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Datasheet for the decision of 11 December 2018

Case Number: T 0930/14 - 3.3.10

Application Number: 09757183.0

Publication Number: 2296614

IPC: A61K8/34, A61K8/36, A61K8/49, A61Q17/00

Language of the proceedings: EN

Title of invention:
SYNERGISTIC PRESERVATIVE BLENDS

Patent Proprietor:
LONZA, INC.
Lonza Ltd

Opponent:
Beiersdorf AG

Headword:

Relevant legal provisions:
EPC Art. 100(b), 56

Keyword:
Sufficiency of disclosure (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
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Beschwerdekammern

Boards of Appeal

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Case Number: T 0930/14 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 11 December 2018

Appellant: (Opponent)	Beiersdorf AG Unnastrasse 48 20253 Hamburg (DE)
Respondent : (Patent Proprietor 1)	LONZA, INC. 90 Boroline Road Allendale, NJ 07401-1613 (US)
Respondent: (Patent Proprietor 2)	Lonza Ltd Münchensteinerstrasse 38 4052 Basel (CH)
Representative:	Greiner, Elisabeth df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 80333 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 20 February 2014 concerning maintenance of the European Patent No. 2296614 in amended form.**

Composition of the Board:

Chairman	P. Gryczka
Members:	R. Pérez Carlón
	F. Blumer

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division concerning the maintenance of European patent No. 2 296 614 in the form of the first auxiliary request then pending.

II. Notice of opposition had been filed on the grounds of insufficiency of disclosure (Article 100(b) EPC) and lack of novelty and inventive step (Article 100(a) EPC).

III. The documents filed during the opposition proceedings include the following:

D2: EP 0 365 825 A1
D3: Interne Mitteilung, Spektren 15604-15605, from 14 November 2008
D6: Kathon™ GC, Dow, June 2006
D7: US 2006/0171911 A1
D11: The Quest for the Ideal Preserving System - Reducing traditional Preservatives in Combination with Dermosoft Octiol, J. Jänichen, Euro Cosmetics 7/8 2004, pages 10 to 16
D11a: Typed copy of document D11
D12: Texapon® N 70, Cognis, 19 January 2004
D13: The Benefit of Using Synergistic Mixtures of Preservatives, W. Siegert, SÖFW-Journal 132, December 2006

IV. The main request of the respondents (patent proprietors) corresponds to the request upon which the patent in suit was maintained. It contains four independent claims, which read as follows:

"1. A preservative formulation comprising the combination of two compounds having bactericidal and fungicidal properties, wherein the respective combination is lauryl alcohol/sorbic acid.

3. A preservative formulation comprising the combination of two compounds having bactericidal and fungicidal properties, wherein the respective combination is caprylyl glycol/dehydroacetic acid and wherein the caprylyl glycol is present in a concentration of 25 % to 75 %.

4. A preservative formulation comprising the combination of two compounds having bactericidal and fungicidal properties, wherein the respective combination is methylisothiazolinone/piroctone olamine and wherein the methylisothiazolinone is present in a concentration of 1 % to 5 %.

6. A method of reducing the bacterial and fungal load of a preparation comprising adding the preservative formulation according to any of claims 1 to 5 to the preparation."

V. The arguments of the appellant where relevant for the present decision were as follows:

Sufficiency of disclosure

The method according to claim 6 was not sufficiently disclosed for it to be carried out by a person skilled in the art, since the patent in suit disclosed neither how to measure whether the bacterial and fungal load had been reduced nor which reference indicator should be used.

Sufficiency of disclosure of the invention was also lacking, as the claimed subject-matter was not limited with respect to the amount of active components, the type of microorganisms against which activity was sought, or the composition to be preserved and it did not exclude the presence of further components.

Inventive step

Document D2 was the closest prior art for the formulations of claim 1. The problem underlying the claimed invention was to provide alternative preservative formulations. The claimed solution was a formulation characterised by containing lauryl alcohol, which was an impurity of one of the ingredients of the formulations of D2, and would have thus been obvious for the skilled person.

The composition of D11 containing 0.3% of Dermosoft® Octiol and Euxyl K 702 was the closest prior art for the preservative formulation of claim 3. The problem underlying the claimed invention was to provide an alternative preserving formulation. The solution, which was characterised by requiring a premix, would have been obvious in view of the common knowledge of the person skilled in the art.

Example 4 of D7 was the closest prior art for the formulations of claim 4. The problem was to provide an alternative preservative formulation and the solution, which was characterised by the relative amount of methylisothiazolinone, was obvious for the person skilled in the art.

Even if the claimed formulations were inventive, the conclusion would not have been inevitably applied to

the method of claim 6 as it merely related to an obvious method for adding active components to a preparation.

