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Datasheet for the decision of 21 March 2013

Case Number: T 2055/09 - 3.3.07

Application Number: 03726627.7

Publication Number: 1515691

IPC: A61K8/28, A61K8/44, A61Q15/00

Language of the proceedings: EN

Title of invention:
STABILIZED ANTIPERSPIRANT COMPOSITIONS CONTAINING ALUMINUM-ZIRCONIUM SALTS WITH LOW M:CL RATIO

Patent Proprietor:
The Gillette Company

Opponent:
Henkel AG & Co. KGaA

Headword:
-

Relevant legal provisions:
RPBA Art. 13(1)
EPC Art. 123(2), 56

Keyword:
Late-filed request - admitted (yes)
Amendments - extension beyond the content of the application as filed (no)
Inventive step - (yes)

Decisions cited:

Catchword:
-

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Case Number: T 2055/09 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 21 March 2013

Appellant: (Opponent)	Henkel AG & Co. KGaA Henkelstrasse 67 40589 Düsseldorf (DE)
Representative:	Semrau, Markus Henkel AG & Co. KGaA VTP Patente 40191 Düsseldorf (DE)
Respondent: (Patent Proprietor)	The Gillette Company One Gillette Park- 3E Boston, MA 02127 (US)
Representative:	Hirsch, Uwe Thomas M.H. Procter & Gamble Service GmbH IP Department Frankfurter Strasse 145 61476 Kronberg im Taunus (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 August 2009 concerning maintenance of the European Patent No. 1515691 in amended form.**

Composition of the Board:

Chairman: J. Riolo
Members: R. Hauss
P. Schmitz

Summary of Facts and Submissions

I. European patent No. 1 515 691 was granted on the basis of 15 claims.

II. An opposition was filed against the patent, based on the ground of lack of inventive step under Articles 100(a), 52(1) and 56 EPC.

III. The documents cited during the opposition and appeal proceedings included the following:

D1: US 5 254 332

D2: GB 2 076 289 A

D3: WO 00/10521 A1

IV. The appeal lies from the interlocutory decision of the opposition division, pronounced on 9 July 2009 and posted on 21 August 2009, finding that the patent in the form of the auxiliary request met the requirements of the EPC.

That request contained 13 claims, independent claim 1 reading as follows:

"1. An anhydrous topical antiperspirant composition for application to human skin to reduce perspiration, said composition comprising a dermatologically acceptable carrier, about 6% to 22% by weight (USP) particulate antiperspirant salt suspended in the carrier, wherein the antiperspirant salt comprises an aluminum-zirconium chlorohydrate having a metal-to-chloride ratio of 0.9 to 1.3, and, as a separate material from the antiperspirant salt, a stabilizing basic material suspended in the carrier in an amount sufficient to prevent degradation of said antiperspirant composition or to minimize acid odor, said basic material being selected from arginine, lysine, a salt formed by a

strong base and an amino acid, an inorganic base that is not soluble in water, or a mixture of two or more of these."

Claim 13, the only other independent claim, was directed to a method of reducing perspiration from human skin comprising applying to human skin a topical antiperspirant composition according to claim 1.

V. According to the decision under appeal, either document D1 or document D2 could serve as a starting-point for the assessment of inventive step. With either approach, the claimed subject-matter was found to involve an inventive step.

Document D1 concerned anhydrous stick formulations with antiperspirant and deodorant activity. The composition described in example I of D1 contained a specified aluminium zirconium antiperspirant salt having a metal-to-chloride ratio of 1.4, in combination with sodium bicarbonate as a deodorant active. Starting from the teaching of D1, the skilled person found no motivation in the cited prior-art documents to select an antiperspirant salt with a lower metal-to-chloride ratio and to employ a suspended basic material as defined in claim 1, to enhance the stability and/or maintain the efficacy of the composition.

Document D2 described antiperspirant compositions containing both aluminium chloride and aluminium-zirconium hydroxychloride, the mol ratio of metal-to-chloride being less than 0.9. D2 dealt with the problem of skin irritation caused by the acidic combination of antiperspirant actives by adjusting the pH with a combination of glycine and magnesium hydroxide or oxide. In the absence of any incentive in the cited prior art, it was not obvious for the skilled person striving to enhance product stability to deviate from

the metal-to-chloride ratio recommended in D2. Further requirements defined in the opposed patent, viz. capping the concentration of antiperspirant salt at 22% by weight and separating the basic material from the antiperspirant salt, were not taught in the prior art in combination with the specified metal-to-chloride ratio, nor were they linked with an effect on product stability.

VI. The appellant (opponent) lodged an appeal against that decision. In the statement setting out the grounds of appeal, the appellant submitted that either document D2 or document D3 could be regarded as the closest prior art for the assessment of inventive step.

VII. In reply, the respondent (patent proprietor) submitted arguments and requested that the appeal be dismissed.

VIII. The parties were summoned to oral proceedings. In a preparatory communication dated 12 March 2013, the board indicated that it was minded to regard document D3 as the closest prior art. In the assessment of inventive step the question might be considered whether all embodiments of the product form or of the suspended basic material which came within the ambit of claim 1 had been linked with the alleged technical effect of stabilising the rheology of the compositions. If it were to be decided that the technical effects alleged in the patent could not be taken into account in determining the objective technical problem, the problem would have to be reformulated in a less specific manner, for instance as the provision of further anhydrous antiperspirant compositions.

IX. With a letter dated 18 March 2013, the respondent submitted an auxiliary request.

X. Oral proceedings before the board took place on 21 March 2013. During the oral proceedings, the respondent replaced its previous requests by a sole amended request consisting of eight claims.

Claim 1 of the new request reads as follows (the differences in comparison with claim 1 of the request on which the impugned decision is based are shown in bold):

"1. A **solid stick** anhydrous topical antiperspirant composition for application to human skin to reduce perspiration, said composition comprising a dermatologically acceptable carrier, about 6% to 22% by weight (USP) particulate antiperspirant salt suspended in the carrier, wherein the antiperspirant salt comprises an aluminum-zirconium chlorohydrate having a metal-to-chloride ratio of 0.9 to 1.3, and, as a separate material from the antiperspirant sa1t, a stabilizing basic material suspended in the carrier in an amount sufficient to prevent degradation of said antiperspirant composition or to minimize acid odor, said basic material being selected from arginine, lysine, **sodium glycinate**, **sodium tyrosinate**, **or sodium lysinate**."

Claims 2 to 7 are dependent on claim 1. Independent claim 8 is directed to a method of reducing perspiration from human skin comprising applying to human skin a topical antiperspirant composition according to claim 1 or 4.

XI. The appellant argued as follows:

Admission of the new claim request

The respondent's new request was a reaction to the objection regarding lack of inventive step in the light

of document D3, which had been raised by the appellant in its statement setting out the grounds of appeal. It should therefore have been filed earlier in the appeal proceedings. The request should not be admitted now, because its late presentation on the very day of the oral proceedings, and indeed not until an advanced stage of those proceedings, had unexpectedly confronted the appellant with a new situation. Since, as indicated by the respondent, the proposed modifications of claim 1 were derived not from features present in the claims, but from passages of the description, the appellant could not have expected such amendments when preparing the case for oral proceedings.

Amendments

The amendment of claim 1 requiring that the basic material be selected from arginine, lysine, sodium glycinate, sodium tyrosinate or sodium lysinate introduced subject-matter extending beyond the content of the application as filed, in contravention of Article 123(2) EPC, for the following reasons:

A new list, or selection, of five specific basic materials had been created which was not disclosed in the application as originally filed. Furthermore, said materials had been disclosed only in connection with a concentration range of 0.1 to 10% by weight of stabilising basic material. That limiting concentration range was however missing from amended claim 1.

Inventive step

Document D3 as the closest prior art disclosed anhydrous antiperspirant compositions which could be solid sticks containing particulate suspended aluminium-zirconium chlorohydrate. The compositions of D3 contained a suspended calcium salt, which could

be calcium glycinate. The claimed compositions differed therefrom by including sodium glycinate instead of calcium glycinate. Since both were basic salts formed by a strong base and an amino acid, the skilled person would have regarded sodium glycinate as an obvious alternative to calcium glycinate. Moreover, prior-art documents D3 and D2 both suggested the use of basic materials. Since a stabilising effect had not been shown for all five basic materials mentioned in the claim, the technical problem was the provision of an alternative antiperspirant composition.

