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Datasheet for the decision of 18 December 2024

Case Number: T 2116/22 - 3.3.07

Application Number: 11724603.3

Publication Number: 2575770

IPC: A61K9/14, A61K9/16, A61L24/10, A61P7/04

Language of the proceedings: EN

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

Patent Proprietors:
Baxter International Inc
Baxter Healthcare SA

Opponents:
Ferrosan Medical Devices A/S
Ethicon Inc.

Headword:
Process for making hemostatic compositions/BAXTER

Relevant legal provisions:
EPC Art. 113(1), 123(2), 84, 54, 56
EPC R. 106
RPBA 2020 Art. 12(4), 12(6)

Keyword:

Novelty - main request and auxiliary requests 1-7 (no) - auxiliary request 8 (yes)
Stay of the proceedings (no)
Obligation to raise objections - objection dismissed
Late-filed request - auxiliary request 8 - admitted (yes)
Amendments - auxiliary request 8 - allowable (yes)
Claims - clarity - auxiliary request 8 (yes)
Inventive step - auxiliary request 8 (yes)

Decisions cited:

T 2242/19, T 0439/22, G 0001/24, T 0166/84, T 0426/00, T 1875/07, T 1044/07, T 1473/13, T 1870/16

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Case Number: T 2116/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 18 December 2024

Appellant: (Patent Proprietor 1)	Baxter International Inc One Baxter Parkway Deerfield, IL 60015 (US)
Appellant: (Patent Proprietor 2)	Baxter Healthcare SA Thurgauerstrasse 130 8152 Glattpark (Opfikon) (CH)
Representative:	Alge, Daniel Sonn Patentanwälte GmbH & Co KG Riemergasse 14 1010 Wien (AT)
Appellant: (Opponent 1)	Ferrosan Medical Devices A/S Sydmarken 5 2860 Søborg (DK)
Representative:	Høiberg P/S Adelgade 12 1304 Copenhagen K (DK)
Appellant: (Opponent 2)	Ethicon Inc. U.S. Route 22 Somerville New Jersey 08876 (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 14 July 2022 concerning maintenance of the European Patent No. 2575770 in amended form.**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Lécaillon
	Y. Podbielski

Summary of Facts and Submissions

I. European patent 2 575 770 (hereinafter "the patent") was granted on the basis of 14 claims. The independent claims of the patent read as follows:

"1. A process for making a dry and stable hemostatic composition, said process comprising
a) providing a dry granular preparation of gelatin,
b) coating the granules in said dry granular preparation with a thrombin solution, thereby obtaining thrombin coated gelatin granules,
c) filling said thrombin coated gelatin granules into a final container,
d) finishing the final container to a storable pharmaceutical device containing said thrombin coated gelatin granules as a dry and stable hemostatic composition."

"12. A finished final container obtained by the process of any one of claims 1 to 11."

"13. Kit for administering a hemostatic composition comprising the finished container according to claim 12 and a container with a pharmaceutically acceptable diluent."

"14. Thrombin coated granules of a biocompatible polymer suitable for use in hemostasis, wherein the polymer is gelatin."

II. Two oppositions were filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and

it extended beyond the content of the application as originally filed.

III. A previous appeal was filed by the patent proprietors against the decision of the opposition division to revoke the patent (T 2242/19). The Board set aside the decision under appeal and remitted the case to the opposition division for further prosecution.

IV. Following remittal, the opposition division took the decision that, on the basis of auxiliary request 2, the patent met the requirements of the EPC. The decision was based on an amended main request and two auxiliary requests, wherein the main request and auxiliary request 1 were filed during the first opposition proceedings on 13 March 2019 and auxiliary request 2 was filed during the oral proceedings of the second opposition proceedings on 19 May 2022. Auxiliary request 2 contained 12 claims, wherein the independent claims corresponded to granted claims 1, 12 and 13 (deletion of independent granted claim 14).

V. The following documents cited in the decision of the opposition division, posted on 14 July 2022, are relevant for the present decision:

D2: WO 01/97871 A2
D7: WO 98/31403 A1
D10: EP 0 172 710 B1
D18: US 4 655 211
D19: WO 2005/002510 A2
D21: WO 2009/109963 A1

It was undisputed amongst the parties that D18 was the US equivalent of D10 and that all the arguments based

on D10 equally applied to D18. The following decision hence merely refers to D10.

VI. The opposition division decided in particular as follows:

(a) The subject-matter of claim 13 of the main request was not novel over D2.

(b) Auxiliary request 1 did not meet the requirement of Article 84 EPC.

(c) Auxiliary request 2 was admitted into the proceedings. It fulfilled the requirements of Articles 123(2) and (3), 83, 84 and 54 EPC. Finally it involved an inventive step starting from D7 as closest prior art.

VII. The patent proprietors as well as opponent 1 and opponent 2 lodged an appeal against the above decision of the opposition division.

VIII. With their statement setting out the grounds of appeal the appellants - patent proprietors defended their case on the basis of the amended main request filed on 13 March 2019, and on the basis of auxiliary requests 1 to 6, wherein auxiliary requests 1 to 5 were newly filed with the statement the grounds of appeal and auxiliary request 6 corresponded to auxiliary request 1 filed on 13 March 2019.

IX. With the reply to the opponents' statements setting out the grounds of appeal the appellants - patent proprietors filed further auxiliary requests 7 to 12, wherein auxiliary request 7 corresponded to auxiliary

request 2 forming the basis of the impugned decision and filed on 19 May 2022.

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

Claims 1 and 13 of the main request were identical to granted claims 1 and 14.

Claims 1 of auxiliary requests 1 to 7 were identical to claim 1 of the main request.