For these reasons, none of the independent claims of the patent in suit related to inventive subject-matter.

VI. The arguments of the respondents, where relevant for the present decision were as follows:

Sufficiency of disclosure

The method according to claim 6 for reducing the bacterial and fungal load of a preparation consisted merely in add formulations comprising two components. There is no reason why this method could not have been carried out by the person skilled in the art. The claimed invention was thus sufficiently disclosed.

Inventive step

The respondents agreed with the appellant in the choice of closest prior art with respect to each independent claim. The problem underlying the claimed invention was, in all cases, to provide an alternative preservative formulation which made it possible to use fewer preservative components. The prior art did not hint at the claimed solutions characterised by the combination of two compounds.

VII. Oral proceedings before the board of appeal took place on 11 December 2018.

VIII. The final requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that European patent No. 2 296 614 be revoked.

The respondents requested
- that the appeal be dismissed (i.e., that the patent be maintained on the basis of the main request as filed with the response to the grounds of appeal dated 2 October 2014 which corresponded to the then pending auxiliary request 1 found to be allowable by the opposition division), or subsidiarily,
- that the patent be maintained in the form of one of auxiliary requests 1C, 1D, 2A, 4A, 5A, 7, 8 and 8D,
  - auxiliary requests 1C, 2A, 4A, 5A as filed with the response to the grounds of appeal dated 2 October 2014,
  - auxiliary requests 7 and 8 as filed with letter dated 23 October 2018,
  - auxiliary requests 1D and 8D as filed during the oral proceedings before the board.

IX. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request. Sufficiency of disclosure

2. Independent claims 1, 3 and 4 relate to preservative formulations comprising the combination of two compounds. Claims 2 and 5 are dependent claims.

Claim 6 relates to a method of reducing the bacterial and fungal load of a preparation that entails adding to

it the preservative formulation according to any of claims 1 to 5.

3. The appellant argued that the invention was not sufficiently disclosed for it to be carried out, since it could not be determined whether the method of reducing the bacterial or fungal load of claim 6 would lead to such a reduction since the patent in suit did not disclose either the measurement method, or which reference indicator should be used.

This argument is flawed. In fact, even if the patent in suit does not disclose such a method, it is not disputed that, on the application filing date, such methods would have been well known to the skilled person. This is also confirmed by the prior art cited in the present proceedings (e.g. D11).

4. The appellant further argued that the claims were not limited with respect to the amount of active components, the type of micro-organism against which activity was sought or the composition to be preserved, and they did not exclude the presence of further active components. For these reasons, not every method comprising the step of adding to a preparation a preservative formulation according to the claimed invention would reduce bacterial and fungal load. Also for this reason, the appellant concluded that the claimed invention was not sufficiently disclosed.

4.1 However, determining the amount of formulation required for reducing bacterial and fungal load would have been known by the skilled person. In addition, the examples provide information on the quantities required for the activity. This argument is thus not convincing.

4.2 With respect to the type of microorganisms involved, the appellant has relied on figure 7 of document D10, which should prove that the claimed formulations were not active against every micro-organism.

However, document D10 shows that a mixture containing dehydroacetic acid and Dermosoft® octiol (on the left in figure 7) for two of the microorganisms tested leads to a log CFU lower than a mixture containing only dehydroacetic acid; both mixtures were very effective (log CFU of about 1) against the remaining microorganisms. Thus, D10 fails to proove the arguments of the appellant.

Moreover, claim 6 does not require the claimed formulation to be active against each and every micro-organism. The issue here is whether the skilled person could have obtained working embodiments of the claimed invention, which is considered to be the case, as the examples of the application prove the activity of the claimed formulations against defined types of microorganisms and provide the minimum amounts required.

Thus, this argument is not convincing either.

5. The appellant also argued that a preparation can contain further preservative components. In the presence of additional preservatives, the claimed preservative compositions would not inevitably reduce the bacterial and fungal load over and above the level already achieved by those additional preservatives alone and, for this reason, the claimed method was not sufficiently disclosed.

The examples of the patent show that the addition of

the claimed preservative formulations reduces the bacterial and fungal load. The claimed process is based on this finding. The argument of the appellant does not call into question the sufficiency of disclosure of the claimed method, which in fact can be put into practice merely by adding the claimed formulations to a preparation.

Most of the arguments of the appellant and in particular this one rely on extreme situations and interpret the claims to an unreasonable extent, but they never call into question, let alone on the basis of reliable evidence, that the method is not sufficiently disclosed to achieve the effect, i.e. reducing the bacterial and fungal load of a preparation.

6. The appellant further argued that the examples of the patent in suit lacked sufficient detail and could not be reproduced. According to the appellant, this means that the patent in suit did not provide one way to carry out the invention and the claimed invention was not sufficiently disclosed.

