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Datasheet for the decision of 20 September 2007

Case Number: T 1437/04 - 3.3.09

Application Number: 98928177.9

Publication Number: 0991702

IPC: C08J 7/04

Language of the proceedings: EN

Title of invention:
A hydrophilic coating and a method for the preparation thereof

Patentee:
COLOPLAST A/S

Opponent:
AstraZeneca AB

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 104(1), 111(1)
RPBA Art. 10b(1)

Keyword:
"Main request, Auxiliary Request 1, Amended Auxiliary Request 2, Auxiliary Request 5 - Novelty (no)"
"Auxiliary Request 3, Amended Auxiliary Request 4 - Clarity (no)"
"Amended Auxiliary Request 6 - Novelty (yes); Inventive step of Claim 7 (no)"
"Auxiliary Request 7 - Admissibility (no)"
"Auxiliary Request 8 - Novelty (yes); Inventive step (yes)"

Decisions cited:
-

Catchword:
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Case Number: T 1437/04 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 20 September 2007

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 20 October 2004 rejecting the opposition filed against European patent No. 0991702 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: P. Kitzmantel
Members: N. Perakis
M-B. Tardo-Dino

Summary of Facts and Submissions

I. Mention of the grant of European patent No 0 991 702 in respect of European patent application No 98928177.9 in the name of COLOPLAST A/S, which had been filed as International application No PCT/DK 98/00264 on 19 June 1998 claiming a DK priority of 20 June 1997 (DK 73097), was announced on 22 August 2001 (Bulletin 2001/34). The patent, entitled "A hydrophilic coating and a method for the preparation thereof", was granted with eight claims, product Claims 1 to 6, apparatus Claim 7 and method Claim 8. The three independent Claims 1, 7 and 8 read as follows:

"1. A hydrophilic coating comprising a covalently cross-linked hydrophilic polymer suitable for coating medical devices or instruments for introduction into human cavities, characterised in that said coating comprises a water soluble compound selected from glucose, sorbitol, halides, nitrates, acetates, citrates or benzoates of alkali metals or alkaline earth metals or silver; acetic acid, glycine and urea."

"7. A medical device or instrument suitable for introduction into human cavities and having a hydrophilic coating comprising a cross-linked hydrophilic polymer, characterised in that said coating comprises a water soluble compound selected from glucose, sorbitol, halides, nitrates, acetates, citrates or benzoates of alkali metals or alkaline earth metals or silver; acetic acid, glycine and urea."

"8. A method of producing a medical device or instrument suitable for introduction into human

cavities and having a hydrophilic coating comprising a cross-linked hydrophilic polymer, said coating comprising a water soluble compound, characterised in applying, in one or more steps, a solution of a hydrophilic prepolymer and optionally a monomer, oligomer or polymer and a water soluble compound selected from glucose, sorbitol, halides, nitrates, acetates, citrates or benzoates of alkali metals or alkaline earth metals or silver; acetic acid, glycine and urea, evaporating the solvent and cross-linking the coating by activation through radiation and optionally hydrolysing and optionally neutralising the hydrophilic coating."

Claims 2 to 6 were dependent, directly or indirectly, on Claim 1.

II. A Notice of Opposition was filed against that patent by AstraZeneca AB on 22 May 2002. The Opponent requested the revocation of the patent in its full scope based on the grounds that the subject-mater of the claims lacked novelty and inventive step (Article 100(a) EPC) and that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

The Opposition was *inter alia* supported by the following documents:

D1 : EP-B-0 217 771
D2 : US-A-4 373 009
D3 : US-A-4 459 317
D4 : GB-A-1 600 963

D5 : EP-A-0 093 093
D6 : WO-A-94/16747
D7 : WO-A-89/09246
D10: EP-A-0 591 091

The Opponent contested the novelty of the subject-matter of the independent claims in view of the disclosure of D1, which was considered to have incorporated the disclosures of D2 to D5, and in view of the disclosure of D10. It also contested the existence of an inventive step in view of the obviousness of the combination of *inter alia* D2 to D7 with any of *inter alia* D1, D6 and D10.

The Opponent further contested the sufficiency of the disclosure and argued that essential features were missing necessary for achieving the desired technical effects, ie the reduction of the initial friction of the coating and the provision of a long lasting wetted state.

During the opposition proceedings the Opponent filed *inter alia* the following further document:

Annex D: "Hydrophilic polymer coatings for medical devices", by R. J. LaPorte, Technomic Publishing Company, Inc, 1997, p 57

III. By its decision orally announced on 21 September 2004 and issued in writing on 20 October 2004 the Opposition Division rejected the opposition.
The Opposition Division held that the patent met the requirements of Article 83 EPC since there was sufficient information in the general part of the

description of the opposed patent for a skilled person using his common general knowledge to carry out the invention.

It also held that the subject-matter of the granted Claims 1 to 8, interpreted to involve a hydrophilic coating comprising a covalently cross-linked hydrophilic polymer, was novel over both D1 and D10. In particular concerning D1, it took the view that there was no justification for considering documents D2 to D5 as part of its disclosure, while as regards D10, it considered that it did not disclose a covalently cross-linked hydrophilic polymer suitable for coating a medical device.

