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Datasheet for the decision of 20 June 2024

Case Number: T 2178/21 - 3.3.10

Application Number: 12150108.4

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Language of the proceedings: EN

Title of invention:
Rapidly acting dry sealant and methods for use and manufacture

Patent Proprietor:
Baxter International Inc.
Baxter Healthcare S.A.

Opponent:
Ethicon Inc.

Headword:

Relevant legal provisions:
EPC Art. 83, 54

Keyword:
Sufficiency of disclosure - (yes)
Novelty - (no)

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 2178/21 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 20 June 2024

Appellant: (Patent Proprietor 1)	Baxter International Inc. One Baxter Parkway Deerfield, IL 60015 (US)
Appellant: (Patent Proprietor 2)	Baxter Healthcare S.A. Thurgauerstrasse 130 8152 Glattpark (Opfikon) (CH)
Representative:	Potter Clarkson Chapel Quarter Mount Street Nottingham NG1 6HQ (GB)
Respondent: (Opponent)	Ethicon Inc. U.S. Route 22 Somerville New Jersey 08876 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 15 October 2021 revoking European patent No. 2468310 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	P. Gryczka
Members:	M. Kollmannsberger
	L. Basterreix

Summary of Facts and Submissions

I. The patent proprietor appealed the decision of the Opposition Division to revoke patent EP 2 468 310 under Article 101(3)(b) EPC.

II. The patent had been opposed under Articles 100(a), 100(b) and 100(c) EPC for lack of novelty and inventive step (Articles 54/56 EPC), insufficient disclosure (Article 83 EPC) and added matter (Articles 76(1) and 123(2) EPC).

In its decision the Opposition Division concluded that the invention defined in the claims of the patentee's main request, which differed from the claims of the granted patent only in two modifications in dependent claims, was not sufficiently disclosed. The claims of the patentee's auxiliary requests were either also considered to lack sufficient disclosure and contravene thus Article 83 EPC (auxiliary requests 1-3), to contain added matter (auxiliary requests 4-6, 8-10, 12-14) or the subject-matter defined therein was considered to lack an inventive step over D10 (auxiliary requests 7, 11 and 15).

III. Claim 1 of the main request underlying the appealed decision, which is identical to claim 1 of the granted patent and to claim 1 of the appellant's main request in appeal (auxiliary request 3 underlying the appealed decision, see below), is worded as follows:

"*A dry composition for the achievement of hemostasis or other fluid containment in an in vivo context for*

applying to a vertebrate to facilitate fluid containment, comprising:
a hydrogel-forming component acting as an absorbent;
a first cross-linkable component comprising multiple nucleophilic groups;
and a second cross-linkable component comprising multiple electrophilic groups,
wherein the first and second cross-linkable components cross-link to form a porous matrix having interstices, and the hydrogel-forming component is capable of being hydrated to form a hydrogel to fill at least some of the interstices."

IV. The following document is relevant for the present decision:

D10: WO 2004/028404

V. With its statement setting out the grounds of appeal the appellant argued that the Opposition Division's finding of lack of disclosure regarding claim 1 of the main request was erroneous. Moreover the compositions defined in the claims of the main request as well as of auxiliary requests 1-15 underlying the decision were novel over the cited documents, in particular over D10, and involved an inventive step over this document. Further, the objections regarding added subject-matter, which concerned only dependent claims, were unjustified.

VI. The respondent, in its reply to the grounds of appeal and throughout the appeal proceedings submitted that the Opposition Division's finding of lack of disclosure

was correct. Moreover, the compositions defined in claim 1 of the appellant's main request lacked novelty i. a. over D10, and the compositions defined in the independent claims of all auxiliary requests lacked an inventive step over D10.

VII. The Board summoned the parties to oral proceedings. In a communication under Article 15(1) RPBA the parties were informed that the Board considered the objection of lack of sufficient disclosure to be unconvincing. Novelty and inventive step would have to be discussed at the oral proceedings.

VIII. With its reply to the Board's communication the appellant declared auxiliary request 3 underlying the appealed decision to be its new main request. It submitted auxiliary requests 1-7 for maintenance of the patent in amended form.

IX. Oral proceedings were held on 20 June 2024.

In the course of the oral proceedings the appellant withdrew all auxiliary requests. It requested the appealed decision to be set aside and to maintain the patent in amended form based on the claims of its main request, corresponding to auxiliary request 3 underlying the appealed decision.

The respondent requested the appeal to be dismissed.

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

Reasons for the Decision

1. The appeal is admissible.

2. Sufficient disclosure, Article 83 EPC

2.1 Claim 1 of the appellant's main request is directed to a dry composition comprising a hydrogel-forming component, a first cross-linkable component comprising multiple nucleophilic groups, and a second cross-linkable component comprising multiple electrophilic groups.

The claim defines (i) that the composition is "*for the achievement of hemostasis or fluid containment in an in vivo context for applying to a vertebrate to facilitate fluid containment*". Furthermore the claim defines (ii) that "*the first and second cross-linkable components crosslink to form a porous matrix having interstices, and the hydrogel forming component is capable of being hydrated to form a hydrogel to fill at least some of the interstices*".

2.2 The Opposition Division considered definition (i) to lead to the claimed compositions not being sufficiently disclosed. Definition (ii) was not considered problematic.

The appellant considers neither of these definitions (i) and (ii) to lead to insufficient disclosure of the claimed dry powder composition. The respondent maintains the objection to both of them also in appeal proceedings.

2.3 The claim is directed to a product as such, namely to a dry composition comprising three components.

The claim is not drafted as a method claim or as a second medical use claim under Article 54(5) EPC defining a known product for a specific new use. This is already apparent from the wording of the claim which does not define a product "*for use in*" a therapeutic or prophylactic method. Moreover, the purpose defined in the claim is not necessarily therapeutic. While hemostasis may be considered therapeutic, "other fluid containment" may relate to the containment of e. g. tears, sweat or urine. This also covers non-therapeutic applications.

That the claim is directed to a product as such was undisputed between the parties.

The three components of the claimed composition are known materials. A skilled person can provide a three-component composition comprising the components defined in the claim, e. g. by mixing them as described in paragraph [0033] of the patent.

2.3.1 Regarding feature (i) the ternary composition needs to be merely *suitable for* hemostasis or fluid containment.

In the appealed decision the Opposition Division considered the intended purpose defined in the claim as a "functional requirement", see point II.1.3.2. However, in contrast to a claim defining a composition for use in a specific therapeutic method, where the therapeutic method defined in the claim indeed is a functional feature of the claim (and is in fact the feature on which novelty and inventive step are based),

this is not the case in a product claim stating an intended use. Here the product is claimed as such and it must be merely suitable for the intended use.

The patent contains ample proof that a three-component dry composition as defined in the claim is suitable for fluid containment or hemostasis. The claim does not require any specific results to be achieved nor any specific methods to be applied.

The respondent highlighted in particular the results described in examples 19 and 21 of the patent. In some of the tests, the powder applied did not lead to complete sealing of the bleeding site. These results also lead the Opposition Division to find the claimed invention insufficiently disclosed.

However, the overall effect of hemostasis, to which most of the examples in the description relate, evidently not only depends on the nature of the composition applied. It also depends on other parameters independent from the composition such as the mode of application (e. g. whether used on a support or not), the amount of composition used, the size of the bleeding site, the amount of blood released etc. Failure of some compositions in some of these tests to lead to a complete fluid containment does not throw doubts on the fact that the claimed compositions are, in principle, suitable for the achievement of hemostasis or other fluid containment, i. e. for the purposes defined in the claim.

Thus, the indication of the intended purpose of the compositions defined in the claims, i. e. feature (i) as described above, does not lead to any difficulties

for a skilled person to reproduce the claimed compositions.

2.3.2 Regarding feature (ii) the respondent essentially argued that there was no proof in the patent that the structure defined in the claim has in fact been obtained, i. e. that the cross-linkable components cross-link to form a porous matrix, the interstices of which are at least partly filled by the hydrogel obtained from the hydrogel-forming component.

The Board notes that the claim is not directed to the structure obtained after cross-linking, but to the ternary dry composition present before cross-linking. This composition can be simply obtained by mixing the components. Any argument on insufficient disclosure of such a composition could be based at most on the question of whether a skilled person is able to select the correct components to be mixed, so that the structure defined in the claim is obtained after exposure to reactive conditions.

A skilled person has ample information as to which components may be chosen. Suitable cross-linkable components are described in parts I and II of the patent, their combination with hydrogel formers in part III, and specific combinations of such materials are used in the examples. The patent describes in paragraph [0033] that the two cross-linkable components will cross-link upon contact with a biological fluid to form a porous matrix, and that the hydrogel forming component will, under the same conditions, hydrate to a hydrogel which fills up at least some of the interstices. Such a process is also carried out in the examples, e. g. in examples 17-19 or 22.

That the nucleophilic and the electrophilic cross-linker will cross-link upon exposure to an aqueous environment is evident. That such a structure will be porous appears likewise evident at least if, as in the examples, the crosslinkers are modified PEG-type polymers. That at least some of the interstices may be occupied by the hydrogel that is present during the cross-linking reaction appears reasonable.

In summary, the patent describes a technically meaningful and credible explanation for the structure recited in the claim, formed from the three components of the dry composition once exposed to a reactive environment. It would have been incumbent upon the respondent as an opponent to substantiate its doubts by technically convincing explanations or experimental evidence. The opponent's objections do not go beyond mere allegations.

2.4 Thus, the Board concludes that the patent describes the claimed compositions in sufficient detail in order to allow a skilled person to reproduce them. The requirements of Article 83 EPC are fulfilled.

3. Novelty (Article 54 EPC)

3.1 The appealed decision does not discuss novelty for claim 1 of the main request since auxiliary request 7 underlying the decision, the first of the auxiliary requests the Opposition Division considered to comply with Articles 83 and 76/123(2) EPC, was not attacked for novelty any more. From the Opposition Division's reasoning with respect to inventive step of auxiliary request 7 starting from D10 it can be inferred that the Opposition Division did not consider claim 1 of the

main request novel over D10. It bases its analysis on distinguishing features (concentration ranges) that are absent from claim 1 of the main request, see point II. 5.5 of the appealed decision.

