

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 11 October 2012**

Case Number: T 1179/09 - 3.4.02
Application Number: 00972077.2
Publication Number: 1238293
IPC: G02B1/10, G02B1/04, C08J7/04
Language of the proceedings: EN

Title of invention:

CONTACT LENS COATING SELECTION AND MANUFACTURING PROCESS

Applicant:

Johnson & Johnson Vision Care, Inc.

Headword:

Relevant legal provisions:

EPC 1973 Art. 84

Keyword:

Claim 1, main and auxiliary request - clarity (yes, objection of lack of clarity based on unconvincing "inventive concept" argument)

Decisions cited:

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1179/09 - 3.4.02

D E C I S I O N
of the Technical Board of Appeal 3.4.02
of 11 October 2012

Appellant: Johnson & Johnson Vision Care, Inc.
(Applicant) 7500 Centurion Parkway, Suite 100
Jacksonville, FL 32256 (US)

Representative: Fisher, Adrian John
Carpmaels & Ransford
One Southampton Row
London
WC1B 5HA (GB)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted 15 January 2009
refusing European patent application No.
00972077.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: A. Klein
Members: M. Rayner
L. Bühler

Summary of Facts and Submissions

- I. The applicant has appealed against the decision of the examining division refusing European patent application number 00 972 077.2 (=WO-A-01/27662) concerning a method of forming a coated contact lens.
- II. During the examination proceedings documents including the following were referred to:
- D5 WO-A-93/00391
D6 US-A-5 409 731
D9 US-A-5 871 823
- III. Arguments including the following were presented by the examining division and applicant.

Examining Division

(a) Communication dated 13 November 2006

Document D5 discloses a method of forming a coated contact lens (see the document as a whole) comprising

- * forming a lens from a lens substrate material which is a macromer hydrogel (see page 3, line 4 and page 4, lines 11 to 29) or a silicone based oligo/polymer (see page 4, lines 21 to 24);

- * selecting a coating material (see page 5, line 1 to page 10, line 1 6) such as an acrylate (see page 8, lines 22 to 26);

- * solution coating said lens with said coating material (see any of the examples, in particular examples 8 and 9).

A comparison between the coating conditions/materials used in the application and in document D5 leads to the

conclusion that the coating material must have an expansion factor greater than one. Hence, the essence of claim 1 is anticipated by document D5. Should the applicant dispute this conclusion, it is requested to demonstrate, for instance by experiments, that none of the pairings disclosed/proposed in document D5 implies an expansion factor greater than one. The formulation of the mere wish for a smooth contact lens surface without any large surface defects is a platitude. Therefore, claim is not acceptable under Article 52 EPC for lack of an inventive step within the meaning of Article 56 EPC. The above objection applies in a similar manner to the product claim.

Solution coating methods anticipating the essence of the claimed method are also disclosed in documents D6 (see all the examples) D9 (see claims 3 and 5). In the event this conclusion is disputed the applicant is requested to provide evidence for its view.

(b) Communication dated 23 June 2008

No technical features mentioned by the applicant which allegedly differ from the prior art (in particular pH) is part of the claims.

Applicant

(c) Letter of 12 September 2006

There is no suggestion in document D6 to apply a coating to a silicone-based contact lens such that it expands relative to the lens substrate on transfer from the coating conditions to physiological saline. In most of the Examples of document D6, the coating is applied at a pH which is close to neutral. In Example 5, a

coating of chitosan is applied at a pH of 4.0. However, the amino groups of chitosan have a pK of approximately 6.5, and it is therefore expected that a coating of chitosan would contract, rather than expand, on transfer from a pH of 4.0 to a physiological pH.

(d) Letter dated 20 April 2007

Document D5 contains 24 examples. Almost all of these relate only to polyHEMA lenses. The exceptions are Examples 8, 9 and 12, which also describe the coating of silicone-based hard contact lenses. Example 8 of document D5 teaches that CDI activated PEO-cellulose was incubated with oxygen permeable hard contact lenses. Example 1 teaches that the coating takes place in a potassium bicarbonate buffer at pH 8.5. It is not expected that such a coating would expand when the lens is transferred to physiological saline. Example 12 of document D5 also coats oxygen permeable hard contact lenses with a CDI activated PEC polymer. It is assumed (but it is not explicit) that the coating also took place at pH 8.5. Again, there is no reason to believe that the coating would expand when the lens is transferred to physiological saline. Example 9 of document D5 also involves coating oxygen permeable hard contact lenses with a PEO polymer. The pH of the coating solution is not given, but there is again no reason to believe that the coating would expand when the lens is transferred to physiological saline. It is notable that the only example in document D5 in which a silicone based contact lens is coated at a specified pH is Example 8. In that case, the pH was 8.5. In contrast, the coatings in Examples 3, 4 and 5 of the present application were all applied at a pH less than 4 (see page 15, lines 21-22). Because the examples of document D5 use substantially different conditions from

the examples of the present application, there can be no presumption that they would produce the same result.

(e) Since document D9 does not include a single example of coating a contact lens, let alone a silicone based contact lens, it cannot implicitly disclose the method of claim 1. Moreover, the coatings in D9 are applied by activating the polymer substrate by exposure to monochromatic, continuous UV radiation in the presence of oxygen to provide hydroperoxide groups on the substrate, immersing the activated substrate in a monomer solution, and then subjecting the immersed, activated substrate to UV radiation to induce graft copolymerisation of the monomer onto the substrate. In contrast, the method of the present invention involves applying a solution of the desired coating material to the contact lens. Again, therefore, there can be no presumption that the method disclosed in document D9 will provide the same result as the methods of the present invention.

(f) Letter dated 03 November 2008

It is true that the present claims do not specify the pH at which the coating is carried out. However, they do specify an expansion factor greater than one. If, because of the pH used in the prior art processes, an expansion factor greater than one is not achieved, this constitutes a distinction between the claimed method and the methods of the prior art. This distinction is relied on in support of patentability.

What is certain is that none of the cited references discloses or suggests deliberately selecting a combination of lens substrate material and coating material such that an expansion factor greater than one is achieved.

- IV. The decision under appeal invoked lack of compliance with Article 84 EPC (clarity) and also referred, as obiter dictum, to Article 56 EPC (inventive step), the reasons concerned can be summarised as follows, the **bold typeface** being added by the board.

Inventive Step

A person skilled in the application of coatings on substrates always has to consider the compatibility of the materials involved in the desired environment for operation and/or storage, be it in a given range of temperatures, humidity, pressure etc. Coatings on contact lenses to be worn in the human eye are known. This implies that the substrate and coating material must be compatible to a certain extent when brought to physiological saline. The skilled person also knows that the coating having a thickness that is negligible compared to the substrate's thickness must always follow the expansion or shrinking movement of the much thicker substrate due to a changing environment - otherwise the adhesion of the coating over the entire coating surface would be seriously affected. Furthermore, it is also clear that a coating which does not follow the expansion of the substrate, i.e. the coating having an expansion factor smaller than that of the substrate, would either peel off the substrate or inevitably produce cracks inside the coating. On the other hand, a coating with a higher expansion coefficient than the substrate must - as long as the difference is not so high that the coating peels off the substrate - form waves and folds since the substrate cannot follow the coating's expansion. Accordingly, forming of waves and folds in the coating when the coating expands more than the substrate is not

a discovery of the present application, but it is a known phenomenon for the coating specialist. Consequently, the skilled person always would prefer selecting a coating having a slightly higher expansion factor than the substrate in order to avoid the formation of cracks in the coating. The mere selection of an expansion factor ratio greater than one is not considered as being inventive. The only limiting features of the subject matter of claim 1 appear to be the choice of substrate and coating materials in very broad ranges. Since these materials are known and their selection without a specification of more concrete method steps does not solve any technical problem, in particular, the problem of achieving a relative expansion factor greater than one is not solved by this material selection, the independent claim of the main request cannot be considered inventive.

Clarity of the subject matter of claim 1

(a) The exceptions allowing a claim which attempts to define the invention by a result to be achieved do not apply. **As the idea of providing an expansion factor ratio greater than one is not acceptable as the inventive concept, defining the features and method steps allowing to achieve the desired results is considered necessary and essential and cannot be considered as unduly restricting the scope of the claim.**

(b) The technical features of claim 1 are not sufficient to obtain the desired results to be achieved because the conditions under which a particular coating material is deposited on a particular substrate material are essential features. A claim to a process for producing a product of an invention should

necessarily have the particular product as end result because otherwise there is an internal inconsistency and therefore lack of clarity in the claim. A claim to a lens substrate formed from any non-ionic silicone hydrogel having a water content between 20 and 50% and coated with any anionic coating polymer under any reasonable conditions (pH, ionic strength, temperature, dielectric constant of the coating solution etc.) does not necessarily lead to a deposited polymer having an expansion factor greater than one. Furthermore, a combination of the specified materials under any reasonable coating conditions does not necessarily lead to a coated surface having defects not greater than 4.6 micrometers and a peak to peak roughness less than 475nm over any 10 x 10 micrometers area of the coating. These values also depend on other process parameters and not only on the materials used. The expansion factor may also depend on the conditions under which the coating is applied, which are not claimed. As claim 1 of the main request fails to specify the essential features and process steps which lead to the result to be achieved, the requirements of Article 84 EPC are not met.

- V. The appellant requested that the decision under appeal be set aside and a patent granted on the basis of a main or auxiliary request.

In support of its request, the appellant advanced arguments including the following.

Inventive step

There is no evidence that those skilled in the art either gave consideration to the possible expansion or contraction of a coating on moving from the coating

conditions to physiological saline, it being understood that a coating of the kind used for contact lenses does not necessarily stretch to accommodate movement of the substrate, or knew that waves and folds were known to be formed in lens coatings under some circumstances, and that they were known to be clinically acceptable. Accordingly, the examining division was fundamentally wrong in its conclusion on inventive step.

Clarity

(a) The examining division approach was that exceptions relating to defining the invention by a result to be achieved do not apply on the basis that the idea of providing an expansion factor greater than one was not inventive. In this, it erred. No other justification for its approach was provided.

(b) In rejecting the main and auxiliary requests for lack of clarity, the examining division referred principally to lack of essential features. This reliance was misplaced because what is concerned is requirements for defining a process by reference to the result which is achieved. In such a claim, the process must by definition have the product as its end result. Numerous combinations of lens substrate material, coating material and coating conditions can be selected such that the coating expands relative to the lens substrate on being transferred from the coating conditions to physiological saline. Limiting the claims to particular lens substrate materials and particular coating materials necessarily involves an undue restriction. It is straightforward to test whether the desired expansion factor has been achieved. A procedure for measuring the expansion factor is described on page

6, lines 15-22.

VI. Independent claim 1 according to the main request of the appellant corresponds to that presented before the examining division and is worded as follows.

Main Request

"1. A method of forming a coated contact lens wherein the coated surface of the lens has no defects greater than 4.6 μm , said method comprising:

- a) forming a lens from a lens substrate material which is a silicone based polymer, a silicone based oligomer, or a silicone based macromer hydrogel,
- b) selecting a coating material which will have an expansion factor greater than one relative to the lens substrate material, and
- c) solution coating said lens with said coating material,

wherein the term "expansion factor" means the fractional expansion of the coated lens surface area due to the coating when the lens is taken from the coating condition to a physiological saline solution, and wherein the coated surface has a peak to peak roughness less than 475 nm over any 10 X 10 μm area of the coating."

