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**Datasheet for the decision  
of 12 October 2011**

**Case Number:** T 1540/08 - 3.3.04

**Application Number:** 97937813.0

**Publication Number:** 957173

**IPC:** C12P 7/64

**Language of the proceedings:** EN

**Title of invention:**

Process for preparing fat or oil containing unsaturated fatty acid

**Patentee:**

Suntory Holdings Limited

**Opponents:**

DSM IP Assets B.V.  
Martek Bioscience Corp.

**Headword:**

Process for preparing unsaturated fatty acid/SUNTORY

**Relevant legal provisions:**

EPC Art. 83

**Keyword:**

"Main request - sufficiency of disclosure (yes)"

**Decisions cited:**

T 0225/93, T 0023/02

**Catchword:**

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Case Number: T 1540/08 - 3.3.04

**DECISION**  
of the Technical Board of Appeal 3.3.04  
of 12 October 2011

**Appellant:** Suntory Holdings Limited  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted 6 June 2008  
revoking European patent No. 0957173 pursuant  
to Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman:** C. Rennie-Smith  
**Members:** R. Gramaglia  
G. Alt

## Summary of Facts and Submissions

- I. European patent No. 0 957 173, based on application No. 97937813.0 and having the title "Process for preparing fat or oil containing unsaturated fatty acid" was granted on the basis of 20 claims.
  
- II. Notices of opposition against the present patent were filed by opponents O1 and O2 on the grounds of Articles 100(a), 100(b) and 100(c) EPC that the claims did not fulfil the requirements of Articles 54, 56, 83 and 123(2) EPC.
  
- III. The opposition division revoked the patent on the grounds that the claims then on file (main request and auxiliary request 4, both filed during the oral proceedings on 9 April 2008 and auxiliary requests 1-3 filed on 8 February 2008) did not fulfil the requirements of Article 83 EPC.
  
- IV. The opposition division considered that the measurement method as taught in the patent was incorrect. Owing to the use of an Ulbon HR-1 gas chromatography column, as taught in the contested patent, the peak used to measure the compositional ratio of 24,25-methylenecholest-5-en-3 $\beta$ -ol (hereafter: 24,25-M) comprised not only 24,25-M, but also another sterol, namely ergosta-5,25-dien-3 $\beta$ -ol (hereafter: ergosta-5,25). The opposition division accepted the opponents' experimental data showing that the peak at the relative retention time for 24,25-M and ergosta-5,25 could comprise much more ergosta-5,25 than 24,25-M, and that the ratios of these sterols were unpredictable. Hence, the opposition division concluded that an objection of

insufficiency of disclosure arose because the skilled person did not know whether the purported problem of the contested patent (i.e. to lower the amount of 24,25-M) was solved or not.

V. The patentee (appellant) filed an appeal against the decision of the opposition division.

VI. The following documents are cited in the present decision:

D4 Bajpai P.K et al., J. of Industrial Microbiology, Vol. 8, pages 179-186 (1991);

D5 Bajpai P. et al., JAOCS, Vol. 68, No. 10, pages 775-780 (October 1991);

D6 Lindberg A-M. et al., Appl. Microbiol. Biotechnol., Vol. 39, pages 450-455 (1993);

D8 WO-A-96/21037;

D20 First declaration by Dr. Fujikawa dated 18 August 2006;

D32(2) Results of D4 rework;

D32(3) Results of D5 rework;

D32(4) Results of D6 rework;

D32(5) Results of D8 (Example 5) rework;

- D50 Results of sterol analysis (experimental test report filed by respondent II);
- D53 Sterol analysis (experimental test report filed by the appellant);
- D56A Collated overview of the experimental data.

VII. Oral proceedings were held on 12 October 2011, during which the appellant submitted a new main request and new auxiliary requests 1 to 3.

Claims 1, 10 and 11 of the main request read as follows:

"1. A process of production of unsaturated fatty acid-containing microbial oil containing from 30 to 50% arachidonic acid, comprising submerged culturing of a microorganism belonging to the genus *Mortierella* subgenus *Mortierella* in a fermenter with aeration in a medium containing a nitrogen source, and collecting said unsaturated fatty acid-containing oil from the cultured product, characterised by the use of defatted soybean or processed defatted soybean as said nitrogen source, to restrict the compositional ratio of 24,25-methylenecholest-5-en-3 $\beta$ -ol in said unsaturated fatty acid-containing oil, said composition ratio being not more than 35%."

"10. An unsaturated fatty acid-containing microbial oil having a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio of not more than 35% and obtained by a process according to any one of the preceding claims, containing from 30 to 50% arachidonic acid."

"11. An arachidonic acid-containing microbial oil characterised by a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio of 35% or lower and an arachidonic acid content of from 30 to 50%, and obtained by submerged culture of a microorganism belonging to the genus *Mortierella* subgenus *Mortierella* in a fermenter with aeration, using a soybean-derived nitrogen source."

Dependent claims 2 to 9 related to specific embodiments of the process according to claim 1. Claim 12 was directed to a specific embodiment of the arachidonic acid containing oil according to claim 10 or 11, whereas claim 13 addressed a process for making products incorporating the oil according to claims 10, 11 or 12.

VIII. The submissions by the appellant (patentee), insofar as they are relevant to the present decision, can be summarized as follows:

- The data generally demonstrated a correlation between the defined ratio and the actual ratio for 24,25-M.
- The opposition Division drew an unjustified general conclusion from selected data which were not representative because they relied upon cultures which produced extremely low levels of 24,25-M, and were all based upon on the specific strain ATCC 32222.
- Experiments done in-house in 1996 before the priority date of the patent in suit showed that

the 24,25-M compositional ratios generated in high productivity fermenter cultures were much higher than in flask cultures, whereas the D32 rework related to flask processes.

- No experimental data had been provided by the respondents to the effect that a fall in 24,25-M was obscured by a very large increase in ergosta-5,25, as these sterols gradually increased roughly in proportion with one another during culture.

IX. The submissions by the respondents (opponents), insofar as they are relevant to the present decision, can be summarized as follows:

- The defined 24,25-M ratio was not a reflection of the actual 24,25-M ratio and hence an objection under Article 83 EPC arose because the uncertainty of the measuring method disclosed in the patent prevented the skilled person from knowing whether the purported problem of the contested patent (i.e. to lower the amount of 24,25-M) had been solved or not, by analogy with the situation dealt with in decision T 225/93 (see points 13 to 17 below for more details).
- All sorts of additives could have an influence on the ratio of 24,25-M. These influences were neither described nor easily measurable, inter alia because of the wrong measurement method described in the patent. Hence, also for this reason, Article 83 EPC was not satisfied.

- The experiments by the respondents included ATCC 32222 and CBS 343.66 strains.
- Even if a general correlation existed between the defined compositional ratio and the actual compositional ratio, there was still insufficiency of disclosure, as it was impossible to know whether or not the actual ratio had been lowered in individuals oils, the process parameters being not limiting for a product claim.
- A claim had to be enabled over its entire scope, including embodiments where the strains produced traces of 24,25-M.

X. The appellant (patentee) requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution on the basis of the amended main request or amended auxiliary requests 1 to 3, all filed during the oral proceedings.

The respondents (opponents) requested that the appeal be dismissed or, if not, that the case be remitted to the department of first instance for further prosecution.

### **Reasons for the Decision**

1. The only issues dealt with in the present appeal proceedings were the interpretation of the expression "compositional ratio" in claims 1 and 10 to 12 and insufficiency of disclosure (Article 83 EPC).



*Main request*

*Interpretation of the expression "compositional ratio" in the claims*

2. This expression has by itself no accepted technical meaning. However, the skilled person is able to learn from page 5, lines 18-19 of the patent specification that the compositional ratio of 24,25-M is the ratio of the peak area of 24,25-M to the sum of the peak areas of all the sterols (see page 5, lines 3, 13 and 16) in the gas chromatogram.
3. Claims 1 and 10 to 12 are also silent as to how this "compositional ratio" should be measured and how the peaks used for measuring this "compositional ratio" have to be generated.
4. However, paragraph [0034] expressly states that the compositional ratio of 24,25-M has to be determined by the method described in paragraphs [0035] and [0036] of the patent. As regards generating and measuring the peak areas of all the sterols, it is stated in paragraph [0035] on page 5, lines 13-14 of the patent specification that this can be done by conventional methods. As for generating and measuring the peak of 24,25-M, it is stated in paragraph [0036] of the description that the 24,25-M peak is detected in a retention time of 1.07 to 1.12 times the retention time of desmosterol and that gas chromatography is performed on an Ulbon HR-1 column.
5. In view of the mandatory condition set out in paragraph [0034] of the patent (see preceding point) and the

rationale of decisions such as T 23/02 of 19 July 2005 (see also the Case Law of the Boards of Appeal, 6th edition 2010, III.A.1, page 316), the board agrees with the parties that the expression "compositional ratio" has to be interpreted in the light of paragraphs [0035] and [0036] of the description, which prescribe inter alia the use of an Ulbon HR-1 column for carrying out gas chromatography and generating the 24,25-M peak.

*Sufficiency of disclosure (Article 83 EPC)*

6. The claims relate to a method for lowering the unwanted 24,25-M (see paragraph [0006] of the patent) during the production of an oil containing arachidonic acid (hereafter: "ARA"), and to an oil comprising such a lowered amount of 24,25-M (see paragraph VII supra). The claimed method involves culturing a microorganism in a growth medium comprising a nitrogen source derived from soybean. The compositional ratio of 24,25-M in the oil obtained by applying the claimed method has to be compared with that of an oil obtained through a conventional process using a growth medium comprising a yeast extract as a nitrogen source (see paragraph [0010] and comparative Examples 1 to 3 of the patent). A decrease in the compositional ratio of 24,25-M (the latter should be < 35%) in the oil recovered from the growth medium comprising soybean (hereafter: "S") compared to the compositional ratio of 24,25-M in the oil from the medium comprising yeast (hereafter: "Y") indicates that the technical problem underlying the claimed subject-matter has been solved (see Table 2 of the patent, second column, compare 68% with 25%). This comparison, which should be performed under the same conditions (strain, incubation time, temperature,

- vessel (jar or flask), oxygenation, culture medium, etc), with exception being made for the nitrogen source in the culture medium which should be (processed) defatted soybean (invention) or a yeast extract (reference) will hereafter be termed "the Y/S comparison" for the sake of simplicity.
7. The parties do not dispute that the skilled person, based on the disclosure in the patent, would be able to implement the claimed process and produce the oil as claimed, and compare the peak areas detected in a retention time of 1.07 to 1.12 times the retention time of desmosterol (the "24,25-M peak") in the "S" gas chromatogram with those in the reference "Y" gas chromatogram. Nor do the parties dispute that the total sterol areas can easily be evaluated by conventional methods.
  8. However, as emphasized in point 5 supra, determining whether or not lowering of the 24,25-M has been achieved requires measurement of the compositional ratio of 24,25-M by means of an Ulbon HR-1 column. It has not been disputed by the appellant (see document D20, paragraph 4.2) that when using an Ulbon HR-1 gas chromatography column, as taught in the contested patent, the peak used to measure the compositional ratio of 24,25-M comprises not only 24,25-M, but also another sterol, namely ergosta-5,25. This is because the Ulbon HR-1 column is unable to separate 24,25-M from ergosta-5,25. As a consequence, the skilled person wishing to determine whether or not lowering of 24,25-M has been achieved, would (following the instructions in the patent) be forced to measure an unresolved peak area of a mixture of 24,25-M and ergosta-5,25 ("**the**

**defined 24,25-M ratio**") rather than a peak area of pure 24,25-M ("**the actual 24,25-M ratio**"). After the priority date of the patent in suit, it has been shown that the actual ratio can be determined using an Ulbon HR-17 column, which is able to separate 24,25-M from ergosta-5,25 (see document D20, paragraph 4.3).

9. The issue under dispute in the present appeal proceedings is that of insufficiency of the patent disclosure in view of the relationship between the defined 24,24-M ratio and the actual 24,24-M ratio.
10. The appellant maintains that no objection under Article 83 EPC arises because there is a direct correlation between these two parameters and, therefore, the defined 24,24-M ratio is a valid and effective measure for the actual 24,24-M ratio.

The respondents, however, strongly dispute that the defined 24,24-M ratio is a reflection of the actual 24,24-M ratio and hence argue that an objection under Article 83 EPC arises because the uncertainty of the measuring method disclosed in the patent prevents the skilled person from knowing whether the purported problem of the contested patent (i.e. to lower the amount of 24,25-M) has been solved or not, by analogy with the situation dealt with in decision T 225/93 of 13 May 1997.

11. In the board's view, making a Y/S comparison (see point 6 supra) is the only way to establish whether or not the problem of lowering 24,25-M has been solved. Many of the respondents' arguments in support of insufficiency of disclosure are indeed also based on

this "before"/"after" comparison (see e.g. point 14 infra). Hence, any possible discrepancy between defined 24,24-M ratio and actual 24,24-M ratio pointed by the respondents has to occur within the ambit of a Y/S comparison for it to be relevant to the present case. The board comes thus to the conclusion that an objection of insufficiency of disclosure based on the impossibility of determining whether or not lowering of the 24,25-M has been achieved, can only arise if it can be demonstrated that a decrease of "the defined 24,25-M ratio" is not indicative for a decrease of "the actual 24,25-M ratio" **in the context of a Y/S comparison**. This would be the case if 24,25-M (as measured by HR-17) increases or remains stable upon switching from Y to S.

12. Turning to the respondents' experimental data (see documents D32(2) to D32(5), D53, and D50 referred to in document 56A, which is a collated data graph giving an overview of the experimental data from all of the experiments that have been submitted by all parties, for which analysis by both HR1 and HR17 was done), the board observes that none of these tests deal with a Y/S comparison. They are thus prima facie not relevant because they cannot show that 24,25-M (as measured by HR-17) increases or remains stable upon switching from Y to S.
  
13. The only attempt to show the above mentioned effect is to be found in the respondent I's submission of 5 August 2011 (see the Table on page 6), wherein the oil "Y" of D5 at 6 days (HR-1 = 13; HR-17 = 1) is compared with the oil "Y" of D8, Example 5 at day 2 (HR-1 = 10; HR-17 = 2). Yet, this non-pertinent comparison, where the only common parameter is strain

ATCC 32222, in no way demonstrates that 24,25-M would increase if a Y/S comparison in the sense of point 6 supra (same parameters, exception made for Y or S) is carried out.

14. The respondents also argue that if, in an experiment, the amounts of total sterols and 24,25-M both increase, but total sterols increase more than 24,25-M, the claimed ratio would become lower, despite the actual amount of 24,25-M would increase. One cannot say, using the respondents' argument, that in such circumstance the problem (of lowering the amount of 24,25-M) is solved.

In the board's judgement, this hypothetical experiment conflicts with Tables 1, 2 and 3 (see "Total sterol content") of the patent, showing that the total sterol content does not vary substantially upon switching from Y to S. As for the increase in 24,25-M, no experimental data to this effect have been provided by the respondents (see points 12 and 13 supra), in spite of the fact that performing these comparative tests would have required the mere replacement of Y with S or S with Y in the tests.

15. In support of their view that the defined 24,25-M ratio is not a valid measure for the actual 24,25-M ratio, the respondents further point out that their experiments demonstrate that:

- (i) the defined 24,25-M ratio can be a factor 1.4 to 13 higher than the actual 24,25-M ratio;

(ii) the amounts of 24,25-M and ergosta-5,25 are not always increasing together in proportion with one another;

(iii) the difference HR-1 minus HR17 (corresponding to the amount of ergosta-5,25) is unpredictable.

However, as already highlighted in point 11 supra, the decisive criterion for acknowledging insufficiency of disclosure is that 24,25-M (as measured by HR-17) must increase or remain stable upon switching from Y to S. Results (i) to (iii) have not been obtained in the context of a Y/S comparison (in the sense of point 6 supra, i.e., same parameters, exception made for Y or S). Hence, in the absence of evidence to the contrary, results (i) to (iii) cannot be extrapolated to this specific situation. Moreover, the fact that ergosta-5,25 may be preponderant in a peak does not prevent a tiny amount of 24,25-M in the peak to further decrease upon switching from Y to S.

16. The respondents also maintain that even if a general correlation existed between the defined compositional ratio and the actual compositional ratio, there would still be insufficiency of disclosure, as it is impossible to know whether or not the actual ratio has been lowered in individual oils (the process parameters being not limiting for a product claim).

The board, however, is of the opinion that no such problem arises if the individual oils are taken in the context of a Y/S comparison in the sense of point 6 supra. Once this condition is fulfilled, the skilled person would consider that the problem has been solved

if the defined ratio decreases upon switching from Y to S.

17. Finally, it is the respondent's view that Article 83 EPC is violated because all sorts of additives may have an influence on the compositional ratio of 24,25-M and these influences are neither described nor easily measurable.

The board cannot agree with this contention. In fact, in view of the Y/S test (see points 6 and 11 supra) requiring that the this/these additive(s) must be present in **both** the Y and S cultures in the same concentration(s), the influence of this/these additive(s) would cancel out.

18. In conclusion, no convincing evidence has been provided by the respondents showing that the defined 24,25-M ratio is a not a valid and effective measure for the actual 24,25-M ratio.

19. Unlike the respondents, the appellant provided data resulting from a comparison between a process using a soy-derived nitrogen source and a conventional yeast extract nitrogen source (see document D54 collated in D56A; compare "1S4 Y. ext. Jar 6d" with "1S4 Y. Soy. Jar 6d"). A decrease of about 20% in the compositional ratio of 24,25-M takes place when Y is replaced with S. These results are in line with the comparative results in Example 2 (see Table 2) of the patent in suit. Examples 1 and 3 (see Tables 1 and 3), albeit not covered by the claimed subject matter because the ARA content is lower than the 30 to 50% required by claim 1, further confirm the result in Example 2, as regards the



decrease in compositional ratio of 24,25-M. The comparative test in document D54 also demonstrates that the actual 24,25-M ratio decreases when Y is replaced with S.

20. In view of the foregoing and in the absence of evidence before the board to the contrary, the defined 24,25-M ratio is viewed by the board as a valid and effective measure for the actual 24,25-M ratio. The fact that the latter will be lower than the ratio measured using the method as defined in the patent (because the latter actually measures not only 24,25-M but also ergosta-5,25) is thus of no relevance for the objection under Article 83 EPC.

21. Hence, the claims of the main request satisfy the requirements of Article 83 EPC.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
  
2. The case is remitted to the department of first instance for further prosecution on the basis of the amended main request or amended auxiliary requests 1 to 3, all filed during the oral proceedings.

The Registrar:

The Chairman:

P. Cremona

C. Rennie-Smith