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Datasheet for the decision of 24 September 2015

Case Number: T 1623/11 - 3.4.02

Application Number: 02716060.5

Publication Number: 1360527

IPC: G02B1/04

Language of the proceedings: EN

Title of invention:
A TINTED, HIGH DK OPHTHALMIC MOLDING AND A METHOD FOR MAKING SAME

Applicant:
Novartis AG

Relevant legal provisions:
EPC 1973 Art. 56, 111(1)

Keyword:
Inventive step - (main request: yes)
Remittal (yes) - Adaptation of the description

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Case Number: T 1623/11 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 24 September 2015

Appellant: (Applicant)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Henkel, Breuer & Partner Patentanwälte Erika-Mann Strasse 23 80636 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 24 February 2011 refusing European patent application No. 02716060.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	T. Karamanli
Members:	F. J. Narganes-Quijano
	F. Maaswinkel

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal against the decision of the examining division refusing European patent application No. 02716060.5 (based on the international application No. PCT/EP02/00020).

In its decision the examining division held that the subject-matter of the independent claims of the main and the first auxiliary requests then on file did not involve an inventive step (Article 56 EPC) in view of the disclosure of documents

D6: US-A-5965631
D7: WO-A-9748004
D8: US-A-5030669
D9: US-A-4824688
D10: WO-A-9640479.

The second to fifth auxiliary requests then on file were not admitted into the proceedings by the examining division pursuant to Rule 137(3) EPC.

II. With the statement setting out the grounds of appeal the appellant submitted sets of claims amended according to a main and first and second auxiliary requests and requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims of one of these requests.

III. In its communication under Article 15(1) RPBA annexed to the summons to oral proceedings the board introduced the following document into the proceedings:

A1: WO-A-9926087

and gave its preliminary assessment of the case.

IV. With its reply dated 20 August 2015 the appellant submitted arguments in response to the preliminary assessment of the board.

V. Oral proceedings before the board were held on 24 September 2015.

The appellant confirmed the requests formulated in the statement of grounds of appeal (cf. point II above).

At the end of the oral proceedings the chairwoman announced the decision of the board.

VI. Claim 1 of the main request reads as follows:

"A method for making a soft, edge-to-edge tinted contact lens uniformly tinted throughout the body of the lens comprising:

(a) providing a polymer precursor comprising a silicone-containing macromer which is capable of forming a polymer or copolymer having high oxygen permeability, wherein the polymer precursor comprises 60 to 85 weight percent oxyperm polymerizable material and 15 to 40 weight percent ionoperm polymerizable material in the prepolymerization mixture, based on the total polymerizable material weight;

(b) providing a pigment dispersion comprising a phthalocyanine pigment and a dispersing agent;

(c) mixing the pigment dispersion and the polymer precursor to form a tinted prepolymer mixture;

(d) dispensing the tinted prepolymer mixture into a mold; and

(e) cross-linking or polymerizing the tinted prepolymer mixture in the mold to form a soft, edge-to-edge tinted contact lens uniformly tinted throughout the body of the lens having an oxygen transmissibility (Dk/t) of at least 60 barrers/mm comprising a polymer matrix and the pigment entrapped therein."

The set of claims of the main request also includes dependent claims 2 to 11, all directed to particular embodiments of the method defined in claim 1.

The wording of the claims of the first and the second auxiliary requests is not relevant to the present decision.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request - Inventive step*

2.1 Claim 1 of the main request is directed to a method of making a soft, edge-to-edge tinted contact lens uniformly tinted through the body of the lens, the method comprising the sequence of steps (a) to (e) defined in the claim.

2.1.1 In its decision the examining division held in respect of the claimed method that document D6 represented the closest state of the art.

It has been undisputed during the appeal proceedings that document D6 discloses a method of making a soft contact lens (abstract) comprising the following steps: providing a polymer precursor comprising a silicone-containing macromer (column 6, lines 33 to 41), the precursor comprising an oxyperm and an ionoperm polymerizable material in weight percent proportions of about 60 to about 85 and of about 15 to about 40, respectively (column 7, lines 21 to 41); dispensing the polymer precursor into a mold (column 42, lines 13 to 20); and polymerizing and cross-linking the prepolymer (column 43, lines 54 to 63, and column 45, lines 5 to 18) to form a soft contact lens having an oxygen transmissibility (Dk/t) of at least 60 barrers/mm (column 6, lines 42 to 49).

