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Datasheet for the decision of 27 November 2018

Case Number: T 1889/13 - 3.3.10

Application Number: 02790278.2

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Language of the proceedings: EN

Title of invention:
A HEMOSTATIC KIT, A METHOD OF PREPARING A HEMOSTATIC AGENT AND A METHOD OF PROMOTING HEMOSTASIS

Patent Proprietor:
Ferrosan Medical Devices A/S

Opponent:
Baxter Innovations GmbH

Headword:

Relevant legal provisions:
EPC Art. 100(c), 123(3)

Keyword:
Grounds for opposition - extension of subject-matter (yes)
Amendments - extension beyond the content of the application as filed (yes)

Decisions cited:
G 0001/93, T 0190/99

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1889/13 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 27 November 2018

Appellant: (Patent Proprietor)	Ferrosan Medical Devices A/S Sydmarken 5 2860 Søborg (DK)
Representative:	Høiberg P/S Adelgade 12 1304 Copenhagen K (DK)
Respondent: (Opponent)	Baxter Innovations GmbH Industriestrasse 67 1221 Wien (AT)
Representative:	Sonn & Partner Patentanwälte Riemergasse 14 1010 Wien (AT)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 5 July 2013 revoking European patent No. 1458425 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	P. Gryczka
Members:	R. Pérez Carlón
	F. Blumer

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division to revoke European patent No. 1 458 425.

II. Notice of opposition had been filed on the grounds of added subject-matter (Article 100(c) EPC), insufficiency of disclosure (Article 100(b) EPC), and lack of novelty and inventive step (Article 100(a) EPC).

III. Two interlocutory decisions have been issued in these appeal proceedings. A request for exclusion from the proceedings of the present chairman and rapporteur on the ground of suspected partiality was admitted by decision of the board of 20 May 2015 and rejected by the board in an alternate composition by a decision of 14 March 2017.

IV. The documents filed during the opposition and appeal proceedings include the following:

D2 WO 99/38606
D3 WO 98/08550
D6 US 6,045,570
E2 Schramm *et al.* Gelfoam paste injection for vocal cord paralysis: Temporary rehabilitation of glottic incompetence, The Laryngoscope 88:1978, pages 1268 to 1273

V. The opposition division concluded that the requests before it either went beyond the disclosure of the application as originally filed, or related to non-inventive subject-matter.

VI. With the statement setting out the grounds of appeal, the appellant filed a main request and first to ninth auxiliary requests, which were renumbered at the oral proceedings before the board on 28 November 2018. All of them correspond to requests before the opposition division.

VII. Claim 1 of the main request reads as follows:

"A process for preparing a haemostatic agent comprising the steps of:

A) removing the outer packaging and transferring the containment unit of the medical device comprising:

i) a sterile containment unit defining an internal volume and being comprised of a material impermeable to a fluid,

wherein the containment unit has a single opening and one closure-unit for closing the opening, and

ii) a sterile haemostatic agent in powder form contained in said containment unit and having a volume of less than 90% of the internal volume of the containment unit;

wherein 95% of said haemostatic agent in powder form has a particle size less than 1000 microns,

wherein said haemostatic agent in powder form is gelatine, and

iii) an outer packaging defining a sterile barrier seal enclosing said containment unit;

wherein the remaining volume of at least 10% of the internal volume is a void volume allowing for the addition of a liquid to the sterile haemostatic agent in powder form through the opening

into a sterile field,

B) Opening the containment unit to the external environment,

C) adding a sterile liquid to the containment unit of the medical device,

D) separating the opening of the containment unit of the medical device from the external environment by the closure-unit, and

E) mixing the liquid and the sterile gelatine in powder form contained in the containment unit without substantial exposure of said gelatine and said liquid to an environment external to the containment unit, thereby preparing the haemostatic agent."

Claim 1 of the first to third auxiliary requests contains, like claim 1 of the main request, the feature

"*wherein the remaining volume of at least 10% of the internal volume is a void volume allowing for the addition of a liquid to the sterile haemostatic agent in powder form through the opening*"

and limits the medical device required by claim 1 to those consisting of components i) to iii).

Claim 1 of the fourth auxiliary request relates to a medical device whose remaining volume of at least 10%

of the internal volume is defined as follows:

"*wherein the remaining volume of at least 10% of the internal volume allows for the addition of a liquid to the sterile haemostatic agent in powder form through the opening*".

Lastly, claim 1 of the fifth to ninth auxiliary requests corresponds to claim 1 of the main request and first, fourth, second and third auxiliary requests respectively, further limiting the relative volume of the sterile haemostatic agent with respect to the internal volume of the containment unit to 75%, and that of the remaining volume to at least 25%.

VIII. The arguments of the appellant where relevant for the present decision were as follows:

The feature "the remaining volume of a least 10% of the internal volume is a void volume" found a basis on page 6, lines 11 and 12; page 8, line 37 to page 9, line 1; and page 8, lines 30 to 32, of the application as originally filed. This feature was also the inevitable consequence of steps B) and C) required by claim 1. In addition, it was implicitly disclosed by the application as a whole, read with a mind willing to understand, since the containment unit required by claim 1 only had one opening, and the description of the application only referred to a wide-mouth container in which mixing occurred. In fact, this feature was a mere clarification of the intention of the applicant. For these reasons, no added subject-matter had been inserted.

The argument applied in the same manner to claim 1 of the first to third, fifth, sixth, eighth and ninth

auxiliary requests.

Claim 1 of the fourth and seventh auxiliary requests, despite not containing the limitation "wherein the remaining volume [...] is a void volume", did not extend the scope of protection conferred by the patent as granted, as no embodiment could be envisaged which would be according to claim 1 of these requests but not according to claim 1 as granted.

IX. The arguments of the respondent (opponent) where relevant for the present decision were as follows:

The feature "the remaining volume of at least 10% of the internal volume is a void volume" could not be considered as implicitly disclosed in the application as originally filed. The argument did not change with respect to claim 1 of the first to third, fifth, sixth, eighth and ninth auxiliary requests.

Claim 1 of the fourth and seventh auxiliary requests extended the scope of protection of the patent as granted, as it related to embodiments, such as a process for preparing a haemostatic agent using a half-full syringe, which were not contemplated by claim 1 as granted.

X. The final requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the following requests:

- main request;
- first auxiliary request;
- second auxiliary request (filed as third auxiliary request);

- third auxiliary request (filed as fourth auxiliary request);
- fourth auxiliary request (filed as second auxiliary request);
- fifth auxiliary request;
- sixth auxiliary request;
- seventh auxiliary request;
- eighth auxiliary request;
- ninth auxiliary request,

all requests as filed with the statement setting out the grounds of appeal dated 14 November 2013.

The respondent requested that the appeal be dismissed.

XI. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request, amendments.

2. Claim 1 of the main request relates to a process for preparing a haemostatic agent which requires a medical device having a containment unit with a single opening, one closure-unit, less than 90% of its volume of a haemostatic agent in powder form, and requiring that

"*the remaining volume of at least 10 % of the internal volume is a void volume*".

3. This request was the first auxiliary request before the opposition division, which concluded that claim 1 contained added subject-matter.

4. According to Article 123(2) EPC, a European patent application or European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as originally filed. Article 100(c) EPC defines any deficiency in this respect as a ground for opposition.

The underlying idea is that an applicant or patent proprietor should not be allowed to improve its position by adding subject-matter not disclosed in the application as filed, as it represents an unwarranted advantage damaging to the legal security of third parties relying on the content of the original application (G 1/93, OJ 1994, 541, Reasons 9).

5. It was not disputed that the application as originally filed discloses a medical device containing a sterile haemostatic agent in powder form of a volume being less than 90% of the internal volume of the containment unit (see for example page 4, lines 17-18 and 20-21), and a method of using a device containing a second volume of less than 90% of a first internal volume (claim 49).

6. It was also not disputed that there is no word-by-word basis for the feature "the remaining volume of at least 10 % of the internal volume is a void volume" in the application as originally filed, either in the context of a medical device or of a process for preparing a haemostatic agent.

This feature requires "the remaining volume" to be void, meaning all the volume of the containment unit which is not occupied by the haemostatic agent. This was also not disputed.

7. According to the case law, implicit disclosure refers to what any person in the art would consider necessarily implied by the application as a whole (Case Law of the Boards of Appeal, 8th Edition 2016, II.E. 1.2.2).

8. The application as originally filed discloses medical devices comprising further components in the containment unit, such as a rigid internalised container, a further physical barrier which creates a non-porous divide, or a unit which physically separates thrombin from haemostatic agent (see page 6, lines 31 to 37, and page 7, lines 4 to 7). For this reason alone, the skilled person, reading the application as originally filed with a mind willing to understand, would not have concluded that the remaining volume was necessarily void. Therefore, the feature under examination does not find the required basis in the application as originally filed.

9. The appellant relied on the passage on page 6, lines 11 and 12, which reads "*the volume difference is, at least in part, to allow for adequate addition of a third volume and mixing the volumes*".

This passage, however, does not exclude the presence of components different from haemostatic powder in the containment unit.

In addition, even if, to the benefit of the appellant, it meant that at least a part of the remaining volume was void to allow for addition and mixing, it does not disclose that the whole remaining volume is void.

10. The appellant further relied on the passage on page 8, line 37 to page 9, line 1. This passage reads "*the*

relative volume of the second volume of haemostatic agent relative to the first internal volume is less than in conventional products so as to be suitable for adding a third volume of liquid and for said liquid to be evenly and easily physically dispersed throughout the second volume of haemostatic agent".

This passage however indicates that the relative volume of haemostatic agent to the volume of the container is less than in conventional products. Nevertheless, this does not mean that the whole "remaining volume" is void, as required by claim 1.

11. The appellant also relied on the passage on page 8, lines 30 to 32 as a basis for the afore-mentioned feature.

However, this passage only discloses that mixing can be carried out without exposure to an environment external to the containment unit and without exposure to a non-sterile field. It indicates that the containment unit should allow for adding liquid, but it does not provide a basis for the presence of a void volume, let alone that all of the volume of the containment unit not occupied by haemostatic agent in powder form is void.

12. The appellant argued that the presence of a void volume was necessarily required by process steps B) opening the containment unit to the external environment and C) adding a sterile liquid to the containment unit of the medical device required by claim 1.

As a basis for a process having said steps, the appellant relied on claim 49; example 1; page 4, line 25; page 3, lines 5-10; claim 60; page 7, lines 1-2; and page 7, line 35 to page 8, line 2.

Example 1 relates to a product and does not disclose any process step for preparing a haemostatic agent. For this reason alone, this example cannot provide the required basis. In addition, example 1 contains further limitations, such as the type of haemostatic agent, its relative amount and the type of outer packaging, which are not features of claim 1.

Claim 49 does not disclose steps B) and C) required by claim 1, either.

Page 4, line 25 discloses that the amount of haemostatic agent can represent different percentages of the volume of the containment unit, but is silent on the remainder of said volume.

Page 3, lines 5 to 10, corresponds to the wording of claim 1 as originally filed and relates to a medical device, not to a process. It does not disclose any process steps.

Claim 60 relates to the use of a containment unit defining a volume and a second volume of collagen or collagen-derived powder for the preparation of a haemostatic kit wherein the second volume is less than 90% of the first volume. Claim 60 does not disclose any steps for preparing a haemostatic agent.

The passage on page 7, lines 1 to 2, relates to an embodiment in which the liquid is in a second containment unit whose internal volume is physically separated from the first containment unit, such as to form a kit. However, claim 1 is not limited to a process using a kit, and this passage does not disclose any preparation step.

Lastly, the passage on page 7, line 35 to page 8, line 2, discloses that a user, in a sterile field, can add a third volume of liquid, optionally by opening the containment unit to the external environment, adding by means of [...] pouring the liquid through the at least one opening. Claim 1, however, does not require pouring liquid into the container and, thus, this passage also fails to provide the required basis for steps B) and C) of claim 1.

The argument of the appellant that the presence of a void volume is the unavoidable consequence of steps B) and C) of claim 1 is thus not convincing.

13. The appellant also argued that, by limiting the containment unit to a containment unit having only one opening, the presence of a void volume in said unit remained the sole reasonable option.

There is, however, no reason why a containment unit having only one opening must necessarily have all the internal volume not occupied by haemostatic agent void.

14. The appellant further argued that the application as originally filed defined the container of the invention as a wide-mouth container (page 6, lines 13-16), and that the mixing occurs by shaking in the container (page 7, lines 28-29). Mixing by shaking could only be carried out if a void volume was present.

However, claim 1 of the main request is not limited to a wide-mouth container, but relates to a containment unit in general. For this reason alone, this argument is not convincing. Even if, for the sake of argument,

mixing could only be carried out if some void volume were present, the passages cited by the appellant still do not provide a basis for the embodiment of claim 1, which requires all of the remaining volume to be void, not only a part of it.

15. Lastly, the appellant argued that the feature under examination was merely a clarification. It had always been the intention of the inventor to claim a containment unit having a void volume, and this was evident considering that the section of the application as filed "background of the invention" referred to preparing a haemostatic agent by mixing in an sterile beaker or bowl (page 2, lines 25-35).

However, the intention of the inventor when drafting the application does not provide a basis within the meaning of Article 123(2) EPC. This argument is not convincing, too.

16. The appellant argued that the feature under examination resulted from the whole disclosure of the application, read with a mind willing to understand, and cited T 190/99 in this context.

However, the disclosure in the application as originally filed relates merely to a process using a medical device which has a containment unit with an internal volume, 90% or less of its internal volume being filled with haemostatic agent powder. Whether or not the remaining volume is void is not disclosed, either implicitly or explicitly, as can be seen from the above conclusions (points 7. to 15.).

17. For these reasons, it is concluded that the feature "wherein the remaining volume of at least 10 % of the

internal volume is a void volume" does not find the required basis in the application as originally filed, with the consequence that the appellant's main request is not allowable.

First to third, fifth, sixth, eight and ninth auxiliary requests

18. The situation with respect to the feature "wherein the remaining volume [...] is a void volume" is not modified by any of the first to third, fifth, sixth, eighth and ninth auxiliary requests, which require a medical device consisting of containment unit, haemostatic agent and outer packaging and/or the remaining volume to be of at least 25 % of the internal volume.

Even if the medical device required by claim 1 only consists of a containment unit having a single opening and a closure-unit, haemostatic powder and an outer packaging, the application as filed failed to disclose that the remainder of the internal volume of the containment unit not occupied by haemostatic powder must necessarily be void.

It is thus concluded that these requests also contain added subject-matter and are for this reason not allowable.

Fourth and seventh auxiliary requests

19. Article 123(3) EPC is aimed at protecting the interests of third parties by prohibiting any broadening of the scope of the claims of a granted patent, even if there should be a basis for such broadening in the

application as filed (G 1/93, OJ 1994, 541, Reasons 9).

20. The issue here is whether or not the feature *"wherein the remaining volume of at least 10 % of the internal volume allows for the addition of a liquid to the sterile haemostatic agent in powder form through the opening"* in the fourth auxiliary request - and of 25% in the seventh - extends the scope of protection of the patent as granted.

21. Claim 1 of the patent as granted requires the remaining volume of the containment unit not occupied by haemostatic agent to be void.

In contrast, claim 1 of the fourth and seventh auxiliary requests does not include this limitation. These claims relate to a process for preparing a haemostatic agent requiring a medical device which consists of a containment unit having a single opening and one closure, haemostatic agent in powder form and an outer packaging.

Claim 1 of these requests does not require, as claim 1 as granted, the remaining volume not occupied by the haemostatic agent to be void. The scope of protection of claim 1 of these requests is therefore broader than the scope of the claims as granted.

21.1 The respondent argued that a syringe half-filled with haemostatic powder, commonly used in haemostatic technology (D1), represented an embodiment of claim 1 of the fourth and seventh auxiliary requests but not of claim 1 as granted. This showed that the patent in suit could not be maintained on the basis of the fourth or of the seventh auxiliary request, as the scope of protection conferred by the patent as granted would be

extended.

21.2 The appellant argued that a syringe had two openings and not one, as required by claim 1. There was no evidence on file that there were syringes which could not be opened at the rear by pulling off the plunger.

21.3 In this context, however, it is not of relevance whether or not such syringe is state of the art. The sole issue here is whether or not such an embodiment could be envisaged, which is the case.

Notwithstanding the above, a skilled reader would not consider the part of a syringe covered by the plunger as an "opening", or the plunger as a closure-unit. Even though some exceptional cases such as those cited by the appellant can be envisaged (E2, Figure 1; D2, Figures 2 and 3; D6, Figure 41C; or D3, Example 3), this is not the manner in which a syringe is normally used.

21.4 The appellant argued that it was obvious from the application and the patent in suit that nothing other than a wide-mouth flask partially filled with haemostatic agent was intended. A syringe or any other containment unit was therefore not a part of the invention.

However, the issue under Article 123(3) EPC is not whether or not a device, such as a partially filled syringe, is disclosed in the application or in the patent, but whether or not it is an embodiment of claim 1 of the fourth and seventh auxiliary requests.

This argument is thus not convincing.

22. Lastly, the appellant argued that a syringe partially filled with haemostatic powder would be "full" and thus not according to claim 1 of these requests.

However, the volume of a syringe is normally considered to be its maximum capacity by pulling the plunger to its furthest position, regardless of how much of this volume is filled in a particular moment of time.

This argument is not convincing, too.

23. For these reasons claim 1 of the fourth and seventh auxiliary requests contravenes the requirements of Article 123(3) EPC.

Conclusion

24. As claim 1 of the main request and of the first to third, fifth, sixth, eighth and ninth auxiliary requests contains added subject-matter, and claim 1 of the fourth and seventh auxiliary requests relates to subject-matter extending beyond the protection conferred by the patent as granted, none of the requests of the appellant are allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated