters/UNILEVER

Relevant legal provisions:
EPC Art. 123(2), 54, 56
EPC R. 115(2)
RPBA Art. 15(3)

Relevant legal provisions (EPC 1973):
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Keyword:
"Admissibility of late filed document (yes)"
"Main and first auxiliary request novelty (yes) - no clear and unambiguous disclosure; inventive step (no) - obvious measurement"
"Second and third auxiliary request: amendment supported by the application as filed (no)"

Decisions cited:
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Catchword:
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Case Number: T 0502/07 **-** 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 25 November 2009

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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 22 January 2007 revoking European patent No. 0914329 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: P. Ranguis
Members: G. Seufert
C.-P. Brandt

Summary of Facts and Submissions

I. The Appellant (Patent Proprietor) lodged an appeal against the decision of the Opposition Division of 22 January 2007 on the revocation of the European patent No. 914 329.

II. Independent claim 1 of the patent as granted reads as follows:

1. Process for the manufacture of an ester mixture comprising the steps of:

(a) hydrolysing a sterol ester or a mixture of sterol esters for at least 80%, such that a mixture is obtained comprising phenolic and/or fatty acids, and free sterols; and
(b) separating the phenolic acids and/or fatty acids from the reaction mixture; and
(c) esterifying the so obtained free sterols with C_2-C_{22} fatty acids.

III. In this decision the following numbering will be used to refer to the documents:

(6) US-3,691,211
(10) JP-A-47-029301 - WPI abstract
(10a) Respondent's English translation of JP-47-029301
(10b) Appellant's English translation of JP-47-029301
(11) US-5,290,579
(13) R. Todd Lorenz et al., Analysis of Steryl Esters, 1989, 33-46
(15) JP 69/004974 & English translation
(16) US-2,715,638

IV. Opposition was filed by the Respondent (Opponent) requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC in combination with Article 54 and 56 EPC) and insufficiency of disclosure (Article 100(b) EPC in combination with Article 83 EPC).

V. The decision under appeal was based on a main request filed with letter of 20 October 2006, wherein independent claims 9 and 10 of the patent as granted had been deleted maintaining solely claims 1-8 as granted with a minor correction in the dependency in claim 8, and on an auxiliary request filed during oral proceedings before the Opposition Division.

The Opposition Division held that the subject-matter of the main request as well as the auxiliary request was novel over the documents (10) and (15), as none of these documents discloses the degree of hydrolysis required in step a) of the claimed process, but did not involve an inventive step in view of document (10) alone, or in combination with document (6).

VI. With the statement of the grounds of appeal the Appellant filed a main and three auxiliary requests. The main request corresponds to the main request on which the Opposition Division based its decision and thus to the claims 1-8 as granted.

Claim 1 of the first auxiliary request is distinguished from claim 1 of the main request in that step a) and consequently step b) were modified and reads as follows:

1. Process for the manufacture of an ester mixture comprising the steps of:

(a) hydrolysing a sterol ester or a mixture of sterol esters for at least 80%, such that a mixture is obtained comprising **phenolic acids or phenolic acids and fatty acids**, and free sterols; and
(b) separating **the phenolic acids** from the reaction mixture; and
(c) esterifying the so obtained free sterols with C_2-C_{20} fatty acids.

Claim 1 of the second auxiliary request is based on claim 1 of the first auxiliary request with additional amendments in steps (a) and (c) and reads as follows:

1. Process for the manufacture of an ester mixture comprising the steps of:

(a) hydrolysing a sterol ester or a mixture of sterol esters for at least 80%, such that a mixture is obtained comprising **phenolic acids and fatty acids**, and free sterols; and
(b) separating the phenolic acids from the reaction mixture; and
(c) esterifying **the resulting mixture of free sterols and C_2-C_{22} fatty acids remaining in the reaction mixture**.

Claim 1 of the third auxiliary request is based on claim 1 of the second auxiliary request and contains an additional amendment in step (c), which reads as follows:

(c) esterifying the resulting mixture of free sterols and C_2-C_{22} fatty acids remaining in the reaction mixture **after removal of phenolic acids**.

The Appellant also filed its own translation of document (10), i.e. document (10b)

VII. With letter of 30 January 2008 the Respondent informed the Board of its withdrawal from the appeal proceedings. Accordingly, the request for oral proceedings made in its response to the statement of grounds of appeal was withdrawn.

VIII. With the summons to oral proceedings, the Board sent a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), indicating its preliminary opinion. In particular, the Board indicated that claim 1 as granted would not appear to exclude further process steps, like isolation and purification steps. Furthermore, the alleged fact that step (c) of the process was to be carried out in the reaction mixture was not apparent to the Board in view of the work-up procedure described in example I. Concerning the admissibility of the documents (15) and (16) the Board considered at least document (15) as being already part of the proceedings and prima facie relevant for the assessment of novelty and/or inventive step. It was further indicated that documents (10), (11) and (15) were all considered as describing a process with the steps (a) to (c) without, however, explicitly mentioning the degree of saponification as required in the process step a). Carrying out the hydrolysis as complete as possible or removal of undesired compounds like the phenolic or fatty acids would not, however,

appear to require inventive skills. Furthermore, the Board raised concerns regarding the compliance of claim 1 of the second and third auxiliary requests with the requirements of Article 123(2) EPC.

IX. With letter of 21 September 2009 the Respondent confirming its withdrawal from the appeal proceedings informed the Board that it would not be attending the oral proceedings.

X. With letter dated the 23 October 2009 the Appellant withdrew its request for oral proceedings. It did not comment in substance to the objections raised by the Board in its communication.

XI. The arguments submitted by the Appellant in the written procedure to the extent that they are relevant for this decision can be summarised as follows:

- late filed documents:
Documents (15) and (16) were late filed and should be considered inadmissible. Document (16) was not admitted at first instance and document (15) was found not to be relevant for the purpose of novelty, although it had been admitted by the Opposition Division as ***prima facie*** relevant for this issue without, however, providing any reasons.

- claim interpretation:
From a proper reading of the description of the patent in suit it is clear that the process of the invention does not include steps for the isolation of the sterols from the reaction mixture or their purification prior to the re-esterification step (c). This reading is

supported by paragraph [0028] of the description, example I, wherein the oily layer obtained after removal of the ferulic acid and glycerol is directly and without any isolation esterified, and claim 4, which allows for the presence of 10-95% of unspecified material in the starting material, which will remain in the reaction mixture with the free sterols after step (b).

- inventive step:

Although selected by the Opposition Division, document (10) is not a suitable starting point for the assessment of inventive step as it is not related to the same technical field. The patent in suit aims at providing a simple process for the preparation of sterols for food purposes while document (10) is concerned with the manufacture of pharmaceutical compounds. Document (11), which is at least concerned with the same technical field, namely the production of edible, enriched rice bran oil for food purposes, is a more reasonable starting point for examining inventive step. Irrespective of the unsuitable selection of document (10) as the closest prior art, the subject-matter of claim 1 of the main request is also inventive over the teaching of this document. The process according to document (10) requires a lengthy and complex process for the isolation and purification of the free sterols after their hydrolysis and before their re-esterification. The removal of phenolic and/or fatty acids from the reaction mixture, followed by the addition of the C_2-C_{22} fatty acid to the reaction mixture for the re-esterification without the need for isolation of purified sterols as required by the presently claimed process simplifies the process of the

prior art and is neither taught nor envisaged by document (10).

- amendments:

The amendments in claim 1 of the first auxiliary request narrow the scope of the patent as granted and are supported by the original claim 2 as well as by page 7, lines 29-34 and page 4, lines 9-15 of the description as filed.

Claim 1 of the second auxiliary request is further limited to specify that the reaction mixture after hydrolysis in step (a) comprises phenolic and fatty acid, that in step (b) phenolic acid is removed and that in step (c) the esterification is carried out in the resulting mixture of sterols and C_2-C_{22} fatty acid mixture remaining in the reaction mixture. The use of the remaining fatty acids, after removal of phenolic acids, for re-esterification is supported by page 7, lines 29-34, page 8, lines 13-16 and, more specifically, by the examples I and II of the application as filed. The amendments in the third auxiliary request are based on the same support in the original application as the second auxiliary request. The only difference between these two requests is that the third auxiliary request is "even more linguistically precise".

XII. The arguments of the Respondent in the written procedure to the extent that they are relevant for this decision can be summarised as follows:

- claim interpretation

The Appellant's interpretation that the sterols are not isolated from the reaction mixture in the process of the patent in suit is inaccurate considering that the esterification process is not conducted on the reaction mixture as provided by the hydrolysis step (a), but on sterols which have been "isolated/extracted/separated" from the water soluble components of the original reaction mixture. Furthermore, since claim 1 refers to "a process .... comprising the steps of ...." further isolation steps between steps (b) and (c) are not excluded. Paragraph [0028] of the patent in suit also does not support the Appellant's interpretation, as this passage teaches that no isolation of sterols is necessary prior to the claimed process steps.

- novelty

Claim 1 of the main request lacks novelty over the disclosure of document (10) and (15). Example 1 or example 2 in combination with page 2, lines 5-20 of document (15) describe a process with the same steps as the presently claimed process. In both examples the sterol has been obtained in the form of crystals, which indicates that complete hydrolysis has occurred. Furthermore, example 1 of document (15) states that safflower oil was saponified, which the skilled person would interpret as clearly referring to 100% hydrolysis. A process with all the features of claim 1 is also disclosed in examples 1 and 2 of document (10). The term "triterpene alcohol" referred to in document (10) is considered to fall within the term "sterol" with regard to paragraph [0045] of the patent is suit. Furthermore, document (10) is specifically concerned with oryzanol, which is a preferred embodiment of the

patent in suit. The requirement of hydrolysis of at least 80% is met in view of the use of the strong sodium hydroxide solution which would inevitably result in 100% hydrolysis.

- inventive step:

The patent in suit is concerned with a process for the manufacture of sterol ester mixture as stated in claim 1 and paragraph 1 of the patent in suit. There are no restrictions as to any specific use. For an inventor a reasonable starting point would therefore be known processes for making such mixtures. Document (10) referring to such a process belongs therefore to the same technical field and represents a suitable starting point for assessing inventive step. Concerning inventive step the Respondent agrees with the opinion of the Opposition Division that it would be obvious for the skilled person to aim for a complete conversion of the sterol ester starting material when wanting to obtain the maximum of free, i.e. unesterified, sterol for the re-esterification step. The first auxiliary request lacks inventive step for the same reasons.

- amendments:

The amendments in the second and third auxiliary request are not supported by the application as filed as there is no direct and unambiguous disclosure that the esterification is conducted in the reaction mixture. The reaction mixture in the patent in suit is extracted into two phases and provided that no isolation takes place, which is not excluded, the esterification is conducted in the phase/extract containing the sterol (and fatty acid).

XIII. The Appellant requested

- that the decision under appeal be set aside,

- that the patent be maintained on the basis of the main request or, alternatively, of the first to third auxiliary requests filed with the statement of the grounds of appeal,

- that documents (15) and (16), which were late filed during the opposition procedure, be omitted from the appeal proceedings, and

- that the case be remitted to the first instance for the adaptation of the description, if a set of claims is deemed to meet the requirements of the EPC.

XIV. The Respondent requested that the appeal be dismissed.

XV. At the end of the oral proceedings, which took place on 25 November 2009 in the absence of both parties, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. *Non-appearance at oral proceedings before the Board*

2.1 As announced (see points VII, IX and X above) neither the Appellant nor the Respondent were present at the oral proceedings to which both parties had been duly

summoned. In the present case, the Board considered it appropriate to proceed by holding the oral proceeding as scheduled in the absence of the Appellant (Rule 115(2) EPC and Article 15(3) RPBA).

2.2 In accordance with Article 15(3) RPBA, the Board relied for its decision only on the written submissions of the parties as set out in the Appellant's statement of grounds of appeal and the Respondent's reply. The Board was in a position to decide at the conclusion of the oral proceedings, since the case was ready for decision (Article 15(6) RPBA) and the absence of the Appellant is not a reason for delaying a decision (Article 15(3) RPBA).

2.3 The Appellant had been informed with the Board's communication annexed to the summons to oral proceedings of the objections raised against the patent in suit, to which it did not reply in substance. It could have reasonably expected that during the oral proceedings the Board would consider these objections. Hence, the Board concludes that the Appellant had an opportunity to present comments on the grounds and evidence on which the Board's decision, arrived at during oral proceedings, is based. The right to be heard under Article 113(1) EPC has therefore been satisfied despite the absence of the Appellant at the oral proceedings.

3. *Admission of late filed documents by the Opposition Division*

3.1 Document (15) has been filed by the Opponent/Respondent within the time limit for making written submissions

and/or amendments set by the Opposition Division in the summons to oral proceedings, i.e. two month before oral proceedings. During the oral proceedings the admissibility of this document had been discussed and the Opposition Division had decided to admit the document into the opposition proceedings (see point 3 of the minutes), since it was found **prima facie** relevant for the question of novelty (see point 3 of the reasons of the decision).

3.2 The Board notes that in accordance with Article 114(2) EPC it is within the discretion of the Opposition Division to admit late filed documents, if there are prima facie reasons to suspect that the documents would prejudice the maintenance of the patent in suit. The Opposition Division had apparently agreed with the Opponent's/Respondent's opinion that document (15) discloses a process comprising the steps (a) to (c) (see decision page 7, point 4.3 second paragraph, first sentence). Since the Opponent/Respondent further argued that the degree of hydrolysis was an inherent feature of the process described in document (15), the Opposition Division in the Board's opinion had good reasons to consider this document as **prima facie** relevant for the issues of novelty and/or inventive step and to admit it into the proceedings, notwithstanding the fact that finally it did not follow the Opponent's arguments with respect to an inherent disclosure of the degree of hydrolysis or that it decided to take a different document as starting point for the assessment of an inventive step.

Hence, the Board considers that the Opposition Division had exercised its discretion correctly and that document (15) forms part of the proceedings.

3.3 In view of the negative outcome with respect to inventive step of the claimed subject-matter as set out in point 7 below, a decision of the Board on the admissibility of document (16) is unnecessary.

4. *Sufficiency of disclosure*

4.1 Sufficiency of disclosure was no longer contested during the appeal proceedings, nor does the Board see any reason to take a different view to the Opposition Division. Hence, it is unnecessary to go into more detail in this respect.

