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D E C I S I O N
of 21 May 2003

Case Number: T 0695/00 - 3.3.6

Application Number: 92923333.6

Publication Number: 0612346

IPC: C11B 5/00

Language of the proceedings: EN

Title of invention:
Stabilization of marine oils

Patentee:
F. HOFFMANN-LA ROCHE AG

Opponent:
BASF Aktiengesellschaft Patente, Marken und Lizenzen

Headword:
Stabilization of marine oils/F. HOFFMANN-LA ROCHE

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes): non obvious modification of a prior art process to obtain products with improved properties"

Decisions cited:
-

Catchword:
-

Case Number: T 0695/00 - 3.3.6

D E C I S I O N
of the Technical Board of Appeal 3.3.6
of 21 May 2003

Appellant: (Opponent)
BASF Aktiengesellschaft
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D-67056 Ludwigshafen (DE)

Representative:
-

Respondent: (Proprietor of the patent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 28 April 2000 rejecting the opposition filed against European patent No. 0612346 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: P. Krasa
Members: P. Ammendola
M. B. Tardo-Dino

Summary of Facts and Submissions

I. This appeal is from the decision of the Opposition Division rejecting the opposition filed against the European patent No. 0 612 346 and maintaining the patent as granted on the basis of 30 claims, the independent claims 1 and 30 reading as follows:

"1. A process for the stabilization of fully or partially refined marine oil by means of lecithin, ascorbyl palmitate and a tocopherol and involving a silica treatment, comprising treating said oil with silica having a surface area greater than 500 m^2 per gram, subjecting said silica treated oil to a soft vacuum steam deodorization at a temperature between about 140°C and about 210°C, and incorporating a lecithin, ascorbyl palmitate and a tocopherol in the ratio of 6-3 : 4-2 : 8-4 in the thus-treated oil, whereby the stabilization brought about lasts for several months."

"30. A marine oil stabilized according to the process claimed in any one of claims 1 to 29."

Dependent claims 2 to 29 related to particular embodiments of the process of claim 1.

II. The Appellant (Opponent) filed a notice of opposition, based only on lack of inventive step, citing *inter alia* the following documents:

Document (1) = EP-A-0 340 635;

Document (2) = Welsh W. A. *et al.* "Phosphorous and Trace Metal Removal with a Novel;

Refining Material", paper presented at the American Oil Chemists' Society Annual Meeting 1986;

Document (6) = Han D. *et al.* "Solubilization of Vitamin C in Fish Oil and Synergistic Effect with Vitamin E in Retarding Oxidation", JAOCS, Vol. 68 No. 10, 1991, pages 740 to 743;

Document (7) = "Trisyl® Silica Gele für die Speiseölraffinierung", Product information from Grace Specialty Chemicals Co. Product.

III. During the opposition proceedings the Respondent (Patent Proprietor) filed comparative experimental data under cover of the letters dated 1 October 1996, 21 October 1997 and 30 June 1999.

IV. In its decision, the Opposition Division held that the subject-matter of the claims of the patent as granted was based on an inventive step vis-à-vis the prior art process of Document (1). In particular, it found that the comparative experimental data of 30 June 1999 demonstrated that the oil treatment sequence according to claim 1 of the patent in suit resulted in marine oils whose sensorial properties and aldehyde content were surprisingly improved in comparison with those of the same marine oils purified according to the treatment sequence recommended in this prior art. The decision under appeal also stressed (see point 4.7) that during the opposition proceedings the Respondent had not disputed that it was obvious to use also in the claimed process an antioxidant system which was already known to provide excellent marine oil stabilization.

V. The Appellant appealed against this decision arguing substantially that the experimental evidence provided by the Respondent was not sufficient to demonstrate credibly over the whole range of the process of claim 1 the allegedly superior stability and organoleptic properties of the marine oils obtained therefrom. It further provided, with the statement setting the grounds of appeal, a table of experimental results in which different samples of marine oils showed different anhydride contents and different levels of colour but the same taste and smell qualities and argued that exclusively the differences in oil taste and smell reported in the experimental data provided by the Respondent were possibly significant for determining whether or not the sensorial properties of the marine oils produced by the process of the patent in suit were superior to those obtainable by the prior art process. However, it considered that the reported differences in smell and taste could not be considered reliable, as they resulted from subjective evaluations.

The Appellant further maintained that in the data filed under cover of the letter dated 21 October 1997 in which the invention example B, comprising the additional presence of carbon during the silica treatment, showed no odour improvement in comparison with the corresponding comparative example C, also comprising the additional presence of carbon during the silica treatment, but with the opposite purification sequence. On the contrary, the data filed under cover of the letter dated 30 June 1999 and based on a similar marine oil showed that the carbon-comprising invention example C had instead a very large odour improvement in comparison with the corresponding carbon-comprising comparative examples F with reversed purification sequence. The Appellant concluded from this alleged contradiction that a change in the order of the

purification steps influenced the organoleptic properties of different marine oils to a different extent. Therefore, it further argued that, even if one considered the oil odour and taste level measurements reported by the Respondent in the data of 30 June 1999 as credibly demonstrating superior sensorial properties of the respective oils, such evidence was at most sufficient only to establish the occurrence of this technical effect in respect of the specific marine oils tested.

At the oral proceedings before the Board, the Appellant also argued that the most relevant state of the art was represented by the process disclosed in Document (6).

VI. The Respondent refuted the Appellant's reasoning by maintaining, *inter alia*, that neither the additional experimental data provided by the Appellant nor its observation as to the subjective nature of the test methods used by the Respondent for evaluating the organoleptic properties of marine oils provided sufficient basis to disprove inventive activity for the claimed subject-matter.

It also argued that the contradiction alleged by the Appellant to be present in the experimental results only occurred in respect of marine oil treatments not representative of the relevant prior art. The Respondent maintained that all the experimental data comparing the sensorial properties of the marine oils produced by the purification sequence of the patent in suit and those obtained by the sequence recommended in Document (1) consistently showed the superior properties of the oils of the patent in suit.

VII. The Appellants requested that the decision under appeal be set aside and that the European patent 0 612 346 be revoked.

The Respondent requested that the appeal be dismissed and that the patent be maintained as granted.

VIII. The decision of the Board was announced by the Chairman at the end of the oral proceedings held on 21 May 2003.

Reasons for the Decision

1. *Inventive step regarding the subject-matter of claim 1 of the patent in suit (Articles 52(1) and 56 EPC)*

1.1 Technical background

Marine oils must have certain sensorial properties in order to be suitable for use in the food and cosmetic industry. In particular they must show no or only a limited taste and smell of fish.

The desired organoleptic properties are conventionally achieved in commercial food-grade or cosmetic grade oils by refining treatment(s), such as a deodorization step under application of vacuum at high-temperature.

However, with time even initially fully deodorized and tasteless oils tend to spontaneously develop an increasingly intense smell and taste of fish. This phenomenon, which evidently limits their shelf life, is undisputedly due to the occurrence of oxidation reactions.

Accordingly, means for stabilizing refined marine oils against oxidation and means for purifying them as far

as possible from the oxidation by-products have been proposed for improving their shelf life.

The Board wishes to stress that it is self-evident that the more the amount of undesired contaminants of a marine oil is reduced, the longer the purified oil will need to undergo oxidation before it reaches an unacceptable concentration of such substances. Accordingly, the technical advantage of a process superior in purifying marine oils is achieved also to the extent in which it reduces the concentration of the undesired contaminants **below** the threshold of sensitivity of human taste and smell. This is evident when considering that, even though the further removal of undesired substances from already odourless and tasteless marine oils does not produce immediately perceivable changes of the sensorial properties in these oils, an improvement of such properties may eventually become apparent upon aging, i.e. these oils will remain odourless and tasteless for longer time.

1.2 Claim 1 of the patent in suit defines a process for the stabilization against oxidation of conventional marine oils which have previously been fully or partially refined. It comprises a two step purification stage followed by the addition of a stabilizer mixture of lecithin, ascorbyl palmitate and tocopherol in given ratios.

The purification stage comprises a first treatment with silica (with a specified high surface area) followed by a soft vacuum steam deodorization step.

1.3 Even though the wording of claim 1 - as well as the description of the patent in suit at page 2 lines 3 to 26 - emphasizes exclusively the fact that the claimed process aims at providing prolonged **stability** to

partially or fully refined marine oils, the description of the patent in suit also explicitly emphasizes that during the purification steps of the claimed process **the sensorial properties** of the oils are also improved (see page 3, lines 17 to 19, and examples 5 to 8, i.e. all the invention examples, since examples 1 to 4 do not comprise the "soft" deodorization step).

Accordingly, the Board finds that the person skilled in the art would derive from the patent disclosure as a whole the teaching that the technical problem explicitly addressed in the patent in suit is dual, in that the claimed process aims not only at increasing the stability against oxidation of the commercially available partially or fully refined marine oils but also at improving their organoleptic properties.

1.4 However, the Board notes that (as observed also at point 4.7 of the decision under appeal) the Respondent has not disputed that it was obvious to use in the claimed process an antioxidant system, which was **already** known to provide excellent marine oil stabilization (see, for instance, the Respondent's letter of 1 October 1996 page 2, second paragraph). The Board further notes that the Respondent has explicitly alleged the achievement of an oil stability **superior to that normally provided by this already known antioxidant mixture** (see in the letter of 1 October 1996 page 7, last paragraph) **only in examples of the claimed processes wherein activated carbon is additionally present during the silica treatment.** On the contrary, in the data of 21 October 1997 and 30 June 1999 the Respondent compared the marine oil sensorial properties achieved in some comparative treatment methods to those obtained **in examples of the**

claimed process with as well as without the additional presence of activated carbons.

1.5 The above facts render evident that, even though the patent as a whole alleges that the claimed treatment method for marine oils improved the stability against oxidation as well as the organoleptic properties vis-à-vis those obtainable by the prior art treatment methods, only the improved organoleptic properties have actually been achieved over the whole range of the claimed method. The improvement of the oil stability to a level superior to those already known in the prior art was instead only observed in preferred embodiments of the claimed process additionally comprising activated carbon.

Since only the technical effect of improving the sensorial properties of marine oils is relevant for the whole claimed subject-matter, the Board finds it appropriate to consider only such effect in establishing which is the prior art relevant for the inventive step assessment.

1.6 Relevant prior art

1.6.1 The Board observes that Document (1) also describes a process for producing fish oils which are odourless and tasteless (see e.g. page 2, lines 1 to 6).

This citation, however, discloses two different sequences for the purification steps of this process. In the preferred embodiment (herein "D/S sequence") a soft vacuum steam distillation step precedes a silica treatment (see claim 3 and the description from page 4, line 35 to page 5, line 30). On the contrary, in the

non-preferred embodiment (herein "S/D sequence") disclosed in this citation the silica treatment is carried out before the soft vacuum steam distillation (see the description at page 5, line 28 and example 3). This latter sequence of steps is the same as in the patent in suit.

Document (1) clearly distinguishes these two embodiments, since the experimental data in Table 1 of Document (1) (showing that the fishy taste and smell of the oils obtained by the D/S sequence are improved vis-à-vis those of the oils freshly deodorized according to conventional prior art) and the corresponding statement at page 5, lines 21 to 22 (i.e.: "*The superior quality of the fish oil deodorized and purified by the present invention is summarized and shown in Table 1*") amount to an explicit disclosure that the preferred D/S sequence ensures the achievement of improved taste and smell with respect to conventional deodorization and purification treatments of the prior art. On the contrary, Document (1) provides no explicit or implicit information with respect to the taste and smell properties of the oils produced according to the S/D sequence (see e.g. the description of example 3, the only example referring to such sequence).

In addition, Document (1) implicitly provides an explanation for the superior properties of the oils produced by the D/S sequence in that it explicitly states at page 5, lines 28 to 30, that by this purification sequence it is possible to remove in the final silica treatment the impurities possibly formed during the preceding soft deodorization step. Of course, this disclosure in Document (1) implies that the sensorial properties observed in the presence of such improved level of purity cannot possibly occur when the sequence of purification steps is reversed, i.e. in the non-preferred S/D sequence.

Therefore, the Board concludes that in Document (1) only the process comprising the D/S sequence is clearly disclosed as providing a solution to the same aspect of the dual technical problem addressed in the patent in suit which is relevant for the whole subject-matter (see above point 1.5).

1.6.2 The Appellant maintained at the oral proceedings that the process disclosed in Document (6) (see page 740, right column, lines 2 to 16), i.e. the only other available document disclosing a S/D treatment sequence, represented a state of the art more relevant than that disclosed in Document (1).

1.6.3 The Board observes however that Document (6) is totally silent as to whether or not the level of deodorization of the oils produced by the process disclosed therein is improved with respect to that obtainable by the purification and deodorization processes of the prior art. Therefore, contrary to the D/S sequence of Document (1), the process disclosed in Document (6) does not aim to solve the technical problem at stake.

1.6.4 Therefore, the Board finds that the prior art disclosed in Document (6) is less relevant than the preferred D/S process of Document (1) and, hence, concludes that the latter represents, from the available prior art, the most reasonable starting point for the assessment of inventive step for the process of claim 1.

1.7 Technical problem credibly solved by the claimed process

1.7.1 The Respondent did not provide direct experimental comparison with the relevant prior art, but compared in the experimental report filed under cover of the letter dated 30 June 1999 the sensorial properties of marine oils purified according to the S/D sequence of the invention with or without activated carbon (samples A, A', C and C') to those (samples D and D') obtained by a D/S purification sequence, which comprised a treatment with high surface silica.

These comparative examples - i.e. D and D' - differ from the D/S sequence of Document (1) only in that the silica used therein has a specified high surface area, whereas in Document (1) the surface of the used silica gel is not specified. However, for the person skilled in the art it is self-evident that the silica with a high surface area used in these comparative examples is one of the most efficient adsorbents preferably used for rendering oils of natural origin suitable for human diet (see e.g. Documents (2) and (7)). This has not been contested by the parties. Thus, the Board is satisfied that the sensorial properties observed in the comparative examples D and D' may also be assumed to be at least comparable (if not superior) to those actually achieved in the corresponding purification sequence examples which in Document (1) are alleged to be already improved over the prior art.

1.7.2 Since the smell and taste properties obtained in the invention examples A, A', C and C' of 30 June 1999 are better than those of the corresponding comparative examples D and D', the Board concludes that the data provided by the Respondent are sufficient to demonstrate credibly that in the purification stage of

the claimed process the smell and taste of fish of the commercially available marine oils is reduced to a level which is also lower than that obtainable by using the purification sequence recommended in Document (1).

1.7.3 The Appellant maintained instead that these smell and taste comparisons reported by the Respondent did not represent technically reliable evidence.

The Appellant observed that they resulted from "subjective" evaluations of oil taste and smell carried out by a panel of testers and argued that the subjective nature of these evaluations would deprive this evidence of any reliable technical meaning.

1.7.4 The Board observes that these smell and taste test methods are conventional in the technical field of fish oil purification, as is already evident from the fact that they have been used also in Document (1) to demonstrate the achievement of superior organoleptic properties. At the oral proceedings it was also confirmed by the parties that these are the only possible methods for evaluating the level of smell and taste of fish.

Moreover, the Boards notes that the Appellant implicitly acknowledged the reliability of these inevitably "subjective" test methods. In the analytical data provided under cover of the grounds of appeal, the Appellant has considered the organoleptic properties evaluated by using these smell and taste tests sufficiently reliable at least for establishing that fish oils with different p-anisidine values might have the same level of sensorial properties.

Finally, the Board considers that no evidence has been provided which demonstrates that the variability in the

results of these taste and smell tests - variability which has been implicitly assumed by the Appellant as inevitably deriving from the "subjective" nature of such tests - is actually so significant as to affect the credibility of the test results obtained.

Therefore, in the absence of any clear evidence to the contrary, the Board concludes that the evaluation of taste and smell by a panel of testers is the only generally accepted method for assessing the sensorial properties of marine oils and thus that the experimental data resulting therefrom are a reliable and appropriate basis for evaluating inventive step.

1.7.5 The Appellant further maintained that the improvement of sensorial properties observed in the data provided by the Respondent was at most sufficient to establish the occurrence of this technical effect only with respect to the specific marine oils used in the examples. In support of this statement it alleged the existence of a contradiction between the odour improvements achieved on different fish oils when comparing D/S and S/D sequences comprising activated carbon during the silica treatment (see above item V of the Summary of Facts and Submissions) and considered that this contradiction would demonstrate that the specific order of the purification steps characterizing the claimed method produced or did not produce an improvement of sensorial properties depending on the nature of the fish oil.

1.7.6 The Board observes that, as correctly argued by the Respondent too, the comparative active carbon-comprising examples C of 21 October 1997 and F of 30 June 1999 are not representative of the prior art in respect to which it is necessary to establish that a

technical effect had been obtained by the process claimed in the patent in suit.

The Board notes that the Appellant's reasoning implicitly assumes that when two freshly treated oil samples are both initially odourless and tasteless (such as the oil obtained by the S/D sequence of invention example B and that provided by the D/S sequence of comparative example C in the data of 21 October 1997) they must necessarily have the same sensorial properties.

This assumption does not consider the fact, mentioned above at point 1.1, that two initially odourless marine oils might still have quite different odour properties upon aging. If the initially imperceptible amount of bad-smelling contaminants is in one sample very different from the initially inperceptible amount thereof in the other sample, then one of the two oils will remain odourless for longer and, from the moment in which it starts to smell, its odour will always be the less intense of the two.

Therefore, the Board concludes that the simple fact that the oil produced by the claimed S/D sequence of example B and that produced by comparative D/S sequence of example C are both initially odourless does **not** inevitably imply that the odour properties of the former cannot be superior to those of the latter.

Moreover, even if one assumes for the sake of argument that these two samples also had a substantially comparable odour upon aging, the alleged contradiction between this hypothetical identity of results in the data of 21 October 1997 vis-à-vis the different odours observed in the corresponding examples C and F of 30 June 1999 (see above point V of the Facts and Submissions) could be attributed, for instance, to the

fact that - while the claimed S/D purification process always produces the best possible purification of any marine oils - the comparative D/S sequence only maximizes the level of purity of certain specific marine oils (e.g. of that used in the comparative examples C of 21 October 1997, but not of that used in examples F of 30 June 1999).

Therefore, the data relied upon by the Appellant neither refer to prior art in respect of which the technical effect aimed at must be achieved, nor unambiguously demonstrate that the purification sequence of the process of claim 1 effectively improves the organoleptic properties only of certain marine oils. In the absence of convincing evidence to the contrary, these data based on a few specific marine oils are thus considered sufficient to establish which technical effects have credibly been achieved when using other marine oils as well.

1.7.7 The Board thus concludes that, for the reasons already given (see above points 1.7.1 and 1.7.2), the marine oil purification and stabilization process of claim 1 has credibly solved the technical problem of improving the organoleptic properties of marine oils to a level superior to that obtainable by the prior art treatment methods.

1.8 Inventive step

1.8.1 The process defined in claim 1 of the patent in suit differs from the process disclosed in Document (1) which comprises the D/S purification sequence in several aspects. In particular in that it requires a mandatory S/D purification sequence.

1.8.2 It is self-evident from the reasons in the above sections 1.6 and 1.7 that in particular this distinguishing feature is responsible for the achievement of the improved sensorial properties of the marine oils, i.e. for the solution of the existing technical problem as identified above at point 1.7.7.

Therefore, in the present case the assessment of inventive step boils down to the question of whether or not the notional person skilled in the art would have reversed the D/S purification sequence of the process of Document (1) in the reasonable expectation that this modification would result in marine oils with improved sensorial properties.

1.8.3 The Board stresses again that the only available citations disclosing S/D sequences for the purification of marine oils are Documents (1) and (6).

However, none of these documents discloses that the S/D sequence may provide marine oils with higher purity from bad-smelling or bad-tasting contaminants than the D/S sequence of Document (1). On the contrary, as already respectively discussed the above sections 1.6.1 and 1.6.3, the disclosure in Document (1) implies that the non-preferred S/D sequence is expected to produce a lower level of purity vis-à-vis the preferred D/S sequence and the disclosure of Document (6) is totally silent as to whether the level of sensorial properties of the obtained oils is superior or inferior to that achievable by any other purification methods.

1.8.4 Therefore, the Board concludes that the skilled person would find no reason in the available prior art to expect that the smell and taste of fish of the marine oils obtainable by the purification and stabilization

process of Document (1) might be improved by reversing the D/S sequence of the purification steps.

Accordingly, for this reason alone the subject-matter of claim 1 is not rendered obvious by the available prior art and thus complies with the requirements of Article 56 EPC.

2. *Inventive step regarding the subject-matter of claims 2 to 30 of the patent as granted (Articles 52(1) and 56 EPC)*

2.1 The dependent claims 2 to 29 define preferred embodiments of the method of claim 1 and, therefore, their subject-matter involves an inventive step for the same reasons given above for claim 1.

2.2 The novelty of the marine oil of claim 30 was never contested. This oil inevitably has the improved sensorial properties resulting from the process of claims 1. Therefore, the Board finds that the subject matter of claim 30 involves an inventive step for the same reasons given above for claim 1.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar: The Chairman:

G. Rauh P. Krasa