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**Datasheet for the decision  
of 7 November 2005**

**Case Number:** T 0892/01 - 3.3.02  
**Application Number:** 94102151.1  
**Publication Number:** 0599819  
**IPC:** A61K 47/00  
**Language of the proceedings:** EN

**Title of invention:**

Use of hydroxycarboxylic acids and derivatives for the preparation of topical dermatologic compositions for the treatment of wrinkles

**Patentee:**

Van Scott, Eugene J. Dr.

**Opponents:**

1. Beiersdorf AG
2. SmithKline Beecham plc
3. Clarins S.A.
4. The Procter & Gamble Company
5. Société anonyme dite: L'Oreal
6. Seidel, Silvana

**Headword:**

Treatment of wrinkles/VAN SCOTT, EUGENE J. Dr.

**Relevant legal provisions:**

EPC Art. 54, 56, 100(a), (b), (c), 102(1), (3), 106, 107, 108, 114(1), 123(2)  
EPC R. 64, 71(1)

**Keyword:**

"Main request; auxiliary requests 1-14, 16-20, 22, 24 - whether contrary to Article 123(2) EPC - (yes); auxiliary request 15 - novelty (no); auxiliary requests 21, 23, 25 - inventive step (no)"

**Decisions cited:**

T 0012/81, T 0020/81, T 0051/81, T 0201/83, T 0077/87,  
T 0331/87, T 0475/88, T 0591/90, T 0728/98

**Catchword:**

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Case Number: T 0892/01 - 3.3.02

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.02**  
**of 7 November 2005**

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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted 1 June 2001  
revoking European patent No. 0599819 pursuant  
to Article 102(1) EPC.**

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** G. Rampold  
P. Mühlens

## Summary of Facts and Submissions

I. This appeal is against a decision of the opposition division posted on 1 June 2001 to revoke European patent No. 0 599 819 ("the patent"), claiming priority from 23 December 1986 (US Serial No. 94 56 80) and entitled "Use of hydroxycarboxylic acids and derivatives for the preparation of topical dermatologic compositions for the treatment of wrinkles". The patent was granted to the appellants with effect from 2 April 1997 on the basis of European patent application No. 94 102 151.1, which was filed as a divisional application to European patent application No. 87 117 405.8 on which European patent No. 0 273 202 has been granted.

II. The **divisional application as filed** contained 9 claims, the sole independent claim reading as follows:

"1. Use of at least one member selected from hydroxycarboxylic acids and ketocarboxylic acids, and ester, lactone, and salt forms thereof, for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles."

Dependent claims 2 to 9 related to specific embodiments of the use according to claim 1.

III. The **patent as granted** contained 36 claims *inter alia* relating to:

"1. Use of at least one member selected from hydroxycarboxylic acids and ketocarboxylic acids,

and ester, lactone, and salt forms thereof, for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles.

9. Use according to any of claims 1 to 8 wherein at least one member selected from hydroxycarboxylic acids and ketocarboxylic acids, and ester, lactone, and salt forms thereof is used in an amount of from 10 to 20%.
10. Use according to any of claims 1 to 9 wherein the wrinkles to be treated are human facial wrinkles.
19. Use of a topical composition containing at least one member selected from hydroxycarboxylic acids and ketocarboxylic acids, and ester, lactone and salt forms thereof, for the treatment of wrinkles.
27. Use of the topical composition of any of claims 19 to 26, wherein at least one member selected from hydroxycarboxylic acids and ketocarboxylic acids, and ester, lactone, and salt forms thereof is used in the composition in an amount of from 10 to 20%.
28. Use of the topical composition as claimed in any of claims 19 to 27 wherein the wrinkles to be treated are human facial wrinkles."

IV. Oppositions to the grant of the patent were independently filed by six parties. The opponents (respondents) are referred to in the decision under appeal and in the present decision in the following order:

- **opponent 1** (Beiersdorf Aktiengesellschaft; **respondent 1**) filed opposition by fax on 16 June 1997;
- **opponent 2** (SmithKline Beecham plc; **respondent 2**) filed opposition by fax on 23 December 1997,
- **opponent 3** (Clarins S.A.; **respondent 3**) filed opposition by fax on 30 December 1997;
- **opponent 4** (The Procter and Gamble Company; **respondent 4**) filed opposition by fax on 31 December 1997;
- **opponent 5** (Société L'OREAL; **respondent 5**) filed opposition by letter of 31 December 1997, received by the EPO on 7 January 1998;
- **opponent 6** (Silvana Seidel; **respondent 6**) filed opposition on 30 December 1997 with letter of the same date.

V. Of the numerous documents cited in the opposition and subsequent appeal proceedings, the following remain relevant to the present decision:

- (1a) "Aromathérapie: Traitement des maladies par les essences des plantes", Docteur Jean Valnet, Librairie Maloine S.A. - Editeur 1976, pages 168-175;
- (1b), (18a) GB-A-1 234 297;
- (2) English translation of Japanese Laid-Open Patent Application No. 61-180705;
- (2a) Webster's Third International Dictionary of the English language unabridged, London, G. Bell & Sons, LTD.; entry "smooth";
- (3) Eugene J. Van Scott et al, Hyperkeratinization, corneocyte cohesion,

- and alpha hydroxy acids, J. of the American Academy of Dermatology, Vol. 11, No. 5, Part I, November 1984, pages 867-879
- (4) English translation of parts of Japanese Laid-Open Patent Application No. 40632/80
  - (6) J. Zizmor et al, "Younger Skin, how to get it, how to keep it", Holt, Rinehart and Winston/ New York, 1983, pages 39-53, 96, 97
  - (10) US-A-4 608 370
  - (14) US-A-4 603 146
  - (53) FR-A- 2 204 396
- Annex 1 Memorandum Order of the United States District Court for the District of Delaware dated 27 July 1999 in the consolidated cases Tristrata Technology, Inc. v. Neoteric Cosmetic Inc., et al. and Tristrata Technology, Inc. v. Beiersdorf Inc., and Leiner Health Products, Inc.

VI. The opponents requested revocation of the patent in part or in toto, invoking the following grounds:

- (i) lack of novelty (Articles 100(a) and 54 EPC);
- (ii) lack of inventive step (Articles 100(a) and 56 EPC);
- (iii) insufficient disclosure (Articles 100(b) and 83 EPC); and also
- (iv) added subject-matter (Articles 100(c) and 123(2) EPC).

VII. In the proceedings before the opposition division, the patent proprietors (appellants) requested in their main request that the oppositions be rejected and that the patent be maintained as granted. In the alternative they requested that the patent be maintained in amended



form on the basis of one of the auxiliary requests 1 to 6, filed with their letter of 5 December 2000, or their seventh auxiliary request filed during the oral proceedings of 5 February 2001.

VIII. The essence of the reasoning in the opposition division's decision to revoke the patent was as follows:

(i) As regards the parties' oppositions on the grounds of added subject-matter, the opposition division considered that claim 10, added to the patent during examination proceedings and relating to the use of the topical composition of claim 1 in the therapeutic treatment of human "*facial wrinkles*" (see III above), and likewise claim 28, relating to the use of the topical composition claimed in claim 19 for the general treatment of human "*facial wrinkles*" (see III above), were not adequately supported by the disclosure of the application as filed and were thus contestable under Articles 100(c) and 123(2) EPC. The opposition division also considered that claims 9 and 26 of the first auxiliary request and claims 9 and 25 of the fourth auxiliary request were contestable under Article 123(2) EPC since these claims were introduced *post grant* and likewise related to the therapeutic or general treatment of human "*facial wrinkles*".

The opposition division thus reached the conclusion that the claims in the main request and the first and fourth auxiliary requests contravened the above-mentioned provisions of the EPC and that these requests were accordingly not acceptable.

**(ii)** Concerning the objections under Articles 100(a) and 52(4) EPC to claims 19 to 36 as granted (see III above) the opposition division considered that the disclosure at page 13, lines 13-17, of the application as originally filed, relating to "*the use of hydroxyacids and related compounds as the sole active principle in the prophylactic and therapeutic treatment of cosmetic conditions or dermatologic disorders*", provided adequate support **(a)** for claims 1 to 18 in the "second-medical use format" concerning the use of hydroxycarboxylic acids and related compounds in the therapeutic treatment of wrinkles (see III above) and **(b)** at the same time for claims 19 to 36 relating to the use of compounds for the treatment of wrinkles in general (see III above).

**(iii)** As regards novelty, the opposition division found that both citation (10) and citation (22) anticipated the therapeutic use of hydroxycarboxylic acids in the treatment of wrinkles. On this basis the second, third, fifth and sixth auxiliary requests were refused.

**(iv)** As to the remaining seventh auxiliary request, the opposition division considered that

- (a)** the limitation of claim 1 to the therapeutic use of certain specific hydroxycarboxylic acids and related compounds - selected from those mentioned in dependent claims 4, 6, and 7, and from the huge list in dependent claim 8 as granted and not disclosed in citations (10) or (22) - for the treatment of wrinkles, and
- (b)** a similar limitation of independent claim 2 to the use of a topical composition

containing certain specific hydroxycarboxylic acids and related compounds - selected from those mentioned in dependent claims 20, 22, 24 and 25, and from the huge list in dependent claim 26 as granted - for the treatment of wrinkles in general, conferred novelty on the claimed subject-matter in the patent. It found, however, that in the light of the cited state of the art a skilled person would have reasonably expected hydroxycarboxylic acids in general, including those mentioned in the seventh auxiliary request, to exhibit the same or similar beneficial effects in the treatment of wrinkles, and refused this last request for lack of inventive step.

IX. On 2 August 2001, the appellants lodged an appeal against the decision of the department of first instance and paid the corresponding fee. The statement of grounds of appeal, including auxiliary requests 1 to 15, was filed on 11 October 2001.

X. In advance of the oral proceedings, scheduled to take place on 7 November 2005, the appellants submitted on 7 October 2005 further observations and filed twelve amended sets of claims forming their new main request and auxiliary requests 1 to 11 to replace all previously filed requests.

(a) The **main request** contains 36 claims; claims 1 to 18 are identical to claims 1 to 18 as granted (see III above); claims 19 and 27 and 28 are worded as follows:

19. "Use of a topical cosmetic composition containing an amount effective for the treatment of cosmetic skin conditions of at least one member selected from hydroxycarboxylic acids and ketocarboxylic acids, and ester, lactone, and salt forms thereof, for the treatment of wrinkles.

27. Use of the topical composition of claim 19, wherein at least one member selected from hydroxycarboxylic acids is used in the composition in an amount of from 10 to 20%.

28. Use of the topical composition as claimed in any of claims 19 to 27, wherein the wrinkles to be treated are human facial wrinkles."

**(b)** The **first auxiliary request** consists of 34 claims; independent claim 1 and dependent claim 9 correspond to claims 1 and 9 in the above main request;

independent claim 18 corresponds to claim 19 and dependent claim 26 to claim 27 in the above main request; dependent claims 10 and 28 of the main request have been deleted; the other dependent claims correspond to those in the above main request and are appropriately renumbered.

**(c)** The **second auxiliary request** consists also of 34 claims; independent claim 1 corresponds to claim 1 and dependent claim 9 to dependent claim 10 in the above main request; independent claim 18 corresponds to claim 19 and dependent claim 26 to

claim 28 in the above main request; dependent claims 9 and 27 of the main request have been deleted; the other dependent claims correspond to those in the above main request and are appropriately renumbered.

(d) The **third auxiliary request** consists of 32 claims; independent claim 1 corresponds to claim 1 and independent claim 17 to claim 19 in the above main request; dependent claims 9, 10 and 27 and 28 of the main request have been deleted; the other dependent claims correspond to those in the above main request and are appropriately renumbered.

(e) The **fourth auxiliary request** consists of 14 claims; claims 1, 2, 5, 8, 9 and 12 read as follows:

- "1. Use of a therapeutically effective amount of from 10% to 20% of at least one member selected from hydroxycarboxylic acids for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles.
2. Use of a therapeutically effective amount for the treatment of wrinkles of at least one member selected from 2-hydroxyacetic acid; phenyl 2-hydroxyacetic acid; diphenyl 2-hydroxyacetic acid; 2-methyl-2-hydroxypropanoic acid and ester and salt forms thereof; and hydroxycarboxylic acid lactones, for the preparation of a topical dermatologic

therapeutic composition for use in the treatment of wrinkles.

5. Use according to any of claims 2 to 4, wherein the wrinkles to be treated are human facial wrinkles.
  8. Use of a topical cosmetic composition for the treatment of wrinkles, said composition containing an amount of 10% to 20% of at least one member of hydroxycarboxylic acids effective for the treatment of cosmetic skin conditions.
  9. Use of a topical cosmetic composition containing an amount effective for the treatment of cosmetic skin conditions of at least one member selected from 2-hydroxyacetic acid; phenyl 2-hydroxyacetic acid; diphenyl 2-hydroxyacetic acid; 2-methyl-2-hydroxypropanoic acid and ester and salt forms thereof; and hydroxycarboxylic acid lactones for the treatment of wrinkles."
  12. Use of the topical composition as claimed in any of claims 9 to 11, wherein the wrinkles to be treated are human facial wrinkles."
- (f) The **fifth auxiliary request** consists of 12 claims; independent claims 1 and 2 correspond to claims 1 and 2, and independent claims 7 and 8 to claims 8 and 9 of the above fourth auxiliary request; dependent claims 5 and 12 of the fourth auxiliary request have been deleted; the other dependent

claims correspond to those in the above fourth auxiliary request and are appropriately renumbered.

(g) The **sixth auxiliary request** consists of 13 claims; claims 1, 2, 5, 8 and 11 read as follows:

- "1. Use of a therapeutically effective amount of from 10% to 20% of at least one member selected from hydroxycarboxylic acids for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles.
2. Use of a therapeutically effective amount for the treatment of wrinkles of at least one member selected from 2-hydroxyacetic acid; phenyl 2-hydroxyacetic acid; diphenyl 2-hydroxyacetic acid; 2-methyl-2-hydroxypropanoic acid and ester and salt forms thereof; and hydroxycarboxylic acid lactones, for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles.
5. Use according to any of claims 2 to 4, wherein the wrinkles to be treated are human facial wrinkles.
8. Use of a topical cosmetic composition containing an amount effective for the treatment of cosmetic skin conditions of at least one member selected from 2-hydroxyacetic acid; phenyl 2-hydroxyacetic acid; diphenyl 2-

hydroxyacetic acid; 2-methyl-2-hydroxypropanoic acid and ester and salt forms thereof; and hydroxycarboxylic acid lactones for the treatment of wrinkles.

11. Use of the topical composition as claimed in any of claims 8 to 10, wherein the wrinkles to be treated are human facial wrinkles."

(h) The **seventh auxiliary request** consists of 11 claims; claims 1, 2, and 7 are worded as follows:

- "1. Use of a therapeutically effective amount of from 10% to 20% of at least one member selected from hydroxycarboxylic acids for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles.
2. Use of a therapeutically effective amount for the treatment of wrinkles of at least one member selected from 2-hydroxyacetic acid; phenyl 2-hydroxyacetic acid; diphenyl 2-hydroxyacetic acid; 2-methyl-2-hydroxypropanoic acid and ester and salt forms thereof; and hydroxycarboxylic acid lactones, for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles.
7. Use of a topical cosmetic composition containing an amount effective for the treatment of cosmetic skin conditions of at least one member selected from 2-hydroxyacetic



acid; phenyl 2-hydroxyacetic acid; diphenyl 2-hydroxyacetic acid; 2-methyl-2-hydroxypropanoic acid and ester and salt forms thereof; and hydroxycarboxylic acid lactones for the treatment of wrinkles."

(i) The **eighth auxiliary request** consists of 12 claims; claims 1, 4, 7 and 10 are worded as follows:

- "1. Use of a therapeutically effective amount for the treatment of wrinkles of at least one member selected from 2-hydroxyacetic acid; phenyl 2-hydroxyacetic acid; diphenyl 2-hydroxyacetic acid; 2-methyl-2-hydroxypropanoic acid and ester and salt forms thereof; and hydroxycarboxylic acid lactones, for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles.
4. Use according to any of claims 1 to 3, wherein the wrinkles to be treated are human facial wrinkles.
7. Use of a topical cosmetic composition containing an amount effective for the treatment of cosmetic skin conditions of at least one member selected from 2-hydroxyacetic acid; phenyl 2-hydroxyacetic acid; diphenyl 2-hydroxyacetic acid; 2-methyl-2-hydroxypropanoic acid and ester and salt forms thereof; and hydroxycarboxylic acid lactones for the treatment of wrinkles.

10. Use of the topical composition as claimed in any of claims 7 to 9, wherein the wrinkles to be treated are human facial wrinkles".

(j) The **ninth auxiliary request** consists of 10 claims; independent claims 1 and 6 correspond to independent claims 1 and 7 in the above eighth auxiliary request; dependent claims 4 and 10 of the eighth auxiliary request have been deleted; the other dependent claims correspond to those in the above eighth auxiliary request and are appropriately renumbered.

(k) The **tenth auxiliary request** contains claims 1 to 12; claims 1, 4, 7 and 10 are worded as follows:

"1. Use of a therapeutically effective amount for the treatment of wrinkles of at least one member selected from hydroxycarboxylic acid lactones for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles.

4. Use according to any of claims 1 to 3, wherein the wrinkles to be treated are human facial wrinkles.

7. Use of a topical cosmetic composition containing an amount effective for the treatment of cosmetic skin conditions of at least one member selected from hydroxycarboxylic acid lactones for the treatment of wrinkles.

10. Use of the topical composition as claimed in any of claims 7 to 9, wherein the wrinkles to be treated are human facial wrinkles."

(1) The **eleventh auxiliary request** consists of claims 1 to 10; independent claims 1 and 6 are identical to independent claims 1 and 7 of the above tenth auxiliary request; dependent claims 4 and 10 of the tenth auxiliary request have been deleted; the other dependent claims correspond to those in the above tenth auxiliary request and are appropriately renumbered.

XI. In their written replies to the statement setting out the grounds of appeal and to the appellants' further submissions, respondents 1, 2, 4 and 5 defended their interests by filing observations on a number of occasions.

XII. The appellants and respondents 1, 4 and 5 were represented at the oral proceedings before the board of appeal. By letter dated 17 October 2005 respondent 2 had informed the EPO that it would not be present or represented at the hearing. Although duly summoned pursuant to Rule 71(1) EPC, nobody was present on behalf of respondents 3 and 6.

XIII. The respondents' written and oral submissions gave rise to detailed discussion during oral proceedings of whether all independent claims in the main request and in the auxiliary requests 1 to 11, which were on file at the beginning of the hearing (see X above), did not contravene Article 123(2) EPC. In reply to certain

observations of the board and the respondents' submissions concerning the alleged non-compliance of certain claims with Article 123(2) EPC, the appellants announced their intention to file further requests and requested a short break in which to formulate and submit them. After the break the appellants presented the following additional auxiliary requests:

- (m) The **12th auxiliary request** consists of claims 1 to 18 of the above main request - see X(a);
- (n) The **13th auxiliary request** consists of claims 1 to 17 of the above first auxiliary request - see X(b);
- (o) The **14th auxiliary request** consists of claims 1 to 17 of the above second auxiliary request - see X(c);
- (p) The **15th auxiliary request** consists of claims 1 to 16 of the above third auxiliary request - see X(d);
- (q) The **16th auxiliary request** consists of claims 1 to 17 of the above fourth auxiliary request - see X(e);
- (r) The **17th auxiliary request** consists of claims 1 to 6 of the above fifth auxiliary request -see X(f);
- (s) The **18th auxiliary request** consists of claims 1 to 7 of the above sixth auxiliary request - see X(g);
- (t) The **19th auxiliary request** consists of claims 1 to 6 of the above seventh auxiliary request - see X(h);
- (u) The **20th auxiliary request** consists of claims 1 to 6 of the above eighth auxiliary request - see X(i);
- (v) The **21st auxiliary request** consists of claims 1 to 5 of the above ninth auxiliary request - see X(j);

- (w) The **22nd auxiliary request** consists of claims 1 to 6 of the above tenth auxiliary request - see X(k);
- (x) The **23rd auxiliary request** consists of claims 1 to 5 of the above eleventh auxiliary request - see X(1).

XIV. At a later stage in the oral proceedings the appellants submitted two further auxiliary requests:

- (y) The **24th auxiliary request** consists of claims 1 to 18 which are identical to the above third auxiliary request IX(d), with the sole exception that in all claims the reference to ester forms of the hydroxycarboxylic acids and ketocarboxylic acids, that is, wherever it exists and whatever its context, has been deleted.

- (z) The **25th auxiliary request** consists of one single claim reading as follows:

"1. Use of a therapeutically effective amount for the treatment of wrinkles of at least one member selected from 2-hydroxyacetic acid; phenyl 2-hydroxyacetic acid; diphenyl 2-hydroxyacetic acid; 2-methyl-2-hydroxypropanoic acid and salt forms thereof for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles."

XV. The appellants' submissions presented in the written appeal proceedings and at the hearing before the board, insofar as they remain relevant to the present decision, may be summarised as follows:

[1] As far as the respondents' objections under Articles 100(c) and 123(2) EPC were concerned, the appellants considered that the requirements of the EPC referred to above were met because the subject-matter of all claims as amended either during examination proceedings or *post grant* was, in the appellants' judgment, directly and unambiguously derivable from the application as originally filed.

[2] As regards claim 19 of the main request (see III and X above) and, similarly, the corresponding claims in the auxiliary requests relating to cosmetic treatment of wrinkles (see X above), the appellants argued that these claims had adequate support in the disclosure on page 10, lines 10 to 13 of the application as published (corresponding to claim 36 of the application as filed) in conjunction with the disclosure on page 13, lines 13-18 of the application as filed (page 6, lines 16 and 17 of the application as published - see: "*hydroxyacids and related compounds may also be used alone in the prophylactic and therapeutic treatment of cosmetic conditions or dermatologic disorders . . . . .*").

[3] The appellants further argued that claim 32 of the application as filed disclosed the use of "a therapeutically effective amount" of hydroxycarboxylic acids and related compounds in the treatment of wrinkles. For the appellants, this led to the conclusion that, since the cosmetic composition used in claim 19 *per se* could not contain a "therapeutically effective" amount, such a composition had nevertheless to contain an "effective" amount as shown on page 20, lines 57 and 58 of the application as filed. In the

appellants' opinion, claims containing the feature "in an amount effective for the treatment of cosmetic skin conditions" had, accordingly, a proper basis in the originally filed documents.

**[4]** The appellants admitted that the term "human facial wrinkles" used in claims 10 and 28 of the main request (see III and X above) and in corresponding claims of certain auxiliary requests (see X above) was not literally disclosed in the application as filed. They argued, however, that **(i)** the topical application of hydroxycarboxylic acids and related compounds to the scalp or the face was disclosed in the application as filed in connection with the treatment, for example, of dandruff, oily skin and acne (see page 28, penultimate paragraph of the application as filed; page 17, lines 1-4 of the application as published) and that **(ii)** the treatment of wrinkles was likewise disclosed (see page 35, lines 15-32 of the application as filed; page 20, lines 42-49 of the application as published). The appellants thus concluded that the use of hydroxycarboxylic acids and related compounds for the treatment of human facial wrinkles was directly derivable from the originally filed documents.

**[5]** As to the concentration range of the hydroxycarboxylic acids, as claimed in claims 9 and 27 of the main request (see III and X above) and in corresponding claims of certain auxiliary requests (see X above), the appellants argued that the compositions containing hydroxycarboxylic acids without hydroquinone, referred to on page 36, lines 9-10 of the application as filed (page 20, lines 57 and 58 of the application as published), had to be directly compared

with the compositions which were described in the preceding paragraph on the same page as containing 10 to 20% of the hydroxycarboxylic acids and 3 to 5% of hydroquinone as the active ingredients for eradicating age spots, wrinkles and keratoses. It was thus clear to the appellants that the application documents as originally filed explicitly recommended the use of hydroxycarboxylic acids in an amount of 10 to 20% for the treatment of wrinkles.

**[6]** As regards the novelty of the claims relating to the use of hydroxycarboxylic acids and related compounds in the therapeutic or cosmetic treatment of wrinkles, the appellants alleged that the term "wrinkles" used in the patent had a specific but well-recognised meaning in the field of dermatology. To illustrate this they essentially invoked the content of patent specification (14). The patentee and inventor of (14), who was said by the appellants to be a highly specialised and outstanding scientist in the field of dermatology, explained in (14) the underlying causes of the alterations in aged skin leading to certain specific changes (wrinkling, yellowing, leatheriness, loss of elasticity) in the epidermis, on the one hand, and the dermis, on the other. As far as the common general knowledge about the formation, nature and treatment of skin wrinkles was concerned, the appellants argued that the technical teaching and information provided in document (14), although the latter was a patent specification, could justifiably be considered to represent textbook knowledge in the field of dermatology. In the appellants' opinion, it was thus entirely clear that those skilled in the art, in the light of their general technical knowledge, associated



the term "wrinkles" used in the patent with abnormal changes in the dermis and not in the epidermis. It followed that, in the light of common general knowledge and the prior art of (14), a treatment which had an effect only on the epidermis, would not be considered to be a treatment of wrinkles, as claimed in the patent, because the term "wrinkles", properly construed, defined ridges or furrows in the skin associated with degenerative changes in the dermis.

[7] The correctness of the above interpretation of the term "wrinkles" in the field of dermatology was confirmed, in the appellants' opinion, by the construction of the disputed claim language presented in Annex 1, which was a Memorandum Order of the United States District Court for the District of Delaware and was concerned with the correct construction of the term "wrinkles" as used in a series of US patent family members related to the present European patent.

[8] It was recalled by the appellants that the teaching of the patent was addressed to a person skilled in the art, who was a dermatologist in the present case. According to the appellants, lay consumers did not necessarily understand the term "wrinkles" in the sense outlined above. The lay public regularly confused the dermatologic condition "wrinkles" or "skin wrinkles" with other skin conditions, such as dry skin, lump "wrinkles, "fine lines", ridges and furrows caused by dermal degeneration and other superficial/epidermal irregularities (dryness, cracking, irregular exfoliation, etc.). The discrepancy between the lay public's understanding of the term "wrinkles" and the understanding of this term by the dermatologist led to

the unacceptable consequence that publications intended for consumers frequently used the term "wrinkles" to refer to superficial/epidermal "dry lines" or ridges, whereas publications intended for dermatologists correctly used that term to refer only to ridges or furrows in the skin associated with degenerative changes in the dermis. The appellants argued that the correct construction of the term "wrinkles", as used in the field of dermatology, was crucial to the assessment of novelty and inventive step in the present case.

[9] On the basis of the considerations in the foregoing points, the appellants contended that the claimed use of the topical dermatologic therapeutic or cosmetic composition was novel over the available state of the art. They stated that citation (10), which was cited by the respondents amongst a series of other prior art documents against the novelty of the claimed subject-matter in the patent, disclosed, in contrast to the topical therapeutic or cosmetic composition used in the patent, a composition containing four essential components, namely salicylic acid, resorcinol, lactic acid and ethyl alcohol. These four components acted synergistically to dry up the skin in the epidermis, causing the dead skin to peel off within a relatively short period of time, with the resulting skin exhibiting a fresh and youthful glow. The appellants admitted that citation (10) also ascribed to the composition disclosed in (10) in general terms a smoothing effect on facial lines and wrinkles, but went on to maintain that the application of the composition used in (10) to the skin caused certain changes and effects only in the epidermis and that (10) accordingly

did not teach a treatment of "wrinkles" in line with the proper construction of this term as outlined above.

**[10]** The appellants further argued that citation (10) disclosed for lactic acid contained in the composition of (10) only antiseptic properties. Their conclusion was that lactic acid could thus not be a therapeutic component of said composition.

**[11]** The appellants were also of the opinion that citation (10) was silent about the use of a therapeutic or cosmetic composition containing a hydroxycarboxylic acid and, in particular, lactic acid in an amount effective for the treatment of wrinkles. In conclusion, novelty of the claimed use in the patent over the prior art of (10) was in the appellants' opinion not in question.

**[12]** As regards inventive step in respect of the claims limited to the use of certain selected specific hydroxycarboxylic acids or hydroxycarboxylic acid lactones, the appellants submitted that the state of the art neither disclosed nor in any way suggested the use of such specific hydroxycarboxylic acids or hydroxycarboxylic acid lactones for the treatment of wrinkles. They also submitted that the use of lactones offered the additional advantages that they caused, if at all, only minimal irritation of the skin owing to their reduced penetration into the skin, formed a barrier against chemical irritants and did not cause increased sun sensitivity of the skin.

XVI. The respondents disagreed with the appellants' line of argument and submitted arguments in support of their

disagreement. These arguments, insofar as they remain relevant to the present decision, are summarised below:

**[13]** The respondents argued that the appellants had not succeeded in providing an appropriate basis in the application as filed for claims comprising a combination of the following features:

- (i)** use of a topical cosmetic composition,
- (ii)** containing an amount effective for the treatment of cosmetic skin conditions of at least one member selected from hydroxycarboxylic acids and related compounds,
- (iii)** especially for the treatment of wrinkles.

They concluded that such claims were not directly and unambiguously derivable from the application as filed and contravened Article 100(c) EPC and/or Article 123(2) EPC.

**[14]** The respondents further submitted that the use of a composition, containing at least one member selected from the group hydroxycarboxylic acids and related compounds, for the treatment of "human facial wrinkles" was neither implicitly nor explicitly disclosed in the application as filed. The claims in the main request and certain auxiliary requests relating to the therapeutic or cosmetic treatment of "human facial wrinkles" using said composition therefore extended beyond the content of the application as filed and were thus contestable under Article 100(c) EPC and/or Article 123(2) EPC.

[15] The respondents observed that therapeutic compositions containing higher concentrations of hydroxycarboxylic acids (10 to 20%) were originally only disclosed in relation to therapeutic compositions containing these higher concentrations of hydroxycarboxylic acids in combination with hydroquinone (3 to 5%). Such compositions were judged to be more efficient in eradicating age spots, wrinkles and keratoses within shorter periods of time (see page 36, lines 2-6 of the application as filed; page 20, lines 53-55 of the application as published).

They observed further that the skilled person would have learned from the disclosure at lines 9-13 on page 36 of the application as filed that compositions containing hydroxyacids without hydroquinone were effective for eradication of keratoses and wrinkles, but **not** efficient in eradicating **age spots**, melasmas and lentiginosities, even within 4 months. Thus, the skilled person had, in the respondents' opinion, no sound reason to assume that the compositions without hydroquinone contained the higher concentrations (10 to 20%) of hydroxy acids used to prepare the compositions with hydroquinone which were also efficient in eradicating **age spots**, wrinkles and keratoses within shorter periods of time. The respondents thus concluded that the claimed use of therapeutic or cosmetic compositions containing higher concentrations (10 to 20%) of hydroxy acids in the absence of hydroquinone for the treatment of wrinkles was not directly and unambiguously derivable from the originally filed documents, as would be required for compliance with Article 123(2) EPC, and that claims relating to such use were accordingly not acceptable.

[16] The respondents noted that the patent neither defined the term "wrinkles" nor described or explained the nature of "wrinkles" intended to be treated according to the claimed invention. Consequently, the term "wrinkles" used in the patent had to be interpreted in its broadest way and covered accordingly wrinkles of any kind, for example, wrinkles in the dermis **and** fine wrinkles, superficial/epidermal wrinkles, "dry lines" and furrows or ridges in the skin.

[17] In support of their objection of lack of novelty and inventiveness the respondents asserted that in accordance with standard EPO practice general common knowledge cannot be demonstrated by a statement in a single patent specification. Accordingly, the attempt by the appellants to overcome the objection by invoking general common knowledge based solely on the statements in the patent specification (14) to give the term "wrinkles" a specific meaning, such as ridges or furrows in the skin associated with degenerative changes only in the dermis, could not succeed.

[18] Citation (10) disclosed, in the respondents' opinion, all features of the claimed therapeutic use of 2-hydroxycarboxylic acids and related compounds for the treatment of wrinkles and was, amongst a series of other documents in the proceedings, for example citations (1a) and (1b), prejudicial to the novelty of the claimed subject-matter in the patent.

[19] The respondents maintained that the limitation of certain claims to the use of certain selected specific

hydroxycarboxylic acids or hydroxycarboxylic acid lactones represented an arbitrary selection from the broad range of options for hydroxycarboxylic acids and related compounds envisaged in the patent and was, therefore, not inventive. As far as the additional advantages allegedly associated with the use of hydroxycarboxylic acid lactones was concerned, the respondents argued that these advantages were neither disclosed in the patent nor adequately demonstrated by experimental evidence and could therefore not serve to indicate an inventive step.

XVII. The appellants requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or on the basis of one of the auxiliary requests 1 to 11, all filed with letter dated 7 October 2005, or on the basis of one of the auxiliary requests 12 to 25 filed in the oral proceedings.

The respondents requested that the appeal be dismissed.

### **Reasons for the decision**

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.
2. *Admissibility of late-filed evidence (citations (1a), (1b) and Annex 1)*
  - 2.1 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. 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 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). 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, as appropriate, to reply with evidence of their own.

- 2.2 The board having studied citations (1a) and (1b)=(18a) reached the conclusion that the content of both these documents was sufficiently relevant to justify their introduction into the proceedings. That said, citation (1a) was submitted by respondent 5 on 27 September 2005 with letter of 23 September 2005 and citation (1b) by respondent 1 by facsimile dated 19 October 2005 and received by the Office on 21 October 2005; that is, almost four years after the statement of grounds of appeal had been filed. The board does not condone such lateness *per se*. However, the technical teaching of both citations was immediately and readily understandable to the skilled person and the appellants had in advance of the oral proceedings nearly three weeks in which to consider and prepare arguments in reply to the late evidence. Thus, in the circumstances of this case the board decided to admit citations (1a) and (1b) into the proceedings.



2.3 Annexes 1 to 4 were submitted by the appellants one month before the date of the oral proceedings, with their letter of 7 October 2005. Reference was made by the appellants during the hearing before the board only to Annex 1 in order to provide additional support for their position on the construction of disputed claim language as already presented in the proceedings before the department of first instance and in their statement setting out the grounds of appeal. The board therefore considers that Annex 1 should be admitted into the proceedings and exercises its discretion in favour of the appellants.

3. *Admissibility of late-filed requests*

3.1 The board considers that auxiliary requests (12) to (23) (see XIII above) and also auxiliary requests (24) and (25) (see XIV above) should be admitted into the proceedings, although all these auxiliary requests were filed at the latest possible moment in the appeal proceedings, namely during the hearing before the board.

3.2 As regards of the first of the above-mentioned auxiliary requests (12) to (23), these can fairly be said to have been occasioned by the board's reservations and the respondents' objections under Article 123(2) EPC, raised in their written submissions and at the hearing against the claims relating to the use of topical cosmetic compositions containing hydroxycarboxylic acids and related compounds for the cosmetic treatment of wrinkles. It was immediately clear to the skilled reader that all the auxiliary requests (12) to (23) merely differ from the corresponding requests filed on 7 October 2005 (see X

above) in the deletion of all independent and dependent claims relating to the use of hydroxycarboxylic acids and related compounds in the cosmetic treatment of wrinkles (see XIII above).

3.3 As regards auxiliary requests (24) and (25), the appellants' assertion that these constituted responses to the admission of citations (1a) and (1b) into the proceedings appears *prima facie* correct. Coupled with the fact that the respondents themselves to a large extent prompted the introduction of auxiliary requests (24) and (25) at such a late stage by their own late submission of the cited documents (see 2.2 above), the board exercises its discretion in favour of the appellants.

4. *Main request; auxiliary requests 1-14, 16-20, 22, 24; amendments (Article 123(2) EPC)*

4.1 Article 123(2) EPC, which governs amendments to European patent applications and European patents, specifies that: "A European patent application or a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed". The underlying idea of this sub-article 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 certainty due to third parties relying on the content of the original application.

4.1.1 In accordance with the established jurisprudence of the EPO boards of appeal, the decision on the compliance of amendments with Article 123(2) EPC calls for an inquiry into whether or not the application as originally filed contains sufficient information to enable the person skilled in the art to derive the proposed amendments from it **directly and unambiguously**, including any features implicit therein (see e.g. T 201/83, OJ EPO, 1984, 481; T 331/87, OJ EPO, 1991, 22; T 728/98, OJ EPO, 2001, 319; and, in general, "Case Law of the Boards of Appeal of the EPO", 4th ed. 2001, pages 197 ff).

4.1.2 Pursuant to Article 123(2) EPC the original disclosure, i.e. in the present case the content of European parent application No. 87 117 405.8, filed on 25 November 1987, determines the reservoir of possible amendments. To remove any doubts, the board takes the opportunity of repeating that any reference in this decision to the "application as filed" is to the above-mentioned European parent application No. 87 117 405.8 as filed and any reference to the application as published (references used by the appellants in their submissions) is to the present divisional application as published, i.e. EP-A-0 599 819 A2, published on 1 June 1994.

4.2 As is apparent from paragraphs X and XIV above, the main request (see claim 19); and auxiliary request 1 (see claim 18); auxiliary request 2 (see claim 18); auxiliary request 3 (see claim 17); auxiliary request 4 (see claim 9); auxiliary request 5 (see claim 8); auxiliary request 6 (see claim 8); auxiliary request 7 (see claim 7);

auxiliary request 8 (see claim 7);  
auxiliary request 9 (see claim 6);  
auxiliary request 10 (see claim 7);  
auxiliary request 11 (see claim 6);  
auxiliary request 24 (see claim 17);  
contain one independent claim including at least a  
combination of the following technical features in  
common (highlighted, lettering added by the board):

- (a) Use of a topical cosmetic composition**
- (b) containing an amount effective for the treatment of cosmetic skin conditions** <of at least one member selected from hydroxycarboxylic acids and ketocarboxylic acids and ester, lactone and salt forms thereof or related compounds; or selected from certain specific hydroxycarboxylic acids recited in the respective claims>
- (c) for the cosmetic treatment of wrinkles.**

4.2.1 The appellants argued in writing and at the hearing that claims in the patent relating to the use of a topical cosmetic composition, containing at least one member selected from hydroxycarboxylic acids or related compounds as an active ingredient in an amount effective for the treatment of cosmetic skin conditions, more specifically for the treatment of wrinkles, have a basis in claim 32 in combination with in the disclosure at lines 13-17 on page 13 of the application as filed. These disclosures in the application as filed, presented by the appellants in support of such claims, read as follows:

*"Hydroxyacids and related compounds may also be used alone in the prophylactic and therapeutic treatment of*

*cosmetic conditions or dermatologic disorders characterized by disturbed keratinization, aging, lipid metabolism or inflammation. The representative hydroxyacids are listed below:" (see page 13, lines 13-17).*

Claim 32 is worded as follows:

*"A method for preventing as well as treating wrinkles or skin changes associated with aging of skin comprising the topical application to involved skin of a composition containing a therapeutically effective amount of at least one member selected from the group consisting of hydroxycarboxylic acids and related ketocarboxylic acids, and ester, lactone and salt forms thereof".*

- 4.2.2 A claim containing the combination of the technical features **(a)**, **(b)** and **(c)** mentioned in 4.2 above, in particular
- (a)** the claimed use of a **topical cosmetic composition**
  - (b)** containing hydroxycarboxylic acids or related compounds **in an amount effective for treating cosmetic skin conditions and**
  - (c)** specifically **for the cosmetic treatment of wrinkles**, is not directly and unambiguously derivable from the disclosures at lines 13-17 on page 13 or in claim 32, taken either in isolation or in combination with each other. Nor is such a claim directly and unambiguously derivable from any other disclosure or the whole content of the application as filed.
- 4.2.3 The method claimed in claim 32 stipulates clearly that a composition containing a **therapeutically effective**

**amount** of hydroxycarboxylic acids is applied to involved skin and cannot therefore serve as a basis for a claim containing the above-mentioned features **(a)**, **(b)** and **(c)**.

4.2.4 Out of the total of **29 examples** contained in the application as filed **24 examples** illustrate subject-matter - i.e. a method **for the purpose of enhancing the therapeutic effect** of a composition comprising a cosmetic or pharmaceutical agent by admixing an enhancing effective amount of a hydroxycarboxylic acid - still present in the European parent patent application No. 87 117 405.8 on which European patent No. 0 273 202 has been granted. None of these 24 examples illustrates subject-matter divided out from the above European parent application and claimed in the patent.

All **five remaining examples** in the application as filed relating to subject-matter divided out from the parent application and claimed in the patent-in-suit, illustrate the use of a at least one member selected from the group of hydroxycarboxylic acids and related compounds as the active ingredient solely and exclusively for the preparation of a topical dermatologic **prophylactic** or **therapeutic** composition for the treatment, for example, of oily skin or acne, for skin cleansing (see originally filed Examples 10, 12, 18), or for the treatment of severe dry skin (see originally filed Examples 11, 25). None of the examples nor any other disclosure in the application as filed provides adequate support for the use of hydroxycarboxylic acids or related compounds in an amount effective for the treatment of cosmetic skin

conditions or, in particular, for the cosmetic treatment of wrinkles. Accordingly, the examples also fail to provide any reliable basis for the subject-matter of the claims recited in 4.2 above.

- 4.2.5 Dependent claim 36 of the application as filed, which was also discussed as lending additional support for the claims mentioned in 4.2 above, reads as follows: *"Use of a hydroxycarboxylic acid and/or ketocarboxylic acid and/or ester, lactone, and salt forms thereof according to claims 1 and 4 to 12 for the preparation of a topical cosmetic or pharmaceutical composition with enhanced therapeutic effect"*.

Originally filed claim 1 and dependent claims 4 to 12, to which claim 36 refers (see above), clearly relate to subject-matter - i.e. a **method for the purpose of enhancing the therapeutic effect** of a composition comprising a cosmetic or pharmaceutical agent by admixing with said composition **an enhancing effective amount** of a hydroxycarboxylic acid (see claim 1 as originally filed) - still present in the parent European patent application No. 87 117 405.8 on which European patent No. 0 273 202 was granted. It is thus immediately clear that claim 36 of the application as filed cannot, for that reason alone, serve to support the claims of the patent-in-suit relating to subject-matter which has been divided out from the above European parent application.

- 4.2.6 Even less persuasive is the appellants' argument (see letter dated 7 October 2005, page 7, third paragraph) that feature **(b)** is *"based on the disclosure at page 10, lines 10-13 of the application as published"* (reference

made by the appellants, identical in its wording with claim 32 of the application as filed - see 4.2.1 above), *"considering that the cosmetic composition cannot be therapeutically effective", but is "effective" as shown on page 20, lines 57 and 58 of the published application*" (page 36, lines 9-13 of the application as filed).

In view of the fact that the first reference in the application as published cited by the appellants (page 10, lines 10-13 of the application as published or claim 32 of the application as filed) clearly relates to "a composition containing **a therapeutically effective amount** of at least one member selected from .....", the disclosure "effective" without any further specification cannot, **in the absence of any support in the originally filed documents**, simply be given the meaning *"composition containing an amount effective for the treatment of cosmetic skin conditions of at least one member selected from ....."*, without offending against the provisions of Article 123(2) EPC.

4.2.7 In conclusion, in the board's judgment, the result of the introduction of the claims recited in 4.2 in the requests mentioned in 4.2 above is that all these requests contain subject-matter which is not directly and unambiguously derivable from the application as filed and which, accordingly, extends beyond the content of the application as filed.

4.2.8 Since a decision can only be taken on a request as a whole, none of the further claims of that main request and auxiliary requests 1 to 11 and 24 need to be examined. In these circumstances the appeal insofar as



it relates to the appellants' main request and auxiliary requests 1 to 11 and 24 must be dismissed, as at least one claim of all these requests is not in conformity with Article 123(2) EPC.

4.3 As far as the claims in the present requests relating to the use of hydroxycarboxylic acids and related compounds for the treatment of **human facial wrinkles** are concerned, the opposition division was, in the board's judgment, correct in its finding in the impugned decision that such claims are not adequately supported by the disclosure of the application as filed (see decision under appeal, second paragraph of the Reasons).

4.3.1 In addition to a series of the requests recited in 4.2 above, i.e.  
the main request (claims 10, 28);  
auxiliary request 2 (claims 9, 26);  
auxiliary request 4 (claims 5, 12);  
auxiliary request 6 (claims 5, 11);  
auxiliary request 8 (claims 4, 10); and  
auxiliary request 10 (claims 4, 10);  
the following requests contain a claim relating to the use of hydroxycarboxylic acids and related compounds in the treatment of human facial wrinkles (see "*wherein the wrinkles to be treated are human facial wrinkles*"):  
auxiliary request 12 (see claim 10);  
auxiliary request 14 (see claim 9);  
auxiliary request 16 (see claim 5);  
auxiliary request 18 (see claim 5);  
auxiliary request 20 (see claim 4);  
auxiliary request 22 (see claim 4);

4.3.2 The appellants admitted that an express reference to the treatment of human facial wrinkles cannot be found in the application as filed but argued that there is a sound basis for the claims relating to this particular treatment in the application as filed. Such a basis need not be presented in express terms but it must be sufficiently clear to a person skilled in the art to be directly and unambiguously recognisable as such and not of a vague and general character. The appellants presented the following passages in the originally filed application documents as the basis for the claims mentioned in 4.3.1 above, all introduced either during the granting procedure or *post grant*:

4.3.3 The disclosure at page 28, lines 6-32 of the application as filed (page 16, line 51 to page 17, line 4 of the application as published) reads as follows: *"Topical applications were carried out either by bilateral or sequential comparison. In bilateral comparison the subject was instructed to apply one preparation on one side of the body and the other one on the other side of the body. For psoriasis, eczema, severe dry skin, athlete's foot, etc., where both sides were involved, the subject was instructed to apply two to three times daily one medication on one side of the body for a period of up to several months of time. In the pulse treatment for psoriasis or other inflammatory diseases the medication was applied only once every three days or twice a week. The medication was discontinued whenever a total remission of the lesions occurred prior to the test period of up to several months.*

*For the scalp or face involvement such as in **dandruff, oily skin, acne, and seborrheic dermatitis** the subject was instructed to apply two to three time daily one medication on one side of the scalp or the face and the other medication on the other side of the scalp or the face for a period of up to 12 weeks of time. For age spots, keratoses or warts the medication was continued for up to 4 months of time."*

4.3.4 The disclosure at page 36, lines 24-32, of the application as filed (page 21, lines 7-13 of the application as published) provides under the heading "Acne" the following information to a person skilled in the art: *"Therapeutic compositions containing tetracycline, erythromycin or chlorhexidine with or without the addition of a hydroxyacid were provided to 9 patients having papulopustular or pustular lesions of **acne**. Each participating patient received two medications, with or without the addition of a hydroxyacid to the composition containing an antibiotic. The patients were instructed to apply topically one medication on one side of the body such as the left side forehead, face, back or chest, and the other medication on the other side of the body such as right side forehead, face, back or chest. Twice daily administration was continued for 4 to 12 weeks".*

4.3.5 The disclosure at page 35, lines 15-32, of the application as filed (page 20, lines 42-49 of the application as published) is the only teaching in the application which relates under the heading "Age Spots, Wrinkles, Keratoses and Pigmented Skin Lesions" to the treatment of wrinkles and reads as follows:  
*"Therapeutic compositions packaged in felt pens as*

*described in Examples were provided to 14 patients for treatment of age spots, **wrinkles**, keratoses and other pigmented skin spots. Each participating patient received two felt pens; i.e. with or without the addition of hydroxyacid to the composition containing hydroquinone. The patients were instructed to apply topically one medication on one side of the body such as **on the back of the left hand** and the other medication on the other side of the body such as **on the back of the right hand**. Specific instructions were given to the patients that the medications were applied twice daily and discretely only to the skin lesions of age spots wrinkles, keratoses, inelasma, lentiginos or other pigmented skin spots".*

4.3.6 For the treatment of the specific diseases or disorders mentioned in 4.2.3 and 4.2.4 above, the application as filed provides the express teaching and clear instruction that the medication should be applied, *inter alia* (amongst various other sites of application on the human body), to the patient's face. **No comparable teaching** is made available in the complete application as filed **for the treatment of wrinkles**.

4.3.7 To come to the subject matter claimed in the claims recited in 4.3.1 above, a number of independent choices must be made amongst mutually independent options, namely **(i)** from the medications referred to in 4.3.5 above, i.e "with or without the addition of hydroxyacid to the composition containing hydroquinone", the choice of using compositions containing hydroxyacids without hydroquinone; **(ii)** from the disclosure referred to in 4.3.5 above the choice of the treatment of wrinkles amongst the various other disorders or diseases

mentioned therein; **(iii)** followed by the subsequent choice of applying the medication on the face amongst the various methods of application of the medication mentioned in the disclosures referred to in 4.3.4 and 4.3.3 above (which do **not** refer to the treatment of wrinkles).

Therefore, the claimed combination of features (the use of hydroxycarboxylic acids or related compounds for the preparation of a topical dermatologic composition for the treatment of **facial** wrinkles) is certainly not directly and unambiguously derivable from the disclosure of the application as filed, contrary to what is required for compliance with Article 123(2) EPC.

4.3.8 Since a decision can only be taken on a request as a whole, none of the further claims of auxiliary requests 12, 14, 16, 18, 20 and 22 need to be examined. In these circumstances the appeal insofar as it relates to the appellant's auxiliary requests 12, 14, 16, 18, 20 and 22 must also be dismissed, as at least one claim of all these requests is not in conformity with Article 123(2) EPC.

4.4 According to point I.1.7 of the Minutes of the oral proceedings before the opposition division "the Chairman announced *"the discussion under Article 123(2) EPC to be closed and considered that the main request is not in line with Article 123(2) EPC as there was no basis for the subject-matter of claim 9 and claim 27 (concentration range) claim 10 and claim 28 (human facial wrinkles)"*.

The non-compliance of claims 9 and 27 (see III above) with Article 123(2) EPC, although noted in the Minutes, is not mentioned in the decision under appeal and, accordingly, no reasons are given in the impugned decision for the opposition division's finding expressed in the Minutes.

Dependent claim 9 as granted relates to the use of the topical dermatologic therapeutic composition of claim 1 and, accordingly, dependent claim 27 to the use of the topical dermatologic cosmetic composition of claim 19, wherein in each case at least one member selected from hydroxycarboxylic acids is present in the composition in an amount of 10 to 20% (see III and X above).

4.4.1 In addition to a series of the requests recited in 4.2 above, i.e.

the main request (claims 9, 27) (see X above);

auxiliary request 1 (claims 9, 26);

auxiliary request 4 (claims 1, 8);

auxiliary request 5 (claims 1, 7),

auxiliary request 6 (claim 1);

auxiliary request 7 (claim 1);

and in addition to some of the auxiliary requests recited in 4.3.1 above, i.e.

auxiliary request 12 (claim 9);

auxiliary request 16 (claim 1);

auxiliary request 18 (claim 1);

the following requests contain a claim wherein at least one member selected from hydroxycarboxylic acids is present in the composition in an amount of 10 to 20%:

auxiliary request 13 (see claim 9);

auxiliary request 17 (see claim 1);

auxiliary request 19 (see claim 1).

4.4.2 The appellant presented the disclosure at page 36, lines 2 to 14 of the application as filed (page 20, lines 53-58 of the application as published) to support the subject-matter of the above-mentioned claims. This disclosure reads as follows: *"Therapeutic compositions containing higher concentrations of hydroxyacids (10 to 20%) and hydroquinone (3 to 5%) were judged to be more efficient in eradicating age spots, wrinkles and keratoses within shorter periods of time. Without the addition of a hydroxyacid to the composition of hydroquinone, eradication of age spots, wrinkles or keratoses did not occur within four months of time.*

*It was also found that while compositions containing hydroxyacids without hydroquinone were effective for eradication of keratoses and wrinkles, the compositions were not efficient in eradicating pigmented age spots, melasmas or lentigines within 4 months of time. In any case, with the addition of a hydroxyacid to the composition containing hydroquinone, pigmented age spots, melasmas, lentigines and other pigmented skin spots had been substantially eradicated."*

4.4.3 The board shares the respondents' opinion that therapeutic compositions containing **higher concentrations of hydroxycarboxylic acids (10 to 20%)** are originally only disclosed in relation to therapeutic compositions containing these higher concentrations of hydroxycarboxylic acids in combination with (see **"and"**) hydroquinone (3 to 5%). In the whole context of the disclosure in the application as filed (see 4.4.2 above) it appears clear that **such higher concentrations** of hydroxycarboxylic acids in

combination with hydroquinone are required "*in order to be more efficient in eradicating **age spots**, wrinkles and keratoses **within shorter period of time***" (see page 36, lines 2-6).

4.4.4 In the following portion of the description a comparison is made between the effects achieved **within four months of time**

- (i) by compositions without the addition of a hydroxycarboxylic acid to the composition of hydroquinone (not covered by the present claims; see page 36, lines 6-8) and those achieved
- (ii) by compositions containing hydroxycarboxylic acids without hydroquinone; such compositions are said to be effective for eradication of keratoses and wrinkles, but **not** efficient in eradicating **age spots**, melasmas or lentigines (see page 36, lines 9-13).

The application as filed is entirely silent about the amounts of the active agents, either of hydroquinone or of hydroxyacids, used in the compositions (i) and (ii) for the above comparison (see the merely general references at page 36, lines 6-8 to "*compositions without the addition of hydroxy acid*" and at lines 9-10, to "*compositions containing hydroxyacids without hydroquinone*").

In particular, an answer to the question whether or not the higher concentrations of hydroxyacids (10 to 20%), which are used in composition (i) in combination with hydroquinone "*in order to be more efficient in eradicating **age spots**, wrinkles and keratoses **within shorter periods of time***" (see 4.4.3 above) were also



used in composition **(ii)**, which is employed in the above comparison to test the effects achieved **within four months of time** and which is **not** efficient in eradicating **age spots** (see 4.4.4 above), is certainly not directly and unambiguously derivable from the application documents as filed.

4.4.5 This finding is corroborated by the examples in the application containing at least one member selected from hydroxycarboxylic acids as the active ingredient. The maximum content of the hydroxycarboxylic acid is 10% tropic acid in Example 11 and 10% p-hydroxymandelic acid in Example 25, but only 7% benzilic acid in Example 10 and only 4% ribonolactone in Example 12. Thus, there also no examples in the application as filed to support claims directed to the use of compositions containing the higher concentrations of 10% to 20% of at least a member selected from hydroxycarboxylic acids.

4.4.6 Since a decision can only be taken on a request as a whole, none of the further claims of auxiliary requests 13, 17 and 19 need to be examined. In these circumstances the appeal insofar as it relates to the appellants' auxiliary requests 13, 17 and 19 must also be dismissed, as at least one claim of all these requests is not in conformity with Article 123(2) EPC.

5. **Auxiliary request 15**  
**Novelty (Articles 52(1) and 54(1) and (2) EPC)**

5.1 Claim 1 reads as follows (see XII **(p)** above):

"Use of a therapeutically effective amount for the treatment of wrinkles of at least one member selected from hydroxycarboxylic acids and ketocarboxylic acids, and ester, lactone, and salt forms thereof, for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles."

5.2 Citation (10) discloses a **therapeutic skin treatment** (see e.g. column 1, line 5) which involves applying a topical therapeutic skin care formulation to the face (see e.g. column 1, lines 6-8), said skin care formulation comprising as essential therapeutic components (see column 1, lines 66-67) **salicylic acid (2-hydroxybenzoic acid)**, resorcinol, **lactic acid ( $\alpha$ -hydroxypropionic acid)** and ethyl alcohol, each of these components being used in certain **effective amounts** (see the paragraph bridging columns 1 and 2), *inter alia*, for the treatment of **wrinkles** ("*Lines and wrinkles are smoothed*" - see column 3, line 25).

5.3 The appellants argued that the disclosure of (10) is not prejudicial to the novelty of the claimed invention because this citation relates to a composition of essential components, showing their effects only when synergistically applied. However, the question to be answered for deciding on novelty is whether or not citation (10) discloses

- the use of a therapeutically effective amount for the treatment of wrinkles
- of at least one member selected from hydroxycarboxylic acids

- for the preparation of a topical dermatologic therapeutic composition
  - for use in the treatment of wrinkles;
- or, differently expressed, **whether or not the prior art of (10) falls within the terms of claim 1**. In the judgment of the board this question must be answered in the affirmative.

The purpose of Article 54(1) EPC is to prevent the state of the art from being patented again, as already laid down in Decision T 12/81 "Diastereomers/BAYER" (OJ EPO 8/1982, 296, 301). Since novelty is an absolute concept the examination as to novelty is whether the state of the art is likely to reveal the content of the invention's subject-matter **as claimed in the patent** to the skilled person in a technical teaching. In the board's opinion, the latter is precisely the case here.

- 5.4 The appellants also argued that lactic acid is disclosed in (10) as having only antiseptic properties. The board cannot agree. Both hydroxycarboxylic acids, i.e. lactic acid **and** salicylic acid, all in therapeutically effective amounts are clearly said in (10) to be essential components of the topical therapeutic skin care formulation necessary to achieve "*the objects and advantages of the invention*", i.e. *inter alia*, the effect of smoothing lines and wrinkles (see the paragraph bridging columns 1 and 2 and column 4, lines 25-26.). It is merely disclosed in column 2 lines 29-31, that "*this material*" (lactic acid) "**also has antiseptic properties**".

5.5 The appellants' principal arguments for novelty concern the construction of the disputed term "wrinkles" used in the patent.

5.5.1 In accordance with the generally accepted rules of interpretation of the technical teaching of a claim and also with the established practice of the boards of appeal (cf. "Case Law of the Boards of Appeal of the European Patent Office", 4th Edition, 2001, I.C. 2.1, page 54-56), each claim should be read giving the words the meaning and scope which they normally have in the relevant art, unless in particular cases the description gives the words a special meaning, by explicit definition or otherwise.

However, in the present case, the terms "wrinkles" or "skin wrinkles" are used throughout the application as filed, and likewise in the patent, without being explicitly defined and without giving, at least, any explanation or indication or guidance whatsoever to suggest that such a special meaning should apply in the present case. It follows that the term "wrinkles", wherever it occurs in the present patent and whatever its context, has to be interpreted in its broadest sense.

5.5.2 Despite the absence of any definition or explanation of the term "wrinkles" used in the application as filed and the patent, the appellants, who are the inventors, sought nevertheless during the oral proceedings before the board to give that term a special meaning for the purpose of establishing the novelty of the subject-matter of the disputed patent over the cited prior art by explaining that "wrinkles" and "skin

wrinkles" within the meaning and scope of the patent were only those which were due to aging, in particular in sun-damaged skin, and result from loss of collagen fibres due to diminution in the number and diameter of elastic fibres in the papillary dermis, and also from atrophy of the dermis and reduction in subcutaneous adipose tissue, and deterioration of small blood vessels in the dermis of the skin.

- 5.5.3 In support of their intended construction of the term "wrinkles" in claim 1, the appellants referred to the statements in column 3, lines 50-60, of document (14) that *"the cells which make the fibres of the dermis become smaller and sparser with increasing age, usually in sun-damaged facial skin. There is a great loss of collagen fibres resulting in looseness and easy stretchability of the skin; elastic fibres become abnormal so that the skin does not promptly snap back after being stretched. Since the fibrous components comprise more than 90% of the bulk of which 95% is collagen the degradation of these fibres, especially collagen is mainly responsible for wrinkling, laxness and loss of elasticity"* (see (14) column 3, lines 50-60). The appellants also referred to column 4, lines 31 to 33 and lines 43-46 of (14), disclosing that *"fibroblasts synthesize the fibres of the dermis; new collagen is laid down, strengthening the physical foundation of the skin"* (see lines 31-33). Therefore, *"the production of a new collagen not only repairs damaged skin but results in the fakement and prevention of fine wrinkles and lines"* (see lines 43-46).

- 5.6 On the basis of the above disclosure in document (14) the appellants alleged that it would have been clear to

those skilled in the art that "wrinkles" result only from abnormal changes in the dermis and not in the epidermis. They went on to maintain that the sole effect of applying the therapeutic skin treating composition disclosed in (10) occurs only in the epidermis to achieve deadening of the outer skin layer or epidermis, causing it to dry up and to peel off (see (10), column 4, lines 3-12). The appellants further maintained that the skilled reader would immediately understand that, since the therapeutic skin treatment disclosed in (10) has no effect on the dermis, such treatment in (10) is not a treatment of "wrinkles", if that term is correctly interpreted in the light of the prior art and the general common knowledge.

In view of the above considerations, the appellants sought to justify their allegation that the claimed subject-matter in the patent is novel vis-à-vis the prior art of (10).

5.7 The board cannot agree with the appellants' conclusions for the following reasons:

5.7.1 **First**, on the basis of the facts and evidence available in the proceedings, it is, in the board's opinion, indisputable that the use of a therapeutically effective amount for the treatment of wrinkles of at least one member selected from hydroxycarboxylic acids (i.e. salicylic acid and lactic acid) for the preparation of a topical dermatologic therapeutic composition for use in the therapeutic treatment of **wrinkles** ("*Lines and wrinkles are smoothed*" - see column 3, line 25) **is literally disclosed in citation (10)** - see 5.2 and 5.3 above.

5.7.2 In Article 54(2) EPC, "the state of the art" is clearly and unambiguously defined as "everything made available to the public by means of a written or oral description, by use, or in any other way before the date of filing of the European patent application". A document normally forms part of the state of the art, even if its disclosure is deficient, unless it can unequivocally be proven that the disclosure of the document is not enabling, or that the literal disclosure of the document is manifestly erroneous and does not represent the intended technical reality. Such a non-enabling or erroneous disclosure should then not be considered part of the state of the art (see e.g. T 77/87, OJ EPO 1990, 280; T 591/90 of 11 December 1991). The onus of proving the allegation that the disclosure of (10) is erroneous or not reliable or does not represent the intended technical reality rests in the present case with the appellants (proprietors).

5.7.3 The board has no doubts at all on the outstanding scientific and professional qualifications of the appellants, leading them to their personal and subjective evaluation of the teaching in (10). However, in the absence of any objective evidence and real proof, the appellants' personal evaluation of the teaching of (10) and their subjective opinion are insufficient to prove in an unequivocal manner that the therapeutic skin treatment described in (10) is indeed unsuitable for use in the treatment of wrinkles in the broadest sense of that term, as used in (10) and likewise in the patent, and that the disclosure of (10) is accordingly erroneous and does not represent the intended technical reality. Consequently, document (10), **as it stands**, is

certainly to be taken into consideration when determining the problem to be solved and assessing novelty and inventive step.

5.8 **Second**, anyone invoking common general knowledge bears the burden of proof that general knowledge is involved. The proof is regularly supplied in citing literature (see T 475/88 of 23 November 1989). Document (14) is a US patent specification. Common General knowledge cannot as a rule be demonstrated by a statement in a single patent specification, since the technical information in a single patent specification or a scientific article might be based on special premises or the personal view of the author, even if it is shown, as is the case here, that the inventor designated in the patent is a recognised scientist in the field. In the board's opinion, the appellants, with whom the onus of proof rests, were unable to provide clear and unequivocal evidence to demonstrate that their proposed construction of the term "wrinkles" forms part of the common general knowledge, e.g. through recognition in a standard textbook. A patent specification can only as an exception supply general knowledge if no standard literature yet exists in a new area of research (see T 51/87, OJ EPO 1991, 177). In the board's opinion, such an exceptional situation does not exist in the present case.

5.8.1 Moreover, from document (14) itself, which the appellants invoked in support of their case, appears derivable that the term "wrinkles", as understood by dermatologists, is considerably broader and embraces not only wrinkles occurring in the dermis but, for example, also those appearing in the epidermis. In



column 1, lines 30-33 it is stated (emphasis added by the board): "*Serious microscopic alternations of the **epidermis** and the dermis occur decades before these become clinically visible. **Wrinkling**, yellowing, leatheriness, loss of elasticity are very late changes.*" In the board's opinion it appears clear to a person skilled in the art that formation of wrinkles in the dermis causes wrinkling of the epidermis as well. Such wrinkles are those which are directly visible to the naked eye. This view is supported by the disclosures, for example in document (3).

5.8.2 The board cannot accept the appellants' argument that the teaching of the present patent relates to a specific group of skilled persons, namely dermatologists, whereas the patent literature forming part of the state of the art, for example citation (10) and the other prior art documents cited in the present proceedings, relate in first place to "lay consumers". It requires only a moment's thought to appreciate that this cannot be the case; in the absence of any particular information or teaching to the contrary, the addressee of the present patent is of course the same group of skilled persons (dermatologists) as that of the cited patents, for example citation (10) and all the other cited scientific articles representing the state of the art in the present case.

5.9 **Third**, in the absence of virtually any information in the application as filed and the patent (description and claims) **(i)** as to the nature of the wrinkles actually treated by the claimed invention and, accordingly, as to the meaning and scope of the term "wrinkles" used in the patent and also

(ii) as to the meaning and scope of the feature "effective amount for the treatment of wrinkles", the subject-matter of the claims is not properly delimited against the prior art of (10). It follows that for the purposes of assessing novelty and inventive step the term "wrinkles" in claim 1 is to be construed as embracing wrinkles in the broadest sense of that term.

5.10 **Fourth**, at the appeal stage, the appellants invoked in support of their case also a Memorandum Order of the United States District Court for the District of Delaware dated 27 July 1999 in the consolidated cases *Tristrata Technology, Inc. v. Neoteric Cosmetic Inc., et al.* and *Tristrata Technology, Inc. v. Beiersdorf Inc.*, and *Leiner Health Products, Inc.* (see Annex 1), relating to the Court's construction of disputed claim language.

5.10.1 As regards the relevance of Annex 1, as a general remark, it should be noted that the principle of "examination by the European Patent Office of its own motion" (Article 114(1) EPC) applies before the opposition division and the board of appeal. This is made clear both by the terms of that provision and by Article 102(1) to (3) EPC, which stipulates that decisions concerning oppositions hinge upon the opposition division's and, accordingly, the board's opinion with regard to patentability (Article 52 et seq. EPC) and other requirements of the Convention. In forming its opinion, the board is not in any way bound by the opinion of a national court either within or outside the territory of the contracting states to the EPC. For the sake of completeness, it may nevertheless

be noted that the content of the Memorandum Order in Annex 1 is **not out of line with the board's opinion.**

5.10.2 The relevant portion of that Order at page 4, lines 2-10 from the bottom reads as follows (emphasis added by the board):

*"The plain meaning of wrinkle is a small ridge or furrow ..... in the skin. Webster's Ninth New Collegiate Dictionary 1362 (1986). **The Patents do not define wrinkle, however, they do describe the nature of wrinkles.** The '171" (i.e. US-A 5 091 171) "and '938" (i.e. US-A- 5 385 938) **"Patents state** that visible fine wrinkles are due to diminution in the number and diameter of elastic fliers in the papillary dermis, and also due to atrophy of dermis as well as reduction in subcutaneous adipose tissue, and coarse wrinkles are due to excessive deposition of abnormal elastic materials in the upper dermis and thickening of the skin. (US-A 5 091 171, col. 32, lines 23-30; US-A-05 385 938, col. 32, lines 1-8). **Thus, the Court construes the term wrinkle** as a ridge or furrow in the skin associated with degenerative change in the dermis."*

5.10.3 However, in contrast to the '171 (i.e. US-A 5 091 171) and '938 (i.e. US-A- 5 385 938) patents, to which the cited Memorandum Order refers (see 5.10.2 above), neither the European patent application as filed nor the patent contains a corresponding description or explanation of the nature of the wrinkles to be treated. It is thus clear that the term "wrinkle" used in the present claims is deprived of any special meaning and scope and that the construction of this term in the

above Memorandum Order based on the description and explanation of the term "wrinkles" in the '171 and '938 patents **cannot** be applied to the construction of the claim language used in the patent.

5.11 To summarise, the board holds that citation (10) is prejudicial to the novelty of at least claim 1 because the **broadly claimed use** of hydroxycarboxylic acids and related compounds in the treatment of wrinkles in that claim is not properly delimited against the state of the art disclosed in citation (10) and made available to the public within the meaning of Article 54(2) EPC. As explained above, this holds true even if the description is used to interpret the present claims in accordance with Article 69 EPC.

5.12 Therefore, the board does not need to examine the allegations of the respondents that the claims also lack novelty vis-à-vis a series of other citations presented by the parties in the course of the first-instance opposition and subsequent appeal proceedings. In these circumstances, the appeal in so far as it relates to auxiliary request 15 must accordingly be dismissed.

6. ***Auxiliary requests 21, 23 and 25***  
***Inventive step (Articles 52(1) and 56 EPC)***

6.1 Since - as seen below - the board's principal objections on the grounds of lack of inventive step are the same, the above mentioned auxiliary requests can be treated together.

6.2 Claim 1 of auxiliary request 21 reads as follows (see X(j) and XIII(v) above):

"1. Use of a therapeutically effective amount for the treatment of wrinkles of at least one member selected from 2-hydroxyacetic acid; phenyl 2-hydroxyacetic acid; diphenyl 2-hydroxyacetic acid; 2-methyl-2-hydroxypropanoic acid and ester and salt forms thereof; and hydroxycarboxylic acid lactones, for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles."

Claim 1 of auxiliary request 23 reads as follows (see X(1) and XIII(x) above):

"1. Use of a therapeutically effective amount for the treatment of wrinkles of at least one member selected from hydroxycarboxylic acid lactones for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles."

The sole claim of auxiliary request 25 reads as follows (see XVI(z) above):

"1. Use of a therapeutically effective amount for the treatment of wrinkles of at least one member selected from 2-hydroxyacetic acid; phenyl 2-hydroxyacetic acid; diphenyl 2-hydroxyacetic acid; 2-methyl-2-hydroxypropanoic acid and salt forms thereof for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles."

6.3 In view of the **limitation** of

- (a) claim 1 of auxiliary request 21 to the use of a therapeutically effective amount for the treatment of wrinkles of (i) any of the four specific 2-hydroxycarboxylic acids recited therein, or (ii) an ester or a salt thereof or (iii) hydroxycarboxylic acid lactones, for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles (see 6.2 above);
- (b) claim 1 of auxiliary request 23 to the use of a therapeutically effective amount for the treatment of wrinkles of hydroxycarboxylic acid lactones, for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles (see 6.2 above); and
- (c) claim 1 of auxiliary request 25 to the use of a therapeutically effective amount for the treatment of wrinkles of (i) any of the same four specific 2-hydroxycarboxylic acids as used in claim 1 of auxiliary request 21, or (ii) a salt thereof, for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles (see 6.2 above);

**novelty** within the meaning of Article 54(1) EPC can be acknowledged because none of the documents available in the proceedings appears to disclose all the technical features of the claims of the above requests.

6.4 The board is of the opinion that, in view of the reasoning as developed in point 5 above, the disclosure of citation (10) should be considered to represent the closest state of the art.

- 6.4.1 The appellants have not demonstrated, by exact comparison with the closest prior art of (10), any unexpected, e.g. superior, effect associated
- either with the use of any of the four selected specific 2-hydroxycarboxylic acids or an ester or a salt thereof (see claim 1 of auxiliary requests 21 and 25),
  - or with the use of hydroxycarboxylic acid lactones (see claim 1 of auxiliary requests 21 and 23),
- as the active component of a topical dermatologic therapeutic composition for use in the treatment of wrinkles.

Consequently, the conclusion must be drawn that certain alleged additional advantages associated with the use of the above-mentioned specific 2-hydroxycarboxylic acids and hydroxycarboxylic acid lactones referred to by the appellants in the statement setting out the grounds of appeal have not been properly demonstrated. Such alleged but unsupported advantages cannot be taken into consideration for the identification of the problem underlying the above-mentioned auxiliary requests and hence for the assessment of inventive step, where comparison is made with highly pertinent prior art (see e.g. T 20/81, OJ EPO 1982, 217).

- 6.4.2 Hence, the problem to be solved in auxiliary requests 21, 23 and 25 can be seen only as to suggest an alternative to the use of lactic acid or salicylic acid in a therapeutically effective amount for the treatment of wrinkles for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles, as disclosed in (10).

6.4.3 The solution is the use of

- any of the four selected specific 2-hydroxycarboxylic acids or an ester or a salt thereof (see claim 1 of auxiliary requests 21 and 25),
- or of hydroxycarboxylic acid lactones (see claim 1 of auxiliary requests 21 and 23).

for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles **in the broadest sense of that term.**

Having regard to the disclosure of the patent and the results presented therein and in the absence of any evidence to the contrary, the board is satisfied that the problem posed is plausibly solved.

6.4.4 The question still remains whether or not an inventive step was necessary to arrive at the present invention when starting from the teaching of citation (10) as the closest state of the art and taking into consideration the teaching and information of the other documents and the arguments provided by the parties present in the proceedings.

6.4.5 In citation (10) itself there was, in the board's judgment, already a clear hint suggesting to those skilled in the art that hydroxycarboxylic acids, such as salicylic acid (2-hydroxybenzoic acid) and lactic acid ( $\alpha$ -hydroxypropionic acid), are essential therapeutic components which are useful, *inter alia*, for the preparation of compositions which are effective for the treatment of facial lines and wrinkles.



This view is further confirmed by the state of the art according to citation (2) which discloses the use of lactic acid and its salt to make the skin **smooth** and to impart a suitable degree of moisture and "tightness" to the skin. A smooth skin obviously means "wrinkle-free" [see underlined meaning of smooth in document (2a)].

6.4.6 Moreover, those skilled in the art seeking in the state of the art further hints or suggestions as to how the problem posed can be solved would have come upon, as examples only, citations (1a), or (1b) = (18a), or citation (4), which they would certainly have considered with great interest, because they disclose, *inter alia*, the use of various hydroxycarboxylic acids for the preparation of topical dermatologic therapeutic compositions for the treatment of wrinkles.

6.4.7 Citation (1a) refers to the treatment of diseases using extracts of plant materials and, more specifically, to the treatment of diseases using lemon juice as the active agent. This citation discloses the composition and components of lemon juice. The principal known components of lemon juice include, *inter alia*, (i) a series of various hydroxycarboxylic acids and salts thereof, such as citric acid (2-hydroxy-1,2,3-propanetricarboxylic acid; page 169, lines 10-12), malic acid (page 169, line 13), calcium and potassium citrate (page 169, line 13), and (ii) hydroxycarboxylic acid lactones, such as ascorbic acid (Vitamin C), in an amount of 40 to 50 mg/100 mg of the fruit. It is also disclosed in (1a) that the application of lemon juice to the human skin has the effect of preventing the formation of wrinkles (see page 172, line 17) and of

avoiding the formation of rides (see page 174, lines 3-4).

6.4.8 The same beneficial effect of citric acid and salicylic acid in the treatment of human facial wrinkles is also described in citation (4) (see page 1, lines 2-5).

6.4.9 The use of lemon juice for the treatment of wrinkles is also disclosed in citation (53) - see page 1, lines 3-4 and line 12.

6.4.10 Citation (1b) = (18a) discloses that esters of malic acid (2-hydroxybutanoic acid) are useful, *inter alia*, for the prevention and treatment of wrinkles (see page 1, line 24; page 5, line 23). The examples illustrate the treatment of wrinkles in a number of test persons: 3. Mrs. A., 54 years, brunette (page 6); 6. Mrs. B. 50 years, brunette (page 7).

6.4.11 In view of the structural closeness of lactic acid (2-hydroxybenzoic acid) to the homologue thereof, i.e. 2-methyl-2-hydroxypropanoic acid used as the active agent in claim 1 of auxiliary requests 21 and 25, or the esters of malic acid (2-hydroxybutanoic acid) to the esters used as the active agents in claim 1 of auxiliary request 21, the skilled person would have expected these compounds to exhibit identical or at least similar beneficial properties to those exhibited by the compounds disclosed in the cited prior art when used for the preparation of topical dermatologic compositions for the treatment of wrinkles. Unless evidence was available to refute this assumption by showing that the small shift in structure to the claimed area was unexpectedly associated with a

significant improvement in the property relevant to the solution of the stated problem, the presumption must prevail that the claimed use represents only predictable effects and is therefore obvious. The onus was on the appellants to refute this inference based on the information so far available.

Ascorbic acid, which is known to be an essential component of prior art compositions for the treatment of wrinkles (see 6.3.4 above), is also used in the patent as a suitable member of the group of hydroxycarboxylic acid lactones and is recited as the active agent for the therapeutic treatment of wrinkles in auxiliary requests 21 (see claim 3) and 23 (see claim 3).

6.4.12 Those skilled in the art seeking a solution to the problem posed would moreover have learned e.g. from document (6) that "all  $\alpha$ -hydroxycarboxylic acids work the same way" (see page 53, line 1). This teaching inevitably pointed those persons in the direction of the claimed solution.

6.4.13 For the above reasons, the subject-matter of auxiliary requests 21, 23 and 25 lacks an inventive step and these requests are consequently not allowable.

7. The appellants suggested that citation (14) should be considered to represent the closet state of the art. Citation (14) discloses, inter alia, that "*vitamin A acid influences ultrastructural and proliferative properties of epidermal cells* (see column 1, lines 53-55). It further discloses *that the invention relates to the use of low strength vitamin A acid (retinoic*

*acid) known clinically as retinoin, in moderating and preventing the aging changes of the exposed areas of the skin, especially the face. In particular, the methods of the present invention retard the effect of normal aging of the skin due to impairment of the differentiation of epidermal epithelial cells and due to loss of collagen fibres and deterioration of small blood vessels of the dermis of the skin. These methods comprise applying topically to the epidermis of the skin effective amounts of vitamin A acid in a program of maintenance therapy, whereby epithelial growths are substantially reduced and prevented and the skin substantially regains and maintains firmness, turgor and elasticity during the therapy. Generally, the maintenance therapy is begun in middle age when epithelial growths and other changes begin to appear clinically" (see column 1, line 65 to column 2, line 16). As already mentioned in 5.5.3 above, citation (14) discloses the use of vitamin A acid for the therapeutic treatment of skin disorders, e.g. wrinkles in the epidermis and dermis (see column 4, lines 39-46).*

- 7.1 The result arrived at if (14) 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 suggesting an alternative to the use of vitamin A acid for the preparation of a topical dermatologic therapeutic composition for use in the treatment of wrinkles, does not lead to a more favourable outcome for the appellants.

The solution to this problem is the same as already outlined in 6.4.3 above.

7.2 In the board's opinion, those skilled in the art, having studied the closest state of the art, such as the prior art cited in 6.3.6 to 6.3.10 above, and being guided by the technical problem and on the basis their common general knowledge and also from their familiarity with closely related art would have expected the problem to be solvable by substituting hydroxycarboxylic acids, and ester, lactone, and salt forms thereof for vitamin A acid used in (14). In the present situation, those persons were provided with a clear hint from the prior art pointing them in the direction of the claimed use, and it was only necessary to confirm experimentally that the highly probable result was in fact obtained. The necessity of experimentally confirming a reasonably expected result does not render an invention unobvious.

8. In these circumstances, the appeal in so far as it relates to auxiliary requests 21, 23 and 25 must accordingly also be dismissed.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

A. Townend

U. Oswald