The independent claim of auxiliary request 8 read as follows:

"1. A process for making a dry and stable hemostatic composition, said process comprising
a) providing a dry granular preparation of gelatin,
b) coating the granules in said dry granular preparation with a thrombin solution, wherein thrombin is applied in sprayed form, thereby obtaining thrombin coated gelatin granules,
c) filling said thrombin coated gelatin granules into a final container,
d) finishing the final container to a storable pharmaceutical device containing said thrombin coated gelatin granules as a dry and stable hemostatic composition."

XI. On 18 October 2024, the Board issued a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal containing its preliminary opinion in preparation of the oral proceedings scheduled to take place on 18 December 2024.

XII. With the letter dated 30 October 2024, the appellants - patent proprietors requested postponement of the oral proceedings until after the Enlarged Board of Appeal had rendered a decision on the pending referral G 1/24.

XIII. In a communication dated 14 November 2024, the Board indicated its opinion that there was no need to stay the proceedings nor to postpone the oral proceedings and that the issue could be further discussed during the oral proceedings.

XIV. Oral proceedings were held before the Board on 18 December 2024.

XV. The appellants - patent proprietors requested that the decision under appeal be set aside and the patent be maintained based on the main request filed during the first opposition proceedings on 13 March 2019 or, alternatively, on the basis of one of the auxiliary requests 1 to 12 wherein:

- auxiliary requests 1 to 5 were newly filed with the statement setting out the grounds of appeal on 23 November 2022,
- auxiliary request 6 corresponds to auxiliary request 1 filed during the first opposition proceedings on 13 March 2019,
- auxiliary request 7 corresponds to auxiliary request 2 filed during the oral proceedings in the second opposition proceedings on 19 May 2022 and allowed by the opposition division,
- auxiliary requests 8 to 12 were newly filed with the reply to the statement setting out the grounds of appeal on 31 March 2023.

Finally the appellants - patent proprietors requested to stay the proceedings until a decision had been made by the Enlarged Board of Appeal in case G 1/24.

XVI. Both appellants - opponents requested that the decision under appeal be set aside and the patent be revoked.

They further requested that auxiliary requests 1 to 12 not be admitted into the appeal proceedings.

XVII. The arguments of the appellants - patent proprietors, as far as relevant for the present decision, can be summarised as follows:

(a) The subject-matter of the claims of the main request was novel over D10. The process claim 1 as well as the product claim 13 of the main request were to be read in the light of the description, in particular paragraph [0014] of the patent. The coating step b) was hence limited to a coating process avoiding thorough wetting of the gelatin granules with the thrombin solution to prevent thrombin degradation. Example 1 of D10 involved soaking of the gelatin particles with a thrombin solution and therefore differed from the presently claimed process. Furthermore the gelatin particles of example 1 of D10 were not of granular nature as defined in step a) of present claim 1. As a consequence the final product of example 1 of D10 also differed from the one defined in claim 13 of the main request.

(b) The answers of the Enlarged Board of Appeal to the questions submitted to it in case G 1/24 would be absolutely decisive for the issue of whether the description was to be taken into account in the

present case to construe the claims for the assessment of novelty and inventive step and hence for the decision in the present case. A stay of the proceedings until a decision had been made by the Enlarged Board of Appeal in case G 1/24 was therefore justified.

(c) Rejecting the request for a stay of the proceedings constituted a substantial procedural violation. The objection under Rule 106 EPC requesting to rectify this decision was therefore justified.

(d) Auxiliary requests 1 to 7 met the requirement of Article 54 EPC for the same reasons as the main request.

(e) Auxiliary request 8 was to be admitted into the appeal proceedings because its subject-matter had already been included in the first instance proceedings and it directly addressed the novelty objection in view of D10 raised in the statements of the grounds of appeal of the appellants - opponents.

(f) Claim 1 of auxiliary request 8 was clear and fulfilled the requirement of Article 123(2) EPC.

(g) Auxiliary request 8 met the requirement of Article 54 EPC. The objection of the appellants - opponents relied on an artificially created embodiment selected from many other theoretically disclosed embodiments.

(h) Auxiliary request 8 complied with the requirement of Article 56 EPC. D7 represented the closest prior art. However, starting from any of D7, D2 or D10 as

closest prior art, the objective technical problem to be solved resided in the provision of a method to manufacture a thrombin coated gelatin product having the technical effects listed in paragraph [0014] of the patent including in particular less premature degradation during the preparation process and increased storage stability. None of the cited documents suggested to perform the present claimed process, in particular the coating of gelatin granules with a thrombin solution by spraying, to solve the problem posed.

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

(a) The subject-matter of claims 1 and 13 of the main request was not novel over D10. Paragraph [0014] did not further define the claimed process but disclosed a specific embodiment thereof and preferred features. The process claim 1 as well as the product claim 13 of the main request were therefore not limited thereto. Example 1 of D10 disclosed a process for the coating of gelatin granules with a thrombin solution resulting in dry thrombin coated gelatin granules and hence anticipated the claimed process and product.

(b) A stay of the proceedings was not justified since the answers of the Enlarged Board of Appeal to the questions submitted to it in case G 1/24 were not decisive for the case. Whether the description was taken into account or not to construe the claims, their scope remained the same because paragraph [0014] did not provide any definition of the terms "coating" or "coated" but merely a specific

embodiment and preferred features of the claimed process and product.

(c) For the same reasons, the objection under Rule 106 EPC requesting to rectify the decision not to stay the proceedings should be dismissed.

(d) Auxiliary requests 1 to 7 did not meet the requirement of Article 54 EPC for the same reasons as the main request.

(e) Auxiliary request 8 should not be admitted into the appeal proceedings because it should have already been filed during the first instance proceedings, it had not been substantiated, it did not overcome the objections raised for the main request and raised new objections.

