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Datasheet for the decision of 6 March 2014

Case Number: T 0445/12 - 3.3.10

Application Number: 05800821.0

Publication Number: 1809344

IPC: A61L27/18

Language of the proceedings: EN

Title of invention:
BIOMEDICAL DEVICES CONTAINING AMPHIPHILIC BLOCK COPOLYMERS

Patent Proprietor:
Johnson and Johnson Vision Care, Inc.

Opponent:
Novartis AG

Headword:

Relevant legal provisions:
EPC Art. 84, 111(1), 123(2)
RPBA Art. 13(1), 13(3)

Keyword:
Clarity of claim - main request and auxiliary request 2 (no) - no unequivocal meaning of feature "substantially non-polymerizable"
Amendments - auxiliary requests 1 and 3 - added subject-matter (yes)
Admissibility of late-filed auxiliary request 4 - (no)
Admissibility of late-filed auxiliary request 5 - (yes)
Remittal to first instance - auxiliary request 5 (yes)

Decisions cited:
T 0337/95, T 0728/98

Catchword:

Europäisches Patentamt
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Case Number: T 0445/12 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 6 March 2014

Appellant: (Patent Proprietor)	Johnson and Johnson Vision Care, Inc. 7500 Centurion Parkway, Suite 100 Jacksonville, FL 32256 (US)
Representative:	Kirsch, Susan Edith Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Opponent)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Breuer, Markus Henkel, Breuer & Partner Patentanwälte Erika-Mann-Straße 23 80636 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 22 December 2011 revoking European patent No. 1809344 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: P. Gryczka
Members: J. Mercey
C. Schmidt

Summary of Facts and Submissions

I. The Appellant (Proprietor of the patent) lodged an appeal against the decision of the Opposition Division revoking European patent No. 1 809 344.

II. Notice of Opposition had been filed by the Respondent (Opponent) requesting revocation of the patent in its entirety on the grounds of Articles 100(a), (b) and (c) EPC).

III. The Opposition Division found *inter alia* that the subject-matter of claim 1 of each of the then pending main request and auxiliary requests 1 to 4 contravened Article 84 EPC, since one of the features added to said claims during the opposition proceedings, namely "substantially non-polymerizable", even when supplemented by the specification that "substantially non-polymerizable means that when the amphiphilic block copolymers are polymerized with other polymerizable components, the amphiphilic block copolymers are incorporated into hydrogel formulations without significant covalent bonding to the hydrogel such that any covalent bonding present is not by itself sufficient to retain the amphiphilic block copolymer in the hydrogel matrix" was unclear, in particular in view of the terms "substantially", "significant" and "sufficient". All the then pending requests were found to meet the requirements of Rule 80 and Article 123(2) and 123(3) EPC.

IV. During the appeal proceedings the Appellant filed the following documents:

(14) Organic Chemistry, Stanley H. Pine, pages 947 to 952,

(15) Declaration of Dr. Vanderlaan,
(16) US-A-4273633,
(17) US-A-4425472,
(18) Webster's Third New International Dictionary, pages 1535 and 1759,
(19) US-A-5891930,
(20) US-A-6172015,
(21) US-A-2011/0081293.

V. With letter dated 1 May 2012, the Appellant submitted a main request and auxiliary requests 1 to 4, auxiliary request 2 thereof being replaced by auxiliary request 2 filed with letter dated 25 February 2013. The main request and auxiliary request 2 correspond to the main request and auxiliary request 3, respectively, underlying the decision under appeal. During oral proceedings before the Board, held on 6 March 2014, the Appellant filed fresh auxiliary requests 3 to 5, and renumbered previously filed auxiliary requests 3 and 4 as auxiliary requests 6 and 7, respectively.

Claim 1 of the main request reads as follows:

"A silicone hydrogel comprising the reaction product of a reaction mixture comprising at least one silicone containing component; at least one amphiphilic block copolymer; and at least one hydrophilic component; wherein the amphiphilic block copolymers are substantially non-polymerizable; and wherein the amphiphilic block copolymer comprises 1 to 20 weight% hydrophobic segments and 80 to 99 weight% hydrophilic segments."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the term "substantially" has

been deleted from the feature "substantially non-polymerizable".

Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the feature "substantially non-polymerizable" has been defined as meaning "that when the amphiphilic block copolymers are polymerized with other polymerizable components, the amphiphilic block copolymers are incorporated into hydrogel formulations without significant covalent bonding to the hydrogel such that any covalent bonding present is not by itself sufficient to retain the amphiphilic block copolymer in the hydrogel matrix".

Claim 1 of auxiliary request 3 differs from claim 1 of the main request in that the feature "wherein the amphiphilic block copolymers are substantially non-polymerizable" has been deleted and the hydrophilic segments are defined as being "derived from hydrophilic polymers selected from the group consisting of poly-N-vinyl-2-pyrrolidone, poly-N-vinyl-2-piperidone, poly-N-vinyl-2-caprolactam, poly-N-vinyl-3-methyl-2-caprolactam, poly-N-vinyl-3-methyl-2-piperidone, poly-N-vinyl-4-methyl-2-piperidone, poly-N-vinyl-4-methyl-2-caprolactam, poly-N-vinyl-3-ethyl-2-pyrrolidone, and poly-N-vinyl-4,5-dimethyl-2-pyrrolidone, polyvinylimidazole, poly-N-N-dimethylacrylamide, poly-N-vinly-N-methylacetamide, polyvinyl alcohol, polyacrylic acid, polymethacrylic acid, poly(hydroxyethyl methacrylate), mixtures and copolymers thereof" and the hydrophobic segments are defined as being "derived from hydrophobic polymers formed from monomers selected from the group consisting of octamethylcyclotetrasiloxane; 1,3-bis-aminopropyltetramethyldisiloxane; 1,3-bis-hydroxypropyltetramethyldisiloxane;

dichlorodimethylsilane, 1,1,3,3-tetramethyldisiloxane; 4,4'-azobis(4-cyanovaleric acid); toluenediisocyanate, isophoronediisocyanate; 1,3-bis-vinyltetramethyldisiloxane; 3-methacryloxypropyltris(trimethylsiloxy)silane; pentamethyldisiloxanyl methylmethacrylate; and methyldi(trimethylsiloxy)methacryloxymethyl silane; monomethacryloxypropyl terminated mono-n-butyl terminated polydimethylsiloxane; 3-[tris(trimethylsiloxy)silyl] propyl allyl carbamate; 3-[tris(trimethylsiloxy)wily1] propyl vinyl carbamate; trimethylsilylethyl vinyl carbonate; trimethylsilylmethyl vinyl carbonate;and 2-propenoic acid, 2-methyl-2-hydroxy-3-[3-[1,3,3,3-tetramethyl-1-[trimethylsilyl)oxy]disiloxanyl]propoxy] propyl ester and combinations thereof".

Claim 2 of auxiliary request 3 reads:

"The hydrogel of claim 1 comprising 1 percent to 15 percent amphiphilic block copolymer."

Claim 1 of each of auxiliary requests 4 and 5 is identical to claim 1 of auxiliary request 3 except that in claim 1 of auxiliary request 5, in the definition of the hydrophobic segments "3-[tris(trimethylsiloxy)wily1] propyl vinyl carbamate" has been amended to "3-[tris(trimethylsiloxy)sily1] propyl vinyl carbamate".

Auxiliary request 4 comprises five dependent claims, whereas auxiliary request 5 consists of a single independent claim only.

VI. The Appellant argued that auxiliary requests 3 to 5 filed during the oral proceedings should be admitted

into the proceedings, since they all simplified the procedure and did not raise any issues with which either the Board or the Respondent could not reasonably expected to deal. More particularly, the deletion of those dependent claims which did not have a basis in the description as filed overcame the objection under Article 123(2) EPC, such that auxiliary request 4 was admissible. The deletion of all dependent claims in auxiliary request 5 left no doubt in this respect.

The Appellant further submitted that the claims of all requests did not extend beyond the content of the application as filed. In particular, basis for the feature "non-polymerizable" in claim 1 of auxiliary request 1 was page 5, lines 11 to 12 of the application as filed, whereby the term "substantially" had been deleted. Basis for the definition of "substantially non-polymerizable" in claim 1 of auxiliary request 2 was page 5, lines 11 to 20 of the application as filed. Claim 1 of auxiliary requests 3 to 5 was based on original claims 1, 8 and 14, together with page 9, lines 2 to 9. Furthermore, since all of the original claims were dependent on claim 1, combinations of said claims were allowable, as these were preferred embodiments of the invention, there being no reason for not combining them, such that the subject-matter of the dependent claims of *inter alia* auxiliary request 4 found support in the application as filed.

With regard to clarity, the Appellant argued that the feature "substantially non-polymerizable" in claim 1 of the main request was an expression used regularly and well understood in the art, referring to documents (14) to (21) in this respect. The skilled person would understand this expression to mean a bulk polymer which included a *de minimis* amount of polymerizable polymer

chains. This interpretation was supported by the definition of the feature "substantially non-polymerizable" given in paragraph [0021] of the specification of the patent in suit, namely as meaning that when the amphiphilic block copolymers were polymerized with other polymerizable components, the amphiphilic block copolymers were incorporated into hydrogel formulations without significant covalent bonding to the hydrogel such that any covalent bonding present was not by itself sufficient to retain the amphiphilic block copolymer in the hydrogel matrix. Claim 1 of auxiliary request 2 included this definition of the expression "substantially non-polymerizable", such that it was also clear. At the oral proceedings before the Board, the Appellant additionally argued that in view of the open wording of the claim, the exact boundaries of the contested feature were in fact irrelevant to the question of clarity.

VII. The Respondent argued that auxiliary requests 3 to 5 filed during the oral proceedings should not be admitted into the proceedings, since the objections it had raised which had prompted their filing had been raised in its reply to the Grounds of Appeal dated 21 September 2011 and had thus known to the Appellant since this date, there having been no new developments in the case in the meantime. In particular, auxiliary request 4 raised issues under Article 123(2) EPC which the Respondent could not be expected to deal with at this late stage of the proceedings.

The Respondent submitted that the main request and auxiliary requests 1 to 4 contained subject-matter which contravened Article 123(2) EPC. More particularly, in view of the incorporation of the feature that "the amphiphilic block copolymer comprises

1 to 20 weight% hydrophobic segments and 80 to 99 weight% hydrophilic segments" from original claim 8 into claim 1 of all these requests, claim 8 being originally dependent on claim 1 only, there was no basis in the application as filed for the subject-matter of all dependent claims which had originally been dependent on claim 1 only, as they represented undisclosed intermediate generalisations. In claim 1 of auxiliary request 1 there was additionally no basis for the feature "non-polymerizable", the passage referred to by the Appellant as providing a basis therefor, namely page 5, lines 11 to 26 of the application as filed providing a basis for the feature "substantially non-polymerizable" only. With regard to claim 1 of all of auxiliary requests 3 to 5, there was no basis for the combination of the features of original claims 1, 8, 11 and 14, since claims 11 and 14 were dependent on claim 8 only and not on each other, such that its subject-matter also represented an undisclosed intermediate generalisation.

The feature "substantially non-polymerizable" in claim 1 of the main request did not fulfil the requirements of Article 84 EPC, since said expression had no unequivocal generally accepted meaning in the relevant art. It was thus unclear how many polymerizable groups the copolymer in question might contain, said expression not being equivalent to *de mimimis* levels of polymerizable chains in the amphiphilic block copolymer. Furthermore, whether a polymer was itself polymerizable or not depended on reaction conditions and reaction partners. The definition of said feature in paragraph [0021] of the patent in suit rendered the feature even more obscure in view of the use of the relative terms "significant" and "sufficient" and did not correspond to *de minimis* levels of polymerisation

as argued by the Appellant. Furthermore, said definition raised even more questions regarding the clarity of the contested feature, since the wording "when the amphiphilic block copolymers are polymerized with other polymerizable components, the amphiphilic block copolymers are incorporated into hydrogel formulations without significant covalent bonding to the hydrogel such that any covalent bonding present is not by itself sufficient to retain the amphiphilic block copolymer in the hydrogel matrix" implied that the amphiphilic block copolymers might indeed by polymerizable, only significant covalent bonding to the hydrogel being excluded. Furthermore, the part of this definition which defined the degree of covalent bonding as not by itself being sufficient to retain the amphiphilic block copolymer in the hydrogel matrix was in functional terms, said function, however, not being verifiable by tests or procedures adequately specified in the description or known to the skilled person. Consequently, the inclusion of this definition of "substantially non-polymerizable" into claim 1 of auxiliary request 2 could also not remove the lack of clarity.

VIII. The Appellant requested that the decision under appeal be set aside and the case be remitted to the first instance for further prosecution on the basis of the main request or, subsidiarily, on the basis of auxiliary request 1, both requests filed with letter dated 1 May 2012, or on the basis of auxiliary request 2, filed with letter dated 25 February 2013, or on the basis of any of auxiliary requests 3 to 7 filed during oral proceedings before the Board.

The Respondent requested that the appeal be dismissed.

IX. At the end of the oral proceedings, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. Article 84 EPC

2.1 It is established jurisprudence of the Boards of Appeal of the EPO that, in order to ensure legal certainty, a claim must clearly define the subject-matter for which protection is sought. This requirement serves the purpose of ensuring that the public is not left in any doubt as to which subject-matter is covered by a particular claim and which is not (see T 728/98, OJ EPO 2001, 319, point 3.1 of the reasons as well as T 337/95, OJ EPO 1996, 628, points 2.2 to 2.5 of the reasons).

2.2 In the present case, claim 1 of the main request is directed to a silicone hydrogel comprising the reaction product of a reaction mixture comprising *inter alia* at least one amphiphilic block copolymer, wherein during the opposition proceedings, the claim was amended such that the amphiphilic block copolymers were defined as being "substantially non-polymerizable", said feature having been taken from the description. The Respondent and Opposition Division found the claim to be unclear in view of the feature "substantially non-polymerizable". It has not been contested that it has to be examined whether this amendment fulfils the requirement of clarity.

2.3 It thus needs to be determined whether the feature "substantially non-polymerizable" has a meaning generally accepted by those skilled in the relevant art.

2.4 The Board holds that the feature is unclear, since the term "substantially" is a relative term which does not clearly define to which extent the amphiphilic block copolymers may be polymerizable.

2.5 The Appellant essentially argued that the expression "substantially non-polymerizable" was regularly used in the art, and reflected the *de minimis* levels of polymerizable polymer chains in the amphiphilic block copolymer, said definition being further supported by paragraph [0021] of the specification of the patent in suit. The Respondent essentially argued that the amount of polymerizable polymer chains could certainly be in any single figure percentage, if not more, the limits of said expression being thus unclear. Even if one turned to the description of the patent in suit for assistance, the definition given in paragraph [0021] was in itself unclear and did not correspond to *de minimis* levels.

2.6 In order to show that said expression has a meaning generally accepted by those skilled in the relevant art, the Appellant referred to documents (14) to (21).

2.6.1 Of these documents, the only two which are the type of document which may possibly provide a meaning generally accepted by those skilled in the relevant art are the reference books (14) and (18), namely a textbook and a (non-technical) dictionary, respectively. Document (15) is the opinion of a single expert and documents (16), (17) and (19) to (21) are patent specifications, which

the skilled person would not necessarily consult when seeking a generally accepted meaning of a term. In any case, none of the documents (15) to (17) and (19) to (21) provides a quantitative definition of the expression "substantially non-polymerizable". Document (14) merely describes known polymerizable groups and document (18) provides dictionary definitions of the prefix "non" and the word "polymerizable" but not of "substantially", neither of these reference books thus providing a definition of the feature "substantially non-polymerizable".

2.6.2 The Appellant has thus not provided any suitable evidence of a generally applicable definition of the feature "substantially non-polymerizable" which has clear explicit boundaries, nor is the Board aware of any. Thus, on the basis of the cited documents, this feature cannot be accorded a definition having general validity.

2.7 The Appellant further argued that said feature would be understood by the skilled person to mean a polymer which was on paper non-polymerizable but in reality comprised a tiny amount of polymerizable groups and filed declaration (15) in this respect. The qualifying term "substantially" was merely a reflection of the physical reality that it was impossible to make a polymer which was totally devoid of polymerizable groups and thus not entirely non-polymerizable, but said polymer would still be considered to be non-polymerizable within standard manufacturing tolerances, such that the feature was to be interpreted as equivalent to *de minimis* levels of polymerizable polymer chains present in the amphiphilic block copolymer.

2.7.1 However, the Appellant has not provided any evidence in the form of reference books which support this interpretation (see points 2.6.1 and 2.6.2 above), the opinion of a single expert (see document (15)) not being able to compensate for this fact.

2.8 The Appellant argued that this interpretation of the feature "substantially non-polymerizable", namely as equivalent to *de minimis* levels of polymerizable polymer chains being present in the amphiphilic block copolymer, was supported by paragraph [0021] of the specification of the patent in suit, since this passage specified that any covalent bonding present was not by itself sufficient to retain the amphiphilic block copolymer in the hydrogel matrix, such that the skilled person would understand that extremely low levels of polymerizable polymer chains were meant and that levels of, for example, 3%, were excluded.

2.8.1 However, paragraph [0021] does not define the feature "substantially non-polymerizable" as meaning a non-polymerizable polymer which includes a *de minimis* amount of polymerizable polymer chains, but rather gives a very particular definition of this contested feature, namely "substantially non-polymerizable means that when the amphiphilic block copolymers **are polymerized** with other polymerizable components, the amphiphilic block copolymers are incorporated into hydrogel formulations without significant covalent bonding **to the hydrogel** such that any covalent bonding present is not by itself sufficient to retain the amphiphilic block copolymer in the hydrogel matrix" (emphasis added).

2.8.2 This paragraph thus implies that the amphiphilic block copolymers may indeed by polymerizable, only

significant covalent bonding to the hydrogel being excluded. This is not the same as the presence of *de minimis* levels of polymerizable polymer chains, as argued by the Appellant. Thus, as submitted by the Respondent, this passage in fact highlights a further lack of clarity in the feature "substantially non-polymerizable", namely that in the absence of reaction conditions, the skilled person does not know with what, and under what conditions, the amphiphilic block copolymer should not be polymerizable. In addition, the covalent bonding of the amphiphilic block copolymer to the hydrogel referred to in paragraph [0021] could result from reactive groups other than polymerizable groups, such as by reaction of a hydroxy group on the amphiphilic block copolymer with an acid group on the hydrogel, the skilled person not having any means at his disposal to distinguish between such covalent bonds and those formed by polymerization.

2.8.3 Furthermore, even if the skilled person knew what sort of covalent bonding was being referred to, the allowable degree of said covalent bonding to the hydrogel is merely defined in this passage as being not "significant", this relative term also having no generally accepted meaning in the art in this context. The additional information given in said paragraph that the degree of covalent should not by itself be "sufficient" to retain the amphiphilic block copolymer in the hydrogel matrix, is in terms of a result to be achieved, said result, however, not being verifiable by tests or procedures adequately specified in the description or known to the skilled person. Even though the Appellant argued that it was possible to determine whether a polymer was entrapped in or covalently bonded to a hydrogel matrix by virtue of extraction techniques referred to in the patent in suit, no quantitative

limits are given which would allow the skilled person to know whether a particular polymer/hydrogel fulfils the requirement that the covalent bonding present is not by itself sufficient to retain the amphiphilic block copolymer in the hydrogel matrix.

2.8.4 Thus, the description of the application as filed does not give a clear definition of what is meant by the feature "substantially non-polymerizable", such that even when resorting to information derived from the description, said feature is not unambiguously defined.

2.9 Having first argued that the feature "substantially non-polymerizable" was clear, since it meant that the reaction mixture of claim 1 contained a *de minimis* amount of polymerizable polymer chains, the Appellant then argued for the first time at a later stage of the oral proceedings before the Board that it was in any case not essential to the invention to define the limits of the term "substantially", since the substantially non-polymerizable block copolymer component was **comprised** in a reaction mixture, said open definition including the presence of **any amount whatsoever** of polymerizable polymer chains in the reaction mixture, so long as some non-polymerizable polymers were present. Therefore, the actual amount of polymerizable polymer chains in the reaction mixture was irrelevant and the claim as a whole was clear.

2.9.1 However, said argumentation merely highlights a further lack of clarity in the subject-matter of claim 1, namely whether or not, in view of the open language, which results in the reaction mixture "comprising" substantially non-polymerizable amphiphilic block copolymers, the term "substantially" is in fact restrictive at all regarding the amount of

polymerizable polymers present. This argumentation of the Appellant thus does not convince the Board.

2.10 To summarize, it has not been shown that the feature "substantially non-polymerizable" has an unequivocal generally accepted meaning in the relevant art, with the consequence that this feature casts doubts as to the actual subject-matter covered by the claim, such that claim 1 of the main request does not fulfil the requirements of clarity imposed by Article 84 EPC.

Auxiliary request 1

3. Article 123(2) EPC

3.1 Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the term "substantially" has been deleted from the feature "substantially non-polymerizable", the Respondent arguing that there was no basis in the application as filed for the resulting feature, namely "non-polymerizable". The Appellant submitted that basis for the feature "non-polymerizable" was the expression "substantially non-polymerizable" on page 5, lines 11 to 12 of the application as filed, whereby the term "substantially" had been deleted.

3.2 The Board holds that these two features are not equivalent, since substantially non-polymerizable means that the relevant amphiphilic block copolymers are polymerizable to some, non-defined (see point 2 above), extent, whereas non-polymerizable means that the copolymers are not polymerizable at all.

3.3 The Appellant argued that the feature "the amphiphilic block copolymers are substantially non-polymerizable"

would be understood by the skilled person in the light of the passage on page 5, lines 11 to 12 of the application as filed to mean a "non-polymerizable" copolymer which included a *de minimis* amount of polymerizable polymer chains, such that the restriction to "non-polymerizable" merely involved the deletion of the *de minimis* amount of polymerizable polymers.

However, the passage at page 5, lines 11 to 26, which corresponds to paragraph [0021] of the specification of the patent in suit, provides a very specific definition of the feature "substantially non-polymerizable" and does not disclose a "non-polymerizable" copolymer which includes a *de minimis* amount of polymerizable polymer chains (see points 2.8.1 and 2.8.2 above). Thus said passage fails to provide a basis for the feature "non-polymerizable".

3.4 The Appellant further argued that deletion of the term "substantially" did not add subject-matter, as it was analogous to the deletion of the term "about" from the expression "about 5", it being well accepted practice of the EPO that "about 5" clearly and unambiguously disclosed the value of 5.

However, there is a difference between a real number A, wherein the expression "about A" may in particular cases directly and unambiguously disclose the number A, and the present situation where the definition given in the application as filed for the term "substantially non-polymerizable" does not indicate that the polymers may be non-polymerizable, but rather indicates that when the amphiphilic block copolymers **are polymerized**, a minor degree of covalent bonding to the hydrogel may in fact be present. Thus, this argument of the Appellant does not convince the Board.

3.5 The Appellant further argued that since the passage on page 5, lines 11 to 26 of the application as filed indicated that "while a minor degree of covalent bonding **may** be present" (emphasis added), it disclosed the possibility of there being no covalent bonding at all, which in turn implied that the amphiphilic block copolymers were non-polymerizable. This definition was supported by the description as a whole, which only described monomers which led to amphiphilic block copolymers which were non-polymerizable.

However, as indicated in point 2.8.2 above, the passage on page 5, lines 11 to 26 in fact implies that the amphiphilic block copolymers may indeed be polymerizable. Only significant covalent bonding to the hydrogel, which may be derived from a source other than polymerization, is excluded. There is thus no implicit disclosure in this passage that the amphiphilic block copolymers are non-polymerizable. Thus, even if all the specific monomers described in the application as filed lead to particular amphiphilic block copolymers which were non-polymerizable on paper, this still does not amount to a disclosure that the amphiphilic block copolymers in general are non-polymerizable.

3.6 The Board thus concludes that the application as filed does not disclose the feature "non-polymerizable", either explicitly or implicitly, with the consequence that amended claim 1 of auxiliary request 1 extends beyond the application as filed, contrary to the requirements of Article 123(2) EPC.

Auxiliary request 2

4. Article 84 EPC

4.1 Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the feature "substantially non-polymerizable" has been defined as meaning "that when the amphiphilic block copolymers are polymerized with other polymerizable components, the amphiphilic block copolymers are incorporated into hydrogel formulations without significant covalent bonding to the hydrogel such that any covalent bonding present is not by itself sufficient to retain the amphiphilic block copolymer in the hydrogel matrix".

4.2 For reasons given in points 2.8.1 to 2.8.3 above, the feature "substantially non-polymerizable" is unclear even when taking this definition into account, such that claim 1 of this request also fails to meet the requirement of clarity imposed by Article 84 EPC.

Auxiliary request 3

5. Article 123(2) EPC

5.1 Claim 2 of auxiliary request 3 is directed to the hydrogel of claim 1 comprising 1 percent to 15 percent amphiphilic block copolymer, the hydrogel of claim 1 comprising the product of *inter alia* an amphiphilic block copolymer comprising 1 to 20 weight% hydrophobic segments and 80 to 99 weight% hydrophilic segments.

5.2 The Respondent submitted that this request was not allowable, since *inter alia* the dependent claims comprised added subject-matter. More particularly, there was no basis in the application as filed for the combination of the features referred to above in point 5.1.

5.3 Basis for each of these individual features is original claims 2 and 8, respectively. However, since original claims 2 and 8 were each dependent on claim 1 only, the originally filed claims alone cannot provide a basis for the combination of these features. Basis can also not be found in the description as filed, since this does not disclose a hydrogel comprising 1 percent to 15 percent amphiphilic block copolymer at all, let alone in combination with it comprising the product of an amphiphilic block copolymer comprising comprising 1 to 20 weight% hydrophobic segments and 80 to 99 weight% hydrophilic segments. The only passage of the description as filed which discloses amounts of amphiphilic block copolymer is page 6, lines 15 to 18, and this merely discloses amounts of 2, 4 and 5 to 12 or 15 percent, but not **1** percent. Therefore, the application as filed does not directly and unambiguously disclose a hydrogel comprising the combination of features which is the subject-matter of claim 2.

5.4 The Appellant argued that since all of the original claims, including claims 2 and 8, were dependent on claim 1, combinations of said claims were allowable, as these were preferred embodiments of the invention, there being no reason for not combining them, such that the subject-matter of the claim 2 did not represent an undisclosed combination of features.

However, in the absence of a specific link between those two embodiments in the application as filed, their combination is not explicitly disclosed. In this respect, the Board observes that the fact that certain subject-matter may be rendered obvious on the basis of the content of the technical information provided by the application as filed is not relevant to the

assessment of what is directly and unambiguously disclosed thereby.

5.5 The Board thus concludes that claim 2 of auxiliary request 3 extends beyond the application as filed, contrary to the requirements of Article 123(2) EPC, such that this request is not allowable.

Auxiliary request 4

6. Admissibility of late-filed request

6.1 In auxiliary request 4 filed during the oral proceedings before the Board, dependent claims have been deleted, such that only five dependent claims remain.

6.2 The Respondent argued that there was no basis in the application as filed for all those dependent claims which had originally been dependent on claim 1 only, as they represented undisclosed combinations of features resulting in undisclosed intermediate generalisations. The Respondent submitted that this request should not be admitted into the proceedings as it had raised this objection to dependent claims in its letter dated 21 September 2011 in connection with all requests then on file. The failure of the Appellant to delete all of the dependent claims to which it had objected would require the Respondent to examine each and every remaining dependent claim for a possible basis in the application as filed, which was unreasonable at such a late stage in the proceedings, it being the responsibility of the Patent proprietor (Appellant) to indicate a basis for the subject-matter of each of its claims.

6.3 The Appellant argued that all remaining dependent claims had a basis not only in the original dependent claims, but also in the general parts of the description of the application as filed, such that they did not result in added subject-matter and the request should be admitted. It also submitted that the Respondent had raised precise objections to the dependent claims only during the oral proceedings before the Board, such that it must be allowed a possibility to respond thereto.

6.4 The Board notes that the Respondent's objections under Article 123(2) EPC to dependent claims had been on file since 21 September 2011 for all requests pending at that time. The Appellant argued merely in general terms that the subject-matter of dependent claims which was described in the description as preferred could be combined, even if said claims had been dependent on claim 1 only, but did not indicate any **specific basis** for the particular combinations of the features of the dependent claims and those features added to claim 1 during the opposition (appeal) proceedings. The Board is also not able *prima facie* to find such a basis, such that there are doubts as to whether the claims meet the requirements of Article 123(2) EPC.

6.5 Late filed auxiliary request 4 thus does not clearly overcome the objections under Article 123(2) EPC, with the consequence that the Board exercises its discretion not to admit this request into the proceedings (Articles 13(1) and (3) RPBA).

Auxiliary request 5

7. Admissibility of late-filed request

7.1 In auxiliary request 5, all dependent claims have been deleted, such that only independent claim 1 remains.

7.1.1 The Respondent repeated its submission that it had raised the objection under Article 123(2) EPC to the dependent claims at a very early stage in the proceedings, such that the Appellant could and should have responded much earlier. The Respondent had no objections under Article 84 or Rule 80 EPC to the claim of this request.

7.1.2 The Appellant argued that in view of the deletion of all dependent claims, said request necessarily overcame all objections to these claims.

7.1.3 The Board holds that the amendments are in response to the Appellant's objections under Article 123(2) EPC to the dependent claims, by deletion thereof clearly overcomes them, and thereby simplifies the case.

7.1.4 For these reasons the Board exercises its discretion to admit the Appellant's auxiliary request 5 into the proceedings.

