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Datasheet for the decision of 22 November 2022

Case Number: T 1919/19 - 3.3.10

Application Number: 15165862.2

Publication Number: 2939697

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Language of the proceedings: EN

Title of invention:
HEMOSTATIC SPONGE

Patent Proprietors:
Baxter International Inc.
Baxter Healthcare S.A.

Opponent:
Ethicon, Inc.

Headword:

Relevant legal provisions:
EPC Art. 76(1), 54(2), 54(3), 84, 56, 87(1), 113(1)
EPC R. 103(1)(a)
RPBA Art. 12(4)

Keyword:
Divisional application - added subject-matter
Substantial procedural violation - reimbursement of appeal fee (no)
Right to be heard - opportunity to comment (yes)
Late-filed request - submitted with the statement of grounds of appeal - auxiliary requests 1-6 not admitted, auxiliary request 14 admitted
Priority - auxiliary request 14 (yes)
Novelty - auxiliary request 14 (yes)
Inventive step - auxiliary request 14 (yes)
Claims - clarity in opposition proceedings - clarity (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1919/19 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 22 November 2022

Appellant: (Patent Proprietor 1)	Baxter International Inc. One Baxter Parkway Deerfield, IL 60015 (US)
Appellant: (Patent Proprietor 2)	Baxter Healthcare S.A. Thurgauerstrasse 130 8152 Glattpark (Opfikon) (CH)
Representative:	SONN Patentanwälte OG Riemergasse 14 1010 Wien (AT)
Respondent: (Opponent)	Ethicon, Inc. P.O. Box 1222 New Brunswick NJ 08903 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 23 April 2019 revoking European patent No. 2939697 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	P. Gryczka
Members:	M. Kollmannsberger
	L. Basterreix

Summary of Facts and Submissions

I. The patentee's appeal lies from the Opposition Division's decision to revoke the disputed patent under Articles 101(2) and 101(3)(b) EPC.

II. The following documents are referred to in this decision:

D3:	US 2006/0258560 A1
D4:	WO 2011/124640 A1 (published parent application)
D5:	W O01/16210 A1
D7:	US 61/321,661 (first priority document)
D8:	EP 2 179 753 A2
D9:	HemoPatch Product Generation Report, Baxter
D10:	Preclinical testing of HemoPatch Variants, 04.02.2010
D12:	Assessment of blood penetration into a hemostatic sponge according to EP 2 939 697 B1 and a dry tissue sealant according to US 2006/028560, 2019

III. The patent was granted on the basis of a divisional application. It had been opposed under Articles 100(a) and Articles 100(c) EPC for lack of novelty, lack of inventive step and unallowable amendments with respect to the originally filed parent application.

IV. In its decision the Opposition Division concluded that claim 1 of the granted patent extended beyond the content of the parent application as originally filed and contravened thus Article 76(1) EPC. A total of seven claim sets was pending before the Opposition Division as auxiliary requests for maintenance of the patent in amended form. The claims of auxiliary request 1 complied with Article 76(1) and 123(3) EPC and the amendments did not give rise to a lack of clarity under Article 84 EPC. Claim 1 of this request was novel over D3 and D8 and enjoyed the claimed priority. However, starting from example 4 of D5 the claimed hemostatic sponge was obvious over document D5.

V. With its grounds of appeal the appellant requested

(i) to set aside the impugned decision and to maintain the patent as granted, i. e. to reject the opposition under Article 101(2) EPC;

(ii) should the patent not be maintained as granted, the appellant further requested that the case be remitted to the Opposition Division for assessment of inventive step of auxiliary request 1 pending before it (auxiliary request 7 in the appeal proceedings) due to a substantive procedural violation and that the appeal fee be reimbursed under Rule 103(1)(a) EPC;

(iii) should the board not remit the case to the Opposition Division, the appellant requested that the patent be maintained in amended form on the basis of auxiliary requests 1-18 as filed with the grounds of appeal.

These requests were maintained throughout the appeal proceedings.

VI. In its reply to appeal the respondent (opponent) requested that the appeal be dismissed and that auxiliary requests 1-6 and 8-13 and document D12 not be admitted into the appeal proceedings. In the course of the appeal proceedings the respondent furthermore requested that auxiliary requests 14-18 not be admitted to the appeal proceedings.

VII. With notification of 15 October 2021 the parties were summoned to oral proceedings which took place on 22 November 2022 (all relevant issues were finally discussed). A communication under Article 15(1) RPBA 2020, including a preliminary opinion on some of the disputed points, had been issued on 1 August 2022.

VIII. The independent product claims of the appellant's requests relevant for the present decision are worded as follows:

Claim 1 of the granted patent reads:

A hemostatic porous composite sponge comprising
i) a matrix of a biomaterial and
ii) a single hydrophilic polymeric component, said polymeric component comprising electrophilic reactive groups, wherein said hydrophilic polymeric component is a hydrophilic crosslinker, and wherein i) and ii) are associated with each other so that the reactivity of the polymeric component is retained, wherein associated means that

- said polymeric component is coated onto a surface of said matrix of a biomaterial, or
- said matrix is impregnated with said polymeric material, or
- both.

