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**Datasheet for the decision
of 24 July 2012**

Case Number: T 0849/09 - 3.3.10

Application Number: 99937607.2

Publication Number: 1100447

IPC: A61K 7/42

Language of the proceedings: EN

Title of invention:
Sunscreen compositions

Patentee:
THE PROCTER & GAMBLE COMPANY

Opponents:
BEIERSDORF AG
Merck Patent GmbH
DSM NUTRITIONAL PRODUCTS AG

Headword:
Sunscreen compositions/PROCTER & GAMBLE

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no) - obvious to try - expectation of success"

Decisions cited:
-

Catchword:
-



Case Number: T 0849/09 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 24 July 2012

Appellant I:
(Opponent 1)

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Appellant II:
(Opponent 3)

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(Opponent 2)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted 24 February 2009
rejecting the opposition filed against European
patent No. 1100447 pursuant to Article 101(2)
EPC.**

Composition of the Board:

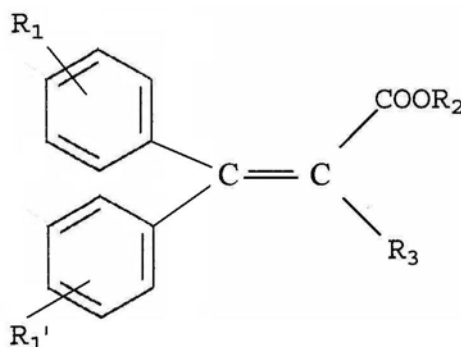
Chairman: P. Gryczka
Members: J.-C. Schmid
F. Blumer

Summary of Facts and Submissions

I. The Appellants I and II (Opponent 1 and 3) lodged an appeal against the decision of the Opposition Division, rejection the opposition against European patent No. 1 100 447, independent claims 1 and 9 thereof reading as follows:

"1. A composition suitable for use as sunscreen characterized in that the composition comprises:

- a) a safe and effective amount of a UVA-absorbing dibenzoylmethane sunscreen active;
- b) a safe and effective amount of a stabilizing agent having the formula



wherein R₁ and R₁' are independently in the para or meta position and are independently a hydrogen atom or a straight- or branched chain C₁-C₈ alkyl radical, R₂ is a straight- or branched-chain C₁-C₁₂ alkyl radical; and R₃ is a hydrogen atom or a -CN radical;

- c) a safe and effective amount of a UVB sunscreen that is 2-phenyl-benzimidazole-5-sulfonic acid,

provided that the composition comprises less than or equal to 5% inorganic sunblock; and

- d) a carrier suitable for application to the skin;

wherein the mole ratio of the stabilizing agent to the UVA-absorbing dibenzoylmethane sunscreen active is less than 0.8 and wherein the composition is substantially free of benzylidene camphor derivatives."

"9. A composition suitable for use as sunscreen characterized in that the composition comprises :

- a) from 2% to 3%, by weight of the composition, of UVA-absorbing dibenzoylmethane sunscreen active selected from the group consisting of 4-isopropyl-dibenzoylmethane, 4-(1,1-dimethylethyl)-4'methoxy-dibenzoylmethane, and mixtures thereof;
- b) from 1.5% to 2.25%, by weight of the composition, of a stabilizing agent selected from the group consisting of 2-ethylhexyl-2-cyano-3,3-diphenyl-acrylate, ethyl-2-cyano-3,3-diphenylacrylate, 2-ethylhexyl-3,3-diphenylacrylate, ethyl-3,3-bis(4-methoxyphenyl)acrylate, and mixtures thereof;
- c) from 1.0% to 1.5%, by weight of the composition, of 2-phenyl-benzimidazole-5-sulfonic acid; and
- d) a carrier suitable for application to the skin;

wherein the mole ratio of the stabilizing agent to the UVA-absorbing dibenzoylmethane sunscreen active is less than 0.65."

II. The opponents requested in their notices of opposition the revocation of the patent in suit in its entirety for lack of novelty and inventive step (Article 100(a) EPC) and lack of disclosure of the invention (Article 100(b) EPC). *Inter alia* the following documents were submitted in the opposition proceedings:

- (1) EP-A-0 780 119,
- (4) Commercial leaflet "Eusolex® OCR Eusolex® OS ... zwei traditionsreiche Schattenspender neu im Merck'schen Programm, Merck, dated Februar 1997,
- (6) "Sunscreen Use in Cosmetic Formulas", *Cosmetic & Toileteries*, vol. 107, (1992), pages 45 to 47,
- (7) P. Finkel "Formulierung kosmetischer Sonnenschutzmittel", *SÖFW-Journal*, vol. 122, no. 8, (1996), pages 543 to 548,
- (13) "Sun Products Documentary", *Cosmetic & Toileteries*, vol. 102, (1987), pages 23 to 36,
- (18) E. Charlet and P. Finkel, "UV-Filter in Sonnenschutzmitteln- Grundlagen und praktische Erkenntnisse", *Parfümerie und Kosmetik*, vol.64, Nr. 4, (1983), pages 186 to 196.

III. The Opposition Division held that the claims of the patent-in-suit as granted satisfied the requirements of the EPC. The late-filed document (18) was not admitted into the proceedings. The patent-in-suit satisfied the requirement of sufficiency of disclosure, since the

objection under Article 83 EPC based on the wording "safe and effective amount" and "carrier suitable for application to the skin" was not substantiated and appeared to be rather an objection under Article 84 EPC. The claimed subject-matter could not directly and unambiguously be derived from a single prior art document and, hence, was novel. Document (1), from which the claimed subject-matter differed by the presence of a specific UVB-absorber, was the closest prior art document to the invention. The technical problem to be solved was the provision of a sunscreen with improved properties. The solution proposed was the choice of the specific UVB-sunscreen 2-phenyl-benzimidazole-5-sulfonic acid (PBSA). The comparative data filed by the Respondent revealed that the composition according to the patent-in-suit had a higher sun protection factor (SPF) compared to the compositions according to document (1). This solution was not rendered obvious by any of the prior art documents. The subject-matter of independent claims 1 and 9 as granted therefore involved an inventive step.

IV. At the oral proceedings before the Board, held on 24 July 2012, the Respondent (Proprietor of the patent) defended the maintenance of the patent in suit on the basis of the main request (claims as granted), the auxiliary requests 1 to 2 filed with letter dated 19 November 2009, the auxiliary request 3 (claim 9 as granted) and the auxiliary request 4 filed during these oral proceedings. The main request and the auxiliary request 4 comprised claim 1 as granted, whereas the main request and auxiliary requests 1 to 3 comprised independent claim 9 as granted. Appellant I withdrew its request for the reimbursement of the appeal fee.

V. The submissions of the Appellants can be summarized as follows:

As regards claim 9 as granted the closest prior art document was document (1), especially lotion 2 which satisfied all the characteristics of the composition of claim 9, except the presence of PBSA. The lack of accuracy of the results presented in the experimental report E6 filed by the Respondent with the letter dated 7 February 2011 did not permit to conclude that the presence of PBSA in the claimed composition gave a superior SPF when compared to compositions according to document (1). The technical problem solved by the invention could therefore only be seen in the provision of alternative sunscreen compositions. At the filing date of the patent-in-suit only nine approved UV-filters in Europe were available, PBSA being the sole water-soluble UV-filter (see part A of the table on page 545 and the table on page 544 of document (7)). There were only two water-soluble UV filters listed in the FDA file, document (6), that came into account, namely 2-phenyl-benzimidazole-5-sulfonic acid (PBSA) and TEA-salicylate. However, PBSA has a much higher UV-absorption coefficient than TEA salicylate, namely PBSA has an ϵ of 13400 at 286 nm and 8400 at 324 nm for PBSA, compared to an ϵ of only 3000 at 298 nm for TEA salicylate (see page 3 of the Appellant II's letter dated 20 Juni 2012).

Since it was well known, e.g. from document (18), that SPF of emulsions were improved by combining oil-soluble and water-soluble UV-filters, the skilled person would

have added the well known PBSA water-soluble filter in lotion 2 of document (1) in order to improve its SPF. The subject matter of claim 9, hence, did not involve an inventive step (Article 56 EPC).

In addition, the invention defined in claim 1 as granted was not sufficiently disclosed to be carried out by the skilled person. The subject-matter of claim 1 as granted lacked novelty with respect to document (1) in combination with the general knowledge of the skilled person. According to Appellant II, with respect to claim 1, the closest prior art was document (4) and the subject-matter of claim 1 as granted lacked an inventive step with respect the combination of document (4) with document (1).

Auxiliary request 4 comprising claim 1 as granted should not be admitted in the appeal proceedings, since it could have been filed earlier.

VI. According to the Respondent, the closest prior art was document (1). The technical problem underlying the patent-in-suit was the provision of a composition having improved sunscreen protection. There was a clear trend emerging from the statistical analysis of the results of the experimental report E6 revealing that a composition according to the patent-in-suit and comprising PBSA had improved sun protection when compared to the compositions of document (1) comprising other conventional UVB-filters, including the water-soluble UVB filter TEA salicylate. Document (1) provided no incentive to improve the sun protection factor of the disclosed compositions. Thus, the skilled person would have no motivation to modify the

compositions of document (1), i.e. to choose the amounts of the components, to choose specifically PBSA and to choose a ratio of less than 0.65. Hence, the compositions of claim 9 as granted were therefore not obvious in the light of the prior art. The claimed subject-matter involved an inventive step.

VII. The Party as of right (opponent 2) made no submission in these appeal proceedings.

VIII. The Appellants (opponents 1 and 3) requested that the decision under appeal be set aside and that the patent be revoked.

The Respondent (patentee) requested that the appeal be dismissed, or, subsidiarily, that the patent be maintained on the basis of any one of the auxiliary requests 1 and 2 filed with letter dated 19 November 2009, or on the basis of granted claim 9 alone (auxiliary request 3), or on the basis of auxiliary request 4 as filed during the oral proceedings before the Board.

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

Reasons for the Decision

1. The appeal is admissible.

2. *Admissibility into the proceedings of document (18)*

Document (18) was filed on 15 December 2008 before the Opposition Division which decided during the oral proceedings held on 16 January 2009 not to admit it into the proceedings, since it was *prima facie* not more relevant than other cited documents (see point 4 of the minutes; point 1 of the reasons of the contested decision). However, document (18) was again filed by both Appellants in their statement of grounds for appeal (see pages 1 and 2, respectively, point "Beweismittel"). During the oral proceedings before the Board, the Respondent submitted that this document was not in the appeal proceedings, since it was not admitted by the Opposition Division into the proceedings.

As respects admissibility of a late-filed document, the crucial criteria to be taken into account is whether or not the new document is *prima facie* pertinent. Document (18) is taken from a standard text book and reflects common general knowledge in the field of sunscreens. It provides *inter alia* evidence that it was known to achieve higher SPF in emulsions by combining oil- and water-soluble sunscreens. It is thus relevant for the assessment of inventive step, since it provides evidence relevant to the Appellants' argument based on common knowledge in the technical field (see point 3 below). Furthermore, the content of this document (18) only illustrates common general knowledge and does not change the Appellants' line of arguments against inventive step already brought forward in front of the Opposition Division and set out in their statement of grounds of appeal, which is based on documents (1)

and/or (4). In addition, the Respondent had sufficient time to take position on the teaching of document (18), since this document was known to him since the proceeding in front of the Opposition Division.

Accordingly, document (18) is admitted in the appeal proceedings.

Main request and auxiliary requests 1 to 3

3. *Inventive step*

Since these requests all comprise independent claim 9 as granted, the Board first examines the objection of lack of inventive step brought forward by the Appellants against this claim.

3.1 *Closest prior art*

Document (1) relates to a cosmetic light-screening composition, comprising from 1 to 3 % by weight of a dibenzoylmethane type UVA-sunscreen agent and from 0.5 to 4.5 % by weight of a α -cyano- β,β -diphenylacrylate stabiliser, the mole ratio of the acrylate to the dibenzoylmethane derivative being less than 0.8, if the amount of the dibenzoylmethane is 1% or more, and, optionally, at least one conventional UVB-filter (see claim 1). The preferred stabilizer is 2-ethylhexyl-2-cyano-3,3-diphenyl-acrylate (see claim 2) and the dibenzoylmethane derivative may be 4-tert-butyl-4'-methoxydibenzoylmethane (see claim 4).

