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Datasheet for the decision of 13 June 2023

Case Number: T 1114/20 - 3.3.07

Application Number: 11724602.5

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Language of the proceedings: EN

Title of invention:
PROCESS FOR MAKING DRY AND STABLE HEMOSTATIC COMPOSITIONS

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

Opponents:
Ethicon Inc.
Ferrosan Medical Devices A/S

Headword:
Process for hemostatic compositions / BAXTER

Relevant legal provisions:
RPBA 2020 Art. 12(4), 12(6), 13(1), 13(2)
EPC Art. 100(a), 54, 56, 84
EPC R. 80

Keyword:

Argument and item of evidence filed during appeal proceedings - admittance (yes)
Admittance of (late-filed) requests - auxiliary requests 18, 19, 22, 23 (yes)
Admittance of (late-filed) requests - auxiliary requests 9 (15:10), 10 (18:00), 14 to 17, 21, 24 to 26 (no)
Novelty - main request and auxiliary requests 1 to 4, 11 to 13, 18, 19 (no)
Inventive step - auxiliary request 5 (11:00), 9 (16:10), 20, 22, 23 (no)
Claims - clarity - auxiliary requests 6 to 8 (no)
Amendment occasioned by ground for opposition - auxiliary request 10 (no)

Decisions cited:

T 1480/16, T 1151/18, T 0995/18, T 0424/21, T 2920/18, T 0535/20, T 0494/18, T 2091/18, T 1569/17, T 0355/19, T 1819/07

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Case Number: T 1114/20 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 13 June 2023

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)
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Respondent: (Opponent 2)	Ferrosan Medical Devices A/S Sydmarken 5 2860 Søborg (DK)
Representative:	Høiberg P/S Adelgade 12 1304 Copenhagen K (DK)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 2 March 2020 revoking European patent No. 2575775 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Lécaillon
	L. Bühler

Summary of Facts and Submissions

I. European patent 2 575 775 (hereinafter "the patent") was granted on the basis of 11 claims. Independent claim 1 of the patent as granted read as follows:

"1. A process for making a dry and stable hemostatic composition, said process comprising

a) providing a first component comprising a dry thrombin preparation,
b) providing a second component comprising a dry preparation of a crosslinked gelatin,
c) providing said first component and said second component in a combined form in a final container by filling said first component and said second component into said final container so as to obtain a dry mixture in said final container,
d) finishing the final container to a storable pharmaceutical device containing said first component and said second component in a combined form as a dry and stable hemostatic composition."

II. Two oppositions were filed against the patent on the grounds that its subject-matter lacked novelty and inventive step and it extended beyond the content of the application as originally filed.

III. The opposition division took the decision to revoke the patent. The decision was based on the patent as granted as the main request, and on 14 auxiliary requests numbered auxiliary requests 1 to 4, 5 (11:00), 6 to 8, 9 (15:10), 9 (16:10), 10, 10 (18:00) and 11 to 12.

IV. The decision of the opposition division, posted on 2 March 2020, cited *inter alia* the following documents:

D1: US 2005/0284809 A1
D9: WO 97/44015 A1
D17: US 7 320 962 B2
D20: Wikipedia entry for the term "mixture", "last edited" on 23 April 2019

V. The opposition division decided *inter alia* as follows:

(a) The subject-matter of the main request and auxiliary requests 1 to 4 and 11 to 12 was not novel over D1.
(b) Auxiliary request 5 (11:00) and auxiliary request 9 (16:10) did not meet the requirements of Article 56 EPC.
(c) Auxiliary requests 6 to 8 did not meet the requirements of Article 84 EPC.
(d) The late-filed auxiliary requests 9 (15:10) and 10 (18:00) were not admitted into the opposition proceedings.
(e) Auxiliary request 10 did not fulfill the requirements of Rule 80 EPC.

VI. The patent proprietors (appellants) lodged an appeal against the above decision of the opposition division.

VII. With their statement setting out the grounds of appeal the appellants defended their case on the basis of the patent as granted as the main request, and on the basis of auxiliary requests 1 to 4, 5 (11:00), 6 to 8, 9 (15:10), 9 (16:10), 10 (18:00) and 10 to 24 filed therewith. Auxiliary requests 1 to 4, 5 (11:00), 6 to 8, 9 (15:10), 9 (16:10), 10 (18:00) and 10 to 12

corresponded to those underlying the contested decision.

With letter dated 12 May 2023, the appellants further filed an auxiliary request 25.

During the oral proceedings, the appellants withdrew their former auxiliary request 20. They replaced it with a new request (hereinafter: auxiliary request 20) and filed an additional request, numbered auxiliary request 26.

VIII. The content of the claims upon which the present decision is based can be illustrated as follows:

Claim 1 of the main request was already reproduced above (see point I.).

Claim 1 of auxiliary request 1 corresponded to claim 1 of the main request wherein the following feature was added at the end of the claim:

> "wherein said first component is a dry thrombin preparation in particulate form, preferably in powder form, and/or wherein said dry preparation of a crosslinked gelatin is a particulate material, preferably a granular material."

Claim 1 of auxiliary request 2 corresponded to claim 1 of the main request wherein the following feature was introduced at the end of step c) before step d):

> "wherein said mixture is obtained by mixing the two components in the solid state before filling the final container or by adding the two components successively into the final container and mixing is achieved by agitation of the final container".

Claim 1 of auxiliary request 3 was based on claim 1 of the main request and incorporated both modifications of auxiliary requests 1 and 2.

Claim 1 of auxiliary request 4 was based on claim 1 of auxiliary request 1 wherein the following feature was added in the preamble part after "A process for making a dry and stable hemostatic composition":

> "comprising a first component comprising a dry thrombin preparation and a second component comprising a dry preparation of a crosslinked gelatin".

Claim 1 of auxiliary request 5 (11:00) corresponded to claim 1 of the main request wherein it was specified at the end of the claim "wherein step c is performed under aseptic conditions".

Claim 1 of auxiliary request 6 corresponded to claim 1 of the main request wherein:

- the following feature was added in the preamble part after "A process for making a dry and stable hemostatic composition":

> "comprising a first component comprising a dry thrombin preparation and a second component comprising a dry preparation of a crosslinked gelatin",

and

- the following feature was added at the end of the claim:

> "wherein the dry thrombin preparation in the hemostatic composition are thrombin particles having a mean particle diameter from 1 to 100 µm and/or wherein the dry preparation of crosslinked gelatin in the hemostatic composition are

crosslinked gelatin particles having a median particle size from 20 to 1000 µm" (emphasis added).

Claim 1 of auxiliary request 7 corresponded to claim 1 of the auxiliary request 6 wherein the last feature was limited to the combination of both options, *i.e.* "and/or" limited to "and" (emphasis added).

Claim 1 of auxiliary request 8 corresponded to claim 1 of auxiliary request 7 wherein the following feature was added at the end of the claim:

"wherein the dry compositions have an equilibrium swell in the range of 400% to 1000%".

Claim 1 of auxiliary request 9 (15:10) corresponded to claim 1 of the main request wherein:

- the following feature was added in the preamble part after "A process for making a dry and stable hemostatic composition":

"comprising a first component comprising a dry thrombin preparation and a second component comprising a dry preparation of a crosslinked gelatin",

and

- the following feature was added at the end of the claim:

"wherein the dry thrombin preparation in the hemostatic composition are thrombin particles having a mean particle diameter from 1 to 100 µm."

Claim 1 of auxiliary request 9 (16:10) corresponded to claim 1 of auxiliary request 9 (15:10) wherein the following feature was added at the end of the claim:

"wherein the mean particle diameter is the median size as measured by laser diffractometry."

Claim 1 of auxiliary request 10 (18:00) corresponded to claim 1 of the main request wherein:
- the following feature was added in the preamble part after "A process for making a dry and stable hemostatic composition":

> "comprising a first component comprising a dry thrombin preparation and a second component comprising a dry preparation of a crosslinked gelatin",

and,
- wherein the following feature was added at the end of the claim:

> "wherein the dry compositions have an equilibrium swell in the range of 400% to 1000%".

Claim 1 of auxiliary request 10 corresponded to claim 1 of the main request wherein:
- the feature "wherein step d) comprises an ethylene oxide sterilization step" was added at the end of the claim,
- dependent claim 3 was deleted, and
- dependent claim 4 was split into two separate dependent claims renumbered claims 3 and 4, as follows:

> "3. Process according to claim 1 or 2, wherein said first component is a dry thrombin preparation in particulate form.
>
> 4. Process according to claim 3, wherein said dry thrombin preparation in particulate form is a dry thrombin preparation in powder form."

Claim 1 of auxiliary request 11 corresponded to claim 1 of the main request wherein the following feature was added at the end of the claim:

> "wherein the dry and stable hemostatic composition is provided so as to be reconstituted to form a hydrogel."

Claim 1 of auxiliary request 12 was reworded to a use claim and read as follows:

"1. Use of a finished final container for reconstituting a dry and stable hemostatic composition to form a hydrogel;
wherein the finished final container is obtained by a process for making the dry and stable hemostatic composition, said process comprising
a) providing a first component comprising a dry thrombin preparation,
b) providing a second component comprising a dry preparation of a crosslinked gelatin,
c) providing said first component and said second component in a combined form in the final container by filling said first component and said second component into said final container so as to obtain a dry mixture in said final container,
d) finishing the final container to a storable pharmaceutical device containing said first component and said second component in a combined form as the dry and stable hemostatic composition."

Claim 1 of auxiliary request 13 corresponded to claim 1 of the main request wherein:

- the following feature was added in the preamble part after "A process for making a dry and stable hemostatic composition":

"comprising a first component comprising a dry thrombin preparation and a second component comprising a dry preparation of a crosslinked gelatin",

and

- wherein the following feature was added at the end of the claim:

"wherein said first component is a dry thrombin preparation in powder form and wherein said dry preparation of a crosslinked gelatin is a granular material."

Claim 1 of auxiliary request 14 corresponded to claim 1 of the main request wherein:
- the following feature was added in the preamble part after "A process for making a dry and stable hemostatic composition":

"comprising a first component comprising a dry thrombin preparation and a second component comprising a dry preparation of a crosslinked gelatin",

and
- wherein the following features were added at the end of the claim:

"wherein the dry compositions have an equilibrium swell in the range of 400% to 1000% and wherein the equilibrium swell is determined according to the method in the description".

Claim 1 of auxiliary request 15 was based on claim 1 of auxiliary request 14 wherein the last feature was modified to read as follows:

"wherein the equilibrium swell is determined by subtracting the dry weight of the gelatin preparation from its weight when fully hydrated and thus fully swelled, dividing the difference by the dry weight and multiplying the result by 100 to give the measure of swelling, wherein the dry weight is measured after exposure of the material to an elevated temperature for a time sufficient to remove substantially all residual moisture, e.g., two hours at 120°C, and wherein the full equilibrium hydration of the material is achieved

by immersing the dry material in a suitable diluent, such as aqueous saline, for a time period sufficient for the water content to become constant, typically for from 18 to 24 hours at room temperature."

Claim 1 of auxiliary request 16 corresponded to claim 1 of the main request wherein:
- the following feature was added in the preamble part after "A process for making a dry and stable hemostatic composition":
"comprising a first component comprising a dry thrombin preparation and a second component comprising a dry preparation of a crosslinked gelatin",
and
- wherein the following features were added at the end of the claim:
"wherein the dry compositions have an equilibrium swell in the range of 400% to 1000%"
"and wherein the dry preparation of a crosslinked gelatin is prepared as disclosed in WO 98/08550 A1."

Claim 1 of auxiliary request 17 corresponded to claim 1 of the main request wherein the feature "wherein step d) comprises an ethylene oxide sterilization step" was added at the end of the claim.

Claim 1 of auxiliary request 18 corresponded to claim 1 of the main request wherein the following feature was added at the end of the claim:
"wherein a dry preparation of a crosslinked gelatin and a dry thrombin preparation are mixed in powder form in step c), wherein the final container is a syringe."

Claim 1 of auxiliary request 19 corresponded to claim 1 of auxiliary request 18 wherein the following feature was added at the end of the claim:

"wherein the dry thrombin preparation is lyophilized or spray dried thrombin and wherein the dry preparation of a crosslinked gelatin are gelatin granules."

Claim 1 of auxiliary request 20 corresponded to claim 1 of auxiliary request 18 wherein the following feature was added at the end of the claim:

"wherein the dry thrombin preparation is an aseptically spray dried thrombin."

Claim 1 of auxiliary request 21 corresponded to claim 1 of auxiliary request 7 wherein the feature "wherein the mean particle diameter is the median size as measured by laser diffractometry" was added after defining the mean particle diameter of thrombin particles and after defining the median particle size of gelatin particles.

Claim 1 of auxiliary request 22 corresponded to claim 1 of the main request wherein it was specified at the end of the claim "wherein step c is performed under aseptic conditions, wherein the first and second component have been appropriately sterilized and wherein all further steps are performed aseptically".

Claim 1 of auxiliary request 23 corresponded to claim 1 of auxiliary request 22 wherein the term "appropriately" had been deleted.

Claim 1 of auxiliary request 24 was based on claim 1 of the main request wherein in the preamble the term

"comprising" was replaced by "consisting essentially of the steps".

Claim 1 of auxiliary request 25 corresponded to claim 1 of the main request wherein the feature "by filling said first component and said second component into said final container" in step c) was amended to "by dry powder filling said first component and said second component into said final container" (emphasis added).

Claim 1 of auxiliary request 26 corresponded to claim 1 of the main request wherein the following feature was added at the end of the claim:

> "wherein said final container further contains an amount of a stabilizer effective to inhibit modification of the polymer when exposed to the sterilizing radiation, preferably ascorbic acid, sodium ascorbate, other salts of ascorbic acid, or an antioxidant."

IX. Amongst the items of evidence filed by the parties during the appeal proceedings, the following documents filed by respondent 1 (opponent 1) with its reply to the statement setting out the grounds of appeal are relevant for the present decision:

D27: Wikipedia entry for the term "mixture", dated 16th October 2020, obtained from Wikipedia (https://en.Wikipedia.org/wiki/Mixture)
D28: US 4752466 B
D29: "Thrombin, Topical U.S.P. Thrombin-JMI®" package insert, Jones Pharma Incorporated, Manufactured by GenTrac Inc.
D30: Extract from ndrugs.com (site offering information regarding generic drugs approved by the FDA) regarding "Thrombogen-JMI®", accessed 23rd November 2020

X. Oral proceedings were held before the Board on 13 June 2023.

XI. The appellants requested that the decision under appeal be set aside and the patent be maintained as granted (main request), or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 1 to 4, 5 (11:00), 6 to 8, 9 (15:10), 9 (16:10), 10 (18:00) and 10 to 26, wherein:
- auxiliary requests 1 to 4, 5 (11:00), 6 to 8, 9 (15:10), 9 (16:10), 10 (18:00), 10 to 19 and 21 to 24 were filed with the statement setting out the grounds of appeal, or
- auxiliary request 25 was filed on 12 May 2023, and
- auxiliary requests 20 and 26 were filed during the oral proceedings on 13 June 2023.