The Opposition Division further decided that the claimed subject-matter involved an inventive step. It considered D1 to represent the closest prior art from which the claimed coating differed in that it comprised a hydrophilic polymer which was covalently cross-linked. The Opposition Division, basing itself on the technical evidence in the patent specification, considered that the use of covalently cross-linked polymers in the coatings of D1, though known from D7, was not obvious in view of the surprisingly improved water retention and friction properties.

IV. On 14 December 2004 the Opponent (Appellant) lodged an appeal against the decision of the Opposition Division and paid the appeal fee on the same day. The Appellant requested that the decision of the Opposition Division be set aside and that the patent be revoked in its entirety.

V. In the Statement setting out the Grounds of Appeal filed on 24 February 2005 the Appellant maintained all its previously raised objections.

Thus, it argued that on a proper reading of D1, this document anticipated the claimed coatings because its disclosure comprised the covalently cross-linked hydrophilic polymers of D2 to D5 referred to in D1. It further argued that D10 was a further novelty-destroying document for the claimed subject-matter because of its use of the covalently cross-linked binder polymer (a), which was disclosed to exhibit some hydrophilic properties affording swelling and low friction properties. Another argument on the basis of D10 was that the UV-curing, though intended for the cross-linking of the binder prepolymer (a), would inevitably covalently cross-link the hydrophilic polymer (b).

With regard to inventive step, the Appellant considered documents D2 and D7, which disclosed hydrophilic coatings comprising a covalently cross-linked hydrophilic polymer, to represent the closest prior art. It argued that the skilled person starting from these documents and intending to prolong the duration of the wetted state of the coating, would obviously turn to documents such as D1 or D6, which disclosed the use of a water soluble compound (referred to as osmolality-increasing compound in these documents) for conserving slipperiness of the coating for a longer time. Furthermore, on the basis of the results obtained from its own complementary experiments, submitted with the Grounds of Appeal, the Appellant contested the existence of any unexpected or surprising effect.

With regard to the issue of sufficiency of disclosure the Appellant argued that the technical evidence in the patent specification did not support the desired advantages because it was contradicted by its own complementary experiments and because the alleged advantageous friction coefficient and water retention were not measured under actual use conditions, ie the friction coefficient was not measured against living tissues and the water retention was not measured with the medical device introduced into a human cavity. The Appellant further argued that the patent did not disclose all the features necessary for obtaining the claimed advantages and that the invention was not realizable for all the embodiments falling within the ambit of the claims.

VI. The Respondent (Patent Proprietor) in its written submissions dated 14 September 2005 requested that the appeal be dismissed and the patent be maintained as granted or alternatively be maintained on the basis of Auxiliary Request 1.

Auxiliary Request 1 differed from the Main Request (granted claims) only as far as the subject-matter of Claim 8 was concerned, and specifically in that the hydrophilic polymer was specified to be a "covalently" cross-linked hydrophilic polymer.

The Respondent further requested that the late-filed experimental evidence of the Appellant be not admitted in the procedure and that, if it was, the case should be remitted to the Opposition Division for a decision based on it. It additionally requested apportionment in

its favour of the costs incurred by the late introduction of this evidence.

With regard to the substantive issues, the Respondent maintained that the claimed subject-matter was novel over the opposed documents D1 and D10 as they did not disclose hydrophilic coatings comprising a covalently cross-linked hydrophilic polymer. In relation to the question of inventive step the Respondent considered D7, which disclosed covalently cross-linked polymer coatings, to represent the closest prior art. It argued, based on the examples of the patent in suit, that the coatings of D7 would be known to the skilled person to be less attractive than coatings comprising non-cross-linked polymers in terms of preservation of the wetted state and of coefficient of friction. On that basis it drew the conclusion that the skilled person would not be motivated to introduce any known water soluble compound into a coating comprising a covalently cross-linked hydrophilic polymer in order to simultaneously prolong wetted state and reduce initial friction.

With regard to the late-filed data of the Appellant, the Respondent contested their relevance not only because they did not reproduce the experimental setup in the opposed patent but also on the ground that they deviated from the rational choices the skilled person would make (unrealistic long dipping time and direct coating of PVP K90 onto the PVC catheter leading to loss of coating). These choices prevented a fair comparison with the results of the patent. In this respect the Respondent filed in Appendices B and C experimental evidence showing that too-long a dipping time led to the depletion of the photo-initiator and

thus to less cross-linking of the hydrophilic polymer. On the basis of further evidence (Appendix A) it confirmed the results shown in the patent. The Respondent concluded that the patent, contrary to the allegations of the Appellant, enabled the complete scope of the claims as granted.

VII. With the letter dated 20 August 2007 the Respondent submitted further Auxiliary Requests 2 to 6. Auxiliary Requests 2, 4 and 6 were replaced by amended versions at the oral proceedings.

