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Datasheet for the decision of 2 August 2022

Case Number: T 2274/19 - 3.3.10

Application Number: 04779021.7

Publication Number: 1663297

IPC: A61L26/00, A61K38/36, A61K38/39, A61K38/48, A61K9/10, A61K47/36, A61K47/42, A61L24/10, C12N9/74

Language of the proceedings: EN

Title of invention:
HEMOSTATIC COMPOSITIONS CONTAINING STERILE THROMBIN

Patent Proprietor:
ETHICON, INC.

Opponent:
Baxter International Inc.

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Amendments - allowable (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 2274/19 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 2 August 2022

Appellant: (Opponent)	Baxter International Inc. One Baxter Parkway Deerfield, Ill. 60015, U.S.A. (US)
Representative:	SONN Patentanwälte OG Riemergasse 14 1010 Wien (AT)
Respondent: (Patent Proprietor)	ETHICON, INC. U.S. Route 22 Somerville, NJ 08876-1515 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 28 May 2019 concerning maintenance of the European Patent No. 1663297 in amended form.**

Composition of the Board:

Chairman	P. Gryczka
Members:	A. Zellner
	F. Blumer

Summary of Facts and Submissions

I. The opponent's appeal lies from the decision of the opposition division to maintain European patent No. 1 663 297 in amended form under Article 101(3)(a) EPC.

II. The patent has been attacked under Article 100(a) EPC for lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), and under Article 100(b) and (c) EPC for insufficient disclosure and unallowable amendments.

III. The following documents, which have been cited during the opposition proceedings, are also relevant for the present decision:

D3: EP 1 559 438
D5: US 6,045,570
D8: WO 02/087636

IV. In the opposition proceedings, the patent proprietor defended the patent in amended form. The opposition division came to the conclusion that the proprietor's main request did not meet the requirements of Article 54 EPC, and that auxiliary request 1 did not meet the requirements of Article 83 EPC. Auxiliary request 2 was found to meet the requirements of the EPC. In particular, the subject-matter claimed therein was found to be novel in view of the disclosure of document D3 (Article 54 EPC) and based on an inventive step (Article 56 EPC). Document D5 was considered the closest prior art for the composition according to product claim 1, and document D8 for the method according to claim 3. The opposition division also came

to the conclusion that the request met the requirements of Article 123(2) and (3), and of Article 83 EPC.

V. This decision was appealed by the opponent. According to the appellant (opponent), the opposition division erred in their decision when holding auxiliary request 2 to fulfill the requirements of Articles 123(2), 83, 54 and 56 EPC.

VI. In reply to the appellant's statement setting out the grounds of appeal, the respondent (patent proprietor) submitted arguments in support of the allowability of its main request (auxiliary request 2 of the contested decision). In addition, auxiliary requests 1 to 30 and arguments to support their allowability were filed.

VII. The appellant reacted to the respondent's submissions with further arguments concerning inventive step. It was also argued that the respondent's auxiliary requests should not be admitted into the proceedings.

VIII. In a communication under Article 15(1) RPBA the Board informed the parties of its preliminary opinion that the main request of the respondent met the requirements of Articles 123(2) and 83 EPC, and that the subject-matter claimed therein was novel in view of the disclosure of document D3 (Article 54 EPC). With respect to inventive step, the parties were informed about the factual issues to be discussed during the oral proceedings.

IX. In reply to the Board's communication, the respondent filed further arguments concerning inventive step of the main request.

X. Oral proceedings were held on 2 August 2022.

XI. The respondent's main request contains two independent claims, which read as follows:

"1. A sterile hemostatic composition, comprising:
a continuous, biocompatible liquid phase comprising sterile thrombin; and
a solid phase comprising particles of a biocompatible polymer suitable for use in hemostasis and which is substantially insoluble in said liquid phase,
said continuous liquid phase comprising said solid phase and said sterile thrombin substantially homogenously dispersed there through, wherein the weight ratio of solid particles to liquid is 1:1 and said sterile thrombin comprises enzymatic activity, and wherein the biocompatible polymer comprises gelatin and the liquid phase is aqueous."

"3. A method for making a sterile hemostatic composition, comprising:
providing a biocompatible liquid having thrombin dissolved therein,
combining said liquid comprising said thrombin with particles of a biocompatible polymer suitable for use in hemostasis and which is substantially insoluble in said liquid,
mixing said liquid comprising said thrombin and said particles under conditions effective to form a continuous liquid phase comprising said thrombin and said particles substantially homogenously dispersed there through, thereby forming a substantially homogeneous hemostatic composition; and
irradiating said substantially homogeneous hemostatic composition with an amount of ionizing radiation and for a time effective to provide a sterile,

substantially homogeneous hemostatic composition, wherein the weight ratio of solid particles to liquid is 1:1 and wherein said thrombin maintains at least a portion of its enzymatic activity and wherein said liquid phase is aqueous."

XII. The appellant's arguments can be summarised as follows:

Claims 1 and 3 of the main request have been amended and do not find a basis in the application documents as filed. Neither did dependent claims 5 to 7. The request did thus not meet the requirements of Article 123(2) EPC. Since the method according to claim 3 was inter alia defined by way of a technical effect to be achieved, and the skilled person did not find any guidance how to select biocompatible polymers in order to achieve this effect, the request did not meet the requirements of Article 83 EPC either. In addition, the claimed subject-matter was not novel in view of the disclosure of document D3, and not based on an inventive step in view of the technical teaching of documents D5 and D8. The request did thus also not meet the requirements of Articles 54 and 56 EPC.

XIII. The respondent's arguments can be summarised as follows:

Basis for amended claims 1 and 3 can be found in the description as originally filed, which referred to a specific value for the ratio of solid to liquid phase which leads to compositions comprising hemostatic properties. With respect to the appellant's argumentation concerning insufficient disclosure, the respondent argued that the appellant has not substantiated the objection, and that the skilled person was in a position to perform the claimed method,

in particular in view of the disclosure in the description of the contested patent. Novelty was given, since document D3 did not disclose the weight ratio as required by independent claims 1 and 3. Concerning inventive step, the respondent submitted that neither of documents D5 or D8 provided the skilled person with sufficient information in order to amend the teaching therein according to the claimed composition and method. The main request therefore met the requirements of Articles 123(2), 83, 54 and 56 EPC.

XIV. The appellant (opponent) requests that the decision under appeal be set aside and that the European patent No. 1 663 297 be revoked.

XV. The respondent (patent proprietor) requests that the appeal be dismissed or that the patent be maintained on the basis of any one of auxiliary requests 1 to 30.

Reasons for the Decision

Main request (Auxiliary request 2 of the contested decision)

1. *Amendments (Article 123(2) EPC)*

1.1 The appellant argued that the main request contravened Article 123(2) EPC, because claims 1 and 3 did not have a basis in the application as originally filed. The objection related to the deletion of the functional feature

"... wherein the ratio of said liquid phase and said solid phase is effective to provide said composition with hemostatic properties ..."

from original claim 1, the feature

"... wherein the ratio of said continuous liquid phase and said particles is effective to provide said composition with hemostatic properties ..."

from claim 8, and the addition of the feature

"... wherein the weight ratio of solid particles to liquids is 1:1 ..." into these claims.

According to the appellant, the application as filed did not disclose that hemostatic properties of the claimed composition could be achieved by the specific weight ratio of solid particles to liquids of 1:1. The appellant also argued that the value of 1:1 as such has been singled out from the original disclosure.

1.2 The appellant's argumentation is not convincing. The reasons are as follows:

1.3 The features deleted from original claims 1 and 8 defined a ratio of liquid phase and solid phase (claim 1) or of continuous liquid phase and particles (claim 8) by way of the effect to be achieved, i.e. providing the compositions with hemostatic properties.

This feature has been replaced by the ratio of solid particles to liquid (1:1), required to achieve the effect initially indicated in the claims.

1.4 The description as originally filed discloses on page 4, lines 12 to 16, that the *"... liquid phase and solid particulate phase are present in relative amounts effective to provide a composition (...) suitable for*

use in providing hemostasis ...". In the same context, the value of 1:1 is disclosed as a specific weight ratio for certain embodiments. The teaching of this part of the description as filed is that the specific weight ratio of 1:1 is an example for a composition for which the effect of providing hemostasis is achieved.

1.5 The amendments objected to by the appellant are thus based on claims 1 and 8, in combination with page 4, lines 12 to 16 of the description, as originally filed.

1.6 The appellant argued that the selection of the specific value 1:1 leads to new combinations of features of dependent claims. In particular, the appellant referred to dependent claims 5 to 7 and argued that, although the feature "*... wherein the weight ratio of solid particles to liquids is 1:1 ...*" as such was disclosed on page 4 of the description as filed, this part of the description did not mention the additional features of dependent claims 5 to 7.

1.7 This argument is not convincing.

The wording of dependent claims 5 to 7 of the main request is identical to that of claims 10 to 11 of the application as filed, apart from the number of the claim they depend on (claim number 10 appears twice in the application as filed). Claims 10 to 11 of the application as filed are dependent on method claim 8, which corresponds to amended claim 3 of the main request. The combination of features according to claims 5 to 7 (dependent on method claim 3) of the main request thus corresponds to the combination of features according to claims 10 to 11 (dependent on claim 8) of the application as filed, the only amendment being the replacement of the functional feature by the weight

ratio, which is allowable under Article 123(2) EPC (see point 1.4 of this decision). Thus, claims 5 to 7 of the main request are also based on the application as filed.

1.8 The main request therefore meets the requirements of Article 123(2) EPC.

2. *Sufficiency of disclosure (Article 83 EPC)*

2.1 The appellant argued that the contested patent did not disclose the method of claim 3 in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The appellant submitted that the claim contained the feature *"... wherein said thrombin maintains at least a portion of its enzymatic activity ..."*, which defined the claimed subject-matter in terms of a technical effect to be achieved. The skilled person therefore had to be provided with sufficient information how this particular technical effect could be achieved. According to the appellant, the large number of known biocompatible polymers made it impossible to select appropriate polymers which did indeed lead to the desired effect. Since the contested patent did not contain any working examples within the scope of the amended claims, no guidance on how to select those polymers was available.

2.2 The appellant's argumentation is not convincing.

2.2.1 Claim 3 of the main request relates to a method for making a sterile hemostatic composition. The method comprises providing a biocompatible liquid having thrombin dissolved therein, combining said liquid with particles of a biocompatible polymer - which is further defined as being suitable in hemostasis and being

substantially insoluble in the liquid - and mixing to form a continuous phase comprising thrombin and the particles substantially homogeneously dispersed therein, thereby forming a substantially homogenous hemostatic composition. The method further comprises irradiating the composition with ionizing radiation to provide a sterile, substantially hemostatic composition, wherein the weight ratio of solid particles to aqueous liquid is 1:1 and wherein said thrombin maintains at least a portion of its enzymatic activity.

2.2.2 The appellants argumentation only related to the feature that *"... said thrombin maintains at least a portion of its enzymatic activity ..."*.

2.2.3 The description of the patent as filed contains examples of methods for making compositions wherein thrombin maintains at least a portion of its enzymatic activity (see the examples 2 and 3, in particular Tables 2, 3). These examples are, as admitted by the respondent, not within the scope of the claims, since the weight ratio of solid particles to liquids therein is approximately 1:5, whereas claim 3 requires a ratio of 1:1. However, the appellant has not provided any arguments or verifiable facts why the skilled person was not in a position to modify the examples according to the ratio required by the claim, or why thrombin should not maintain at least a portion of its enzymatic activity when making sterile hemostatic compositions which have a 1:1 ratio of solid particles to liquid, rather than a ratio of 1:5 as in the examples. The description of the patent as filed also mentions further examples of polymers which can be selected for the intended purpose (page 3, line 26 to page 4, line 6). The Board considers neither the modification of the

weight ratio of solid particles to liquid, nor the selection of a different polymer to represent an undue burden for the skilled person who tries to put the claimed method into practice. The appellant has furthermore not shown by way of example, or even argued, which part of the claim cannot be put into practice.

Claim 3 of the main request, in combination with the description of the contested patent, therefore provides the skilled person with a clear guidance on how to perform the method as claimed, and how to obtain sterile hemostatic compositions wherein the thrombin maintains at least a portion of its enzymatic activity.

2.3 The main request thus meets the requirements of Article 83 EPC.

3. *Novelty (Article 54 EPC)*

3.1 The appellant argued that the opposition division's decision with respect to novelty was erroneous, because the feature *"... the weight ratio of solid particles to liquid is 1:1 ..."* of claims 1 and 3 was also disclosed in document D3 (paragraph [0008]), and its priority document D4 (page 3, lines 19 to 21). The composition according to claim 1, and the method according to claim 3 were thus not novel.

3.2 The Board does not follow the appellant's argumentation.

As has been pointed out by the respondent, paragraph [0008] of document D3 relates to a definition of the expression *"substantially homogenous"*. According to the cited paragraph, this expression denotes the physical

state of the compositions or pastes, which are disclosed in the document. Accordingly, a solid is uniformly dispersed throughout the liquid. The ratio of *"solid : liquid"* is therefore substantially the same throughout the compositions or pastes, irrespective of the weight ratio of these components. The passage referred to by the appellant does not relate to the weight ratio of solid particles to liquid in the compositions or pastes, but to the uniform distribution of solid particles and liquid therein.

3.3 The feature referred to by the appellant is thus not disclosed in document D3. The main request meets the requirements of Article 54 EPC.

4. *Inventive step (Article 56 EPC)*

4.1 The contested patent aims at providing sterilized hemostatic compositions containing sterile thrombin (paragraphs [0001] and [0005]). It addresses the problem of compromised sterility of gelatin-based hemostats when handling them at the site of use due to exposure to the environment (paragraph [0002]), and the problem of thrombin being denatured by exposure to sterilizing conditions, which leads to a loss of its enzymatic activities (paragraph [0003]).

The claims of the contested patent are directed to a sterile hemostatic composition comprising sterile thrombin (independent claim 1), and to a method for making a sterile hemostatic composition (independent claim 3), wherein thrombin comprises enzymatic activity, or maintains at least a portion of it.

4.2 In its decision, the opposition division acknowledged the presence of an inventive step considering the

disclosure of documents D5 (for product claim 1) and D8 (for method claim 3) as closest prior art. The parties agreed on that choice of closest prior art. The Board concurs with that conclusion.

Claim 1

4.3 Claim 1 relates to a sterile hemostatic composition. The opposition division identified the features relating to the *"weight ratio of solid particles to liquid is 1:1"* and to a *"sterile"* composition as differing features. In its decision, the division argued that the combination of both technical features allowed the storage of the composition prior to its administration, and that the objective technical problem could be formulated as the provision of a composition which can be prepared a long time before use, without compromising the enzymatic activity of thrombin. The solution provided was considered to involve an inventive step because there was no motivation in document D5 to provide sterile thrombin dispersed in a sterile aqueous composition, and because document D9 discouraged the skilled person from carrying out a sterilization process in the presence of water.

4.4 The appellant argued that document D5 already disclosed the feature *"sterile hemostatic composition"*. Since the only differing feature - according to the appellant the *"weight ratio of solid particles to liquid is 1:1"* - did not lead to a particular technical effect, the problem which had effectively been solved could only be seen in the provision of an alternative sterile hemostatic composition. The provision of the claimed solution was obvious, since the skilled person would change the ratio of compounds within a known

composition as a matter of routine, for example in order to change its viscosity.

4.5 The respondent submitted that the key features of the invention were that sterile thrombin surprisingly had enzymatic activity, and that sterile thrombin could thus be used in the preparation of a sterile hemostatic composition. According to the respondent, document D5 did not directly and unambiguously disclose the use of sterile thrombin for preparing a hemostatic composition. Neither did the document disclose a hemostatic composition which was inevitably sterile. As a result, the composition according to claim 1 of the main request differed from the compositions according to document D5 in that the composition was sterile, thus comprised sterile thrombin, and in that the weight ratio of solid particles to liquid was 1:1. The respondent agreed with the opposition division's definition of the technical problem, and with the reasoning for non-obviousness of the solution provided. The respondent furthermore argued that the technical teaching of document D9 did not render the claimed composition obvious, in particular because the teachings of documents D5 and D9 were incompatible.

4.6 The Board comes to the following conclusions:

Differing features

4.7 Document D5 discloses mixtures which assist hemostasis comprising a gelatin slurry and preferably thrombin powder (column 7, lines 21 to 25). The Board concurs with both parties, that document D5 does not disclose a weight ratio of solid particles to liquid of 1:1 (see columns 7 and 8 as referred to by the parties).

The feature *"... wherein the weight ratio of solid particles to liquid is 1:1 ..."* thus represents a first differing feature.

4.8 The parties disagreed whether document D5 discloses a *"... sterile hemostatic composition ..."* comprising *"... sterile thrombin ..."*.

For the following reasons the Board follows the argumentation of the respondent:

4.8.1 Document D5 discloses in column 7, starting from line 21, the preparation of a mixture which assists hemostasis and comprises a gelatin slurry. The slurry is made preferably under sterile conditions, by mixing gelatin powder, saline or water, and preferably adding thrombin powder and calcium ions (lines 22 to 25). According to lines 33 to 37, the gelatin is heat-sterilized. The document further discloses that the ingredients for the gelatin slurry can be provided in a sterilely pre-packaged system or kit (lines 50 to 51), and that a sterile vial is provided with the kit (line 58). This system is then opened under sterile conditions immediately before use, and mixing of the individual components under sterile conditions leads to a hemostatic composition (column 7, line 61 to column 8, line 8).

Document D5 thus explicitly discloses that the gelatin used for the composition is sterilized, that handling during preparation and use of the composition is done under sterile conditions, that the system or kit is pre-packaged in a sterile way and that the vial provided as part of the kit is also sterile.

The document does, however, not disclose that thrombin

as used for preparing the composition is sterile (see lines 25, 40, 55 and 66 in column 7). It does also not disclose that the final hemostatic composition is sterilised after its preparation. The feature *"... sterile hemostatic composition ..."* according to claim 1 of the main request is thus not disclosed in document D5. Neither is a composition disclosed, which comprises a liquid phase comprising *"... sterile thrombin ..."*.

4.8.2 The appellant argued that since all of the steps for the preparation of the slurry were performed under sterile conditions, all of the components used in the preparation process, including thrombin, implicitly had to be sterile. The alternative would not make sense. The appellant further submitted that this conclusion also followed from the disclosure of paragraph [0003] of the contested patent. Accordingly, it was known in the art to use aseptically prepared thrombin in order to reduce the risk of compromising the sterility of the mixtures.

This argument is not convincing. Although document D5 discloses that the slurry and the final mixture are prepared under sterile conditions, the only starting material which is said to be sterile is gelatin powder (column 7, lines 33 to 37). The Board also follows the respondent's argument that the use of aseptically prepared thrombin and the preparation of hemostatic mixtures under sterile conditions does not necessarily mean that all of the components used for that purpose were initially sterile, even if the compounds were handled under sterile conditions. Paragraph [0003] of the contested patent refers to the risk of compromising the sterility of previously sterilized materials even if aseptically prepared thrombin was used. The use of non-sterilized thrombin was therefore known in the art.

Handling of a material under aseptic/sterile conditions does not render it sterile, but only reduces the risk of (further) contamination, irrespective whether it has previously been sterilized or not.

4.8.3 The appellant also argued that the use of sterile thrombin was state of the art at the filing date of document D5 and that it was imposed by regulations in this field to only use sterile compositions if they were intended for injection into the human body. Sterilization of thrombin was thus a matter of routine for the skilled person.

The Board does not follow this argumentation. The appellant has not provided any evidence to support this allegation. The Board also concurs with the respondent's argument that the skilled person would use non-sterilized, but aseptically prepared, thrombin, since sterilization of thrombin was known to lead to a loss in enzymatic activity (see paragraph [0003] of the contested patent).

4.8.4 The appellant further argued that claim 1 was a product claim, pertaining to a sterile composition. The question whether the thrombin used for the preparation of the slurry according to document D5 was sterile, or not, was not pertinent for the question whether the resulting slurry was sterile.

The Board does not find it pertinent whether the thrombin is already sterile at the time the hemostatic composition is prepared, or whether the final composition is sterilised after having been prepared from sterile or non-sterile components. Sterilization of the thrombin containing final composition leads to sterilization all of its components. This conclusion

was not disputed by the appellant.

4.8.5 The appellant finally argued that the term "sterile" as used in the claim had to be interpreted in the light of the description (paragraph [0011]). It was therefore sufficient that the composition was substantially free of living germs and/or microorganisms. This, however, was to be expected from a composition intended for injection into the human body, and thus also for the composition as disclosed in document D5.

This argument is not convincing. In the skilled person's understanding, the term "sterile" implies that a substance was exposed to a sterilization treatment (see paragraphs [0014] and [0022] of the contested patent). Such a sterilization treatment is, however, not disclosed in document D5 for either thrombin or the final mixture, sterility of the composition can thus not be assumed.

4.8.6 As a result, the appellant's argumentation does not rebut the conclusion drawn under point 4.8.1 of this decision. The composition according to claim 1 of the main request therefore also differs from the disclosure of document D5 in that the composition is sterile and thus comprises sterile thrombin.

Technical effect and objective technical problem

4.9 The parties agreed that the specific weight ratio of solid particles to liquid being 1:1 does not lead to a particular technical effect. The Board concurs.

4.10 The provision of sterile compositions, which can be prepared well before their use, reduces the risk of contamination by exposure to the environment at the

site of their use, for example while handling their components during mixing in an operating theatre.

4.11 The objective technical problem can thus be seen as to provide a sterile hemostatic composition comprising active thrombin, which is stable and can thus be prepared in advance of its use.

Solution provided

4.12 The solution to the objective technical problem is the sterile hemostatic composition according to claim 1, which comprises sterile thrombin comprising enzymatic activity.

4.13 This solution solves the objective technical problem.

Sterile compositions can be stored and can thus be prepared before they are used. The data provided in Table 2 of the contested patent show that loss of enzymatic activity of thrombin can be reduced if the thrombin containing composition has been stabilized with the biocompatible polymer gelatin before sterilization (examples 1e and 1g). These sterile compositions comprise sterilized thrombin, but still show remaining enzymatic activity (72.6 and 79.2 % loss in thrombin activity on day 6; thus remaining activity of 27.4 and 20.8 %, respectively). Although the examples are not within the scope of the claim, because the weight ratio of solid particles to liquid is not 1:1 as required by claim 1, the Board does not see any reason why the different weight ratio should lead to a different conclusion.

Inventiveness of the claimed solution

4.14 The appellant did not refer to any other document than D5. This document, however, does not suggest to sterilize thrombin before using it in the preparation of the hemostatic compositions, or to sterilize the thrombin containing composition before its use (see columns 7 and 8 of the document). The skilled person can therefore not find any teaching towards the solution according to claim 1 of the main request.

4.15 According to the contested patent, the skilled person would also not be inclined to sterilize thrombin or thrombin-containing compositions due to its known denaturation and loss of enzymatic activity during a sterilization process (paragraph [0003], lines 25 to 27). Although this conclusion was challenged by the appellant, no evidence was provided to support the appellant's position.

4.16 The provision of a sterile hemostatic composition according to claim 1 of the main request is therefore based on an inventive step (Article 56 EPC).

Claim 3

4.17 Claim 3 relates to a method for making a sterile hemostatic composition. The opposition division based their assessment of inventive step on the disclosure of document D8 as closest prior art. The technical problem was seen in the provision of an alternative method, and the claimed method was considered to be an inventive solution.

4.18 The appellant argued that the claimed method only differed from the disclosure of document D8 in that the weight ratio of solid particles to liquid is 1:1. Since this feature did not lead to any particular technical

effect, the problem to be solved could only be seen in the provision of an alternative, and the proposed solution was considered to be obvious in view of the common general knowledge, because the skilled person would modify the ratio in order to e.g. adjust the viscosity of the composition according to the intended use. The appellant further argued that the hydrated gelatin pledget of document D8 fell within the wording of claim 3, since microscopically it consisted of a plurality of particles homogeneously dispersed in solution. The feature relating to the biocompatible polymer being in the form of a plurality of particles homogeneously dispersed through the liquid phase could therefore not be seen as an additional distinguishing feature. But even if this were the case, different physical forms were already contemplated according to the teaching of document D8, and the main teaching of document D8 was to prepare a mixture of gelatin with e.g. before sterilization by irradiation treatment. The provision of an composition comprising a biocompatible polymer in a different physical form was thus still obvious.

4.19 The respondent considered the claimed method to differ from the method disclosed in document D8 in that the weight ratio of solid particles to liquid in the irradiated substantially homogeneous hemostatic composition is 1:1, and in that the composition was in the form of a continuous liquid phase comprising thrombin and particles of a biocompatible polymer substantially homogeneously dispersed therein. The respondent argued inventive step based on the latter feature. According to the respondent, it was essential for the invention that the composition is in a liquid form and comprises thrombin particles when being irradiated, rather than in the form of a slurry or a

paste.

4.20 The Board comes to the following conclusions:

Differing features

4.21 Document D8 discloses in paragraph [0019] a method for making a sterile hemostatic composition. The method comprises exposing to E-beam radiation (step f) a composition comprising a cross-linked gelatin in the form of a pledget (step b) and hydrated by sterile saline (step c). According to paragraph [0034], the composition to be sterilized comprises a medicament, such as thrombus enhancing agents, which, according to paragraph [0027] include thrombin. Document D8 does not disclose any information concerning the enzymatic activity of a hemostatic composition comprising thrombin, in particular not after having been sterilized by irradiation treatment.

The parties agreed that document D8 did not disclose a weight ratio of solid particles to liquid of 1:1. The feature *"... wherein the weight ratio of solid particles to liquid is 1:1 ..."* thus represents a first differing feature.

4.22 Disagreement between the parties existed whether document D8 disclosed compositions in the form of a continuous liquid phase comprising thrombin and particles of a biocompatible polymer substantially homogeneously dispersed there through.

4.23 The Board follows the argumentation of the respondent. Document D8 discloses the preparation of cross-linked gelatin (see the example) and cross-linked gelatin in the form of a pledget (see paragraph [00019], step b).

According to paragraphs [0007] and [0008], the structural integrity of the pledget is essential for the intended use, i.e. the hemostatic composition being injected via a syringe. The composition as disclosed in document D8, comprising a pledget in hydrated form (see paragraph [00019], step c), which is then transferred into a cannula (see paragraph [00019], step d) cannot be interpreted as a continuous liquid phase comprising particles of cross-linked gelatin substantially homogeneously dispersed there through.

4.24 Although the parties argued the nature of a pledget with reference to further documents during the written procedure, they refrained from any such reference during the oral proceedings. The Board also does not consider it necessary to refer to any additional documents for the understanding of the term pledget.

4.25 With reference to paragraphs [0006], [0011], [0018] and [0027] and the claims, the appellant argued that although document D8 specifically disclosed an embodiment comprising a pledget, the general disclosure of the document was not limited to that specific embodiment, but rather contemplated all other forms of cross-linked gelatin.

The Board does not follow this line of argumentation. It is correct that the use of cross-linked gelatin in other forms than a pledget is not explicitly excluded from the disclosure of document D8. There is, however, no disclosure of any other specific form, in particular not of particles dispersed in a continuous liquid phase.

4.26 Therefore, the method according to claim 3 of the main request also differs from the disclosure of document D8

in that the liquid comprising thrombin and particles of the polymer is mixed *"... to form of a continuous liquid phase comprising said thrombin and said particles substantially homogenously dispersed there through, thereby forming a substantially homogeneous hemostatic composition ..."*, before irradiating the composition.

Technical effect and objective technical problem

4.27 As for the composition according to claim 1 of the main request, the parties agreed that the weight ratio of solid particles to liquid of 1:1 does not lead to a particular technical effect. The Board concurs.

4.28 Concerning the feature relating to the physical state of the composition to be irradiated, no particular technical effect has been shown in comparison to the method disclosed in document D8.

4.29 The objective technical problem can thus be defined as to provide a method for making an alternative sterile, active thrombin containing hemostatic composition.

Solution provided

4.30 The solution provided for the objective technical problem is the method according to claim 3, in which the composition to be irradiated to form the sterile composition is in the form of a continuous liquid phase comprising thrombin and particles of a biocompatible polymer substantially dispersed there through.

4.31 For the same reasons as given in point 4.13 of this decision, the Board considers the problem as defined in point 4.29 to be solved.

Inventiveness of the claimed solution

4.32 The solution according to claim 3 is not obvious for the person skilled in the art. Document D8 emphasizes on the structural integrity of the hydrated, cross-linked gelatin (see paragraphs [0007] and [0008]). When looking for an alternative physical form of the hemostatic composition, the skilled person would thus not consider deviating from that general teaching and replace the hydrated pledget as disclosed in D8 with a composition comprising thrombin and polymer particles homogeneously dispersed in a continuous liquid phase. Such a modification is also not considered obvious because document D8 does not disclose any information about the enzymatic activity of thrombin-containing sterile compositions after being sterilized via irradiation.

5. The main request therefore meets the requirements of Article 56 EPC.

Further requests

6. Since the Board decides to allow the main request of the respondent there is no need for a decision on any of the auxiliary requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated