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**Datasheet for the decision
of 2 May 2023**

Case Number: T 0867/20 - 3.3.10

Application Number: 14747181.7

Publication Number: 3019205

IPC: A61L15/26, A61L15/44, A61L15/64

Language of the proceedings: EN

Title of invention:
HEMOSTATIC PAD ASSEMBLY KIT AND METHOD

Patent Proprietor:
Ethicon, Inc

Opponent:
Baxter International Inc.

Headword:

Relevant legal provisions:
EPC Art. 123(2), 54, 56
RPBA 2020 Art. 13(2)

Keyword:

Amendments - allowable (yes)

Novelty - (yes)

Inventive step - (yes)

Amendment after summons - exceptional circumstances (no)

Decisions cited:

Catchword:



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Case Number: T 0867/20 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 2 May 2023

Appellant: Baxter International Inc.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
23 January 2020 concerning maintenance of the
European Patent No. 3019205 in amended form.

Composition of the Board:

Chairman A. Zellner
Members: M. Kollmannsberger
L. Basterreix

Summary of Facts and Submissions

- I. The opponent's appeal lies from the decision of the Opposition Division to maintain the patent in amended form under Article 101(3) (a) EPC based on the patent proprietor's main request submitted during opposition proceedings.
- II. The following documents are referred to in this decision:
- D1: US 4,002,173
D2: US 2002/0015724 A1
D3: US 2010/0172958 A1
D9: Instructions for Gelfoam® Plus Hemostasis Kit, revision date 01/2011
D17: Goodchild J. H., Donaldson M., An Evidence-Based Dentistry Challenge: Treating Patients on Warfarin (Coumadin), Dent Implantol Update 2009 Jan; 20(1); 1-8
- III. In the contested decision the Opposition Division came i. a. to the following conclusions:
- (a) The splitting up of granted independent process claim 1 into three independent process claims using different distinguishing features was an appropriate reaction to the novelty objection re D1 and not objectionable under Rule 80 EPC.
- (b) The objections raised under Article 123(2) EPC against independent claims 1, 2, 3 and 8 as well as against the dependent claims were not valid.

(c) The independent claims were novel over D1, D2 and D3.

(d) Regarding inventive step the closest prior art for claims 1, 2 and 3 was D1 whereas the closest prior art for the device claim 8 was D9. The claimed subject-matter was inventive starting from these documents.

IV. In its ground of appeal the appellant contested each of these findings. It requested the impugned decision to be set aside and the patent to be revoked.

V. With its reply to the appellant's grounds of appeal the respondent (patent proprietor) requested the appeal to be dismissed. As auxiliary requests it filed 56 claim sets for maintenance of the patent in amended form based thereon.

VI. On 18 July 2022 the parties were summoned to oral proceedings. A communication under Article 15(1) RPBA 2020 was issued on 12 January 2023. Oral proceedings took place on 2 May 2023.

VII. The final request of the respondent was to set aside the impugned decision and to maintain the patent in amended form based on auxiliary request 32. All higher ranking requests were withdrawn.

VIII. The appellant's final request was to set aside the impugned decision and to revoke the patent.

IX. The independent claims of auxiliary request 32 read as follows:

Claim 1:

"A method of making a hemostatic wound treatment pad comprising a bioabsorbable scaffold having one or more layers constructed from materials selected from oxidised polysaccharide, bioabsorbable synthetic polymer or combinations thereof, and having a wound facing surface and an opposing surface; said scaffold wetted with a biocompatible liquid that is not blood or plasma selected from the group consisting of water, an aqueous solution, normal saline, ethanol, and ethanol-water mixture; and a hemostatic powder that adheres by moisture to at least the wound facing surface of said bioabsorbable scaffold;

the method comprising:

- a) wetting the scaffold with the biocompatible liquid; and
- b) contacting the scaffold with the hemostatic powder and adhering at least a portion of the hemostatic powder to at least the wound facing surface of the scaffold;

wherein the hemostatic powder is dry fibrinogen, or dry thrombin, or a mixture of dry fibrinogen and dry thrombin."

