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D E C I S I O N
of 26 November 2003

Case Number: T 0452/99 - 3.3.2

Application Number: 92500054.9

Publication Number: 0514311

IPC: A61L 2/18

Language of the proceedings: EN

Title of invention:

Procedure for disinfecting and cleaning contact lenses

Patentee:

DIRYGESA, S.L.

Opponent:

ALLERGAN

Headword:

Process for cleaning and disinfecting contact lenses/DIRYGESA

Relevant legal provisions:

EPC Art. 83, 123, 54, 56

Keyword:

"Sufficiency of disclosure (yes): contested features no longer part of the claims"

"Inventive step of main request (no): obvious alternative"

"Inventive step of auxiliary request (yes): unobvious effect"

Decisions cited:

T 0127/85

Catchword:

-



Case Number: T 0452/99 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 26 November 2003

Appellant: DIRYGESA, S.L.
(Proprietor of the patent) Jesus Aprendiz, num. 6
E-28009 Madrid (ES)

Representative: Bunke, Holger, Dr.rer.nat. Dipl.-Chem.
Prinz & Partner GbR
Manzingerweg 7
D-81241 München (DE)

Representative: ALLERGAN
Party as of right: 2525 Dupont Drive
Irvine, CA 92713-9534 (US)

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

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 9 March 1999
revoking European patent No. 0514311 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: J. Riolo
Members: M. Ortega Plaza
C. Rennie-Smith

Summary of Facts and Submissions

- I. European patent No. 0 514 311 based on application number 92 500 054.9 was granted on the basis of 19 claims.

Independent claim 1 as granted read as follows:

"1. A process for cleaning and disinfecting contact lenses, that submerges said lenses in a container together with a hydrogen peroxide solution and a tablet or any other galenic form characterized in that the tablet or the other galenic form produces from the beginning peroxide controlled unstabilization, in order to obtain its activation due to oxygen lability increase in the whole solution mass, with consequent increase of its germicide and cleaning effects, producing hydrogen peroxide degradation down to a level allowing the solution to be compatible with the eye."

- II. Opposition was filed and revocation of the patent in its entirety was requested pursuant to Articles 100(a) on the grounds of lack of novelty and inventive step and 100(b) EPC for insufficiency of disclosure.

- III. The following documents *inter alia* were cited in the proceedings:

(1) US-A-4 568 517

(3) EP-A-0 147 100

(11) English translation of EP-B-0 209 071 as submitted to the UK Patent Office.

- IV. The appeal lies from a decision to revoke the patent under Article 102(1) EPC.

The opposition division considered that the European patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

In particular, the opposition division considered that the subject-matter of the patent in suit concerned a process for disinfecting and cleansing contact lenses based on an alleged new effect, i.e. the selective activation of the peroxide, and that the contested patent did not contain sufficient information to carry out the alleged invention without undue burden within substantially the whole area claimed. Furthermore, the opposition division was of the opinion that the functional features employed in order to define the alleged invention had no well recognised meaning in the art.

Moreover, in the opposition division's view there was a lack of exemplification in the description of the contested patent teaching how to achieve the intended functions and effects.

- V. The appellant (patentee) lodged an appeal against that decision. It filed a main and an auxiliary request with its grounds of appeal.
- VI. The respondent (opponent) withdrew its opposition by its letter of 21 February 2002.

VII. A communication of the Board was sent on 23 July 2003. The Board objected under Article 123(2) EPC only to amended claim 1 of the main request, no objection was raised against the set of claims of the auxiliary request. However, reference was made to T 127/85. In this communication some Board directions were given, *inter alia*, reminding the patentee within the context of the language discussion (Article 14(2) and Rule 5 EPC), that either the application in the originally filed English translation had to be taken as basis for the amendments or the patentee had to file a certificate that the translation filed with the appellant's letter of 23 October 2000 corresponded to the text of the originally filed Spanish language application.

VIII. Oral Proceedings were held before the Board on 26 November 2003.

During the oral proceedings the patentee filed a main and an auxiliary request which replaced the requests filed with it grounds of appeal.

Claim 1 of the main request read as follows:

"1. A process for cleaning and disinfecting contact lenses comprising submerging said lenses in a container containing a hydrogen peroxide solution of a concentration of between 0.5 and 6% and catalase as a catalyst activating said hydrogen peroxide, **characterized in that** said catalase is introduced into said solution in the form of a tablet such that, as from the first moment, said catalase is continuously released from said tablet into said solution and that

hydrogen peroxide degradation occurs down to a level allowing the solution to be compatible with the eye."

Claim 1 of the auxiliary request differs from claim 1 of the main request in that the following has been added after the word "eye":

", with said lenses remaining in the solution between half an hour and two hours."

The appellant's arguments may be summarised as follows:

The amended claims related to a process which is based on the description as originally filed and represented a major restriction of the claims as granted.

The process is reproducible without undue burden, since both the amount and concentration of catalase to be employed and the amount of catalase with respect to the concentration of hydrogen peroxide, are within usual ranges in the field. The same applies with respect to the volume to be used which must be adapted to the size of the lenses.

The technical means for preparing controlled or sustained released tablets are those conventional for the skilled person in the art.

The experiments which were submitted by the opponent in the opposition proceedings were not relevant since they did not relate to a process using the catalase in the form of a tablet and hence they did not reproduce the invention.

The appellant stated that novelty relied upon the fact that the tablet used for the process is in a sustained release or controlled release form which, since the catalase is released as from the first moment into the hydrogen peroxide solution, is different from a delayed release tablet.

With respect to the inventive step issue, the appellant contended that document (1) represented the closest prior art since it also related to a process for cleansing and disinfecting contact lenses, wherein hydrogen peroxide was used together with a tablet containing a catalase.

The difference between the process disclosed in document (1) and the process claimed in the patent in suit rested on the fact that the catalase was not delay released (see column 2, lines 37 to 44 of document (1)).

Document (3) disclosed a further process for the cleansing and disinfecting of contact lenses, wherein hydrogen peroxide and a sustained release tablet were used (see in particular page 5, lines 6 to 10).

The appellant confirmed that the tablet of document (3) contained an inorganic neutralizer such as sodium sulphite but the inorganic neutralizer was in the tablet in a delayed release form.

The problem to be solved by the patent in suit could be defined as the provision of an improved process for cleansing and disinfecting contact lenses, the process being shorter in time.

The solution related to the provision of a process using hydrogen peroxide and a neutralizer as from the first moment.

Such a solution although very simple was neither disclosed nor suggested in the prior art.

- IX. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or alternatively the auxiliary request 1, both filed during the oral proceedings.

Reasons for the Decision

1. *Admissibility*

1.1 The appeal is admissible.

1.2 Admissibility of the requests

The first request was identical to the auxiliary request No. 1 as filed on 19 July 1999, i.e. with the grounds of appeal. Therefore the Board considers the main request to be admissible.

With respect to the auxiliary request filed during the oral proceedings before the Board, the following has to be said. This request was *prima facie* very relevant in order to overcome the objection of lack of inventive step discussed during the oral proceedings. Although the opposition was withdrawn and the respondent (opponent) was absent at the oral proceedings before

the Board, the Board has also to evaluate the public interest.

Therefore, the Board has to consider whether the amendment introduced in claim 1 could have been expected from the written procedure or makes a fresh case at the last moment.

It is in fact the case that the opponent raised the question during the opposition proceedings as to whether the specification of the time for performing the process was an essential feature to be contemplated in the main claim, when considering the problem to be solved as defined by the appellant.

Therefore, the introduction of such a feature in the main claim, although based in the description, was to be expected when facing a restriction of the subject-matter claimed in order to overcome an objection of lack of inventive step.

Hence, the Board considers that the admissibility of the auxiliary request filed during the oral proceedings before the Board is not contrary to the public interest since it does not make a fresh case.

Accordingly, the auxiliary request is also admissible.

2. *Article 123 EPC*

The Board sees no objection under Article 123(2) EPC to the amended claim 1 of the main and auxiliary requests, since on the one hand the originally filed English translation has to be read within a technically

meaningful context, independently from linguistic deficiencies, and on the other there is a specific basis for the technical features specified in the claims (cf. originally filed English translation of the application *inter alia* page 9, lines 14 to 17, page 13, lines 1, 2).

With respect to Article 123(3) EPC, the restricted process includes more specific features than the process claimed as granted.

Therefore the amended requests meet the requirements of Article 123 EPC.

3. *Article 83 EPC*

Both requests relate to a drastic restriction of the subject-matter claimed in the patent as granted. The reasoning of the decision of the opposition division no longer applies to the amended claims because the features underlying its decision are no longer part of the amended claims.

Moreover, the process of cleansing and disinfecting with hydrogen peroxide in the presence of a tablet which releases the catalase as from the first moment is sufficiently supported by the originally filed description. The description contains enough information to allow the skilled person in the field of pharmaceutical technology, in particular with general knowledge of the cleansing and disinfecting of contact lenses, to reproduce the claimed invention. The specific technical means required for performing the process claimed such as the preparation of a non-retard

tablet or the total volume required for the cleansing, are conventional and only require the general knowledge of the skilled person and routine experimentation.

Additionally, the tests submitted by the respondent cannot challenge the reproducibility of the invention, since they do not correspond to the claimed invention (*inter alia* they do not use a tablet).

The Board is satisfied that the skilled person would be able in the light of the description, making use of general knowledge, to reproduce the claimed invention without undue burden.

4. *Novelty*

None of the documents cited during the opposition and appeal proceedings discloses a process for cleansing and disinfecting contact lenses with hydrogen peroxide in the presence of catalase as from the first moment. Both requests include these features. Therefore the subject-matter claimed in both requests meets the requirements of novelty (Article 54 EPC).

5. *Inventive step*

5.1 Main request

5.1.1 The closest prior art is document (1) which relates to a process for disinfecting contact lenses with hydrogen peroxide.

Document (1) discloses a process wherein the contact lenses are submerged in a predetermined volume of an

aqueous solution consisting essentially of hydrogen peroxide at a concentration of about 3% or less, which is effective to disinfect the lenses in a disinfection period of less than 6 hours. The disinfection period is followed by a decomposition of the hydrogen peroxide by addition of a neutralizer. The neutralizer can be added as a coated tablet which liberates the neutralizer **after** the disinfection period has elapsed (column 2, lines 16 to 44).

Document (1) discloses the use of catalase among other neutralizers (column 4, lines 41 to 46).

The process of document (1) provides means for cleansing and disinfecting the contact lenses (column 7, lines 47 to 49).

The coating of the tablet of document (1) to be chosen is a **function of the time** the disinfection process lasts and of the moment in which the tablet is added to the hydrogen peroxide solution, since the disinfecting period has to elapse before the catalase is released into the solution (column 5, last paragraph, and column 6, first paragraph).

5.1.2 The appellant defined the problem to be solved by the patent in suit as regarding the provision of an improved process for cleansing and disinfecting contact lenses, i.e. a process shorter in time.

However, the process features defined in claim 1 of the main request encompass possibilities such as those requiring about the same time as the process of document (1) (by using hydrogen peroxide in larger

amounts and allowing the catalase to act as a neutralizer from the first moment) which do not necessarily involve an improvement over document (1).

The appellant contended that the description of the patent showed that the claimed process was effective in cleaning and disinfecting the contact lenses in a time of half an hour to two hours. However, such a feature is not reflected in claim 1 of the main request.

Therefore, the problem to be solved has to be reformulated in relation to the main request as the provision of an alternative process to that of document (1).

- 5.1.3 In the light of the description the problem has been plausibly solved.

However, the solution concerning the use of a sustained release tablet cannot be considered to involve an inventive step in view of the absence in the claim of a reference either to the time required for the process or to the actual amounts of hydrogen peroxide. Thus, without reference to the time taken larger amounts of hydrogen peroxide may be used and decomposition can take place from the beginning, giving analogous results to those of document (1).

Accordingly, claim 1 of the main request does not meet the requirements of Article 56 EPC.

5.2 Auxiliary request

5.2.1 The above analysis as to the closest prior art applies *mutatis mutandis* to claim 1 of the auxiliary request, however, this claim 1 specifies the time for the process of cleansing and disinfecting as follows: "with said lenses remaining in the solution between half an hour and two hours".

Therefore claim 1 of the auxiliary request concerns a process which is functionally defined. It is merely a question of routine experimentation, using the technical information from the description and employing conventional sustained release tablets with no-retard effect, to fine tune the specific amounts of hydrogen peroxide required.

5.2.2 The problem to be solved by the subject-matter of claim 1 of the auxiliary request relates to the provision of an improved process for cleansing and disinfecting contact lenses requiring a shorter time (half an hour to two hours instead of overnight).

This problem has been plausibly solved in the light of the description.

The solution relates to the use of a sustained release tablet containing and liberating catalase into a 0,5 to 6% hydrogen peroxide solution **as from the first moment** and **continuously** until the hydrogen peroxide degradation has occurred down to a level compatible with the eye.

5.3 It remains to be assessed whether the solution would be obvious to the skilled person facing the problem defined above.

As already mentioned in point 4 above, none of the cited documents relates to the simultaneous use of hydrogen peroxide and catalase for cleansing and disinfecting contact lenses.

On the contrary, document (1) uses catalase as a neutralizer to decompose the remaining hydrogen peroxide after the disinfection period.

Furthermore, document (11) explicitly discourages the skilled person from using hydrogen peroxide and catalase simultaneously as a solution to the problem: "The simultaneous use of hydrogen peroxide and decomposing catalyst is impossible since then, as a result of the presence of the decomposing catalyst, the hydrogen peroxide will be decomposed into oxygen and water before it can have an adequate sterilising effect on the lens..., which requires ... up to 4 hours" (page 2, end of first paragraph).

Accordingly, the skilled person would not have thought of using a sustained release tablet which releases catalase from the first moment in order to shorten the time for the cleansing and disinfection of contact lenses.

Consequently, the Board is satisfied that the subject-matter claimed in the auxiliary request involves an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with an order to maintain the patent on the basis of the set of claims of the auxiliary request 1 and a description to be adapted thereto.

The Registrar:

The Chairman:

A. Townend

J. Riolo