5. *Interpretation of the claims*

5.1 Claim 1 of the patent in suit concerns a process for the preparation of an ester mixture comprising hydrolysing a sterol ester or sterol ester mixture to yield a mixture of phenolic and/or fatty acids and free sterols, separating the phenolic and/or fatty acids from the reaction mixture and esterifying the so obtained free sterols with C_2-C_{22} fatty acids.

5.2 According to the Appellant this claim, in view of the description, does not include processes whereby the free sterols obtained in step (b) are isolated prior to the re-esterification step (c). In its opinion step (b), which requires the separation of phenolic and/or fatty acids from the reaction mixture, leaves a reaction mixture comprising the sterols and any acid left after

step (b). The C_2-C_{22} acids are added to the reaction mixture containing the sterols and any remaining acids and esterification to form sterol esters is carried out in **the reaction mixture** (emphasis added by the Appellant).

5.2.1 In support of its interpretation the Appellant referred to paragraph [0028] of the description of the patent in suit, which in its opinion clearly shows that the process of the invention does not include the isolation of sterols from the reaction mixture prior to re-esterification.

5.2.2 Furthermore, the Appellant referred to example I of the patent in suit, in which a crude soap stock containing ferulic acid esters of sterols, tri-acyl glycerols and fatty acid soaps is used as a starting mixture. This mixture is hydrolysed to form a mixture containing free sterols, i.e. unesterified sterols, fatty acids, ferulic acid and glycerol. The ferulic acid and the glycerol are removed, leaving the sterol and the fatty acids in the oily layer. This oily layer is then esterified directly without any isolation of the free sterols.

5.2.3 Finally, the Appellant pointed to claim 4 of the patent is suit, which requires that the sterol ester or the sterol ester mixture is present in the reaction mixture at concentrations of 5% to 90%. The Appellant concluded that if the process as granted is carried out on such a starting material, it is clear and inevitable that 10-95% of further unspecified material may be present in the reaction mixture, which will remain in the

reaction mixture together with the free sterols after separation of the phenolic and/or fatty acids.

5.3 The Board cannot follow the Appellant's interpretation of the claims.

5.3.1 Claim 1 as granted refers to a process for the preparation of an ester mixture **comprising** the steps (a) to (c). The expression "comprising the steps" in this context is not limiting and does not exclude further process steps to be carried out before the step (a), after the step (c) or even between each of the steps provided that such "in between" steps are technically meaningful and feasible. Isolation and purification steps are therefore not excluded.

5.3.2 The Board, considering the wording of the claim as well as the description and example I of the patent in suit, which is the only detailed example of the claimed process, can also not agree with the Appellant's opinion that the re-esterification step (c) is carried out in the reaction mixture without isolation of the sterols. Step (c) of the claimed process refers to the esterification of the "so obtained sterols". The meaning of this expression is not equivalent to the meaning the "reaction mixture comprising the sterols" and such a particular meaning, in the opinion of the Board, is also not apparent from the description or example I of the patent in suit.

5.3.3 In example I the reaction mixture after hydrolysis, however already without the solvent, is acidified by addition of water containing hydrochloric acid, thus forming separable layers. After the separation of the

phenolic acid together with glycerol, which is a part of the reaction mixture, with the aqueous bottom layer, the top layer containing the sterols (and fatty acids) is washed with water, which could be considered as a purification step, and dried by evaporating the water under vacuum (5mm) at 95°C for 1 hour. Thus, the reaction mixture has been worked up and the sterols have been "isolated" from the reaction mixture before esterification took place.

5.3.4 The Board acknowledges that in example I the sterols are isolated in combination with specific fatty acids, namely those present in rice bran oil. This, however, is due to the fact that example I reflects a specific embodiment of the invention, i.e. where the starting material contains a source of fatty acids (i.e. in example I alkali salts of free fatty acids and tri-acyl glycerols) and the fatty acids have not been removed. Claim 1, however, is not limited to such a particular embodiment. Step (a) of claim 1 merely refers to the hydrolysis of a sterol ester or a sterol ester mixture, which includes pure sterol esters or sterol ester mixtures as acknowledged in the patent in suit (see column 4, lines 31-33). There is also no indication in the patent in suit that the sterol esters are necessarily sterol esters with fatty acids (see paragraph [0018]). Carrying out the process of example I with such a starting material will result in the isolation of free sterols without fatty acids. Furthermore, according to the wording of claim 1 the fatty acids can be removed before esterification.

5.3.5 The Board is also unable to find support for the Appellant's interpretation that no isolation of the

sterols prior to re-esterification takes place in the statement of paragraph [0028] of the description. This statement refers to the possible use of a specific starting material, namely a mixture of sterol and sterol derivatives (i.e. sterol esters). Reference to the isolation of sterols is only made in the context of isolating specific sterols **prior** to subjecting the mixture to the claimed process. Furthermore, paragraph [0028] refers to the re-esterification of fatty acid sterol esters and phenolic acid sterol ester (meaning apparently the re-esterification of the sterols obtained from fatty acid and phenolic acid ester sterols) with fatty acids and the esterification of the already present free sterol. There is no disclosure that the re-esterification of the sterols takes place in the reaction mixture or even with the same fatty acids resulting from the hydrolysis and remaining in the reaction mixture.