Auxiliary request

"1. A method of forming a coated contact lens wherein the coated surface of the lens has no defects greater than 4.6 μm , said method comprising:

- a) forming a lens substrate from a non-ionic silicone hydrogel having a water content between 20 and 50%, and

b) coating said lens substrate with an anionic coating polymer under conditions such that the coating polymer has an expansion factor greater than one relative to the lens substrate material, wherein the term "expansion factor" means the fractional expansion of the coated lens surface area due to the coating when the lens is taken from the coating condition to a physiological saline solution, and wherein the coated surface has a peak to peak roughness less than 475 nm over any 10 X 10 μm area of the coating."

Reasons for the Decision

1. The appeal is admissible.
2. In the decision under appeal, the "knockout" reason for refusal related not to lack of clarity as such but to "providing an expansion factor ratio greater than one" not being acceptable as the inventive concept. This situation is reflected in the first part of the sentence presented in bold typeface in section IV(a) of the Facts and Submissions above.
3. The sentence mentioned in point 2 is also used to justify a preceding remark about not applying exceptions allowing a claim which attempts to define the invention by a result to be achieved. Moreover, it is the springboard for the subsequent "essential features" line of argument relating to clarity actually used as a reason to refuse the application. Therefore, should the first part of the sentence be in error, no justification for the subsequent line of argument was presented, so that the case of the examining division on clarity would become unconvincing.

4. In reviewing the examination procedure as set out in section III of the Facts and Submissions above, the board notes that arguments of the appellant in relation to documents D5, D6 and D9 were not countered, in particular that the conditions used in the disclosure of these documents do not disclose or suggest selecting a coating material with an expansion factor greater than one relative to the lens substrate material. The board did not therefore find any convincing argument concerning "mere selection" by which the examining division reached the "knockout" reason referred to in point 2 above.

5. In the decision, the division's approach to lack of patentability, in the form of obiter dictum, took coatings on contact lenses to be worn in the human eye, generally known from, for example, documents D2 or D5, as starting point and filled in missing subject concerning "providing an expansion factor ratio greater than one" matter in the claim not by reference to another document but by reference to the knowledge of the skilled person. In doing this, the arguments of the appellant during the proceedings with reference to the other prior art in the file were ignored. The approach of the division therefore simply targets the "providing an expansion factor ratio greater than one" feature without really showing it to be consistent with the knowledge of the skilled person in the context of the available prior art. Accordingly, the board does not consider the decision to offer any convincing argument concerning "mere selection" by which the examining division reached the "knockout" reason referred to in point 2 above

6. Since, consequent to the foregoing, the board considers the first part of the sentence mentioned in point 2 is

in error, the situation set out in the last sentence of point 3 above exists. The board consequently concurs with the appellant that the arguments of the examining division pertaining to essential features set out in section IV(b) of the Facts and Submissions above were misplaced and that it is the "undue limitation" and "without undue experimentation" tests which have to be met in the present case. This, again concurring with the appellant, is so for the reasons advanced by the appellant in section V(b) of the Facts and Submissions above. That a person might choose to use materials or process parameters not meeting the claim is not relevant to the clarity thereof.

7. Accordingly, the arguments of the examining division failed to convince the board of a lack of clarity of the subject matter of claim 1 of the main or auxiliary request.
8. The board observes that the concerns of the examining division in relation to clarity appear rather more to relate to sufficiency, which was not dealt with in the decision under appeal.
9. Moreover, the appellant did not specify a complete set of papers on appeal upon which request for grant of a patent is requested. For example, the description has not been adapted, nor, deliberately, was any such adaptation offered for examination before the first instance.
10. Since the board is an appeal instance, its role is primarily to review the case as presented on appeal, rather than to exercise powers within the competence of the first instance to decide the case effectively in the role of first instance for the first time, for

example in relation to not yet decided issues pertaining to patentability, only obiter dictum remarks having been made in the decision under appeal, Article 83 in relating to sufficiency or to unresolved issues relating to amendment of the description. In view of the foregoing and having settled the matter appealed, i.e. clarity of claim 1 of the main and subsidiary requests, the board considers it appropriate to remit the case to the first instance for further prosecution.

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 for further prosecution.

The Registrar:

The Chairman:



L. Fernández Gómez

A. Klein

Decision electronically authenticated