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**Datasheet for the decision  
of 11 October 2007**

**Case Number:** T 0216/05 - 3.3.06

**Application Number:** 98123311.7

**Publication Number:** 0909808

**IPC:** C11D 3/20

**Language of the proceedings:** EN

**Title of invention:**

Process for cleaning and disinfecting contact lenses

**Patentee:**

ALCON LABORATORIES, INC.

**Opponent:**

Knobbe, Martens, Olson & Bear, LLP

**Headword:**

Protein removal agent/ALCON

**Relevant legal provisions:**

EPC Art. 123(2), 56

**Keyword:**

"Added subject-matter (main and first to fifth auxiliary requests): yes"

"Inventive step (sixth auxiliary request): no - obvious modifications"

**Decisions cited:**

G 0010/91

**Catchword:**

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Case Number: T 0216/05 - 3.3.06

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.06  
of 11 October 2007

**Appellant:** ALCON LABORATORIES, INC.  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 17 January 2005  
revoking European patent No. pursuant to  
Article 102(1) EPC.

**Composition of the Board:**

**Chairman:** P.-P. Bracke  
**Members:** P. Ammendola  
U. Tronser

## Summary of Facts and Submissions

I. This appeal is from the decision of the Opposition Division to revoke the European patent No. 0 909 808 concerning a process for cleaning and disinfecting contact lenses by using an aqueous single solution (hereinafter "SS") containing a protein removal and cleaning agent and an antimicrobial agent.

II. Claims 1 and 13 of the patent as granted read:

"1. *Use of at least one polycarboxylate or corresponding acid, or a combination thereof, as a protein removal agent and cleaning agent in an aqueous single solution for both cleaning and disinfecting a contact lens, said solution additionally comprising an ophthalmically acceptable antimicrobial agent in an amount effective to disinfect the lens.*"

"13. *Process for cleaning and disinfecting a contact lens with a single solution product which comprises performing the following steps on a daily basis:*

*rubbing a small amount of the single solution over the surfaces of the lens;  
rinsing the lens with the same single solution to remove all debris; and*

*soaking the lens in the same single solution for a time sufficient to disinfect the lens;*

*wherein the single solution comprises a protein removal and cleaning agent which consists*

*essentially of a polycarboxylate or corresponding acid, or a combination thereof for removing protein deposits from the lens and in an amount effective to clean the lens, an ophthalmically acceptably antimicrobial agent in an amount effective to disinfect the lens; and an aqueous vehicle therefor; and provided that the solution does not contain lysozyme therein."*

- III. The Opponent had sought revocation of the patent in suit on the grounds of lack of novelty and inventive step (Article 100(a) in combination with Articles 52(1), 54 and 56 EPC) by relying, *inter alia*, on document (1) = US 4,808,239.
- IV. The Opposition Division had revoked the patent because none of the amended sets of claims according to the then pending main and auxiliary requests of the Patent Proprietor complied with the requirements of the EPC.
- V. The Patent Proprietor (hereinafter Appellant) lodged an appeal against this decision also requesting oral proceedings as an auxiliary measure. It filed with the grounds of appeal four sets of amended claims as main request and first to third auxiliary requests. The grounds of appeal also contained some experimental data.
- VI. The Opponent (hereinafter Respondent) in its reply also requested oral proceedings.
- VII. The Board summoned the parties to oral proceedings to be held on 11 October 2007.

VIII. The Appellant filed with letter of 4 September 2007 six sets of amended claims labelled as **main request** and **first to fifth auxiliary requests** replacing its previous requests.

IX. The Respondent commented the last requests of the Appellant in a letter dated 28 September 2007, thereby raising for the first time objections under Article 100(c) EPC in respect of features in the claims of these requests that were already present in the granted claims.

X. Oral proceedings took place before the Board as scheduled. At the hearing the Appellant approved the consideration of Article 100(c) EPC as a fresh ground of opposition and filed another set of amended claims labelled as **sixth auxiliary request**.

XI. For the present decision it is sufficient to consider the following independent claims of the Appellant's requests:

claim 9 of the **main request**, which is identical to claim 13 as granted (see above section II);

claim 9 of the **first auxiliary request**, which differs from claim 13 as granted only in that the wording "*consists essentially of*" has been replaced with "*consists of*";

claim 9 of the **second auxiliary request**, which differs from claim 13 as granted only in that the wording "*and wherein the protein removal and cleaning agent*

*consists of a polycarboxylate or corresponding acid, or a combination thereof.*" has been added at the end of the claim;

claim 9 of the **third auxiliary request**, which differs from claim 13 as granted only in that the wording "*to clean the lens,*" has been replaced with "*to clean the lens as sole protein removal and cleaning agent,*";

claim 6 of the **fourth auxiliary request**, which differs from claim 13 as granted only in that the wording "*, wherein the polycarboxylate or corresponding acid is citric acid, sodium, potassium or ammonium citrate, or mixtures thereof.*" has been added at the end of the claim;

claim 1 of the **fifth auxiliary request**, which is identical to claim 6 of the fourth auxiliary request;

and

claim 1 of the **sixth auxiliary request**, which differ from claim 1 as granted (see above section II) in that the wording "*Use of at least one polycarboxylate or corresponding acid, or a combination thereof, as*" has been replaced with "*Use of a combination of least one polycarboxylate and corresponding acid, as*" and in that the wording "*, wherein the polycarboxylate or corresponding acid is citric acid, sodium, potassium or ammonium citrate, or mixtures thereof, whereby the solution contains the polycarboxylate or corresponding acid in an amount of from 0.013 to 0.13 moles per litre of solution and wherein the solution is surfactant-free.*" has been added at the end of the claim.

XII. In respect of the basis in the application as originally filed for the feature of the claimed process reading "*provided that the solution does not contain lysozyme therein*" (hereinafter this feature is indicated as "the proviso"), the Appellant argued that the skilled person would consider a technical nonsense to introduce lysozyme in SSs. This would also be implicit in the disclosure of the application as filed that lysozyme formed the deposits to be removed by the SS of the invention. Accordingly, in the examples of the application as filed lysozyme was only used for artificially soiling the contact lenses needed in order to test the invention.

In respect of the inventiveness of the use according to claim 1 of the sixth auxiliary request the Appellant, after having initially argued at the oral proceedings that no combination of citrate and citric acid was present in the SSs of document (1), did not dispute the Respondent's reply thereto that this document explicitly mentioned the partial conversion of citric acid into the citrate acting as calcium chelating agent and that such conversion had also necessarily occurred in the examples in this citation, wherein the pH is 7. The Appellant argued however that a skilled person starting from the prior art of document (1) would have no reason to replace the essential surfactant ingredient used in the examples of this citation by the optional citric acid and citrate ingredients. Indeed, this document attributed the cleaning activity to the surfactant only, the citric acid and citrate only being disclosed therein as optionally contributing to such activity.

XIII. The Respondent refuted these arguments by maintaining, *inter alia*, that the skilled person would not consider the addition of lysozyme to SSs as a technical nonsense and, hence, that the proviso contained in the claims of the main and of the first to fifth auxiliary requests amounted to added subject-matter.

Moreover, document (1) would not only disclose the presence of both citrate and citric ingredients in the examples prepared starting from citric acid and having pH 7, but also described that the combination of these ingredients *per se* was sufficient to produce removal of protein and calcium containing deposits from contact lenses. As the protein removal ability of citrates and citric acid was already known, the subject-matter of claim 1 of the sixth auxiliary request lacked an inventive step.

XIV. The Appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the claims according to the main request or alternatively any of the first to fifth auxiliary requests filed under cover of the letter dated 4 September 2007 or the sixth auxiliary request submitted during the oral proceedings.

The Respondent requested that the appeal be dismissed.



## Reasons for the decision

*Appellant's main request and the first to fifth auxiliary requests: added subject-matter (Articles 100(c) and 123(2) EPC)*

1. The proviso that the solution of the invention should not comprise lysozyme is contained, *inter alia*, in all independent process claims of the Appellant's requests, i.e. in claim 9 of the main request and of the first to third auxiliary requests, in claim 6 of the fourth auxiliary request and in claim 1 of the fifth auxiliary request (see section XI of the Facts and Submissions).

The Respondent has during these appeal proceedings argued for the first time that the proviso lacked of a basis in the application as originally filed (see section IX of the Facts and Submissions).

As the same proviso was already present in, *inter alia*, claim 13 of the patent as granted (see section II of the Facts and Submissions) and since added subject-matter was not a ground of opposition during the preceding opposition proceedings, this objection attempts to introduce a fresh ground of opposition, that of Article 100(c) EPC.

At the oral proceedings the Appellant has however expressly approved the consideration of this fresh ground of opposition and, thus, the compliance of the above identified proviso with the requirements of Article 123(2) EPC has been discussed by the parties (see section X of the Facts and Submissions).

Hence, the Board can decide thereupon (see the opinion of the Enlarged board of appeal G 10/91, OJ EPO 1993, 420, point 18 of the reasons).

2. It is undisputed that the application as filed does not disclose explicitly that the solution of the invention should not comprise lysozyme.

The Appellant has, however, stressed that lysozyme is present in tears and forms the protein deposits that soils the worn contact lenses to be cleaned by the SS of the invention. This would be evident from the disclosure in the application as originally filed that:

a) the protein removal agents of the invention promote the solubilisation of cationic lysozyme deposits and displace lysozyme bound by polymers (see the application as originally filed, from page 4, lines 18 to page 5, lines 4),

and

b) whereas lysozyme was absent from the solutions of the invention exemplified in the application, lysozyme solutions were used for artificially soiling the lenses needed as specimen for testing the efficacy of the invention (see the application as originally filed, examples).

Hence, in the Appellant's opinion, the skilled reader of the application as originally filed would necessarily consider as a technical nonsense to add lysozyme into the SS of the invention.

2.1 The Boards notes initially that the above identified proviso excludes the presence of lysozyme in any amount, i.e. even in amounts that cannot possibly result in any appreciable quantity of deposit on the lenses.

Moreover, the original disclosure identified in a) and b) refers to the deposit of lysozyme under conditions which are substantially different from those occurring during the use of the cleaning composition of the invention. In particular, it refers to the conditions artificially created in order to rapidly deposit lysozyme onto lenses, including e.g. heating the lenses immersed in a lysozyme solution at 90°C, or to those normally occurring during lens wearing into the eyes and thus, *inter alia*, in presence of several ingredients, such as the lysozyme binding polymers and calcium ions, that are not present or present in much different amounts during the lens cleaning with the SS of the invention. Hence, it cannot even be concluded from the cited disclosure in the application as filed that if lysozyme were present in substantial amounts in the SS of the invention, e.g. in the same concentration as in tears, it would also necessarily deposit during the cleaning process in such an amount to appreciably impair the efficacy of such process.

Accordingly, the disclosure of the application as originally filed is found insufficient for rendering plausible that the addition of lysozyme in any amount in the SS of the invention would appear a technical nonsense to the skilled person.

- 2.2 Therefore, the proviso under consideration is found neither explicitly disclosed in the application as filed nor necessarily implied therein.

As this proviso has no basis in the application as filed, its presence in claim 9 of the main request and of the first to third auxiliary requests, in claim 6 of the fourth auxiliary request and in claim 1 of the fifth auxiliary request violates the requirements of Article 123(2) EPC.

Hence, none of these requests is allowable.

*Appellant's sixth auxiliary request: inventive step for the subject-matter of claim 1 (Articles 52(1) and 56 EPC EPC)*

3. This claim describes the use of a given amount of a combination of citrate and citric acid (hereinafter "citrate combination") as protein removal agent and cleaning agent in surfactant-free Ss also containing an effective amount of an antimicrobial agent (see section XI of the Facts and Submissions).

The Respondent has only objected to this claim in respect of the presence of inventive step.

- 3.1 The Board notes that the patent in suit explicitly acknowledges that the invention lays in the finding that Ss based on polycarboxylates, such as the citrate combination, are comparable to those based on surfactants in removing deposits from contact lenses (see patent as granted, paragraphs 1, 5, 8 and 32).

Moreover, paragraphs 13, 15 and 16 clarify that these polycarboxylates, and in particular citrate and/or citric acid, achieve even in the absence of surfactants a significant degree of cleaning of contact lenses, that are mildly deposited with proteins, calcium and mixed deposit of this latter, through complexation/solubilisation in particular of cationized organic molecules, such as lysozyme at physiological pH values, or of calcium deposits. In particular, citrate is disclosed as able to disrupt intermolecular bridging linking calcium ions to proteins, lipid- or mucous-type soils or microbial cells contaminating the lens surface.

- 3.2 The problem addressed by the patent in suit can, therefore, be identified as that of finding **further** compounds that are capable of cleaning contact lenses mildly soiled with proteins and calcium containing deposits and that are also suitable as ingredients of SSs, i.e. an alternative to the ophthalmically acceptable protein removal and cleaning agents of the SSs of the prior art.
- This has not been disputed among the parties.

- 3.3 Since document (1) mentions specifically the removal of proteins and/or calcium containing deposits from contact lenses and the SSs of the examples therein are obtained starting from citric acid and contains a conventional germicide, i.e. an antimicrobial agent, the Board also concurs with the parties that this prior art represents a suitable starting point for the assessment of inventive step.

- 3.4 It must be stressed that during the oral proceedings before the Board the Appellant has no longer disputed

the evident fact that at pH 7, i.e. at the physiological pH necessarily present to render the SSs of the prior art ophthalmically acceptable (see e.g. the examples in document (1)), part of the citric acid possibly used to produce SSs would necessarily release hydrated protons, thereby converting itself into citrate. Indeed, this common general knowledge is even expressed in column 4, lines 10 to 16, of document (1) where it is stated that citric acid is (similarly to EDTA) preferred as source of hydrated protons because it forms citrate anions and thus is simultaneously a source of hydrated protons and chelating agents. Hence, it is undisputed that the use of citric acid in the production of the SSs of this prior art equates to the introduction therein of a citrate combination in the sense of present claim 1.

3.5 It also is undisputed that the claimed subject-matter solves the posed problem, i.e. that the citrate combination according to claim 1 represents an alternative to the protein removal and cleaning agents present in the SSs exemplified in document (1).

3.6 The Board notes however that document (1) contains also extensive information as to the ability of citric acid and of the citrate anion (also possibly formed upon release of the acid proton from the former) to remove protein and calcium-containing deposits. Indeed, document (1) after having recalled at column 2, lines 30 to 41, that the deposits formed on worn contact lenses consists of proteinaceous material, lipids and calcium, whereby the calcium may be deposited also as calcium-protein or calcium-lipid complex, describes at column 3, lines 22 to 37, the ability of citric acid to act as chelating agent for calcium deposits and at column 3,

line 41 to 43 and lines 63 to 67, that hydrated protons are optionally used in the SS to promote the entire cleaning process through protonation of the deposited proteins, i.e. a mechanism different from that of the chelating agents that are believed to remove inorganic and organic calcium by means of chelation or salt formation. Finally, as indicated already above (see point 3.4), document (1) recognises expressly the use of the citrate combination spontaneously formed in the SSs prepared starting from citric acid as a preferred means for simultaneously obtaining both the protonation and the chelation mechanisms.

- 3.7 The Board finds therefore that document (1) discloses that citrate combinations are effective protein removal agents and are also capable of contributing to the cleaning of other debris from worn contact lenses due to the ability of citrate to chelate calcium.

Hence, the use of a citrate combination as protein removal and cleaning agent in aqueous SSs for both cleaning and disinfecting contact lenses is already disclosed in document (1).

- 3.8 However, it is undisputed that the SSs of the examples containing the citrate combination disclosed in document (1) contain also a surfactant and that the citrate combination amount therein is lower than that required in claim 1 under consideration.

Hence, the question to be answered is whether or not the skilled person starting from this prior art examples would have arrived without exercising inventive ingenuity at the conclusion that the surfactant protein

removal and cleaning agent of document (1) could be omitted and the amount of the citrate combination could be increased, so as to arrive at the presently claimed subject-matter, in the reasonable expectation that these modifications would not impair the ability of the citrate combination to promote the removal of protein and calcium deposits.

3.9 The Appellant has argued that the fact that only the surfactant is mentioned in document (1) (see e.g. claim 1) as the mandatory cleaning ingredient of the SS, would necessarily imply that only this ingredient provides the necessary cleaning of worn contact lenses. Hence, the skilled person would not contemplate replacing such ingredient by the citrate combination, which is only used in document (1) to further promote the cleaning action ensured by the essential surfactant ingredient.

3.10 The Board finds instead that the fact that the surfactant is considered essential in document (1) does not deprive of credibility the portions of document (1) - indicated at point 3.6 above - wherein it is expressly taught that the citrate combination formed in the SSs of this prior art is *per se* provided of the ability to remove protein and calcium containing deposits from contact lenses via chelation and protonation of these debris. Neither the chelation nor the protonation mechanisms disclosed in the portions of document (1) identified above imply an interaction with the surfactant ingredient. Hence, it is well possible that surfactants had been considered essential by the authors of document (1) for other reasons. In particular, from the description at column 3, lines 57 to 67, it seems



that the specific function of the surfactant is rather to remove unfolded proteins and lipid clathrates. Accordingly, nothing in document (1) suggests that the protein and calcium containing deposits removing ability of the citrate combination would be, in the absence of surfactants, substantially impaired.

The Board notes, finally, that no technical effect deriving from the specific concentration range of the citrate combination required in claim 1 is alleged, let alone proved, in the patent in suit or in the submissions of the Appellant. Hence, this feature distinguishing the claimed subject-matter from the prior art can only be considered arbitrary.

- 3.11 Accordingly, the person skilled in the art, searching for a solution to the posed problem (see above point 3.2) would have considered obvious to omit the surfactant ingredient in the examples of document (1), as the desired cleaning effects are disclosed in this citation to be already produced by the citrate combination *per se*.

Nor is an inventive step required for arbitrarily increasing the amount of the citrate combination in the examples of document (1) so as to arrive in the claimed range, as this citation contains no indication of the criticality of the amount of citric acid ingredient to be used or of any other reason apparently suggesting to the skilled person that the citrate combination would lose its efficacy as protein removal and cleaning agent when increasing its concentration.

Therefore, the skilled person would consider obvious to solve the posed technical problem of providing an alternative to the prior art by means of these modifications of the prior art examples, thereby arriving at the claimed use without exercising any inventive ingenuity.

3.12 Thus, the Board concludes that the subject-matter of claim 1 according to the sixth auxiliary request of the Appellant does not involve an inventive step. Hence, this claim does not comply with the requirements of Articles 52(1) and 56 EPC and, therefore, the sixth auxiliary request is not allowable.

**Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:

G. Rauh

P.-P. Bracke