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DECISION of 26 September 2001

Case Number:

T 0382/98 - 3.3.2

Application Number:

91304098.6

Publication Number:

0456458

IPC:

A61K 7/42

Language of the proceedings: EN

Title of invention: Cosmetic composition

Patentee:

UNILEVER PLC, et al

Opponent:

The Boots Company PLC

Headword:

Cosmetic Composition/UNILEVER

Relevant legal provisions: EPC Art. 56

Keyword:

"Main, first and second auxiliary requests - invention step: no - obvious choice within prior art teaching"

Decisions cited:

T 0198/84

Catchword:



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Boards of Appeal

Chambres de recours

Case Number: T 0382/98 - 3.3.2

DECISION of the Technical Board of Appeal 3.3.2 of 26 September 2001

Appellant: (Opponent)

The Boots Company PLC 1 Thane Road West

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Representative:

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Respondent:

(Proprietor of the patent)

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Decision under appeal:

Interlocutory decision of the Opposition Division of the European Patent Office posted 17 February 1998 concerning maintenance of European patent No. 0 456 458 in amended form.

Composition of the Board:

Chairman:

U. Oswald

Members:

J. Riolo

S. U. Hoffmann

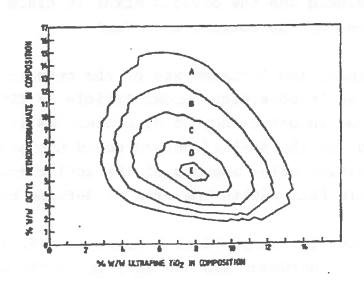
# Summary of Facts and Submissions

I. European patent No. 0 456 458 based on application No. 91 304 098.6 was granted on the basis of 10 claims.

Independent claim 1 as granted read as follows:

"A composition for topical application to human skin to provide protection from excessive exposure to ultraviolet rays, which comprises:

- a. an effective amount of titanium dioxide having an average particle size of less than 100 mm as an inorganic sunscreen;
- b. an effective amount of octyl methoxycinnamate as an organic sunscreen; and
- c. a cosmetically acceptable vehicle for the sunscreens; the weight concentration of the titanium dioxide and octyl methoxycinnamate being within the region designated C in the accompanying drawing."



II. Notice of opposition was filed against the granted patent by the appellant (opponent).

The patent was opposed under Article 100(a) EPC for lack of novelty and lack of inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC.

The following document was inter alia cited during the proceedings:

- (3) GB-A-2 217 987.
- III. The interlocutory decision of the Opposition Division established that the patent could be maintained in an amended form on the basis of the first auxiliary request as submitted during the oral proceedings.

The set of claims as maintained by the Opposition Division corresponded to the set of claims as granted in which the wording in claim 4 "or are encompassed by" was deleted and the obvious error in claim 1 "mm" was replaced by the correct unit "nm".

The Opposition Division was of the opinion that the appellant's objections under Article 83 EPC did not show the insufficiency of disclosure as it was not argued why the skilled person could not produce a composition using amounts of the active agents so that it would fall within the area as defined by the claims.

As to novelty compared with document (3), it concluded that this document did not anticipate the subject-matter of claim 1 of the contested patent which represented a selection over this disclosure.

Starting from document (3) as closest state of the art, the Opposition Division maintained that, in view of the unexpected synergistic effect achieved in the selected area defined by the specific amounts of titanium dioxide and octyl methoxycinnamate, the subject-matter of the contested patent involved an inventive step.

In that respect, it did not accept the appellant's argument that the expression used by the respondent was not suitable for proving a synergistic effect since no evidence was provided to show that there was not linear dependency between the SPF (Sun Protection Factor) and the concentration of the sunscreen agent, contrary to the requirement of this expression.

- IV. The appellant lodged an appeal against the said decision.
- V. Oral proceedings were held before the Board on 26 September 2001.

During the oral proceedings, two sets of claims were filed as auxiliary requests I and II. In these successive auxiliary requests, the compositions covered by claim 1 were those with titanium dioxide and octyl methoxycinnamate levels in contoured regions D and E respectively. The dependent claims of these requests were adapted accordingly, ie dependent claims 4 and 5 were deleted in auxiliary requests I and II respectively as their feature was introduced in the main claim.

VI. The appellant contested the findings of the Opposition Division that the subject-matter of the patent in suit was novel.

It expressed the view that the criteria set out in decision T 198/84 (OJ EPO 1985, 209, point 5), to be

applied when considering the novelty of an invention allegedly based on a selection, were not fulfilled in the present case.

As to inventive step, it filed experimental data to show that the relationship between SPF and the concentration of the organic sunscreen was not a straight line but a curve and that the respondent's expression would therefore always underestimate the contribution any concentrations of organic sunscreen would indeed make when used in combination. It accordingly concluded that no synergistic effect was shown for the specific area defined by the respondent and that the claimed subject-matter was therefore not inventive.

VII. The respondent (patentees) submitted that the conclusions of the Opposition Division with respect to novelty were correct.

As regards inventive step, it argued that the expression did not in fact imply a linear correlation between the sunscreen concentration and SPF as it simply stated the intuitive obviousness that a sunscreen with SPF S mixed in any proportions with another sunscreen with SPF S will still exhibit an SPF of S. It moreover maintained that the expression was scientifically correct as it was inspired by Beer's law.

VIII. The appellant requested that the decision under appeal be set aside and that European patent No. 0 456 458 be revoked.

The respondent requested that the appeal be dismissed and that the patent be maintained with the claims as maintained by the Opposition Division or auxiliarily with the set of claims of auxiliary requests I or II

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filed during the oral proceedings.

# Reasons for the Decision

- The appeal is admissible.
- Main request
- 2.1 Articles 123 and 84 EPC

No objection under Articles 123 and 84 EPC was raised by the appellant and the Board sees no reason to differ.

## 2.2 Article 83 EPC

During the oral proceedings, the Board expressed the view that the written objections raised under Article 83 EPC did not appear to be very convincing and invited the appellant to comment further on this ground. In reply to this invitation, the appellant skipped this ground and argued directly with its novelty and inventive step objections. Under these circumstances, the Board supports the Opposition Division's conclusions in the decision under appeal in that respect.

### 2.3 Novelty

During the oral proceedings, both parties argued that, having regard to the decisive importance of the actual demonstration of a synergistic effect for the assessment of novelty and inventive step it was hardly possible to decide separately on novelty and inventive step without having considered the existence of such effect.

The Board acknowledges the relevance of the demonstration of an effect in the present case and under these specific circumstances agrees to deal directly with the inventive step issue.

#### 2.4 Inventive step

2.4.1 The contested patent relates to compositions containing titanium dioxide and octyl methoxycinnamate for topical application to human skin to provide protection from the damaging effects of sunlight (page 2, lines 5 and 6, claims 1 and 10).

The Board agrees with the parties that document (3) can be regarded as the closest prior art.

Example 11 on page of document (3) describes a composition for topical application to human skin to provide protection from excessive exposure to ultraviolet rays, which comprises an effective amount of titanium dioxide having an average particle size of less than 100 nm as an inorganic sunscreen (MT100T°), an effective amount of octyl methoxycinnamate as an organic sunscreen (Parsol MCX°) and a cosmetically acceptable vehicle for the sunscreens.

The weight concentrations of titanium dioxide and octyl methoxycinnamate in this example are 5% w/w and 1% w/w respectively.

The ranges for the inorganic sunscreen and for the organic sunscreen disclosed in document (3) are 0.5 to 30%, preferably 2,5 to 10% for titanium dioxide and 0,1 to 10% for the other sunscreen agent (page 1, line 21, page 2, line 26, page 3, line 3).

According to the respondent, a synergistic effect was present in the sunscreen compositions when the amounts

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of the sunscreen agents were selected such as to fall within area C as defined in claim 1 of the contested patent.

In order to demonstrate this effect, it made the assumption that when a sunscreen with an SPF of S, having a concentration of sunscreen agent of X, is mixed in any proportion with another sunscreen with an SPF of S, having a concentration of sunscreen agent of Y, the mixture will still exhibit an SPF of S (ie SPF of Xn + SPF of Y(1-n) = S; n being the number of parts).

In its opinion, this expression was suitable for predicting the expected SPF of any sunscreen mixtures so that any mixtures producing a better than expected SPF were considered to provide a synergistic effect.

As to the validity of the expression, it submitted that this expression was not only intuitively obvious but also scientifically sound as it was based on Beer's law.

In that respect, the Board notes that, as accepted by the respondent during the oral proceedings, it can be derived from Beer's law that SPF = exp (scl) (wherein s is the specific absorption coefficient of the considered sunscreen agent, c its concentration and l the thickness of the layer). This means that, according to the law referred to by the respondent, the SPF varies exponentially with respect to its concentration.

Having regard to the experimental data provided by the appellant together with its grounds of appeal and accepted by the respondent as being, moreover, well known to those skilled in the art, it appears that the SPF of titanium dioxide varies linearly with respect to its concentration whereas the SPF of octyl

methoxycinnamate varies according to a curve different from Beer's law.

Accordingly, the respondent's assumption that the expression is scientifically correct because it is based on Beer's law does not hold good.

It should also be added that the complexity of a system containing an organic agent mixed with an inorganic agent in combination with various vehicles is in any case far remote from the ideal conditions required for applying Beer's law.

The Board is also not convinced of the intuitive obviousness of the expression used by the respondent. In fact, the expression does not take into account the dilution effect of the sunscreen agents which occur when mixing together two sunscreens. In fact this dilution influences the SPF values of each sunscreen agent as its concentration in the resulting mixture is lower. The SPF diminution for an identical dilution factor is however not the same for each sunscreen as it depends on the type of relationship between SPF and concentration which is specific for each sunscreen composition. It will thus be different for two sunscreens showing two different relationships between SPF and concentration and, in the case of sunscreens showing a non-linear relationship, such as a curve, it will moreover also be influenced by the shape of the curve.

In the present case, it is indeed apparent from the figures provided by the appellant, showing that the relationships between SPF and concentration for titanium dioxide and octyl methoxycinnamate are different (straight line versus curve), that their SPF will be affected in diverse ways by the dilution phenomena.

Moreover, it is also expected from the shape of the curve obtained for octyl methoxycinnamate, which shows very different curvatures of the line at the beginning and the end, that a decrease in its concentration upon mixing will have a very different impact on the variation in its SPF, depending on whether the final concentration of octyl methoxycinnamate in the mixture remains at the beginning or at the end of the curve.

Accordingly, as the expression used in the patent in suit does not take these aspects into account, it does not appear to be accurate to predict the SPF values of sunscreen mixtures.

The respondent produced, moreover, no evidence showing that its expression was nevertheless accepted and actually used as such in the field of sunscreens to demonstrate a synergistic effect.

Under these circumstances, the Board concludes that the presence of a synergistic effect for the compositions of the patent in suit has not been plausibly shown, as the skilled person has no reliable values with which to compare in order to assess whether there are any enhanced protection effects.

In view of the fact that the expression used in the patent is not accurate for the purpose of predicting the expected SPF of a mixture containing titanium dioxide and octyl methoxycinnamate as explained above, all other arguments provided by the respondent to demonstrate the presence of a synergistic effect are pointless as they are not based on an accurate assumption.

- 2.4.2 Accordingly, the problem to be solved by the subjectmatter of claim 1 of the patent in suit as against document (3) can only be seen in the provision of alternative sunscreen compositions.
- 2.4.3 This problem is solved by the composition according to claim 1 of the contested patent and, in the light of the description and examples of the patent in suit, the Board is satisfied that it has been solved.
- 2.4.4 Thus, the question to be answered is whether the proposed solution, ie using weight concentration of titanium dioxide and octyl methoxycinnamate within the region C of claim 1 of the contested patent, would have been obvious to the skilled person faced with the problem defined above in the light of the prior art.

In that respect, document (3) already describes in example 11 a sunscreen composition containing a mixture of titanium dioxide and octyl methoxycinnamate.

The Board notes that the concrete example disclosed in example 11 falls outside the scope defined by the region C of claim 1 of the contested patent.

However, document (3) teaches that the ranges for titanium dioxide for the organic sunscreen may vary between 2,5 to 10% and 0,1 to 10% respectively, ie also within the region C as defined in claim 1 of the contested patent.

Accordingly, the Board is satisfied that the skilled person faced with the problem as defined above under 2.4.2 would prepare the compositions according to the contested patent without inventive activity just by following the teaching of document (3) since he would expect any compositions foreseen in that document to be also equally suitable as sunscreen compositions. The

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area C of claim 1 of the contested patent is therefore merely the result of an obvious choice within the prior art teaching.

2.4.5 In the light of these facts, the Board can only conclude that the subject-matter of claim 1 does not involve an inventive step as required by Article 56 EPC.

Since claim 1 of the set of claims under consideration is not allowable, there is no need for the Board to consider the remaining claims.

First and second auxiliary requests

As no effect has been shown for regions D and E introduced in the first and second auxiliary requests respectively, the reasoning under 2.4 also holds good for these sets of claims.

#### Order

# For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- The patent is revoked.

The Registrar:

The Chairman:

A. Townend

U. Oswald