Claim 5:

"A prep kit for a hemostatic wound treatment pad comprising:

- a) at least one powdered hemostatic material;
- b) a bioabsorbable scaffold wherein said bioabsorbable scaffold is selected from a bioabsorbable polysaccharide, a bioabsorbable synthetic polymer, or a combination thereof;
- c) a biocompatible liquid selected from the group consisting of water, an aqueous solution, a normal saline, a thrombin solution, a fibrinogen solution, ethanol, and an ethanol-water mixture;
- d) an application tray; and

e) a means for wetting said bioabsorbable scaffold with said liquid wherein said means for wetting is: (1) a liquid transfer pad optionally wherein said liquid transfer pad comprises a bundle of surgical gauze; (2) a spray bottle; (3) a transfer pen; or (4) a liquid tray having size accommodating immersion of said bioabsorbable scaffold with the wound facing side facing into said liquid tray; wherein components a) to e) are combined into a unitary packaging unit."

X. The appellant's essential submissions with respect to the claims of this request were the following:

The claims defined subject-matter extending beyond the application as originally filed, Article 123(2) EPC. In particular, in method claim 1 the original use step had been deleted and no feature was in the claim that would require the hemostatic pad to be suitable for immediate use. Furthermore, the definition of the liquid as water was not based on the original disclosure and the claim was lacking a definition of "dry" as defined in paragraph [011] of the description. Regarding claim 8 the appellant objected to the combination of features (b) and (c) with feature (e) as not being originally disclosed. Moreover, the appellant objected to the combination of bioabsorbable scaffolds and bioabsorbable liquids in this claim.

Method claim 1 was not novel over D2, in particular over the method disclosed in paragraph [0118]. The suspended fibrinogen particles filtered through the sponge could be read on the hemostatic powder of the method defined in the claim.

The method defined in claim 1 was not inventive when starting from D1, example 21. The replacement of the hemostatic powder used in D1 by dry fibrinogen or dry thrombin would have been obvious to a skilled person.

The prep kit defined in claim 5 was not inventive over the prep kit disclosed in D9/D17. The claimed prep kit differed only in the nature of the scaffold and in the wetting means in feature (e); both of these differences were obvious alternatives for a skilled person.

XI. The respondent's essential submissions with respect to the claims of this request were the following:

The claims were based on the original disclosure. All of the features objected to by the appellant were directly and unambiguously derivable from the original application documents.

Claim 1 was novel over D2. A fibrinogen suspension did not read on the feature "*dry fibrinogen*" of the claim.

The method defined in claim 1 was inventive over D1. A skilled person would not have replaced the hemostatic powder used in D2 by dry fibrinogen or dry thrombin, as defined in the claim.

The prep kit defined in claim 5 was inventive over the prep kit of D9/D17. This prep kit did not have an application tray as defined in the claim and a skilled person would not have had any reason to add one.

XII. The decision was announced at the end of the oral proceedings.

Reasons for the Decision

1. The appeal is admissible

2. Amendments, Article 123(2) EPC

For the original disclosure reference is made to the published PCT application, WO 2015/006088 A1.

2.1 Claim 1

Claim 1 defines a method for making a hemostatic pad and is based on original claim 12.

2.1.1 Original claim 12 relates to a method of making and using a wound treatment pad. It defines three steps, the last one being the application of the wound treatment pad to the wound. For compliance of the claim with Article 53(c) EPC this step has been omitted in method claim 1 together with the reference to the use in the preamble.

The appellant objected to the omission of the use step. In particular it argued that the claim did not contain any technical feature defining the suitability of the pad prepared in steps (a) and (b) for immediate use. Following the instructions in the description the pad however had to be used immediately. Paragraph [014] defined a maximum period of two minutes, and according to paragraph [028] the application was immediate. Amended claim 1 was not limited to in-situ usable pads and extended thus beyond the original disclosure.

This objection is not convincing. Original claim 12 does not require immediate use of the assembled pad. Neither does the description state this to be mandatory. As outlined in paragraph [025], the first paragraph of the detailed description of the invention, the original invention relates in item (iii) to a method of assembling a hemostatic pad, and, separately, in item (iv) to a method of using the pad. The passage referred to by the appellant, paragraph [014], does relate to a method of making and using the pad, however, this does not mean that a method of assembling alone is not originally disclosed, e. g. in paragraph [025].

2.1.2 Claim 1 was limited to methods for preparing pads where the hemostatic powder is dry fibrinogen, dry thrombin or a mixture thereof. These powders are disclosed in original claims 2-4. The appellant argued that, since these claims did not relate to a method, but to a device as such, these features could not be introduced into the method claims. On the other hand, if these features were taken from paragraph [011] of the description, where they were disclosed in relation to the method of preparing the device, the definition of "dry" mentioned in this paragraph should have been introduced into the claims as well.

The Board disagrees. It is clear from the application as originally filed, e. g. from method claim 12 referring back to device claim 1, that the devices and the methods for their preparation are linked. Thus, defining the hemostatic powder mentioned in original method claim 12 specifically as set out in original claims 2-4 does not add any originally undisclosed information.

2.1.3 The appellant objected to the feature "water" as biocompatible liquid. Original claim 5 did not include water as such in the list of biocompatible liquids, only aqueous solutions.

However, the disclosure of water as a biocompatible liquid in the context of the prep kit in par. [015] provides a basis for defining water also in claims directed to the preparation of pads. The application as a whole makes it clear that the prep kit and the pad relate to the same invention.

2.2 Claim 5

Claim 5 is directed to a prep kit for a hemostatic pad comprising features (a) to (e) and is based on original claim 14. Feature (e) is disclosed in original claims 19 and 20.

2.2.1 The appellant objected in particular to the combination of features (b) and (c) with feature (e). It argued that these features were not interrelated in the original claim set. If taken from paragraph [015] of the description, various features which are presented there as obligatory are not recited in the claim. This was the case e. g. for surgical gauze present in the liquid transfer pad in feature (e) and the layer structure of the scaffold materials. Also, paragraph [015] did not include the wetting means (e) as a part of the unitary packaging; it referred to features (a) to (d) only. Moreover, ethanol for (c) was not mentioned there at all.

It is uncontested that feature (e) is disclosed in original claims 19 and 20, which refer back to original claim 14. Original claim 14 discloses all of features

(a) to (d), albeit features (b) and (c) in a more general way. Features (b) and (c), the materials making up the scaffold and the liquid, have been defined more specifically according to the description or according to dependent claims; the materials for feature (b) are also disclosed in original claim 23.

The Board considers this to be allowable. Introducing specific definitions for different parts of the prep kit defined in original claim 14 from dependent claims on the one hand and from the description on the other hand does not add originally undisclosed subject-matter. The different possibilities for the wetting means (e) in original claims 19/20 and the definitions of the scaffolds (b) and the liquids (c) are each originally presented as preferred. Ethanol, specifically mentioned by the appellant, is mentioned e. g. in paragraph [012]. The materials for the scaffold (b) are disclosed in original claim 23 without any limitation on their physical structure. The inclusion of the wetting means (e) inside the kit follows directly from a combination of original claims 14, 19 and 20. There is no disclosure that, for technical or other reasons, certain preferred wetting means (e) may be used together with only some of the preferred liquids (c) or scaffolds (b). A combination of these preferred features does not add originally undisclosed information.

- 2.2.2 The appellant also objected to the combination of bioabsorbable scaffolds (b) and bioabsorbable liquids (c). In its view the combination from original claims 16 and 23 results in the "singling out of an arbitrary combination of features".

However, this is not the case. The two lists are still generic, so nothing has been singled out. The well-known two-list principle only applies in case the selection from such lists results in a specific, hitherto undisclosed combination.

3. Novelty, Article 54 EPC

D2 discloses in paragraphs [0117] and [0118] the preparation of a hemostatic sponge. A suspension of thrombin and a suspension of fibrinogen is filtered through the sponge, thus loading the sponge with the hemostatic material.

The appellant considers that the filtering of the suspensions through the sponge in D2 can be read on the feature requiring the hemostatic powder to adhere by moisture to at least the surface of the scaffold as defined in the claims. The appellant argued in particular that the claims did not require the hemostatic powder to be in a flowable or otherwise powder-like shape. According to paragraph [0011] of the patent, only a particulate form having a water content of less than 4% by weight was required. This was also fulfilled by the suspensions disclosed in D2, in particular since the thrombin was suspended in 100% alcohol.

The Board follows the Opposition Division's assessment in that the suspensions used in D2 cannot be read on the "*hemostatic powder*" in the claims, see point 3.2 of the reasoning. The claims require the wet scaffold to be contacted with a powder, not with a suspension as disclosed in D2. A suspension is not a powder, even if it contains material in particulate form.

4. Inventive step, Article 56 EPC

4.1 Method claim 1

4.1.1 It was uncontested that example 21 of D1 represents the closest prior art for the method claim. Example 21 of D1 discloses a method during which amylose succinate powder is sprinkled on a crosslinked amylose succinate sponge. The sponge so obtained is, after drying, used for hemostatic tests.

4.1.2 The method defined in claim 1 differs from D1 in the nature of the powder used. Dry fibrinogen or dry thrombin, or a mixture thereof, are used, whereas D1 uses amylose succinate.

4.1.3 Based on this difference the objective technical problem to be solved can be formulated as the alternative preparation of a hemostatic pad.

This problem has been solved by the claimed method, characterized by the use of dry thrombin or dry fibrinogen as hemostatic powder material.

This was likewise uncontested.

4.1.4 The appellant argued that the claimed powders would have been considered equivalent to the hemostatic materials in D1. Thrombin and fibrinogen were both known hemostatic agents.

4.1.5 The Board does not doubt that thrombin and fibrinogen are known hemostatic agents.

However, the decisive point is not whether dry fibrinogen or dry thrombin were known as hemostatic powders, but rather whether a skilled person would have applied such a powder to the cross-linked amylose scaffolds of D1. The Opposition Division has reasoned why this would not have been the case, see point 4.4 of the reasoning, and this reasoning is convincing.

D1 is directed to new materials, crosslinked polyglucan succinates or glutarates, which have hemostatic properties. These materials may be applied in sponge or in powder form, see column 2 line 65 to column 3 line 10. Improved hemostatic action may be obtained if the powder is additionally applied to the surfaces of the sponge, column 8 lines 10-22. Example 21 shows such an arrangement. Amylose succinate powder is immobilized on an amylose succinate sponge and the resulting composite material is tested for hemostatic activity.

A skilled person reading D1 would have considered example 21 to illustrate the hemostatic activity of the newly discovered materials, in different physical form. In the passage on page 8, lines 10-22 relating to powder application the purpose of adding the powder is explained. The additional presence of the powder allows the sponge to be removed, thus leaving only a minimum amount of hemostatic material behind at the bleeding site. The disclosure of the powder is closely linked to the nature of the newly provided materials; there is no disclosure in D1 that any type of hemostatic powder could be used for this purpose.

Thus, starting from D1 a skilled person would not have added dry thrombin or dry fibrinogen to the sponges in D1 when looking for an alternative method to prepare hemostatic pads.

- 4.1.6 Thus, the method defined in D1 is inventive over the cited documents.
- 4.2 Product claim 5
- 4.2.1 It was common ground that D9 represents the closest prior art for the prep kit defined in claim 8; also the Opposition Division assessed inventive step starting from this document. D9 is a package leaflet of a commercial product, GELFOAM[®] PLUS hemostasis kit. D17 further illustrates the device disclosed in D9.
- 4.2.2 The prep kit of D9 contains a Gelfoam sponge (bioabsorbable scaffold), thrombin powder (feature (a) of the claim), saline (feature (c) of the claim), and two syringes. The method of use of the prep kit is described in the fourth column of D9. Basically, the thrombin is dissolved in the saline solution, the reconstituted thrombin solution is aspirated into one syringe, ejected into a receptacle and combined with further saline from the second syringe. Then, the sponge is immersed in the thrombin solution and withdrawn.
- 4.2.3 Various differences of the prep kit defined in claim 5 and the one disclosed in D9/D17 were discussed during the proceedings.

It was uncontested that the material of the sponge is different. D9 uses gelatin while the claim requires polysaccharides or synthetic polymers.

It was likewise uncontested that the wetting means (feature(e)) is not disclosed in D9/D17. For the

wetting means in the claim, there are various possibilities, one of which is a "liquid tray".

The appellant argued that the cardboard package holding the components could be read on the feature "application tray". This feature was undefined and covered also the cardboard box since it could be used as a tray.

However, this cardboard box is just a package used to protect the kit. The cardboard box corresponds to the packaging unit combining the components (a) to (e) defined at the end of claim 5, not to the tray defined in feature (d). Moreover, the cardboard box cannot be seen as a tray useful in the preparation or application of the kit. In column 4 of D9 it is stressed various times that the preparation and application of the pad must be carried out under sterile conditions. The appellant argued that also a cardboard box could be sterilized, or that it could be used unsterilized under emergency conditions. Be this the case or not, this is not what is disclosed in D9 to a skilled person.

Thus, feature (d), the application tray, is not present in D9/D17.

In summary, the material of the scaffold (feature (a)), wetting means (feature (e)) and the application tray (feature (d)) are not disclosed in D9/D17.

- 4.2.4 The least ambitious technical problem to be solved that can be formulated starting from D9/D17 is the provision of an alternative prep kit useful for the preparation of a hemostatic device.

4.2.5 This problem has been solved by the prep kit defined in claim 5 which is characterized by the presence of an application tray, a wetting means as defined in feature (e) and a scaffold made of the materials defined in feature (a).

It was uncontested that the problem has been solved. The appellant argued that the claimed solution was obvious from the cited prior art.

4.2.6 The Board shares the view of the Opposition Division that the material of the scaffold as well as the provision of wetting means as defined in feature (d) does not involve any inventive activity. However, the Board also agrees to the conclusion of the Opposition Division that the addition of a further application tray (d) is not rendered obvious by the prior art, see point 4.5 of the reasoning.

The method carried out in D9 uses a receptacle, see points 9 and 10 in the fourth column of D9. This receptacle corresponds to the liquid tray defined as one of the wetting means in feature (e). Thus, the addition of a liquid tray to the kit is obvious. Likewise, the materials defined in the claim as scaffolds cover cellulose derivatives which are well known for this purpose.

However, the method of D9 does not require any further tray to be used. A skilled person would have seen no reason to add any further tray to the prep kit disclosed in D9/D17. The inclusion of the application tray (d) in the prep kit as defined in claim 5 is not rendered obvious by D9/D17.

- 4.2.7 Thus, the provision of the prep kit defined in claim 5 involves an inventive step when starting from D9/D17.
- 4.3 Starting from D4 as closest prior art document
 - 4.3.1 In its submission of 31 March 2023, about one month before the date of the oral proceedings, the appellant filed arguments why the claims of the patent as maintained as well as of the auxiliary requests lacked an inventive step when starting from D4.
 - 4.3.2 Admissibility of these arguments is subject to the provisions of Article 13(2) RPBA 2020. New arguments at this stage of the procedure are generally not admitted anymore, unless exceptional circumstances apply.
 - 4.3.3 The appellant did not invoke any exceptional circumstances. Instead, the appellant referred to point F.I of its statement setting out the grounds of appeal. There, it is stated that all inventive step attacks from the opposition proceedings, in particular the ones submitted with the notice of opposition, the preparatory statement for oral proceedings and in the oral proceedings itself, are maintained. Thus, in the appellant's view the arguments filed on 31 March 2023 were in fact already part of the appeal proceedings.
 - 4.3.4 The Board disagrees. The Opposition Division reasoned in point 4.1 of its decision why a skilled person would not have started from any of the documents invoked by the appellant during opposition proceedings other than the ones discussed in its decision. In particular it stressed that D4 did not disclose any method for the preparation of a kit, but just the use of a hemostatic device. This document could thus not be a valid

starting point for claims being directed to the preparation of a kit.

With the statement setting out the grounds of appeal the appellant did not argue that this assessment is wrong, i. e. why a skilled person would have started from D4 in the first place. It only argued that one could use any documents as a starting point, as long as this was feasible. However, the reasoning in the Opposition Division's decision that D4 was *not* a document feasible as a starting point of the inventive step analysis was not addressed.

The statement of grounds of appeal does not contain any detailed argumentation regarding lack of inventive step over D4. A general reference to submissions in opposition proceedings cannot replace such an argumentation, already because the arguments submitted during the opposition proceedings have been addressed in the Opposition Division's decision. It is this decision that is the subject of the appeal, Article 12(1) RPBA 2020, and the appeal must be substantiated with arguments reasoning why the decision was, in the appellant's view, erroneous.

- 4.3.5 The arguments filed with letter of 31 March 2023 were thus not already part of the appeal proceedings. They constitute an amendment of the appellant's appeal case which, in the absence of exceptional circumstances, is not admitted into appeal proceedings under Article 13(2) RPBA 2020.

5. In summary the claims of auxiliary request 32 fulfil the requirements of the EPC.

6. For the question of the adaptation of the description to the amended claims the case is remitted to the Opposition Division.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of the main request, claims 1 to 10, filed as auxiliary request 32 on 20 October 2020 with the reply to the grounds of appeal, and a description to be adapted.

The Registrar:

The Chairman:



L. Malécot-Grob

A. Zellner

Decision electronically authenticated