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**Datasheet for the decision
of 27 January 2009**

Case Number: T 0368/06 - 3.3.10

Application Number: 97912423.7

Publication Number: 0888780

IPC: A61L 2/18

Language of the proceedings: EN

Title of invention:

Treatment composition for contact lenses and method for
treating contact lenses with the same

Patentee:

Menicon Co., Ltd.

Opponent:

Hödl Joseph

Headword:

Treatment composition for contact lenses/MENICON

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (yes) - non-obvious solution"

Decisions cited:

-

Catchword:

-



Case Number: T 0368/06 - 3.3.10

DECISION
of the Technical Board of Appeal 3.3.10
of 27 January 2009

Appellant: Hödl Joseph
(Opponent) Drei Raine 1
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Representative: Best, Michael
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Respondent: Menicon Co., Ltd.
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Representative: Paget, Hugh Charles Edward
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
9 February 2006 concerning maintenance of
European patent No. 0888780 in amended form.

Composition of the Board:

Chairman: R. Freimuth
Members: J. Mercey
F. Blumer

Summary of Facts and Submissions

I. The Appellant (Opponent) lodged an appeal on 9 March 2006 against the interlocutory decision of the Opposition Division posted on 9 February 2006 which found that European patent No. 888 780 in amended form met the requirements of the EPC.

II. The decision under appeal was based on an amended set of thirteen claims, independent claims 1, 2 and 5 thereof reading as follows:

"1. Use of a composition to treat a contact lens, which composition includes at least one compound selected from the group consisting of 2-amino-2-methyl-1,3-propanediol, 2-amino-2-methyl-1-propanol, and salts thereof, as a component effective for preventing said contact lens from being stained, wherein said at least one compound is included in said treating composition in an amount of 0.01-3 wt.%."

"2. A composition for cleaning a contact lens which includes, in an aqueous medium, an effective amount of protease and not less than 5 w/v% of at least one compound as a stabilizing component for stabilizing said protease, said at least one compound being selected from the group consisting of 2-amino-2-methyl-1,3-propanediol, 2-amino-2-methyl-1-propanol, and salts thereof, and being a component effective for preventing said contact lens from being stained."

"5. A method of treating a contact lens for giving said contact lens an anti-staining property, said method comprising the steps of:

(i) preparing a treating solution which includes 0.01-3 wt.% of at least one compound selected from the group consisting of 2-amino-2-methyl-1,3-propanediol, 2-amino-2-methyl-1-propanol, and salts thereof, as a component effective for preventing said contact lens from being stained; and

(ii) contacting said contact lens with said treating solution."

III. Notice of Opposition had been filed by the Appellant requesting revocation of the patent as granted in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC). *Inter alia* the following documents were submitted in opposition proceedings:

- (2) PubMed-Abstract of H. Kikuchi et al., *Tohoku J Exp Med.* 1994, 173, 391 to 397,
- (3) PubMed-Abstract of R. A. Stinson, *Clin Chem.* 1993, 39, 2293 to 2297,
- (5) PubMed-Abstract of F. Schiele et al., *Clin Chim Acta.* 1981, 112, 187 to 195,
- (7) PubMed-Abstract of K. Lewandrowski et al., *Clin Chem.* 1992, 38, 2286 to 2294,
- (8) PubMed-Abstract of B. E. Miller et al., *Exp Lung Res.* 1987, 12, 135 to 148 and
- (12) US-A-5 422 073.

IV. The Opposition Division held that the subject-matter of the then pending main request was novel and involved an inventive step, document (12) being considered to represent the closest prior art.

V. The Appellant submitted that the subject-matter of claims 1, 2 and 5 as maintained by the Opposition Division was not inventive and also identified document (12) as the closest prior art. With letter dated 23 January 2009, it further submitted document (15):

(15) ANGUS Chemical Company Technical Bulletin TB 69
TRIS AMINO®

the relevant disclosure of which was described in document (12), namely that 2-amino-2-hydroxymethyl-1,3-propanediol (TRIS) held the pH of contact lens cleaning solutions in the range most favourable for hydrolysis of protein films on lens surfaces. The Appellant submitted that the hydrolysis of protein films on lens surfaces was technically equivalent to the removal of proteinaceous deposits. In the light of this disclosure, the problem to be solved by the subject-matter of claim 5 could be seen merely as the provision of an alternative method of treating a contact lens achieving an anti-staining effect. It argued that although all of the examples in the specification of the patent in suit did indeed solve the problem, it was questionable whether all 2-amino-2-methyl-1,3-propanediol (AMPD) and/or 2-amino-2-methyl-1-propanol (AMP) containing compositions would have an anti-staining effect, and in view of the presence of additional components in Examples 2 and 3 of the specification of the patent in suit, a causal effect between AMPD and/or AMP and the anti-staining effect had not been shown. With regard to inventiveness of the claimed solution, since it was known from document (12) that TRIS may advantageously be used in a solution which is used to remove stains from contact lenses, and in view of the very high

structural similarity between AMPD, AMP and TRIS, documents (2), (3), (5), (7) and (8) further teaching that AMPD, AMP and TRIS had similar buffering properties, the skilled person would have expected that in a method of treating contact lenses, solutions comprising AMPD, AMP or TRIS would have similar protein removal capacity. For the same reasons, the use according to claim 1, which related to essentially the same subject-matter as the method of claim 5, and the composition of claim 2, were also not inventive.

VI. The Respondent (Patent Proprietor) submitted that the claimed subject-matter was inventive and also started from document (12). In view of this prior art, the problem to be solved by the subject-matter of claim 5 was to provide an alternative method of treating a contact lens maintaining an anti-staining effect. It argued that document (12) disclosed merely that TRIS was useful as a pH maintaining agent in contact lens solutions but did not disclose any anti-staining properties of TRIS *per se*. It was therefore not obvious to replace TRIS with either AMP or AMPD, since none of the cited prior art disclosed an anti-staining effect for any of these compounds, the argumentation of the Appellant being based on hindsight. For the same reasons, the use according to claim 1 and the composition according to claim 2 also involved an inventive step. With letter dated 19 December 2008, the Respondent filed auxiliary requests 1 to 3.

VII. The Appellant requested that the decision under appeal be set aside and the patent be revoked.

The Respondent requested that the appeal be dismissed or, subsidiarily, the decision under appeal be set aside and the patent be maintained on the basis of any of auxiliary requests 1 to 3, all requests submitted on 19 December 2008.

VIII. At the end of the oral proceedings held on 27 January 2009, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments and Novelty*

The amendments made to the claims as maintained by the Opposition Division were not objected to by the Appellant, nor does the Board see any reason to question their allowability under Article 123(2) and (3) EPC of its own motion. Furthermore, the appealed decision found the claimed subject-matter to be novel (cf. point IV *supra*). Novelty was no longer contested during the appeal proceedings, nor does the Board see any reason to take a different view to the Opposition Division. Hence, it is unnecessary to go into more detail in this respect.

3. *Inventive step*

3.1 Claim 5 relates to a method of treating a contact lens using a solution including at least one of AMPD or AMP, whereas independent claim 2 relates to a contact lens cleaning composition which additionally mandatorily

includes a protease. For this reason, it is appropriate that the subject-matter of claim 5 is examined first as to its inventive ingenuity, since the solution defined therein is broader than that of claim 2. In case the subject-matter of claim 5 involved an inventive step, then the subject-matter of independent claim 1, which relates to the use for treating a contact lens of the same composition as defined in claim 5, and that of the protease-containing composition of claim 2, would also be inventive. Both parties conceded on these findings. Since the Respondent never argued that the amounts of the AMPD and AMP defined in the claims were either purposive or critical, the fact that different amounts of AMPD and AMP are defined in claim 2 as opposed to in claims 1 and 5, namely not less than 5 w/v% as opposed to 0.01 to 3 wt.%, has no significance for the evaluation of inventive step.

3.2 According to the established jurisprudence of the Boards of Appeal it is necessary, in order to assess inventive step, to establish the closest state of the art, to determine in the light thereof the technical problem which the invention addresses and successfully solves, and to examine the obviousness of the claimed solution to this problem in view of the state of the art. This "problem-solution approach" ensures assessing inventive step on an objective basis and avoids an *ex post facto* analysis.

3.3 Claim 5 is directed to a method of treating a contact lens. Document (12) (see col. 2, lines 23 to 31), describes the disclosure of document (15) (see page 4, left hand column, passage entitled "Contact Lens Cleaner"), namely that TRIS holds the pH of contact

lens cleaning solutions in the range most favourable for hydrolysis of protein films on lens surfaces. The hydrolysis of protein films on lens surfaces corresponds to the anti-staining properties described in the patent in suit, as submitted by the Appellant. Thus, the Board considers, in agreement with the Respondent, the Appellant and the Opposition Division, that in the present case the above-mentioned passage of document (12) represents the closest state of the art and, hence, takes it as the starting point when assessing inventive step.

3.4 In view of this state of the art the problem underlying the subject-matter of claim 5 consists in providing an alternative method of treating a contact lens which achieves an anti-staining effect.

3.5 As the solution to this problem, claim 5 proposes a method which uses a solution including 0.01 to 3 wt.% of at least one of AMPD or AMP.

3.6 In view of the results of Example 1 given in Table 1 of the specification of the patent in suit, which show that AMPD- and AMP-containing solutions reduce the amount of protein adhering to a contact lens and thus achieve an anti-staining effect, it is credible that the problem underlying the patent in suit has been successfully solved.

The Appellant argued that it had not been convincingly shown that the problem had been successfully solved, since in Examples 2 and 3 other compounds apart from AMPD or AMP, such as surface active agents and disinfectants, were also present in the solutions

tested, such that the anti-staining effect could not be unambiguously attributed to the presence of the AMPD or AMP. However, since no additional compounds are present in the solutions tested in Example 1, apart from buffering amounts of acid or base, this example clearly demonstrates that solutions containing AMPD or AMP alone have an anti-staining effect, when used in a process for treating contact lenses, such that the Appellant's argument is devoid of merit.

The Appellant further submitted that it was doubtful whether any solution containing 0.01 to 3 wt.% of at least one of AMPD or AMP would solve the problem, i.e. achieved an anti-staining effect when brought into contact with contact lenses. However, the Appellant, who bears the burden of proof for its allegations, has neither provided substantiating facts nor corroborating evidence that not all solutions used in the process according to the invention would provide an anti-staining effect when treating a contact lens, with the consequence that its unsubstantiated allegation is not to be taken into account by the Board, which of its own motion has no reasons to doubt the success of the claimed solution.

3.7 Finally, it remains to be decided whether or not the proposed solution to the problem underlying the patent in suit is obvious in view of the cited prior art.

3.7.1 None of the documents addressed by the Appellant taught an anti-staining effect for AMPD or AMP. More particularly, the documents (2), (3), (5), (7) and (8) do not address anti-staining at all, let alone of either AMPD or AMP, but instead merely describe their

buffering properties. Furthermore, these documents do not belong to the same technical field as the present invention, since they do not address contact lenses. There is thus no suggestion in any of these documents to use a solution comprising at least one of AMPD and AMP in a process to treat a contact lens to achieve an anti-staining effect.

3.7.2 The Appellant argued that since document (12) taught that a TRIS-containing solution was advantageous for the removal of protein stains on lens surfaces, the skilled person, seeking an alternative method of treating a contact lens which achieves an anti-staining effect, would have expected solutions containing compounds structurally and chemically similar to TRIS to also be effective in achieving anti-staining. Thus the use of solutions containing AMPD and/or AMP, said compounds being structurally very similar and having similar buffering properties to TRIS, as shown by documents (2), (3), (5), (7) and (8), would have provided an obvious alternative.

However, document (12) does not teach a causal link between the protein stain removal effect described therein and TRIS *per se*, but rather merely teaches that the buffering properties of TRIS are favourable for allowing the hydrolysis of protein stains. Since, the teaching of document (12) has to be taken at its face value, it addresses exclusively the buffering property of TRIS and is silent with respect to any anti-staining effect thereof. Thus, there is no incentive for the skilled person to substitute TRIS for another, even structurally and chemically similar compound, when seeking an alternative method of treating contact

lenses for achieving an anti-staining effect, i.e. for solving the problem underlying the invention. Thus all of the Appellant's arguments in support of inventive step which were based on the premise that TRIS was described as having any anti-staining effect are not supported by the facts, since such an anti-staining effect for TRIS is not taught by document (12).

- 3.8 For these reasons, the Board concludes that the method of treating a contact lens according to independent claim 5, and by the same token (see point 3.1 above) the use to treat a contact lens of independent claim 2 and the composition of independent claim 1, together with the subject-matter of dependent claims 3, 4 and 6 to 13, involves an inventive step within the meaning of Articles 52(1) and 56 EPC.

Auxiliary requests

Since the main request is allowable for the reasons set out above, there is no need for the Board to decide on the lower ranking auxiliary requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

C. Rodríguez Rodríguez

R. Freimuth