**Internal distribution code:**

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

**Datasheet for the decision of 2 February 2021**

**Case Number:** T 0962/18 - 3.3.10

**Application Number:** 10819241.0

**Publication Number:** 2480260

**IPC:** A61L15/16, A61L15/64, A61L27/00, A61F13/00, A61L15/28

**Language of the proceedings:** EN

**Title of invention:**
COMPOSITE LAYERED HEMOSTASIS DEVICE

**Patent Proprietor:**
Ethicon, Inc

**Opponent:**
Baxter Healthcare S.A.

**Headword:**

**Relevant legal provisions:**
EPC Art. 54(2), 84, 56

**Keyword:**
Novelty - (no) - main request
Clarity - (no) - auxiliary requests 1 to 3
Inventive step - (no) - (no) - auxiliary request 4 - (yes) - auxiliary request 5

**Decisions cited:**

**Catchword:**

Europäisches Patentamt
European Patent Office
Office européen des brevets

**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

**Case Number: T 0962/18 - 3.3.10**

# D E C I S I O N
# of Technical Board of Appeal 3.3.10
# of 2 February 2021

| | |
|---|---|
| **Appellant:** (Opponent) | Baxter Healthcare S.A.<br>Thurgauerstrasse 130<br>8152 Glattpark/Opfikon (CH) |
| **Representative:** | J A Kemp LLP<br>14 South Square<br>Gray's Inn<br>London WC1R 5JJ (GB) |
| **Respondent:** (Patent Proprietor) | Ethicon, Inc<br>U.S. Route 22<br>Somerville, NJ 08876-0151 (US) |
| **Representative:** | Kirsch, Susan Edith<br>Carpmaels & Ransford LLP<br>One Southampton Row<br>London WC1B 5HA (GB) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 7 February 2018 concerning maintenance of the European Patent No. 2480260 in amended form.** |

**Composition of the Board:**

| | |
|---|---|
| **Chair** | P. Gryczka |
| **Members:** | R. Pérez Carlón |
| | W. Van der Eijk |

## Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division on the maintenance of European patent No. 2 480 260 in the form of the main request then pending.

II. Notice of opposition was filed on the grounds of lack of novelty and inventive step (Article 100(a) EPC).

III. The documents filed during the opposition proceedings include the following:

D2 EP 0 815 879 A2
D4 US 2006/0051398 A1
D6 US 2009/0004455 A1
D11 US 5,795,584
D14 The Shorter Oxford English Dictionary on Historical Principles, Oxford University Press 1973, Volume I, page 1171

IV. Claim 1 of the main request before the opposition division corresponds to claim 1 of the patent as granted and reads as follows:

*"A hemostatic composite structure comprising:*
*a) a bioabsorbable fabric or non-woven substrate having at least two major oppositely facing surface areas and*
*b) a continuous non-porous polymer-based film that is laminated on one major surface of said substrate."*

V. The opposition division concluded that the hemostatic composite of claim 1 was novel over the composite disclosed in paragraphs [0078]-[0080] of D6, containing a mesh and a collagenic non-porous layer, since the

mesh, which was a substrate (a) according to claim 1 was not laminated on a surface of the non-porous collagenic layer (b), but embedded in it.

Document D2 was the closest prior art. The problem underlying the claimed invention was to provide a more handleable, stable and efficient hemostatic structure. The claimed solution, characterised by the fact that the substrate contained a non-porous film layer laminated on one of the surfaces, would not have been obvious for the skilled person, and was thus inventive.

VI. With the reply to the grounds of appeal, the respondent (patent proprietor) filed a main request corresponding to the main request before the opposition division, and auxiliary requests 1 to 10.