XII. The respondent argued as follows:

Admission of the new claim request

The amended request had been drafted in reaction to the board's communication issued in preparation of the oral proceedings, in which new aspects had been brought up in the context of the assessment of inventive step starting from document D3 as the closest prior art. At no time in the entire proceedings had the appellant presented a detailed argumentation based on D3. Due to the short time available, and the time taken by the communication chain between the representative and the respondent company, approval of the new request had been received only on the day before the oral proceedings. In view of the board's preliminary comments, the amendments were predictable and could therefore not have surprised the appellant.

Amendments

In support of the amendments in claim 1, the respondent referred to paragraphs [0015] to [0017] and [0024] of the patent specification.

Inventive step

The claimed antiperspirant sticks differed from the compositions of the closest prior art D3 in that a specific suspended basic material was present.
As shown in examples 1 and 2 of the patent in suit, the technical effect provided by that feature was the stabilisation of stick hardness. The cited prior art contained no teaching that the deterioration of stick hardness over time could be prevented by including any one of the suggested stabilising basic materials.

XIII. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

XIV. The respondent requested that the patent be maintained on the basis of the set of claims (having the title Auxiliary Request I) submitted during the oral proceedings before the board. All previous requests were withdrawn.

Reasons for the Decision

1. The appeal is admissible.

2. Admission of the new claim request

2.1 The request concerned was filed at a late stage of the appeal proceedings, viz. on the day of the oral proceedings before the board.

2.2 According to Article 13(1) of the Rules of Procedure of the Boards of Appeal (RPBA), any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion, which is to be exercised in view of *inter*

alia the complexity of the new subject-matter, the current state of the proceedings and the need for procedural economy. According to Article 13(3) RPBA, amendments sought to be made after oral proceedings have been arranged are not to be admitted if they raise issues which the Board or the other party or parties cannot reasonably be expected to deal with without adjournment of the oral proceedings.

2.3 In its communication dated 12 March 2013, the board pointed out that the technical effect, alleged in the patent in suit, of stabilised product rheology appeared to be supported by evidence only in the case of solid-stick compositions and for certain choices of separately suspended basic material. That could be relevant for the determination of the technical problem in the context of the problem-and-solution approach.

That aspect had not previously been mentioned in the appellant's submissions.

The respondent's amended claim request restricts the claimed compositions to solid-stick compositions, and furthermore restricts the choice of mandatory suspended basic materials, in accordance with the board's remarks.

As a consequence, the board comes to the conclusion that the respondent's amended request was filed as a direct reaction to the board's communication, and that, furthermore, the nature of the amendments cannot be regarded as surprising or as shifting the focus of the inventive-step discussion.

2.4 In these circumstances, the board finds it appropriate to exercise its discretion under Article 13(1) RPBA to admit the request into the proceedings.

3. Amendments (Article 123(2) EPC)

3.1 The limitation "solid stick" which was introduced into claim 1 is based on page 7, lines 14 to 16 of the application as filed (corresponding to the first two sentences in paragraph [0024] of the patent specification indicated by the respondent), where solid sticks are disclosed as the most preferred formulation type.

3.2 According to the teaching of the application as filed, the separately suspended basic material could be selected from 1) salts formed by a strong base and a weak acid, 2) basic amino acids, 3) salts formed by a strong base and an amino acid, and 4) inorganic bases that are not soluble in water.

The restriction of the selection of the mandatory basic material to arginine, lysine, sodium glycinate, sodium tyrosinate or sodium lysinate finds a basis in the passage on page 4, line 22 to page 5, line 22 of the application as filed (corresponding to paragraphs [0015] to [0017] of the patent specification indicated by the respondent), where arginine and lysine are listed together with glycine and tyrosine as examples of basic amino acids and the three sodium salts are listed together with further glycinate salts as examples of salts formed by a strong base and an amino acid.

At the beginning of said passage on page 4, lines 24 to 26 of the application as filed, it is mentioned that the basic material will "typically" be present in an amount of about 0.1% to 10% by weight. Hence, the concentration range is disclosed as merely optional and constitutes a separate limitation independent of the choice of material.

The list of five specific basic materials as introduced into claim 1 was effectively obtained by the deletion of elements from a range of alternative options given for the mandatory basic material. The appellant's objection that a new combination was created does not apply to this situation, because the list of basic materials does not stand for a combination of features, the members of the list being, in fact, independent alternatives for one single technical feature.

3.3 With regard to Article 123(2) EPC, the board thus comes to the conclusion that the amendments discussed above do not give rise to subject-matter going beyond the content of the application as filed.

4. Inventive step

Patent in suit

4.1 The patent in suit seeks to provide an anhydrous antiperspirant composition comprising a particulate aluminium-zirconium chlorohydrate salt with a metal-to-chloride ratio of 0.9 to 1.3, such salts being known from the prior art as particularly efficacious antiperspirant agents (see the patent specification, claim 1, paragraphs [0001], [0004], [0005], [00026]). Since aluminium-zirconium chlorohydrate salts with such a low metal-to-chloride ratio are rather acidic, stability problems are encountered when trying to formulate those actives into the compositions. The hardness of solid products deteriorates over time, and products can develop an undesirable acid odour. The technical problems to be solved in formulating the desired type of composition are identified in the patent in suit as the stabilisation of the compositions and/or the prevention of acid odour (see the patent specification, paragraphs [0007] and [0008]).

The patent in suit proposes to solve those problems by suspending a stabilising basic material in the antiperspirant compositions, as a separate material from the antiperspirant salt.

According to claim 1 of the present request, the mandatory suspended basic material is selected from arginine, lysine, sodium glycinate, sodium tyrosinate or sodium lysinate.

Closest prior art

4.2 It was common ground between the parties that document D3, which concerns the same formulation type and antiperspirant active as the patent in suit, represented the closest prior art. The board sees no reason to differ.

4.3 Document D3 describes anhydrous antiperspirant formulations employing as the antiperspirant active a suspended particulate aluminium or aluminium-zirconium salt.

In addition to the antiperspirant active, the anhydrous formulations of D3 also contain a suspended water-soluble calcium salt, which according to the technical teaching of D3 provides the benefit of increasing the antiperspirant efficacy of the compositions (see D3: claims 1, 18; page 4, lines 17 to 24; page 3, lines 18 to 20; page 10, lines 5 to 7 and page 9, lines 20 to 25).

A preferred antiperspirant salt of D3 (see page 6, lines 5 to 6) is aluminium-zirconium chlorohydrate with an Al:Zr ratio of 2 to 10 and a metal-to-chloride ratio of 0.9 to 2.1, which encompasses the sub-range of 0.9 to 1.3 required by the patent in suit.

Aluminium-zirconium tetrachlorohydrate-gly, which is used in most example formulations of D3, is known to have the formula $Al_4Zr(OH)_{12}Cl_4$ Gly·n H_2O, which has a metal-to-chloride ratio of 5:4 = 1.25. Document D3 (see page 7, lines 3 to 5) specifies that the compositions will ideally contain 20% to 25% by weight of the aluminium-zirconium salt, corresponding to 17% to 20% active (USP), which is within the range defined in present claim 1. Examples 9 to 12 of D3 describe solid-stick anhydrous antiperspirant compositions comprising a topical carrier and suspended particles of aluminium-zirconium tetrachlorohydrate-gly at such concentrations.

Technical problem and solution

4.4 The solid-stick compositions defined in claim 1 of the present request differ from example formulations 9 to 12 of D3 in that a suspended basic material selected from arginine, lysine, sodium glycinate, sodium tyrosinate or sodium lysinate must be present.

4.5 The alleged technical effect of this is improved product stability in terms of stick hardness.

4.6 The technical problem with regard to claim 1 may thus be defined as the provision of solid-stick anhydrous antiperspirant compositions comprising aluminium-zirconium chlorohydrate with a low metal-to-chloride ratio of 0.9 to 1.3, having improved structural stability.

4.7 In the light of the comparative tests described in paragraphs [0027] to [0029] of the patent specification the board is convinced that this technical problem is solved by the composition defined in claim 1 of the present request, for the following reasons:

4.7.1 As described in the patent in suit, anhydrous solid-stick antiperspirant formulations containing particulate aluminium-zirconium chlorohydrate and separately suspended sodium glycinate (example 1) or lysine (example 2) as the basic material were tested against a comparative sample not containing any suspended basic material. Stick hardness was measured before and after one month of high-temperature storage at 45°C. The hardness of example formulations 1 and 2 decreased but remained satisfactory, whereas the comparative sample showed an appreciable drop in stick hardness to an unacceptable level.

4.7.2 According to the established jurisprudence of the boards of appeal, if comparative tests are chosen to demonstrate an inventive step on the basis of an improved effect, the nature of the comparison must be such that the alleged advantage or effect is convincingly shown to have its origin in the distinguishing feature of the claimed subject-matter compared with the closest prior art. To this end, the comparative sample must be adequately representative of the closest prior art. It must also be rendered credible that the alleged technical effect is obtained over the entire scope claimed.

- In the comparative tests described above (see paragraph 4.7.1 *supra*), the only parameter which was varied was the presence of a suspended basic material. Thus the comparison correctly pertains to the distinguishing feature of the claimed compositions over the closest prior art D3 (see paragraph 4.4 *supra*).

- The test samples, i.e. example formulations 1 and 2 and the comparative sample described in the patent specification, contained aluminium-zirconium

chlorohydrate and an anhydrous carrier typical of a stick formulation, closely resembling the carrier of examples 9 to 12 of the prior art D3. A difference lies in the fact that the tested compositions did not contain suspended particulate calcium chloride dihydrate, whereas example formulations 9 to 12 of D3 did. There is however no reason to assume that the presence of suspended calcium chloride dihydrate particles, not known to have any particular properties linked to stick stability, would affect the outcome of the comparative tests. Thus the comparative sample described in the patent in suit, albeit not including a suspended calcium salt, can be regarded as adequately representative of the pertinent aspects of the anhydrous antiperspirant compositions of D3.

- Due to structural similarity and in the absence of any evidence to the contrary, the lysine and sodium glycinate used in example formulations 1 and 2 of the comparative tests are regarded as duly representative of the group of five basic materials defined in claim 1, which are all selected from basic amino acids and salts formed by a strong base and an amino acid. Hence it is credible that the observed technical effect of stabilised stick hardness can be obtained over the entire scope of the basic materials claimed.

Obviousness of the solution

4.8 It remains to be established whether, having regard to the state of the art, the compositions defined in present claim 1 would be obvious to the skilled person seeking to solve the above-mentioned technical problem of providing stabilised stick formulations.

4.9 Document D3 itself is focused on the improvement of antiperspirant efficacy and does not address the

question of deteriorating stick hardness. According to the technical teaching of document D3, the antiperspirant efficacy of an anhydrous antiperspirant composition comprising an aluminium-zirconium antiperspirant salt is increased by adding a water-soluble calcium salt (see D3: claim 18; page 10, lines 5 to 7 and page 9, lines 20 to 25). The calcium salt may, *inter alia*, be calcium glycinate, although calcium chloride and calcium nitrate are preferred. Basic properties are not required. Since only calcium salts are recommended, nothing in document D3 supports the appellant's view that sodium glycinate would be regarded as an obvious equivalent to calcium glycinate. In particular, D3 does not suggest that suspended calcium glycinate or other glycinates such as sodium glycinate might serve as stabilisers to prevent the deterioration of stick hardness, nor does D3 mention in its teaching any of the five basic materials listed in claim 1 of the present request.

4.10 Documents D1 and D2 likewise do not suggest employing any one of the five specified basic materials in separately suspended form in an anhydrous solid-stick antiperspirant composition.

4.11 As a consequence, the composition defined in claim 1 and dependent claims 2 to 7 involves an inventive step within the meaning of Article 56 EPC.

4.12 The method defined in claim 8 is also inventive, since it involves the application of the inventive composition of claim 1.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the set of claims filed during the oral proceedings before the board and a description yet to be adapted.

The Registrar: The Chairman:

L. Fernández Gómez J. Riolo

Decision electronically authenticated