Claim 1 of **Auxiliary Request 3** reads as follows:

"1. A hydrophilic coating comprising a covalently cross-linked hydrophilic polymer suitable for coating medical devices or instruments for introduction into human cavities, characterised in that said coating comprises a water soluble compound selected from glucose, sorbitol, halides, nitrates, acetates, citrates or benzoates of alkali metals or alkaline earth metals or silver; acetic acid, glycine and urea, whereby a device or instrument having said coating shows a significant increase in water retention and a significant decrease of friction coefficient against living tissue compared to a device having a cross-linked hydrophilic coating without a water soluble compound and shows a significant increase in water retention compared to a device having a coating of the same type of non-cross-linked polymer or physically cross-linked polymer containing osmolality-increasing ingredients."

Claim 1 of **Auxiliary Request 5** reads as follows:

"1. A hydrophilic coating comprising a covalently cross-linked hydrophilic polymer suitable for coating medical devices or instruments for introduction into human cavities, characterised in that said coating comprises a water soluble compound selected from glucose, sorbitol, halides, nitrates, acetates, citrates or benzoates of alkali metals or alkaline earth metals or silver; acetic acid, glycine and urea, said coating being obtainable by applying, in one or more steps, a solution of a hydrophilic prepolymer and optionally a monomer, oligomer or polymer and said water soluble compound, evaporating the solvent and cross-linking the coating by activation through radiation and optionally hydrolysing and optionally neutralising the hydrophilic coating."

VIII. With the letter dated 24 August 2007 the Appellant requested that its late-filed supplemental experiments be allowed into the proceedings, on the one hand because they were filed in reply to the observation in the decision under appeal (paragraphs 3.3.3 and 5.3.1) that the Appellant's arguments lacked an experimental basis and on the other hand because they were *prima facie* highly relevant. It further requested that no apportionment of costs be granted. Finally it contested the comments of the Respondent on its late-filed supplemental experiments.

IX. At the oral proceedings of 20 September 2007 the Respondent amended the Auxiliary Requests 2, 4 and 6 and filed further Auxiliary Requests 7 and 8.

Claim 1 of **Amended Auxiliary Request 2** reads as follows:

"1. A covalently cross-linked hydrophilic coating comprising a covalently cross-linked hydrophilic polymer suitable for coating medical devices or instruments for introduction into human cavities, characterised in that said coating comprises a water soluble compound selected from glucose, sorbitol, halides, nitrates, acetates, citrates or benzoates of alkali metals or alkaline earth metals or silver; acetic acid, glycine and urea."

Claim 1 of **Amended Auxiliary Request 4** reads as follows:

"1. A covalently cross-linked hydrophilic coating comprising a covalently cross-linked hydrophilic polymer suitable for coating medical devices or instruments for introduction into human cavities, characterised in that said coating comprises a water soluble compound selected from glucose, sorbitol, halides, nitrates, acetates, citrates or benzoates of alkali metals or alkaline earth metals or silver; acetic acid, glycine and urea, whereby a device or instrument having said coating shows a significant increase in water retention and a significant decrease of friction coefficient against living tissue compared to a device having a cross-linked hydrophilic coating without a water soluble compound and shows a significant increase in water retention compared to a device having a coating of the same type of non-cross-linked polymer or physically cross-linked polymer containing osmolality-increasing ingredients."

Independent Claims 1, 6 and 7 of **Amended Auxiliary Request 6** read as follows:

"1. A covalently cross-linked hydrophilic coating comprising a covalently cross-linked hydrophilic polymer suitable for coating medical devices or instruments for introduction into human cavities, characterised in that said coating comprises urea."

"6. A medical device or instrument suitable for introduction into human cavities and having a covalently cross-linked hydrophilic coating comprising a covalently cross-linked hydrophilic polymer suitable for coating medical devices or instruments for introduction into human cavities, characterised in that said coating comprises urea."

"7. A method of producing a medical device or instrument suitable for introduction into human cavities and having a hydrophilic coating comprising a cross-linked hydrophilic polymer, said coating comprising a water soluble compound, characterised in applying, in one or more steps, a solution of a hydrophilic prepolymer and optionally a monomer, oligomer or polymer and a water soluble compound selected from glucose, sorbitol, halides, nitrates, acetates, citrates or benzoates of alkali metals or alkaline earth metals or silver; acetic acid, glycine and urea, evaporating the solvent and cross-linking the coating by activation through radiation and optionally hydrolysing and optionally neutralising the hydrophilic coating." (This claim is identical to granted Claim 8).

Claim 1 of **Auxiliary Request 7** is identical to Claim 7 of Amended Auxiliary Request 6.

Claims 1 and 6 of **Auxiliary Request 8** are identical to Claims 1 and 6 of Amended Auxiliary Request 6.

X. The written and oral submissions made by the Appellant, insofar as they are relevant to the present decision, can be summarized as follows:

- The subject-matter of Claim 1 of the Main Request lacked novelty over D10 because it disclosed a hydrophilic coating comprising a hardenable prepolymer/binder (a), which was a covalently cross-linked polymer with a certain degree of hydrophility.
- The patent in suit did not disclose what degree of hydrophility constituted the border line for distinguishing hydrophilic polymers from hydrophobic polymers.
- The patent specification at paragraph [0023] disclosed that any cross-linked coating might be the cross-linked hydrophilic coating and by extension any cross-linked polymer might be the cross-linked hydrophilic polymer.
- Hydrophilic polymer (b) of D10 was also to some extent covalently cross-linked, since at least some mixing of the coating components must be assumed to inevitably occur leading to the exertion of a cross-linking effect on this polymer by the photo-initiator incorporated into the binder (a).
- D1 was a further novelty destroying document because by referring to documents D2, D3, D4 and D5 it encompassed their content which comprised covalently

cross-linked hydrophilic polymers as part of the coatings.

- The subject-matter of Claim 1 of Auxiliary Request 1 was identical to that of Claim 1 of the Main Request and thus lacked novelty over D10.
- Auxiliary Requests 3, 5, 7 and 8 and Amended Auxiliary Requests 2, 4 and 6 were late-filed and should not be admitted in the proceedings.
- The subject-matter of Claim 1 of Amended Auxiliary Request 2 was not different from that of Claim 1 of the Main Request and lacked novelty over D10.
- The expression "(a) covalently cross-linked hydrophilic coating" used in Claim 1 of that request did not limit the "hydrophilic coating" of Claim 1 of the Main Request because the claim related to a coating "comprising a covalently cross-linked hydrophilic polymer", its scope still encompassing further, different hydrophilic polymers.
- The subject-matter of Auxiliary Request 3 lacked clarity because the additional features of Claim 1, distinguishing this claim from that of the Main Request, were defined by the result to be achieved, involved unclear terms such as "significant increase", "significant decrease", and necessitated the performance of comparative tests in order to determine the extent of the claimed subject-matter.
- The same objection applied to the subject-matter of Claim 1 of Amended Auxiliary Request 4 which comprised the same objectionable, additional features.
- The subject-matter of Claim 1 of Auxiliary Request 5 lacked novelty over D10.

- The further definition of the coating by its preparation method did not distinguish the claimed coating from the coating disclosed by D10.
- The subject-matters of Claims 1 to 7 of Amended Auxiliary Request 6 were novel over D10.
- Concerning the issue of inventive step, D7 represented the closest prior art, which disclosed a coating comprising a covalently cross-linked hydrophilic polymer.
- The technical problem to be solved was to improve the water retention and the friction properties of the hydrophilic coating, which was realized by the addition in the coating of a water soluble compound, which in independent Claims 1 and 6 was limited to urea.
- The combination of either D1 or D6, the sole opposed document disclosing urea as water soluble compound, with D7 was obvious for the skilled person aiming at the improvement of the coating's water retention and friction properties.
- The effect of lowering the initial friction was just a bonus effect, which inevitably resulted from the obvious combination of D6 with D7.
- There was no proof that urea was more advantageous than other osmolality-increasing compounds (these compounds falling within the definition of water soluble compounds).
- The subject-matter of Claim 1 of Auxiliary Request 7, which was identical to the subject-matter of Claim 7 of the previous auxiliary request, lacked an inventive step for the same reasons.
- The subject-matter of Claim 1 of Auxiliary Request 8 lacked inventive step over the combination of D7

with D6 since it was identical to the subject-matter of Claim 1 of Amended Auxiliary Request 6.

- The objection of insufficient disclosure was dropped for Auxiliary Request 8.
- The Respondent should not be granted an apportionment of costs in its favour because the complementary experimental evidence submitted with the grounds of appeal had been filed in reaction to the Opposition Division's decision on sufficiency of disclosure criticising the Opponent's failure to submit evidence supporting its rebuttal of the Patentee's allegations (section 3.3.3).

XI. The written and oral submissions made by the Respondent, insofar as they are relevant to the present decision, can be summarized as follows:

- The subject-matter claimed in all the requests was novel over the disclosure of D10.
- D10 made a clear distinction between the hardenable prepolymer (a) and the hydrophilic polymer (b), the former being not considered a "true" hydrophilic polymer despite its having some hydrophilic character.
- The hardenable prepolymer (a) was a separate phase from the hydrophilic polymer and should not be water soluble, which meant that the prepolymer was hydrophobic; see the exemplified acrylated urethane resin (Ebecryl 4830).
- The interpretation of the Appellant that the prepolymer was hydrophilic went against the teaching of D10 and gave the term "hydrophility" a meaning that it did not merit.

- The definition of the term "hydrophility" in the patent was qualitative. Paragraph [0016] of the patent, in the same manner as Annex D, disclosed that hydrophilic polymers swell in the presence of water which is retained in the coating.
- The term "affinity" between the binder phase and the hydrophilic phase, used in D10, did not mean that the hardenable prepolymer (a) and the hydrophilic polymer (b) mixed in a way to allow cross-linking of the latter.
- Further, the exemplified hydrophilic polymers such as polyethylene glycol could not cross-link.
- The catalyst was chosen to be effective for hardening the prepolymer (a).
- Document D1 was not novelty destroying because the content of documents D2 to D5 to which it made reference did not form part if its disclosure.
- The Auxiliary as well as the Amended Auxiliary Requests 2 to 8, though late-filed, should be admitted in the procedure because they were *bona fide* attempts to overcome the objections raised by the Appellant.
- The subject-matter of Claim 1 of Amended Auxiliary Request 2 was novel over D10 because it concerned a coating which, as a whole, was covalently cross-linked.
- The subject-matters of Claim 1 of Auxiliary Request 3 and Amended Auxiliary Request 4 were clear because the patent specification, in particular table 1, gave unambiguous instructions how to conduct the tests for the comparison. The term "significant" was a statistical term, which the skilled person had no difficulties in understanding.

The definition by the result to be achieved was a "pass or fail" test which the skilled person would conduct without undue burden.

- The coating of Claim 1 of Auxiliary Request 5 was novel over D10 because the preparation method had the structural consequence that the water soluble compound was trapped in the interstices of hydrophilic cross-linked polymer (paragraph [0016] of the description).
- This was not the case in D10, because only the dispersed non hydrophilic phase was cross-linked.
- The subject-matter of Amended Auxiliary Request 6 was novel over D10, since it did not disclose the use of urea as a water soluble compound.
- It also involved an inventive step over the combination of D6 with D7, the closest prior art, since the improvement, ie the reduction of the initial friction, was neither disclosed in the prior art nor derivable from it.
- The subject-matter of Claim 1 of Auxiliary Request 7 was novel and inventive for the reasons given for Claim 7 of the previous request.
- The subject-matter of Claim 1 of Auxiliary Request 8 was also novel and inventive for the reasons given for Claim 1 of the Amended Auxiliary Request 6.
- Apportionment of costs should be granted in favour of the Respondent for having to scrutinize the late-filed supplemental evidence submitted by the Appellant in the appeal proceedings. Such evidence should have been filed in the Opposition Division proceedings according to the Guidelines D-V,4.3.

– The case should be remitted to the Opposition Division to enable further discussion of the substantial issues.

XII. The Appellant (Opponent) requested that the decision under appeal be set aside and that the patent be revoked in its entirety. It further requested that the (Amended) Auxiliary Requests 2 to 8 be not admitted, being late-filed.

XIII. The Respondent (Patent Proprietor) requested that the appeal be dismissed or that the patent be maintained on the basis:

- of the set of Claims 1 to 8 filed with letter dated 14 September 2005 (Auxiliary Request 1)

or

- of the set of Claims 1 to 10 filed with the letter dated 20 August 2007 (Auxiliary Requests 3 and 5)

or

- of the set of Claims 1 to 8 (Auxiliary Request 2)

or

- of the set of Claims 1 to 10 (Auxiliary Request 4)

or

- of the set of Claims 1 to 7 (Auxiliary Request 6)

or

- of the set of Claims 1 to 6 (Auxiliary Request 7

or

- of the set of Claims 1 to 6 (Auxiliary Request 8),

all as filed during the oral proceedings.

It maintained its request for apportionment of costs and for remittal to the Opposition Division, independently of the admittance of the tests filed by

the Opponent, in order to allow both parties to further argue their case.

Reasons for the Decision

1. The appeal is admissible.

2. ***The Main Request*** *- Novelty (Article 54 EPC)*

2.1 The subject-matter of Claim 1 of the Main Request lacks novelty over the disclosure of D10.

2.2 D10 discloses a hydrophilic coating (page 3, lines 37-38) suitable for coating medical devices or instruments for introduction into human cavities (page 2, lines 1-7). The coating comprises a water soluble compound such as glucose, sorbitol, an inorganic or organic salt (page 7, lines 21-30; page 8, lines 20-28) and a covalently cross-linked polymer/binder (a), resulting from a hardenable prepolymer which has a certain degree of hydrophility and is thus to be considered hydrophilic, albeit to a lesser degree than the so-called "hydrophilic polymers (b)" (page 6, lines 12-14 and 24-34; Claim 1). Thus D10 discloses all the features constituting the subject-matter of Claim 1.

2.3 The Board remarks that although D10 refers to osmolality-increasing compounds and not to water soluble compounds, it discloses that these osmolality-increasing compounds are water soluble (page 8, lines 20-28). Therefore there is no difference between the osmolality-increasing compounds of D10 and the claimed water soluble compounds. Moreover D10 (page 8, lines

20-28) discloses examples of osmolality-increasing compounds which are the same as the water soluble compounds of the claimed subject-matter.

2.4 Furthermore the hardenable prepolymer/binder (a) of D10, once it has been radiation-cured in the presence of a photo-initiator, possibly one which comprises ethylenic unsaturations, is a covalently cross-linked polymer (page 4, line 56 to page 5, line 3; page 6, lines 12-14).

As stated above, this covalently cross-linked binder (a) is also to be considered as a hydrophilic polymer in the terms of the patent in suit, which does not specify the required "effectiveness" of the hydrophility or any "degree of hydrophility" which could be regarded as establishing a frontier between the hydrophilic character of the cross-linked binder (a) and of the hydrophilic polymer used according to the patent in suit. On the contrary, the general statement in paragraph [0023] could be interpreted to mean that the cross-linked hydrophilic polymer might be any cross-linked polymer, thus certainly including the covalently cross-linked binder polymer (a) of D10.

2.5 Since the subject-matter of Claim 1 lacks novelty over D10, the Main Request is not allowable.

3. ***Auxiliary Request 1*** - *Novelty (Article 54 EPC)*

The subject-matter of Claim 1 of Auxiliary Request 1 is identical to that of Claim 1 of the Main Request. Consequently, for the reasons given above (section 2) it lacks novelty over the disclosure of D10.

Since the subject-matter of Claim 1 lacks novelty, the Auxiliary Request 1 is not allowable.

4. ***Amended Auxiliary Request 2*** *- - Novelty (Article 54 EPC)*

Amended Auxiliary Request 2 was submitted at the oral proceedings and corresponds to Auxiliary Request 2 submitted with the letter dated 20 August 2007.

The amendment concerns the deletion of the objectionable vague term "system" from the expression "(a) covalently cross-linked hydrophilic coating system" (Claims 1 and 7).

The Board considers that the subject-matter of Claim 1 of this request, which is not clearly different from the subject-matter of Claim 1 of the Main Request, lacks novelty over the disclosure of D10.

It is the Board's understanding that the claimed covalently cross-linked hydrophilic coating comprising a covalently cross-linked hydrophilic polymer still encompasses coatings with hydrophilic polymers which are not covalently cross-linked and for that reason, analogously to Claim 1 of the previous requests, the subject-matter of this claim lacks novelty over the disclosure of D10.

Since the subject-matter of Claim 1 lacks novelty, the Amended Auxiliary Request 2 is not allowable.

5. ***Auxiliary Request 3*** - *Clarity (Article 84 EPC*)

Auxiliary Request 3 was submitted with the letter dated 20 August 2007.

Over and above the fact that, as compared to the granted claims, this request comprises two additional independent claims, Claims 7 and 9, the subject-matter of Claims 1 and 8 comprises additional functional features over those of the corresponding claims of the main request which render the claimed subject-matter unclear.

The lack of clarity stems on the one hand from the use of vague terms such as "significant increase", "significant decrease", "a coating of the same type", "osmolality-increasing ingredients", and on the other hand from the presence in Claim 1 of a characterising definition directed at a comparison of properties of cross-linked and uncross-linked polymers which thus lacks an enabling precision.

Since the subject-matter of Claims 1 and 8 lacks clarity, the Auxiliary Request 3 is not allowable.

6. ***Amended Auxiliary Request 4*** - *Clarity (Article 84 EPC)*

6.1 Amended Auxiliary Request 4 was submitted at the oral proceedings held before the Board and corresponds to Auxiliary Request 4 submitted with the letter dated 20 August 2007.

The amendment concerns the deletion of the objected term "system" from the expression "(a) covalently

cross-linked hydrophilic coating system" (Claims 1 and 8).

The subject-matter of Claims 1 and 8 suffers from the deficiencies identified above in relation to the subject-matter of Claims 1 and 8 of Auxiliary Request 3 (section 5). It is therefore considered to lack clarity under Article 84 EPC.

Since the subject-matter of Claims 1 and 8 lacks clarity, the Amended Auxiliary Request 4 is not allowable.

6.2 For the sake of completeness, the Board further considers that the subject-matter of Amended Auxiliary Request 4 cannot be distinguished from that of Auxiliary Request 3. As already stated above (section 4), the claimed covalently cross-linked hydrophilic coating comprising a covalently cross-linked hydrophilic polymer still encompasses coatings with hydrophilic polymers which are non covalently cross-linked.

7. ***Auxiliary Request 5*** - *Novelty (Article 84 EPC)*

Auxiliary Request 5 was submitted with the letter dated 20 August 2007.

Over and above the fact that, as compared to the granted claims, this request comprises two additional independent claims, Claims 7 and 9, the subject-matter of Claim 1 still lacks novelty over D10.

The subject-matter of Claim 1 of Auxiliary Request 5 compared to that of Claim 1 of the Main Request comprises the further characterisation of the coating by its preparation method. It is the Board's understanding that the differences in the preparation methods of the claimed coating and that of D10, the former involving a solution of the hydrophilic prepolymer, the latter involving a dispersion, do not lead to differences of the coatings *per se*. The Board notes that D10, like the patent in suit, concerns cross-linked polymer structures which include the osmolality-increasing agent, ie the water soluble compound of the patent, within its network structure (D10: page 7, lines 29-36; patent in suit: paragraph [0016]). Thus, in the absence of convincing evidence to the contrary, the fitting of the water soluble compound into the polymer networks must be considered to lead to fully equivalent structures.

Since the subject-matter of Claim 1 lacks novelty, the Auxiliary Request 5 is not allowable.