XII. Respondents 1 and 2 requested that the appeal be dismissed, *i.e.* that the patent be revoked. They further requested that auxiliary requests 9 (15:10), 10 (18:00) and 13 to 24, 25 and 26 not be admitted into the appeal proceedings.

Respondent 1 further requested that:
(a) the case be remitted to the first instance in case auxiliary requests 9 (15:10), 10 (18:00) and 13 to 24 were admitted,
(b) the new arguments presented under items E.I of the appellants' statement of the grounds of appeal not be admitted, and
(c) D27 to D30 be admitted if this new argument and/or auxiliary request 19 was admitted.

Respondent 2 also requested that:

(d) Auxiliary request 9 (16:10) not be admitted into the appeal proceedings.

XIII. The arguments of the appellants, as far as relevant for the present decision, can be summarised as follows:

(a) The argument submitted under item E.I of the statement of the grounds of appeal should be admitted. No objection against the admittance of D27 was raised.

(b) The subject-matter of claim 1 of the main request was novel over example 5 of D1. In particular, upon a fair reading of claim 1 the skilled person would understand that the starting components remained in an unmodified state in the final dry mixture namely in the form of a loose powder. It followed that a composition in compressed form as in example 5 of D1 was not encompassed by the subject-matter of said claim 1.

(c) Auxiliary requests 9 (15:10), 10 (18:00), 14 to 19, 21 to 24, 25 and 26 should be admitted into the appeal proceedings mainly because:
- the decision of the opposition division not to admit auxiliary requests 9 (15:10) and 10 (18:00) was wrong because these requests did not lack clarity,
- auxiliary requests 14 to 19 and 21 to 24 were filed in direct reaction to the decision of the opposition division and could not have been filed earlier,
- auxiliary request 25 was filed in response to the preliminary opinion of the Board, which constituted exceptional circumstances justified by cogent reasons, and

- auxiliary request 26 represented a reversal to granted claim 9 which was allowable according to established case law and did not represent an amendment to the appellants case in the sense of Article 13 RPBA.

(d) Auxiliary requests 1 to 4, 11 to 13, and 18 to 19 further specified that the final composition of the claimed process did not encompass compacted particles as disclosed in example 5 of D1. These requests therefore fulfilled the requirements of Article 54 EPC.

(e) Auxiliary requests 5 (11:00), 22 and 23 met the requirements of Article 56 EPC. The closest prior art D1 would not provide any motivation to the skilled person to perform step c), let alone all the further process steps, under aseptic conditions. On the contrary, D1 taught away from cumbersome aseptic conditions by stating that the final sterilisation with gamma irradiation was not detrimental. The subject-matter of auxiliary request 20 did also involve an inventive step as neither D1 nor any further document suggested the non-trivial aseptic spray drying of thrombin.

(f) Auxiliary requests 6 to 8 fulfilled the requirements of Article 84 EPC. No method of measurement was required for an absolute value such as the median particle size. Moreover, the laser diffractometry disclosed in the description applied to both type of particles.

(g) The process of auxiliary request 9 (16:10) differed from the one of example 5 of D1 in that the final hemostatic composition was obtained in the form of

loose particles, *i.e.* not compressed, and the thrombin particles within said composition had a specific mean particle diameter. Contrary to the conclusion of the opposition division, the claimed final hemostatic composition did not show any gel-blocking phenomenon. Starting from D1 there was no reasonable expectation of success to arrive at an alternative hemostatic composition having good reconstitution properties without compressing the particles. As a result, auxiliary request 9 (16:10) met the requirements of Article 56 EPC.

(h) Claims 3 and 4 of auxiliary request 10 were modified to avoid a renumbering of the claims following the amendments made to claim 1 of this request. Hence, this modification was also occasioned by a ground of opposition and auxiliary request 10 fulfilled the requirements of Rule 80 EPC.

XIV. The arguments of the respondents, as far as relevant for the present decision, can be summarised as follows:

(a) The argument of the appellants submitted under item E.I of their statement of the grounds of appeal should not be admitted because it should have been filed earlier and it introduced complexity. D27, filed in direct response thereto, should be admitted into the appeal proceedings if this argument was.

(b) Example 5 of D1 anticipated the subject-matter of claim 1 of the main request. In particular this claim did not exclude a compression step nor did it restrict the final composition to any particular physical form.

(c) Auxiliary requests 9 (15:10), 10 (18:00), 14 to 19, 21 to 24, 25 and 26 should not be admitted into the appeal proceedings *inter alia* because:
- auxiliary requests 9 (15:10) and 10 (18:00) were *prima facie* not allowable,
- auxiliary requests 14 to 19 and 21 to 24 were late filed and should have been filed in the first instance proceedings and furthermore they did not overcome the raised issues and/or they introduced new ones,
- the preliminary opinion of the Board did not introduce any new issue, which would justify the submission of auxiliary request 25 at this late stage of the appeal proceedings, and furthermore this request did not overcome the raised issues and it introduced new ones, and
- the subject-matter of auxiliary request 26 had never been discussed before in the entire proceedings and constituted therefore a new case. The filing of auxiliary request 26 during the oral proceedings was consequently detrimental to procedural economy and not justified by any exceptional reasons.

(d) The features introduced in auxiliary requests 1 to 4, 11 to 13, 18 and 19 did not further limit the form of the final composition of the claimed process. These requests did therefore not fulfill the requirements of Article 54 EPC.

(e) The subject-matter of claims 1 of auxiliary requests 5 (11:00) as well as 22 and 23 differed from the closest prior art process of example 5 of D1 only in that step c) or all the further steps were performed under aseptic conditions. No effect

resulting from said distinguishing features had been substantiated. The objective technical problem resided in the provision of an alternative process. Using aseptic conditions for the preparation of compositions for use on the human body was a common sterilisation method as shown in D17. Auxiliary requests 5 (11:00), 22 and 23 did thus not meet the requirements of Article 56 EPC.

(f) Auxiliary requests 6 to 8 did not meet the requirements of Article 84 EPC, due to the lack of measurement method for the particle size parameters introduced therein.

(g) The process of auxiliary request 9 (16:10) differed from the one of example 5 of D1 merely in that the thrombin particles within the final hemostatic composition had a specific mean particle diameter. No effect resulting from said distinguishing features had been substantiated. The objective technical problem resided in the provision of an alternative process. The presently claimed particle range was arbitrarily selected and encompassed commercially available particles. As a result, auxiliary request 9 (16:10) did not meet the requirements of Article 56 EPC.

(h) Auxiliary request 10 infringed Rule 80 EPC because the modifications made to claims 3 and 4 were not occasioned by a ground of opposition.

Reasons for the Decision

Main request - Patent as granted

1. Novelty

1.1 Admittance of argument and item of evidence relevant to the issue of novelty of the main request

1.1.1 According to respondent 1, the argument developed under item E.I of the appellants' statement setting out the grounds of appeal should not be admitted into the appeal proceedings, because:

(a) it constituted a new argument regarding the interpretation of term "mixture" based on a new section of D20 (starting from "mixtures are unlike chemical compounds, because…"), which had not been discussed during the first instance proceedings and represented therefore an amendment in the sense of Article 12(4) RPBA 2020,

(b) the appellants waited until the appeal proceedings to rely on a more restrictive definition of the term "mixture" based on this new section of D20, despite having filed D20 on 24 May 2019, and

(c) this new argument introduced complexity, since it required to investigate whether the new section of D20 was reflective of the normal meaning of the term "mixture" or not.

1.1.2 The Board observes that, during the opposition proceedings, the appellants referred generally to D20 and more particularly to the first sentence thereof (see submission of 24 May 2019). The appellants did then indeed not refer to any other particular passage of D20. However, the interpretation of the term "dry

mixture" made by the appellants did not change. Merely further arguments in support thereof were provided in the statement of the grounds of appeal based on further passages of D20.

Furthermore, D20 is short (only 4 pages long) and not technically complicated (Wikipedia entry) and the respondents have had knowledge of its content since 24 May 2019.

Accordingly the Board admits this argument into the appeal proceedings, because it merely constitutes a further development of an already made interpretation of the term "dry mixture", it does not introduce any particular complexity and it is not against procedural economy (Article 12(4) RPBA 2020).

1.1.3 Concerning D27, the Board observes that it is a more recent Wikipedia entry for the term "mixture". Compared to D20 (a previous Wikipedia entry for this term), it contains after the item "there is little or no energy change when mixture forms" the reference "(see Enthalpy of mixing)". According to respondent 1, D27 makes clear that the absence of "energy change" refers to the enthalpy of mixing *i.e.* to ideal gases and ideal solutions. The extrapolation of the statement of D20 to any mixture as done by the appellants, would thus not be reasonable. Hence, D27 was submitted by respondent 1 in direct response to part of the appellants' new argument detailed under item E.I of their statement of the grounds of appeal and its submission is not against procedural economy. Furthermore, D27 has almost the same content as D20, so that it does not introduce any complexity.

Accordingly, the Board admits D27 into the appeal proceedings (Article 12(4) RPBA 2020).

1.2 Novelty over D1

1.2.1 According to the impugned decision, the subject-matter of granted claim 1 would not be novel over D1. The appellants contested that D1 disclosed a final dry mixture according to present claim 1.

1.2.2 D1 (see example 5) discloses a process for the preparation of a hemostatic composition comprising the following steps: (i) thoroughly mixing a crosslinked gelatin powder (*i.e.* a dry preparation of crosslinked gelatin) with a thrombin powder (*i.e.* a dry thrombin preparation), (ii) compacting the mixture to pellets which are then cut to squares and (iii) filling said squares into a syringe (*i.e.* a final container) and (iv) sterilizing the syringe (*i.e.* finishing the final container to a storable pharmaceutical device).

1.2.3 It was undisputed that this embodiment of D1 encompassed the steps a) and b) of the process of granted claim 1 as well as the steps of filling a final container with a mixture of both components (corresponding to step c) of the granted process) and a finishing step (step d) of the granted process). As mentioned above, the main point of dispute was the nature of the mixture of thrombin and crosslinked gelatin.

1.2.4 According to the appellants, the packed particles of D1 did not correspond to the final "dry mixture" and "dry hemostatic composition" of granted claim 1.

In particular, a skilled person would understand the "dry mixture" obtained in step c) of claim 1 as well as the "dry and stable hemostatic composition" of step d) of claim 1 as referring to mere mixtures of the components defined in steps a) and b) without any modification thereof, in particular without any compaction as in D1. This would be revealed *inter alia* by the reference in the final step d) of granted claim 1 to the "first" and "second" components *i.e.* as in steps a) and b). In case of doubt it would be confirmed by the description as a whole, which would make clear that the particulate form is retained throughout the process and in particular in the final composition.

It would follow that packed particles provided in the form of pellets as in example 5 of D1 would not be encompassed by present claim 1. Indeed upon compression the physical and chemical properties of the mixture of starting dry preparations would be modified (including the density, the formation of pores, the possibility of having a capillary flow). This would not be foreseen in granted claim 1.

1.2.5 This argumentation is not convincing.

1.2.6 Granted claim 1 is clear *per se* and defines the final composition solely as being a "dry mixture" (step c)) or a "dry and stable hemostatic composition" (step d)) without further specification as to the type of mixture. Furthermore, step c) of granted claim 1 does not impose any limitation on the type of mixture as it only defines the provision of both components "in combined form" and filling the two components to obtain the dry mixture. Also the reference in step d) to the "first" and "second" component further specifies "in combined form". The use of the terms "in combined form"

therefore clearly indicates that the starting components do not necessarily remain in their individual initial form. The Board therefore considers that granted claim 1 encompasses any type of dry mixture of the two components. In particular, contrary to what the appellants seem to imply, the claim is not limited to a dry powder mixture. Finally, since granted claim 1 is worded as "comprising" the claimed steps, a compaction/cutting step is not excluded. Hence, the claim is broad but remains clear *per se*.

1.2.7 There is consequently no need, to consult the description to clarify the subject-matter of granted claim 1. In this context, the Board notes that paragraph [0015] of the patent cited by the appellants does also not limit the dry mixture to any specific type of mixture, in particular not to an uncompacted dry mixture. This paragraph only explains that the mixing of the two components can be done either before filling in the final container or once in the final container. This does not preclude from any additional compaction/cutting step.

In this context, the argument of the appellants that the dry mixture of the invention must be understood as suitable to perform both embodiments for the mixing/ filling step described in paragraph [0015] is not convincing. These embodiments are clearly defined as alternatives and the "dry mixture of the invention" is the product resulting from these steps. The starting dry preparations must be suitable to perform both embodiments, not the final dry mixture, which may thus even have a different form in each case.

1.2.8 Moreover, as underlined by the respondents, paragraph [0056] of the granted patent describes as an example of

the invention the compaction under vacuum of thrombin particles and the compaction under vacuum of their mixture with gelatin particles. This confirms, if necessary, that the claims do not exclude a compaction step.

During the oral proceedings, the appellants argued that this compaction which may be encompassed in the claimed process would be understood by the skilled person as being different from the compaction performed in D1. The compaction step defined in paragraph [0056] would be a mild one and would not result in a modification of the properties of the mixture as in D1 (see point 1.2.4, 3rd paragraph).

This argument is not convincing, because there is no indication in the patent of a particular level of compaction that would be acceptable or not.

1.2.9 It remains to be determined whether the compositions of D1 constitute "dry mixtures" according to granted claim 1.

1.2.10 The appellants referred to D20 which *inter alia* specifies that (i) mixtures can be separated by physical methods, (ii) there is little or no energy change upon formation of a mixture and (iii) individual substances keep their properties in a mixture. According to the appellants, the packed particles of D1 would not fulfill these criteria because (i) once compacted to composites gelatin and thrombin cannot be separated anymore, (ii) there is significant energy input provided for compaction and (iii) the compression applied in D1 significantly changes the properties of the components.

1.2.11 The Board does not share this view.

As explained by respondent 1, no evidence has been provided in support of the allegation that the components of example 5 of D1 cannot be separated once they have been compacted (criteria (i)). The mere fact that the particles were compacted, *i.e.* that they are closer to each other, does not mean that they cannot be identified and sorted in the same manner as unpacked particles (*e.g.* under a microscope). Moreover the Board observes that D20 states earlier (see first page, lines 8-9) that "Some mixtures can be separated into their components by using physical (mechanical or thermal) means".

Furthermore, as confirmed by D27, the absence of energy change mentioned in D20 appears to refer to the enthalpy of mixing, which tends to zero for ideal gases and ideal solutions but cannot be extrapolated to any mixtures, including those of the patent and of D1. Moreover some energy input is always required when performing a mixing step. It cannot therefore be considered that the criteria (ii) would distinguish the claimed mixture from those of D1.

Finally, no evidence has been provided in support of the allegation that the compression applied in D1 significantly changes the properties of the components (criteria (ii)). The paragraphs of D1 cited by the appellants relate to the improved wettability and/or water-swellability of the mixture obtained due to the increased density following compaction. There is no indication in these paragraphs that the properties of the individual components are modified.

1.2.12 With respect to D1, the appellants also argue that D1 itself makes a distinction between compacted particles and loose ones. It would be clear that the loose ones correspond to the present ones, not the packed ones.

This argument is not convincing. Any distinction made in D1 between packed and loose particles has no influence on the interpretation of the granted claims.

1.2.13 Accordingly, the Board considers that the packed particles of example 5 of D1 constitute a "dry mixture" according to granted claim 1.

1.2.14 Hence, the process of example 5 of D1 anticipates the subject-matter of granted claim 1 (Article 100(a) EPC in combination with Article 54 EPC).

Auxiliary requests

2. Admittance

2.1 Auxiliary requests 1 to 8 and 10 to 12

The admittance of these auxiliary requests, which formed part of the first instance proceedings, was undisputed.

2.2 Auxiliary requests 9 (15:10) and 10 (18:00)

Auxiliary request 9 (15:10) and auxiliary request 10 (18:00) were filed during the oral proceedings in opposition and were not admitted into the opposition proceedings. The appellants considered that auxiliary requests 9 (15:10) and 10 (18:00) did not lack clarity, so that the decision of the opposition division not to admit them was wrong.

The Board notes that the opposition division considered that these late filed requests were *prima facie* not allowable under Article 84 EPC due to the lack of measurement method in the claim for the introduced parameters. The opposition division exercised its discretion under Article 114(2) EPC by applying the correct criteria and there is no indication that this has been done in an unreasonable way (see finding of lack of clarity due to a missing measurement method in point 6. below).

Hence, the Board sees no reason to overrule the decision not to admit auxiliary requests 9 (15:10) and 10 (18:00) into the proceedings (Article 12(6) RPBA 2020).

2.3 Auxiliary requests 14 to 24

Auxiliary requests 14 to 24 were newly filed with the statement setting out the grounds of appeal. Their admittance is to be decided according to Article 12(4) and 12(6) RPBA 2020.

2.3.1 Auxiliary requests 14 and 15

In these requests, a method of measurement of the equilibrium swell was specified. According to the appellants, the filing of these requests constituted a direct response to the decision of the opposition division regarding auxiliary request 8. In particular it would not have been possible to file them at an earlier stage, since the reasoning regarding the equilibrium swell was not known before the issuance of the decision of the opposition division.

The Board disagrees.

As argued by the respondents, the absence of earlier reasoning of the opposition division regarding the method of measurement of the equilibrium swell was triggered by the appellants themselves, since they filed auxiliary requests 8 and 10 (18:00) containing the feature of equilibrium swell within the time limit prescribed by Rule 116 EPC (auxiliary request 8) and during the oral proceedings in opposition (auxiliary request 10 (18:00)), *i.e.* only after the opposition division provided its preliminary opinion. Moreover the reasoning of the opposition division regarding the lack of measurement method for the parameter of equilibrium swell was in line with well-established practice at the EPO and was thus not surprising. The Board considers therefore that these requests should have been filed already in first instance.

Finally the amendments introduce additional complexity since they appear to *prima facie* introduce new issues linked to the definition of the measurement method for the equilibrium swell (see *e.g.* lack of compliance with the requirements of Article 84 and Rule 43(6) and Article 123(2) EPC raised by the respondents in their reply to the statement of the grounds of appeal).

As a result, auxiliary requests 14 and 15 are not admitted into the appeal proceedings (Articles 12(4) and 12(6) RPBA 2020).

2.3.2 Auxiliary request 16

According to the appellants, the filing of this request constituted a direct response to the decision of the opposition division.

One of the modifications performed in auxiliary request 16 was the introduction of a specific equilibrium swell without any measurement method therefor. The Board observes that this feature was already present in auxiliary request 8 and auxiliary request 10 (18:00) filed during the first instance proceedings. The clarity issue due to the lack of measurement methods for parameters had already been raised in the impugned decision for auxiliary request 8, albeit in relation to the particle size, and as a *prima facie* lack of clarity for auxiliary request 10 (18:00). The Board is therefore of the opinion that auxiliary request 16 does not suitably address the issues raised in the impugned decision (Article 12(4) RPBA 2020).

As a result, auxiliary request 16 is not admitted into the appeal proceedings (Article 12(4) RPBA 2020).

2.3.3 Auxiliary request 17

As argued by the appellants, the filing of a request corresponding to auxiliary request 17 was requested during the oral proceedings in opposition (see Minutes, point 41). This was not admitted by the opposition division considering that this auxiliary request should have been filed earlier. The appellants argued that auxiliary request 17 was thus filed in direct response to the decision of the opposition division, since the reasons for the decision were not available before the oral proceedings before the opposition division. There was therefore no possibility to file auxiliary request 17 earlier.

The opposition division explained that the objection under Rule 80 EPC addressed by auxiliary request 17 had

been raised in writing during the first instance proceedings on 20 January 2020. According to the opposition division, even if there was no preliminary opinion of the opposition division on this specific point, filing this request at a late stage of the proceedings (19:05) was not considered appropriate.

The Board observes that the opposition division exercised its discretion under Article 114(2) EPC by applying the correct criteria and there is no indication that this has been done in an unreasonable way.

Hence, the Board sees no reason to overrule the decision not to admit the request corresponding to auxiliary request 17 into the proceedings. Auxiliary request 17 is not admitted into the appeal proceedings (Article 12(6) RPBA 2020).

2.3.4 Auxiliary request 21

Auxiliary request 21 has been amended by specifying that the particle size of the thrombin and gelatin particles was measured by laser diffractometry. The appellants argued that this modification had been made to overcome the lack of clarity objection raised for auxiliary requests 6 to 8 in the decision of the opposition division.

The Board however observes that the impugned decision (see point 8.3, page 22, 2nd paragraph) already stated that no method of measurement of particle size of gelatin was disclosed in the patent / original application, thus also not laser diffractometry, which is disclosed in page 4 of the original application only in relation to the thrombin particles. The Board

therefore considers that this auxiliary request, which includes exactly this feature, does not suitably address the issues raised in the impugned decision (Article 12(4) RPBA 2020).

As a result, auxiliary request 21 is not admitted into the appeal proceedings (Article 12(4) RPBA 2020).

2.3.5 Auxiliary request 24

According to the appellant this auxiliary request was filed in direct response to the impugned decision to address the novelty objection raised for the main request.

However the Board observes that the replacement of "comprising" with "consisting essentially of the steps" *prima facie* lacks any explicit basis in the original application and consequently introduces complexity to the case.

Hence, auxiliary request 24 is not admitted into the appeal proceedings (Article 12(4) RPBA 2020).

2.3.6 Auxiliary requests 18, 19, 22 and 23

The respondents argued that auxiliary requests 18, 19, 22 and 23 should not be admitted into the appeal proceedings because they should have been filed earlier as they addressed objections already raised in the notices of opposition and the preliminary opinion of the opposition division.

The Board observes that present auxiliary requests address issues raised in the impugned decision (novelty issue addressed in auxiliary requests 18-19; inventive

step issue raised for auxiliary request 5 addressed in auxiliary requests 22-23). The amendments are not complex. Furthermore, some kind of structure can be recognised amongst these auxiliary requests despite not being strictly convergent. Finally, the Board is of the view that, in case of numerous different objections raised in the notice(s) of opposition, it would be inequitable to always expect the patent proprietor to address the objections raised by filing requests covering all the conceivable permutations of amendments relating to the disputed features under all grounds of opposition. The filing of the present request with the statement setting out the grounds of appeal still constitutes a fair attempt to react to the impugned decision.

Accordingly, the Board admits auxiliary requests 18, 19, 22 and 23 into the appeal proceedings.

2.4 Auxiliary requests 25 and 26

Auxiliary requests 25 and 26 were filed after notification of the summons to oral proceedings, namely with the letter dated 12 May 2023 and during the oral proceedings on 13 June 2023 respectively. Their admittance is to be decided according to Articles 13(1) and 13(2) RPBA 2020.

2.4.1 Auxiliary request 25

According to the appellants, auxiliary request 25 was filed in response to the preliminary opinion of the Board dated 8 February 2023. Auxiliary request 25 would address the objections the Board had with regard to the main request and the already submitted auxiliary requests, since the Board did not accept the

interpretation that the hemostatic compositions were provided as dry mixtures with no compression step (*i.e.* that packed particles were not encompassed by the claimed subject-matter) in the main request and auxiliary requests 1 to 4, 11, 12, 13, 18 and 19. The appellants therefore considered that this constituted exceptional circumstances and that it was justified and appropriated to file a single further auxiliary request wherein this “dry powder mix” nature was characterized in an even more pronounced manner.

Moreover the appellants considered that there were several cogent reasons why auxiliary request 25 had not been filed before including the technically not meaningful interpretation of D1 in the decision of the opposition division, the shifting of the burden of proof for novelty from the opponents to the patent proprietors and the interpretation that filling powdered material into a final container did not exclude "compression steps" in the Board's preliminary opinion. Auxiliary request 25 was in particular filed as a last possibility to safeguard patentability for the appellants to overcome the reasons provided in the preliminary opinion of the Board with regard to the lack of novelty of auxiliary requests 13, 18 and 19.

Furthermore, in the appellant's view, the introduction of merely two words did not introduce any complexity, the modification immediately overcame the objection lack of novelty raised in the preliminary opinion and the limitation to one single claim significantly improved procedural economy.

These arguments are not convincing.

The Board observes that the issue of interpretation of the claims and D1, in particular the question of whether packed particles would be encompassed by the claimed final hemostatic composition had been the key issue in the present case since the notices of opposition. The fact that the Board, in line with the reasoning followed in the impugned decision and by the respondents, may not follow the interpretation made by the appellants of further auxiliary requests filed with the statement of the grounds (*i.e.* auxiliary requests 13, 18 and 19) cannot *per se* constitute exceptional circumstances which would justify the filing of a new auxiliary request addressing this exact same key issue. Furthermore, contrary to the opinion of the appellants, the preliminary opinion of the Board did not introduce any new aspect and did not represent any new development of the case. Finally it is established case law that there is no absolute right for a patent to a such a "last chance" request (see Case law of the Boards of Appeal, 10th Edition 2022, V.A.4.5.10).

Regarding the alleged shift of the burden of proof, the Board notes that the preliminary opinion merely stated that the data provided by the appellants did not support the allegations made in respect of a technical effect. This is a mere evaluation of the evidence provided. Furthermore this issue concerned the assessment of the inventive step and is therefore not related to the argued surprising evaluation of novelty of auxiliary requests 13, 18 and 19.

Moreover, the Board disagrees regarding the alleged lack of complexity of the amendments. Indeed the basis in the original application provided by the appellants for this modification is *prima facie* not straightforward and it is not immediately apparent how

the introduced modification would overcome the issue of lack of inventive step.

The Board is therefore of the opinion that there are, in the present case, no exceptional circumstances justified by cogent reasons which would justify to admit auxiliary request 25 in the appeal proceedings (Article 13(2) RPBA 2020). Additionally, the amendment made *prima facie* does not overcomes the issue of inventive step raised so far and gives rise to a new objection, in particular an objection of lack of compliance with the requirements of Article 123(2) EPC (Article 13(1) RPBA 2020). Hence, auxiliary request 25 is not admitted into the appeal proceedings.

2.4.2 Auxiliary request 26

The appellants explained that auxiliary request 26 contained a single claim which corresponded to granted claim 9 and would therefore not constitute an amendment to the case of the appellants. According to established Case Law, a reversal to granted claims should always be allowed. Moreover, this auxiliary request would overcome the issues of lack of novelty and inventive step raised so far and would not introduce any new issue.

The Board disagrees.

First of all the Board observes that, independently of the case law relied upon by the appellants, present auxiliary request 26 does actually not correspond to the set of granted claims. Compared to the granted claims, the claim of auxiliary request 26 combines the subject-matter of granted claims 1 and 9, *i.e.* all the

other claims as granted were deleted in auxiliary request 26.

Regarding the question of whether the deletion of granted claims and the limitation to the subject-matter of granted claim 9 in present auxiliary request 26 represents an amendment to the appellants' case in the sense of Article 13 RPBA 2020, different approaches have been developed in the case law (see Case Law of the Boards of Appeal V.A.4.2.2.d)). In one approach, the deletion of a claim category, of dependent claims or of alternatives within claims were held not to be amendments to the appeal case within the meaning of Article 13 RPBA 2020 (see *e.g.* T 1480/16, T 1151/18 and T 995/18). In another approach, deletions of claims or of alternative embodiments within claims were regarded as amendments and subjected to the discretion of the Board regarding their admission under Article 13 RPBA 2020 (see *e.g.* T 424/21, T 2920/18, T 532/20, T 494/18, T 2091/18, T 1569/17 and T 355/19). However, in both approaches a common decisive criteria which led to the admittance of the auxiliary requests in question was the absence of modification of the factual and legal framework of the appellant's case and the absence of a need for new discussions *e.g.* of novelty or inventive step. In T 2091/18 the new request was admitted essentially because new objections were raised by the board in its communication.

Contrary to the appellant's opinion, it cannot therefore be generally stated that the deletion of granted claims never represents an amendment to the case of the appellant within the meaning of Article 13 RPBA 2020. Furthermore, although auxiliary requests differing from previously admitted requests only in the deletion of one or more claims have been admitted in

several cases, even when the request was submitted at a very late stage of the proceedings, the case law does not support the conclusion that such requests should always be allowed. The assessment of auxiliary requests based on mere deletions of claims or alternatives within claims remains an issue to be assessed on a case by case basis.

In the present case, the claimed subject-matter has been limited to that of granted dependent claim 9. The appellants relied therewith on the presence of a stabilizer as a distinguishing feature over D1. The issues of novelty and inventive step of this feature over D1 have never been discussed in the proceedings so far. As stated in T 532/20 (see reasons 9.8), the mere fact that this feature was part of a granted dependent claim does not make it part of the appellants' appeal case. The established practice before oppositions divisions and the Boards of Appeal is indeed that the discussion of a request is usually first limited to its independent claim and if this claim is found not to be allowable, then there is no need to discuss the dependent claims as the request is not allowable as a whole. It follows that the subject-matter of auxiliary request 26 represents a "fresh case" and thus an amendment to the appellants' case in the sense of Article 13 RPBA, which is detrimental to procedural economy (Article 13(1) RPBA 2020).

The Board observes that the appellants have not provided any exceptional circumstances justified by cogent reasons that would justify the admittance of auxiliary request 26 in the appeal proceedings (Article 13(2) RPBA 2020). In particular, for the same reasons as detailed for auxiliary request 25 (see point 2.4.1),

the preliminary opinion of the Board cannot be considered to represent such exceptional circumstances.

As a result, auxiliary request 26 is not admitted into the appeal proceedings (Articles 13(1) and 13(2) EPC).

2.5 Auxiliary requests 9 (16:10), 13 and 20

In view of the conclusions reached regarding inventive step or novelty of auxiliary requests 9 (16:10), 13 and 20 (see items 3., 5. and 8.), a decision on their admittance was not needed.

Auxiliary requests 1 to 4, 11 to 13, 18 and 19

3. Novelty

3.1 The features introduced in auxiliary requests 1 to 4, 11 to 13, 18 and 19 are already disclosed in example 5 of D1 as follows:

(a) the starting dry thrombin and the dry crosslinked gelatin are in the powder form, which is a particulate form and according to the patent (see paragraph [0014]) "a special sub-class of granular material" (auxiliary requests 1, 3, 4, 13 and 19),

(b) the thrombin and gelatin components are mixed in powder form, *i.e.* in the solid state, before filling the final container (auxiliary requests 2, 3, 18 and 19),

(c) the syringe of example 5 of D1 contains a paste which is obtained by adding an aqueous solution (namely saline) to the syringe containing the dry thrombin preparation and the dry crosslinked

gelatin and which is applied to a porcine spleen biopsy defect model (example 5, paragraphs 58 and 59). It was undisputed by the appellants that this application required the paste to be flowable. As explained in the impugned decision (see point 25.2), the skilled person would recognise the terms "hydrogel" and "flowable paste" as being interchangeable in the context of the invention (see paragraph [0045] of the patent referring to a "hydrated product" generating a "flowable paste" *i.e.* a "hydrogel" as mentioned in paragraph [009] of the patent). Hence, D1 discloses a dry and hemostatic composition suitable to be reconstituted with an aqueous solution to form a flowable paste *i.e.* suitable to be reconstituted to a hydrogel, as well as the use of a finished final container to reconstitute such a composition to form a hydrogel (auxiliary requests 11 and 12),

(d) the final container is a syringe (see auxiliary requests 18 and 19), and

(e) thrombin is lyophilized, because "Thrombogen-JMI" is lyophilized thrombin powder, as evidenced by D28-D30, whose admittance was not contested by the appellants (auxiliary request 19).

Hence, the novelty objection raised for the main request applies *mutatis mutandis* to these requests.

3.2 The appellants' arguments regarding the novelty of these auxiliary requests are not convincing for the reasons detailed below under items 3.2.1 to 3.2.5.

3.2.1 The main argument of the appellants with respect to auxiliary requests 1, 3, 4, 13, 18 and 19 was that the

features specifying that the thrombin and gelatin components were in particulate (auxiliary requests 1, 3 and 4) or powder/granular (auxiliary requests 13, 18 and 19) form applied not only to the starting material but also to the final product in the syringe, which had itself to be understood as being in particulate or powder form. This would be clear *inter alia* because the corresponding feature was introduced after step d) in claim 1.

The Board disagrees. There is no reference in the introduced features to the final composition. This composition is only defined as "a dry and stable hemostatic composition" which comprises the first (thrombin) component and the second (gelatin) component in "combined form" (see step d) of auxiliary requests 1, 3, 4, 13, 18 and 19 and preamble of auxiliary requests 4 and 13). The features merely define the form of the starting material up to their mixing. However, especially as the claim is worded as a comprising claim and hence does not exclude any further step being carried out on the mixture, these features do not limit the final product to any particular form. As a result the cutted pellets of example 5 of D1 still anticipate the final composition.

3.2.2 Furthermore, contrary to the opinion of the appellants, the feature of auxiliary requests 18 and 19 specifying that a dry preparation of a crosslinked gelatin and a dry preparation of thrombin, *i.e.* first and second components, are "mixed in powder form in step c)" does not exclude any compacting step between mixing the components and filling them into the container as in example 5 of D1. The wording of claims 1 of these auxiliary requests does furthermore not limit the form

of the dry mixture in the final container obtained in step c), in particular not to a powder.

3.2.3 Regarding auxiliary request 2 and 3, the fact that one of the two alternatives introduced with the new feature is not disclosed in D1 is irrelevant, since example 5 of D1 discloses the other alternative (*i.e.* a step of "mixing both components in the solid state before filling the final container") and a claim must be novel as a whole.

3.2.4 Concerning the feature relating to the reconstitution in the form of a hydrogel introduced in auxiliary requests 11 and 12, the appellants brought forward that according to the patent a hydrogel would be a preferred embodiment of a flowable paste but could not be equated therewith. The Board is however unable to find in the paragraphs of the patent cited by the appellants any basis for such an interpretation, because:
- paragraphs [0022], [0024] and [0035] refer indeed to hydrogel as a preferred embodiment but of the more general reconstituted hemostatic composition not of a flowable paste, and
- paragraph [0028] relates to the crosslinking of gelatin particles and [0031] and [0033] to rehydration aids for the crosslinking and do not define any feature that would distinguish a hydrogel from a flowable paste reconstituted with an aqueous solution.

3.2.5 According to the appellants, the rewording of independent claim 1 in the form of a use claim in auxiliary request 12 would overcome the issue relating to the possible presence of a compression step. This argument is not convincing because auxiliary request 12 relates to the use of a final container obtained following the process of the main request, which does

not exclude any compression step for the reasons provided for the main request.

3.3 Accordingly, auxiliary requests 1 to 4, 11 to 13, 18 and 19 do not fulfill the requirements of Article 54 EPC.

Auxiliary requests 5 (11:00), 20, 22 and 23

4. Novelty

The respondents did not raise any objection of lack of novelty for these auxiliary requests. The Board agrees that the requirements of Article 54 EPC are fulfilled.

5. Inventive step

5.1 The patent relates to the preparation of a hemostatic composition comprising a dry mixture of a dry thrombin preparation and a dry preparation of a crosslinked gelatin in a final container. The main purpose of the patent is the provision of a two components product in a convenient single-composition format allowing easy one-step reconstitution for medical use (see *e.g.* paragraphs [0007] to [0009]).

In agreement with all the parties, the Board considers D1 to represent the closest prior art. The disclosure of D1 and its closest example, example 5, is already discussed under point 1.2.2.

5.2 The processes claimed in present auxiliary requests differ from the one of example 5 of D1 in that (i-1) step c) is performed under aseptic conditions (auxiliary requests 5 (11:00), 22 and 23) and (i-2) sterile starting components are used and all further

steps are performed aseptically (auxiliary requests 22 and 23), or
(ii) an aseptically spray dried thrombin is used (auxiliary request 20).

5.3 No unexpected effect directly resulting from these distinguishing features has been substantiated.

5.4 The objective technical problem can thus only be formulated as the provision of an alternative process for the preparation of a dry and stable hemostatic composition comprising a dry mixture of thrombin and crosslinked gelatin.

5.5 As brought forward by respondent 1 with reference to for example D17 (see column 3 lines 32-34), the preparation of pharmaceutical products under aseptic conditions is a well-known technique in the field of hemoactive, including hemostatic, compositions. The skilled person willing to solve the problem posed would thus have used such conditions either in addition to the final sterilisation in example 5 of D1 or even as alternative to this final irradiation. In particular regarding auxiliary request 5 (11:00), the appellants stated themselves during the oral proceedings that step c) would be considered by a skilled person at high risk of contamination. It would thus have appeared obvious to perform in particular this step under aseptic conditions.

Accordingly, in the absence of any unexpected effect linked to the choice of aseptic conditions and/or the use of sterile starting materials, it would have been obvious for the skilled person to apply these conventional measures to the process of example 5 of D1.

5.6 The appellants' arguments regarding the inventiveness of these auxiliary requests are not convincing for the reasons detailed below under items 5.6.1 to 5.6.3.

5.6.1 The arguments relating to the absence of a compression step and the advantages of loose particles compared to packed ones are irrelevant since these features do not constitute distinguishing features compared to the closest prior art for the reasons detailed for the main request (for auxiliary requests 20, 22 and 23) and for auxiliary requests 18 and 19 (for auxiliary request 20).

5.6.2 During the oral proceedings the appellants insisted on the fact there would be no motivation starting from D1 to use cumbersome aseptic conditions nor sterilised starting materials. D1 stated that the final sterilisation by gamma irradiation would not affect the hemostatic efficacy of the composition. Contrary to the appellants' opinion, the Board does not consider that D1 is teaching away from using alternative conventional sterilisation techniques, such as those described in D17. In particular paragraphs [0046] and [0059] of D1 referred to by the appellants merely state that, in the case of D1, the gamma irradiation was not detrimental. There is no mention of any drawback with other sterilisation techniques, which could constitute a teaching away. Moreover, in absence of any unexpected effect, there is no need for a particular motivation for the skilled person to use conventional techniques to provide an alternative process.

5.6.3 Furthermore, there is no evidence on file supporting the argument of the appellants that aseptically spray drying of thrombin would not be trivial. As argued by

the respondents, spray drying of thrombin is well-known (see *e.g.* D9 page 3 lines 19-20) and there is no evidence, in particular not in the patent, that aseptic spray drying would not be commonly available to the skilled person.

5.6.4 Finally, the patent proprietor argued that the use of aseptic conditions would lead to the avoidance or reduction of the final Gamma irradiation of D1. However the advantage of avoiding harsh sterilization conditions due to stability issues with thrombin would be expected by the skilled person in view of its common general knowledge

5.7 As a result, auxiliary requests 5 (11:00), 20, 22 and 23 do not meet the requirements of Article 56 EPC.

Auxiliary requests 6 to 8

6. Clarity

6.1 Claims 1 of auxiliary requests 6 to 8 all contain an additional feature defining the particle size of thrombin (specific "mean particle diameter") and gelatin (specific "median particle size"). However none of these claims encompass the methods of measurement of the defined parameters. It is therefore not clear from the claims themselves how the parameters are to be determined.

6.2 Furthermore while the mean particle diameter of thrombin particles is said to be the median size as measured by laser diffractometry in paragraph [0014] of the patent (corresponding to the last paragraph of original page 4 mentioned in the impugned decision), no method of measurement of the median particle size of

gelatin particles is provided at all in the patent. There is in particular no indication that would allow to conclude that the same method is used for thrombin and gelatin particles. Furthermore, various methods for particle size measurement are known from common general knowledge. As stated in the impugned decision, these methods involve various measurement principles, they will not all lead to the same result within an acceptable margin error. As a result, the claimed parameter for gelatin particles cannot be clearly and reliably determined by indications in the description and/or by objective procedures usual in the art.

6.3 It follows that claims 1 of auxiliary requests 6 to 8 do not clearly identify the products encompassed by it (see Case Law of the Boards of Appeal, 10th Edition, 2022, II.A.3.5, in particular page 328 first paragraph and paragraph bridging pages 328 and 329).

6.4 In this context the appellants argued that the claimed parameters, in particular the "mean particle diameter", would be a clear and absolute parameter such as for example the weight of a product. For such parameters no measurement method would be required.

This argument is not convincing. It is indeed part of common general knowledge that various methods leading to different results can be used to determine the particle size, including the mean particle diameter which may refer to the count, volume, mass or surface area diameter as brought forward by respondent 1 (see also case Law of the Boards of Appeal, 10th Edition, 2022, II.A.3.5, page 329 referring to T 1819/07). The claimed parameters do thus not represent absolute values, whose measurement would always lead the same result independently of the method used.

6.5 Accordingly, auxiliary requests 6 to 8 do not fulfill the requirements of Article 84 EPC.

Auxiliary request 9 (16:10)

7. Novelty

The respondents did not raise any objection of lack of novelty for this auxiliary request. The Board agrees that the requirements of Article 54 EPC are fulfilled.

8. Inventive step

8.1 As previously (see 5.1), the Board considers D1 to represent the closest prior art in agreement with all the parties.

8.2 The process claimed in the present auxiliary request differs from the one of example 5 of D1 only in that a specific particle size is defined for the thrombin particles in the final hemostatic composition. For the reasons already detailed for the novelty of auxiliary requests 1, 3 and 4, the amendments performed to present claim 1 do indeed not limit the form of the final hemostatic composition, in particular not to loose particles. According to D1, the cutted pellets of example 5 are constituted of "packed particles", even if no particular particle size is defined.

8.3 No unexpected effect directly resulting from this distinguishing feature has been substantiated. In particular the improved reconstitution behaviour of the hemostatic composition brought forward by the appellants has not been appropriately substantiated

compared to the final compositions of example 5 of D1, let alone as being attributable to any difference in the particle size of thrombin.

8.4 The objective technical problem can thus only be formulated as the provision of an alternative process for the preparation of a dry and stable hemostatic composition comprising a dry mixture of thrombin and crosslinked gelatin.

8.5 In the absence of any effect, the presently claimed range of particle size constitutes an arbitrary selected range, in particular as commercially available thrombin particles having particle sizes (see D9, page 3 lines 9 to 15, size distribution of "up to 50 µm", "up to 20 µm" "1 to 10 µm" or "up to 5 µm") within the present claimed range (namely mean particle diameter from 1 to 100 µm) are commonly known. Furthermore, the assertion of the appellants that the compression step in D1 would lead to thrombin particles necessarily having higher particles size than the claimed range has not been substantiated. Moreover, even if this would be the case, there is not evidence that the thrombin particle size in the final compacted hemostatic composition of D1 could not be adjusted by routine measures, for example by modifying the compression force applied.

Finally the appellants' arguments relating to the absence of a compression step and the advantages of loose particles compared to packed ones are irrelevant since these features do not constitute distinguishing features compared to the closest prior art as explained above (see 8.2).

8.6 Hence, auxiliary request 9 (16:10) does not fulfill the requirements of Article 56 EPC.

Auxiliary request 10

9. Rule 80 EPC

9.1 In auxiliary request 10 the feature of dependent claim 3 was introduced in independent claim 1 to overcome the lack of novelty objection raised for the main request. Furthermore the former dependent claim 4 which included a non-limiting preferred feature was split into two dependent claims wherein this feature was made the subject-matter of the additional dependent claim.

9.2 During the oral proceedings the appellants referred to their statement setting out the grounds of appeal in which they explained that this splitting had been made to avoid a renumbering of the following claims and was therefore a direct consequence of the modification made to claim 1 of auxiliary request 10. It followed that the splitting was also occasioned by a ground of opposition.

9.3 This argument is not convincing. As stated in the impugned decision the mere convenience of avoiding a renumbering of the claims cannot be seen as a consequence of the amendment to claim 1 and thus as occasioned by a ground of appeal. The Board hence considers that the splitting of original claim 4 in two claims is thus not occasioned by a ground for opposition.

9.4 Auxiliary request 10 does consequently not meet the requirements of Rule 80 EPC.

Requests for remittal

10. Since none of the auxiliary requests were found to comply with the requirements of the EPC, the request for remittal of respondent 1 does not need to be decided upon.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated