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D E C I S I O N
of 19 June 1995

Case Number: T 0712/92 - 3.3.4

Application Number: 86306922.5

Publication Number: 0219220

IPC: A61L 2/18

Language of the proceedings: EN

Title of invention:
Method and composition for the simultaneous cleaning and disinfecting of contact lenses

Patentee:
ALLERGAN, INC

Opponent:
Pilkington Visioncare Inc.
Bausch & Lomb Inc.
Alcon Pharma GmbH
CIBA-GEIGY Patentabteilung

Headword:
cleaning lenses/ALLERGAN

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty (yes)"
"Inventive step (no) - obvious to try with reasonable expectation of success"

Decisions cited:
T 0124/87; T 0293/88; T 0219/83; T 0547/88; T 0666/89; T 0741/91; T 0296/93; T 0119/82; T 0229/85; T 0009/86

Catchword:
-

Case Number: T 0712/92

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 19 June 1995

Appellant: ALLERGAN, INC
(Proprietor of the patent) 2525 Dupont Drive
Irvine, California 92715 (US)

Representative: Hutchins, Michael Richard
FRY HEATH & SPENCE
The Old College
53 High Street
Horley
Surrey RH6 7BN (GB)

Respondent 01: Pilkington Visioncare Inc
(Opponent 01) 2429 Sandhill Road
Menlo Park CA 94025 (US)

Representative: Woodcraft, David Charles
BROOKS & MARTIN
High Holborn Road
52/54 High Holborn
London, WC1V 6SE (GB)

Respondent 02: Bausch & Lomb Inc.
(Opponent 02) 1400 North Goodman Street
Rochester, New York 14602 (US)

Representative: Allam, Peter Clerk
LLOYD WISE, TREGEAR & CO.
Norman House
105-109 Strand
London WC2R OAE (GB)

Respondent 03: (Opponent 03)

Alcon Pharma GmbH
Blankreutestr. 1
D-79108 Freiburg (DE)

Representative:

Lederer, Franz, Dr.
Lederer, Keller & Riederer
Patentanwälte
Prinzregentenstrasse 16
D-80538 München (DE)

Respondent 04: (Opponent 04)

CIBA-GEIGY AG
Patentabteilung
Postfach
CH-4002 Basel (CH)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office dated 19 June 1992 revoking European patent No. 0 219 220 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: L. Galligani
J. Saisset

Summary of Facts and Submissions

I. European Patent No. 0 219 220 (application No. 86 306 922.5) relating to a method and composition for the simultaneous cleaning and disinfecting of contact lenses was revoked pursuant to Article 102(1) EPC by the Opposition Division with decision dated 19 June 1992. The Opposition Division held that the subject-matter of the main and seven subsidiary requests on file, although novel, lacked an inventive step.

II. During the procedure before the Opposition Division a large number of documents were relied upon by the parties. Among them the following are of particular relevance for the purpose of the present decision:

(1) US Serial No. 352 861 of 20 April 1973;
(2) US-A-3 553 139;
(3) DE-B-1 617 189
(4) Lo et al., J. Am. Optom. Assoc., 1969, pages 1106 to 1109;
(5) L. E. Janoff, Review of Optometry, January 1984, pages 79 to 82;
(6) C. Stauffer et al., J. Biol. Chem., Vol. 244, No. 19, 10 October 1969, pages 5333 to 5338;
(7) GB-A-1 156 237
(8) US-A-4 155 868
(9) WO-A-85/03247
(10) EP-A-0 140 669
(11) EP-A-0 141 607
(12) DE-A-2 854 278
(13) US-A-4 096 870
(14) GB-A-2 139 260

(15) DE-A-2 221 047

(16) Economic Microbiology, Volume 5, Microbial Enzymes and Bioconversions, 1980, A. H. Rose ed., Academic Press London, pages 49 to 97.

III. The Opposition Division considered document (1) to be the closest prior art and defined the problem to be solved as being the provision of an improved method for both cleaning and disinfecting contact lenses. In its view, the simultaneous application of a peroxide and a proteolytic enzyme for the care of contact lenses was obvious to try for the skilled person having regard to further prior art documents such as, for example, document (2) and document (3), which disclosed detergent compositions containing such agents in combination. Document (4) provided for the skilled person a link between the field of detergents and that of compositions for cleaning contact lenses. The Opposition Division further observed that also the combined teachings of document (1) and document (5) rendered the claimed solution obvious for the skilled person. As regards the seven subsidiary requests, the Opposition Division expressed the view that the restriction of the peroxide to hydrogen peroxide and of the lenses to ones with hydrophilic surfaces represented a limitation to the known most suited peroxide [cf. document (5)] and to lenses for which the application of proteolytic enzymes or hydrogen peroxide was already known as such. Thus, this could not provide a basis for establishing an inventive step.

IV. The Appellants lodged an appeal against the decision of the Opposition Division, paid the appeal fee and submitted the Statement of Grounds together with a

revised set of claims, new citations and the affidavits of Dr H. L. Karageozian, Dr M. A. Voet and Dr K. S. Ambrus.

V. All Respondents made counterstatements and submitted further arguments and evidence in support of their case.

By letter dated 17 December 1993, the Appellants replied and filed declarations of Professors E. G. Woodward, N. Efron and B. Holden.

VI. With letter dated 7 March 1995, the Appellants filed a revised set of claims (Claims 1 to 4) as a main request together with further evidence.

Claim 1 reads as follows:

"A method for simultaneously cleaning and disinfecting contact lenses having a hydrophilic surface, which method comprises contacting a contact lens having a hydrophilic surface with a solution comprising from 0.5% to 10% w/v of hydrogen peroxide and an effective amount of peroxide-active proteolytic enzyme selected from subtilisin and pancreatin for a time sufficient to remove substantially all protein accretions and to disinfect the lens."

Dependent Claim 2 to 4 relate to specific embodiments of the method according to Claim 1.

VII. In a communication pursuant to Article 11(2) of the rules of the procedure of the Boards of Appeal, the Board made preliminary observations on the case.

VIII. By letter dated 2 June 1995, Respondents 03 sent comments in respect of the new main request together with further documents. Among them the following document was cited:

(17) Grant & Hackh's Chemical Dictionary, 5th edition, 1987, McGraw-Hill Book Company, New York USA, page 420.

By letter dated 13 June 1995, the Appellants replied thereto.

IX. Oral proceedings took place on 19 June 1995.

During oral proceedings, the Appellants filed, as an auxiliary request, Claims 1 to 4 which differed from the claims of the main request merely in that the selected proteolytic enzyme was subtilisin.

Respondents 03 submitted the following additional documents:

(18) Advanced Inorganic Chemistry, F. A. Cotton and G. Wilkinson, 1980, J. Wiley & Sons, New York, USA, page 299;
(19) CRC Handbook of Chemistry and Physics, D. R. Lide ed, 1991, CRC Press Boca Raton USA, page **4**-97.

X. The Appellants' submissions may be summarised as follows:

(a) the patent-in-suit provided a one-step method for cleaning and disinfecting soft contact lenses which constituted a considerable simplification of

known two-step methods [cf. documents (5), (12) and (13)] to the benefit of the users who could thereby take much better care of their lenses. A simplification of known methods could constitute a basis for an invention (cf., for example, decision T 293/88, OJ EPO 1992, 220, point 4.3.09). In judging inventive step, any hindsight had to be avoided and account had to be taken of the fact that the claimed method satisfied a long-felt want (cf. the affidavit of Dr Woodward), was a commercial success, was surprisingly simple and effective so that others had tried to copy it. The relevant question in respect of inventive step was not merely whether the proposed method was "obvious to try", i.e. whether the skilled person **could** have tried it, but rather whether the skilled person **would** have tried it with a reasonable expectation of success, this not being merely "the hope to succeed" (cf. T 296/93 of 28 July 1994, to be published in the OJ EPO).

(b) In respect of the combination of proteolytic enzymes with peroxides, in particular with hydrogen peroxide, prior art documents were quite discouraging as they emphasized the resulting inactivation of the enzymes. This was true for different technical areas such as that of enzymes [cf. document (6)], of laundry detergents [cf. document (7)] and of denture cleansers [cf. document (8)]. The rapid inactivation by hydrogen peroxide of enzymes used to clean contact lenses was also indicated in:

(20) Bausch & Lomb Broschure "Technically Speaking", circa 1984.

(c) In view of this prejudice, the skilled person would not have derived from the prior art any incentive to combine a proteolytic enzyme such as subtilisin or pancreatin with an amount of hydrogen peroxide in the range given in Claim 1 in order to achieve simultaneous cleaning and disinfection of contact lenses. Nor would the skilled person have expected such a combination to work at all. This was also for the Appellants an unexpected result for which a proper scientific explanation had yet to be found. Moreover, the combination of the two agents resulted in a synergistic effect (cf. examples in the specification) which was even less foreseeable. Although the Respondents had disputed this effect, none of them had repeated exactly the experiments according to the patent specification. Rather, they had provided their own experiments by using different approaches. Under these circumstances, caution had to be applied and the Appellants had to be given the benefit of the doubt (cf. decisions T 219/83, OJ EPO 1986, 211 and T 547/88 of 19 November 1993, not published in the OJ EPO).

(d) Document (1), referred to by the Opposition Division and by the Respondents as the closest prior art, was an old document merely concerned with the provision of new proteolytic enzymes for cleaning contact lenses. The passage on page 11, lines 12 to 19, on fair reading, taught sequential treatment of contact lenses with a

protease formulation and a non-toxic agent suitable for use in sterilising, i.e. with an agent non-causative of mucosal irritation (cf. affidavit of Dr Karageozian). Even assuming that document (1) taught simultaneous use of a protease and a non-toxic sterilising agent, it related to different proteolytic enzymes, to different sterilising agents and to different amounts thereof. Thus, novelty of the claimed subject-matter was not affected by this document. Furthermore, the skilled person would not have received from this document any incentive to use hydrogen peroxide in the concentration ranges recited in Claim 1 because of its known irritating effect on the eye.

(e) Document (9) - published just before the priority date of the patent-in-suit - was a more up-to-date state of the art than document (1) (cf. decision T 741/91 of 22 September 1993, not published in the OJ EPO). This document clearly indicated that the trend in the care of soft contact lenses was towards the use of heat disinfection because cold disinfection with chemicals often left residues which caused ocular problems (see page 3, third paragraph). As shown by documents (10) and (11), this was in fact the route that had been followed, for example, by Respondents 02, after their initial unsuccessful attempts to establish a valid one-step cleaning and disinfecting method with chemicals (cf. third affidavit of Dr Huth dated 7 April 1992 which discussed the result of the Ogunbiyi's affidavit). As a matter of fact, the patent-in-suit had gone in a different direction,

namely a direction which the average skilled person, a person with a degree in chemistry and an expertise in the art of contact lenses, would not have followed in view of the technical prejudice against the combination of enzymes with peroxides. For these reasons, the claimed subject-matter involved an inventive step.

XI. In reply thereto, the Respondents argued essentially as follows:

(a) Respondents 03 emphasised that the subject-matter of the claims at issue was a method, not a product per se. Thus, in evaluating novelty, it was not proper to make a comparison with compositions to be stored. Moreover, when judging novelty, the total information content of document (1) had to be taken into account (cf. decisions T 124/87, OJ EPO 1989, 491 and T 666/89, OJ EPO 1993, 495) as the skilled reader would have perceived it. This document affected the novelty of Claim 1 of the main request because it disclosed a method for simultaneous cleaning and sterilising soft contact lenses with a solution comprising a combination of proteases and peroxides such as percarbonates, perborates, persulfates (cf. page 11, lines 12 to 19) which was essentially equivalent to the method of the said claim. This was because:

- the term "sterilizing" of document (1) was synonymous of the term "disinfecting" used in Claim 1;

- the quoted peroxides of document (1), when dissolved in water, generated disinfecting amounts of hydrogen peroxide;

- the term "pancreatin" of Claim 1 defined a group of enzymes including trypsin, chymotrypsin, carboxypeptidase and others, i.e. the enzymes quoted in document (1) [cf. page 7, lines 14 to 17; cf. document (17)];

- the term "generally" used on page 11, line 18 in connection with the amount of sterilising agent to be used did not exclude higher amounts than those indicated.

Thus, there was no real technical difference between the teaching of document (1) and the method of Claim 1 of the main request that could justify the acknowledgment of novelty.

(b) With respect to inventive step, Respondents 02 considered that the closest prior art was represented by document (11) which taught cleaning and disinfecting soft contact lenses in aqueous solutions of a proteolytic enzyme (e.g. subtilisin or pancreatin) in a single step by heating to a temperature of between 60 and 100°C and disclosed that the method was effective in spite of the concurrent heat deactivation of the enzyme. In view of the fact that the use of heat for disinfecting contact lenses was inconvenient (cf. the affidavits of Prof. Woodward and Prof. Efron submitted by the Appellants), the problem of finding a single-step method based on cold

disinfection, found an obvious solution in the substitution of heat by hydrogen peroxide which in 1985, i.e. at the time of priority, was the disinfecting agent of choice [cf. document 5)] and was known to be compatible with subtilisin [cf. document (6)].

Both Respondents 03 and 04 considered document (1) to represent the closest prior art. In their submissions, the substitution of disinfecting amounts of perborate by disinfecting amounts of hydrogen peroxide did not involve an inventive step as there was no prejudice in the art against their combined use, especially in view of the large body of evidence in respect of the cleaning and bleaching effects of combinations of proteolytic enzymes with hydrogen peroxide-generating compounds from neighbouring fields such as that of laundry detergents [cf., for example, document (14)] and denture cleansers [cf. document (8)].

(c) All Respondents maintained that the Appellants had not provided any valid evidence for the occurrence of a synergistic effect. In this respect, Respondents 04 observed that the examples had failed to make any comparison between the effect of the simultaneous (alleged invention) and the sequential (state of the art) treatment of lenses with a proteolytic enzyme and hydrogen peroxide. Thus, in their submissions, the results of the examples could not be considered probative of any synergistic effect.

XII. The Appellants requested that the decision under appeal be set aside and that the patent be maintained on the basis of Claims 1 to 4 filed by letter dated 7 March 1995 (main request) or on the basis of the set of Claims 1 to 4 filed during oral proceedings (auxiliary request).

The Respondents requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

Late-filed evidence and other matters

2. As regards documents (18) and (19) submitted during oral proceedings by Respondents 03, the Board considers that these documents relate to general technical knowledge (definition of peroxoborates and physical constants of inorganic compounds, respectively) which, having regard to the large body of evidence already on file, does not add anything that could be regarded as important for the purpose of reaching the final decision. Therefore, the Board exercises its discretion under Article 114(2) EPC to disregard them. Under the provisions of the same article, the Board disregards also document (20) as the parties were unable to provide any evidence that it had been made available to the public before the priority date of the patent-in-suit.

Formal allowability of the amended claims of the main and auxiliary requests

3. Claim 1 of both the main and auxiliary request is restricted in comparison with Claim 1 as granted as it is limited to contact lenses having a hydrophilic surface and to the use of a specified proteolytic enzyme (either subtilisin or pancreatin) and of hydrogen peroxide in a specified w/v concentration range. All these amendments find formal support in the application as originally filed. Thus, there are no objections under Article 123(2) and (3) EPC to the amended claims.

