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**Datasheet for the decision
of 1 February 2012**

Case Number: T 1684/09 - 3.3.03

Application Number: 99952577.7

Publication Number: 1137955

IPC: G02B 1/04, A61L 27/00,
C08G 77/20

Language of the proceedings: EN

Title of invention:
Photocurable siloxane polymers

Applicant:
AMO Groningen B.V.

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 84, 123(2)
EPC R. 103(1)(a)

Keyword:
"Amendments - added subject-matter (no)"
"Claims - clarity (yes)"
"Novelty (yes)"
"Inventive step (yes) - after amendment"
"Reimbursement of the appeal fee (no)"

Decisions cited:
-

Catchword:
-



Case Number: T 1684/09 - 3.3.03

D E C I S I O N
of the Technical Board of Appeal 3.3.03
of 1 February 2012

Appellant: AMO Groningen B.V.
(Applicant) P.O. Box 901
NL-9700 AX Groningen (NL)

Representative: Holmberg, Martin Tor
Bergenstråhle & Lindvall AB
P.O. Box 17704
S-118 93 Stockholm (SE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 7 April 2009
refusing European patent application
No. 99952577.7 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: B. ter Laan
Members: O. Dury
R. Cramer

Summary of Facts and Submissions

I. The appeal by the applicant lies against the decision of the examining division posted 7 April 2009 to refuse European patent application N°. 99 952 577.7.

II. The application as filed was based on 28 claims of which claim 1 read:

"1. A polysiloxane copolymer having functional acryl groups capable of being photopolymerized into a solid intraocular lens, having a specific gravity greater than about 1.0, a refractive index suitable for restoring the refractive power of the natural crystalline lens, wherein said polysiloxane has siloxane monomer units selected among substituted or unsubstituted arylsiloxanes, arylalkylsiloxanes and alkyl(alkyl)siloxanes."

III. The following documents were referred to during the examination proceedings or cited in the search report:

D0: WO-A-99 47 185
D1: EP-A-0 094 153
D2: EP-A-0 578 087
D3: US-A-4 423 195
D4: EP-A-0 414 219
D5: US-A-5 391 590
D10: US-A-4 216 140
D11: Mazurek et al., Makromol. Chemie, 178,
pages 1005-1017, 1977.

IV. In a communication dated 8 December 2008 accompanying the summons to oral proceedings to be held on 26 March

2009, the examining division informed the applicant that the sets of claims then on file did not meet the requirements of Art. 123 (2) EPC, Art. 84 EPC and Art. 52 and 56 EPC. In reply, in a submission dated 23 February 2009 the applicant filed a new set of claims as the sole request replacing all former requests and also asked for an early notice and cancellation of the oral proceedings. On 9 March 2009 a telephone conversation was held, during which "The applicant was informed about the preliminary opinion of the examining division according to which the objections under Art. 84 EPC and Art. 52-56 EPC as set out in the summons to oral proceedings are not overcome by the present amendments. It was also noted that the patentability of the claims (Art. 53 (c) EPC 2000) (would) be a subject of discussion in the oral proceedings". Furthermore, the representative was asked to inform the examining division if the applicant would attend the oral proceedings. By letter dated 12 March 2009 the applicant informed the examining division that they would not attend the oral proceedings, which were held on 26 March 2009 in the absence of the applicant.

V. The decision under appeal was based on the sole request filed with letter of 23 February 2009. The examining division held, *inter alia*, that:

- the subject-matter claimed extended beyond the content of the application as filed (Art. 123 (2) EPC);
- the requirements of Art. 84 EPC were not met, in particular because the parameters "specific gravity" and "refractive index" recited in the claims were unclear;

- regarding Art. 56 EPC, the claimed subject-matter lacked an inventive step over D10. An additional objection of lack of inventive step over D1 was further given as an opinion at the end of the contested decision.

The application was therefore refused.

In point 13 of the section "Facts and Submissions" the examining division indicated: "In the oral proceedings held on 26.03.2009 the examining division decided to refuse the application according to Article 97(2) EPC, because it does not meet the requirements of Articles 84, 52-56 and 123(2) EPC. Although the applicant has not been informed explicitly about the new deficiencies under Article 123(2) EPC in amended claim 1 prior to the oral proceedings, a decision was taken on this objection during the oral proceedings in accordance with the Official Journal 10/2008 p. 471.".

- VI. On 4 June 2009, the applicant (appellant) lodged an appeal against the above decision. The prescribed fee was paid on the same day. In its statement of grounds of appeal filed on 4 August 2009 the appellant requested that the decision of the opposition division be set aside and a patent be granted on the basis of the main request, or in the alternative, of any of auxiliary requests 1-3 filed therewith. The appellant further requested the reimbursement of the appeal fee.
- VII. In a communication issued by the Board on 16 November 2011 accompanying the summons to oral proceedings, it was *inter alia* pointed out that the clarity of the parameters "specific gravity" and "refractive index"

recited in the claims would have to be assessed. Reference was made to Wikipedia for establishing the definition of "specific gravity".

VIII. Together with its reply filed on 5 January 2012 the applicant submitted a new main request and an auxiliary request replacing all former requests.

IX. Oral proceedings were held on 1 February 2012 in the presence of the appellant.

After having given arguments regarding clarity the appellant filed a new main request (two claims) replacing all former requests. The claims read as follows (regarding claim 1, additions are indicated in **bold** and deletions as ~~strike-through~~, both as compared to claim 1 of the application as filed):

"1. A polysiloxane copolymer having functional acryl groups capable of being photopolymerized into a solid intraocular lens, having a specific gravity greater than ~~about~~ 1.0, **having** a refractive index **above 1.39 and up to 1.60 at 25°C** ~~suitable for restoring the refractive power of the natural crystalline lens,~~ wherein said polysiloxane **copolymer is an acrylterminated terpolymer comprising 4 to 65 mol% 3,3,3-triflouropropylmethylsiloxane, 1 to 50 mol% of diphenylsiloxane, and dimethylsiloxane monomer units** ~~has siloxane monomer units selected among substituted or unsubstituted arylsiloxanes, arylalkylsiloxanes and alkyl(alkyl)siloxanes~~ **for injection directly into the capsular sac of the human eye directly in connection with that a defective natural crystalline lens has been surgically removed.**

2. The polysiloxane copolymer according to claim 1 characterized in that said copolymer comprises 28 mol% trifluoropropylmethyl siloxane, 4 mol% diphenyl siloxane, and dimethylsiloxane monomer units."

X. The appellant's arguments may be summarised as follows:

Art. 123 (2) EPC

(a) The requirements of Art. 123 (2) EPC were met because the subject-matter of claims 1 and 2 was derivable from the combination of claim 4 with passages of the application as filed.

Art. 84 EPC

(b) It was clear from the wording of the claims that the parameters recited in claim 1 characterised the polysiloxane terpolymer, i.e. the prepolymer injected in the eye bag before being photopolymerised. Anyway, the refractive index of the polymerised lens would not be very different from that of the injected prepolymer.

(c) Water was usually considered as reference substance for the determination of the specific gravity of liquids, as indicated e.g. in the Wikipedia reference cited by the Board. Considering that the aim of the application was to provide a polymer lens that does not float on the aqueous solution present in the capsular bag of the eye, there was no reason why a different reference would be used in the application in suit.

Even if the aqueous solution present in the eye was not pure water, there was no technically significant difference in terms of density between pure water and the aqueous solution present in the eye. Therefore, the reference liquid used in the application was water.

The relevant temperature for the surgeon practising lens replacement was the injection temperature i.e. room temperature. The application as filed disclosed a single value of 25°C for room temperature. It was the only value that made sense and would be considered by the skilled person for the determination of specific gravity. There were no technically significant differences in specific gravity by measuring at different temperatures, such as 20°C, 25°C and 37°C. A temperature of 4°C that was admittedly sometimes used for the density of the reference substance (i.e. water) would not make sense in the framework of the present field of surgery.

- (d) Regarding the determination of the refractive index, the skilled person knew that the standard value 589 nm (sodium D line) was to be used. Should the use of a different wavelength be contemplated, compensation measures were commonly used to take that into account. Concerning the dependence of refractive index on temperature, the refractive index in the application had been measured at 25°C, as apparent from the examples.
- (e) No solvent was required for the measurement of specific gravity and refractive index of the

acryl-terminated terpolymers defined in claims 1 and 2.

- (f) The term "directly" used twice in claim 1 meant that the injection of the prepolymer was done shortly after the removal of the natural lens.

Art. 54 EPC

- (g) None of the documents cited in the proceedings disclosed the combination of technical features, in particular the specific acryl-terminated terpolymer, according to claim 1. Hence, novelty was given.

Art. 56 EPC

- (h) Starting from D5 as the closest prior art, the problem to be solved was to provide copolymers that could simplify the surgical process of lens replacement while at the same time allowing the surgeon to adjust the refractive index of the replacement lens over a large range.
- (i) The examples of the application as filed showed that that problem had been effectively solved by the acryl-terminated polysiloxane terpolymer defined in claim 1. Those terpolymers did not float on the aqueous solution present in the eye and led to a complete filling of the capsular bag with exclusion of said aqueous solution during the injection, thus simplifying the surgical process.

- (j) None of the documents of the prior art cited in the proceedings addressed the above-identified problem and none of those documents disclosed the specific terpolymers defined in claim 1. The subject-matter of claims 1 and 2 was, therefore, inventive.
- (k) The same conclusions would be drawn starting from either D1 or D4 as the closest prior art.

Reimbursement of the appeal fee

- (l) The contested decision was based on a ground, namely Art. 123 (2) EPC, that had not been mentioned amongst the deficiencies listed in the minutes of the telephone conversation held on 9 March 2009, so that the applicant had had no opportunity to present comments upon it. Since the objection under Art. 123 (2) EPC that had been raised previously referred to a different set of claims, the appellant had been led to believe that no objections under Art. 123 (2) EPC existed as regards the claims then on file. Hence, the right to be heard had not been respected so that reimbursement of the appeal fee was justified.

XI. The appellant (applicant) requested that the decision under appeal be set aside and a patent be granted on the basis of the sole request (claims 1 and 2) filed during the oral proceedings. The appellant further requested the reimbursement of the appeal fee.

XII. The Board announced its decision at the end of the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. Amendments
 - 2.1 Claim 1 corresponds to claim 1 as originally filed with the following amendments:
 - replacement of "suitable for restoring ... lens" by "above 1.39 and up to 1.60 at 25°C";
 - definition of the polysiloxane copolymer as an acryl-terminated terpolymer of dimethylsiloxane, diphenylsiloxane and 3,3,3-trifluoropropyl methylsiloxane, each monomer being defined in specific amounts;
 - addition of "for injection ... removed".
 - 2.2 According to page 5, lines 22-28 of the application as filed, the polysiloxane copolymers according to the present invention should have a refractive index above 1.39 and up to 1.60 in order to restore the refractive index of a natural lens. This statement is of general nature and hence applies to all embodiments illustrating the "present invention" in the sense of the application as filed, in particular the specific terpolymers as defined in claim 1. The range of the refractive index now claimed is, according to that passage, equivalent to the wording "suitable for restoring the refractive power of the natural crystalline lens" used in claim 1 of the application as filed.
 - 2.3 The temperature of 25°C corresponds to the only temperature disclosed in the application as filed in

relation to measurement of the refractive index (examples 2-4: page 11, lines 1 and 20-21; page 12, line 2) and makes sense in view of the technical field of eye surgery. Hence, that value can be accepted as information generally applicable to the temperature of measurement of the refractive index in the present application.

- 2.4 The specific terpolymers defined in claim 1 are disclosed as a preferred embodiment of the polysiloxane copolymers of the present invention on page 6, lines 18-25 of the application as filed, in particular page 6, lines 19, 20 and 23-25.
- 2.5 The feature "for injection ... removed" can be found on page 4, lines 15-16 of the application as filed in the form of a general statement that is applicable to any embodiment illustrating the "present invention" in the sense of the application as filed.
- 2.6 The subject-matter of claim 1 is, therefore, directly and unambiguously derivable from the application as filed.
- 2.7 The same is valid concerning claim 2 since the specific terpolymer defined therein corresponds to a "more preferred" embodiment recited on page 6, lines 25-27 of the application as filed.
- 2.8 The requirements of Art. 123 (2) EPC are therefore met.

3. Clarity

- 3.1 The "specific gravity" of a given substance A is the density of said substance A at a specific temperature T_A to the density of a reference substance B at a specific temperature T_B , which may or may not be the same as the temperature T_A .

The application as filed does not indicate which reference substance is used for the measurement of specific gravity. However, water is usually considered as the reference for liquids (see e.g. Wikipedia or any scientific encyclopaedia). In view of the technical field of the present application and in the absence of any indication to the contrary in the application as filed, there is no reason to consider anything else than the usual reference, i.e. water.

As to the temperature, there is no reason not to accept the appellant's argument that there is no technically significant effect by using different temperatures such as 20, 25 or 37°C. In this regard, a temperature of 4°C that is sometimes used for the density of water would not make sense in the framework of the present field of surgery.

- 3.2 Since the refractive index is a well known parameter that can be determined using method(s) commonly used in the art, the Board is satisfied that the skilled person can determine whether or not a given composition falls inside or outside the claimed scope as regards the refractive index requirements set therein.

3.3 The subject-matter of claim 1 is directed to the polysiloxane terpolymer, i.e. the prepolymer injected in the eye bag before being photopolymerised *in situ*. Therefore, there can be no doubt that the parameters recited in claim 1 characterise said prepolymer as such, which is confirmed by the description (e.g. page 5, lines 22-31).

3.4 In view of the above, the claimed subject-matter is defined clearly and the requirements of Art. 84 EPC are met.

4. Novelty

4.1 D10 discloses in example 9 a hydroxyl terminated terpolymer comprising 85 mol.% dimethylsiloxane, 5 mol.% diphenylsiloxane and 10 mol.% 3,3,3-trifluoropropyl-methylsiloxane, terminated with hydroxyl groups. The subject-matter now being claimed differs from that copolymer in that the terpolymer is acryl-terminated and not hydroxyl-terminated, so that novelty is given already for that reason. Whether the requirements of refractive index and specific gravity are satisfied because the copolymers used in example 9 of D10 are very similar to those prepared e.g. in examples 7-8 of the present application, does therefore not play any role. Under these circumstances it is also irrelevant whether or not the feature "for injection ... removed" is a method for treatment according to Art. 53 (c) EPC that could be considered as a novelty conferring feature (Art. 54 (4) (5) EPC).

4.2 None of the other documents on file discloses an acryl-terminated polysiloxane terpolymer made up of the three specific monomers defined in present claims 1 and 2.

4.3 The subject-matter of claims 1 and 2 is therefore novel.

5. Inventive step

5.1 Closest prior art

5.1.1 The present application concerns photocurable siloxane polymers useful in the preparation of intraocular lenses by forming the lens in the capsular bag of the eye after the extraction of a cataract (page 1, lines 5-13).

5.1.2 Among the cited documents, only D4 and D5 deal with the problem of *in situ* polymerisation of polymeric lenses for the treatment of cataract.

D4 discloses a method for the treatment of cataract by implantation of intraocular lenses made *in situ* by photopolymerisation and following the extraction of the natural lens. The polymers used are acrylic polymers and not polysiloxanes (claims 1, 6; page 1, lines 1-14, 32-37, examples).

D5 also discloses a method for the treatment of cataract by implantation of intraocular lenses made *in situ* by photopolymerisation and following the extraction of the natural lens. The polymers are derived from the crosslinking of a two components mixture of polysiloxanes (claims 1, 4, 8, 11, 12; examples 3-4).

Not only do the polysiloxanes used in D5 present less toxicological risks than the polyacrylates of D4, as described on page 3, lines 23-25 of the application as filed, they are, from a chemical point of view, more closely related to the subject-matter of claims 1 and 2. Hence, D5 is considered as the closest prior art document.

5.1.3 The first instance considered D10 in combination with D1 for denying the presence of an inventive step. However, the closest prior art should be a document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most technical features in common, i.e. requiring the minimum of structural modifications. D10 however concerns self-extinguishable room temperature vulcanizable polyorganosiloxane compositions for use as sealing material for construction purposes (col. 5, lines 24-33), so that it cannot be considered to be a promising starting point for the skilled person confronted with the problem of lens implantation. The same is valid regarding D1 that does not relate to *in situ* polymerised intraocular lenses. Therefore, neither of D10 or D1 can serve as the closest prior art document.

5.2 Problem to be solved

According to the application as filed, the problem to be solved as compared to D5 may be seen as to provide polysiloxane copolymers that simplify the surgical process of lens replacement while at the same time allowing the surgeon to adjust the refractive index of

the replacement lens over a large range (see page 8, lines 15-22; page 9, lines 5-20).

5.3 Solution

The solution to the above problem resides in the acryl-terminated polysiloxane terpolymers defined in claim 1.

5.4 Success of the solution - Problem effectively solved

5.4.1 Examples 7 and 8 together with examples 11.1.b, 11.2.b and 12 of the application as filed show that the claimed polymers are suitable for simple lens replacement allowing adjustment of the refractive index.

5.4.2 There is no hint in the cited prior art nor any other reason that could lead to suppose that the problem would not be solved over the whole scope of the claims. Therefore, the Board is satisfied that the above-defined problem is effectively solved over the whole scope of the claims.

5.5 Obviousness

5.5.1 It remains to be decided whether or not it was obvious to solve the above-identified problem by modifying the teaching of D5 in such a way as to arrive at the subject-matter of claim 1.

5.5.2 D5 does not provide a suggestion, nor a motivation, to select three monomers so as to arrive at a terpolymer according to present claim 1. Therefore, D5 by itself does not render the claimed subject-matter obvious.

5.5.3 The only other document dealing with the problem of lens replacement by photocurable polymers is D4. However, like D5, it does not disclose the present specific terpolymers. Therefore, the combination of D5 with D4 would not lead to the subject-matter now being claimed.

5.5.4 None of the other documents on file mentions the present terpolymers, nor do they deal with lens replacement, so that they contain no suggestion of the solution proposed by claim 1 in order to solve the above-defined problem.

5.5.5 Therefore, the subject-matter of claim 1, as well as that of dependent claim 2, is inventive.

6. Reimbursement of the appeal fee

6.1 According to Rule 103 (1) (a) EPC the appeal fee shall be reimbursed if the appeal is allowed and if reimbursement is equitable by reason of a substantial procedural violation.

6.2 The present patent application had not only been refused for not complying with Art. 123 (2) EPC, but also because claim 1 of the sole valid request did not meet the requirements of Art. 84 EPC and Art. 56 EPC and because claim 4 did not meet the requirements of Art. 53 (c) EPC.

6.3 The latter objections had been clearly identified in the telephone conversation of 9 March 2009. Therefore, the appellant should have known that major objections to the grant of a patent were still present and that

its actual request was not allowable in view of those objections. In deciding not to attend the oral proceedings, the appellant has deliberately chosen not to make use of the opportunity to defend its case during oral proceedings.

6.4 Since the non-compliance of even only one claim with even only one disposition of the EPC is sufficient to refuse a request as a whole, the present application would have been and in fact was refused for several reasons additional to those under only Art. 123 (2) EPC.

6.5 Under these circumstances, the Board comes to the conclusion that no substantial procedural violation has taken place. Even if such violation had taken place, reimbursement would not have been equitable as it was in any case necessary for the applicant to file an appeal in order to overcome the objections other than those under Art. 123 (2) EPC. The request of reimbursement of the appeal fee is, therefore, refused.

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 on the basis of the sole request (claims 1-2) filed during the oral proceedings of 1 February 2012 and after any necessary consequential amendment of the description.
3. The reimbursement of the appeal fee is refused.

The Registrar:

The Chairman:

E. Görgmaier

B. ter Laan