Claim 1 of auxiliary request 1 reads (amendments with respect to the granted patent <u>underlined</u>):

A hemostatic porous composite sponge comprising
i) a matrix of a biomaterial and
ii) a single <u>crosslinker which is</u> hydrophilic polymeric component, said polymeric component comprising electrophilic reactive_groups, wherein said hydrophilic polymeric component is a hydrophilic crosslinker, and wherein i) and ii) are associated with each other so that the reactivity of the polymeric component is retained, wherein associated means that
- said polymeric component is coated onto a surface of said matrix of a biomaterial, or
- said matrix is impregnated with said polymeric material, or
- both.

The independent product claims of auxiliary requests 2-6 are amended with respect to the granted patent at least by the same feature; their exact wording is not relevant to the decision.

Claim 1 of auxiliary request 7 reads:

A hemostatic porous composite sponge comprising
i) a matrix of a biomaterial and
ii) a single hydrophilic polymeric component, said polymeric component comprising electrophilic reactive groups, wherein said hydrophilic polymeric component is

a hydrophilic crosslinker, and wherein i) and ii) are associated with each other so that the reactivity of the polymeric component is retained, wherein associated means that
- said polymeric component is coated onto a surface of said matrix of a biomaterial, or
- said matrix is impregnated with said polymeric material, or
- both,
wherein the single hydrophilic polymeric component is a polyalkylene oxide polymer.

The wording of claim 1 of auxiliary request 8 is not relevant for the present decision. The same holds for auxiliary requests 9-13; it is only relevant that these requests do not contain the additional feature concerning the polyalkylene oxide polymer introduced into claim 1 of auxiliary request 7.

Claim 1 of auxiliary request 14 reads as follows:

A hemostatic porous composite sponge comprising
i) a matrix of a biomaterial and
ii) a single hydrophilic polymeric component, said polymeric component comprising electrophilic reactive groups, wherein said hydrophilic polymeric component is a hydrophilic crosslinker, and wherein i) and ii) are associated with each other so that the reactivity of the polymeric component is retained, wherein associated means that
- said polymeric component is coated onto a surface of said matrix of a biomaterial, or
- said matrix is impregnated with said polymeric material, or
- both,

wherein the single hydrophilic polymeric component is a polyalkylene oxide polymer, and
wherein the thickness of the coating is from about 0,01 mm to 1 mm.

IX. The appellant's submissions relevant to the present decision are the following:

Claim 1 of the patent as granted did not contain added subject-matter. A restriction of the hydrophilic polymer to polyalkylene oxides was not necessary, the Opposition Division's assessment on this point was flawed. Regarding the other objections raised by the opponent the Opposition Division was correct in holding them unfounded.

Auxiliary requests 1-6 should be admitted into the procedure. They were filed together with the statement setting out the grounds of appeal as a reaction to the decision of the Opposition Division.

Auxiliary request 7 corresponds to auxiliary request 1 before the Opposition Division. The assessment of inventive step during oral proceedings before the Opposition Division suffered from a procedural violation; the Opposition Division did not consider the arguments submitted with respect to D10. Thus, the case should be remitted to the Opposition Division under Article 111 EPC and the appeal fee should be reimbursed under Rule 103(1)(a) EPC.

Auxiliary requests 14-18 should be admitted into the appeal proceedings. Their filing was a legitimate response to the Opposition Division's decision; these requests could not have been filed during the opposition procedure.

The hemostatic composite sponge defined in claim 1 of auxiliary requests 7 and 14 was novel over the cited documents, in particular over D3 and D8.

Regarding inventive step it was important to recognize that in the claimed sponge hydrogel formation was achieved between the electrophilic polymer and the proteins of the blood, whereas in the cited prior art documents a second crosslinker was necessary. Furthermore, D9, D10 and D12 showed unexpected improvements over D3 and D5. D8 was a document according to Article 54(3) EPC not to be considered for inventive step under Article 56 EPC.

X. The respondent's submissions relevant to the present decision are the following:

The Opposition's Division was correct in considering that the missing nature of the hydrophilic polymer extended claim 1 of the granted patent beyond the original disclosure. Moreover, the feature in claim 1 that only a single polymer bearing electrophilic groups is present found no support in the application as filed.

Auxiliary requests 1-6 and 14-18 should not be admitted into the appeal proceedings under Article 12(4) RPBA 2007. These requests should have been submitted already during opposition proceedings.

No procedural violation occurred during opposition proceedings regarding the assessment of inventive step of auxiliary request 7. Moreover, not only was the Opposition Division's decision correct in that inventive step starting from D5 was denied, the claims of this request furthermore lacked novelty over D3 and D8.