Claim 1 of auxiliary request 1 contains, in addition to the features of claim 1 of the main request, the following:

*"wherein the hemostatic composite device is obtainable by contacting one major surface of said substrate with said polymer-based film and heating the substrate and the film so that a portion of the substrate is adhered to the film."*

Claim 1 of the auxiliary request 2 contains all the features of claim 1 of the main request, adding

*"wherein the hemostatic composite device is obtainable by contacting one major surface of said substrate with said polymer-based film in a lamination system with a metal roller set to a temperature of 50-120°C and running at a rotating speed of 0.30 to 0.61 m per minute (1 to 2 feet per minute), and heating the*

*substrate and the film so that a portion of the substrate is adhered to the film."*

Claim 1 of the auxiliary request 3 contains all the features of claim 1 of the main request, adding

*"wherein the hemostatic composite device is obtainable by covering one side of said non-porous polymer-based film with a first silicon based release paper and contacting the other side of said film with one major surface of said substrate, placing a second release paper on the other surface of said substrate and placing the first release paper/film/substrate/second release paper structure in a lamination system with a metal roller set to a temperature of 50-120°C and running at a rotating speed of 0.30 to 0.61 m per minute (1 to 2 feet per minute), and heating the substrate and the film so that a portion of the substrate is adhered to the film."*

Claim 1 of auxiliary request 4 contains all the features of claim 1 of the main request adding

*"wherein the film layer is made from a polymer material having a glass transition temperature of less than 25°C."*

Claim 1 of auxiliary request 5 contains all the features of claim 1 of the main request adding

*"wherein the substrate contains oxidized regenerated cellulose and the continuous non-porous, top coat film is a copolymer comprising poly (ethylene diglycolate-co-glycolide)."*

VII. The arguments of the appellant relevant to the present decision were as follows.

The feature "is laminated" merely limited the claimed hemostatic composite by requiring it to be made of layers, joined together by any means. This was the meaning of the term which could be found in a dictionary (D14). The hemostatic composite disclosed in document D6 had all the features required by claim 1 of the main request, as it had two layers held together. The hemostatic composite of claim 1 of the main request was thus not novel.

Claim 1 of auxiliary requests 1 to 3 contained characteristics coming from the description of the patent application and defining the product by means of process features. It was however not clear what technical features were imparted to the hemostatic composite by the product-by-process features. The amended claim 1 of these requests lacked therefore clarity.

With respect to the hemostatic composite of claim 1 of auxiliary request 4, either D2 or D6 could be considered as the closest prior art for the assessment of inventive step. Starting from D6, the problem underlying the claimed invention would be to provide an alternative hemostatic composite. The claimed solution, characterised in that the non-porous film material had a glass transition temperature below 25°C, would have been obvious for a person skilled in the art, as D6 itself already contemplated materials which could have had the required glass transition temperature.

Claim 1 of auxiliary request 5 was not convergent with the higher-ranking requests and should thus not be

admitted into the proceedings. Document D6 was the closest prior art. The problem underlying the claimed invention was the provision of an alternative material. The claimed solution was characterised by the chemical nature of the components (a) and (b) of the hemostatic composite. It would have been obvious for the skilled person to use these materials having regard to D6 and D4. The claimed solution was thus not inventive.

VIII. The arguments of the respondent relevant to the present decision were as follows.

Claim 1 of the main request related to a hemostatic composite obtainable by the lamination process of a pre-formed film (b) and a substrate (a). Since the composite of D6 was not obtainable by any lamination method, the claimed hemostatic composite was novel.

The process features introduced in claim 1 of auxiliary requests 1 to 3 were clear to the skilled reader. The claimed composite could not be defined in a different manner since the product characteristics which were the inevitable result of these process features could not be clearly expressed.

Document D6 was the closest prior art for the subject-matter claimed in the auxiliary requests 4 and 5. The problem underlying the claimed invention was to provide a hemostatic composite having good processability and good handling properties. The solution was the composite of claim 1 of auxiliary request 4, characterised by having a glass transition temperature of less than 25°C. As there was no indication towards this feature, the skilled person would only have arrived at the claimed invention with the benefit of hindsight. The claimed hemostatic composite was thus

inventive.

The hemostatic composite of claim 1 of auxiliary request 5 was characterised by the chemical nature of components (a) and (b). Component (b) was only disclosed in the context of adhesion barriers (D4), not in connection with hemostasis. For this reason alone, the claimed solution would not have been obvious for the person skilled in the art and was thus inventive.

IX. Oral proceedings before the board of appeal took place on 2 February 2021.

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

- The appellant requested that the decision under appeal be set aside and that the European patent No. 2 480 260 be revoked.

- The respondent requested that the appeal be dismissed and the patent be maintained as upheld by the opposition division (main request) or, auxiliarily, according to one of auxiliary requests 1-10, filed with a letter dated 24 October 2018.

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

## Reasons for the Decision

1. The appeal is admissible.

2. Main request, novelty

2.1 Claim 1 of the main request relates to a hemostatic composite comprising (a) a bioabsorbable fabric or non-

woven substrate having at least two major oppositely facing surface areas and (b) a continuous non-porous polymer-based film that is laminated on one major surface of said substrate.

2.2 It is not disputed that document D6 discloses a haemostatic composite comprising a bioabsorbable non-woven substrate, preferably a collagen foam, and a non-porous polymer based film, preferably made of collagen, attached to it (example 2, [0082]-[0085]).

2.3 The respondent argued that the hemostatic composite structure according to claim 1 was novel since the non-porous layer of the hemostatic composite of D6 was neither

- continuous nor
- laminated on the collagen foam.

2.4 Feature "continuous [...] film"

The respondent argued that the reinforcement element of the non-porous collagen film (b) rendered this layer "discontinuous".

However, this argument cannot be followed. The feature "continuous" limits the film required by claim 1 by requiring it to extend without interruption on the surface of the substrate (a). It does not require it to be homogeneous.

Film (b) of the composite of example 2 of D6 extends without interruption on the surface of the absorbing layer and is thus "continuous", as required by claim 1. The feature "continuous film" therefore does not distinguish the claimed hemostatic composite from that

of D6.

2.5 Feature "film that is laminated"

2.5.1 The respondent considered the feature "film that is laminated" to require the claimed composite structure to be obtainable by a lamination process. The claimed composite thus included a portion of the film which migrated into the substrate, as shown by Figure 3 of the patent. The composite of D6, which was the result of a gel-impregnation process, lacked layer interpenetration due to the strong surface tension and viscosity of the partially gelled layer brought in contact with the substrate. It was thus not a composite according to claim 1 regardless of which lamination technique were considered.

2.5.2 The board is, however, of the view that the feature requiring that the "film that is laminated on" a surface limits the claimed composite merely to be obtainable by placing layer upon layer of material (see "Laminate" in document D14, fourth acception). D6 thus discloses a product having a collagen film laminated on a collagen substrate, in the broadest sense of the term "laminated".

2.5.3 The respondent also argued that in D6 the porous substrate was brought into contact with a collagen gel whereas claim 1 required by the term "laminated" a pre-made collagen film. The claimed haemostatic composite device was also for that reason novel.

The board does not share the respondent's view that claim 1 requires the composite to be obtainable by lamination of a preformed film. In the board's view the term "laminated" does not necessarily imply that two

preformed films are "put together" for obtaining the claimed material. Claim 1 indeed requires component (b) to be a film, but does not require it to be in the form of a film before being attached to substrate (a).

2.5.4 It is thus concluded that example 6 of document D2 discloses a film that is laminated on a major surface of a substrate, as required by claim 1.

2.6 Example 2 of document D6 thus discloses a hemostatic composite having all the features required by claim 1. The claimed haemostatic composite is thus not novel, and the respondent's main request is not allowable.

3. Auxiliary requests 1 to 3, clarity

3.1 In claim 1 of auxiliary requests 1 to 3 the hemostatic composite was further defined by adding that it is obtainable by means of process features coming from the description of the patent application.

3.2 Since these process features were not part of the claims as granted they are open to examination with respect to clarity in these appeal proceedings. This was undisputed.

3.3 It was also not disputed that the process features defined in these claims (contacting, heating, etc.) were, in principle, clear per se.

3.4 Claim 1, however, relates to a hemostatic composite. In order to arrive to a conclusion on the issue of clarity, it needs to be examined whether the process features required by claim 1 of auxiliary requests 1 to 3 impart identifiable and unambiguous technical features to the claimed hemostatic composite (Case Law

of the Boards of Appeal, 9th Edition 2019, II.A.7.1, last paragraph).

3.5 Claim 1 of auxiliary request 1 requires the claimed hemostatic composite structure to be *"obtainable by contacting one major surface of said substrate (a) with said polymer-based film (b) and heating the substrate and the film so that a portion of the substrate is adhered to the film"*.

3.6 According to the respondent, the heating step forced a portion of the film to migrate into the substrate, as disclosed in paragraph [0045] of the patent. This was possible due to the energy imparted to the molecules by heating. The resulting composite was more resistent to lamination than a composite prepared without this step.

3.7 It is however not possible to clearly identify the subject-matter claimed by means of the structural features derived from the process features required by claim 1 and even less to examine whether such feature would distinguish the claimed subject-matter from the prior art.

The appellant argued that the inevitable result of the product-by-process features was that a part of the film melted and migrated into the substrate.

However, whether this is or not the case depends on many parameters not defined in claim 1. Firstly, it depends on the nature of the layers and heating temperature. The same heating conditions and material, furthermore, could lead to different structures depending on additional variables such as the heating time, heating gradient, whether pressure is applied, or the thickness of the layers, just to mention a few. If

a solvent or an adhesive were present, melting and interpenetration would not necessarily have to be achieved. It is thus not clear what structural features are the inevitable result of the process steps required by claim 1.

As there is no identifiable and unambiguous technical feature which inevitably derives from the process features of claim 1, the claimed subject-matter is not clear (Article 84 EPC) with the consequence that the first auxiliary request is not allowable.

3.8 The situation is analogous with respect to the product features that are imparted to the claimed product by the process features included in claim 1 of auxiliary requests 2 and 3.

These features require, in addition to those of claim 1 of auxiliary request 1, a lamination system working under specific conditions. The issue, however, remains what structural features are unambiguously imparted to the hemostatic composite by those process features. Lacking information on the layer's material or its thickness, just to mention a few variables, no conclusion can be drawn in this respect.

The board is thus of the view that the haemostatic composite of claim 1 of these requests is not clear (Article 84 EPC) and these requests are thus not allowable for that reason alone. The board therefore refrains from commenting on the other objections raised against these requests under the headings of lack of novelty over D6 and added subject matter.

4. Auxiliary request 4, inventive step

4.1 Claim 1 of auxiliary request 4 is directed to a hemostatic composite having all the features of the composite of claim 1 of the main request, and further requiring the film layer to be made from a polymer material having a glass transition temperature of less than 25°C.

4.2 Both parties were of the opinion that document D6 represented a suitable starting point for examining inventive step. The board agrees. Document D6 relates (see example 2) to a hemostatic composite having a bioabsorbable non-woven substrate (a) and a non-porous film made from a polymer material (b) laminated on one major surface of that substrate. The polymer material of component (b) of the hemostatic composite of D6, which is collagen, does not necessarily have a glass transition temperature of less than 25°C.

4.3 Technical problem underlying the invention

The respondent defined the technical problem underlying the claimed invention as providing a hemostatic composite having good handling properties and good processability.

4.4 Solution

The solution to this technical problem is the hemostatic composite having a substrate (a) and a continuous, non-porous polymer-based film (b) of claim 1, characterised in that the polymer of the film layer has a glass transition temperature of less than 25°C.

4.5 Success

In the following, it will be examined whether the

subject-matter of claim 1 is inventive on the assumption that the technical problem as defined above has been credibly solved by the features of claim 1; an issue that was under dispute between the parties. As the conclusion of the board on the issue of inventive step is negative, there is no need to further elaborate on this point.

4.6 It remains to be decided whether the proposed solution to the objective problem defined above would have been obvious for the skilled person in view of the prior art.

The glass transition temperature of an amorphous solid, like a polymer, is the temperature over which it becomes soft, ductile or rubbery. Below its glass transition temperature, a polymer is a hard and brittle solid.

Hemostatic implants need to adapt to the place of implantation, and even to be rolled if used in laparoscopy (D6, [0058]).

The patent discloses that materials with a low glass transition temperature allow the composite to be soft, pliable and conformable. It is however well known that these properties are required in a hemostatic material (D6, [0058]), and it is obvious that materials having a high glass transition temperature would not have these properties.

The skilled person, seeking a suitable hemostatic composite having good handling and processability i.e. the required flexibility and pliability, would have chosen a polymer material for layer (b) having a transition glass temperature below room temperature,

and would thus have arrived at the claimed invention without requiring inventive skills.

4.7 The respondent argues that there was no evidence on file of that common general knowledge. The board, however, considers that no evidence on the definition of the glass transition temperature of a substance is required since this parameter/physical constant and its consequences on the physical behaviour of a polymer is well known to the skilled person.

4.8 The respondent argues that the problem as defined in point 4.3 above could not be derived from D6. In addition, D6 disclosed polymers as suitable equivalents to non-porous collagen which could or could not have the required glass transition temperature. The skilled person would thus only have arrived at the claimed invention with the benefit of hindsight.

However, the problem of handling and processability is inherent to hemostatic composites since these properties are necessary for their use. In addition, D6 discloses the use of these composites in laparoscopy [0058] were handling is obviously a key issue.

Indeed document D6 does not disclose the glass transition temperature of the materials suitable for non-porous layer (b). However, the choice of those having a low glass transition temperature would have been obvious having regard to the common general knowledge of the person of the art in order to provide the required flexibility and pliability. This argument cannot thus be followed.

4.9 The board is for these reasons of the view that the hemostatic composite of claim 1 of auxiliary request 4

is not inventive (Article 56 EPC). This request is thus not allowable.

5. Auxiliary request 5

5.1 At the oral proceedings before the board of appeal, the appellant referred to its written submissions in point 9.6 of the grounds of appeal with respect to auxiliary request 5.

5.2 Auxiliary request 5 corresponds to a request filed before the opposition division. It was filed again with the reply to the grounds of appeal. It is thus part of the proceedings following Article 12(1) RPBA 2007, unless the board makes use of its discretion to decide otherwise.

5.3 The appellant argued that auxiliary request 5 should not be admitted into the proceedings as it represented a non-convergent approach with respect to the preceding requests.

Claim 1 of this request corresponds to claim 6 as granted. It limits the materials of the claimed haemostatic composite to the most preferred embodiment. The board fails to see how the limitation towards the most preferred embodiment of the invention could represent in this case non-convergent subject-matter in the sense that the respondent's case went in a completely different direction. The appellant's argument is thus not convincing.

5.4 Inventive step

5.4.1 Closest prior art.

It was not disputed that D6 is the closest prior art for the hemostatic composite of claim 1 of auxiliary request 5. Document D6 discloses a haemostatic composite structure comprising a non-porous film and an absorbing substrate.

5.4.2 Problem underlying the claimed invention

The appellant argues that the sole problem solved by the claimed haemostatic composite is to provide an alternative.

As the board arrived at the conclusion that the claimed subject-matter is inventive even as an alternative, it is not necessary to examine whether a more ambitious problem would also have been solved.

5.4.3 Solution

The claimed solution is the hemostatic composite of claim 1, characterised by having an absorbing layer made of oxidised regenerated cellulose and a top coat film comprising poly (ethylene diglycolate-co-glycolide).

5.4.4 Success

It was not disputed that the problem of providing an alternative has been solved by the claimed composite. The board sees no reason to differ having regard to the data on table 1 for the hemostatic composites of example 4.

5.4.5 Obviousness

Document D6 suggests oxidised cellulose as an absorbing

material [0028]. It does not hint, however, at poly (ethylene diglycolate-co-glycolide) as a suitable non-porous material.

Document D4 discloses films of poly (ethylene diglycolate-co-glycolide) in the context of adhesion prevention. D4 does not relate to hemostasis.

The skilled person, seeking an alternative, would not have been prompted towards the combination of materials required by claim 1 of auxiliary request 5, alone for the reason that poly (ethylene diglycolate-co-glycolide) was not disclosed in the context of hemostasis. The subject matter of claim 1 thus involves an inventive step (Article 56 EPC).

5.5 The board thus concluded that the respondent's auxiliary request 5 is allowable.

## 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 as follows:

Claims 1-11 of auxiliary request 5, filed with letter of 24 October 2018, with a description and figures still to be adapted.

The Registrar: The Chair:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated