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D E C I S I O N
of 30 July 2003

Case Number: T 0494/00 - 3.3.2

Application Number: 93919533.5

Publication Number: 0660676

IPC: A23L 2/00

Language of the proceedings: EN

Title of invention:

Novel compositions

Patentee:

SMITHKLINE BEECHAM PLC

Opponent:

BASF Aktiengesellschaft Patente, Marken und Lizenzen

Headword:

Aqueous Compositions/SMITHKLINE BEECHAM PLC

Relevant legal provisions:

EPC Art. 84, 123(2)

Keyword:

"Amendments allowable under Article 123(2) EPC (no): claim 1 of the main and auxiliary requests extends beyond the contents of the application as filed"

Decisions cited:

-

Catchword:

-



Case Number: T 0494/00 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 30 July 2003

Appellant: SMITHKLINE BEECHAM PLC
(Proprietor of the patent) New Horizons Court
Brentford,
Middlesex TW8 9EP (GB)

Representative: White, Susan Mary
GlaxoSmithKline
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Brentford, Middlesex TW8 9GS (GB)

Respondent: BASF Aktiengesellschaft
(Opponent) Patente, Marken und Lizenzen
D-67056 Ludwigshafen (DE)

Representative: -

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 3 April 2000
revoking European patent No. 0660676 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: M. Ortega Plaza
P. Mühlens

Summary of Facts and Submissions

I. European patent No. 0 660 676 based on application No. 93 919 533.5 (published under the PCT Treaty as WO-A-94 06310) was granted on the basis of 11 claims.

Independent claim 1 as granted reads as follows:

"1. A process for preparing a stable aqueous composition for the preparation of optically clear products for use in human or animal healthcare, said process comprising:

a) dispersing 0.1-1.0% (w/w based on the product of step e) of an antioxidant in 2-20% (w/w based on the product of step e) of an emulsifier or mixture of emulsifiers having an HLB (hydrophilic/lipophilic balance) value of between 10-18 while heating to a temperature of approximately 40°C;

b) dispersing 0.1 to 5.0% (w/w based on the product of step e) of one or more oil-soluble ingredients or 0.1-2.0% (w/w based on the product of step e) of one or more oil-soluble ingredients as a 20-30% (w/w based on the dispersion) dispersion in a suitable oil in the mixture in a) above while heating to between about 80-200°C so as to yield a transparent mixture,

c) adding optionally a further oil-soluble ingredient;

d) raising the temperature of the mixture as appropriate whilst maintaining stirring to maintain a transparent mixture, and

e) combining the mixture with water having a minimum temperature of 95°C while continuously stirring to provide a transparent composition."

Independent claim 3 as granted read as follows:

"3. An aqueous composition for the preparation of optically clear products for use in human or animal healthcare obtainable by the process of claim 1 or 2."

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

The patent was opposed under Article 100(a) EPC for lack of novelty and lack of inventive step.

III. The appeal lies from a decision of the Opposition Division revoking the patent under Article 102(1) EPC.

The following documents were cited in the opposition proceedings:

(1) EP-B-0 055 817

(2) EP-A-0 479 066

The Opposition Division considered that claim 3 of the main request (set of claims as granted) did not meet the requirements of novelty vis-à-vis document (2).

The opposition division acknowledged that the compositions disclosed in document (2) were prepared by a different process. However, in its opinion, there was no hint that the product *per se* was different. In

particular, it stated that the products according to the patent in suit showed micelles or particles of the same size as that of the products disclosed in document (2).

The opposition division did not accept the late introduction of some test results (in relation to document (1)) submitted by the patentee during the oral proceedings of 21 March 2000.

With respect to the auxiliary request filed by the patentee during the oral proceedings of 21 March 2000, the opposition division considered it to be allowable within the meaning of Article 123 EPC. In the opposition division's view the amendments could "be deduced from page 2, lines 58, 59 of the patent".

The opposition division took the view that the proviso introduced in claim 1 restricted the concentration of the carotenoid present in the compositions to a certain range. However, it considered that this specification was arbitrary and insufficient for the subject-matter of claim 3 to involve a selection with respect to the contents of document (2).

IV. The appellant (patentee) lodged an appeal against the said decision.

It stated that the auxiliary request as filed during the oral proceedings before the opposition division was its main request.

Claim 1 of the main request reads as follows:

"1. A process for preparing a stable aqueous composition for the preparation of optically clear products for use in human or animal healthcare, said process comprising:

a) dispersing 0.1-1.0% (w/w based on the product of step e) of an antioxidant in 2-20% (w/w based on the product of step e) of an emulsifier or mixture of emulsifiers having an HLB (hydrophilic/lipophilic balance) value of between 10-18 while heating to a temperature of approximately 40°C;

b) dispersing 0.1 to 5.0% (w/w based on the product of step e) of one or more oil-soluble ingredients or 0.1-2.0% (w/w based on the product of step e) of one or more oil-soluble ingredients as a 20-30% (w/w based on the dispersion) dispersion in a suitable oil in the mixture in a) above while heating to between about 80-200°C so as to yield a transparent mixture, **subject to the proviso that where the oil-soluble ingredient is a carotenoid, the concentration is in the range 0.1 to 2.0% (w/w based on the product of step e), expressed as the pure substance, (emphasis added)**

c) adding optionally a further oil-soluble ingredient;

d) raising the temperature of the mixture as appropriate whilst maintaining stirring to maintain a transparent mixture, and

e) combining the mixture with water having a minimum temperature of 95°C while continuously stirring to provide a transparent composition."

The wording of independent claim 3 of the main request was identical to that of claim 3 as granted.

- V. A communication from the Board was sent on 31 January 2002 pointing to the fact that the amendment introduced in the process claim 1 did not necessarily affect the independent product claim 3, which remained the broadest claim.

A preliminary negative opinion with respect to the requirements of Article 123(2) EPC was given. The clarity of the proviso within a different context from that of the description as filed was also questioned. The appellant was invited to clarify the meaning of the proviso and to state the basis for the amendments in the application as filed.

- VI. The appellant replied to the above mentioned communication in its letter of 31 May 2002. It filed an auxiliary request (set of claims No. 2).

Claim 1 of the auxiliary request was identical to claim 1 of the main request.

Independent claim 3 of the auxiliary request reads as follows:

"3. An aqueous composition for the preparation of optically clear products for use in human or animal healthcare obtainable by the process of claim 1 or 2, **wherein when the oil-soluble ingredient is a carotenoid, the concentration is in the range 0.1 to 2.0% w/w based on the product of step e, expressed as the pure substance (emphasis added).**"

- VII. A communication from the Board was sent on 30 August 2002 pointing to some inconsistencies between the amended claims and the originally filed description.
- VIII. The appellant did not file a further set of claims with its letter of 29 October 2002, but requested oral proceedings before the Board.
- IX. On 15 January 2003 the parties were summoned to attend oral proceedings. The Board informed the parties that it considered the written proceedings closed and that in the case of new sets of claims filed thereafter their admissibility was to be considered by the Board.
- X. In a letter of 28 July 2003 the respondent (opponent) informed the Board that it would not attend the oral proceedings.
- XI. Oral proceedings before the Board were held on 30 July 2003.
- XII. At the beginning of the oral proceedings the appellant submitted three further sets of claims for consideration by the Board but provisionally maintained its main request (set of claims filed during the oral proceedings before the opposition division) and its auxiliary request (set of claims filed with the letter of 31 May 2002).

With respect to the admissibility of the late filed requests the appellant argued that the new requests related to an attempt to overcome the Board's former objections with respect to Articles 84 and 123(2) EPC.

The appellant stated that neither the opposition division nor the opponent had raised any objection, with respect to Articles 84 and 123(2) EPC, to the amended set of claims filed during the oral proceedings before the department of first instance. Furthermore, the appellant also argued that the new sets of claims had been drafted, on reflexion and for the sake of clarification, when the oral proceedings before the Board were being prepared.

With respect to the allowability of the amendments under Articles 84 and 123(2) EPC of the main and auxiliary requests the appellant made reference to its submissions filed during the written proceedings.

The appellant's arguments in connection with the allowability of the amendments may be summarised as follows: the only amendment introduced during the opposition proceedings concerned the proviso at the end of step (b) of claim 1, the other amendments were introduced in the PCT international phase, and neither the examiner during the preliminary examination, nor the examining division, lodged any objection in respect to Article 123(2) EPC. Moreover, the opponent had not raised any objection in that respect either.

However, the appellant acknowledged that there were some inconsistencies between the claims and the description, but the skilled reader would have been able to understand the claims and to find the necessary support in the application as originally filed. In particular, it cited pages 2 and 3 of the application

as originally filed as the basis for the proviso introduced in claim 1.

Further submissions concerned the following arguments:

- (A) The reference to "% w/v" of oil-soluble ingredient "as the pure crystalline ingredient", appearing on page 2 of the description, was an obvious transcriptional error. It had been intended as "% w/w" as reflected in the amended claims.

- (B) The introduction of the phrase "based on the product of step e" had its basis in the description, particularly in the Examples. The amounts given in percentages in the application as originally filed were intended as relative to the end composition.

The appellant further submitted during the oral proceedings that the skilled reader of the specification would readily appreciate that the percentage ranges of the various constituents defined in claim 1 related to the product specified in the final step (step e) of the claim. Additionally, with respect to the proviso, it stated that the amount of carotenoid given on page 3, lines 4, 5 of the application as originally filed was expressed as a percentage by weight of the pure substance for the carotenoid. In the appellant's opinion this equated to a concentration with respect to the final composition of step e, since the percentage referred to the relative amount with respect to the total composition, ie added up to 100.

The appellant also submitted that the proviso was not used outside the context of the disclosure in the application as originally filed. Furthermore, the reference to a pure crystalline ingredient on page 2 of the description was consistent with the preference for 0.1-2.0% by weight of carotenoid expressed as the pure substance appearing on page 3 of the application as originally filed. The word "pure" was of significance only to distinguish the situation where the ingredient is used in the form of an oil dispersion from that where it is used as a solid substance. Claim 1 as granted (ie claim 1 previous to the introduction of the proviso) covered compositions in which the oil-soluble ingredient is a carotenoid present in the range 0.1 to 5.0% w/w when used as a solid substance (ie as the pure substance), or in the range 0.1 to 2.0 w/w when used as an oil dispersion. In the amended claim, when the oil-soluble ingredient is a carotenoid, it can only be present in the range 0.1 to 2.0% w/w regardless of whether it is used pure or in the form of an oil dispersion. The appellant concluded that the proviso clearly did not confer different meanings to those already present in claim 1 prior to the amendment.

The appellant argued that step (c) of the process in claim 1, and by inference step (d), were substeps of step (b). These sub-process steps were consistent with the description (page 4 and Example 2), where a second oil-soluble ingredient, beta-carotene, was added with further heating after dispersion of a first oil-soluble ingredient, apo-carotenal. The skilled reader would not, in the appellant's view, interpret step (c) as making provision for the presence of an additional oil-soluble ingredient over and above the amount defined in

step (b). The final total carotenoid content was limited, in the appellant's opinion, to 0.1 to 2.0% w/w of the product specified in step (e) by the wording of step (b) in claim 1.

In the auxiliary set of claims the amendment introduced in claim 1 was also introduced in claim 3.

With respect to the novelty of the subject-matter claimed, the appellant argued that the process for preparing the compositions claimed was different to that disclosed in document (2), as acknowledged by the opposition division.

The appellant also stated that the beta-carotene microemulsion particles produced by the process set out in claim 1 of the patent in suit were indeed different in terms of micelle size and isomer distribution from those prepared according to the process in document (2). It referred to some experimental data relating to particle size and isomer distribution submitted with its grounds of appeal.

The appellant stated that the absence of an antioxidant and the use of w/v rather than w/w units to define the quantities in some of the experiments did not mean that they were not relevant for the assessment of the novelty of the compositions prepared according to the contested patent. Moreover, having regard to the density of water which was the diluent in the claimed compositions, the fact that the ingredients in the tested microemulsions were defined in terms of "w/v" rather than "w/w" was of no consequence for the

information they conveyed regarding the physical properties measured.

The appellant stated that the antioxidant was an essential feature of the compositions according to the contested patent, in which it was included for stability purposes. However, the antioxidant did not contribute to the isomer distribution of beta-carotene or micelle particle size.

XIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the set of claims filed in the oral proceedings before the opposition division (main request) or on the basis of the auxiliary request filed with letter dated 31 May 2002.

The respondent did not file any requests in the appeal proceedings.

Reasons for the Decision

1. *Admissibility*

1.1 The appeal is admissible.

1.2 However, the admissibility of the sets of claims filed by the appellant during the oral proceedings before the Board has to be considered.

The appellant argued, in justification of the late filing of these requests, that they concerned an attempt to overcome objections previously raised by the

Board in the written proceedings and which had never been raised in the first instance proceedings.

However, the issues relating to Articles 84 and 123(2) EPC were already pointed out by the Board in its communications of 31 January 2002 and 30 August 2002, ie the later communication was sent almost one year before the date of the oral proceedings. The appellant did not file a further set of claims with its response of 29 October 2002 to the Board's communication of 30 August 2002 and did not at that time request any extension of the time limit in order to provide further submissions.

The Board's communication sent on 15 January 2003 as an annex to the summons to oral proceedings informed the parties that the written proceedings were closed.

Therefore, the Board holds that the appellant had sufficient time and ample opportunities to provide further amended claims before the oral proceedings. If the appellant chose to file the new sets of claims at such a late stage, it risked facing an objection with respect to their admissibility, all the more as they were filed after the respondent had announced that it was not attending the oral proceedings.

In conclusion, the Board considers the three requests submitted during the oral proceedings to be inadmissible, since they were filed too late.

2. *Article 123 EPC*

2.1 Claim 1 is identical in the main and auxiliary requests.

Claim 1 differs from claim 1 as granted in that the following proviso has been introduced at the end of step b: "**subject to the proviso that where the oil-soluble ingredient is a carotenoid, the concentration is in the range 0.1 to 2.0% (w/w based on the product of step e), expressed as the pure substance**".

2.2 A primary purpose of the appeal proceedings is to examine the correctness of the first instance decision. The appeal lies from the decision of the opposition division revoking the patent and the appellant requests the maintenance of the patent as amended. Therefore, the Board is fully entitled to examine whether the main and auxiliary requests filed during the opposition and appeal proceedings meet the requirements of Article 123 EPC.

2.3 Accordingly, the Board has first to assess whether the proviso mentioned above contravenes Article 123(2) EPC.

2.4 As the basis for the proviso introduced in claim 1, the appellant referred to page 2, lines 20 to 26 and page 3, lines 4 to 5 of the application as originally filed.

The description in the application as originally filed (page 2, lines 20 to 26) discloses "an aqueous composition for the preparation of optically clear products for human or animal health care comprising" *inter alia* "0.1 to 2.0% w/w of an oil-soluble ingredient as a 20-30% w/w dispersion in a suitable oil

or 0.1 to 5.0% w/v as the pure crystalline ingredient" (*emphasis added by the Board*). The range 0.1 to 0.5 % w/v expressly relates to the **specific situation** in which the **only** oil-soluble ingredient is a pure ingredient, with the further requirement that it be in solid crystalline form.

In the application as originally filed it is further stated that "Preferably **the oil-soluble colouring ingredient** is a carotenoid" and that "Suitably the **amount** of carotenoid is 0.1-2.0%, preferably 0.1-1.0% **by weight expressed as the pure substance**" (*emphasis added by the Board*)(page 3, lines 3 to 5).

However, this passage specifies the **amounts by weight expressed as the pure substance** when a carotenoid is used as the oil-soluble **colouring** ingredient. Each amount is expressed as a percentage, but it is not disclosed whether this is a percentage expressed with respect to the basic product comprising the minimum required ingredients, after the addition of water, or with respect to the final optically clear product referred to in the application as originally filed just before the mention of the carotenoid as a colouring agent: "Surprisingly it has been found that the composition of the present invention is able to yield a **product** (*emphasis added by the Board*) with desirable properties, particularly high water solubility using ingredients, which have hitherto been found to be difficult to solubilise satisfactorily in this kind of product." (paragraph bridging pages 2 and 3).

Therefore, there is no disclosure, in the application as originally filed, of the definition of a **concentration** of carotenoid in the range 0.1 to 2.0% (**w/w based on the product of step e**), expressed as the pure substance.

Additionally, the proviso introduced in claim 1 has to be read within the context of that claim, which considers the possibility of using **one or more oil-soluble ingredients** without any indication of their physical state (solid, liquid, oily, crystalline) or of their purity.

Moreover, the wording "expressed as the pure substance" at the end of the proviso reinforces the lack of support for the amendment, since a concentration of a component used either as a mixture or as a non-pure substance may be calculated as a percentage expressed as the pure substance actually present in the final composition of step (e). Such a situation, which arises after the introduction of the proviso in claim 1, has no basis in the application as originally filed.

2.5 Finally, the Board considers the introduction of the proviso within the context of the claim unallowable, since the condition set in the description as originally filed had a restricted specific meaning, which can only be linked to the preparation of compositions having as the only oil-soluble component a single carotenoid used as a pure crystalline ingredient.

2.6 The Board cannot follow the appellant's argument that the skilled reader would consider claim 1 to relate only to two options in the case of carotenoids - ie

either as a pure solid substance or as a 20-30% w/w dispersion in a suitable oil - because these are the commercially available products. The claim is indeed not restricted by the origins of the oil-soluble ingredient in general or of the carotenoid in particular and the description confirms that according to the invention carotenoids may be used which are obtained from natural sources by known processes (page 3, lines 6 to 9).

With respect to the appellant's argument that the passages on pages 2 and 3 had to be read together, it has to be stressed that the passage on page 2 of the description cited by the appellant does not consider the cases, reflected by claim 1, where **more than one** oil-soluble ingredient is used in the process for preparing the composition. That passage only provides a basis for compositions in which the **only** oil-soluble substance used is a **pure crystalline** ingredient. Hence, even accepting the appellant's submission that the passages appearing separately on pages 2 and 3 would be combined by the skilled reader, their content will provide support only for the case in which the oil-soluble ingredient is a **single carotenoid in the form of a pure crystalline substance**.

According to the appellant, the amount of carotenoid expressed as a percentage on page 3 of the application as originally filed equates to the concentration of the carotenoid in the composition from step (e). However, neither the passage on page 3 nor the passage on page 2 refers to a particular preparation process. Moreover, as already mentioned, an amount may be expressed as a percentage relative to the other components, in this

case the components of step (a) in which the carotenoid is to be dispersed, or relative to the final optically clear product if used as a colouring agent. None of these situations concerns the product in step (e).

2.7 In view of the above, the Board concludes that claim 1 of the main and auxiliary requests contravenes Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

A. Townend

U. Oswald