The hemostatic sponge defined in the independent claim of auxiliary request 14 was not novel over D3 and D8. Moreover, it lacked an inventive step not only over D5, but also over D3 and D8. In particular, these documents disclosed the use of only one polymeric crosslinker for the formation of the hydrogel which induces hemostasis. D8 could be cited against inventive step since the priority claim of auxiliary request 14 was invalid.

XI. The decision was announced at the end of the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. The appellant's main request - patent as granted

2.1 The Opposition Division concluded that the patent as granted contained unallowable amendments with respect to the parent application as originally filed and thus contravened Article 76(1) EPC.

In particular the Opposition Division found the definition of the hydrophilic polymeric component, comprising electrophilic reactive groups, but not being limited to polyalkylene oxides, to extend beyond the original parent application.

2.2 Claim 1 of the granted patent reads:

A hemostatic porous composite sponge comprising
i) a matrix of a biomaterial and
ii) ~~one~~ a single hydrophilic polymeric component, said polymeric component comprising electrophilic reactive groups, wherein said hydrophilic polymeric component is a hydrophilic crosslinker, and wherein i) and ii) are associated with each other so that the reactivity of the polymeric component is retained, wherein associated means that
- said polymeric component is coated onto a surface of said matrix of a biomaterial, or
- said matrix is impregnated with said polymeric material, or
- both.

Changes are highlighted with respect to claim 1 of the parent application as filed, which is on file as D4.

The disputed amendments are the definition of the reactive groups as being electrophilic, without a corresponding restriction of the hydrophilic polymeric component to polyalkylene oxide polymers, and the amendment of "*one*" to "*a single..., said*". These two issues are addressed below.

2.3 Polyalkylene oxide

2.3.1 The hydrophilic polymeric component (feature ii of the claim) is described on page 5 of the original parent application.

2.3.2 Paragraphs 3 and 4 on this page define the presence of a single hydrophilic polymeric component having electrophilic reactive groups. This disclosure is clearly limited to polyalkylene oxide polymers ("*is a single polymeric component and is a polyalkylene oxide polymer*").

The limitation to polyalkylene oxide polymers is absent from claim 1 of the granted patent. Thus, if based on this passage alone the claim extends beyond the original disclosure.

2.3.3 The appellant essentially argued that the disclosure on page 5 is broader than just paragraphs 3 and 4. In particular it was argued that the first paragraph defined the hydrophilic polymeric component to be a crosslinker and to have reactive groups, and that paragraph 5 defined preferred electrophilic groups of this cross-linker. Also a combination of paragraphs 3 and 5 lead to the wording of the claim.

2.3.4 However, paragraph 5 defines "*preferred*" electrophilic groups and refers thus to the electrophilic groups mentioned for the first time in the preceding paragraph, where they are disclosed as being attached to polyalkylene oxide polymers. On the other hand, paragraph 1 is not limited to polyalkylene oxides, but does not mention electrophilic reactive groups. A combination of paragraphs 3 and 5 cannot lead to the subject-matter defined in the claim either since paragraph 3 is clearly limited to polyalkylene oxides.

2.3.5 It was also argued that the feature of electrophilic groups was not inextricably linked to the polyalkylene oxides. However, as discussed above, electrophilic reactive groups are disclosed in paragraphs 3-5 of page

5 relating to polyalkylene oxides. The original parent application does not directly and unambiguously disclose such groups detached from these specific polymers.

2.4 *One* vs. *single*

2.4.1 The respondent furthermore objected to the replacement of the word *one* with *single* in granted claim 1. In particular, it was argued that due to the reference *"said polymeric component"* the granted claim now excluded the presence of polymers having other, or no reactive groups. There was no basis in the original application for such an exclusion. There were even examples in the original disclosure, like examples 7 and 8, in which a second polymer (fucoidan or thrombin) was used.

2.4.2 The Opposition Division held this amendment to be based on the original disclosure, see point 1.1.3 of the impugned decision.

2.4.3 The appellant argued that the meaning of *one* and *single* was identical. Moreover, it was clear from the whole original disclosure that the idea of the invention was to use only one hydrophilic reactive polymer.

2.4.4 In the view of the Board this amendment, i. e. the replacement of *one* by *a single* and defining that this single polymer has electrophilic reactive groups, does not extend beyond the original disclosure.

That an amended claim excludes certain embodiments which were encompassed by the original disclosure is the consequence of any limiting amendment and is as such not objectionable under Article 123(2)/76(1) EPC.

Neither is the decisive issue whether *one* and *a single* linguistically have the same meaning or not. The question to be answered is whether the original application discloses, at least as a possibility, that there may be only one hydrophilic polymer, this polymer having electrophilic reactive groups.

In the Board's view this is the case. Original claim 1 defines a composite containing one hydrophilic polymer comprising reactive groups. The first paragraph on page 5 of the description states that *the* polymer is a crosslinker and that *its* reactive groups should react upon application of the sponge to the patient. The continuous reference to *the* polymer or *the* polymeric component in this passage and in other parts of the original disclosure, e. g. in the description of the invention in the last paragraph on page 3 makes it clear that the use of only one reactive polymer is a feature of the invention clearly disclosed as such. Also most of the examples only contain one hydrophilic reactive polymer. That the original disclosure also envisages, as an option, to add further activators of blood coagulation, as defined on pages 7-9 or in examples 6 and 7, which may be of a polymeric nature, does not change this disclosure.

The presence of electrophilic groups on the polymer is disclosed e. g. on page 5, in each of paragraphs three, four and five. The disclosure is limited to polyalkylene oxide polymers, but this is the unallowable amendment discussed above; it is not related to the presence of a single hydrophilic reactive polymer.

2.5 Thus, since claim 1 of the granted patent does not specify the nature of the hydrophilic polymer as being a polyalkylene oxide derivative claim 1 of the granted patent contains an unallowable amendment with respect to the parent application, contrary to Article 76(1) EPC.

3. Auxiliary requests 1-6

3.1 These requests were filed with the statement of grounds of appeal. Their admission is subject to Article 12(4) RPBA 2007, see transitional provisions in Article 25(2) RPBA 2020.

Under Article 12(4) RPBA 2007 the Board may hold requests inadmissible if they could have been presented during first instance proceedings.

3.2 The independent claims of auxiliary requests 1-6 have been amended in that feature ii) now defines a *single cross-linker* being a hydrophilic polymeric component, rather than defining a *single hydrophilic polymeric component*.

3.3 The appellant argued that these requests should be admitted since they were a reaction to the Opposition Division's decision. Thus, they could not have been filed earlier. In particular, it referred to points 1.1.4 to 1.1.7 of the decision.

3.4 However, these passages of the decision relate to the Opposition Division's assessment of the unallowable amendments. On this point the only issue decided against the appellant was the missing combination of electrophilic groups and polyalkylene oxides.

The respondent pointed out that a legitimate reaction to the decision would have been the filing of requests combining electrophilic groups and polyalkylene oxides. Such requests were in fact filed before the Opposition Division as auxiliary requests 1 and 2 (now 7 and 8).

The Board agrees with the respondent. The filing of requests being amended to relate to *a single crosslinker* is not a reaction to the Opposition Division's decision. Auxiliary request 1 does not require polyalkylene oxides and is thus in any case no reaction to the Opposition Division's decision. Auxiliary requests 2-6 address the polyalkylene oxides issue but additionally contain the amendment to a s*ingle crosslinker*, a feature which had never been discussed before the Opposition Division.

3.5 Thus, auxiliary requests 1-6 should have been filed before the opposition division and are therefore not admitted into the appeal proceedings.

4. Auxiliary request 7 - Procedural violation, remittal and refund of the appeal fee

4.1 The appellant alleges a procedural violation committed by the Opposition Division when deciding on inventive step of auxiliary request 1 pending during oral proceedings, which corresponds to auxiliary request 7 in the present appeal proceedings. The appellant states that the Opposition Division misinterpreted the experimental results shown in D10. In the appellant's view the Opposition Division's reasoning was based on tables 4 and/or 6 of D10 which had not been discussed during oral proceedings. This amounted to a violation of the appellant's right to be heard enshrined in Article 113(1) EPC.

However, the Board comes to the conclusion that no procedural violation was committed by the Opposition Division. Misunderstanding a document or drawing the wrong conclusions from a document, even should this have happened, qualify at most as an error of judgement, but not as a procedural violation. Regarding the procedure, D10 was extensively discussed during oral proceedings as documented in the minutes, page 6. The appellant had ample opportunity to present its arguments based on D10; the right to be heard under Article 113(1) EPC was thus respected. The reasons for the decision summarize in point 2.6.10 the patent proprietor's arguments citing various parts of D10, i.a. tables 4 and 6. Thus, the Opposition Division has considered such arguments; it cannot be expected that the Opposition Division gives a thorough reasoning of its conclusions on the spot during oral proceedings. Whether the Opposition Division's assessment of D10 and the relevance of D10 for the question of inventive step were "correct" or not, is not a matter of procedure, but of the substantive assessment of inventive step.

4.2 Thus, the appellant's request for a remittal of the case to the Opposition Division "*for a proper assessment of inventive step*", as set out in its grounds of appeal, cannot be granted.

The review of the Opposition Division's decision, including its assessment of inventive step of auxiliary request 1 as pending before it, is the very purpose of appeal proceedings, see Articles 110 and 111 EPC. A substantive procedural violation justifying a remittal, e. g. under Article 11 RPBA 2020, has not occurred.

4.3 A refund of the appeal fee under Rule 103(1) EPC, as requested by the appellant, can neither be granted, since no substantive procedural violation occurred, Rule 103(1)(a).

5. Auxiliary request 7 - novelty

5.1 D8 is a European patent application published during the priority year of the disputed patent. Its filing date lies before the priority dates claimed for the present patent. D8 represents thus state of the art under Article 54(3) or 54(2) EPC, depending on the validity of the priority claim. In both cases D8 is to be considered for the question of novelty. This was undisputed.

5.2 D8 discloses hemostatic implants including a porous substrate having a first and a second hydrogel precursor applied thereto, see [0002]. The example ([0068]) uses a sheet of oxidized cellulose as a substrate. This sheet is impregnated with a trilysine solution (first hydrogel precursor) and dried. Then, a melted polyalkylene oxide, bearing electrophilic substituents, is applied on one side of the sheet and forms a film on it.

This example reads on claim 1 of auxiliary request 7. The sheet of oxidized cellulose is a biomaterial according to feature i) of the claim. Feature ii) is also fulfilled, since the polyalkylene oxide derivative is the single hydrophilic polymeric component as defined in the claim. Trilysine, the second precursor used in D8, is not a polymer. The polymeric component is coated onto the surface of the matrix, as required by the claim.

5.3 The appellant defended the novelty of the claim over D8 on the basis of two features, namely *sponge* and *single hydrophilic polymeric component*.

5.3.1 Sponge

The appellant argued that the term "*hemostatic porous composite sponge*" in claim 1 implied the capacity to absorb body fluids when applied to the site of injury. It referred to paragraph [0023] of the patent. It was an essential part of the claimed invention that body fluids, in particular blood, could enter the sponge and react with the immobilized reactive polymer inside the sponge. On the contrary, the material in D8 was a tissue sealant where the reaction took place already at the surface of the composite.

This is not convincing. The matrix in D8 is made of oxidized cellulose, which is a porous material (see claim 3 of D8). Pads made from oxidized cellulose are mentioned in the patent itself as being suitable, see example 6. The patent description holds the terms sponge, pad and fleece as interchangeable, see [0017]. Furthermore, paragraph [0006] of D8 explicitly describes that physiological fluids are wicked through the porous substrate upon application, dissolving the hydrogel precursors, thus initiating coagulation. Even if one follows the appellant's definition of the term "*hemostatic porous composite sponge*", such a sponge is described in D8.

5.3.2 Trilysine

It is undisputed that D8 uses two different hydrogel precursors. In the example preparation the first precursor is the electrophilic polyethylene oxide derivative coated on one side of the cellulose sheet. The second one is trilysine, applied from a solution.

The claim requires a single hydrophilic polymeric component. However, the claim does not exclude the presence of a low molecular component like trilysine.

The appellant referred to paragraph [0039] of D8 where trilysine is named *multifunctional nucleophilic polymer*. However, trilysine is a tripeptide with a molecular weight of about 400 Da. A trimer does not qualify as a polymer in the general use of this term. The patent itself describes the molecular weight of the polymeric components to be in a range between 500 Da and 50000 Da (see [0046]). According to paragraph [0085] of the patent the polymeric components should have a molecular weight of at least 1000 Da, preferably at least 5000 Da, especially at least 8000 Da. This corroborates the view that trilysine is not a polymeric component. Its presence is thus not excluded by claim 1 of auxiliary request 7.

5.4 Thus, the hemostatic sponge defined in claim 1 of auxiliary request 7 is not novel in view of D8. The patent cannot be maintained on the basis of this request.

6. Auxiliary requests 8-13

6.1 Auxiliary requests 8-13 correspond to auxiliary requests 2-7 pending before the Opposition Division.

6.2 Auxiliary request 8 corresponds to auxiliary request 2 as filed during oral proceedings before the Opposition Division. The Opposition Division did not admit this request into the proceedings, see point 3 of the impugned decision. The appellant has not provided any arguments as to why this decision would be flawed. The Board sees thus no reason to reverse it and does not admit this request under Article 12(4) RPBA 2007.

6.3 The independent claims of auxiliary requests 9-13 do not require the hydrophilic polymeric component to be a polyalkylene oxide. Thus, these requests contain unallowable amendments under Article 76(1) EPC in the same way than the claims of the granted patent.

7. Auxiliary request 14 - admissibility

7.1 Auxiliary request 14 was filed with the statement of grounds of appeal. Its admission is thus subject to Article 12(4) RPBA 2007, see transitional provisions in Article 25(2) RPBA 2020.

Auxiliary request 14 is based on auxiliary request 1 underlying the impugned decision, defining the hydrophilic polymeric component as a polyalkylene oxide, combined with the features of auxiliary request 3 underlying the impugned decision, defining the thickness of the coating of this polymer, in case it is coated onto a surface of the matrix.

7.2 In the respondent's view this request should not be admitted to appeal proceedings. The situation was the same as for auxiliary requests 1-6. Auxiliary request 14 should have been submitted already in opposition proceedings. Moreover, neither the clarity of the amendments nor inventive step of this request were discussed before the Opposition Division.

7.3 However, the situation is not the same as for auxiliary requests 1-6.

7.3.1 Whereas those requests, as outlined above, cannot be seen as a reaction to the Opposition Division's decision, auxiliary request 14 can. The Opposition Division held all requests submitted during the written phase to contravene Article 76(1) EPC. A new auxiliary request 1 was filed during oral proceedings which overcame this objection, but in the end was held not to be inventive. The introduction of a limiting feature present in the highest ranking request of the written opposition procedure is thus a reaction to the Opposition Division's decision.

7.3.2 Moreover, auxiliary requests 1-6 introduced a feature never discussed before the Opposition Division. Auxiliary request 14, to the contrary, is based on a combination of requests already pending before the Opposition Division. Thus, arguments concerning the individual features were already on file during opposition proceedings. In particular the feature defining the thickness of the coating was the feature introduced into the highest ranking auxiliary request filed during the written phase of the opposition proceedings.

7.3.3 The respondent stressed that this request should have been filed during opposition proceedings since the objection under Article 76(1) EPC was already made in the notice of opposition.

However, in view of the multitude of objections raised in the notice of opposition the Board understands the appellant's position that it would have been difficult to address every combination of these objections with an appropriate auxiliary request.

7.3.4 In summary, the Board considers the present situation not to be one where auxiliary request 14 would have had to be filed already during the opposition procedure. The filing of this request together with the statement setting out the grounds of appeal addresses the findings of the decision, does not introduce issues to be discussed which were not on file during opposition proceedings and its filing at the outset of the appeal procedure may be justified.

Auxiliary request 14 is thus admitted to the proceedings. The Board does not exercise its power under Article 12(4) RPBA 2007 to hold it inadmissible.

8. Auxiliary Request 14 - amendments

8.1 The objection which lead to the claims of the granted patent not to comply with Article 76(1) EPC does not apply to claim 1 of auxiliary request 14. The claim defines that the single hydrophilic polymeric component is a polyalkylene oxide polymer.

8.2 No further objections were raised against the claims of auxiliary request 14. The Board is satisfied that the claims are based on the original disclosure. In particular the definition that the composite sponge comprises "*~~one~~ a single hydrophilic polymeric component, said polymeric component comprising electrophilic reactive groups, wherein said hydrophilic* *polymeric component is a hydrophilic crosslinker*" is based on page 5, third paragraph, of the parent application as filed. This paragraph, in the same way as the claim, is directed to polyalkylene oxide polymers substituted by electrophilic groups. The feature defining the thickness of the coating is based on page 9, second full paragraph of parent application as originally filed.

9. Auxiliary request 14 - clarity (Article 84 EPC)

9.1 Claim 1 of auxiliary request 14 was amended by the introduction of the feature "*wherein the thickness of the coating is from about 0,01 mm to about 1 mm*". Since this feature has been taken from the description this amendment may be examined for clarity under G03/14.

9.2 The respondent argued that the use of "about" rendered the claimed range unclear. Moreover, according to [0043] of the description the coating may be discontinuous. It was argued that it was unclear what was meant by the thickness of a discontinuous coating and how this should be measured.

9.3 The Board does not agree. The use of "about" for defining the claimed range does not amount to more than the recognition of general measurement errors, a situation well known to a person skilled in the art. Neither has the respondent provided technical reasons which would preclude the measurement of the thickness of a discontinuous coating. Obviously, such a thickness must be measured at places where the coating is present.

9.4 Thus, the amendments in claim 1 of auxiliary request 14 do not introduce any lack of clarity.

10. Auxiliary request 14- Novelty

10.1 Novelty of claim 1 of this request was objected to over D8 and over D3.

10.2 D8

Novelty over D8 is provided by the feature "*wherein the thickness of the coating is from about 0,01 mm to about 1 mm*". Example of D8 corresponds to the claimed sponge with the polymeric component coated onto a surface of the matrix. However, D8 does not give any details of the thickness of this coating. Novelty of the claimed sponge with respect to D8 was not contested.

10.3 D3

10.3.1 Example 7 of D3 discloses a matrix made of collagen coated with a mixture of gelatin and PEG-SPA.

It is uncontested that PEG-SPA is a hydrophilic polymer containing electrophilic groups according to the definition in part ii) of claim 1.

According to the impugned decision the claims of the granted patent are novel over this disclosure because gelatin is a (second) hydrophilic polymer, the presence of which is excluded by part ii) of claim 1.

10.3.2 The respondent argued that such an interpretation is arbitrary, since the gelatin could as well be seen to form, together with the collagen, the matrix biomaterial defined in part i) of the claim. Such an arrangement was also referred to in the patent, e. g. in par. [0049].

However, claim 1 of auxiliary request 14, in the same way as claim 1 of the granted patent, requires a biomaterial matrix coated with or impregnated with a single hydrophilic component. The gelatin does not form part of the matrix, since it is sprayed onto the collagen together with the PEG-PSA. This is described in example 7, see [0117], but also in the general description in [0087]. Thus, the gelatin is a second hydrophilic polymeric component, which is excluded by the wording of the claim.

10.3.3 The appellant furthermore argued that the material of D3 could not considered to be a sponge. According to the respondent the material of D3 is lyophilized and thus porous, as required by the feature "sponge".

The material in D3 is consistently named "tissue sealant". Sponges are mentioned in D3, but only as additional materials , see [0067] or [0075], or in the framework of comparative tests for showing improved performance of the tissue sealants of D3, see tables 5 or 6. Sponges are mentioned as a possible alternative form for the materials prepared in D3, among others like granules, sheets, membranes etc., see the end of paragraph [0087]. However, this rather confirms the finding that the material prepared in example 7 is not in the form of a sponge. This finding is further corroborated by example 7 stating blood penetration through the collagen matrix not to happen. The mere fact that the material is obtained via a lyophilisation step does not mean that it must be in the form of a sponge.

10.3.4 Thus, the claimed composite sponge is novel also over D3.

11. Auxiliary request 14 - inventive step

11.1 The claims are directed to a hemostatic composite sponge comprising a matrix of a biomaterial and a single hydrophilic polymeric component as a crosslinker. The invention is based on the finding that upon contact with blood the crosslinker, which has electrophilic reactive groups as substituents, reacts with the proteins of the blood and induces thus the formation of a hydrogel, see paragraph [0020] of the description.

11.2 In the impugned decision D5 was seen as closest prior art and inventive step was denied starting from this document. The respondent also raised objections starting from D3 and D8.

11.3 Starting from D5

11.3.1 The examples closest to the claimed invention are examples 4 and 5 of D5.

Example 4 discloses a hemostatic sponge having a collagen matrix impregnated with two different PEG derivatives, one with electrophilic ("COH102") and one with nucleophilic reactive groups ("COH206").

11.3.2 Claim 1 of auxiliary request 14 differs from this disclosure in that only one hydrophilic polymer is present in the claimed composite sponge.

11.3.3 The least ambitious technical problem that can be formulated starting from D5 is the provision of alternative hemostatic sponges.

This problem is solved by the claimed sponges, which are characterized by the use of one single polymeric component as a cross-linker. The respondent has pointed to example 26 of the patent in order to argue that superior hemostatic and adhesive properties are not achieved by the claims. However, for solving the technical problem as stated above such properties are not necessary.

11.3.4 Thus, it has to be decided whether the claimed solution to this problem was obvious for a person skilled in the art.

The Opposition Division held the claimed products to be obvious alternatives to the ones described in the example 4 of D5, making reference to the general disclosure on page 8 of D5. This passage describes the possibility to use a single multifunctional polymer.

11.3.5 The Board does not agree with this analysis.

It is correct that D5 mentions the use of one polymeric crosslinker together with functionalized small molecule as one, although not the preferred, possibility, e. g. on the bottom of page 8, and also in other passages, such as page 10 lines 10-14 or page 11 lines 12-25.

However, this disclosure must be read in the whole context of D5. D5 discloses medical sealants which are optimized as regards their physical strength, see "field of the invention" on page 1. This is achieved by using different components which crosslink together once brought into contact with each other, in this way forming interpenetrating polymer networks, see "field of the invention" on page 1, "summary of the invention" on page 3 and "detailed description of the invention" on pages 5 and 6. These compositions are said to have a variety of uses, among them as tissue sealants, as tissue or surgical adhesives, or as vehicles for drug delivery (pages 23-25). Sponges are mentioned in the general description with respect to examples 4 and 5 only (see page 6, lines 10 and 11). Hemostatic applications are specifically mentioned on page 19, where nucleophilic and electrophilic polyethylene glycol derivatives are used to form a hydrogel by reaction with each other.

Thus, as stressed by the appellant, the idea behind D5 clearly is to form a sealing hydrogel by reacting two components present in the composite. The disclosure of D5 is based on a different principle than what is done in the disputed patent. D5 nowhere mentions the idea underlying the patent, namely to achieve a hemostatic effect by using only one polymeric component having electrophilic reactive groups which then crosslinks with the nucleophilic blood proteins as a second component. Starting from the teaching of D5 a skilled person would not have omitted the nucleophilic polymeric component present in examples 4 or 5 in order to obtain an alternative hemostatic sponge. The use of only one polymeric crosslinker together with a low-molecular crosslinker described in the passages referred to by the respondent is neither mentioned in the context of hemostasis nor of sponges. A skilled person had no reason to apply such a teaching to the specific disclosure of sponges in examples 4 and 5.

11.3.6 The respondent also pointed to D6. D6 discloses that crosslinkers may be used to form hydrogels with biological fluids, such as blood. However, D5 discloses the formation of hydrogels by means of two crosslinkers and the application for the preparation of hemostatic sponges. A skilled person would not have had any reason to consider D6 without knowledge of the invention, i. e. without knowing that for such sponges the presence of one hydrophilic polymer with electrophilic reactive groups is enough. A combination of D5 and D6 is based on hindsight.

11.3.7 Thus, starting from D5 the claimed hemostatic sponges solve the problem of providing an alternative to the disclosure of D5 in a non-obvious way. The various documents referred to by the appellant in order to show unexpected improvements of the claimed sponges, i. e. D9, D10 or D12 need not to be addressed.

11.4 Starting from D3

11.4.1 The example of D3 closest to the claimed composite sponge is example 7.

11.4.2 As set out above in the context of the novelty discussion, this example uses two functional polymers, namely the electrophilic PEG-SPA and collagen, which has nucleophilic amino groups. Furthermore, the material made in example 7 of D3 is not a sponge, but a tissue sealant.

11.4.3 Starting from D3 the technical problem to be solved can be formulated in a similar way than if starting from D5, namely the provision of an alternative hemostatic composite material.

This problem has been solved by means of the claimed composite which is characterized by being a sponge and having only one hydrophilic polymeric component as a cross-linker.

11.4.4 The claimed solution was not obvious for a skilled person from D3. There is nothing in D3 that prompts a skilled person to use only one hydrophilic reactive polymer. In example 7 the coating agent for the matrix is a mix of the PEG-PSA and the nucleophilic collagen. Throughout the description of D3 the importance of the collagen is stressed, see [0008], [0009], [0015] or [0017]. There is no teaching whatsoever to use the electrophilic polymer alone. Whether the use of a sponge may be suggested by D3 or not is thus irrelevant.

11.4.5 The respondent's main argument was that the collagen could be seen as a part of the matrix, so that only one hydrophilic polymer is in fact used. However, as set out above the collagen is not a part of the matrix, but is applied together with the other hydrophilic polymer, i. e. the PEG-PSA.

11.5 It was also argued that the claimed subject-matter lacks inventive step starting from D8. It has however first to be examined whether D8 is prior art under Article 56 EPC.

11.5.1 D8 is a European patent application published on 28 April 2010, i.e. after the first priority date of 17 October 2008 claimed for the present patent from the first priority document which is on file as D7. In case the priority claimed from this priority document is valid, D8 is not prior art under Article 54(2) and 56

EPC and cannot be taken into account for the assessment of inventive step. This was uncontested.

11.5.2 The respondent argued that the priority claim from D7 was invalid. It was stressed that the third paragraph on page 5 of the original parent application, disclosing the "*single hydrophilic polymer component*", is absent in D7. Thus, the corresponding feature in claim 1 of auxiliary request 14 found no basis in the priority document.

11.5.3 However, the absence of this paragraph does not mean that the priority claim is invalid.

The disclosure on page 2, first full paragraph of D7 corresponds to claim 1 of the parent application as filed. The hydrophilic polymer component being a polyalkylene oxide having electrophilic reactive groups is disclosed in the passage bridging pages 3 and 4 of D7.

The only feature which is not explicitly described in the priority document D7, whereas it is explicitly described in the parent application as filed in the "missing" paragraph, is the word "*single*". However, this amendment does not hinge on the presence of the missing paragraph, as set out in point 2.4 above.

The additional feature of claim 1 of auxiliary request 14, the thickness of the coating, is disclosed in D7 on page 6. This was not contested.

Thus, the priority date of 17 October 2008 is validly claimed for the subject-matter of claim 1 of auxiliary request 14. No additional objections were raised against any dependent claim.

11.5.4 Since the claims of auxiliary request 14 validly claim the priority of D7, D8 is no state of the art for the assessment of inventive step under Article 56 EPC.

11.6 The composite sponge defined in claim 1 of auxiliary request 14 complies thus with the requirement of inventive step, Article 56 EPC.

12. In summary, the amended version of the claims in the form of auxiliary request 14 fulfil the requirements of the EPC; the patent may thus be maintained on the basis of this claim set under Article 101(3)(a) EPC. The appellant's further auxiliary requests need not to be addressed.

13. Since the description still needs to be adapted to the amended claim set, the Board exercises its power under Article 111 EPC to remit the case to the Opposition Division for the adaption of the description.

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 claims of auxiliary request 14 filed with the statement of grounds of appeal and a description yet to be adapted.

The Registrar:

C. Rodríguez Rodríguez

The Chairman:

P. Gryczka

Decision electronically authenticated