3.2 The respondent objects lack of novelty of claim 1 of the main request over D10. The disputed issue is whether D10 discloses a hydrogel-forming component in the context of a ternary composition as defined in the claims, i. e. together with a nucleophilic and an electrophilic cross-linkable component.

3.3 D10 is directed to dry tissue sealant compositions comprising a cross-linking agent and a synthetic collagen, or a synthetic gelatin (see claim 1). The respondent's novelty objection is based on paragraph [0008] of the description which additionally discloses, as an alternative, the presence of a *combination of synthetic collagen and synthetic gelatin*, in addition to the crosslinking agent. A similar disclosure can be found in paragraph [0049] of D10. Thus, D10 discloses a dry tissue sealant composition containing three components.

3.4 It was undisputed that the crosslinking agent of D10 corresponds to the electrophilic (second) cross-linker as defined in present claim 1 (see paragraph [0012] of D10). It was likewise undisputed that the synthetic collagen of D10, due to its high content in lysin having free amino groups, corresponds to the nucleophilic (first) cross-linker as defined in the present claim.

The disputed issue was whether the synthetic gelatin disclosed in D10 corresponds to the hydrogel forming component of the present claim, i. e. to a component

which may be hydrated to form a hydrogel to fill at least some of the interstices of the network formed by the crosslinkers.

3.5 Paragraph [0054] of D10 discusses the advantages of using synthetic collagens and gelatins as opposed to materials derived from natural sources. It is stated that synthetic gelatin can be provided as consistently and reproducibly crosslinked material. Crosslinked gelatin is a hydrogel former according to the present patent, see paragraph [0077] and is also used in the examples, see e. g. example 8.

3.6 The appellant argued that synthetic gelatin is not disclosed as a hydrogel former in D10 but, in the same way as the collagen, as a reaction partner for the electrophilic crosslinker, see e. g. paragraph [0014]. In the appellant's view, the three components in D10 just formed a combined network together, without a hydrogel former being located, after hydration, at least partly inside the interstices of a network formed by the other two components.

It is correct that D10 does not explicitly describe a structure as mentioned in claim 1. However, D10 describes the components that are used in compositions according to the claim, and these components will behave in the same way than in the present patent. The Board stresses that the claim is directed to a mixture of three components and only requires a hydrogel former that is *capable of* being hydrated to form a hydrogel to fill at least some of the interstices of the porous matrix formed by the cross-linkers.

The crosslinkers in D10 are according to the present claim and will thus form a porous network. Crosslinked

gelatine is surely capable to be hydrated to form a hydrogel, and will also occupy at least some of the interstices formed, in the same way as described in the patent.

3.7 The appellant further argued that the gelatine described in D10 is not in fact crosslinked, but monomeric. It was referred to paragraph [0057] of D10 and also to example 12, in particular paragraph [0135] and table 7. The appellant argued that from these passages it was clear that synthetic collagen was predominantly monomeric. Thus, the control of crosslinking mentioned in paragraph [0054] for collagen and gelatine was rather to be understood as leading to a predominantly monomeric material containing only a low degree of crosslinking. According to the appellant monomeric gelatine did not form hydrogels at all, but rather dissolved in aqueous environment. Reference was made to example 5 of the patent in this respect.

However, the passages cited by the appellant do not describe that the gelatine used is 100% monomeric. Some part of the gelatine will still be crosslinked. Moreover, even if the appellant's argument that the gelatin in D10 is presented as being predominantly non-crosslinked was accepted this does not render present claim 1 novel over D10. The claim does not require crosslinked gelatine as a hydrogel former. Also non-crosslinked gelatine is capable of being hydrated to form a hydrogel, as shown in the patent itself, see paragraph [0079]. The argument that non-crosslinked gelatine will necessarily dissolve is not convincing. Example 5 does show non-crosslinked gelatine to dissolve in distilled water, however, at 70°C only, not under *in-vivo* conditions as defined in the claim. Also non-cross-linked gelatin *is capable of* fulfilling the

requirements defined in the claim, at least to some degree.

3.8 The claim defines a mixture of three components, two crosslinkers forming a porous network between themselves when exposed to reactive conditions, and a hydrogel former. D10 describes a mixture of three components, one component being described as a crosslinker, one component not being named "crosslinker" but undisputedly acting like one, meaning that a porous network is formed under reactive conditions. Furthermore, D10 describes a further component which is capable to be hydrated to form a hydrogel. This mixture of three components described in D10 will behave in the same way than in the patent. There is no convincing explanation nor proof on file that it wouldn't, and that the claim defines anything different from what is disclosed in D10. Thus, claim 1 of the appellant's main request lacks novelty over D10.

4. Since claim 1 of the appellant's main and sole request lacks novelty over D10 the revocation of the patent under Article 101(3)(b) EPC must be confirmed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated