

Candidate's Answer Paper

European Patent Office
Directorate General 2

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Munich

Dear Sirs,

European Patent Application No.
Our Ref: X.1234

This is in response to the communication pursuant to Article 96(2) and Rule 51(2) EPC dated

Please replace claims 1 to 5 at present on file by the revised claims 1 to 7 enclosed herewith in triplicate. A copy of the original claims, showing in manuscript the amendments made, is also enclosed for the Examiner's convenience.

As requested by the Examiner, claim 1 has been amended to include the definition of the group R¹-X- in accordance with the requirements of Art. 84 and Rule 29(6) EPC. The definition has been taken from [page 97], last lines of Document I. This amendment finds basis at [page 90] 4th paragraph, 1st sentence of the application documents as filed, where it is stated that the structure of the siloxanes (A') corresponds to formula (1) in Document I. Further basis may be found in the present application at [page 90] last paragraph, 3rd line, where the R¹-X- groups are described as ethylenically unsaturated, and at [page 90] 5th paragraph, lines 1-2, where R¹ is described as an ethylenically unsaturated group bonded to a silicon atom of the reactive siloxane by a urethane group X. The importation of the definition from Document I is in accordance with the requirements laid down in T 689/90 as the description as filed leaves no doubt to a skilled reader: (i) that protection is sought for this feature; (ii) that the feature contributes to achieving the technical aim of the invention and is thus included in the solution of the technical problem underlying the invention; (iii) that the feature clearly belongs to the description of the present application as filed; and (iv) that the feature is precisely defined and identifiable within Document I.

The Shore-D hardness in claim 1 has been specified as having a lower limit of 70 (see [page 92] 4th paragraph, 3rd line) and the contact angle has been specified as at least 100° (see [page 91] 2nd paragraph, last sentence).

Claim 1 has also been amended to specify that the number of R¹-X- groups represents between 5 and 10% of the total number of all silicon-bonded organic groups. This finds basis at [page 90] 5th paragraph, lines 4-6.

Claim 2 finds basis in the definition of R¹-X- in Document I at [page 97], last lines. As explained above with regard to claim 1, this amendment does not add subject-matter.

Claim 3 finds basis at [page 92] 5th paragraph (Examples 8 to 10).

Claim 4 corresponds to original claim 2 with the addition feature that the polymerisation is carried out at a temperature of no more than 60°C (see [page 91] 4th paragraph, last sentence).

Claims 5 to 7 correspond to original claims 3 to 5.

The polymers of claim 1 are novel over the polymers disclosed in the cited prior art because they contain a number of R¹-X- groups which represent between 5 and 10% of the total number of all silicon-bonded organic groups.

In Document II, $1 \leq m \leq 3$ and $(m+n) \leq 150$. The only specific disclosure is given in the Example where $(m+n)=100$ and $m=3$. This corresponds to 3 R¹X groups and 200R groups, i.e. R¹-X- groups represent about 1.5% of the total number of all silicon-bonded organic groups.

In Document III, $m = 1$ and $100 \leq n \leq 150$. Again the only specific disclosure is given in the Examples where $n=100$. This corresponds to 1 R¹X group and 204 R groups, i.e. R¹-X- groups represent only about 0.5% of the total. It will be noted that this specific disclosure gives the largest possible percentage derivable from Document III because n cannot be less than 100.

The claimed polymers also involve an inventive step. Use of the specified percentage of R¹-X- groups gives rise to an improvement which is in no way expected in the light of the prior art. Thus Examples 8 to 10 differ from Examples 2 to 4 in their percentage of R¹-X- groups only. In other respects Examples 8 to 10 correspond to Examples 2 to 4, having the same monomer components in the same proportions, and being prepared in an analogous manner.

Examples 2 to 4 have $m=3$ and $(m+n)=100$, as in Document II, i.e. a percentage of R¹-X- groups of about 1.5%. Examples 8 to 10, however, have a percentage of 10% (see [page 92] 5th paragraph). Thus Examples 2 to 4 fall outside claim 1 while Examples 8 to 10 fall within claim 1.

Examples 8 to 10 have comparable clarity, oxygen permeability and contact angle to Examples 2 to 4, but Examples 8 to 10 also have considerably greater Shore-D hardness and considerably reduced swelling in water.

Thus the polymers of claim 1 satisfy the requirements for an inventive selection with respect to the prior art as laid down in T 198/84 and T 279/89. The percentage sub-range is (a) narrow relative to the range disclosed in Document II, (b) removed from the preferred embodiments (Examples) of Document II, and (c) is not an arbitrarily chosen subgroup but involves an unexpected improvement.

In terms of the problem/solution approach, the problem is to obtain polymers having improved hardness and reduced swelling while retaining good clarity, oxygen permeability and contact angle. The solution cannot be said to be obvious, whichever prior art document one takes as the starting point.

Thus claim 1 is novel and involves an inventive step. The further claims likewise are novel and involve an inventive step by virtue of their dependence on claim 1.

Thus it is believed that the claims as amended satisfy the requirements of the EPC, especially with regard to novelty, inventive step, clarity, disclosure in the documents as filed and unity.

If, however, there are considered to be any points outstanding, the Examiner is requested either to telephone the writer or to issue a further communication. Only as a precaution, in case the Examiner is minded to reject the application, I request oral proceedings.

Please acknowledge receipt of this letter by stamping and returning the enclosed acknowledgement copy.

Yours faithfully,

Z. Badura
Authorised Representative

Claims

1. Cross-linked, glass-clear, transparent copolymers with a degree of cross-linking which prevents the polymers from swelling in water by more than 10% by volume, and with a Shore-D hardness in the range from 70 to 85, and with a contact angle of at least 100°, obtainable by copolymerisation of glass-clear, streak-free monomer mixtures containing an initiator (E) in an amount of 0.001 to 0.5% by weight of the monomers, said monomer mixtures consisting of
 - (A) 15 to 40% by weight of a component which is (A¹) a siloxane of the formula (1),
$$R_3Si-O-[(R^1-X)Si(R)-O]_m-[Si(R)_2-O]_n-SiR_3 \quad (1),$$
wherein the number of siloxane units does not exceed 150, R = independently of one another C₁- to C₄- alkyl or phenyl, and at least one R¹-X- group is present, wherein R¹ is an ethylenically unsaturated group and X is -R³-O-CO-NH-R⁵-NH-CO-O-R⁴-, each of R³ and R⁴ being a linear or branched divalent alkalene residue and R⁵ a linear or cyclic alkalene residue, and wherein the number of R¹-X- groups represents between 5 and 10% of the total number of all silicon-bonded organic groups; wherein (A¹) may be partly replaced by (A²) which is a fluoroalkyl methacrylate in which the fluoroalkyl group contains 2 to 10 C atoms, in an amount of no more than 10 % by weight of the total weight of the components (A) to (D),
 - (B) 40 to 80 % by weight of a methacrylic acid alkyl ester the alkyl group of which contains 1 to 5 C atoms,
 - (C) 2 to 10 % by weight of an hydroxy group-containing acrylate and/or methacrylate, and
 - (D) 0 to 10 % by weight of compounds having at least two ethylenically unsaturated copolymerisable groups.
2. A polymer according to claim 1 wherein R¹ is CH₂=C(R²)-CO-O- and R² is H or CH₃,
3. A polymer according to claim 1 or 2 wherein the reactive siloxane has a degree of polymerisation of 100 and contains polymerisable methacrylate groups, their number being 10% of all the organic groups bonded to siloxane groups.
4. Process for the production of polymers according to any one of claims 1 to 3, characterised in that a glassclear mixture is prepared from the monomers in the stated amounts with the initiator, the mixture is degassed by being placed briefly in a vacuum prior to polymerisation, the polymerisation is subsequently initiated under inert gas, and the polymerisation is carried out at a temperature of no more than 60°C.
5. Use of the polymers of any one of claims 1 to 3 for the manufacture of contact lenses.
6. Contact lens made from a polymer according to any one of claims 1 to 3.
7. Process for the production of the contact lens according to claim 6 using the process according to claim 4, characterised in that the polymerisation is performed in a mould, the lens blank thus obtained is shaped into the desired form by machining and the surfaces of the lens thus obtained are finally polished.

Notes to Examiner

1. There is no basis in the application documents as filed for limiting the claims to specify that a proportion of the R groups must be phenyl. Such a limitation would contravene Art. 123(2) and may not be made. The further test results provided in the client's letter cannot therefore be used in support of patentability.

In fact, according to [p. 90] 4th paragraph, lines 8-12, short-chained groups such as methyl and ethyl, and in particular methyl, are preferred.

There is a note at [p. 90] 4th paragraph, last sentence that the choice of the groups R also influences the optical properties, but this is not sufficient basis. It cannot be determined from this disclosure that the presence of phenyl groups in particular allows the refractive index to be controlled.

2. Possible divisional application to polymer of Example 6. Our specific component (D) = NPDA is not referred to in prior art and gives improvement over Example 2 in terms of increased hardness and reduced swelling.
3. Possible divisional application to polymer of Example 7 if we can argue for unexpected advantage.
4. Possible divisional app. to preparation process of original claim 2, limited to photochem. initiator - advantage: see [p. 91], 5th paragraph, lines 3-5.