It has also been undisputed during the appeal proceedings that, as already found by the examining division in its decision, the claimed method differs from the method disclosed in document D6 only in that the polymer precursor is mixed with a dispersion comprising phthalocyanine pigment and a dispersing agent so that the resulting contact lens is an edge-to-edge tinted contact lens uniformly tinted throughout the body of the lens.

The appellant, however, has contested the finding of the examining division in its decision that the distinguishing feature mentioned above constituted a common practice in the art of colouring contact lenses as evidenced by documents D7 to D10 and that for this reason the claimed method did not involve an inventive step.

2.1.2 By virtue of the distinguishing feature of the claimed method over the disclosure of document D6 identified in

point 2.1.1 above, the resulting soft contact lens is a soft, edge-to-edge tinted contact lens uniformly tinted through the body of the lens as claimed.

According to the description of the application (page 2, penultimate paragraph to page 3, first paragraph, and the paragraph bridging pages 22 and 23), tinting a lens as claimed has the technical effect of enabling the user to easily locate the lens in a clear solution within a lens storage, disinfecting or cleaning container. The appellant has referred to this technical effect and has submitted that the objective problem solved by the claimed invention is enabling the user to easily locate the lens in an ophthalmic solution. In its decision the examining division formulated the objective problem in similar terms.

2.1.3 In its decision the examining division focused on the claims then on file directed to a contact lens and held that the skilled person would have arrived at the claimed contact lens in view of the common practice shown in documents D7 to D10. The present claims, however, are exclusively directed to the method of manufacture of the lens, and in the board's view the teaching of documents D7 to D10 does not render obvious the claimed method over the disclosure of document D6 for the following reasons:

Document D7 discloses a contact lens having a tinted annular mask with diffraction-reducing edges for improving the wearer's vision (abstract and paragraphs bridging pages 2 and 3), and document D9 discloses contact lenses having a colour pattern simulating the human iris (abstract). In addition, in document D7 the annular mask is imparted on the contact lens by application of a mask of a copper phthalocyanine pigment

(page 17, line 12) suspended in a solvent onto the surface of a contact lens mold so that the mask is incorporated in the lens surface or in the region of the lens body adjacent to the lens surface when the lens is cast in the mold and polymerized (page 16, last paragraph), and in document D9 a hydrogel containing a phthalocyanine pigment (column 2, line 24) is first applied on a previously formed contact lens and then cured *in situ* (abstract). Thus, none of documents D7 and D9 addresses the objective problem formulated above and, in addition, the mere application of the tinting techniques disclosed in documents D7 and D9 to the method of document D6 would not result in the claimed method.

D10 discloses tinting curable moldable compositions by means of a masterbatch dispersion containing a pigment (title and abstract, together with the paragraph bridging pages 13 and 14). The claimed pigment is not disclosed in the document, and although the document mentions in its introductory part materials used in the field of soft contact lenses (page 3, lines 15 to 18), there is no specific disclosure relating to the tinting of contact lenses. Therefore, document D10 does not address the objective problem under consideration and does not disclose the distinguishing feature of the claimed method identified above.

Document D8 discloses colouring a contact lens with a copper phthalocyanine for the purpose of "aid in location or finding a tiny lens" (column 12, lines 45 to 57), and the document addresses at least a partial aspect of the objective problem formulated above. However, the colouring method disclosed in this document involves the use of a gas-stream dispersion technique for directly incorporating the pigment in the polymeric

material from which the lens is then formed (abstract and column 12, lines 26 to 44) and, as explicitly taught in the document (see column 12, lines 41 to 44), this dispersion technique does not require a surfactant or a dispersing aid. Therefore, document D8 teaches away from the use of a dispersing agent as required by the claimed method.

The board concludes that the method of claim 1 involves an inventive step over the disclosure of document D6 as closest state of the art and the teaching of documents D7 to D10.

2.2 During the appeal proceedings the board introduced document A1 (cf. point III above). Document A1 discloses the manufacture of soft contact lenses by dispensing a polymer precursor into a mold and polymerizing or cross-linking the precursor (abstract). In addition, document A1 addresses explicitly the objective problem under consideration (page 1, first to fourth paragraphs, and page 19, second paragraph) and proposes uniformly tinting the contact lens by mixing the polymer precursor with a pigment dispersion comprising a phthalocyanine before the mixture is dispensed into the mold (abstract together with page 11, third paragraph, page 12, third paragraph, page 13, second paragraph, and page 18, third paragraph).

However, as submitted by the appellant, while in document A1 the polymer precursor is a purely hydrophilic, homogeneous prepolymer (page 2, first and last paragraphs, page 4, first paragraph, and the examples) and the document requires the use of an aqueous pigment dispersion constituted by the phthalocyanine pigment and a water-soluble polymeric dispersing agent (page 12, third paragraph, and page 13,

second paragraph), the contact lenses of document D6 are of the silicone-hydrogel type and their manufacture involves a mixture of oxyperm and ionoperm polymerizable materials (abstract and column 3, lines 1 to 35), generally comprising not only hydrophilic but also hydrophobic components (see column 6, lines 22 to 41, column 26, line 32 to column 27, line 8, column 28, lines 41 to 67, and column 38, line 45 to column 39, line 25; see also the materials "A" to "D" in columns 17 to 43 and the specific examples in columns 46 to 70, all of them involving the use of hydrophobic materials, and in particular of siloxane-containing monomers or macromers). In addition, the main aim of document A1 is to achieve the coexistence of the oxyperm and the ionoperm polymerized materials as two different co-continuous phases in the micro-morphology of the lens material (column 8, line 16 *et seq*.).

Having regard to these considerations, the board concurs with the appellant's submissions that the skilled person, confronted with the objective problem under consideration, would have been dissuaded from considering the possibility of applying the teaching of document A1 to the method of document D6 in view of the fact that document A1 requires the use of a pigment dispersion under aqueous conditions that would have risked seriously compromising the delicate balance between the two coexistent phases of the micro-morphology of the lenses of document D6 (column 8, lines 40 to 61), to the detriment of the properties of the contact lenses (transparency, homogeneity, balance between oxygen and ion permeability, ophthalmic compatibility, etc.). In addition, the tinting technique disclosed in document A1 is applied to lenses essentially consisting of an homogeneous hydrogel, and the skilled person would have been concerned that the

application of this tinting technique to the lenses of document D6 would result in a non-homogeneous dispersion of the pigment in the body of the lens due to the non-homogeneous, multi-phase structure of the lens material. Therefore, the skilled person would have had no expectation that the tinting technique taught in document A1 would be applicable to the method of document D6, let alone that such an approach would have preserved the ophthalmic properties of the lenses and would have resulted in a contact lens uniformly tinted through the body of the lens as taught in document A1.

2.3 The remaining documents on file are less pertinent than the documents considered in points 2.1 and 2.2 above.

2.4 The board notes that the claimed method contains no restriction as to the amount of pigment in the prepolymer mixture or as to the degree of tinting of the lens. As a consequence, the method would also encompass particular embodiments resulting in contact lenses tinted to a degree beyond that required in order to render the lens visibly discernible in an ophthalmic solution, and even tinted to a degree sufficient to change the perceived colour of the wearer's eyes, with the consequence that the objective problem formulated above would not be commensurate with the claimed method in respect of these particular embodiments. However, these embodiments would still solve the generic problem of tinting the contact lenses of document D6 (for instance, for modification of eye colour as mentioned in document D6, see column 4, lines 31 to 36) and it follows from the analysis in points 2.1 to 2.3 above that also these embodiments would not be rendered obvious by the available prior art.

2.5 In view of the above considerations, the board concludes that the method defined in claim 1 of the main request involves an inventive step over the documents on file (Article 56 EPC 1973). The same conclusion applies to dependent claims 2 to 11 of the main request directed to particular embodiments of the method of claim 1.

3. The board is also satisfied that the claims according to the present main request fulfil the remaining requirements of the EPC.

4. Since the description of the application, on which the examination was carried out, is not fully consistent with the invention as now claimed, at the end of the oral proceedings the board announced its intention to remit the case to the examining division for adaptation of the description. The appellant had no objection to a remittal. Hence, the board, exercising its discretion under Article 111(1) EPC 1973, decided to remit the case to the department of first instance for the description to be adapted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent with the following claims and a description to be adapted:

   Claims 1 to 11 of the main request filed with the statement of grounds of appeal.

The Registrar: The Chairwoman:

M. Kiehl T. Karamanli

Decision electronically authenticated