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**D E C I S I O N**  
**of 16 March 1999**

**Case Number:** T 0453/95 - 3.3.2

**Application Number:** 88308018.6

**Publication Number:** 0356583

**IPC:** A61K 7/06

**Language of the proceedings:** EN

**Title of invention:**  
Scalp treatment method

**Patentee:**  
Redeken Laboratories Inc.

**Opponent:**  
Henkel Kommanditgesellschaft auf Aktien  
Unilever Plc / Unilever NV

**Headword:**  
Chelating agent/REDKEN LABORATORIES

**Relevant legal provisions:**  
EPC Art. 52(4), 54, 56  
EPC R. 27(1)(b)

**Keyword:**  
"Novelty (yes): feature non-derivabile from the prior art"  
"Inventive step (main request) (no): no relationship between  
the feature imparting novelty and the technical effect of the  
invention. (Auxiliary request) (yes): non-obvious effect of  
chelating agents"

**Decisions cited:**  
T 0450/97

**Catchword:**

-



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Boards of Appeal

Chambres de recours

Case Number: T 0453/95 - 3.3.2

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.2**  
**of 16 March 1999**

**Appellant:** Henkel  
(Opponent) Kommanditgesellschaft auf Aktien  
TFP/Patentabteilung  
40191 Düsseldorf (DE)

**Respondent:** Redken Laboratories Inc.  
(Proprietor of the patent) 6625 Variel Avenue  
Canoga Park, CA 91303 (US)

**Representative:** Holdcroft, James Gerald, Dr.  
Graham Watt & Co.  
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**Decision under appeal:** Interlocutory decision of the Opposition Division  
of the European Patent Office posted 4 April 1995  
concerning maintenance of European patent  
No. 0 356 583 in amended form.

**Composition of the Board:**

**Chairman:** P. A. M. Lançon  
**Members:** C. Germinario  
W. Moser

## Summary of Facts and Submissions

- I. European Patent No. 0 356 583 was granted in response to European patent application No. 88308018.6 on the basis of a set of 12 claims for all the designated Contracting States.
- II. Notice of opposition was filed by the appellant (opponent), requesting revocation of the patent in its entirety on the grounds that the claimed subject-matter was excluded from patentability pursuant to Article 52(4) EPC and on the grounds of lack of novelty and inventive step.

The following documents were cited, *inter alia*, during the proceedings before the opposition division:

- (1) H. Janistyn: Handbuch der Kosmetika und Riechstoffe, Vol. III: Die Körperpflegemittel, 2nd Edition, 1973, pages 285, 287, 295-297, 301
- (5) DE-A-3 211 913
- (6) WO-A-88/04931

- III. The opposition division maintained the patent on the basis of an amended claim 1 and a description accordingly adapted. The text of the claim 1 reads as follows:

"A cosmetic method for reducing normal average daily hair loss characterized by periodically distributing onto the scalp of a person subject to hair loss, a composition having an active ingredient consisting

essentially of a sufficient amount of active chelating agent to chelate at least 0.3 milligrams of divalent calcium per millilitre of composition, and leaving the composition in contact with the scalp for at least eight hours".

- IV. The opposition division held that claim 1, as amended, fulfilled the requirements of Article 123(2) and (3) EPC and that the claimed cosmetic method was not excluded from patentability pursuant to Article 52(4) EPC.

Moreover it argued that the specific purpose of the chelating agent, ie reducing normal hair loss, was not disclosed in any of the cited prior documents. For this reason, it held that the claimed subject-matter was novel.

In relation to inventive step, the opposition division considered the two documents (5) and (6). As to document (5), which described compositions comprising the chelating agent glycine, it stressed that the purpose of these compositions was not that of minimising the normal daily hair loss, but rather that of regenerating the dead hair follicles.

As to the document (6), which disclosed methods and compositions comprising, *inter alia*, the chelating agent EDTA, the opposition division argued that there was in the document no indication at all as to the scope of this component.

For this reason, neither of these two documents could suggest that the chelating agents would be able to

prolong the follicles' active phase, by interacting with the  $\text{Ca}^{+2}$  ions in the hair follicles, thereby reducing normal hair loss.

- V. The appellant lodged an appeal against this decision. Oral proceedings were held on 16 March 1999.

In the statement setting out the grounds of appeal and during the oral proceedings, the appellant contended that document (1) disclosed hair lotions for maintaining a healthy hair growth and preventing hair loss. Since this was the scope of all the different hair compositions described in that document, including those comprising the chelating agents glycine or lactic acid cited on pages 297 and 301, the document was considered as prejudicial to the novelty of the subject-matter of claim 1.

The appellant also cited document (6) as prejudicial to the novelty of the subject-matter of claim 1, since in its contention, the document described directly or implicitly all the features of the claimed method.

As regards inventive step, the appellant indicated either of the documents (5) or (6) as the possible closest prior art. Starting from the former, it maintained that it would have been obvious for the skilled person to increase the application time from 10 minutes, as disclosed in this prior document, to at least eight hours, as required by the patent at issue. As to the latter document, the appellant contended that it was known to the skilled person, as recognised in the patent in suit, that high concentrations of  $\text{Ca}^{+2}$  ions inhibited cell growth. Thus, the problem being

known, the proposed solution was obvious for the skilled person.

- VI. The respondent (patent proprietor) emphasised that none of the cited documents disclosed or suggested the use of a chelating agent to reduce the concentration of  $\text{Ca}^{+2}$  ions in the hair follicles, thereby preventing normal daily hair loss, nor application times of at least eight hours.

At the oral proceedings, the respondent filed, as an auxiliary request, a new set of 12 claims having an amended claim 1. The text of claim 1 reads as follows:

"A cosmetic method for reducing normal average daily hair loss characterized by periodically distributing onto the scalp of a person subject to hair loss, a composition having **as the principal active ingredient an ingredient** consisting essentially of a sufficient amount of active chelating agent to chelate at least 0.3 milligrams of divalent calcium per millilitre of composition, and leaving the composition in contact with the scalp for at least eight hours" (emphasis added by the Board).

- VII. The appellant requests that the decision of the opposition division be set aside and the patent be revoked.

The respondent requests that the appeal be dismissed (main request) or that the decision under appeal be set aside and the patent be maintained on the basis of claims 1 to 12 submitted during oral proceedings as auxiliary request.

## Reasons for the Decision

1. The appeal is admissible.

### *Main request*

2. Article 123(2) and (3) EPC

Claim 1 has been amended during the proceedings before the opposition division in that the claimed method has been qualified as "cosmetic". In the Board's judgement, the term "cosmetic" can be regarded as implicitly disclosed in the application as filed, eg in the paragraph bridging pages 3 and 4. Furthermore, the introduction of this feature implies a restriction of the scope of claim 1. Therefore, claim 1 as amended meets the requirements of Article 123(2) and (3) EPC.

3. *Article 52(4) EPC*

The objection raised by the appellant during the opposition procedure in relation to Article 52(4) EPC, was not maintained in the proceedings before the Board of Appeal. The opposition division held that the claimed subject-matter was not excluded from patentability since it did not include any therapeutic treatment. The Board shares this opinion of the opposition division.

4. *Novelty - Article 54 EPC*

- 4.1 The cosmetic method for reducing normal average daily



hair loss according to claim 1, is characterised in that a composition having an active ingredient consisting essentially of a sufficient amount of active chelating agent to chelate at least 0.3 milligrams of divalent calcium per millilitre of composition, is distributed onto the scalp and left on the scalp for at least eight hours.

In order to establish the scope of claim 1, it must be made clear, firstly, that the expression in claim 1 "..composition having an active ingredient.." does not confine the claimed method to the use of a composition having a chelating agent as unique active agent, but, on the contrary, allows the presence of other active agents, which may all significantly contribute, according to their own mechanism of action, to preventing hair loss. Secondly, the wording of claim 1 requires, as an essential condition of the claimed method, that the scalp be treated with a chelating agent which is sufficient in **amount** and in **activity** to chelate the defined quantity of divalent calcium **at the point of time when the composition is applied.**

- 4.2 Document (6) relates to methods and compositions for reducing hair loss and for promoting new hair growth comprising, as an active agent, isolated omental lipids (see claims 1, 36 and 38). The document also discloses specific compositions which comprise, in addition to the active ingredient, 0.1% of trisodium EDTA, ie a chelating agent. The compositions at issue are: lotion 2-36A (page 33), lotion 2-17C (page 34), Activa<sup>TM</sup>-Cream (page 43) or Cream 2-19C (page 45). According to claims 19 and 22, the purpose of the chelating agent EDTA is that of providing antioxidant

or preservative activity, which is understandable when considering the sensitivity of the lipidic material to chemical and microbiological attacks. Therefore it is evident that the scope, in the compositions of document (6), of an agent exhibiting chelating activity is that of inhibiting, within the composition, any detrimental process catalysed by the presence of metal ions.

Under these circumstances, it is irrelevant for the invention of (6) that the chelating agent be still sufficiently active to chelate at least 0.3 mg of divalent Calcium per millilitres solution at the time when the composition is applied onto the scalp. For this reason, it would be impossible for the skilled person to derive this feature, otherwise essential for the present invention, from the teaching of this prior document. In the Board's view, moreover, it would be very unlikely that this condition could, at all, be met, even implicitly, by the compositions of (6) considering that they comprise EDTA in an amount corresponding to the minimum sufficient amount (0,1%) envisaged in the patent at issue for the active chelating agent.

In view of the lack of teaching of this essential feature, document (6) is not regarded as prejudicial to the novelty of the subject-matter of claim 1.

- 4.3 Document (1) has also been cited by the appellant. This document is a textbook which relates, in the cited passages, to hair lotions and other hair compositions. The introductory part of this document (page 285) illustrates the general knowledge in 1973 and explains

the different applications of these compositions, namely that of maintaining a healthy hair growth (lines 1 to 3) and that of preventing hair loss (lines 5 to 7 from the bottom). Some specific lotions comprising the chelating agents glycine or lactic acid are disclosed on pages 297 and 301. The appellant contended that these specific compositions were prejudicial to the novelty of the claimed subject-matter.

The Board considers that the appellant's conclusions are the result of an undue combination of passages, which are not necessarily related. In other words, nothing in this prior document would actually teach the skilled person that the specifically cited lotions are intended for, or exhibit, hair loss prevention activity rather than growth promotion activity. Nor is the condition disclosed that the chelating agent must be present in an amount and activity sufficient to chelate at least 0.3 mg of  $\text{Ca}^{+2}$  ions per ml solution upon application of the lotions.

For these reasons, document (1) is not regarded as prejudicial to the novelty of the subject-matter of claim 1.

In view of the foregoing, claim 1 and dependent claims 2 to 12 are regarded as novel.

5. *Inventive step - Article 56 EPC*

5.1 The closest prior art

Two documents, ie documents (5) and (6), have been

discussed in the decision under appeal for purposes of inventive step. Both documents describe hair compositions comprising a chelating agent. However, only the latter relates also to a method for preventing hair loss. For this reason, the Board considers that document (6) represents the closest prior art.

During the proceedings, much emphasis was given to the fact that document (6) related to the treatment of hair loss and baldness caused by specific diseases and, additionally, that this document said nothing about the application time envisaged for the compositions therein described.

In the Board's view, however, the invention in (6) is not limited to the treatment of states caused by a disease, such as "common pattern baldness", but rather it is directed to prevent any form of hair loss, including normal daily hair loss, and to promote hair growth in general. This is evident from the subject-matter of the majority of the claims, which are not directed to the treatment of any pathological state, the only exceptions being claims 52, 53 and 54.

As to the application time of at least eight hours required by present claim 1, it is noted that example I of document (6) describes, on page 33, the composition 2-36A which is a lotion comprising trisodium EDTA. The procedure for use of this composition is described on page 37. The lotion is said to be applied topically to bald and balding areas, after the hair have been washed and dried. Preferably the lotion is applied once or twice a day. The passage does not specify how long the application time is, but nor even that the composition

must be removed after application.

Since, normally, a topical application implies that the applied composition is left on the application point to develop the desired activity without being removed, there is no reason for the Board, lacking any explicit indication to the contrary, to conclude that the lotion of (6), which is indeed a topical composition, has to be rinsed or washed away after application. The Board is therefore convinced that the regimen of application of once or twice a day (in the morning and in the evening), as disclosed in document (6), actually and necessarily implies application times of at least eight hours as requested by claim 1.

- 5.2 For the formulation of the technical problem underlying the present invention, it should be further considered that no arguments or evidence produced during the proceedings would justify the conclusion that the method according to claim 1 implies any advantage over the method according to document (6). Under these circumstances, the technical problem to be solved by the invention is that of providing an alternative method to prevent normal average daily hair loss.

The solution proposed by the patent in suit is the method of claim 1 in which one parameter of the previously known method has been modified, in that the amount and activity of the chelating agent are such that they are still sufficient to chelate at least 0.3 mg divalent calcium per ml of composition when the composition is used on the scalp.

- 5.3 In consideration of the fact that the scope of claim 1

does not exclude the presence in the composition of other active ingredients in addition to the chelating agent (see point 4.1 above), the Board is unable to recognise any difference between the claimed method and the one described in document (6) in addition to the novelty-imparting feature already discussed under point 4.2 above, namely that the chelating agent is applied onto the scalp in an amount and in activity sufficient to chelate at least 0.3 mg divalent calcium per ml of composition. As seen above, the compositions of (6) cannot be considered to exhibit, upon application, the same chelating activity.

- 5.4 The meaning and scope of this functional feature needs to be properly established in relation to the specific wording of claim 1. In fact, claim 1 is not directed to a method for chelating divalent calcium accumulated in the hair bulbs but to a method for reducing hair loss regardless of any mechanism of action. In fact, as already seen, the expression "...composition having an active ingredient..." not only does not exclude from the scope of claim 1 that the same composition may comprise further active ingredients which contribute to prevent hair loss, but does not even exclude that the final effect achieved by the claimed method may be produced **exclusively** by these additional non-cited active ingredients, and that the cited chelating agent may be "active" simply in preventing, upon metal-ion chelation, any detrimental modification of the composition.

Thus the wording of claim 1 does not provide any cause/effect relationship between the specific chelating activity and the reduction of hair loss; said

in other words, there is no relationship between the functional feature imparting novelty to the claimed method and the final technical effect achieved by the same method.

On the other hand, no improvement entailed in the claimed subject-matter over the method or the compositions of document (6) has been proved, discussed or at least made plausible by the respondent. For this reason, the modification of the closest prior art proposed by claim 1 is not even related to any practical result concerning the effects already obtained by the method of (6) or the properties of the composition used in that method.

Under these circumstances, the Board wishes to stress that the notion of "non-obviousness" is related to the concept of "invention", which in its turn implies a technical character. If the invention is defined in an independent claim by a single novel feature which is based on a modification of the closest prior art, and which in itself cannot be said to result in any practical effect, then the modification is arbitrary and is irrelevant in assessing the existence of an inventive step. For this reason, the method according to claim 1 is not regarded as involving an inventive step within the meaning of Article 56 EPC.

*Auxiliary request*

6. *Articles 123(2) and (3) EPC*

The subject-matter of claim 1 has been amended with regard to claim 1 as maintained by the opposition

division in that the wording "having an active ingredient consisting" has been replaced by "having as principal active ingredient an ingredient consisting".

The new text finds support, for the purposes of Article 123(2) EPC, in the application as filed on page 18, lines 29 to 30. Moreover, the amendment does not extend the protection conferred by the granted claims since it makes plain that the hair loss reduction is caused mainly by the chelating agent, as principal active ingredient, whereas the granted claim envisaged an undefined number of possibilities. Thus, claim 1 meets also the requirements of Article 123(3) EPC.

7. *Novelty - Article 54 EPC*

At the oral proceedings, the appellant underlined that the composition used in the claimed method could comprise the active chelating agent in an amount as low as 0.1%. Therefore, in spite of the new wording of the claim, which required that the chelating agent was the principal active ingredient, the amount of 99.9% of the composition was still open for any kind of non-active, or less active, ingredients. Thus the claim did not exclude the presence in the composition of the omental lipids according to document (6). For this reason, in the appellant's contentions, the subject-matter of claim 1 lacked novelty.

The Board cannot follow these arguments as the considerations which lead it to recognise the novelty of the claims according to the main request, apply in the same way to claim 1, and claims dependent thereon,



of the auxiliary request. In fact, the novelty of the claimed method derives from the specific amount of (still) active chelating agent at the time of the application of the composition onto the scalp (see point 4.2). Therefore, the presence of other optional active ingredients in the composition is immaterial to the novelty of the claim which is guaranteed by the feature of the chelating agent.

8. *Inventive step - Article 56 EPC*

8.1 In the Board's judgement, the new wording of the claim 1 identifies a cause/effect relationship between the activity of the chelating agent, as the principal active ingredient of the composition, and the technical effect to be achieved by the claimed method, ie reducing hair loss. Thus the Board recognises that the main contribution to the achievement of said technical effect is given by the chelating agent which reduces the amount of divalent calcium in the hair bulbs or follicles.

8.2 The Board holds that the closest prior art (document 6) and the underlying technical problem (an alternative method to reduce normal average daily hair loss) as identified and formulated in relation to the main request, remain valid also in reference to the auxiliary request.

8.3 The solution proposed by the patent in suit is the method of claim 1 in which a chelating agent of a defined activity is maintained for a defined period of time in contact with the scalp. On the basis of the results of the test reported on page 6 of the

description of the patent, the Board is convinced that the technical problem is actually solved by the claimed method.

- 8.4 As already discussed in relation to the main request, the chelating agent present in the compositions of document (6) is not said to give any contribution to the achievement of the final effects of preventing hair loss and promoting hair growth. On the contrary, the document makes it plain (see claims) that the desired effects result from the use of a composition containing isolated omental lipids as principal active agent. This is confirmed specifically by examples I and II. The former describes two hair compositions: lotions 2-36A and 2-17C. Although both compositions comprise EDTA, this chelating agent is not cited in the section entitled "PREFERRED LOTION INGREDIENTS" on page 35. On the other hand, the latter example reports an experimental study to demonstrate the effectiveness of the isolated omental material and its effect in synergism with other ingredients of the composition. Yet, EDTA is not even taken into account as possible agent having some influence on the effect of the omental lipids or some effect in itself (see pages 40 to 42). Therefore, the skilled person could not find in document (6) any suggestion that the chelating agent (EDTA), beyond some stabilising effect on the composition, could produce any activity resulting in or contributing to the final effect of preventing hair loss. Still less that a chelating agent alone could already achieve that result.

As to document (6), the appellant contended that it was known to the skilled person, as recognised in the patent, that high concentration of  $\text{Ca}^{+2}$  ions inhibited the cell growth. Thus, the problem being known, the proposed solution could only be obvious for the skilled person.

The Board cannot follow these arguments. In fact, the knowledge that high amounts of  $\text{Ca}^{+2}$  ions inhibited cell-growth was completely irrelevant to the solution of the technical problem, if not supported by the further teaching given by the patent at issue that the quiescence and senescence phases of the hair follicles were accompanied by increasing contents in divalent calcium and that the reduction of this content could prolong the active follicle phase.

- 8.5 The skilled person could not find any more explicit hint to investigate the activity of chelating agents for preventing hair loss in document (5). This document describes compositions comprising, among other ingredients, the amino acid glycine, which exhibits chelating properties. However the purpose of these compositions is that of promoting hair growth and reducing the formation of dandruff. These effects are obtained applying the claimed compositions on the scalp for about 10 minutes. Therefore, even conceding that the skilled person would recognize in the use of glycine the use of a chelating agent, nothing in the teaching of (5) could suggest that said chelating agent, when exhibiting the defined necessary activity and when applied for at least eight hours, could prevent normal daily hair loss.

In conclusion, none of the documents cited in the context of the inventive step, taken alone or in combination, could direct the skilled person to the solution of the technical problem as proposed by claim 1 of the auxiliary request.

Therefore, in the Board's judgement, the subject-matter of claim 1, and, accordingly, of dependent claims 2 to 12 of the auxiliary request involves an inventive step.

9. Claim 1 of the auxiliary request is in amended form. The scope of this claim was limited during the appeal proceedings in order to delimit the invention with respect to the content of document (6), which was considered by the Board as the most relevant prior art document. This document is not acknowledged in the description of the patent in suit.

Decision T 450/97 (OJ EPO, 1999, 67) laid down (point 4) that, since the novel and inventive character of the invention is defined on the basis of the closest prior art, the document representing this closest prior art is essential for the understanding of the invention. Therefore, citation of this document in the amended description, according to Rule 27(1)(b) EPC, is regarded as mandatory.

For this reason, the Board exercises the discretionary power conferred by Article 111(1) EPC and remits the case to the Opposition Division for further prosecution and adaptation of the description to the claims held valid by the Board.

**Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of the following documents:
  - (a) claims 1 to 12 submitted during oral proceedings as auxiliary request, and
  - (b) a description to be adapted thereto.

The Registrar:

The Chairman:

P. Martorana

P. A. M. Lançon