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**Datasheet for the decision
of 30 September 2008**

Case Number: T 0718/06 - 3.3.10

Application Number: 02002043.4

Publication Number: 1201229

IPC: A61K 7/48

Language of the proceedings: EN

Title of invention:

Concentrated liquid formulations comprising a microbicidally active ingredient

Applicant:

Ciba Holding Inc.

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 56, 111(1)

Keyword:

"Main request, claims 1 and 2: inventive step (yes) - unexpected improvement, fair comparison"
"Remittal (yes)"

Decisions cited:

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Catchword:

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Case Number: T 0718/06 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 30 September 2008

Appellant:

Ciba Holding Inc.
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CH-4057 Basel (CH)

Representative:

Dr Richard Schumacher
Ciba Holding Inc.
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CH-4057 Basel (CH)

Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 20 December 2005
refusing European application No. 02002043.4
pursuant to Article 97(1) EPC.

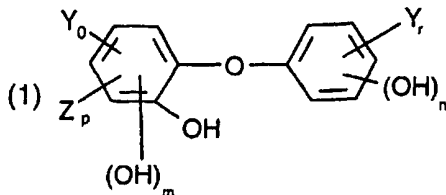
Composition of the Board:

Chairman: R. Freimuth
Members: P. Gryczka
D. S. Rogers

Summary of Facts and Submissions

I. The present appeal lies from the decision of the Examining Division posted on 20 December 2005 refusing the European patent application No. 02 002 043.4 published under the publication No. EP 1 201 229 and filed as a divisional application to the application No. 97923969.6. The set of claims underlying the contested decision (present main request) read as follows:

"1. A concentrated liquid formulation (b) comprising (b1) 10 to 25% by weight of a microbicidally active ingredient selected from the 2-hydroxydiphenyl ether, of the formula

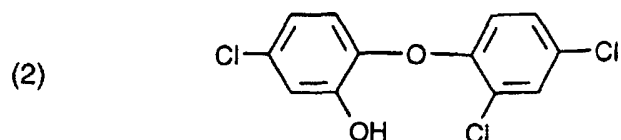


in which

Y is chlorine or bromine,
Z is SO₂H, NO₂ or C₁-C₄alkyl,
r is 0 to 3,
o is 0 to 3,
p is 0 or 1,
m is 0 or 1 and
n is 0 or 1,

(b2) 10 to 70% by weight of cumene sulfonate,
(b3) 10 to 50% by weight of lactic acid;
(b4) 5 to 75% by weight of 1,2-propanediol,
and water to 100%.

2. A liquid formulation according to claim 1, wherein component (b1) has the formula



3. The use of a liquid formulation according to any one of claims 1 or 2 as antimicrobially active ingredient in cosmetic products.

4. The use of a liquid formulation according to any one of claims 1 or 2 as antimicrobially active ingredient in household articles.

5. The non-therapeutic use of a liquid formulation according to any one of claims 1 or 2 as antimicrobially active ingredient for hard and soft surfaces.

6. The non-therapeutic use according to claim 5, wherein the liquid formulations are used for human skin.

7. The use of a liquid formulation according to claim 1 or 2 as a preservative in cosmetic products and household articles.

8. The use of a liquid formulation according to claim 1 or 2 as disinfectant for textiles.

9. The non-therapeutic use of a liquid formulation according to claim 1 or 2 as decontamination agent or disinfectant for the skin and hard surfaces."

II. The Examining Division held that the claimed subject-matter fulfilled the requirements of Articles 76(1) and 84 EPC and was novel. However, the subject-matter of claim 1 lacked inventive step in view of the teaching of documents

(1) EP-A-0 259 249 and

(2) WO 96/06152.

According to the Examining Division the claimed concentrated liquid formulation differed from that disclosed in document (2) by the fact that it was more concentrated and contained lactic acid instead of citric acid. The comparative experiments on which the Applicant (Appellant) relied to prove that the claimed compositions were more stable than those of document (2) showed that at least one composition falling under the claims of the application in suit was in terms of storage stability worse than a composition according to document (2). Thus, the problem of improving the stability of the compositions was not solved. In addition, the comparative examples did not demonstrate that the selection of lactic acid amounted to an unexpected microbicidal activity over citric acid. For these reasons, the claimed compositions did not involve an inventive step.

III. The Appellant argued that the problem underlying the present invention when considering document (2) as representing the closest prior art was to provide a storage stable concentrated formulation of an antimicrobically active compound. The results of the

comparative tests filed during the examination proceedings demonstrated that the replacement of citric acid present in the compositions according to the closest prior art by lactic acid as required for the claimed compositions improved the storage stability of the concentrated compositions. These comparative tests were performed with different concentrations of the required components and thus covered the whole scope of the claims. The comparison made by the Examining Division in the contested decision in order to deny the improvement in stability was not fair since it involved two compositions differing not only by the replacement of citric acid by lactic acid, but also, by the concentration of the different components. Since no prior art suggested that the replacement of citric acid by lactic acid improved the storage stability of concentrated solution, the claimed subject-matter involved an inventive step.

- IV. The Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 9 underlying the decision under appeal (main request) or, alternatively, on the basis of the first or second auxiliary request filed with a letter dated 19 June 2008.

- V. At the end of the oral proceedings which took place on 30 September 2008, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request: claims 1 and 2

2. It was not contested in the decision under appeal that claims 1 and 2 found a basis in the parent application as filed as well as in the current application as filed and that they defined a clear and novel subject-matter (Articles 76 (1), 123(2), 84 and 54 EPC). The Board, on its own, sees no reason to challenge these findings.