8. ***Amended Auxiliary Request 6***

8.1 Admissibility

Amended Auxiliary Request 6 was submitted at the oral proceedings of 20 September 2007 and is based on a previous version of that request filed with the letter dated 20 August 2007 after deletion in Claims 1 and 6 of the term "system" from the expression "a covalently cross-linked hydrophilic coating system".

Furthermore, the subject-matter of Claims 1 and 6 of this request corresponds essentially to that of granted Claims 1 and 6 (Main Request), with the limitation that the water soluble compound is urea.

Claims 2-4 are identical to those of the Main Request. Claims 5 and 7 corresponded to Claims 6 and 8 of the Main Request.

In view of the limitation of Claims 1 and 6 and the identity of the remaining claims with the claims of the Main Request, the Board exercising its discretion under Article 10b(1) of RPBA admitted this late-filed request into the proceedings.

8.2 Novelty of Claims 1 to 6

The subject-matter of these claims is novel over D10, which does not disclose urea as an osmolality-increasing compound (ie a water soluble compound according to the claims). The Appellant (Opponent) did not contest the novelty of these claims.

8.3 Inventive step of Claims 1 to 6

The subject-matter of Claims 1 and 6 also involves an inventive step.

8.3.1 The closest prior art

The Board in agreement with the parties considers that D7 represents the closest prior art. D7 (page 3, line 19 to page 4, line 15; page 6, line 25 to page 7, line 23; page 11, line 26 to page 12, line 7) discloses

a coating suitable for medical applications comprising a covalently cross-linked hydrophilic polymer, which provides durability to the coating, the coating providing for a low coefficient of friction in wet conditions.

The coating and the medical device of Claims 1 and 6, respectively, differ from the disclosure of D7 in that the coating further contains a water soluble compound which is urea.

8.3.2 The technical problem

The addition of urea has been argued to provide coatings with improved initial friction. Hence, in agreement with the general objectives set out in paragraph [0011] of the patent specification and the information contained in its Table 1, the provision of hydrophilic coatings having improved initial friction can be accepted to constitute the technical problem to be solved by the claimed invention.

That this problem is effectively solved by the use of urea as water soluble compound is made plausible by the data in Table 1 (Examples A, 1 and 2). Indeed, the covalently cross-linked hydrophilic coating of Example A not comprising a water soluble compound exhibits an initial friction of 0.10 N whereas after addition of urea the initial friction drops to 0.03 N (Example 1). This improvement was not observed with a different water soluble compound (Example 2: sodium chloride).

8.3.3 The obviousness of the claimed solution

The Board in agreement with the Respondent considers that the addition of urea to the covalently cross-linked hydrophilic coating of D7 was not obvious to the skilled person in the art. Though D6 (page 3, line 27 to page 4, line 5; page 4, lines 19-30; page 4, line 34 to page 5, line 3) discloses hydrophilic coatings suitable for medical applications comprising the water soluble compound urea as an osmolality-increasing agent, the use of urea in D6 is merely related to the improvement of the water retention and D6 does not address the different property of initial friction. In the absence of any indication in the art, the skilled person would not have expected that the addition of urea to the covalently cross-linked hydrophilic coating of D7 would improve the initial friction of the coating. The Board thus acknowledges that this improvement was not foreseeable and that the solution of the technical problem is not obvious in view of D6 and D7.

8.3.4 The Board does not concur with the argument of the Appellant that urea is not more advantageous than other water soluble osmolality-increasing agents. As already stated above (section 8.3.2) the addition of urea provided an improved coating in terms of initial friction whereas sodium chloride, another common water soluble osmolality-increasing agent (D10: page 7, lines 29-30; D1: page 2, lines 46-49), did not.

8.3.5 Finally the Board does not concur with the Appellant that this technical improvement is to be considered simply a bonus effect. The Board has not identified in the cited prior art any hint to the above specified

technical problem and its solution and the Appellant was also unable to provide any evidence underpinning its objection of obviousness in that respect. Thus, the argument of a bonus effect is based on hindsight.

8.4 Novelty and inventive step of Claims 2 to 5

The additional features of dependent Claims 2 to 5 relate to preferred embodiments of the independent Claim 1 and are therefore novel and inventive.

8.5 Novelty of Claim 7

The method of producing a medical device according to this claim is novel over the disclosure of D10. Claim 7 requires the use of a solution of a hydrophilic prepolymer in the preparation of the hydrophilic coating whereas D10 discloses the use of a dispersion of the prepolymer/binder (a) (page 3, lines 52-55; page 5, lines 8-10). The Appellant (Opponent) acknowledged the novelty of the subject-matter of Claim 7.

8.6 Inventive step of Claim 7

The Board considers that the subject-matter of Claim 7, which, in contrast to the subject-matter of Claims 1 and 6 is not limited to the water soluble compound urea, lacks an inventive step.

8.6.1 Closest prior art

As for the discussion of inventive step of the subject-matter of Claims 1 to 6, the Board in agreement with

the parties considers D7 as the closest prior art. The Board notes that D7 discloses a method for the preparation of a hydrophilic coating which involves a solution of the hydrophilic prepolymer (page 3, line 31 to page 4, line 9; claim 23). Thus the claimed method differs from the method disclosed in D7 only in the addition of a water soluble compound selected from specific compounds or groups of compounds.

8.6.2 The technical problem

The patent specification discloses in paragraph [0011] that the claimed cross-linked hydrophilic coating comprising a water soluble compound shows a significant increased water retention and significant decrease of the friction coefficient against living tissue as compared to a coating without a water soluble compound. The Board thus concludes, in agreement with the Appellant, that the technical problem to be solved is the provision of a cross-linked hydrophilic coating with improved water retention and improved friction coefficient.

The solution suggested by the subject-matter of Claim 7 is the addition to the hydrophilic coating of the water soluble compound selected from the specific compounds or groups of compounds.

The relevant technical evidence of the patent (Table 1, Example A, Example 1 and Example 2) shows that this technical problem has effectively been solved.

8.6.3 The obviousness of the claimed solution

The Board, in agreement with the Appellant, considers that the solution of the problem is obvious in view of D1 or D6.

D1 (page 2, lines 42-49) and D6 (page 2, line 32 to page 3, line 23; page 4, line 34 to page 5, line 3) disclose water soluble osmolality-increasing agents, like those of the claimed invention, which improve the friction characteristics and the water retention of hydrophilic coatings.

Thus the skilled person, who starts from the coating of D7, which comprises a covalently cross-linked hydrophilic polymer, and who seeks to improve the friction characteristics and the water retention of that coating, would find in D1 or D6 the incentive to use a water soluble, osmolality-increasing compound and would arrive at the claimed subject-matter without exercising an inventive step.

8.6.4 The Board does not concur with the Respondent that the technical problem should relate to the improvement of the initial friction, in the same manner as set out above for the obviousness assessment of Claims 1 and 6 (section 8.3.2), because there is no technical evidence that this technical problem has been solved over the whole range claimed by all the specified water soluble compounds. The Board remarks that the patent in suit contains only one example of a water soluble compound with improved initial friction, ie urea. The second worked example, ie the one using sodium chloride, does not show an improvement of the initial friction. Hence,

in the circumstances of the case, the Board does not consider that a single successful example can be representative of the large variety of water soluble compounds covering various chemical classes, in particular in view of the second unsuccessful example, and concludes that the assumption of the Respondent is at variance with the factual situation.

8.7 Since the subject-matter of Claim 7 lacks an inventive step, the Amended Auxiliary Request 6 is not allowable.

9. ***Auxiliary Request 7*** - *Admissibility*

Auxiliary Request 7 was submitted at the oral proceedings. Claim 1 of this request was identical to Claim 7 of the Amended Auxiliary Request 6 which was found to lack an inventive step. The filing of this late-filed request is considered to serve no purpose and is therefore dismissed as inadmissible.

10. ***Auxiliary Request 8***

10.1 Admissibility

This request corresponds to Claims 1 to 6 of Amended Auxiliary Request 6 which was considered admissible. The Board consequently considers this late-filed request admissible.

10.2 Substantive issues

The Board has acknowledged above (sections 8.2 to 8.4) that the subject-matter of Claims 1 to 6 of the Amended Auxiliary Request 6 is novel and inventive. As a

consequence, the subject-matter claimed in Auxiliary Request 8 is likewise novel and involves an inventive step.

11. ***Apportionment of costs***

The Respondent requested apportionment in its favour of the costs incurred by the late-filed supplemental evidence of the Appellant. It argued that these extra costs could have been avoided had the Appellant filed this evidence at the Opposition stage.

The Board decides not to order an apportionment of costs since it does not consider that this is justified by reasons of equity as set out in Article 104(1) EPC.

The filing of additional evidence with the Statement of Grounds of Appeal with the intention of disproving conclusions drawn in the first instance decision, this being the case here, is to be considered a legitimate means of defending a party's stance. In view of the Opposition Division's conclusions in relation to the issue of sufficiency, the Appellant moreover carried the burden of proof in that respect (cf Guidelines D-V, 4.3). The Appellant's conduct, which is also in agreement with Article 11a(1) RPBA, cannot therefore be criticised.

12. ***Remittal***

12.1 Since the subject-matter of Auxiliary Request 8 fulfils the requirements of the EPC, the Board, exercising its power according to Article 111(1) EPC, remits the case to the Opposition Division with the order to maintain

the patent on the basis of that request after any necessary consequential amendment of the description.

12.2 Contrary to the request of the Respondent, this remittal does not allow any further discussion before the Opposition Division of the matters decided in this decision which have the legal status of *res judicata*. The request of the Respondent has no legal basis.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of the set of Claims 1 to 6 of the 8th auxiliary request as submitted during the oral proceedings after any necessary consequential amendment of the description.

3. The request for apportionment of costs is refused.

The Registrar: The Chairman:

G. Röhn P. Kitzmantel