More specifically, lotion 2 disclosed on page 4 is a oil-in-water sunscreen emulsion comprising 2 wt% of

butyl methoxy dibenzoylmethane, 1.5 wt% 2-ethylhexyl-2-cyano-3,3-diphenyl-acrylate (octocrylene) and having a mole ratio of octocrylene (stabilizing agent) to the UVA-absorbing dibenzoylmethane sunscreen active of 0.45.

Document (1) further teaches that according to the desired degree of protection further UV-filters may be added to the composition, these being conveniently selected from the lists of filters disclosed in document (6) or (7), said lists including 2-phenyl-benzimidazole-5-sulfonic acid (see document (1) page 2, lines 47 to 50; document (6), tables I, II, III and IV; document (7), page 545, compound A6). Furthermore document (1) specifically discloses sunscreen compositions containing 1 to 12% of a further UVB-filter (see claim 7 and page 2, line 56).

Accordingly, document (1) discloses all the features required for the compositions by claim 9 as granted, but not in combination.

The Board, in agreement with the Parties, considers that this document represents the closest prior art to the invention. In particular, lotion 2, which is an oil in water emulsion satisfying all the requirements of claim 9 as granted, except the presence of 0.1 to 1.5% of PBSA, constitutes the starting point for the assessment of inventive step.

3.2 *Technical problem underlying the invention*

The technical problem to be solved is the provision of a sunscreen composition having improved sun protection factor (SPF).

3.3 *Solution*

The solution proposed is the sunscreen composition according to claim 9 as granted, which is characterized by the presence of 1 to 1.5% of PBSA.

3.4 *Success*

The Respondent principally relied on the experimental report E6 filed with the letter dated 7 February 2011 in order to show that the compositions of claim 9 have improved sun protection compared to the compositions described in document (1).

In this experimental report six sunscreen compositions are compared. Each composition comprises 2% avobenzene (butyl methoxy dibenzoylmethane) and 1,5% octocrylene. Composition 1 comprises no further UV-filter. Compositions 2 to 6 differ from composition 1 only in that they further comprise 1% by weight of octinoxate, oxybenzone, benzylidene camphor, ensulizole (PBSA) or TEA salicylate, respectively. All these further UV-filters are listed in document (1) via the cross-reference to documents (6) and (7). Hence, compositions 1 to 4 and 6 are comparative compositions reflecting document (1), whereas composition 5 comprising PBSA as UVB-filter is a composition according to the patent-in-suit.

The Appellants argued that the results presented in this experimental report did not convincingly show that composition 5 according to the patent-in-suit had a

superior SPF than the compositions illustrating the prior art.

In the present case, however, it is not necessary to decide on the contentious issue of whether the results of the comparative experiments convincingly demonstrate that the claimed sunscreen composition 5 have a higher SPF than the comparative composition 1 to 4 and 6. Indeed, the Appellants' objections in the issue obviousness of the proposed solution with regard to the state of the art anyway prevail even if it is accepted in favour of the Respondent that the technical problem of improving the SPF has effectively been solved by the claimed compositions (see point 3.5 below).

3.5 *Obviousness*

Proceeding from this premise, the only outstanding issue which remains to be decided is whether or not the proposed solution to that problem of improving the SPF is obvious in view of the state of the art.

Lotion 2 disclosed in document (1) is a sunscreen emulsion containing butyl methoxy dibenzoylmethane and octocrylene, both being oil-soluble UV-filters as acknowledged by the Parties. According to document (18) which represents general knowledge in sunscreen formulations, high sun protection factor can be achieved in oil-in-water emulsions by combining an oil-soluble UV-filter with a water-soluble UV-filter (see paragraph 3.4.2 on page 191 and paragraph 5.4 on page 193). As the sunscreen emulsion lotion 2 of document (1) only comprises oil-soluble UV-filters (butyl methoxy dibenzoylmethane and octocrylene), the person skilled

in the art aiming to improve the degree of sun protection has thus the clear incentive to add a water-soluble UV-filter to the known composition. He would therefore choose from the list of the further UV-filters proposed in document (1), via the cross-reference to documents (6) and (7), those being water-soluble (see page 2, lines 47 to 50).

Tables I and II of cross reference document (6) list the conventional UV-filters registered with the FDA and used in suntan/sunscreen preparations (see page 45 and 46), whereas tables III and IV list the UV-filters present of the entire FDA file (see page 47). Cross reference document (7) enumerates the twenty one UV-filters admitted onto the EU cosmetics directive (see page 545).

According to the Appellants' submission, there are only two water-soluble UV-filters of these lists that come into account, namely 2-phenyl-benzimidazole-5-sulfonic acid (PBSA) and TEA-salicylate. The Board also notes that these two UV-filters are the water-soluble UVB-filters that are compared in the experimental report E6 filed by the Respondent.

According to the uncontested submission of the Appellant II, PBSA has a much higher UV-absorption coefficient than TEA salicylate (see also the UV-absorption spectra of PBSA and TEA-salicylate on page 31 of document (13)). Accordingly, on account of its UV-absorption spectrum, PBSA is the most promising water-soluble UV-filter candidate to be added in lotion 2 of document (1) in order to improve its SPF. Hence, the skilled person aiming at improving the SPF of

lotion (2) of document (1) would have considered to add PBSA to lotion 2 with an expectable chance of success. Document (1) furthermore teaches that the additional UVB-filter should suitably be present in the sunscreen composition in concentrations of 1 to 12% by weight (page 2, second paragraph, claim 9), which concentrations are within the claimed range.

The Board concludes from the above that document (18) gives the person skilled in the art a concrete hint as to how to solve the problem underlying the patent in suit as defined in point 3.2 above of providing a composition having improved sun protection, namely by adding to the composition of the closest prior art document (1), the water-soluble UV-filter PBSA in concentrations within the claimed range thereby arriving at the claimed compositions, all the more since document (1) explicitly foresees the presence of further water soluble UVB-filter.

3.6 Hence, the subject-matter of claim 9 does not involve an inventive step.

Auxiliary request 4

4. *Admissibility*

Appellant II objected to the admissibility of this request for the mere reason that it was late filed.

However, auxiliary request 4 is directed to claims 1 to 8 as granted, which claims were at issue throughout the opposition and appeal proceedings. Accordingly, this

auxiliary request does not raise any new issue. Hence, the Board decides to admit it in these proceedings.

5. Auxiliary request 4 contains claim 1 as granted.

Claim 1 as granted differs from claim 9 as granted in that component (a) is broadened to any UV-absorbing dibenzoylmethane sunscreen actives and component (b) to any stabilizing agents of the formula as indicated the claim 1 as granted. The amounts of the components of the composition indicated in claim 9 as granted are also generalised in claim 1 as granted to "safe and effective amounts" and the ratio of the stabilizing agent to the UVA-absorbing dibenzoylmethane sunscreen active is broadened to "less than 0.8". Furthermore claim 1 as granted requires that the composition is substantially free of benzylidene camphor derivatives and comprises less than 5% inorganic sunblock, whereas the compositions of claim 9 as granted being open-defined by the term "comprising" allows the presence of any further components.

Accordingly, claim 1 as granted encompasses the compositions of claim 9 as granted which do not further comprise benzylidene camphor derivatives and containing less than 5% inorganic sunblock.

The finding of lack of inventive step of the subject-matter of claim 9 as granted (see point 3.6 above) is not based upon compositions of claim 9 comprising benzylidene camphor derivatives or inorganic sunblock (see point 3.5 above). Therefore, the considerations concerning inventive step given in point 3.5 above and the conclusion drawn in point 3.6 above with regard to

the compositions of claim 9 as granted, comprising no benzylidene camphor derivatives and no inorganic sunblock apply to compositions of claim 1 as granted, with the consequence that claim 1 as granted necessarily comprises subject-matter which does not involve an inventive step.

In these circumstances, Respondent's auxiliary request 4 is not allowable for lack of inventive step pursuant to Article 56 EPC for the same reasons as the main request and auxiliary requests 1 to 3.

Order

For these reasons it is decided that:

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

The Registrar

The Chairman

C. Rodríguez Rodríguez

P. Gryczka