3. *Inventive step*

- 3.1 The present application is directed to a liquid formulation comprising a microbicidally active ingredient selected from 2-hydroxydiphenyl ethers. Liquid formulations containing the same microbicidally active ingredients are disclosed in document (2), which was considered in the decision under appeal as representing the closest prior art. The Board considers, in agreement with the Appellant, that this document represents the closest state of the art and, hence, takes it as the starting point for assessing inventive step.

Document (2) discloses formulations comprising, *inter alia*, the same microbicidal active 2-hydroxydiphenylethers as defined in present claim 1, cumene sulfonate, citric acid, 1,2-propanediol (propylene glycol) and water (see claims 1, 2, 5, 11 and 16; examples 1 to 3). The compositions are diluted in the sense that they contain from 0,01 to 0,2% by

weight of the microbicidal active substance (claim 1 and page 1, third paragraph). The compositions can contain an aliphatic monocarboxylic acid (page 3, compounds (b₃)) thereby encompassing lactic acid which is however not specifically mentioned. The formulations are used for the disinfection and cleansing of the human skin and of hard objects (page 1, lines 2 and 3).

3.2 Having regard to this prior art, the Appellant submitted that the technical problem underlying the present application was to provide a concentrated formulation of a microbicidally active substance which is stable during storage (see also application as filed page 9, penultimate paragraph).

3.3 As the solution to this problem, the present application proposes the formulation according to claim 1 in which the components are present in the weight percentage ranges defined in the claim and which is characterized in that it contains 10 to 50% by weight of lactic acid.

3.4 In order to demonstrate that the technical problem as defined above has effectively been solved by the claimed formulations the Appellant relied on the results of the comparative examples filed in the examination proceedings with the letter dated 18 October 2005. In these tests the storage stability of three compositions in accordance with present claim 1 were compared to compositions differing only by the replacement of lactic acid by citric acid (comparisons A1-A2, B1-B2 and C1-C2). In each of the three comparative tests the formulation in accordance with the invention containing lactic acid was clearer than

the formulation containing citric acid after one day of storage as indicated in the test report and shown by the photographs annexed to it. The claimed compositions are thus more stable than the composition of the prior art in the sense that less precipitation of solids occurs during storage. These comparisons are fair since in each of the three comparisons, the composition in accordance with the present invention differed from that illustrating the closest prior art only by the nature of the acid, said feature characterising the claimed composition vis-à-vis the closest prior art. The alleged improvement of storage stability over the closest prior art is thus adequately supported by the comparative experiments filed during the examination proceedings. The Board is thus satisfied that the technical problem as defined above is effectively solved by the claimed formulations.

The Examination Division arrived at the conclusion that the technical problem was not solved by comparing the stability of formulation C1 in accordance with the invention with that observed for formulation A2 illustrating the prior art. However, the two compositions A2 and C1 differ not only by the replacement of citric acid by lactic acid, but also essentially by the concentration of the components (10% lactic acid in C1, 40% citric acid in A2; 37% 1,2-propanediol in C1 and 5% in A2). Therefore, the conclusion of the Examining Division denying the fact that the problem underlying the present application has effectively been solved is not based on a fair comparison and must be rejected.

- 3.5 It remains to be decided whether or not the proposed solution to the objective technical problem as defined above is obvious in view of the state of the art.
- 3.6 Whereas document (2) generally describes that diluted formulations can contain a monocarboxylic acid (page 3, paragraph (b₃)), it does not specifically mention lactic acid and thus, cannot teach that this particular acid improves the storage stability of concentrated liquid formulation containing microbicidally active 2-hydroxydiphenyl ethers. The same conclusion applies to document (1) which although disclosing the possible presence of saturated carboxylic acids (page 4, lines 49 to 51) does not mention lactic acid, let alone its ability to improve the storage stability of concentrated formulations. Thus, document (2) alone or in combination with document (1) does not point to the claimed solution proposed for solving the problem underlying the present application.

The Examining Division did not rely on any further documents in the decision under appeal to challenge obviousness. The Board is not aware of any further relevant document and is, thus, satisfied that the state of the art addressed in the proceedings does not render the claimed invention obvious.

4. The Board concludes from the above that the subject-matter of claim 1 and, consequently, that of dependent claim 2 of the main request involves an inventive step within the meaning of Articles 52(1) and 56 EPC.

5. *Remittal*

Having so decided, the Board has not, however, taken a decision on the whole matter, since the independent "use type claims" 3 to 9 have not been examined in the first instance proceedings in particular with respect to their conformity with the requirements of Articles 84 and 123 (2) EPC. In addition, it has not been established in the examination proceedings whether or not the expression "non-therapeutic" in claims 5, 6 and 9 is a technical feature which defines the subject-matter claimed pursuant to Rule 43(1) EPC and whether or not this expression successfully excises from the claims subject-matter excluded from patentability by the provision of Article 53(c) EPC. Under these circumstances the Board considers it appropriate to exercise the power conferred to it by Article 111(1) EPC to remit the case to the Examining Division for the purpose of examining *inter alia* these fresh issues.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution on the basis of claims 1 to 9 underlying the decision under appeal (main request).

The Registrar:

The Chairman:

C. Rodríguez Rodríguez

R. Freimuth