There is, however, no evidence on file that the examples as described in the patent specification cannot be reproduced. This argument must thus be rejected.

7. The appellant did not convince the board that the claimed invention is not sufficiently disclosed for it to be carried out by the person skilled in the art.

Inventive step

8. *Claim 1*

8.1 Claim 1 is directed to a preservative composition comprising the combination of lauryl alcohol and sorbic acid.

8.2 Closest prior art

The opposition division and the parties considered that document D2 was the closest prior art. The board sees no reason to differ.

It has further not been disputed that document D2 discloses a composition with a preservative effect containing sorbic acid (page 2, lines 35-37), in combination with a salt of formic acid and an inorganic or aliphatic, saturated organic acid.

Example 2 of D2 discloses a shower gel containing sorbic acid, sodium formate and phosphoric acid as preservatives, and the sodium salt of lauryl alcohol diglycol ether sulfate.

8.3 Technical problem underlying the invention

The respondents defined the technical problem underlying the claimed invention as to provide a preservative formulation which makes it possible to use fewer preservative components.

8.4 Solution

The solution to this technical problem is the claimed preservative formulation, characterised in that it

contains lauryl alcohol.

8.5 Success

Table 5 of the patent in suit shows that the problem as formulated above has been credibly solved by the claimed preservative formulations, which are active against Gram(+) and Gram(-) bacteria, yeast and mold. The combination of lauryl alcohol and sorbic acid is effective on its own and does not require further antimicrobial agents.

The appellant argued that claim 1 was drafted using open language ("comprising") and thus did not exclude the presence of further components in the claimed formulation. For this reason, it argued, the problem as formulated above was not solved over the whole subject-matter claimed.

However, the feature required to solve the problem mentioned above is the combined presence of lauryl alcohol and sorbic acid, which work synergistically (Table 5) as components of the claimed invention. Thus, the appellant's argument here is not convincing.

8.6 Thus it remains to be decided whether the proposed solution to the objective problem defined above is obvious from the prior art.

8.6.1 The closest prior art D2 discloses a combination of three components as a preservative system: sorbic acid, formate salts and acids.

The prior art would not have prompted the skilled person to combine lauryl alcohol with sorbic acid at all, let alone trying to obtain a formulation requiring

fewer antimicrobial components. For this reason, the preservative formulations of claim 1 are inventive, within the meaning of Article 56 EPC.

8.6.2 The appellant argued that it was to be expected that the compositions of Examples 1 and 2 of D2 contained lauryl alcohol as D3 and D12 showed that it was a common impurity of sodium sulfate of lauryl alcohol diglycol ether. With this knowledge, the skilled person, trying to obtain an alternative, would have considered adding this compound to sorbic acid and thus have arrived at the claimed invention without using inventive skill.

However, the role of the sodium sulfate of lauryl alcohol diglycol ether in the compositions of D2 is that of a surfactant (page 3, line 35) and not a preservative. Even if lauryl alcohol could have been present in the compositions of D2, there is no indication, either in this document or anywhere else in the available prior art, that it causes any preservative activity. This is confirmed by Table 5 of the patent in suit, which show lauryl alcohol alone not to be active against the micro-organisms tested. For these reasons, the skilled person would not have been prompted to combine lauryl alcohol with sorbic acid, even when seeking an alternative, let alone when trying to reduce the number of active components required in a preservative formulation.

This argument of the appellant is thus not convincing.

9. *Claim 3*

Claim 3 relates to a preservative formulation comprising caprylyl glycol and dehydroacetic acid in

which the concentration of the former is 25 % to 75 %.

9.1 Closest prior art

Both parties considered document D11 to represent the closest prior art, and the board sees no reason to differ.

In the following, reference is made to document D11a, which is a more readable version of document D11 and was used by both parties as the basis for discussion during the oral proceedings.

It has not been disputed that document D11a discloses two preservative formulations, namely, Dermosoft® Octiol, which consists on caprylyl glycol, and Euxyl K 702, which contains 7% dehydroacetic acid among other ingredients (D13, page 48, Product B).

Document D11a further discloses (page 3, page 7) an oil-in-water formulation containing 0.3 % of each of these preservative formulations, which has been tested for inhibition of different micro-organisms.

The appellant argued that the opposition division should not have taken the oil-in-water formulations of D11a as the starting point for examining inventive step but, instead, the combination of Dermosoft® Octiol and caprylyl glycol.

However, the embodiment suggested by the appellant is not disclosed in D11a.

9.2 Technical problem underlying the invention

The technical problem underlying the claimed invention

is how to provide a preservative formulation which makes it possible to use fewer preservative components.