8. Article 123(2) EPC

8.1 Claim 1 and only claim of this request differs from claim 1 of the main request in that the feature "wherein the amphiphilic block copolymers are substantially non-polymerizable" has been deleted and and the hydrophilic segments are defined as being "derived from hydrophilic polymers selected from the group consisting of poly-N-vinyl-2-pyrrolidone, poly-N-vinyl-2-piperidone, poly-N-vinyl-2-caprolactam, poly-N-vinyl-3-methyl-2-caprolactam, poly-N-vinyl-3-methyl-2-piperidone, poly-N-vinyl-4-methyl-2-piperidone, poly-N-

vinyl-4-methyl-2-caprolactam, poly-N-vinyl-3-ethyl-2-pyrrolidone, and poly-N-vinyl-4,5-dimethyl-2-pyrrolidone, polyvinylimidazole, poly-N-N-dimethylacrylamide, poly-N-vinly-N-methylacetamide, polyvinyl alcohol, polyacrylic acid, polymethacrylic acid, poly(hydroxyethyl methacrylate), mixtures and copolymers thereof" and the hydrophobic segments are defined as being "derived from hydrophobic polymers formed from monomers selected from the group consisting of octamethylcyclotetrasiloxane; 1,3-bis-aminopropyltetramethyldisiloxane; 1,3-bis-hydroxypropyltetramethyldisiloxane; dichlorodimethylsilane, 1,1,3,3-tetramethyldisiloxane; 4,4'-azobis(4-cyanovaleric acid); toluenediisocyanate, isophoronediisocyanate; 1,3-bis-vinyltetramethyldisiloxane; 3-methacryloxypropyltris(trimethylsiloxy)silane; pentamethyldisiloxanyl methylmethacrylate; and methyldi(trimethylsiloxy)methacryloxymethyl silane; monomethacryloxypropyl terminated mono-n-butyl terminated polydimethylsiloxane; 3-[tris(trimethylsiloxy)silyl] propyl allyl carbamate; 3-[tris(trimethylsiloxy)sily1] propyl vinyl carbamate; trimethylsilylethyl vinyl carbonate; trimethylsilylmethyl vinyl carbonate;and 2-propenoic acid, 2-methyl-2-hydroxy-3-[3-[1,3,3,3-tetramethyl-1-[trimethylsilyl)oxy]disiloxanyl]propoxy] propyl ester and combinations thereof".

8.2 Basis for the subject-matter of this claim is the combination of original claims 1, 8 and 14, together with page 9, lines 2 to 11 of the description of the application as filed. Claim 14, which defines the hydrophobic segments, is dependent on claim 8, which defines the weight% of the hydrophobic and hydrophilic segments, claim 8 being dependent on claim 1, with the

list of hydrophilic segments disclosed on page 9, lines 2 to 11 of the description being described as preferred.

8.3 The Respondent submitted that the combination of the specific definitions of the hydrophilic and the hydrophobic segments was not disclosed, as there was no basis for the combination of the features of original claims 1, 8, 11 and 14, since claims 11 and 14, which disclosed the hydrophilic and hydrophobic segments, respectively, were each dependent on claim 8 only and not on each other, such that the combination of these specific hydrophilic and hydrophobic segments, which resulted in a new sub-group of compounds, was not disclosed in the application as filed.

However, the combination of claims 1, 8 and 14 is undisputedly disclosed. In order to define the hydrophilic segments, the selection of merely a single list of such segments from the description of the application as filed is necessary, namely those preferred hydrophilic segments defined at page 9, lines 2 to 11.

8.4 Thus, the subject-matter of claim 1 of auxiliary request 5 does not extend beyond the content of the application as filed.

8.5 The amendments bring about a restriction of the scope of the claims as granted, and therefore of the protection conferred thereby, which is in keeping with the requirements of Article 123(3) EPC.

8.6 The Respondent had no objections under Article 84 or Rule 80 EPC to the claim of this request, and the Board also has none.

9. Remittal

Having so decided, the Board has not taken a decision on the whole matter, since the decision under appeal dealt exclusively with amendments which allegedly contravened the provisions of Articles 84 and 123(2) and Rule 80 EPC, which objections are no longer pertinent due to the amendments made. As the Opposition Division has not yet ruled on the other grounds for opposition, e.g. insufficient disclosure, novelty and inventive step, and the Appellant having requested remittal, the Board considers it appropriate to exercise its power conferred on it by Article 111(1) EPC to remit the case to the Opposition Division for further prosecution on the basis of the claim according to auxiliary request 5 in order to enable the first instance to decide on the outstanding issues.

Auxiliary requests 6 and 7

10. Since the auxiliary request 5 is remitted to the first instance for the reasons set out above, there is no need for the Board to decide on the lower ranking auxiliary requests.

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 for further prosecution on the basis of

auxiliary request 5 (one single claim) filed during the oral proceedings before the Board.

The Registrar: The Chairman:

M. Kiehl P. Gryczka

Decision electronically authenticated