

Internal distribution code:

- (A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [X] To Chairmen
(D) [-] No distribution

**Datasheet for the decision
of 26 June 2012**

Case Number: T 1676/11 - 3.3.10

Application Number: 09159082.8

Publication Number: 2078532

IPC: A61L24/10, A61L24/04,
B01F13/00, B01F15/02,
B65D25/08, A61K9/00, B01F3/12,
A61L33/12

Language of the proceedings: EN

Title of invention:
Medical device comprising a haemostatic agent and haemostatic
kit comprising the medical device

Applicant:
Ferrosan Medical Devices A/S

Headword:

Relevant legal provisions:
EPC Art. 76(1), 56

Keyword:
Added subject-matter (yes, main and first auxiliary requests)
Inventive step (no, second to seventh auxiliary requests)

Decisions cited:
T0591/90

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T1676/11 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 26 June 2012

Appellant: Ferrosan Medical Devices A/S
(Applicant) Sydmarken 5
2860 Søborg (DANEMARK)

Representative: Noergaard, Jens Viktor
Høiberg A/S
St. Kongensgade 59 A
1264 Copenhagen K (DANEMARK)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 3 March 2011 refusing European patent application No. 09159082.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: P. Gryczka
Members: R. Pérez Carlón
D. Rogers

Summary of Facts and Submissions

- I. The present appeal lies from the decision of the examining division to refuse European patent application No. 09 159 082.8, which is a divisional of European patent application No. 02 790 278.2.
- II. The examining division considered in the contested decision that the claimed subject-matter of all the requests then pending lacked an inventive step.
- III. *Inter alia*, the following documents had been cited:
- D1: US A 5 743 312
 - D3: Hill, Kalantarian and Jones, *J. Thorac. Cardiovasc. Surg.* **1994**, vol 108, pages 1151-1152, and
 - D5: WO A 99/44901
- IV. The applicant appealed this decision and requested that a patent be granted upon the basis of the main request, or upon the basis of one of auxiliary requests 1 to 5 filed with the grounds for appeal. The appellant also submitted that the examining division infringed its right to be heard by not allowing sufficient opportunity to comment on D5 as closest prior art.
- V. With the summons to oral proceedings, the board informed the appellant that it should be prepared to discuss, *inter alia*, whether the feature "void volume" found a basis in the parent application as originally filed.
- VI. Under cover of a letter dated 24 May 2012, the appellant filed a new main request and auxiliary

requests 1 to 7.

VII. During the oral proceedings held before the board on 26 June 2012, the appellant withdrew its objection that a procedural violation occurred before the examining division. Two auxiliary requests were filed, labelled as fourth and fifth auxiliary requests, which replaced the previous fourth and fifth auxiliary requests filed under cover of a letter dated 24 May 2012.

VIII. Claim 1 of the requests upon which this decision is based read as follows:

Main request:

"A medical device for preparing a haemostatic paste, consisting of:

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

wherein the containment unit further comprises at least one opening to an external environment and at least one closure-unit for closing the at least one opening, and

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

wherein said sterile haemostatic agent is capable of forming a putty-like paste in the presence of a third volume of liquid; 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 third volume of liquid from an external environment to the sterile haemostatic agent in powder form through the at least one opening and mixing of the sterile haemostatic agent in powder form and the added liquid within the containment unit without present exposure to an environment external to that of the containment unit." (Highlighting added by the board).

Claim 1 of the first auxiliary request contains, instead of the feature highlighted in claim 1 of the main request, the feature "*wherein the remaining internal volume is a void volume allowing for the addition...*"; it differs hence from claim 1 of the main request in that the feature "at least 10%" has been deleted.

Claim 1 of the second auxiliary request differs from claim 1 of the main request in that the passage highlighted is replaced by the wording "*wherein the remaining internal volume allows for the addition...*". The features "at least 10%" and "void" have been, hence, deleted.

Claim 1 of the third auxiliary request differs from claim 1 of the main request in that the passage highlighted above is replaced by "*wherein the volume difference between the first internal volume and the second internal volume allows for the addition...*".

Claim 1 of the fourth auxiliary request contains the wording of the second auxiliary request, closer defines the containment unit as in feature i) as *"the containment unit and the closure unit being made from a material selected from polyethylene, polypropylene, PVC and PET"* and restricts *"the containment unit further comprises a single opening to an external environment and one closure-unit for closing the opening"*.

Claim 1 of the fifth auxiliary request differs from claim 1 of the fourth auxiliary request in that the feature *"wherein said outer packaging is able to endure radiation sterilisation at 3.5 Mrad (Beta) with a bioburden of less than 100 CFU/unit"* has been added to feature iii).

Claim 1 of the sixth auxiliary request reads:

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

A) removing the outer packaging of the medical device consisting of:

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

wherein the containment unit further comprises at least one opening to an external environment and at least one closure-unit for closing the at least one opening, and

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

internal volume of the containment unit;

wherein said sterile haemostatic agent is capable of forming a putty-like paste in the presence of a third volume of liquid; and

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

B) opening the containment unit to the external environment,

C) adding a sterile liquid to said containment unit, by pouring the liquid through the at least one opening of the containment unit;

D) closing the at least one opening of the containment unit by the closure-unit, and

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

Claim 1 of the seventh auxiliary request contains, additionally to the wording of claim 1 of the sixth auxiliary requests, the feature "*the containment unit and the closure unit being made from a material selected from polyethylene, polypropylene, PVC and PET*", after feature A.i).

IX. The arguments of the appellant can be summarised as follows:

As a basis for the feature "void volume", the appellant cited the disclosures on page 4, lines 17-18, 20-21 and 25-28, page 8, lines 30-31 and 37-39 and page 6, lines 11-13 of the parent application. A volume difference allowing for the addition of a liquid into the container necessarily implied the presence of a void volume in said container.

Turning to inventive step, D3, which was the closest prior art, differed from the subject-matter of claim 1 of the second and third auxiliary requests in that it did not disclose an amount of less than 90% of the haemostatic agent in the jar, and in that an outer packaging was not provided. The problem solved by the claimed invention was to provide a device which allowed for the rapid, simple and sterile preparation of a haemostatic mixture. The disclosure of D3 was so unclear that the skilled person would not consider modifying its teaching, and even if he would, the solution of D3 was the use of a different haemostatic agent. As secondary indicia of the presence of an inventive step, the appellant mentioned that seven years had elapsed between D3 and the priority of the present application, the commercial success of the medical device claimed, and that said device had been approved by the FDA (Food and Drug Administration) and EMA (European Medicines Agency). Before the present invention, Gelfoam was commercialised in jars which were full; the claimed device allowed for a simplification in its use. The materials subject-matter of claim 1 of the fourth and fifth auxiliary requests could be sterilised by Beta irradiation, were less prone to breakage and lighter. The methods subject-matter of the sixth and seventh auxiliary requests, additionally, provided reproducibility in the preparation of the hemostatic paste which could not be

- achieved when following the teaching of D3. For these reasons the claimed subject-matter involved an inventive step.
- X. The appellant requested that the decision under appeal be set aside and that a patent be granted upon the basis of the claims of the main request, or alternatively upon the basis of the claims of any of auxiliary requests 1 to 7, the main request and auxiliary requests 1, 2, 3, 6 and 7 having been filed under cover of a letter dated 24 May 2012, and auxiliary requests 4 and 5 having been submitted at the oral proceedings before the board on 26 June 2012.
- XI. At the end of the oral proceedings, the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request, first auxiliary request, Article 76(1) EPC:

2. The present application is a divisional application from the parent application No. 02 790 278.2. For the requirements of Article 76(1) EPC to be fulfilled, it is necessary that the content of the application does not go beyond the content of the parent application as filed.

In order to determine whether or not the subject-matter of the amended claims offends against Article 76(1) EPC, it has to be examined whether technical information has been introduced which a skilled person would not have objectively and unambiguously derived from the parent application as filed, either explicitly

or implicitly.

3. Independent claim 1 of the main request and of the auxiliary request 1 contain the feature "wherein the remaining volume [...] of the internal volume is a *void volume* allowing for the addition..."

The appellant acknowledged that this feature cannot be found, *expressis verbis*, in the parent application, but concluded that a "void volume" was implicitly disclosed therein, since otherwise the adding and mixing steps required when using the claimed device could not be carried out.

The passages cited by the appellant as a basis in the parent application disclose that:

- the second volume (which corresponds to the volume of the haemostatic agent) represents from 10% to 90% of the first internal volume (volume of the containment unit); page 4, lines 17-18 and 25-28;
- the second volume is a subset within the first internal volume (page 4, lines 20-21);
- the relative volume of the second volume relative to the first volume is suitable for adding a third volume of liquid and for said liquid to be evenly and easily physically dispersed (page 8, lines 30-31 and 37-39); and
- the volume difference allows for adequate addition of a third volume and mixing of the volumes (page 6, lines 9-13).

4. The presence of a void volume is not the clear and unambiguous consequence of what is explicitly mentioned in the passages cited by the appellant. It is not disputed that a "void volume" could be a possible embodiment which fulfills the requirements set out in the passages cited by the appellant, but it is not the only one. Only as an example, a syringe of a first internal volume filled with less than 90% of a haemostatic agent (second internal volume) fulfills the limitations listed under point 3, above. However, the remaining volume, which would allow for the mixing of the haemostatic paste and a third volume of a liquid, is not a void since it is filled by the plunger of the syringe. The presence of a void volume is, thus, not the necessary and immediate consequence of the features of the parent application and is, therefore, not implicitly disclosed in said parent application.

5. Since the feature "void volume" has not been disclosed, either implicitly or explicitly, in the parent application, the subject-matter of the main and first auxiliary requests extends beyond the content of the parent application as originally filed (Article 76(1) EPC), with the consequence that the main request and the first auxiliary request are not allowable.

Auxiliary requests 2-7:

6. Claim 1 of these requests does not contain the expression "void volume". Since the board arrived to the conclusion that the subject-matter of these requests was not patentable, it is not necessary to further investigate whether they included added subject-matter.

7. Novelty was not objected to in the contested decision and the board sees, on the basis of the prior art documents on file, no reason to raise such an objection.

Auxiliary request 2, Article 56 EPC:

8. Closest prior art:

8.1 The board agrees with the applicant and the examining division that document D3 represents the closest prior art.

8.2 Document D3 describes the preparation, in an operating theater, of a hemostatic agent whereby thrombin mixed with 10 mL diluent was placed in a Gelfoam jar, the lid replaced and the contents agitated. Thus, document D3 discloses a jar of Gelfoam (a haemostatic agent according to the invention) to which at least 10 mL of diluent could be added, with a lid which can be replaced, and enough void space to carry out the mixing of its contents (see page 1, second full paragraph, first three lines).

8.3 It is undisputed that D3 does not disclose

- whether the volume of haemostatic agent in the jar amounts to less than 90% of its total volume, and
- an outer packaging defining a sterile area.

8.4 The appellant has argued that the disclosure of document D3 was unclear, since it was not indicated whether the Gelfoam jar already contained Gelfoam before adding thrombin and diluent or whether it was empty. In this later case, D3 would merely disclose an empty Gelfoam jar with a lid.

The board is, however, of the view that the disclosure of D3 should be read trying to give to it a logical technical sense. It is not reasonable that, in order to prepare an haemostatic paste, a surgeon in an operating theater would add the diluent to a Gelfoam jar which did not contain the haemostatic agent.

- 8.5 The appellant has further argued that, according to the method disclosed in D3, part of the Gelfoam powder needed to be removed from the jar to allow for the addition of diluent, since D3 mentions "the difficulty of removing the Gelfoam powder" (page 1, second paragraph, second sentence).

However, claim 1 of the second auxiliary request is directed to a device and not to a process. Therefore, the fact that the disclosed Gelfoam jar was obtained in D3 by the alleged step of removing a part of the powder is irrelevant.

- 8.6 The appellant also argued that document D3 disclosed two different embodiments with different haemostatic agents, i. e. "Gelfoam" and "Avitene": the skilled person would not further develop a Gelfoam jar but a jar of Avitene, since the authors of D3 considered the later the best option.

However, it is the first embodiment described in D3, i.e. "Gelfoam", which has the largest number of features in common with the claimed subject-matter. D3 identifies the problem underlying the present invention, namely the possibility of contamination in connection with this first embodiment. As such, this embodiment represents the most promising springboard, and is, hence, the closest prior art.

9. Technical problem underlying the invention:

The appellant defined the problem underlying the present invention as that of providing a device allowing for the rapid, simple and sterile preparation of a haemostatic mixture (page 1, lines 6-8 and page 4, lines 5-6 of the application as originally filed).

10. Solution:

The appellant claims, as a solution to this problem, the medical device subject-matter of claim 1, which is characterised in that it includes an outer packaging defining a sterile area and a relative volume of haemostatic agent of less than 90% of the container.

11. Success:

An outer sterile packaging will necessarily improve the sterility of the haemostatic agent. The improvement in sterility of the final product with respect to the jar disclosed in document D3 is, hence, credible. There are no doubts that the preparation of the haemostatic agent using the device subject-matter of claim 1 is simple and fast.

Thus, the board is satisfied that the technical problem underlying the claimed invention is credibly solved by the medical device subject-matter of claim 1.

12. Finally, it remains to be examined whether the claimed solution was obvious for the person skilled in the art.

12.1 Document D3 already recognises the problem of contamination (D3, second paragraph, second sentence). It was known in the art, for example from D1, that

placing a medical device in an outer packaging defining a sterile barrier seal provides sterility to the content and the device itself (see figure 2 and column 4, lines 47-52). It was, thus, obvious for the skilled person to add to the jar known from D3 an outer packaging defining a sterile barrier in order to obtain a sterile device which allowed a fast and easy preparation of the hemostatic mixture.

12.2 As acknowledged above, document D3 does not explicitly mention whether the amount of Gelfoam is less than 90% of the volume of the jar. Document D3, however, describes that 10 mL of saline had been added to the jar, so that an empty space had to be present in said jar. Determining the volume of the empty space required for adding and mixing the diluent falls within the routine task of the person skilled in the art. This difference does not add any additional teaching to the disclosure of D3, in particular since the sole purpose of limiting the amount of haemostatic agent to less than 90% of the total volume is to allow the addition of diluent and mixing of the contents.

12.3 Therefore, the device according to claim 1 of the second auxiliary request is not inventive over the combination of the teaching of document D3 and of document D1.

13. The appellant has argued that the lack of detailed information in document D3 rendered said document unclear and not enabling and would dissuade the skilled person from carrying out any modification to its teaching.

The board is, however, of the view that the disclosure of D3, despite its lack of detail, offers the skilled

person sufficient information about the device used therein. Furthermore, document D3 already identifies the problem of contamination, so the skilled person would indeed attempt to modify the teaching of D3 in order to solve said problem. The present case is not comparable with the case at issue in decision T 591/90 (not published in the Official Journal of the EPO), mentioned by the appellant, in which the board dealt with an erroneous disclosure in a prior art document. In this case, the disclosure of D3 is not erroneous.

14. The appellant mentioned that document D3 taught a different solution, namely the use of a different haemostatic agent, and never addressed the possibility of modifying how Gelfoam was used or packaged.

The authors of document D3 are members of the Department of Surgery of the West Virginia University School of Medicine and refer to results obtained in an operating theater. The authors of D3 are not manufacturers and use for their purpose commercial sources of haemostatic agents. For these reasons, they turned their attention to other commercial materials which could be more suitable for their goals. However, the skilled person in the field of the present application, namely the manufacturing of medical devices, has a different approach and would be capable of modifying the devices disclosed in D3.

15. The appellant further argued that there was no motivation to use a sterile wrapping starting from D3. As explained before, the board sees this motivation in the disclosure of document D3 itself, which already recognises the risk of contamination when using Gelfoam jars.

16. The appellant also argued that even adding an external sterile packaging to the jar of D3 would not lead to the subject-matter claimed, since some of the Gelfoam powder needed to be removed from the full jar disclosed there to arrive at the claimed medical device.

This argument must, however, be rejected since D3, as explained before (see point 8.5), discloses a jar with a void volume which allows for the addition of the diluent and the mixing.

17. The appellant also mentioned, as secondary indicia of the presence of an inventive step, the commercial success of the product, the fact that 7 years had elapsed between the publication of D3 and the priority of the application, and that the product had been approved by the FDA and the EMA.

Commercial success can be due to various factors such as marketing and not only to the inventiveness of the solution. In order to approve a medical device, the relevant government agencies do not require that it involves an inventive step, but rely on different requirements. Finally, the time elapsed between the publication of D3 and the priority of the present application does not necessarily prove an inventive step, since other reasons such as commercial strategies could have been involved.

These arguments of the appellant therefore fail to convince the board.

18. Thus, the subject-matter of claim 1 of the second auxiliary request is not inventive (Article 56 EPC) and the second auxiliary request is therefore not

allowable.

Third auxiliary request, Article 56 EPC:

19. Claim 1 of the third auxiliary request differs from that of the second auxiliary request in that the wording "wherein the remaining internal volume allows for the addition..." has been replaced by "wherein the volume difference between the first internal volume and the second volume allows for the addition...". As acknowledged by the appellant, the amendment serves to define in different terms the volume difference, but does not alter the inventive step analysis with respect to claim 1 of the previous request, since the claimed device remains essentially the same. The subject-matter of the third auxiliary request is, therefore, not inventive for the same reasons already explained for the second auxiliary request.

Fourth auxiliary request, Article 56 EPC:

20. Claim 1 of this request contains the wording of claim 1 of the second auxiliary request and, additionally, the feature "the containment unit and the closure unit being made from a material selected from polyethylene, polypropylene, PVC and PET".

As recognised by the appellant during the oral proceedings before the board, the plastic materials defined in claim 1 of the fourth auxiliary request had been frequently used in the art before the priority date of the application. Therefore, the mere fact that the containment unit and the closure unit are made of these materials is an obvious alternative for the skilled person.

The appellant explained that the use of plastic allowed an easier sterilisation via Beta irradiation, the containers were less prone to breakage and lighter. However, these advantages do not go beyond the well known properties of plastic containers. This line of argument must therefore be rejected.

The subject-matter of the fourth auxiliary request is thus not inventive in the sense of Article 56 EPC and is, therefore, not allowable.

Fifth auxiliary request, Article 56 EPC:

21. In addition to the features of the previous request, claim 1 of the fifth auxiliary request contains the limitation "wherein said outer packaging is able to endure radiation sterilisation at 3.5 Mrad (Beta) with a bioburden of less than 100 CFU/unit".

This functional feature merely restricts the material of the outer packaging, not the sterilisation method. The description mentions that PET fulfills the conditions subject-matter of claim 1 of the fifth auxiliary request (see page 8, line 18).

As explained with respect to the fourth auxiliary request, the application as filed does not disclose any particular effect linked to the use of PET, and the appellant could not provide any advantage which could go beyond those well established in the art for said material. The appellant also recognised that these materials were well known in the medical field.

Therefore, the material of the outer packaging as defined by the subject-matter of claim 1 of the fifth auxiliary request is an obvious alternative for the

person skilled in the art, and this additional distinguishing feature does not provide an inventive step to the subject-matter claimed.

The fifth auxiliary request is, therefore, not allowable since its subject-matter is not inventive in the sense of Article 56 EPC.

Sixth auxiliary request, Article 56 EPC:

22. Claim 1 of the sixth auxiliary request is directed to a process for preparing a haemostatic paste using the medical device subject-matter of claim 1 of the second auxiliary request. Since said device does not involve an inventive step (see points 8-18 supra), the process claimed could only be inventive if the process steps *per se* would be based on an inventive activity.

23. Closest prior art:

Document D3, which remains the closest prior art, discloses a process for preparing a haemostatic paste comprising adding a sterile liquid to a containment unit containing the haemostatic paste by pouring said liquid through the opening of said containment unit, closing the containing unit, and mixing after replacing the lid, thus avoiding exposing the haemostatic agent and the liquid to the environment external to the containment unit. Opening the containment unit to the external environment is not explicitly mentioned in D3, but it is implicit that the containment had been opened before adding the liquid in the light of the wording "replaced the lid" (page 1, second paragraph, line 2).

Document D3 fails to disclose the following features of

claim 1 of the sixth auxiliary request:

- the step of removing the outer packaging of the medical device (feature A, first sentence),
- that the sterile haemostatic agent in powder form in the containment unit has a volume of less than 90% of the first internal volume of the containment unit (feature A.ii, first paragraph), and
- that the medical device has an outer packaging defining a sterile barrier seal enclosing said containment unit (feature A.iii).

24. Technical problem underlying the invention:

In the light of the prior art, the problem to be solved by the subject-matter of claim 1 of the sixth auxiliary request is to provide a rapid, simple and sterile process for the preparation of a haemostatic paste.

25. Solution:

The appellant claims, as a solution to this problem, the process subject-matter of claim 1 of the sixth auxiliary request, characterised in the step of removing an outer packaging from a medical device, said outer packaging defining a sterile barrier, in which the sterile haemostatic agent has a volume of less than 90% of the volume of the container.

26. Success:

For the reasons already explained (see point 11, above) with respect to the corresponding medical device, the problem posed is considered solved by the process subject-matter of claim 1 of the sixth auxiliary

request.

27. Finally, it remains to be examined whether the claimed solution was obvious for the person skilled in the art.

The process steps of claim 1 merely reflect the obvious steps for using the non inventive device of the second auxiliary request. As already explained before (see point 12 supra), an external outer packaging defining a sterile barrier seal (feature A.iii) is an obvious option for improving sterility, and the step of removing said non-inventive outer packaging (feature A, first sentence) is, for the same reasons, obvious for the person skilled in the art. Feature A.ii) merely limits the amount of haemostatic agent so that the diluent could be added, and determining the amount of empty space needed falls within the normal skills of the person of the art (see reasons in point 12.2 above).

The sixth auxiliary request is, therefore, not allowable because the subject-matter of claim 1 does not fulfill the requirements of Article 56 EPC.

28. The appellant argued in favour of this request that the process subject-matter of its claim 1 allowed better reproducibility, since a part of the haemostatic agent, i. e. Gelfoam powder, did not need to be removed from the jar when the containment unit comprised less than 90% by volume of said powder.

However, this advantage is also achieved in the closest prior art, since the Gelfoam jar to which the diluent is added is not full but allows the direct addition of the diluent (see point 12.2) above. An inventive step cannot therefore be based on this known feature.

Additionally, removing a part of the Gelfoam from the container is not excluded from claim 1 in the light of the wording "comprising". This argument must therefore be rejected.

Seventh auxiliary request, Article 56 EPC:

29. Analogously to claim 1 of the sixth request, the subject-matter of the seventh auxiliary request is directed to obvious process steps for using the non-inventive medical device subject-matter of claim 1 of the fourth auxiliary request and is, for the same reasons already explained with respect to the fourth and sixth auxiliary requests, not inventive in the sense of Article 56 EPC.

30. The board concludes, therefore, that none of the requests on file 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