(f) Claim 1 of auxiliary request 8 did not fulfil the requirements of Articles 84 and 123(2) EPC, because it was not clear from its wording, whether the thrombin *per se* or the thrombin solution was applied in sprayed form. On the other hand, the original description stated that the coating step with the thrombin solution was performed by spraying.

(g) The subject-matter of claim 1 of the main request was not novel over D2. Claims 1, 2, 4, 5, 9 to 11, 14 and 18 of D2 as well as page 4 lines 1 to 5 and 21 to 26, page 5 lines 11 to 15, page 7 lines 4 to 6, page 8 lines 21 to 24 and page 10 lines 1-13 of D2 disclosed the preparation of dry collagen hemostatic pellets comprising a carrier based on a biomaterial, which could be gelatin and in the form of granules, and coated with a contacting layer

containing a collagen gel and thrombin, wherein the coating could be done by a fluid bed process. This disclosure anticipated the claimed process.

(h) Auxiliary request 8 did not comply with the requirement of Article 56 EPC. D2 or D10 represented the closest prior art. However, starting from any of D7, D2 or D10 as closest prior art, the objective technical problem to be solved resided in the provision of an alternative process since no technical effect compared to the prior art had been substantiated. Starting from D10 or D7 as closest prior art, the distinguishing feature of coating by spraying was rendered obvious in view of common general knowledge, D2, D19 or D21. The further distinguishing feature with respect to D7 as closest prior art (*i.e.* the nature of the carrier material) was suggested in D7 itself or in D2. Finally the distinguishing features with respect to example 1 of D2 as closest prior art (*i.e.* the nature of the carrier granules and of the coating solution) were suggested in D2 itself.

Reasons for the Decision

Main request

1. Novelty over D10

1.1 The appellants - opponents considered that example 1 of D10 anticipated the subject-matter of *inter alia* independent claims 1 and 13 of the main request.

1.2 D10 relates to a hemostatic agent containing a flake shaped carrier with thrombin and Factor XIII fixed thereupon (see claim 1). As argued by the appellants -

opponents, example 1 of D10 discloses a process characterised by the following steps:

(i) the provision of biodegradable powder gelatin as a mixture of flake substance having a size of 20 to 200 µm (in its longest dimension; see page 5 lines 45 to 47),

(ii) soaking the gelatin powder with a solution containing thrombin and Factor XIII for 2 minutes at 0 °C followed by freeze-drying to fix the thrombin and Factor XIII on the gelatin by ionic bonding and physical adsorption (see page 5 lines 47 to 53),

(iii) filling the obtained hemostatic agent into a syringe (see page 6 line 1).

1.3 Step (i)

1.3.1 According to the appellants - patent proprietors, gelatin flakes would not correspond to gelatin granules according to claim 1 of the main request.

1.3.2 As argued by the appellants - opponents, the sole limitation imposed on the granules according to the patent is their size (particle sizes of 0.1 to 5000 pm, see paragraph [0010]). The size of the gelatin "flakes" of example 1 of D10 (20 to 200 µm) falls within the range defined in the patent. Furthermore, as mentioned by appellant - opponent 2, according to paragraph [0010] of the patent, granular materials having fine grain size may be referred to as "powders". Hence, the use of the term "powder" in D10 does not necessarily exclude a granular form, contrary to the opinion of the opposition division in the impugned decision.

1.3.3 It follows that the gelatin flakes of D10 fulfil the requirements defined for granules in the patent and above step (i) corresponds to step a) of present claim 1.

1.4 Step (ii)

1.4.1 Concerning above step (ii) and step b) of claim 1 of the main request, the parties disagreed on the meaning of the terms "coating" and "coated" in the present claims.

1.4.2 The appellants - patent proprietors considered that these terms had to be interpreted taking into account the whole patent. The skilled person would have understood the coating step and the thrombin coated gelatin granules defined in the present claims as being limited respectively to a process as specified in paragraph [0014] of the patent and to thrombin coated gelatin granules prepared thereby. This process included (i) avoiding thorough wetting during contact of thrombin with the polymer (*i.e.* gelatin) and (ii) swelling of only the outer layer of the polymer granules. Such a specific coating process was not performed in example 1 of D10, in particular since the soaking step of example 1 of D10 did not avoid thorough wetting. Indeed coating and soaking had different meanings. Furthermore, claim 1 specified that "the granules in said dry granular preparation" were to be coated which confirmed that the granules were maintained dry during the coating step. This would allow to apply the coating only on the outside surface of the granules.

The appellants - patent proprietors then argued that the process of D10 was a soaking process which

encompassed thorough wetting. It followed that the stability of thrombin could not be ensured (as explained in paragraph [0013] of the patent) and that thrombin would not only be coated on the outside surface but it would also be present inside the gelatin granules.

1.4.3 The Board observes that the wording of claim 1 of the main request does not restrict the coating step to the specific coating conditions mentioned in paragraph [0014] of the patent. While the limitation of the final product being a "dry and stable" hemostatic composition in present claim 1 may imply some limitations on the process steps, these encompass any process features resulting in a dry and stable product such as indeed the ones described in paragraph [0014] of the patent but also any other process features providing a dry and stable product.

In the present case, the term "coating" or "coated" has a clear meaning in the field of pharmaceutical preparations and corresponds to the application of a material to the surface of a pharmaceutical solid product. This is usually done by applying the coating material as a solution or suspension to the pharmaceutical solid product and evaporating the vehicle. This was not disputed by the parties.

Furthermore, the Board concurs with the appellants - opponents that paragraph [0014] of the patent does not provide a different definition of the term "coating" or "coated" than the one commonly accepted in the art. The description provides first a description of the process in broad terms as in present claim 1 (see paragraph [0005] of the patent) before describing more specific embodiments and preferred features, such as in

paragraph [0014]. As argued by the appellants - opponents, this paragraph merely indicates some of the precautions which may be taken when performing a coating process so as to obtain a stable composition. It does not exclude any other coating process providing a stable composition. The attempt of the appellants - patent proprietors to use this paragraph of the description to restrict the scope of the claims represents an undue limitation thereof. Whether read alone or in the light of the entire description, the meaning of the coating step or the coated product remains the same and the process of claim 1 is merely further limited to those providing a dry and stable product.

The Board sees therefore no reason to restrict the meaning of the term "coating" or "coated" used in the claims to the specific conditions described in paragraph [0014] of the description. It follows that the claims do also not encompass any limitation to granules coated only on the outside surface.

1.4.4 Above step (ii) of D10 defines the application of thrombin as a solution to the gelatin flakes followed by evaporation of the vehicle (freeze-drying). These steps corresponds to the definition of a coating process. Moreover, as mentioned by appellant - opponent 2, example 1 of D10 specifies that the thrombin and Factor XIII are fixed on the gelatin flakes by "ionic bonding and physical adsorption". As argued by appellant - opponent 2, physical adsorption commonly refers to a surface process, which confirms that a coating occurred.

Furthermore since the thrombin containing solution is applied for 2 minutes at 0°C and subsequently dried by

freeze-drying there is no reason to expect degradation of thrombin (these conditions differ from those mentioned in paragraph [0013] referred to by the appellants - patent proprietors). The patent itself indicates that dry thrombin containing hemostatic compositions would be storage stable (see paragraph [0012] of the patent). Hence the requirement of process claim 1 that the final hemostatic composition is dry and stable is fulfilled by the product of the process of example 1 of D10.

1.4.5 As a result, step (ii) corresponds to a coating process as defined in step b) of present claim 1.

1.5 Step (iii)

Step (iii) identified above concerns filling the obtained hemostatic agent into a syringe, which was used for later reconstitution and application to rats (see paragraph bridging pages 5 to 6). The Board concurs with the appellants - opponents that this step corresponds to steps c) and d) of present claim 1. This was not disputed by the appellants - patent proprietors.

1.6 Accordingly, the process disclosed in example 1 of D10 anticipates the process of present claim 1.

1.7 Finally, the product obtained in example 1 of D10 corresponds to thrombin coated gelatin granules suitable for hemostasis as claimed in claim 13 of the main request.

1.8 The argument of the appellants - patent proprietors that present claim 13 had to be interpreted taking into account the whole patent and hence as relating to

thrombin coated gelatin granules prepared by a process as specified in paragraph [0014] of the patent, is not convincing. The wording of claim 13 does indeed not restrict the thrombin coated gelatin granules to any process of preparation. The reasons detailed above concerning the interpretation of the term "coated" in the claims apply hence even more to present claim 13.

1.9 It follows that the product obtained in example 1 of D10 anticipates the subject-matter of claim 13 of the main request.

1.10 Accordingly, the subject-matter of claims 1 and 13 of the main request is not novel in view of D10 (Article 54 EPC).

2. Request to stay the proceedings

2.1 In the context of the issue of novelty and in particular the discussion regarding the interpretation of the terms "coating" and "coated" used in the claims, the appellants - patent proprietors requested the Board to stay the proceedings in view of the pending referral G 1/24.

2.2 The appellants - patent proprietors argued that the following questions which have been referred to the Enlarged Board of Appeal by Board 3201 in case T 439/22 were absolutely decisive for the present case:

1. Is Article 69 (1), second sentence EPC and Article 1 of the Protocol on the Interpretation of Article 69 EPC to be applied to the interpretation of patent claims when assessing the patentability of an invention under Articles 52 to 57 EPC?

2. May the description and figures be consulted when interpreting the claims to assess patentability and, if so, may this be done generally or only if the person skilled in the art finds a claim to be unclear or ambiguous when read in isolation?

3. May a definition or similar information on a term used in the claims which is explicitly given in the description be disregarded when interpreting the claims to assess patentability and, if so, under what conditions?

2.3 According to the appellants - patent proprietors, not considering the description when construing the claims for assessing novelty and consequently inventive step in the present case would amount to anticipating the answers of the Enlarged Board of Appeal. A stay of the proceedings would therefore be justified to ensure that the case was adjudicated based on a stable and predictable legal framework.

2.4 The provisions in the EPC concerning a stay of proceedings following a referral to the Enlarged Board of Appeal only concern the referring Board; in view of Article 112(3) EPC a referring Board cannot give a final decision on the appeal before the Enlarged Board has given its answers to the referred questions. Thus the referring Board in effect stays the proceedings. There is, however, no legal basis in the EPC nor in the Rules of Procedure of the Boards of Appeal requiring that any other board stays its proceedings to await the outcome of the proceedings before the Enlarged Board of Appeal. The decision whether or not to stay the proceedings in such cases is thus a discretionary one.

2.5 The appellant referred to decision T 166/84 and section V.A.11.6.15 of the Case Law of the Boards of Appeal, 10th edition which concern the stay of first instance proceedings when a referral to the Enlarged Board of Appeal is pending. The strict approach taken in T 166/84, namely to stay the proceedings whenever the outcome of the proceedings depends entirely on the outcome of the referral, has been applied by some boards in proceedings before them (see in this regard *e.g.* T 426/00, T 1875/07 and T 1044/07). However, it has also been put into question for lack of a legal basis, and considered not to apply to proceedings before the Boards of Appeal (see T 1473/13, where another approach was developed, see Reasons 7.2.1 and 7.2.2, see also T 1870/16, Reasons 1.5).

2.6 The Board considers that a strict application of the approach taken in T 166/84 would in effect deny a board to exercise discretion when deciding whether or not to stay the proceedings. The discretion is however the inevitable consequence of the fact that there is no legal basis for requiring a board who has not referred the relevant questions to the Enlarged Board of Appeal to stay the proceedings.

2.7 Even if the strict approach of T 166/84 is applied to the case in hand, the Board reaches the conclusion that the proceedings should not be stayed. The appellants - patent proprietors defined the claimed process and product in broad terms. A similar description in broad terms is to be found in the description (see paragraph [0005]) before turning to more specific embodiments and preferred features as in paragraph [0014] of the patent. Therefore, as detailed above (see point 1.4.3), the Board considers that:

- whether the claims are read in isolation or in light of the description, the meaning of the terms "coating" and "coated" used in the claims remains the same, and
- paragraph [0014] does not provide a definition of the terms "coating" or "coated".

It follows that the outcome of the present case does not depend on the outcome of the referral, *i.e.* the answers to questions 1 to 3 above.

2.8 As a result, the Board decides not to stay the proceedings in view of the pending referral G 1/24.

3. Objection under Rule 106 EPC

3.1 During the course of the oral proceedings, the appellants - patent proprietors filed the following objection under Rule 106 EPC:

3.2 "At 10:35, the Chairman of the Board of Appeal announced that claim 1 of the main request was not novel over document D10. In light of the preceding discussions in the oral proceedings and the preliminary opinion dated 18 October 2024, in particular item 2.3.5 thereof, we must presume that the Board did not interpret claim 1 in light of the description, in particular paragraphs [0013] and [0014] of the opposed patent.

However, as explained in our written submission dated 30 October 2024, pending referral **G 1/24** is **absolutely decisive** for the present case:

The finding of lack of novelty of claim 1 can only be upheld if the questions referred to the Enlarged Board

of Appeal are to be answered in a certain manner (in particular as "no", "no", "no").

This finding of lack of novelty of claim 1 amounts to anticipating the answers of the Enlarged Board of Appeal. The Enlarged Board of Appeal, however, has given no indication whatsoever on how it intends to answer these questions.

The proprietors have been deprived of their fundamental right to have their case adjudicated based on a stable and predictable legal framework. This unfairly prejudices the rights of patent proprietors, and constitutes a **substantial procedural violation** (cf. T 166/84, OJ 1984, 489, and Case Law of the Boards of Appeal, 10th edition, section V.A.11.6.15), at least under Art 112, 113 and 125 EPC.

This finding based on unsettled legal interpretations would also infringe the European Convention on Human Rights, specifically with regard to Article 1 of Protocol No. 1, which enshrines the right to property.

To rectify this substantial procedural violation, the Board is requested to stay proceedings until a decision has been made by the Enlarged Board of Appeal in case G 1/24."

3.3 The Board assumes that the reference of the appellants - patent proprietors to a substantial procedural violation is a reference to a fundamental violation of Article 113 EPC referred to in Article 112a(2)(c) EPC as a ground on which a petition for review may be based.

3.4 The Board notes that the appellants - patent proprietors have based their objection under Rule 106 EPC on the fact that they do not agree with the decision of the Board not to stay the proceedings. This, however, is not an issue of the right to be heard.

3.5 In fact, the Board considers that the decision to reject the request to stay the proceedings does not suffer from any procedural deficiency because:

(a) there is no legal basis requiring a technical board of appeal to stay the proceedings due to a pending referral in a different case, *i.e.* such a decision to stay the proceedings remains a discretionary one, and

(b) the Board observes that the appellants - patent proprietors requested to stay the proceedings in writing with the letter dated 30 October 2024 and during the oral proceedings on 18 December 2024. The appellants - patent proprietors had hence ample opportunities to present their comments on the issue of a stay of the proceedings, so that no violation of their right to be heard occurred (Article 113(1) EPC).

3.6 Moreover, contrary to the appellants - patent proprietors' opinion, the outcome of the referral G 1/24 is not decisive for the present decision, including on novelty of the main request.

3.7 In view of the above, the Board cannot identify any prejudice to the rights of the appellants - patent proprietors to have their case adjudicated based on a

stable and predictable legal framework and their right to protection of property.

3.8 The objection under Rule 106 EPC is therefore dismissed.

Auxiliary requests 1 to 7

4. Novelty

Claims 1 of auxiliary requests 1 to 7 are identical to claim 1 of the main request. Accordingly the finding of lack of novelty of claim 1 of the main request (see points 1.1 to 1.6) applies *mutatis mutandis* to claims 1 of auxiliary requests 1 to 7. Hence, auxiliary requests 1 to 7 do not meet the requirement of Article 54 EPC.

Auxiliary request 8

5. Admittance

5.1 Auxiliary request 8 was newly filed with the reply of the appellants - patent proprietors to the statement of the grounds of appeals of the appellants - opponents.

5.2 Both appellants - opponents objected to the admittance of this auxiliary request. According to them, this auxiliary request represented an amendment to the appellants - patent proprietors' case since, even if some claims were already present in some previous auxiliary requests, present auxiliary request 8 including the deletion of several independent claims was newly filed.

The appellants - opponents argued that auxiliary request 8 should have been filed during the first

instance proceedings since it addresses issues raised by the appellants - opponents since the beginning of the opposition proceedings (see notices of opposition). Appellant - opponent 2 considered that admitting auxiliary request 8 would force the Board to act as a department of first instance, which would be in contravention of Article 12(2) RPBA.

Moreover, in the appellants - opponents' view, auxiliary request 8 was not substantiated, it did not overcome the objections raised for the main request and raised further new objections.

5.3 The appellants - patent proprietors argued that auxiliary request 8 corresponded to auxiliary request 2 filed during the first instance proceedings on 13 March 2019, wherein merely claims 11 to 13 were deleted. The subject-matter of auxiliary request 8 would thus have been already included in the first instance proceedings and the appellants - opponents did not raised any objection against the admittance of said previous auxiliary request.

Furthermore, according to the appellants - patent proprietors auxiliary request 8 directly addressed the objection of lack of novelty over D10 raised by the appellants - opponents in their statements of grounds of appeal. Finally this auxiliary request did not introduce any complexity.

5.4 The Board observes that auxiliary request 8 as such represents an amendment to the appellants - patent proprietors' case because, despite including claims already present in auxiliary requests filed during the first instance proceedings, e.g. auxiliary request 2 filed on 13 March 2019, the specific constellation of

the claims of auxiliary request 8 was not submitted before (Article 12(4) RPBA, first paragraph). Its admittance must therefore be decided in accordance with Articles 12(4) and 12(6) RPBA.

The Board considers that there was no compelling reason for the appellants - patent proprietors to file this auxiliary request during the first instance proceedings since the opposition division maintained a higher ranked request (Article 12(6) RPBA).

Furthermore, auxiliary request 8 directly addresses the objection of lack of novelty over D10 raised in the appellants - opponents' statements of grounds of appeal and was hence filed as early as possible in the appeal proceedings. The amendments performed do not lead to major complexity. Finally in their reply to the statements setting out the grounds of appeal (see page 18, 3rd full paragraph), the appellants - proprietors identified the basis for the amendments in the original application and provided substantial reasons therefor (Article 12 (4) RPBA).

5.5 As a consequence, the Board admits auxiliary request 8 into the appeal proceedings (Articles 12(4) and 12(6) RPBA).

6. Clarity

6.1 Claim 1 of auxiliary request 8 corresponds to claim 1 of the main request wherein step b) was amended so as to read "coating the granules in said dry granular preparation with a thrombin solution, wherein thrombin is applied in sprayed form, thereby obtaining thrombin coated gelatin granules" (emphasis added).

6.2 The appellants - opponents were of the opinion that the introduction of a product-by-process feature in the process claim 1 of auxiliary request 8 rendered the claim unclear. According to them, it would not be clear whether the thrombin *per se* or the thrombin solution was applied in sprayed form.

6.3 The Board observes that this objection builds on an overly formalistic reading of present claim 1. The Board further considers that the skilled person would without any ambiguity understand step b) of present claim 1 as a coating step wherein the gelatin granules are coated with a thrombin solution which is applied in sprayed form.

6.4 Accordingly, the Board comes to the conclusion that claim 1 of auxiliary request 8 complies with Article 84 EPC.

7. Amendments

7.1 Appellant - opponent 2 contended that claim 1 of auxiliary request 8 would not fulfil the requirement of Article 123(2) EPC. In its view, the wording of original page 5, on which the amendment to present claim 1 was based, clearly stated that the coating with the thrombin solution was performed by spraying while amended claim 1 prescribed that thrombin *per se* was applied by spraying *i.e.* that it had properties imparted by a spraying process.

7.2 As argued by the appellants - patent proprietors, this objection is very formalistic. As stated above in the context of the assessment of clarity, the Board considers that step b) of present claim 1 defines a coating step wherein the gelatin granules are coated

with a thrombin solution which is applied in sprayed form. Such a process step is directly and unambiguously disclosed as a preferred embodiment on page 5, 3rd paragraph of the original description.

7.3 As a result, claim 1 of auxiliary request 8 meets the requirement of Article 123(2) EPC.

7.4 The appellants - opponents did not raise any objection of lack of compliance with Article 123(2) EPC for the dependent claims of auxiliary request 8 nor any objection of lack of compliance with Article 123(3) EPC. The Board is satisfied that the claims of auxiliary request 8 fulfil the requirements of Articles 123(2) and 123(3) EPC.

8. Novelty

8.1 The Board observes that the finding of lack of novelty of claims 1 and 13 of the main request in view of D10 was overcome by the amendments made in auxiliary request 8, namely the deletion of said product claim 13 and the limitation of said process claim 1 to coating with the thrombin solution applied in sprayed form. This was not disputed by the appellants - opponents.

8.2 During oral proceedings, the appellants - opponents maintained only their written objections of lack of novelty over D2.

8.3 The appellants - opponents argued that the combination of claims 1, 5, 9 to 11 and 14 of D2 disclosed collagen hemostatic pellets comprising a carrier based on a biomaterial, which may be gelatin, and coated with a contacting layer containing a collagen gel and thrombin. Appellant - opponent 1 indicated furthermore

that D2 disclosed a fluid bed process, which would be a form of spray coating (see D2, page 8 lines 21 to 24 and page 10 lines 1-13 as "best mode"). Appellant - opponent 2 considered in particular that the encapsulation of the carrier biomaterial with the collagen gel described in claim 18 of D2 implicitly disclosed a coating step. The appellants - opponents further referred to claim 2 of D2 according to which the pellets had a water content in the range of 1-25%. The pellets would thus be dry in the sense of the patent (see paragraph [0011] of the patent). Furthermore D2 would refer to granules for the carrier (see page 4 lines 1 to 5 and page 7 lines 4 to 6 of D2) and the size of the pellets defined in claim 4 of D2 would correspond to granules according to the patent (see paragraph [0010] of the patent). Finally the pellets would be stored in a container and would be storage stable thanks to the solidified collagen gel (see page 5 lines 11 to 15 and page 4 lines 21 to 26 of D2).

8.4 The appellants - patent proprietors were *inter alia* of the opinion that the appellants - opponents based their novelty objection on an artificially created embodiment selected from many other theoretically disclosed embodiments.

8.5 The Board considers that D2 does not provide a direct and unambiguous disclosure of collagen pellets containing a gelatin carrier in granular form coated with a contacting layer comprising a collagen gel and thrombin. Indeed gelatin must be selected from a list of several possible biomaterials in claim 14 of D2 and its granular form represents merely one out of several options on page 4 lines 1 to 5 and page 7 lines 4 to 6.

Regarding the argument of the appellants - opponents that the size of the pellets would be the same as the one disclosed for the gelatin granules in the patent, the Board observes that the particle size defined in the patent characterises the starting gelatin granules, while the particle size provided in D2 relates to the final pellets.

It follows that at least the step of providing a dry granular preparation of gelatin (step a)) of claim 1 of auxiliary request 8 is not directly and unambiguously disclosed in D2.

8.6 Hence, the subject-matter of claim 1 of auxiliary request 8 is novel in view of D2 (Article 54 EPC).

8.7 The appellants - opponents did not raise any objection of lack of compliance with Article 54 EPC for the further claims of auxiliary request 8. The Board is satisfied that the claims of auxiliary request 8 fulfil the requirement of Article 54 EPC.

9. Inventive step

9.1 Closest prior art

9.1.1 The parties disagreed on the choice of the closest prior art document. In line with the impugned decision, the appellants - patent proprietors considered D7 as the closest prior art. The appellants - opponents presented arguments starting from D7 but argued that D2 and D10 would also represent suitable closest prior art documents.

9.1.2 Auxiliary request 8 relates to a process for the preparation of a dry and stable hemostatic composition

comprising thrombin coated gelatin granules wherein the coating step is performed by spraying a thrombin solution on gelatin granules.

9.1.3 The prior art documents cited by the parties disclose the following subject-matter:

- D7 discloses a process of making a bioadhesive composition based on co-lyophilization of collagen pellets and a thrombin solution (lyophilized for storage in a final delivery container), which composition has hemostatic properties once reconstituted (see page 1 lines 5-7, page 3 line 27 to page 4 line 11, page 10 lines 5 to 6 and example 1 pages 15 to 16),
- D10 discloses the preparation of a hemostatic agent comprising thrombin coated gelatin granules wherein the coating is performed by soaking a thrombin solution on the gelatin granules for 2 minutes at 0°C (see above, points 1.1 to 1.9), and
- D2 generally describes collagen hemostatic pellets containing a biomaterial carrier, which may be gelatin optionally in granular form, coated with a contacting layer comprising a collagen gel, which gel may contain thrombin, and the preparation thereof such as by a fluid bed process (see D2, claims 1, 5, 9 to 11 and 14, page 4 lines 1 to 5 and 21 to 26, page 7 lines 4 to 6, page 5 lines 11 to 15, page 8 lines 21 to 24 and page 10 lines 1-13; see also above, points 8.3 to 8.5).

9.1.4 The Board considers that D10 and D2 are not less relevant starting points than D7. As discussed for the assessment of novelty of the main request in view of D10 (see point 1.4.4, 2nd paragraph), D10 as well as D2 relate to dry products, which are expected to be stable

upon storage according to the patent. Hence, contrary to the view of the opposition division, these documents do thus address the stability requirement. Furthermore, D7 does not relate to a combination of gelatin and thrombin while D10 and to some extent D2 relate to such products or at least encompass them. It follows that an inventive step has to be acknowledged starting from each of these documents for auxiliary request 8 to meet the requirement of Article 56 EPC.

9.2 Problem solution approach starting from D10

9.2.1 As argued by the appellants - opponents, the process of claim 1 of auxiliary request 8 differs from the process disclosed in example 1 of D10 in that the coating is performed by spraying the thrombin solution on the gelatin granules.

9.2.2 As argued by the appellants - patent proprietors, the patent renders credible that this specific coating process maintains thrombin activity during the preparation process and storage (see paragraphs [0014] and [0071]). However, as argued by the appellants - opponents, no improvement has been substantiated compared to the product of example 1 of D10, which is considered stable (see point 1.4.4, 2nd paragraph).

In this context, the improved hemostatic effect relied upon by the appellants - patent proprietors during the oral proceedings with reference to paragraph [0014] has not been substantiated compared to the prior art and cannot thus be taken into account in the formulation of the objective technical problem.

9.2.3 The objective technical problem is therefore seen as the provision of an alternative process for the preparation of a dry and stable hemostatic composition.

9.2.4 During the oral proceedings, the appellants - opponents agreed with this approach. They then considered that the claimed process would be obvious in light of D2, D19 and D21, which all disclosed coating by spraying, as well as in light of common general knowledge. They argued that the skilled person would have been motivated to apply known alternative coating processes, including spraying. According to them, using a known coating process to prepare a known coated product would not involve an inventive step.

9.2.5 D2 generally discloses that the carrier may be coated with some layers, possibly applied by spraying, wherein the carrier may be gelatin and the layers contain thrombin alone or with collagen, wherein the last coated layer is collagen (see page 6 last paragraph, page 7 lines 13 to 15 and page 10 lines 1 to 5 and lines 15 to 23).

D19 relates to hemostatic products based on chitosan and polysaccharides and states that "fluidized bed microencapsulation is commonly used for preparing encapsulated water-soluble food ingredients and pharmaceutical compositions" (see page 21, 1st paragraph).

D21 describes a dry gelatin sponge comprising a thrombin layer at its surface, which layer may be applied by PipeJet™-technology which would be, according to the appellants - opponents, a spraying method (see page 5 lines 27-29, page 7 lines 1 to 4, example 15 on pages 43 to 45).

9.2.6 The Board agrees with the appellants - opponents that coating by spraying is commonly known. However, given the known instability of thrombin in solution (see e.g. the patent, column 1 lines 43 to 51), the issue in the present case is to determine whether the skilled person would have performed the coating by spraying with a reasonable expectation of maintaining thrombin activity.

9.2.7 As argued by the appellants - patent proprietors during oral proceedings, D2 does not concern specifically gelatin granules coated with thrombin. In particular, the single example of D2 concerns the preparation of collagen-coated fibrinogen granules, *i.e.* it neither involves the use of gelatin nor of thrombin. Moreover, D2 does not address the stability of thrombin during coating and in such a final product (*i.e.* absent any outer collagen layer). In the Board's view, D2 would not have provided the skilled person with a reasonable expectation of success of maintaining thrombin activity when applying it in sprayed form as a coating layer on gelatin granules.

9.2.8 As argued by the appellants - patent proprietors during the oral proceedings, D19 concerns neither thrombin nor gelatin, so that the skilled would not have found a motivation to apply the coating process of D19, despite being mentioned as commonly known, in the present specific case.

9.2.9 D21 also relates to a different product, namely gelatin sponge, and a specific spraying process based on moving the product to be coated along x and y axes (see example 15, page 44 of D21). As argued by the appellants - patent proprietors during the oral

proceedings, in view of the different shapes and sizes of the granules of D10 compared to the sponge of D21, the Board considers that the skilled person would not have been motivated to apply the PipeJet^{TM}-technology to the granules of D10. Moreover, D21 does not provide information regarding maintenance of thrombin activity (only the uniformity of the thrombin distribution was evaluated).

9.2.10 The Board comes therefore to the conclusion that the skilled person would not have applied the known spraying processes(from common general knowledge, D2, D19 or D21) to the preparation of the product of D10 with a reasonable expectation of maintaining thrombin stability during the preparation of the product.

9.3 Problem solution approach starting from D2

9.3.1 During oral proceedings the appellants - opponents focused on example 1 of D2 as a starting point. The parties agreed that the claimed process differs from the one of example 1 of D2 at least in the nature of:
(i) the carrier granules (gelatin instead of fibrinogen in example 1 of D2), and
(ii) the coating solution (thrombin solution instead of collagen solution in example 1 of D2).

9.3.2 For similar reasons as detailed above (see point 9.2.2), and as argued by the appellants - opponents, no improved effect has been substantiated compared to the process of D2 and the objective technical problem to be solved can be formulated as done under point 9.2.3.

9.3.3 The appellants - opponents argued that D2 would already teach the above features (i) and (ii). In particular, according to appellant - opponent 2, the mere addition

of thrombin in the collagen solution of example 1 of D2 would lead to a process falling under the scope of present claim 1. A replacement of the collagen solution by a thrombin solution was not required.

9.3.4 As detailed under points 8.5 and 9.2.7, the Board considers that D2 does not unambiguously disclose nor suggest to prepare specifically gelatin granules coated with a thrombin solution by spraying, let alone with a reasonable expectation of maintaining thrombin activity during the preparation of such a product according to example 1 of D2. In particular, as argued by the appellants - patent proprietors during the oral proceedings, the skilled person would not necessarily have expected thrombin activity to be maintained upon washing and solubilization in methanol at a concentration of 2 g/l as taught in example 1 of D2.

9.3.5 Accordingly, the Board considers that the above identified distinguishing features (i) and (ii) would not have appeared obvious to the skilled person willing to solve the problem posed starting from example 1 of D2.

9.4 Problem solution approach starting from D7

9.4.1 It was undisputed amongst the parties that the subject-matter of claim 1 of auxiliary request 8 differs from the one of D7 at least in (i) the use of gelatin granules instead of collagen pellets and (ii) a coating step of the granules with a thrombin solution applied in sprayed form.

9.4.2 Contrary to the opinion of the appellants - patent proprietors, no improved effect directly linked to these distinguishing features compared to D7 has been

substantiated. With respect to the reference in the impugned decision to T 2242/19 (see impugned decision pages 18 to 19), the Board notes that the conclusion reached therein regarding sufficiency of disclosure, namely that the patent provided sufficient information to prepare a dry and stable hemostatic composition, does not imply that storage stability necessarily constitutes an improved technical effect compared to the prior art. In the present case, the claimed compositions as well as those of D7 may both be considered storage stable.

9.4.3 It follows that the objective technical problem can be formulated in the same way as starting from D10 (see point 9.2.3).

9.4.4 The appellants - opponents followed a similar approach in their written submissions and subsequently argued that the skilled person would have (i) replaced the collagen pellets of D7 by gelatin granules in view of D7 (see page 2 lines 12 to 15) itself or D2 and (ii) performed a coating step as commonly known in the art and disclosed in D2, D19 or D21.

9.4.5 The Board considers that the skilled person would not have replace the collagen pellets in D7 by gelatin granules. The passage of D7 referred to in this context by appellant - opponent 1 described the content of a further prior art document in the background art section relating to known hemostatic compositions. The skilled person would not have considered this disclosure as suggesting that gelatin could be an alternative to collagen in the products of D7. Furthermore even if gelatin is mentioned as a possible biomaterial carrier in D2, D2 primarily concerns collagen containing hemostatic compositions. Thus, the

skilled person would not have considered it obvious to replace the collagen of the pellets of D7 with gelatin granules.

Furthermore, for similar reasons as detailed under points 9.2.5 to 9.2.9, the skilled person would not have been motivated to apply the known spraying processes (from common general knowledge, D2, D19 or D21) to the preparation of the product of D7 with a reasonable expectation of maintaining thrombin activity during preparation and storage of the product.

9.5 Accordingly, the subject-matter of claim 1 of auxiliary request 8 involves an inventive step when starting from D10, D2 or D7. The same conclusion applies *mutatis mutandis* to the dependent claims of auxiliary request 8, which have not been objected to by the appellants - opponents. Hence, the claims of auxiliary request 8 meet the requirement of Article 56 EPC.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division with the order to maintain the patent on the basis of the claims of auxiliary request 8 filed on 31 March 2023 and a description to be adapted thereto if necessary.

The objection under Rule 106 EPC is dismissed.

The Registrar: The Chairman:

A. Vottner A. Usuelli

Decision electronically authenticated