

**Internal distribution code:**

- (A) [ ] Publication in OJ  
(B) [ ] To Chairmen and Members  
(C) [X] To Chairmen  
(D) [ ] No distribution

**D E C I S I O N**  
**of 26 April 2006**

**Case Number:** T 0999/01 - 3.3.02

**Application Number:** 91913705.9

**Publication Number:** 0549592

**IPC:** A61K 31/215

**Language of the proceedings:** EN

**Title of invention:**

Stabilized retinoid-containing skin care composition

**Patentee:**

JOHNSON & JOHNSON CONSUMER COMPANIES, INC.

**Opponent:**

L'OREAL

The Procter & Gamble Company

**Headword:**

Skin care composition/JOHNSON & JOHNSON

**Relevant legal provisions:**

EPC Art. 54, 56, 83, 100, 106, 107, 108

EPC R. 57a, 64

**Keyword:**

"Late-filed evidence: not admitted into the proceedings"

"First auxiliary request; novelty (no) - no proper selection"

"Secondary auxiliary request: limitation of claim 1 violates Article 123(2) EPC"

"Third auxiliary request: novelty (yes) - no specific disclosure of the active ingredient in the prior art; inventive step (yes) - solution to the problem of providing a stable skin care composition including retinol as the active ingredient not obvious"

**Decisions cited:**

G 0009/92, G 0004/93, G 0001/03, T 0012/81

**Catchword:**

-



Case Number: T 0999/01 - 3.3.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.02  
of 26 April 2006

**Appellant I:**  
(Opponent)

L'OREAL  
14, Rue Royale  
F-75008 Paris (FR)

**Representative:**

Dossmann, Gérard  
Bureau Casalonga & Josse  
Bayerstrasse71/73  
D-80335 München (DE)

**Appellant II:**  
(Opponent)

The Procter & Gamble Company  
One Procter & Gamble Plaza  
Cincinnati, OHIO 45202 (US)

**Representative:**

Clemo, Nicholas Graham  
Procter & Gamble Technical Centres Limited  
Patent Department  
Rusham Park  
Whitehall Lane  
Egham, Surrey TW20 9NW (GB)

**Respondent:**  
(Patent Proprietor)

JOHNSON & JOHNSON CONSUMER COMPANIES, INC.  
199 Grandview Road  
Skillman  
New Jersey 08558 (US)

**Representative:**

Fisher, Adrian John  
CARPMAELS & RANSFORD  
43-45 Bloomsbury Square  
London WC1A 2RA (GB)

**Decision under appeal:**

Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
13 July 2001 concerning maintenance of European  
patent No. 0549592 in amended form.

**Composition of the Board:**

**Chairman:** J. Riolo  
**Members:** G. Rampold  
P. Mühlens

## Summary of Facts and Submissions

I. This appeal is from an interlocutory decision of the opposition division posted on 13 July 2001 to maintain European patent No. 0 549 592 ("the patent") in amended form. The patent is based on European patent application No. 91 913 705.9 (International application No. PCT/US91/04471), entitled "Stabilized retinoid-containing skin care compositions", which was filed on 28 June 1991 claiming a priority date of 27 June 1991 (US 71 92 64).

II. The patent as granted contained a single independent claim directed to:

"1. A skin care composition comprising a water-in-oil emulsion and a retinoid selected from the group consisting of Vitamin A alcohol, Vitamin A aldehyde, retinyl acetate, retinyl palmitate and mixtures thereof, said composition further comprising a stabilizing system selected from the group consisting of:

- a) a chelating agent and at least one oil-soluble antioxidant;
- b) a chelating agent and at least one water-soluble antioxidant; and
- c) antioxidant present in each of the oil and water phases of said emulsion;

said composition retaining at least about 60% of said retinoid after 13 weeks' storage at 40°C."

Dependent claims 2 to 20 related to specific embodiments of the skin care composition according to claim 1.

III. Oppositions to the grant of the patent were independently filed by opponent I (present appellant I) and opponent II (present appellant II) requesting its revocation in full on grounds of lack of novelty and inventive step (Articles 100(a), 54 and 56 EPC) and insufficiency of disclosure (Articles 100(b) and 83 EPC).

IV. Of the numerous documents cited during the opposition, the following remain relevant to the present decision:

- (1) EP-A-0 440 398;
- (2) DE-C-3 514 724;
- (10) English translation of JP-A-58-41813; the translation was filed on 7 November 2001 by appellant I together with the statement setting out the grounds of appeal; in the following, reference is made to this translation since it was never in dispute that the translation correctly reflects the technical teaching and content of the cited original Japanese patent publication;
- (12) V. Bühler, "Vademecum for Vitamin Formulations", Wissenschaftliche Verlagsgesellschaft mbH Stuttgart 1988, pages 8, 9, 17, 18, 75, 92, 95 - 98, 119, 120;
- (13) Declaration by Dr Jonas C. T. Wang filed by the proprietor (respondent) during opposition proceedings on 22 March 2000;
- (14) Test report from Mr I. Oldfield filed by opponent II (appellant II) during opposition proceedings on 26 March 2001;
- (15) J. Gassmueller et al, "Antiflammatorische Wirksamkeit magistraler Rezepturen mit

Glukokortikosteroiden in Eucerinum® -  
Fertiggrundlagen im Vergleich zu Fertigpräparaten  
im UVB-Erythem-Test", Zeitschrift für  
Hautkrankheiten, H+G B (73), 1988, 364-370;  
(16) Internet pages 1/11 - 11/11, fu-berlin.de  
(Arzneiformenlehre TOPIKA)

V. During oral proceedings before the opposition division, the proprietor (respondent) requested maintenance of the patent in amended form on the basis of the main request, filed with its letter of 19 March 2001, or, if the main request was not allowable, on the basis of its auxiliary request filed during oral proceedings.

Claim 1 of the **main request** before the opposition division read as follows, with the amendments compared to claim 1 as granted indicated in bold italic letters:

"1. A skin care composition comprising a water-in-oil emulsion and a retinoid selected from the group consisting of Vitamin A alcohol, Vitamin A aldehyde, retinyl acetate, retinyl palmitate and mixtures thereof, said composition further comprising a stabilizing system selected from the group consisting of:

- a) a chelating agent and at least one oil-soluble antioxidant; and
- b) antioxidant present in each of the oil and water phases of said emulsion;

***provided that when said composition comprises stabilizing system a), it does not contain a water-soluble antioxidant, and when said composition comprises stabilizing system b), it does not comprise a chelating agent,***

said composition retaining at least about 60% of said retinoid after 13 weeks' storage at 40°C."

Claim 1 of the **auxiliary request** before the opposition division (present main request) reads as follows, with the amendments compared to claim 1 as granted indicated in bold italic letters:

- "1. A skin care composition comprising a water-in-oil emulsion and a retinoid selected from the group consisting of Vitamin A alcohol, Vitamin A aldehyde, retinyl acetate, retinyl palmitate and mixtures thereof, said composition further comprising a stabilizing system selected from the group consisting of:
- a) a chelating agent and at least one oil-soluble antioxidant; and
  - b) antioxidant present in each of the oil and water phases of said emulsion;
- provided that when said composition comprises stabilizing system a), it does not contain a water-soluble antioxidant, and when said composition comprises stabilizing system b), it does not comprise a chelating agent, and further provided that said composition does not comprise vitamin A, vitamin B<sub>6</sub>, vitamin C, vitamin D<sub>2</sub>, vitamin E, vitamin K<sub>3</sub>, progesterone and testosterone propionate,***
- said composition retaining at least about 60% of said retinoid after 13 weeks' storage at 40°C."

VI. The essence of the opposition division's reasoning in the interlocutory decision under appeal was as follows:

(A) As regards the respondent's main and auxiliary requests, the opposition division considered that the disclaimers introduced in claim 1 of the main and auxiliary requests (see V above), excluding

- the presence of a water-soluble antioxidant from stabilizing system a), and
- the presence of a chelating agent from stabilizing system b),

conferred novelty on claim 1 over the prior art of citation (1) which is comprised in the state of the art under Article 54(3) and (4) EPC.

(B) It was, however, pointed out by the opposition division in the decision under appeal that citation (2) disclosed in its single claim a composition comprising certain amounts of vitamin A (retinol), vitamin B<sub>6</sub>, vitamin C (a water-soluble antioxidant), vitamin D<sub>2</sub>, vitamin E (an oil-soluble antioxidant), vitamin K<sub>3</sub>, progesterone and testosterone propionate emulsified in Eucerinum cum aqua as an ointment base. It was also mentioned in the decision under appeal that citations (15) and (16) provided adequate evidence to show that Eucerinum cum aqua was a water-in-oil (W/O) ointment base well known in the art and that the (W/O) ointment base Eucerinum cum aqua would not reasonably be expected to undergo phase reversal by the addition of the minor amounts of active agents disclosed in citation (2). On the basis of the foregoing observations, the opposition division concluded that the disclosure of (2) destroyed the novelty of the claimed subject-matter in the main request.



(C) As regards the auxiliary request, the opposition division considered that citation (2) represented an accidental anticipation of the claimed subject-matter in the patent and that the disclaimer newly added to claim 1 of the auxiliary request (see V above) reflected correctly the novelty-destroying teaching of citation (2). It concluded that the disclaimer was thus acceptable under the terms of Article 123(2) EPC and that the claimed subject-matter in the auxiliary request was adequately delimited by this newly introduced disclaimer against the prior art of (2).

(D) The opposition division also found that citation (10) described in claim 1 in conjunction with the disclosure at the end of page 7 a stable emulsified composition comprising a vitamin A compound (retinoid); an antioxidant selected from di-t-butyl-hydroxytoluene (BHT), butylhydroxyanisol (BHA) and tocopherol; and an ethylenediamine tetraacetic acid salt (EDTA salt) as the chelating agent. It was further indicated in (10) that said emulsified composition might be present either in the form an oil-in-water (hereinafter referred to as O/W) or a water-in-oil (hereinafter referred to as W/O) emulsion. In the view of the opposition division, it was readily apparent from the disclosure in the first full paragraph on page 8 of citation (10) that the term "vitamin A" used in this citation did not refer to the compound retinol (synonym for vitamin A or vitamin A alcohol) as such, but was rather used as a generic term to define retinoids in general, such as, for example, vitamin A palmitate or vitamin A acetate, which were explicitly mentioned in the cited passage in (10).

(E) The opposition division did not share the view of both opponents that the general teaching in (10) and, in particular, the disclosure in claim 1 on page 3, lines 9 to 16, in conjunction with the reference to emulsions of either the O/W type or W/O type at the end of page 7 anticipated the claimed subject-matter in both the main and the auxiliary requests. On the contrary, it considered that the general teaching in (10) referred to by the opponents failed to disclose all features specified in claim 1 of either request. In the opposition division's opinion the specific combination of a W/O emulsion with the specific retinoids mentioned in claim 1 of either request represented a new selection over the general teaching of citation (10).

(F) It was also pointed out in the decision under appeal that certain tests (14) carried out on behalf of opponent II allegedly demonstrated that example 4 of (10) was a W/O emulsion. This result was in contrast to the result of the tests (13) submitted on behalf of the proprietor showing that example 4 was in fact an O/W emulsion. The opposition division agreed with the proprietor's arguments during the hearing that the tests (14) were not an exact repetition of example 4 of citation (10) and failed thus to provide adequate evidence that example 4 was indeed a W/O emulsion. The opposition division's final conclusion on this issue was that none of the working examples in (10) disclosed a W/O emulsion and that the subject-matter of the main and the auxiliary request was thus a novel selection over the prior art of (10).

(G) As regards inventive step, the opposition division considered citation (10) to represent the closest state of the art. Starting from the prior art of (10) it determined the problem to be solved as that of further improving the storage stability of emulsions containing Vitamin A alcohol, Vitamin A aldehyde, retinyl acetate, retinyl palmitate or mixtures thereof. It found that the experimental data in the patent description provided sufficient evidence that this problem was adequately solved by the provision of the W/O emulsions as defined in claim 1 of the auxiliary request. In the view of the opposition division, the prior art of (10) did not provide those skilled in the art with any hint or suggestion that the problem posed could be successfully solved

- either by selecting from the two options (O/W or W/O) disclosed in (10) a W/O emulsion in connection with stabilizing system a), that is to say the same stabilizing system as used in (10) [see auxiliary request, claim 1, alternative a)];
- or by using a W/O emulsion in connection with stabilizing system b) [see auxiliary request, claim 1, alternative b)].

VII. Two parties involved in the opposition proceedings appealed against this decision in the following sequence:

- appellant I (opponent I) filed its appeal on 31 August 2001 by letter of 28 August 2001;
- appellant II (opponent II) filed its appeal on 31 August 2001 by letter of 29 August 2001.

Both appellants paid the appeal fees and filed their statements of grounds within the prescribed time limit.

VIII. The respondent filed with a letter of 26 March 2002 observations in reply to the appeal statements and submitted, in addition to its main request that the appeals be dismissed, three further sets of claims forming its first, second and third auxiliary requests.

Claim 1 of the **first auxiliary request** reads as follows, with the amendments compared to claim 1 as maintained indicated in bold italic letters:

"1. A skin care composition comprising a water-in-oil emulsion and a retinoid selected from the group consisting of Vitamin A alcohol, Vitamin A aldehyde, retinyl acetate, retinyl palmitate and mixtures thereof, said composition further comprising a stabilizing system selected from the group consisting of:

- a) a chelating agent and at least one oil-soluble antioxidant; and
- b) antioxidant present in each of the oil and water phases of said emulsion;

provided that

- i) when said composition comprises stabilising system a), it does not contain a water-soluble antioxidant, and
- (ii) when said composition comprises stabilizing system b), it does not comprise a chelating agent, **and the oil-soluble antioxidant is selected from the group consisting of butylated hydroxytoluene (BHT), ascorbyl**

*palmitate, butylated hydroxyanisole (BHA), phenyl- $\alpha$ -naphthylamine, and mixtures thereof,* said composition retaining at least about 60% of said retinoid after 13 weeks' storage at 40°C."

Claim 1 of the **second auxiliary request** reads as follows, with the amendments compared to claim 1 as maintained indicated in bold italic letters:

- "1. A skin care composition comprising a water-in-oil emulsion and a retinoid selected from the group consisting of Vitamin A alcohol, Vitamin A aldehyde, retinyl acetate, retinyl palmitate and mixtures thereof, further comprising a stabilizing system selected from the group consisting of:
- a) a chelating agent and at least one oil-soluble antioxidant; and
  - b) antioxidant present in each of the oil and water phases of said emulsion;
- provided that
- i) when said composition comprises stabilizing system a), it does not contain a water-soluble antioxidant; **and the retinoid is Vitamin A alcohol**
  - (ii) when said composition comprises stabilizing system b), it does not comprise a chelating agent, **and the oil-soluble antioxidant is selected from the group consisting of butylated hydroxytoluene (BHT), ascorbyl palmitate, butylated hydroxyanisole (BHA), phenyl- $\alpha$ -naphthylamine, and mixtures thereof** said composition retaining at least about 60% of said retinoid after 13 weeks' storage at 40°C.

Claim 1 of the **third auxiliary request** reads as follows, with the amendments compared to claim 1 as maintained indicated in bold italic letters:

"1. A skin care composition comprising a water-in-oil emulsion and ***Vitamin A alcohol***, said composition further comprising a stabilizing system selected from the group consisting of:

- a) a chelating agent and at least one oil-soluble antioxidant; and
- c) antioxidant present in each of the oil and water phases of said emulsion;

provided that

- i) when said composition comprises stabilizing system a), it does not contain a water-soluble antioxidant;
- (ii) when said composition comprises stabilizing system b), it does not comprise a chelating agent, ***and the oil-soluble antioxidant is selected from the group consisting of butylated hydroxytoluene (BHT), ascorbyl palmitate, butylated hydroxyanisole (BHA), phenyl- $\alpha$ -naphthylamine, and mixtures thereof,***

said composition retaining at least about 60% of said retinoid after 13 weeks' storage at 40°C."

IX. In a communication dated 16 June 2005 the parties were duly summoned to oral proceedings before the board, fixed for 18 October 2005. In a letter of 27 June 2005 the respondent's representative requested an adjournment of the oral proceedings sine die, on the grounds that he was unable to attend oral proceedings on that date for certain private and personal reasons which he exactly explained and for which he provided

- adequate evidence in his letter. The board thus acceded to the respondent's request and summoned the parties to oral proceedings on the new date of 26 April 2006.
- X. In a letter of 27 June 2005 the representative of appellant II informed the board that appellant II did not intend to be represented at the oral proceedings.
- XI. In a further submission in advance of the oral proceedings before the board, received on 24 March 2006, appellant I supplemented its pleadings with arguments and evidence purported to be suggestive of the reduced chemical stability of a composition comprising a water-in-oil emulsion and Vitamin A (retinol) in combination with stabilizing system a) in accordance with claim 1 of the patent as maintained, compared to a corresponding oil-in-water emulsion containing the same components.
- XII. Oral proceedings before the board were held on 26 April 2006 in the presence of appellant I and the respondent.
- XIII. At the appeal stage the appellants did not maintain the ground of opposition according to Article 100(b) EPC. Their submissions in writing and during oral proceedings, so far as relevant to this decision, can be summarised as follows:
- [1] The introduction of the disclaimer (reading: *"provided that said composition does not comprise vitamin A, vitamin B<sub>6</sub>, vitamin C, vitamin D<sub>2</sub>, vitamin E, vitamin K<sub>3</sub>, progesterone and testosterone propionate"*) into claim 1 as maintained by the opposition division to restore novelty by delimiting the claimed subject-

matter in the patent against the prior art according to citation (2) resulted in a violation of Article 123(2) EPC. In support of this objection appellant I referred to G 1/03 (OJ EPO 2004, 413) as establishing that a disclaimer must satisfy the following two conditions:

- the subject-matter excluded by way of disclaimer must be defined specifically and strictly limited to the actual scope of the novelty-destroying prior art;
- the state of the art under Article 54(2) EPC to be excluded by the disclaimer must be an accidental anticipation, that is to say it must be so unrelated and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention.

The appellants concluded that in the present case the disclaimer in question fulfilled neither of these two conditions.

[2] Appellant I considered that the content of citation (1), which formed part of the state of the art under Article 54(3) and (4) EPC, was prejudicial to the novelty of the claimed subject-matter in claim 1 of all requests. It argued that this document taught and disclosed the use of antioxidants which were both oil-soluble and water-soluble, for example, hydroquinone, propyl gallate, nordihydroguaiaretic acid and mixtures thereof. All these antioxidants were described on page 5, lines 19 to 20, of the patent description as oil-soluble antioxidants "*which are useful in the compositions of the present invention*". Each of the compositions disclosed in Examples X to XII of (1) contained one of the aforementioned antioxidants in



combination with BHT, which meant, in the appellant's opinion, that the cited examples had to be construed as containing only oil-soluble antioxidants and were thus prejudicial to the novelty of the claimed subject-matter in the patent.

[3] If the board reached the conclusion that the disclosure of (1) was not novelty-destroying, claim 1 of all current requests had, in the appellant's opinion, to be refused for lack of clarity. In this context the appellant argued that it was clear from the disclosure at lines 37 to 39 on page 3 of (1) that the antioxidants hydroquinone, propyl gallate and nordihydroguaiaretic acid which were in the patent description (*loc. cit.*) solely described as oil-soluble antioxidants were indeed both oil-soluble and water-soluble. It was thus not clear, in the appellant's opinion, whether in cases where the claimed compositions comprised stabilizing system a) the disclaimer excluded the above-mentioned oil-soluble antioxidants which at the same time were water-soluble.

[4] As regards the prior art of citation (10), both appellants contested the finding of the opposition division in the decision under appeal that the subject-matter of claim 1 of the patent as maintained represented a novel selection over the prior art of (10). They stated that this citation already disclosed skin care compositions for the topical application in the form of stabilized emulsions. These emulsions contained

- as the active ingredient a substance selected from vitamin A, vitamin A palmitate (retinyl palmitate), and vitamin A acetate (retinyl acetate);

- BHT, BHA or tocopherol as an antioxidant agent and
- EDTA salts as a chelating compound.

In accordance with the disclosure at the end of page 7 of (10), the compositions disclosed in (10) were used either in the form of an O/W emulsion or in the form of a W/O emulsion.

[5] Appellant I pointed out that the disclosure of vitamin A in (10) was to be considered on the basis of the evidence provided in the present proceedings (see eg (12), page 95, right-hand column) as a synonym for the same active ingredient (retinoid) termed vitamin A alcohol (retinol) in present claim 1. It followed that citation (10) disclosed only two alternatives for the same composition, i.e. an O/W emulsion or a W/O emulsion. The claimed subject-matter in claim 1 of all requests was thus the result of a selection from one single list and therefore lacked novelty on the basis of the principle, well-established in the case law of the boards of appeal, that only a selection from two different lists of technical features in the same piece of prior art, i.e. in the present case citation (10), could possibly confer novelty on the claimed subject-matter in the patent.

[6] Appellant II argued that in the description of (10) only vitamin A palmitate was exemplified and the only other disclosure in the whole document stated that the vitamin A compound that was used might be one such as vitamin A palmitate or vitamin A acetate, which were both covered by the claims of the present main and first auxiliary requests. Appellant II therefore agreed with the opposition division in so far as the use of the term vitamin A in (10) could not be considered as a

specific disclosure of vitamin A (vitamin A alcohol, retinol) *per se*, as the esters were used in the examples. However, it could not agree with the opposition division's conclusion that the retinoids specified in the claims as maintained constituted a selection. The claims in fact merely listed the well-known differing forms of vitamin A compounds typically used in cosmetic applications. Indeed the patent itself stated that other than retinoic acid, retinal, retinol and retinyl esters were typically used in skin care products. Furthermore, the description of (10) specifically named two vitamin compounds, namely vitamin A acetate and vitamin A palmitate, as being useful therein, the latter being specifically used in the exemplified formulations. Since these were the only compounds disclosed under the generic disclosure of vitamin A, if the disclosure of (10) was taken as a whole, the skilled person would specifically use these compounds as the vitamin A compounds of the invention described therein and hence there could be no new selection of these compounds from the state of the art.

[7] The second question concerned the disclosure of the emulsion within citation (10). There was a specific disclosure in (10) that the compositions of the invention described therein might be either the water-in-oil type (W/O) or the oil-in-water type (O/W). There could thus be no dispute that the understanding of the skilled person of (10) was that the composition might be equally formulated as oil-in-water or water-in-oil emulsions, as both were explicitly described as providing the benefits of the invention underlying (10). Hence the prior art of (10) disclosed directly and unambiguously all of the features claimed in the

patent as maintained and thus deprived the main request of novelty.

[8] As regards inventive step, both appellants considered citation (10) as the closest prior art document as it related to a similar problem to that underlying the patent. Since the only difference in the patent was the specification of a water-in-oil emulsion as opposed to an oil-in-water emulsion, the problem thus underlying the purported invention could only be considered as the further improvement of a vitamin A-containing formulation stabilised with an oil-soluble antioxidant and a chelating agent. The proposed solution was to formulate it as a water-in-oil emulsion. Citation (10), however, taught that oil-in-water and water-in-oil emulsion formulations were both suitable for providing the stabilization benefits for the vitamin A compounds. Whilst (10) did not state that water-in-oil would allow for improved stability it also did not state that oil-in-water would be better than water-in-oil. In other words, the skilled person was taught to contemplate using both oil-in-water and water-in-oil emulsions and would thus have been taught to use both types of emulsion. The benefit of using water-in-oil would have been established by the skilled person as part of his routine activities to assess the two equally described embodiments. The appellants also argued that, even if the benefit of using water-in-oil were to be considered as a surprising effect, which was disputed by them, the selection of one option from a group of only two equally preferred options from the prior art could not contribute to imparting an inventive step on the claimed subject-matter.

[9] It was further pointed out by appellant I that citation (2) disclosed a composition in the form of a water-in-oil emulsion containing, *inter alia*, vitamin A (retinol), vitamin C (ascorbic acid, i.e. a water-soluble antioxidant), and vitamin E ( $\alpha$ -tocopherol acetate, i.e. an oil-soluble antioxidant). The claimed compositions in any request merely represented, in the appellant's opinion, obvious alternatives to those in (2) obtained by either replacing vitamin A (retinol) with a different retinoid compound or by replacing the oil-soluble antioxidant vitamin E ( $\alpha$ -tocopherol acetate) with another conventionally used oil-soluble antioxidant, for example BHT or BHA used in (10).

XIV. The respondent's arguments in writing and during oral proceedings, in so far as they are relevant to the present decision, may be summarised as follows:

[10] In relation to the appellants' objections that the disclosure of citation (2) was limited to compositions containing "Eucerinum cum aqua", whereas the disclaimer in claim 1 of the main request unacceptably extended to other water-in-oil emulsions, the respondent argued that it was not at all clear what was meant by "Eucerinum cum aqua" in (2). Evidence had been provided as to a product sold by Beiersdorf in 1998 or 2000 under the trade mark "Eucerinum<sup>®</sup> cum Aqua", but this did not establish what was meant by this designation in citation (2), a document which was filed in 1985. In these circumstances, therefore, it seemed appropriate to extend the disclaimer to water-in-oil emulsions in general.

[11] The technical problem which the patent addressed was to provide stable formulations of vitamin A. In this context, the respondent pointed out that citation (2) did not in any way address this problem. This citation included vitamin E for its properties as a vitamin, not because it was an antioxidant which helped to stabilise the vitamin A. Accordingly, citation (2) was precisely the kind of state of the art which G 1/03 (*loc. cit.*) refers to when it talks of an "*accidental anticipation under Article 54(2) EPC*".

The respondent thus concluded that the use of the disclaimer in question to exclude possible anticipation by the disclosure of (2) was fully in accordance with the established case law of the Enlarged Board of Appeal.

[12] In the respondent's opinion, the appellants were also incorrect in arguing that there was no basis in the application as filed for the provisos which excluded compositions containing an oil-soluble antioxidant, a water-soluble antioxidant and a chelating agent. Claim 1 of all requests related to two different kinds of stabilizing system. The first comprised a chelating agent and an oil-soluble antioxidant, but no water-soluble antioxidant. The second comprised an antioxidant present in each of the oil and water phases, but it did not contain a chelating agent.

The respondent submitted that the basis for both of these systems was to be found on page 9 of the application as filed (in the present case, equivalent to the published application), at lines 18 to 28. This

passage set out three possible stabilizing systems a), b) and c). Systems a) and c) corresponded to systems a) and b) of claim 1. The question under Article 123(2) EPC was whether it was clear to the reader of the passage on page 9 of the published application that stabilizing system a) did not necessarily include a water-soluble antioxidant, and that stabilizing system c) did not necessarily include a chelating agent. In the respondent's opinion, this was abundantly clear. If system a) had to include a water-soluble antioxidant as well as an oil-soluble antioxidant, it was just an example of system c). Indeed, if system a) had to include a water-soluble antioxidant and system c) had to include a chelating agent, the two systems were identical. The recitation of three distinct possibilities at lines 21 to 28 on page 9 directly and necessarily implied that system a) did not have to include a water-soluble antioxidant, and system c) did not have to include a chelating agent.

Further support for stabilizing system a) of claim 1 of all requests came from claims 12 and 19 as filed. Claim 12 specified that the composition comprised an oil-soluble antioxidant and a chelating agent. Claim 19, which was dependent on claim 12, added the feature that there was also a water-soluble antioxidant. The conclusion was inescapable that claim 12 covered compositions comprising an oil-soluble antioxidant and a chelating agent, but no water-soluble antioxidant. Otherwise, claim 19 would have been redundant. To reinforce the point, the specification then went on to provide a specific example of a formulation which included a chelating agent and an oil-soluble antioxidant, but no water-soluble

antioxidant. This was Sample No. 1 in Table 3 on page 28.

Further support for stabilizing system b) of claim 1 of all requests came from claims 28 and 38 as originally filed. Claim 28 was for a composition comprising an antioxidant in each of the oil and water phases. Claim 38, which was dependent on claim 28, added the feature that the composition further comprised a chelating agent. Again, claim 38 would have been redundant if the compositions of claim 28 necessarily contained a chelating agent. The specification reinforced this point by providing an example of a formulation containing a water-soluble antioxidant, an oil-soluble antioxidant, but no chelating agent. This was Sample No. 2 in Table 2 on page 23.

[13] As regards the objections of lack of novelty over the prior art of citation (1) made by appellant I, the respondent noted that the appellant did not refer to specific passages of (1) but stated that this document taught and disclosed the use of antioxidants which were both oil-soluble and water-soluble. The respondent argued that the relevance of this argument was not clear to it because citation (1) clearly and unambiguously required the presence of "at least one water-soluble antioxidant and at least one oil-soluble antioxidant" (see especially page 3, lines 24/25). The fact that certain antioxidants might function as both water-soluble and oil-soluble antioxidants did not mean, as appellant I implied, that (1) also contemplated formulations containing only one antioxidant. What it meant was that antioxidants such as hydroquinone and propyl gallate could be used as



water-soluble antioxidants, but a separate oil-soluble antioxidant was than also used. This was illustrated in Examples X, XI and XII of (1). Every example of (1) involved the use of a water-soluble antioxidant, an oil-soluble antioxidant and a chelating agent. The respondent also submitted that disclaimer (i) excluded from the claimed compositions in present claim 1 containing stabilizing system a) any conceivable water-soluble antioxidant irrespective of whether that particular water-soluble antioxidant might function as both water-soluble antioxidant and oil-soluble antioxidant as well.

**[14]** It was also pointed out by the respondent that both appellants had asserted that claim 1 of all requests lacked novelty in view of citation (10). Both appellants asserted that Example 4 of (10) was a water-in-oil emulsion which anticipated claim 1 of the main request. In order to demonstrate this, appellant II had provided the results of an experiment (14) which purported to demonstrate that Example 4 of (10) was indeed a water-in-oil emulsion, but the results in (14) were inconsistent with those presented in the Declaration (13) of the inventor. In case of a conflict of evidence in opposition proceedings, the respondent submitted that the benefit of any doubt should be given to the proprietor.

**[15]** In order to attack novelty of claim 1 of the main request, both appellants also sought to combine the disclosure of page 8, lines 3 to 6, of (10) with the specific reference to a W/O type emulsion in the last line on page 7. In the respondent's opinion this was inappropriate. There was no specific disclosure in (10) of a water-in-oil emulsion containing vitamin A

palmitate or vitamin A acetate, and such a composition represented an inventive selection from the disclosures of (10).

[16] The respondent mentioned that appellant I also asserted that claim 1 of all requests did not involve an inventive step in view of the prior art of (2) or (10). Appellant II relied solely on (10). According to the respondent, the problem which was solved by the present invention was the provision of an unusually stable retinoid-containing composition. The question to be addressed was whether it was obvious to the skilled reader of (2) or (10) that an unusually stable retinoid-containing formulation could be achieved by providing the retinoid in a water-in-oil emulsion comprising a stabilizing system as specified in claim 1.

[17] Citation (2) did not even discuss the stability of the vitamin A which it used. Plainly, therefore, it could not have been obvious in view of this document how to produce a retinoid-containing formulation of unusual stability.

[18] Citation (10) made a passing reference to a W/O type emulsion, but all of the examples appeared to be oil-in-water emulsions. There was, in the respondent's opinion, certainly no suggestion in (10) that a water-in-oil emulsion offered any advantages over an oil-in-water emulsion. Accordingly, (10) did not render it obvious that compositions of unusual stability could be obtained using a water-in-oil emulsion.

[19] Claim 1 of the first auxiliary request specified that when the claimed composition comprises stabilizing system b), the oil-soluble antioxidant is one (or more) of four specified antioxidants. These did not include tocopherol, which was used in (2). Accordingly, claim 1 was novel over the disclosures of (2), without any need for a disclaimer.

[20] Claim 1 of the second auxiliary request was similar to claim 1 of the first auxiliary request, but it further specified that when the composition comprises stabilizing system a), the retinoid is vitamin A alcohol. There was no disclosure in (10) of the use of vitamin A alcohol. On the contrary, (10) referred to "*vitamin A palmitate, vitamin A acetate, or the like*". Plainly, (10) taught the use of more stable vitamin A derivatives. It did not in any way suggest that vitamin A alcohol, which was very much less stable than vitamin A palmitate or vitamin A acetate, could be stabilised by using the measures recited in claim 1.

[21] Claim 1 of the third auxiliary request specified that the retinoid was vitamin A alcohol, whether stabilizing system a) or b) was employed. As discussed above, (10) did not address the problem of stabilizing vitamin A alcohol.

XIV. Appellant I requested that the decision under appeal be set aside and that the patent be revoked. Appellant II had requested in writing that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed (main request), or that the patent be maintained in

amended form on the basis of one of the first, second and third auxiliary requests, all filed with its letter dated 26 March 2002.

## **Reasons for the Decision**

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.

### ***Late-filed evidence***

2. It is well-established by the jurisprudence of the boards of appeal that, in considering the admissibility of late-filed evidence, account is to be taken of *inter alia* whether it could have been filed earlier and if so the reason why it was not, and of its relevance and in particular whether it has a greater relevance to the issues than the material already on file (see generally, "Case Law of the Boards of Appeal of the European Patent Office", 4th edition, 2001, pages 324 to 333). Thus, in principle, any new evidence filed on appeal is exceptional *per se* and its admissibility is a matter for the exercise of the board's discretion. In addition to these general principles, the board must also ensure that late filing does not take another party by surprise and that, if late evidence is to be admitted, the other party or parties have sufficient time to consider it and to verify the results presented and, as appropriate, to reply with evidence of their own.
  - 2.1 It is beyond doubt that the evidence filed by appellant I with its letter of 24 March 2006 was late, whether "late" is taken as meaning after the end of the

opposition period, after the end of the opposition proceedings or after the grounds of appeal were filed in the appeal proceedings. The statements of the grounds of appeal were filed by appellant I on 6 November 2001 and by appellant II on 16 November 2001. The board observes that the respondent's comments on the appeals which were its last written submissions in appeal proceedings before the hearing on 26 April 2006 were already filed with its letter of 26 March 2002, about four years before appellant I filed its evidence.

2.2 In its letter of 24 March 2006, appellant I gave no reason or justification at all for the late submission of the comparative evidence it eventually produced. At the hearing, the appellant submitted as justification for the late submission *inter alia* that vitamin A alcohol (retinol) which was used as the vitamin A compound in the experimental evidence provided was difficult to obtain in the pure form required for the comparative tests presented. It also submitted that handling of retinol is dangerous and that legislation in Contracting States allows its use for experiments only under certain restrictions and subject to administrative approval.

2.3 As the respondent, in the board's opinion, correctly replied, the evidence actually filed as late as March 2006 is evidence which the appellant could have produced earlier, not just because ample time had elapsed since the commencement of the appeal proceedings on the patent, but also because it was not contested that the appellant's company had already placed on the market various other products containing retinol and had thus gained sufficient experience in

handling this particular compound prior to the comparative evidence it eventually produced in the present case.

2.4 The issue of lateness was further exacerbated in the present case by the fact that the experimental evidence filed by appellant I on 24 March 2006 was notified to the respondent by the EPO's registered letter dated **30 March 2006** which means it had not sufficient time and opportunity to seriously verify the test results presented by the appellant in advance of the oral proceedings fixed for **26 April 2006** because the experimental evidence provided was based on stability tests, the results of which were determined only after **one month's aging** of the samples.

2.5 In fairness to appellant I, when filing its late evidence it did submit certain arguments as to its possible relevance but relevance and justification for lateness are separate criteria and satisfying the former does not satisfy the latter. In the board's judgment, the lateness of evidence cannot be excused if as in the present case

- no attempt was made convincingly to show why the actual evidence in question was not produced at an earlier date and
- in particular, the respondent was not given sufficient time and opportunity to verify the test results in advance of the hearing before the board.

2.6 Accordingly, the board holds that the evidence filed with the appellant's letter of 24 March 2006 is not admissible.

**Main request; admissibility of the disclaimer introduced during the oral proceedings before the opposition division; Article 123(2) EPC**

3. In the decision under appeal, the opposition division considered that citation (2) represented an accidental anticipation which was prejudicial to the novelty of the claimed subject-matter in the patent as granted. It concluded that the disclaimer introduced into claim 1 during the oral proceedings before it (see V above) to restore novelty by delimiting the claimed subject-matter in the patent against the state of the art of citation (2) was acceptable under Article 123(2) EPC. The disclaimer in question reads as follows (see V above): *"and further provided that said composition does not comprise vitamin A, vitamin B<sub>6</sub>, vitamin C, vitamin D<sub>2</sub>, vitamin E, vitamin K<sub>3</sub>, progesterone and testosterone propionate"*.
- 3.1 Having regard to the recently issued decision G 1/03 (OJ EPO 2004, 413), the board cannot share the opposition division's view. Citation (2) is comprised in the state of the art under Article 54(2) EPC. It discloses an ointment in the form of a W/O emulsion comprising certain amounts of vitamin A (retinol), vitamin B<sub>6</sub>, vitamin C (a water soluble antioxidant), vitamin D<sub>2</sub>, vitamin E (an oil-soluble antioxidant), vitamin K<sub>3</sub>, progesterone and testosterone propionate emulsified in Eucerinum cum aqua. The description in the citation states (see left-hand column, lines 32-36) that the ointment disclosed in the cited document is a skin care composition which may be used for the treatment of diseases of the skin and the eyes and also for cosmetic purposes.

3.2 In accordance with decision G 1/03 (loc. cit., see especially Headnote II) *"a disclaimer may be allowable in order to restore novelty by delimiting a claim against an accidental anticipation under Article 54(2) EPC; an anticipation is accidental if it is so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention"*.

3.3 The respondent specifically relied on the following statement in point 2.1.1 of the Reasons of the cited decision: *"The concept of accidental anticipation is akin to the situation of conflicting applications already discussed, starting from the premise that only novelty is at stake <.....>. A typical situation is the following: the claimed invention concerns a large group of chemical compounds with certain properties which are advantageous for a specific use. One single compound falling within the group turns out to be known for a completely different use and, therefore, only properties irrelevant to the new use are known. In such situations it is felt to be unfair if, in the absence of a basis in the application as filed for a limiting amendment excluding the known compound, that single compound may represent a bar to patenting the entire group"*.

3.4 In this context, the respondent argued that in the ointment of citation (2) vitamin E (tocopherol, i.e. an oil-soluble antioxidant) serves an entirely different purpose and fulfils a different function from its purpose and function in the patent. However, apart from the fact that tocopherol is a well known stabilizing



agent, which is particularly used in vitamin products for the stabilization of vitamin A (see e.g. (12), page 120, left-hand column, lines 5-7), it is not decisive in the present case whether or not a single component of the skin care composition disclosed in (2), for example tocopherol, is possibly used in (2) for a different purpose from its purpose in the patent. What is decisive here is that the product itself, i.e. the ointment disclosed in (2), is a skin care composition which is used in (2) for exactly the same purpose as in the patent, namely for the treatment of diseases of the skin and the eyes and also for cosmetic purposes.

- 3.5 In accordance with decision G 1/03 (*loc. cit.*, see especially point 2.2.2 of the Reasons), *"the fact that the technical field is remote or non-related may be important but is not decisive because there are situations in which the skilled person would also consult documents in a remote field. Even less decisive, as an isolated element, is the lack of a common problem, since the more advanced a technology is, the more the problem may be formulated specifically for an invention in the field. Indeed, one and the same product may have to fulfil many requirements in order to have balanced properties which make it an industrially interesting product. Correspondingly, many problems related to different properties of the product may be defined for its further development. When looking specifically at improving one property, the person skilled in the art cannot ignore other well-known requirements. Therefore, a "different problem" may not yet be a problem in a different technical field. What counts is that from a technical point of view, the disclosure in question must be so unrelated and remote that the person skilled*

*in the art would never have taken it into consideration when working on the invention".*

3.6 In the present case, it is, in the board's opinion, abundantly clear that the skin care composition disclosed in (2) not only concerns the same technical field but also is known for exactly the same use as the claimed invention. Even if the board were to follow the respondent's argument that no common technical problem exists, the skilled person having studied the closest state of the art and guided by the technical problem underlying the claimed invention would have been aware from his common general knowledge and also from his familiarity with related art that tocopherol is a well-known stabilizing agent, which is particularly used in vitamin products for the stabilisation of vitamin A (see e.g. (12), page 120, left-hand column, lines 5-7). He would thus have certainly taken into consideration the state of the art according to (2) when working on the present invention.

3.7 In conclusion, on the basis of the guidance given in decision G 1/03 (*loc. cit.*) the board reached the conclusion that citation (2) is definitely not an accidental anticipation in the sense outlined in the cited decision of the Enlarged Board of Appeal and that the above-mentioned disclaimer introduced in claim 1 is therefore not acceptable under Article 123(2) EPC. Since a decision can only be taken on each request as a whole, there is no need to look into the patentability of the other claims either. For these reasons the respondent's main request must fail.

***First auxiliary request; "reformatio in peius"***

4. Appellant I argued for the first time at the hearing that claim 1 of the first auxiliary request, if admitted by the board, would, in its opinion, result in a contravention of the principle of "prohibition of reformatio in the peius" set out in decisions G 9/92 (OJ EPO 1994, 875) and G 4/93 (OJ EPO 1995, 875). In particular, it argued that deletion of the above-mentioned disclaimer by the non-appealing respondent from claim 1 as maintained and introduction of the following positive features instead ("*the oil-soluble antioxidant is selected from the group consisting of butylated hydroxytoluene (BHT), ascorbyl palmitate, butylated hydroxyanisole (BHA), phenyl- $\alpha$ -naphthylamine, and mixtures thereof*") in claim 1 of the first auxiliary request to restore novelty by delimiting the claimed subject-matter in the patent against the state of the art of citation (2) resulted in an extension of the scope of the patent in the form maintained by the opposition division.
  
- 4.1 As indicated during the oral proceedings, the board does not share this view. It is of the opinion that exclusion of vitamin E (tocopherol) from the list of the possible oil-soluble antioxidants, when the claimed composition comprises stabilizing system b), has the effect that the scope of claim 1 of the first auxiliary request is not extended compared with the scope of claim 1 as maintained.

*Novelty; Article 54 EPC*

4.2 In the decision under appeal, the opposition division concluded that the claimed subject-matter in the main and auxiliary requests before it (see IV above) was novel by selection over the prior art of citation (10), on the grounds that a specific combination was chosen from the technical features disclosed in (10). In particular, it considered that the combination of a "W/O emulsion" with the "specific retinoids mentioned in claim 1 of the above-mentioned requests" represented a new selection over the general teachings of citation (10) (see especially point 9.2 of the Reasons).

4.3 Citation (10) discloses a group of topical dermatological compositions for external use on skin comprising

- (a) a retinoid compound or a group of retinoid compounds designated vitamin A and other vitamin A derivatives, such as vitamin A palmitate (retinyl palmitate) or vitamin A acetate (retinyl acetate) (see especially page 8, lines 3-4);
- (b) an oil-soluble antioxidant, such as di-t-butylhydroxytoluene (BHT), butylhydroxyanisole (BHA) or tocopherol (see especially page 1, claim; page 8, second full paragraph); and
- (c) a chelating agent, i.e. an ethylenediamine tetraacetic acid (EDTA) salt (see especially page 1, claim; page 8, lines 8-9 from the bottom);
- (d) the compositions disclosed in (10) are present in the emulsion form of either the O/W (oil-in-water) type or W/O (water-in-oil) type (see especially end of page 7).

4.4 The opposition division was apparently of the opinion that the claimed group of compositions in claim 1 of the main and auxiliary requests before it represents a selection from two separate lists of technical features described in (10), the first list consisting of all retinoid compounds disclosed in (10) (see feature (a) above), including retinyl acetate and retinyl palmitate also recited in claim 1 of the above-mentioned requests, and the second list consisting of the two equivalent alternatives for the formulation of the compositions disclosed in (10), i.e. either a water-in-oil or an oil-in-water emulsion (see feature (d) above).

4.5 It has been well established in the case law of the boards of appeal since decision T 12/81 (OJ EPO 1982, 296, and in the general "Case Law of the Boards of Appeal of the European Patent Office", 4th Edition, 2001, I.C.4. pages 73-76) that a particular substance or composition, obtained by **selecting** a specific combination of two different technical features

- from the range of possibilities disclosed in a prior art document for one of these features (first list) and
- from the range of possibilities disclosed in the same prior art document for the other of these features (second list),

may in the normal practice rightly be regarded - in the absence of any additional information - as not having been anticipated by prior description but as being a new selection. The new element - indispensable if a substance selection is to be recognised as new for patent law purposes - is attributable to the fact that the specific combination or combinations actually selected from the wide range of all theoretically

(intellectually) possible combinations have not been disclosed to the public in individualised form in the prior art document. This necessarily presupposes that a **selection is made from both the range of possibilities disclosed in the first list and also the range of possibilities disclosed in the second list** because only in this case is the selected substance or composition the result of the combination of **two variable parameters**.

4.6 The respondent argued and the opposition division apparently accepted this argument that this selection principle also applies in the cases as in claim 1 of the main and auxiliary requests before the opposition division and likewise in claim 1 of the present first auxiliary request (see VII above), where the **complete first list** of technical features disclosed in the a prior art document [i.e. here the complete list of all retinoid compounds disclosed in (10)] is combined with a technical feature selected from the second list of technical features disclosed in the same piece of prior art (i.e. here the formulation of the compositions in the form of a W/O emulsion selected from the two equivalent alternatives W/O or O/W emulsion disclosed in (10)]. The board does not share this view.

4.7 It is readily shown that (i), a combination obtained by **selecting** one or more individual technical features from a first list disclosed in the state of the art and **selecting** one or more individual technical features from a second disclosed in the same state of the art, leads to a quite different result from (ii), a combination between the **complete first list of technical features** disclosed in the state of the art

and one or more individual technical features **selected** from the second list disclosed in the same state of the art and that they are thus not comparable.

At its simplest, in the former case, every conceivable combination of an individual technical feature selected from the first list [i.e. in the present case, any individual retinoid compound disclosed in (10)] with any individual technical feature selected from a separate second list (i.e. in the present case a W/O or O/W emulsion) would lead to a true substantive modification of each combination obtained since each of these combinations would be **the result of two variable parameters**, the number of possible combinations thereby multiplying exponentially. Combinations obtained in this way by selecting a specific pair of technical features from the range of possibilities offered in the state of the art [i.e. in the present case a skin care composition comprising a water-in-oil emulsion and a specific retinoid selected from those disclosed in (10)] would be regarded as not having been anticipated by prior description but as being a new selection. The new element would be attributable to the fact that the specific combination actually selected from the wide range of possibilities has not been disclosed to the public in the state of the art in individualised form.

Contrary to the above, the selection in claim 1 of the main and auxiliary requests before the opposition division and likewise in claim 1 of the present first auxiliary request involves combining **the complete list of retinoids disclosed in (10)** with one of the alternatives for the emulsion given in (10). In the

contrast to the case outlined above, such a combination does not result in a real substantive modification of each combination obtained since the complete list of retinoids - seen in the terms of the possible combinations and, accordingly, the claimed compositions - is **not a variable parameter** that would result in an exponential widening of the range of possibilities, so that precisely in this case the group of the claimed compositions is **not** the result of two variable parameters. The role of a new element - indispensable to a selection invention - cannot therefore be attributed to the selection in claim 1 of the above-mentioned requests. On the contrary, the teaching in the (10) to the effect that each of the retinoids listed (the complete list) in the document is to be formulated in the form of a W/O emulsion has already become available to the public in citation (10) as one of only two possible alternatives (possibilities) already envisaged in individualised form in (10).

- 4.8 It follows that the claimed subject-matter in the first auxiliary request lacks, in the board's judgment, novelty over the prior art of citation (10). Hence, the first auxiliary request is also not allowable.

***Second auxiliary request; amendments; Article 123(2) EPC***

5. Claim 1 of the second auxiliary request specifies that when the claimed composition comprises stabilizing system a), the retinoid is Vitamin A alcohol. Neither the description nor the claims of the application as originally filed contain any limitation of one of the two alternative stabilizing systems a) and b) (i.e. in



the second auxiliary request stabilizing system a)) to one or more of the specific retinoid compounds recited in the application as filed.

5.1 Thus, on the basis of what has been explained above (paragraphs 4 to 4.6), the board cannot but conclude that the limitation introduced into claim 1 [i.e. when the claimed composition comprises stabilizing system a), the retinoid can only be vitamin A alcohol] results from a selection from both (i) the range of possibilities of the retinoid compounds disclosed in the application as filed (first list of a variable parameter) and also (ii) the range of possibilities of the stabilizing systems disclosed in the application as filed (second list of a variable parameter) or vice versa and that in this case the selected first embodiment of the claimed invention in claim 1 [a skin care composition comprising vitamin A alcohol as the sole possible retinoid and stabilizing system a)] is the result of the combination of **two variable parameters and as such introduces a new element into claim 1.**

5.2 With regard to Article 123(2) EPC, the underlying idea is clearly that an applicant should not be allowed to improve his position by adding subject-matter not disclosed in the application as filed, which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application. In the light of the considerations in the foregoing points, the introduction of the above-mentioned specific new combination into claim 1, even if this combination represents a limitation of the originally claimed

subject-matter, is not clearly and unequivocally derivable from the application as filed and, accordingly, violates Article 123(2) EPC. For this reason the second auxiliary request cannot be allowed.

***Third auxiliary request; amendments: admissibility; Rule 57a EPC; "reformatio in peius"***

6. The amendments to the claims can fairly be said to be occasioned by grounds for opposition specified in Article 100(a) EPC and to constitute a *bona fide* attempt on the part of the respondent to overcome the appellants' objections to lack of novelty and inventive step in the opposition and appeal statements. The proposed amendments to the granted patent are thus admissible under the terms of Rule 57a EPC.

6.1 In the board's opinion, the amendments do not result in a contravention of the principle of "prohibition of reformatio in the peius" for the reasons set out in the points 4 and 4.1 above.

*Amendments: allowability: Article 123(2) and (3) EPC*

6.2 In the oral proceedings, appellant I held the opinion that the claimed subject-matter in claim 1 of the third auxiliary request was the result of a multiple choice (selections, singling out) from the disclosure in the application as filed for which adequate support in the originally filed documents, contrary to the requirements of Article 123(2) EPC, is missing. In particular, appellant I argued that this multiple choice from the application as originally filed involved the steps of

- (a) excluding by disclaimer (i) the presence of a water-soluble anti-oxidant when the claimed composition comprises stabilizing system a);
- (b) excluding a chelating agent by disclaimer (ii) when the claimed composition comprises stabilizing system b);
- (c) selecting the oil-soluble antioxidant from the group consisting of butylated hydroxytoluene (BHT), ascorbyl palmitate, butylated hydroxyanisole (BHA), phenyl- $\alpha$ -naphthylamine, and mixtures thereof when the claimed composition comprises stabilizing system b);
- (d) selecting retinol from the group of retinoids recited in the application as filed.

6.2.1 In the board's judgment, all the features of the claims of the respondent's third auxiliary request before the board can be found in the application for the patent as filed; and the scope of the claims has not been extended by the amendments made to the claims as granted. Apart from the fact that both disclaimers (i) and (ii) have been introduced into claim 1 in order to restore novelty by delimiting claim 1 against the disclosure of citation (1) which is comprised in the state of the art under Article 54(3) and (4) EPC and are, therefore, not in contradiction to Article 123(2) EPC, the board is able to agree with the respondent's submissions that, *inter alia*, original independent claim 12 and original claim 19 which is dependent on claim 12 provide an adequate basis for the "alleged selection" resulting from the limitation by disclaimer (i), whereas original independent claim 28 and original claim 38 which is dependent on claim 28 provide an adequate basis for the "alleged selection" resulting

from the limitation by disclaimer (ii) (see also the respondent's complete arguments referred to in more detail in XIV [12] above).

- 6.2.2 Claim 1 of the third auxiliary request specifies that the retinoid is vitamin A alcohol, whether stabilizing system a) or b) is employed. The specific combination in claim 1 resulting from the selection of the oil-soluble antioxidant from the group consisting of butylated hydroxytoluene (BHT), ascorbyl palmitate, butylated hydroxyanisole (BHA), phenyl- $\alpha$ -naphthylamine and mixtures thereof and the selection of vitamin A alcohol from the group of retinoids recited in the originally-filed documents finds, in the board's opinion, formal support in claims 13 and 14 of the application as filed. The selection of vitamin A alcohol as the sole retinoid present in the claimed composition is further supported by originally filed claim 2 which is dependent on claim 1 and claim 21 which is dependent on claim 20. Accordingly, the claims now under consideration meet the requirements of Article 123(2) and (3) EPC.

*Novelty; Article 54 EPC*

- 6.3 During the hearing before the board, appellant I maintained its objections already submitted in writing that the claimed subject-matter lacks *inter alia* novelty over the state of the art according to citation (1). In its broadest aspect, this citation discloses a skin care composition comprising a stable water-in-oil emulsion base, including an antioxidant system, a chelating agent and at least one retinoid compound.

The antioxidant system used in citation (1) comprises at least a water-soluble antioxidant and at least an oil-soluble antioxidant, eg BHT, BHA or  $\alpha$ -tocopherol. The water-soluble antioxidant protects the retinoid compounds from endogenous oxidation and the oil-soluble antioxidant protects the retinoid compounds from exogenous oxidation. Both antioxidants are necessary in the skin care compositions disclosed in (1) (see especially page 3, lines 22-27).

It is stated in (1) that certain antioxidants which are useful in the those skin care compositions function as both water-soluble antioxidants and oil-soluble antioxidants and that formulations containing such antioxidants form part of the state of the art according to (1). Examples of such antioxidants are hydroquinone, propyl gallate, nordihydroguaiaretic acid and mixtures thereof (see (1), page 3, lines 38-40).

- 6.3.1 The antioxidant system used in Example X of (1) consists of hydroquinone and BHT whereas that used in Example XI of (1) consists of propyl gallate and BHT and that used in Example XII of (1) of nordihydroguaiaretic acid and BHT.

Appellant I argued in its written submissions and during the hearing before the board that in the patent description (see page 5, lines 19-20) hydroquinone, propyl gallate and nordihydroguaiaretic acid are explicitly mentioned as being suitable oil-soluble anti-oxidants for use in the claimed composition. It concluded therefrom that the above-mentioned examples of skin care compositions in (1) have to be construed as including a stabilising system comprising a

chelating agent and only oil-soluble antioxidants (i.e. stabilizing system a) in the present claim 1) and that the disclosure of (1) is accordingly prejudicial to the novelty of claim 1.

6.3.2 The respondent refuted the appellant's assertions. It held that disclaimer (i) ("*when said composition comprises stabilising system a), it does not contain a water-soluble antioxidant*") excludes from the claimed compositions in present claim 1 containing stabilizing system a) any conceivable water-soluble antioxidant, irrespective of whether that particular water-soluble antioxidant may function as both water-soluble antioxidant and oil-soluble antioxidant and, in particular, those which are characterised in (1) as exhibiting both functions. The board can agree with this line of reasoning and considers that the subject-matter of present claim 1 is appropriately delimited by disclaimer (i) against the above-mentioned disclosure of citation (1).

6.3.3 In this context the appellant also argued that it was evident from the disclosure at lines 37 to 39 on page 3 of (1) that the antioxidants hydroquinone, propyl gallate, and nordihydroguaiaretic acid, although described in the patent description (*loc. cit.*) solely as oil-soluble antioxidants, were indeed both oil-soluble and water-soluble. It was thus not clear, in the appellant's opinion, whether in the cases where the claimed compositions comprised stabilizing system a) the disclaimer excluded the above-mentioned oil-soluble antioxidants which at the same time were water-soluble. Article 102(3) EPC does not allow objections to be based on Article 84 EPC if they do not arise out of the

amendments made to the patent during an opposition. This is the case here (see "Case Law of the Boards of Appeal of the European Patent Office", fourth edition 2001, EPO 2002, VII.C.10.2, pages 488-489). The above-mentioned discrepancy between the claims and the description was already present in the patent as granted, where reference was made in claim 1 to a stabilizing system consisting of a chelating agent and at least one water-soluble antioxidant. Moreover, this discrepancy can easily be removed by the necessary adaptation of the description to the claims considered allowable. In any case, the present claims are sufficiently clear that this issue was not crucial to the understanding of the other issues to be decided in the present case.

6.3.4 The embodiment of present claim 1, wherein the skin care compositions comprise stabilizing system b), is appropriately delimited by disclaimer (ii) (*"when said composition comprises stabilising system b), it does not comprise a chelating agent"*) against the prior art of (1) because the presence of a chelating agent is a compulsory feature of the compositions disclosed in citation (1).

6.4 The embodiment of present claim 1 wherein the claimed skin care compositions comprise stabilizing system b), has been adequately delimited, in the board's judgment, against the state of the art according to citation (2) by the limitation of the oil-soluble antioxidant to certain specific examples, namely butylated hydroxytoluene (BHT), ascorbyl palmitate, butylated hydroxyanisole (BHA), phenyl- $\alpha$ -naphthylamine and mixtures thereof and the exclusion of tocopherol.

6.5 As shown in the 4.1 above, citation (10) discloses a group of topical dermatological compositions for external use on skin, *inter alia*, comprising a retinoid selected from a list of possible retinoid compounds, including vitamin A (see eg the claim on page 1; page 2, line 6; page 3, lines 7, 11, 17, 24, vitamin A palmitate (see eg page 3, line 4 from the bottom, page 4, line 7, line 5 from the bottom; Examples 1, 2 and 4) and vitamin A acetate or the like, page 8, lines 4-5; Example 3).

6.5.1 The novelty of claim 1 over citation (10) was challenged by the appellants *inter alia* on the basis of the disclosure in the right-hand column of document (12) showing that **retinol, all-trans-retionol, vitamin A, vitamin A alcohol and axerophtol** are synonyms for one and the same chemical compound. The respondent replied that "vitamin A" is used in (10) as a pure generic term to include any conceivable retinoid compound and that there is certainly no specific reference in (10) to the use of vitamin A (vitamin A alcohol, retinol *per se*). Hence, with regard to the disclosure of "vitamin A" in the (10) the first question to be considered is whether the disclosure and use of "vitamin A" in citation (10) is to be considered as a generic term or whether it specifically only covers the substance vitamin A (retionol, all-trans-retionol, vitamin A alcohol, axerophtol), as appellant I asserts.

6.5.2 According to the established case law of the boards of appeal (see "Case Law of the Boards of Appeal of the European Patent Office", 4th Edition, 2001, I.C.2.1), in order to determine what has been made available to



the public, the disclosure and information content of a prior art document in its entirety has to be carefully considered for guidance as to what has really been taught in the prior document, i.e its real and implicit information content. In citation (10) the skilled reader is given the following information at lines 3 to 6 on page 8: *"As an example of the employed vitamin A, mention may be made of, for example, vitamin A palmitate, vitamin A acetate or the like, which may be any one commonly employed in this type of composition."*

- 6.5.3 In the board's opinion, the only sensible way of interpreting the above-mentioned information is that the use of the term "vitamin A" in citation (10) cannot be considered as a specific disclosure of the substance vitamin A (retinol, all-trans-retinol, vitamin A alcohol, axerophthol *per se*). Given the general rules of interpretation of the information content of a prior document mentioned above, the board has reached the conclusion that the claimed subject-matter in the third auxiliary request is also novel in relation to citation (10) because this request is limited to the use of vitamin A alcohol (retinol) as the sole option for the retinoid compound of the claimed composition and this particular retinoid compound is not specifically disclosed in (10).

*Inventive Step; Article 56 EPC*

- 6.6 There was general agreement that citation (10) represents the closest and therefore the most relevant state of the art. This citation relates to skin care compositions which contain certain retinoid compounds such as, for example, vitamin A acetate (retinyl

acetate) or vitamin A palmitate (retinyl palmitate) or the like and possess good chemical and physical stability (see 4.1 and 6.5 above). As explained in great detail in the foregoing points, there is no specific disclosure in (10) of the use of vitamin A alcohol (retinol). It is well-known to those skilled in the art that esters of retinol, for example retinyl acetate or retinyl palmitate, are chemically more stable than retinol itself. For example document (12), which is a standard textbook on vitamin formulations and therefore represents the common general knowledge in the field at the priority date of the patent, states in the right-hand column on page 95: "*Since retinol is even less stable than its esters, virtually only retinyl acetate, retinyl palmitate and retinyl propionate are used in pharmaceuticals*".

- 6.6.1 The problem underlying the third auxiliary request in respect of the closest state of the art according to (10) may thus be seen in providing a skin care composition which contains vitamin A alcohol (retinol) as the active ingredient and which is nevertheless chemically stable and capable of providing the active ingredient (retinol) after extended periods of storage. As explained in the patent description, retinol is a preferred form for use as the retinoid compound in skin care products, because retinol is an endogenous compound naturally occurring in the human body and essential for good growth, differentiation of epithelial tissues and reproduction. Retinol is also preferred because it has a much larger safety margin than other retinoids such as retinoic acid (see page 2, lines 38-40).

6.6.2 The solution proposed in the claim 1 of the third auxiliary request is a skin care composition comprising a water-in-oil emulsion and vitamin A alcohol (retinol) as the active ingredient and further comprising

- according to the first embodiment of the claimed invention, a stabilizing system consisting of a chelating agent and at least one oil-soluble antioxidant; with the proviso that the composition does not contain a water-soluble antioxidant; and
- according to the second embodiment of the claimed invention, a stabilizing system consisting of an antioxidant present in each of the water and the oil phases of said emulsion, with the proviso that the composition does not comprise a chelating agent.

6.6.3 As can be seen from the test results in Table 3 (Sample 1) on page 11 of the patent description a skin care composition in the accordance with the first embodiment of the claimed invention, comprising a water-in-oil emulsion and retinol and further comprising a stabilizing system containing a chelating agent (10Wt% of EDTA) and an oil-soluble antioxidant (0.05Wt% of BHT) but containing no water-soluble antioxidant [stabilizing system a)], retains greater than 90% of its original concentration of retinol after being aged for 13 weeks at room temperature (21°C). The same composition retains 89% of its original concentration of retinol after being aged for 13 weeks at 40°C and 83% of its original concentration of retinol after aging for 13 weeks at 50°C.

6.6.4 As can also be seen from the test results in Table 2 (Sample 2) on page 9 of the patent description, a

skin care composition in accordance with the second embodiment of the claimed invention, comprising a water-in-oil emulsion and retinol and further comprising a stabilizing system containing an oil-soluble antioxidant (0.05Wt% of BHT) and a water-soluble antioxidant (0.10Wt% of ascorbic acid) but containing no chelating agent [stabilising system b)], was found to retain 99% of its original concentration of retinol after one week's aging at 50°C and 90% after two weeks' aging at the same temperature.

6.6.5 On the basis of the compendious experimental results presented in the patent and referred to above, the board is satisfied that the claimed skin care compositions exhibit good long-term chemical stability of retinol and that the problem posed has accordingly been plausibly solved over the whole area claimed.

6.7 The question still remains whether or not an inventive step was necessary to arrive at the present invention when starting from the basis of the skin care compositions known from the nearest prior art according to (10). In the board's opinion, neither citation (10) nor any other prior art under Article 54(2) EPC available in the proceedings contains any teaching or hint or suggestion pointing those skilled in the art in the direction of solving the actual problem by the use of a water-in-oil emulsion comprising retinol in combination with a stabilizing system in accordance with either the first or the second embodiment of the claimed invention.

6.7.1 On the contrary, the method of preparing the skin care compositions exemplified in (10) would lead the skilled

person to the conclusion that oil-in-water emulsions are generally preferred over water-in-oil emulsions.

However, in the patent description it is clearly demonstrated (see Table 1 on pages 7-8, Sample B) that, contrary to what could be expected, a skin-care composition in the form of an oil-in-water emulsion comprising retinol and a stabilizing system entirely comparable to that used in Sample 1 in Table 3 on page 11 of the patent description (see 6.6.3 above) does not have acceptable chemical stability. More specifically, after thirteen weeks' aging at room temperature, 87% of the original amount of retinol was found in the emulsion. After thirteen weeks aging at 40°C, just four percent of the original amount of retinol was found in the emulsion. After thirteen weeks' aging at 50°C, no amount of a retinoid was detected in the oil-in-water emulsion. Such an emulsion is deemed in the patent not to have acceptable chemical stability. The improvement of the chemical stability of the water-in-oil emulsion referred to in the 6.6.3 over the corresponding oil-in-water emulsion is sufficiently great to be regarded as unexpected and cannot, in the board's opinion, solely be attributed to the use of an increased amount of the oil-soluble antioxidant (BHT) in the example discussed in 6.6.3 above.

6.7.2 Similarly, the skilled person could not have found in citation (10) or in any other prior art under Article 54(2) EPC available in the proceedings any indication about the possibility of solving the actual problem by the use of a water-in-oil emulsion comprising retinol in combination with the stabilizing

system in the accordance with the second embodiment of the claimed invention.

From the results in the Table 2 of (10) it can be seen that water-in-oil emulsions of retinol do not exhibit the required long-term stability of retinol when:

- (i) no chemical stabilizing system was employed (comparative Sample 3),
- (ii) only a chelating agent was employed (comparative Sample 1),
- (iii) only an oil-soluble antioxidant was employed (comparative Sample 4) or
- (iv) when only a water-soluble antioxidant was employed (comparative Sample 5).

In particular, in the view of the teachings of the prior art, a person skilled in the art could not expect the problem posed to be solvable when

- (v) both a water-soluble and an oil-soluble antioxidant were employed **without the necessity of adding a chelating agent** to the claimed compositions (see Sample 2).

6.8 The result arrived at if, as appellant I also suggested, (2) is taken as the closest state of the art instead of (10), and if the technical problem addressed by the present patent is taken as that of providing further or alternative compositions to those disclosed in (2) having about the same properties and capabilities as those described in (2), does not lead to a more favourable outcome for the appellants.

6.8.1 The appellant submitted that the solution to the problem defined in the 6.8 above was the replacement of vitamin E used as the oil-soluble antioxidant in (2)

with a different oil-soluble antioxidant, for example, BHT or BHA used in (10). It concluded therefrom that the proposed solution to the problem posed was obvious for a man skilled in the art from a combination of the teaching of citation (2) with that of citation (10).

6.8.2 However, the skilled reader of citation (2) would immediately recognise that vitamin E functions in the cited prior art of (2) as both, namely (a) as a physiologically active vitamin compound and (b) also as stabilizing agent for vitamin A (retinol). Thus, those skilled in the art would never have considered solving the problem posed by simply substituting BHT or BHA for vitamin E (tocopherol) since the former compounds act solely as stabilizing agents for vitamin A but do not exhibit any pharmacological or physiological activity exhibited by tocopherol and required to provide alternative compositions to those disclosed in (2) having about the same properties and capabilities in order to solve the problem mentioned in 6.8 above.

6.9 In view of the foregoing observations, the board considers that the claimed subject-matter in the third auxiliary request involves an inventive step, whether starting from citation (10) or citation (2) as the closest state of the art.

**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 with the order to grant a patent on the basis of claims 1 to 12, filed as third auxiliary request with letter dated 26 March 2002 and a description to be adapted.

The Registrar:

The Chairman:

A. Townend

J. Riolo