The main request: novelty (Article 54 EPC)

4. Respondents 03 maintained that the method according to Claim 1 is substantially identical with the method disclosed in document (1) [see Section XI, item (a) supra]. The Board cannot share this view. The method according to the said Claim 1 is characterised by three specific technical features which are not found in document (1), namely **(i)** the type of proteolytic enzyme to be used which is either subtilisin or pancreatin, **(ii)** the type of peroxide to be used which is hydrogen peroxide and **(iii)** the concentration of the latter. Although the term "pancreatin" does not define a unique enzyme but a group of enzymes [cf. document (17)] some of which are recited on page 7, lines 14 to 17 of document (1), it is a scientifically meaningful technical term which defines such a mixture of enzymes as a whole in terms of its origin (extracted from pancreas). This cannot be equated with the recitation of the individual proteolytic enzymes of document (1) where no reference is made to a mixture of enzymes of the "pancreatin" or "subtilisin" kind. As regards hydrogen peroxide and its concentration ranges,

although it is true that the peroxides recited in document (1), when dissolved in water, generate hydrogen peroxide, it is known in the art that the technical effect of disinfection depends upon the nature and the amount of the peroxide used [cf. document (15), pages 6 and 7]. Document (1) does neither refer specifically to the direct use of hydrogen peroxide nor to the use of a concentration of another peroxide capable of generating amounts of hydrogen peroxide corresponding to those recited in Claim 1. Thus, the specification of the hydrogen peroxide and of its concentration range constitute further technical features which distinguish the method of Claim 1 from the method disclosed in document (1). For these reasons, the subject-matter of Claim 1 is novel having regard to document (1). No other prior art document affects the novelty of the said claim so that no objection under Article 54 EPC arises.

The main request: inventive step (Article 56 EPC)

5. In the Board's judgement, the most appropriate starting point for the evaluation of inventive step is represented by document (11). This document, which was published shortly before the priority date of the patent-in-suit, is certainly representative of an up-to-date state of the art which was available to the skilled person at the time the claimed invention was made (cf. decision T 741/91 supra). Document (11) relates to a one-step method for cleaning and disinfecting soft contact lenses (e.g. lenses having a hydrophilic surface) which consists in enzymatically treating the lenses in an aqueous solution of a proteolytic enzyme by heating to a temperature of

between 60 and 100°C. Subtilisin and pancreatin are among the representative proteolytic enzymes (see, for example, page 3, lines 10 to 15 and Example I on page 8). The method, besides providing a less complex and more convenient regimen for the care of contact lenses, is said to have the added benefit of concurrent deactivation of the active enzymes by the time the cycle is completed (cf. page 2, lines 18 to 20). Thus, after treatment according to the method of document (11), the lenses are ready for reinserting onto the eyes (see page 7, lines 31 to 32) because the method is said to be effective and safe (cf. page 4, lines 5 to 8).

6. In the light of document (11), the Board considers that the technical problem to be solved is the provision of a simpler one-step method for cleaning and disinfecting soft contact lenses.

7. As a solution the patent-in-suit proposes the method according to Claim 1 of the main request whereby the enzymatic cleaning of the lenses by means of either subtilisin or pancreatin is carried out in an aqueous solution comprising from 0.5% to 10% w/v of hydrogen peroxide. The evidence on file indicates that the method claimed solves indeed the underlying technical problem as it allows a convenient and effective care of contact lenses.

8. The question to be asked in the present case is whether or not the person skilled in the art, faced with the problem of further simplifying the one-step method according to document (11), would have readily considered carrying out the cleaning step with

pancreatin or subtilisin in an aqueous solution containing disinfecting amounts of hydrogen peroxide, i.e. substituting a cold chemical disinfection step for the heat disinfection step. In this respect, it must be observed that the skilled reader of document (11) easily recognised that thermal disinfection, although effective and safe - and this is important because the proteolytic enzymes used for the care of contact lenses can inter alia induce an allergic response among some users [cf. document (10)] -, had inter alia the obvious inconvenient of requiring the use of heating devices which was not very practical.

9. The Appellants maintain that the skilled person, being aware of the inactivating effect of hydrogen peroxide on the proteolytic enzymes, **would not have** tried this approach with any reasonable expectation that it could work or, much less, that a synergistic effect could be obtained (cf. Section X supra), as there existed a prejudice against combining in a one-step method an enzyme and hydrogen peroxide.

10. The Respondents consider that the teaching in document (11) that an effective cleaning and disinfection of soft contact lenses can be obtained in a one-step method in spite of the deactivation of the proteolytic enzymes by the time the cycle is completed rendered obvious for the skilled person the substitution of heat by hydrogen peroxide, as this was at that time the cold chemical disinfectant of choice [cf., for example, document (5)]. In this respect, Respondents 02 point in particular to the similarities between the heat stability curve of subtilisin reported in Figure 3 of document (16) and the curve of the

change in activity of subtilisin in the presence of hydrogen peroxide reported in Figure 1 of document (6). In their submissions, this comparison would have prompted the skilled person to proceed to the substitution of heat by hydrogen peroxide. In any case - they submit -, no real prejudice against the use of proteolytic enzymes in the presence of hydrogen peroxide-generating compounds could be derived from the literature and no synergistic effect had been made plausible by the Appellants (see Section XI supra).

11. In the Board's judgement, for the reasons outlined hereinafter, the observation made in document (11) about the "added benefit of concurrent deactivation of the active enzymes by the time the cycle is completed" would indeed have given the skilled person, faced with the problem of further simplifying the known one-step method, an important indication in the direction of the solution claimed in the patent-in-suit. The skilled person, a person with a degree in chemistry and an expertise in the care of contact lenses, was aware of the fact that, although it was important for proper cleaning of the lenses to ensure sufficient enzymatic activity, residues of the active enzyme on the lenses could cause problems to the users [allergic reactions, unpleasant odours, discoloration of the lens etc.; cf., for example, document (10), page 2]. Thus, the indication given in document (11) that the cleaning action of the proteolytic enzymes was not compromised by the concurrent heat disinfection and that - as a matter of fact - the concurrent deactivation of the enzyme, far from being a disadvantage, was an added benefit, taught the skilled person that within the framework of a single-step cleaning and disinfection

method a proper balance between enzyme activity and its inactivation had to be sought because it would be advantageous.

12. In the Board's view, the skilled person wishing - for practical reasons - to dispose of thermal disinfection in the known method according to document (11) would have immediately considered the alternative of cold disinfection with chemicals such as peroxides, thimerosal etc., as the latter was common wisdom [cf., for example, documents (1), (9) and (1)]. In view of the fact that by 1985 the use of hydrogen peroxide, in particular of a 3% solution thereof, for disinfecting soft contact lenses after an enzyme cleaning step was well known in the art [cf., for example, documents (5) and (12)], the skilled person would have readily considered the possibility of substituting cold disinfection with hydrogen peroxide for thermal disinfection. The known deactivating effect of hydrogen peroxide on proteolytic enzymes such as subtilisin [cf., for example, documents (6) to (8)] **would not have discouraged** the skilled person from entering into this route because:

- firstly, he or she knew from the prior art [cf., for example, document (6), in particular summary and Figure 1] that the deactivating effect was not sudden and complete, but rather gradual, just like the heat deactivating effect [cf. document (16), in particular Figure 3];

- secondly, the task was not the preparation of a composition to be stored, in which case the stability of the enzyme over the storage period

had to be ensured [cf. in this respect e.g. document (8)], but the carrying out of a simultaneous cleaning and disinfecting activity on contact lenses, i.e. an operation for which a short cycle was an advantage [cf. document (10), page 12, lines 24 to 33] and for which the final deactivation of the enzyme was actually a benefit [cf. document (11)];

- thirdly, combinations of proteolytic enzymes with hydrogen peroxide-generating compounds were successfully used for thoroughly cleaning other kinds of protheses, e.g. dentures [cf., for example, document (8)].

13. Thus, in the Board's judgement, the evidence put forward by the Appellants in support of possible reservations that the skilled person would have had about combining in a one-step method a proteolytic enzyme with hydrogen peroxide must fail in the light of what the skilled person knew shortly before the priority date of the patent-in-suit which was suitable to remove possible doubts. Therefore, The Appellants have not demonstrated the existence - at the time the invention was made - of a **real** prejudice in the art which might have diverted the skilled person away from the method as claimed in the patent-in-suit (cf. T 119/82, OJ EPO 1984, 217, see points 14 and 15 of the Reasons).

14. The Board is of the opinion that a skilled person, faced with the problem of further simplifying the method according to document (11), would have readily tried to carry out in one step cleaning and

disinfection of soft contact lenses by treating the lenses with a proteolytic enzyme such as subtilisin or pancreatin in an aqueous solution of a disinfecting amount of hydrogen peroxide. Based on the quoted prior art knowledge, the skilled person would have reasonably expected this approach to work as he or she knew that, on the one hand, in spite of the gradual loss of enzymatic activity, there would have been sufficient enzyme activity at least in the first part of the cycle [cf. document (6), in particular Figure 1] to ensure removal of the protein accretions (cleaning) and that, on the other hand, the deactivation of the enzyme - in consequence of the presence of hydrogen peroxide - by the time the cycle was completed would have been beneficial [cf. document (11), page 2, lines 18 to 20).

15. As regards the controversial question whether or not there is synergism in the combination of the proteolytic enzyme and hydrogen peroxide, the Board observes, in agreement with the Respondents, that the relevance of the comparisons reported in the examples of the patent-in-suit in relation to an alleged synergism is quite doubtful and that, in any case, a comparison between the effect of the simultaneous (patent-in-suit) and the sequential (state of the art) treatment of lenses with a proteolytic enzyme and hydrogen peroxide is missing. Such a comparison would have been appropriate in order to support a synergistic effect.

16. Although it is true that the simplicity of a proposed technical solution could be indicative of inventiveness, especially if the technical field is of commercial importance and if, despite the considerable

amount of activity in the field, the said solution had escaped those concerned (see, for example, T 229/85, OJ EPO 1987, 237, in particular point 7 of the Reasons and T 9/86, OJ EPO 1988, 12, in particular point 6 of the Reasons), nevertheless the recognition of an inventive step presupposes the absence in the prior art of hints at the proposed solution. In the present case, for the reasons given above, the Board is of the opinion that the skilled person was prompted by the state of the art to go into the direction of the claimed method. The so-called "secondary indicia" relied upon by the Appellants, such as long-felt want and commercial success, cannot alter the Board's finding on obviousness because they are not convincing in the light of what the skilled person would have reasonably expected on the basis of the up-to-date knowledge at the priority date. Moreover, indicia such as commercial success may depend upon factors, such as market monopoly, advertisement policy etc., which are unrelated to technical features of the invention.

17. *Auxiliary request*

Claim 1 of this request is restricted to subtilisin as selected proteolytic enzyme. This is one of the two embodiments of Claim 1 of the main request. Thus, obviously, the same reasoning given in respect of novelty and inventive step of Claim 1 of the main request (cf. points 4 to 16 supra) applies to this claim.

Conclusion

18. For the above reasons, Claim 1 of both the main and auxiliary request lacks an inventive step and, therefore, none of the requests is allowable so that the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

L. McGarry U. Kinkeldey