

**Internal distribution code:**

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

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

**Case Number:** T 1685/09 - 3.3.03

**Application Number:** 99953839.0

**Publication Number:** 1141751

**IPC:** G02B 1/04, A61L 27/00,  
C08G 77/24

**Language of the proceedings:** EN

**Title of invention:**  
Injectable intraocular lens

**Applicant:**  
AMO Groningen B.V.

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 54, 56, 84, 123(2)

**Keyword:**  
"Amendments - added subject-matter (no)"  
"Claims - clarity (yes)"  
"Novelty (yes)"  
"Inventive step (yes) - after amendment"

**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 6 April 2009  
refusing European patent application  
No. 99953839.0 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 6 April 2009 to refuse European patent application N°. 99 953 839.0.

II. The application as filed was based on 22 claims of which claims 1 and 2 read:

"1. Polysiloxanes suitable for the preparation of intraocular lenses by a crosslinking reaction, having a specific gravity of greater than about 1.0, a refractive index suitable for restoring the refractive power of the natural crystalline lens and a viscosity suitable for injection through a standard cannula."

"2. Polysiloxanes according to claim 1, wherein the refractive index ranges between 1.382 up to about 1.60."

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

- D0: W. Noll, Chemie und Technologie der Silicone, 1968, Verlag Chemie GmbH, Weinheim, pages 393-395
- D1: EP-A-0 578 087
- D2: WO-A-93 23 476
- D3: US-A-5 391 590
- D4: US-A-5 116 369
- D5: WO-A-93 21 245
- D6: FR-A-2 309 599
- D7: WO-A-95 17 460
- D8: EP-A-0 094 153

D10: US-A-4 216 140

D11: Mazurek et al., Makromol. Chemie, 178,  
pages 1005-1017, 1977

IV. 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 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. 54 EPC, the subject-matter of claim 1 was anticipated by D10;
- although the objection did not form part of the decision, it was indicated at the end of the contested decision that the claimed subject-matter was not inventive over D8.

The application was therefore refused.

V. 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 the 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 the only auxiliary request filed therewith. The appellant further requested the reimbursement of the appeal fee.

VI. 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".

- VII. Together with its reply filed on 5 January 2012 the applicant submitted a new main request in replacement of all former requests.
- VIII. 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 (one claim) replacing the former main request. The claim reads as follows (additions are indicated in **bold** and deletions as ~~strike-through~~, both as compared to claim 1 of the application as filed):

"1. A polysiloxane ~~suitable for the preparation of intraocular lenses by a crosslinking reaction~~, having a specific gravity greater than ~~about~~ 1.0, having a refractive index ~~suitable for restoring the refractive power of the natural crystalline lens~~ **between 1.38 and up to 1.60** and viscosity **of less than 60 000 Cst at 25°C that is** suitable for injection through a standard cannula **having an 18 Gauge needle dimension or finer, wherein said polysiloxane is a vinylterminated terpolymer comprising 4 to 65 mol% 3,3,3 triflouropropylmethylsiloxane, 1 to 50 mol% of diphenylsiloxane, and dimethylsiloxane monomer units for forming an injectable intraocular lens formed with the capsular bag as a mold as a replacement of a diseased natural lens by a crosslinking reaction.**"

The request for reimbursement of the appeal fee was withdrawn.

IX. 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 present claim 1 was derivable from the combination of claim 2 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 crosslinked. 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. The dependence of refractive index on temperature was not technically significant for the range now defined in claim 1, as had been shown on page 2 of the submission dated 29 December 2011.
- (e) No solvent was required for the measurement of specific gravity and refractive index of the vinyl-terminated terpolymers defined in claim 1.

- (f) The term "injectable intraocular lens" used in claim 1 was usual in the art and its meaning was clear.

*Art. 54 EPC*

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

*Art. 56 EPC*

- (h) Starting from D3 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 vinyl-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 claim 1 was, therefore, inventive.

(k) The same conclusions would be drawn starting from D2 as the closest prior art.

X. The appellant (applicant) requested that the decision under appeal be set aside and a patent be granted on the basis of the sole request (one claim) filed during the oral proceedings.

XI. 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 2 as originally filed with the following amendments:

- replacement of "suitable for restoring ... lens" by "between 1.38 and up to 1.60";
- replacement of "suitable for injection through a standard cannula" by "of less than 60 000 Cst at 25°C ... or finer";
- definition of the polysiloxane copolymer as a vinyl-terminated terpolymer of dimethylsiloxane, diphenylsiloxane and 3,3,3-trifluoropropyl methylsiloxane, each monomer being defined in specific amounts;

- replacement of "suitable for the preparation of ... by a crosslinking reaction" by "forming ... reaction".

2.2 According to page 5, line 28 to page 6, line 1 of the application as filed, the polysiloxane copolymers according to the present invention can have a refractive index between 1.382 and up to about 1.60, preferably between from about 1.38 to 1.46 and more preferably from about 1.38 to 1.43, in order to restore the refractive index of a natural lens. Therefore, there is disclosure for a range having 1.38 as the lower limit and 1.60 as the upper limit. This statement is of a 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 (see point 2.5 below). The range of the refractive index now claimed is, according to page 5, lines 19-22, 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 A passage referring to a viscosity "of less than 60 000 Cst ... or finer" is disclosed on page 6, lines 2-8, in particular lines 5-8, of the application as filed. According to that passage, the present wording is equivalent to the original wording "suitable for injection through a standard cannula" used in claim 1 of the application as filed. Considering that the passage "the polysiloxanes should also have..." follows directly after the passage describing the refractive index ranges of the claimed polysiloxanes, it not only refers to the polysiloxanes of the invention in general,

but also to polysiloxanes having a refractive index as described before, i.e. between 1.38 and up to 1.60. Therefore, the combination of those two features is based on the original disclosure.

- 2.4 The temperature of 25°C corresponds to the only temperature disclosed in the application as filed in relation to the viscosity (example 4; page 13, lines 25-26, and example 5; page 14, line 13). Although the viscosities measured in those examples correspond to dynamic viscosity (unit: cP) and not to cinematic viscosity as recited in claim 1 (unit: cSt), in view of the relation between the two viscosities (cinematic viscosity = dynamic viscosity/density) and considering the technical field of the present application, that value can be accepted as the relevant temperature for the viscosity measurements.
- 2.5 The specific terpolymers defined in claim 1 are disclosed as a preferred embodiment of the polysiloxane copolymers of the present invention on page 7, lines 4-5 and 18-24 of the application as filed.
- 2.6 The feature "for forming ... reaction" is derivable from the passages on page 5, lines 19-20 (polysiloxanes suitable for the preparation of intraocular lenses by a crosslinking reaction), page 11, line 10 (replacement of diseased natural lens), page 11, lines 2-4 (lens formed with the capsular bag as a mold) and page 1, lines 1-5 (injectable intraocular lenses formed within the capsular bag). Those passages all generally refer to the use of the claimed copolymers for *in situ* preparation of intraocular lenses, so that they may be combined for defining the claimed copolymers.

2.7 In view of the above, the subject-matter of claim 1 is directly and unambiguously derivable from the application as filed so that the requirements of Art. 123 (2) EPC are met.

### 3. Clarity

3.1 The subject-matter of claim 1 is directed to the polysiloxane terpolymer, i.e. the prepolymer injected in the eye bag before being polymerised *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, line 28 to page 6, line 8).

3.2 The "viscosity" of claim 1 is a usual parameter and can be determined using common technology. 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 viscosity requirements set therein.

3.3 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.

3.4 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.

3.5 The term "injectable intraocular lens" is accepted in the art (see e.g. D2 and D3). The definition provided in the application as filed (page 2, lines 21-22; page 3, lines 23-25) is in line with that reading and corresponds to known techniques for replacement of a natural lens wherein a material is injected into the empty capsular bag of the eye and cured *in situ*.

3.6 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 terpolymer in that it is vinyl-terminated and not hydroxyl-terminated, so that novelty is given already for that reason. Whether the requirements of specific gravity, refractive index and viscosity are satisfied does therefore not play any role. Under these circumstances it is also irrelevant whether or not the feature "for forming ... reaction" 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 a vinyl-terminated polysiloxane terpolymer made up of the three specific monomers defined in present claim 1.

4.3 The subject-matter of claim 1 is therefore novel.

5. Inventive step

5.1 Closest prior art

5.1.1 The present application concerns crosslinkable siloxane polymers useful in the preparation of an injectable intraocular lens prepared by injection of a polymeric composition in the capsular bag of the human eye and *in situ* polymerisation thereof (page 1, lines 1-5; page 5, lines 7-18).

5.1.2 Among the cited documents, each of D2-D5 deals with the problem of *in situ* polymerisation of polymeric lenses for the treatment of cataract.

D2 discloses injectable intraocular lenses made of a two component mixture of polysiloxanes polymerised *in situ* at body temperature (claim 17; page 1, lines 1-10; page 2, lines 1-3). Although on page 7, lines 2-29, all three monomers recited in present claim 1 are individually mentioned as possible components of the vinyl-terminated polysiloxane used in D2, terpolymers as defined in claim 1 are not disclosed in D2.

The intraocular lenses disclosed in D3 are also derived from crosslinking a two components mixture of polysiloxanes (claims 1, 4, 8, 11, 12; examples 3-4). Similarly to D2, D3 discloses in col. 4, lines 45-50 all three monomers recited in present claim 1 for making vinyl-terminated polysiloxane but fails to disclose the terpolymers now being claimed.

The same is valid regarding the siloxane polymers disclosed in D5 (claims 1, 5, 19; page 1, lines 4-5; page 7, line 12 to page 8, line 5; examples 1-4).

The intraocular lenses disclosed in D4 are made by crosslinking a two-component mixture of polysiloxanes (D4: claims 1 and 3; col. 1, lines 10-14; col. 4, lines 27-30; col. 3, lines 10-18; col. 4, line 9 to col. 6, line 35). D4 neither discloses terpolymers as defined in claim 1 nor vinyl-terminated polymers.

Each of D2, D3 or D5 could be seen as the closest prior art. Since document D3 is cited on pages 3-4 of the application as filed, it is hereinafter considered 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 D3 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 4, lines 25-28; page 10, lines 9-22; page 11, lines 2-4).

## 5.3 Solution

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

## 5.4 Success of the solution - Problem effectively solved

Examples 4-8 of the application as filed show that the claimed polymers are suitable for simple lens replacement allowing adjustment of the refractive index.

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 claim. Therefore, the Board is satisfied that the above-defined problem is effectively solved.



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 D3 in such a way as to arrive at the subject-matter of claim 1.

5.5.2 D3 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, D3 by itself does not render the claimed subject-matter obvious.

5.5.3 The only other documents dealing with the problem of lens replacement by polymers curable *in situ* are D2, D4 and D5. However, like D3, they do not disclose the present specific terpolymers. Therefore, the combination of D3 with D2, D4 and/or D5 would not lead to the subject-matter now being claimed, in particular not with a view to simplify the surgical process of lens replacement.

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.

5.6 The same conclusion is also reached starting from either D2 or D5 as closest prior art.

5.7 Therefore, the subject-matter of claim 1 is inventive.

## 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 (one claim) filed during the oral proceedings of 1 February 2012 and after any necessary consequential amendment of the description.

The Registrar:

The Chairman:

E. Görgmaier

B. ter Laan