5.3.6 The reference to claim 4 can also not support the Appellant's case concerning the interpretation of the claimed process. Claim 4 refers to the sterol ester or sterol ester mixture, which is present in the reaction mixture before hydrolysis. Claim 1, however, is not limited to such sterols mixtures. For this reason alone the Appellant's argument must fail. Furthermore, no information is given as to the identity of the other 10 to 95% of the reaction mixture before hydrolysis, which might be the catalyst necessary for the hydrolysis, the solvent and/or other unspecified components. Depending on the nature of these residual components and of the manner in which the phenolic and fatty acids are separated these further components may be easily removed in the separation step. Claim 4, therefore,

does not represent evidence that the re-esterification is carried out in the reaction mixture containing the sterols and the unspecified material.

Main request

6. *Novelty*

6.1 The Respondent contested the novelty of claim 1 as granted in view of the disclosure of documents (10) and (15), in particular in view of examples 1 or 2 of document (15) and examples 1 and 2 of document (10).

A translation of the Japanese patent to which document (10) refers has been submitted by both parties. The Board is of the opinion that these translations do not differ essentially, in any case they do not differ in those parts which are relevant for the present decision. It should be noted that for the purpose of this decision the Board, when referring to document (10), relied on the English translation provided by the Appellant, document (10b).

6.2 The Board notes that it is a generally applied principle that for concluding lack of novelty, there must be a direct and unambiguous disclosure in the state of the art which would directly and inevitably lead the skilled person to subject-matter falling within the scope of what is claimed.

6.3 Document (10) describes the separation of a crystalline ferulic acid ester from an oryzanol containing oil or fat, the saponification of the ester and the esterification of the obtained triterpene alcohol with

fatty acids (claim 1 of document (10)). In example 1 of document (10) the ferulic acid ester is separated from the alkali residue of rice bran oil and saponified with a 4 M sodium hydroxide solution. The unsaponifiable product (i.e. triterpene alcohol) is then extracted with ether (document (10), example 1, last seven lines). In example 2 the unsaponifiable product is further esterified with safflower oil fatty acids.

Oryzanol as explained in the patent in suit is a mixture of ferulic acid esters of mainly the phytosterols campesterol, β-sitosterol, 24-methyl-cycloartenol and cycloartenol and is a particularly preferred sterol esters group for the patent in suit (see patent in suit, paragraph [0024]). Since document (10) obtains its ferulic acid ester from the same source, namely oryzanol (i.e. oryzanol containing oil and fat), the triterpene alcohol obtained by the saponification is considered by the Board to fall within the term "sterol" according to the patent in suit. It is to be remarked that according to the patent in suit triterpene alcohols are included in the definition sterols (see paragraph [0045] of the patent in suit referring to the triterpene alcohols alpha amyrin, beta-amyrin and lupeol) and that cycloartenol, which is a main component of oryzanol, falls within the definition triterpene alcohol. The saponification step of document (10), therefore, results in a mixture of ferulic acid and free sterols. The extraction with ether separates the unsaponifiable product (i.e. free sterol) from the salts of the ferulic acid, which will remain mainly in the aqueous sodium hydroxide phase. This step corresponds to the separation of the phenolic acid according to step (b) of the presently claimed

process, and the sterol is then esterified with safflower oil fatty acid. Safflower oil mainly contains linolic, oleic, linolenic, palmitic and stearic acids.

Document (10), therefore, discloses the same process for the manufacture of an ester mixture comprising the same steps (a) to (c) as the patent as granted. However, document (10) does not explicitly disclose the claimed degree of hydrolysis in step (a).

6.4 The Board arrives at a similar conclusion for document (15), which discloses in example 1 the saponification of safflower oil (a sterol ester or sterol ester mixture according to paragraph [0029) of the patent in suit)(step a), the separation of unsaponified product from which crystals mainly consisting of β-sitosterol (free sterol according to the invention) are obtained, the isolation of fatty acids from the soap solution obtained in separating the unsaponified product and the esterification of the crystals with the fatty acids (steps (b) and (c)). As in document (10), no reference is made to the degree of hydrolysis document (15).

6.5 The question which needs to be answered is, therefore, whether the degree of hydrolysis of at least 80% is implicitly disclosed as alleged by the Respondent.

6.5.1 The Respondent argued that the required degree of hydrolysis is the inevitable result of the process disclosed in document (10) in view of the fact that the saponification has been carried out with a 4 M sodium hydroxide solution. The use of such a strong solution would result in 100% hydrolysis of the sterol ester. With regard to document (15) the Respondent considered

the fact that in the examples 1 and 2 crystals of the β-sitosterol are obtained as evidence that complete hydrolysis of the sterol ester has occurred. Furthermore, the statement in example 1 that safflower oil was saponified would be interpreted by the skilled reader as referring to 100% hydrolysis of safflower oil.

6.5.2 The Board does not share the opinion of the Respondent. It is not disputed that the 4 M sodium hydroxide solution used in document (10) is a strong alkaline solution. However, no conclusion as to the exact degree of hydrolysis can be drawn from this fact alone. To what degree an ester is hydrolysed depends also on other factors, like the reactivity of the ester, the solvent, the reaction temperature etc. Apparently, to achieve a high degree of saponification of sterol esters a rather high temperature over a period of several hours is necessary (see example I of the patent in suit or document (13), page 40, lines 1-9). Document (10) does not disclose detailed reaction conditions. The name of the solvent is illegible and no information is present as to the hydrolysis temperature or the reaction time.

The reaction conditions for the saponification are even less detailed in document (15). Example 1 merely refers to saponification without providing any reaction details. From the mere fact that crystals of the free sterol have been obtained it cannot be inferred that complete hydrolysis must have occurred as alleged by the Respondent.

6.6 In view of the above, the Board concludes that it cannot be established beyond any reasonable doubt that

the degree of hydrolysis in the saponification step (a) of the documents (10) and (15) is at least 80%, although this would without doubt appear to be desirable for the skilled person. Accordingly, the Board finds that the subject-matter of claim 1 as granted is novel over the disclosure of documents (10) or (15) and thus meets the requirement of Article 54 EPC.

7. *Inventive step*

7.1 According to the established jurisprudence of the Boards of Appeal, it is necessary, in order to assess inventive step, to establish the closest state of the art, to determine in the light thereof the technical problem which the invention addresses and successfully solves and to examine the obviousness of the claimed solution to this problem in view of the state of the art.

The patent in suit is directed to a process for the preparation of ester mixtures comprising the steps of hydrolysing a sterol ester or sterol ester mixture to obtain phenolic and/or fatty acids and sterols, separating the phenolic and/or fatty acids from the reaction mixture and esterifying the sterols so obtained with C_{2-22} fatty acids. Such a process is already disclosed in document (10), which however does not clearly and unambiguously disclose the feature that the hydrolysis has to be carried for at least 80%. This document in the form of its English translation provided by the Opponent/Respondent (document (10a)) has therefore been selected by the Opposition Division

as starting point for the assessment of inventive step in the contested decision.

7.2 The Appellant challenged the Opposition Division's selection of document (10) as closest prior art. In its opinion this choice disregarded the fact that document (10) and the present invention do not belong to the same technical field. Document (10) is concerned with the manufacture of a pharmaceutical, namely a biochemical substitute for gonadotropic and progestogenic hormones, while the present invention aims at providing a process for the preparation of an ester mixture having a cholesterol lowering effect on foods. Instead of document (10) the Appellant considered document (11) as the closest state of the art, which in its opinion is at least concerned with the same technical field, i.e. the production of edible, enriched rice bran oil as foodstuff.

7.3 The Board observes that in a situation such as the present one, where the claimed invention lies in a process for preparing a known product, the documents to be considered when determining the closest prior art are those which describe these compounds and their manufacture.

7.3.1 The present invention concerns the manufacture of sterol C_2-C_{22} fatty acid ester mixtures, which are known products (see also paragraph [0007] of the patent in suit), using sterol esters or sterol ester mixtures as starting material. Preferred fatty acids are for example those obtained from rice bran oils, sunflower oil, safflower, rapeseed, linseed oil etc, which are

rich in long chain fatty acids, particularly C_{18} fatty acids (paragraph [0040] of the patent in suit).

7.3.2 Document (10) refers to the preparation of the same products, i.e. esters of sterol and fatty acids having 18 to 20 carbon atoms, for example safflower oil fatty acids, using the same starting material, i.e. sterol esters, and the same process steps (see point 6.3 above). Whether or not the products so prepared are used for the same or a different purpose represents in the Board's opinion no compelling argument to discard document (10) as the starting point for examining inventive step.

7.3.3 As pointed out by the Board in its communication annexed to the summons to oral proceedings, document (11) is also considered as being concerned with the preparation of the sterol ester fatty acid esters using the same process steps as presently claimed: saponification of a soap stock obtained from rice bran oil, extraction of the unsaponifiable matter with hexane which will remove acids salts and esterification of the so obtained unsaponifiable matter with oleic acid. In document (11) as in document (10) the degree of hydrolysis in the saponification is not mentioned. Document (11) is therefore not considered to be more relevant than document (10), which has been used as the closest prior art in the contested decision. As it is mainly the purpose of the appeal procedure ***inter partes*** to give the loosing party the possibility of challenging the decision of the Opposition Division on its merits and as the Board has no reason to criticize the Opposition Division's selection of document (10) as the closest prior art, the Board sees no reason to

select document (11) instead of document (10) as the starting point for the examination of inventive step.

7.3.4 Hence, the Board in accordance with the Opposition Division and the Respondent selects document (10) as the starting point for the assessment of an inventive step.

7.4 In the light of document (10) as the closest state of the prior art, the Appellant considered the objective technical problem to be solved by the present invention as the provision of a simplified process for the production of sterol fatty acid esters, suitable for use in foods starting from natural products containing sterol esters.

Concerning the simplification the Appellant provided an analysis of the individual steps of example 1 of document (10) consisting of the steps i) to vii) and of example 2 of document (10) consisting of the steps i) to ii). Step i) of example 1 refers to the saponification of rice bran oil dregs to turn the neutral oils into soaps, i.e. splitting the triglycerides which are usually present in such dregs into glycerol and fatty acid (salts). According to the Appellant step i) ***presumably*** also saponifies the sterol esters to form free sterol and some free fatty acid and free ferulic acid. The steps ii) to vii) correspond to the complex isolation of purified sterols from the reaction mixture including fatty acids and ferulic acids, which the Appellant considered to be different from the step of separating phenolic and/or fatty acids from the reaction mixture and leaving the sterol with the rest of the remaining reaction mixture as required

by the claims of the main request. The Appellant further argued that step i) neither implicitly nor explicitly discloses the removal step of the phenolic and ferulic acids. In particular, it does not teach an extraction step with an organic solvent, which the Opposition Division considered to be included in wording of step (b) of the claimed process.

7.5 The Board observes that the presently claimed process is not limited to a particular source for the sterol esters or sterol ester mixtures starting material or to a particular use of the sterol ester products. Moreover, document (10) obtains its sterol ester starting material from the same natural source as the patent in suit, namely rice bran oil, and it is also not apparent why the sterol fatty acids ester mixtures produced therein should be unsuitable for use in foods.

Furthermore, with the process steps being the same in the presently claimed process and the process of document (10) (see point 6.3 above) the Board cannot accept the Appellant's arguments that the presently claimed process represents a simplification over the process of the prior art. As set out above (see point 5), the Board does not share the Appellant's opinion that the sterols are esterified in the reaction mixture and that isolation steps and purification steps are excluded. The Board also does not share the Appellant's interpretation that step i) represents the saponification step (a) of the presently claimed process. In its communication the Board referred to the last seven lines of example 1 and example 2 of document (10). These passages disclose the saponification of the ferulic acid sterol and the extraction of the

unsaponifiable (i.e. free sterol containing product) with ether. Such an extraction step will basically eliminate the water-soluble parts, like the acid salt, thus meeting the requirement of step (b) of the claimed process. The so obtained product was then esterified with safflower oil fatty acid. The steps i) to v) are considered by the Board, in agreement with the opinion of the opposition division, which relied on the same passages as the Board in the translation provided by the Opponent/Respondent, as pre-preparation steps for obtaining the sterol ester to be hydrolysed. Such preparation steps before step a) are not excluded by the wording of claim 1 of the main request (see point 5.3.1 above).

7.6 In the light of document (10) the Board sees the problem to be solved by the present invention in the provision of a further process for the preparation of sterol fatty acid esters mixtures from sterol esters or sterol ester mixtures.

7.7 As the solution to this underlying technical problem the patent in suit proposes the claimed process with the steps (a) to (c) whereby the hydrolysis in step (a) is carried out in such a way so as to achieve a degree of hydrolysis of at least 80%.

Taking the example of the patent in suit into account the Board is satisfied that the technical problem has been solved.

7.8 It remains to be decided whether or not the proposed solution is obvious in view of the prior art.

7.8.1 In the opinion of the Board it is in general the aim of the skilled person faced with the task of providing a particular compound from a particular starting material by a particular reaction, to carry out that reaction in such a way as to provide the desired product in yields as high as possible. It would therefore be an obvious measurement for the skilled person to carry out the hydrolysis of the sterol esters as complete as possible in order to obtain the maximum amount of free sterol, which can then be further esterified with the C_2-C_{22} fatty acids. This view is also reflected in document (6), which refers to just such an hydrolysis step of sterol esters to free sterols (document (6), column 2, lines 21-24). It is the Board's position that such an obvious measurement does not require inventive skills.

7.8.2 The hydrolysis of esters is a well-known reaction and the skilled person reading document (10) can be expected to achieve a high degree of hydrolysis by selecting suitable reaction conditions, for example by adapting the amount of sodium hydroxide, the reaction temperature and the reaction time. This optimisation of parameters belongs to the normal activities of the person skilled in the art. Should he nevertheless require some guidance as to the selection of suitable reaction conditions, there is sufficient information available in the prior art on how to efficiently hydrolyse sterol ester, for example in document (6) (document (6), column 5, line 45 - column 6, line 51).

7.8.3 The Appellant did not provide any arguments against the obviousness of trying to achieve a degree of hydrolysis of at least 80%.

7.9 Thus, the Board concludes that the subject-matter of the main request is obvious to the skilled person in the light of the prior art and does not involve an inventive step in the sense of Article 56 EPC.

First auxiliary request

8. Independent claim 1 of the first auxiliary request differs from claim 1 of the main request in that in step (a) the mixture obtained after the hydrolysis instead of comprising phenolic and/or fatty acids and free sterols comprises 1) phenolic acid and free sterols or 2) phenolic and fatty acids and free sterols, and in that in step (b) phenolic acid is removed.

8.1 The Board has no objection under Article 123(2)(3) or 54 EPC against the subject-matter of first auxiliary request. In view of the negative conclusions on the issue of inventive step as set out below it is not necessary to go into further details concerning these issues.

8.2 Since document (10) discloses already (a) the hydrolysis of a sterol ester to obtain a phenolic acid and free sterol, and (b) the extraction of the sterol with ether, which will separate it from the ferulic acid salts, the Board can see no reason in what way the deletion of the possibility that the hydrolysed reaction mixture comprises fatty acids and free sterols can contribute to an inventive step. The assessment of inventive step as set out in point 7 above for the main request is not affected by this deletion and the conclusions of the Board drawn therein still apply.

It follows from the above that the subject-matter of the first auxiliary request does not involve an inventive step within the meaning of Article 56 EPC.

Second and third auxiliary request

9. *Amendments*

9.1 Claim 1 of the second and third auxiliary request has been amended in that in the hydrolysis step (a) the mixture obtained thereby comprises phenolic **and** fatty acids. The phenolic acid is removed in step (b) and in step (c) esterification of **the resulting mixture of free sterols and C_2-C_{22} fatty acids remaining in the reaction mixture** takes place. In the third auxiliary request the expression "after removal of phenolic acids" has been added at the end of step (c).

9.2 As basis for the re-use of the liberated fatty acid obtained in step (a) and remaining in the reaction mixture after removal of phenolic acid for the re-esterification in step (c), the Appellant referred to page 7, lines 29-34 and page 8, lines 13-16. In its opinion these passages clearly teach the presence of both phenolic and fatty acids and the removal of the phenolic acid by-products. Consequently, if phenolic acids alone are removed, the fatty acids present in the reaction mixture remain.

According to the Appellant, further support for the feature that the esterification step (c) takes place between the mixture of free sterols and the fatty acids remaining in the reaction mixture can be found in examples I and II of the application as filed. In these

examples the crude soap stock is hydrolysed, and then the ferulic acid is removed by phase separation. The resulting mixture of sterols and fatty acids can then be esterified in a two stage process involving first the formation of fatty acid methyl esters followed by an inter-esterification reaction between the methyl esters and the sterols. Since the starting material is rice bran oil, the remaining fatty acids will include C_2-C_{22} fatty acids. Furthermore, the preferred use of C_2-C_{22} fatty acids is supported on page 8, lines 30-33 of the description as originally filed.

9.3 The Board cannot follow the arguments put forward by the Appellant.

The statement of page 7, lines 29-34 of the application as filed refers to the hydrolysis step resulting in "a mixture containing one of more phenolic acids **and or** one or more fatty acids and or one or more sterols" and continues with the statement that "the phenolic acids obtained are a by-product and not needed for further processing they could be conveniently removed from the reaction product". Therefore, this passages does not disclose that fatty acids are necessarily present after the hydrolysis step, nor does it clearly and unambiguously disclose that the fatty acids which are used in step (c) are necessarily those obtained in step (a), in particular as the passage continues with clear reference to possibility of removing also the fatty acids. The statement on page 8, lines 13-16 merely mentions again the preferred removal of phenolic acids before the re-esterification.

The Board also notes that the feature of conducting the esterification with the resulting mixture of free sterols and the C_2-C_{22} fatty acids remaining **in the reaction mixture** is not clearly and unambiguously disclosed in the passages cited by the Appellant or in the examples. The cited passages do not refer to a reaction mixture. Example I describes the hydrolysis of a crude soap stock comprising the γ-oryzanol, fatty acid alkali salts, tri-acyl glycerols, sodium lye and water with sodium hydroxide and ethanol. This mixture is heated to boiling for two hours, which results in nearly complete saponification. After the hydrolysis the mixture is acidified with water and hydrochloric acid. The aqueous phase is removed thereby separating the phenolic acid together with glycerol. The top layer containing the sterol and the fatty acids is then washed with water until neutral and dried by evaporating water under vacuum for 1h. The resulting mixture of sterols and fatty acids is then esterified.

Thus, the re-esterification in example I of the patent in suit does not take place between the sterols and fatty acid **remaining in the reaction mixture** after the removal of the phenolic acid, but with a product (mixture) that has been obtained by working-up the reaction mixture.

Example II merely refers to the repetition of example I whereby the hydrolysis is carried out in an autoclave at a particular temperature and pressure.

9.4 Thus, neither the examples, nor description of the application as filed provides a basis for the amendments made to claim 1 of the second and third

auxiliary request. Nor can the Board find any other basis for these amendments in the application as filed.

Hence, these amendments generate subject-matter which is not clearly derivable from the content of the application as filed, contrary to the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza-Vivancos P. Ranguis