9.3 Solution

The solution to this technical problem is the claimed preservative formulation containing caprylyl glycol, characterised in that it also contains dehydroacetic acid and that caprylyl glycol is present in a concentration of 25 % to 75 %.

9.4 Success

Table 3 of the patent in suit shows the claimed preservative formulation to be active against bacteria and thus the problem as formulated above is credibly solved. This was not contested.

9.5 It thus remains to be decided whether the proposed solution to the objective problem defined above is obvious from the prior art.

9.5.1 The skilled person would not have expected to obtain a preservative formulation requiring fewer active ingredients by choosing this particular combination, as these ingredients could also have formed an antagonising mixture. Dehydroacetic acid is a minor component of Euxyl K 702 (7 %). There is no indication in the prior art that, by adding it, the remaining active ingredients of Euxyl K 702 would no longer be required. For these reasons, the preservative formulation of claim 3 is inventive, within the meaning of Article 56 EPC.

9.5.2 The appellant argued that it was obvious to formulate caprylyl glycol and Euxyl K 702 in the relative amounts

disclosed in the oil-in-water emulsion of D11a as a premix, as their mixture was known to be active. By doing so, the skilled person would inevitably have arrived at the claimed invention without using inventive skills.

However, the problem underlying the claimed invention is how to provide an alternative formulation which allows using fewer components. The skilled reader would not combine part of the components of the preservative formulations disclosed in D11a to make the other components of these formulations redundant.

This argument of the appellant is thus not convincing.

10. *Claim 4*

Claim 4 relates to a preservative formulation comprising methylisothiazolinone and piroctone olamine, in which the concentration of the methylisothiazolinone is 1 % to 5 %.

10.1 Closest prior art

Both parties considered document D7 to be the closest prior art, and the board sees no reason to differ.

Example 4 of D7 discloses an anti-microbial shampoo containing 1 % piroctone olamine and 0.0008 % Kathon GC.

It is not disputed that Kathon GC contains 0.35 % methylisothiazolinone (D6, page 2, second table) or that it is a preservative formulation.

10.2 Technical problem underlying the invention

The technical problem underlying the claimed invention is how to provide a preservative formulation which makes it possible to use fewer preservative components.

10.3 Solution

The solution to this technical problem is the claimed preservative formulation, characterised by the combination of piroctone olamine and methylisothazolinone, the latter at a concentration of 1 % to 5 %.

10.4 Success

Table 4 of the patent in suit proves that the claimed preservative formulation is active versus bacteria, mold and yeast and thus that the problem as formulated above is credibly solved.

10.5 It thus remains to be decided whether the proposed solution to the objective problem defined above is obvious from the prior art.

10.5.1 The skilled person, trying to obtain an alternative formulation requiring fewer active components would not have been prompted to combine the ingredients as required by claim 1, let alone at the required concentration of methylisothiazolinone. D7 discloses compositions containing minute amounts of Kathon GC in which the concentration of methylisothiazolinone is only 28 ppb. Piroctone olamine is disclosed in D7 as anti-microbial with anti-dandruff activity and not as a preservative component (page 3, paragraphs [0037] and [0038]). There is no reason why the skilled person

would combine an anti-dandruff agent with one of the components of a preservative formulation to obtain a preservative formulation needing fewer active components. For this reasons, the formulation of claim 4 is inventive, within the meaning of Article 56 EPC.

10.5.2 The appellant argued that it would have been obvious for the skilled person to provide the combination of components required by claim 4, used in D7 as preservatives, as a premix.

However, the issue here is whether the skilled person would have combined a compound disclosed as an anti-dandruff active with a minor component of a preservative which is itself a minor component of the compositions of D7 when seeking to reduce the number of active components required. This is not considered to be the case.

This argument of the appellant is thus not convincing.

11. *Claim 6*

11.1 Claim 6 relates to a method of reducing the bacterial and fungal load of a preparation that entails adding the preservative formulation according to any of claims 1 to 5 to the preparation.

The appellant argued that the method of claim 6 merely related to an alternative addition method and could not be considered inventive for the same reasons as the preservative formulations of claims 1 to 5.

However, claim 6 also aims at solving the problem of how to provide an alternative method for reducing the bacterial and fungal load of a preparation which makes

it possible to use fewer preservative components. The claimed solution, which is characterised by adding to a preparation a preservative formulation according to claims 1 to 5, is inventive for the same reason as the claimed formulations.

11.2 For these reasons, the state of the art did not hint at the claimed solution, which is thus inventive within the meaning of Article 56 EPC.

12. The subject-matter of independent claims 1, 3, 4 and 6 involves an inventive step. Claims 2, 5, 7 and 8 are dependent claims, whose subject-matter is therefore also inventive.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Sánchez Chiquero P. Gryczka

Decision electronically authenticated