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Datasheet for the decision of 12 October 2023

Case Number: T 0451/20 - 3.3.08

Application Number: 12732896.1

Publication Number: 2726115

IPC: A61L15/32

Language of the proceedings: EN

Title of invention:

Procoagulant peptides and their derivatives and uses therefor

Patent Proprietor:

Ethicon, Inc

Opponent:

Baxter International Inc.

Headword:

Procoagulant peptides/ETHICON

Relevant legal provisions:

EPC Art. 123(2) RPBA 2020 Art. 13(2)

Keyword:

Main request - added matter (yes) Auxiliary requests - exceptional circumstances (no)

Decisions cited:

J 0014/19, T 1294/16, T 1598/18

Catchword:

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Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 0451/20 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 12 October 2023

Appellant: Ethicon, Inc
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Appellant: Baxter International Inc.

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Representative: SONN Patentanwälte GmbH & Co KG

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on 16 December 2019 concerning maintenance of the European Patent No. 2726115 in amended form

Composition of the Board:

Chairwoman T. Sommerfeld

Members: B. Claes

D. Rogers

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Summary of Facts and Submissions

- I. The appeals lodged by the patent proprietor
 (appellant I) and the opponent (appellant II) lie from
 the interlocutory decision of the opposition division
 that European patent No. 2 726 115, as amended in the
 form of auxiliary request 4 (filed during the oral
 proceedings), and the invention to which it relates
 meet the requirements of the EPC. The patent, entitled
 "Procoagulant peptides and their derivatives and uses
 therefor", was granted for European patent application
 No. 12 732 896.1, which was filed as the international
 patent application published as WO 2013/003045 (the
 application as filed).
- II. With the statement of grounds of appeal, appellant I filed sets of claims of a main request (claims as granted) and of 17 auxiliary requests (auxiliary request 17 being identical to auxiliary request 4 considered in the decision under appeal).
- III. With the statement of grounds of appeal, appellant II argued that with regard to auxiliary request 4, the decision under appeal was wrong because, inter alia, the claims extended beyond the content of the application as filed (Article 123(2) EPC).
- IV. Both appellants replied to the appeal of the other party.
- V. The parties were summoned to oral proceedings and subsequently the board issued a communication pursuant to Article 15(1) RPBA in which it expressed its preliminary opinion on matters that seemed to be of

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particular significance for the decision to be taken. The board expressed, inter alia, its opinion that claims 1 and 15 of the main request (claims as granted) failed to meet the requirements of Article 123(2) EPC, and that this also applied mutatis mutandis to the corresponding claims of auxiliary request 17.

VI. In response to the communication of the board, appellant I withdrew all of its claim requests submitted on appeal (main request and auxiliary requests 1 to 16 filed with the statement of grounds of appeal) and filed new auxiliary requests 1 to 3. Former auxiliary request 17 became the new main request.

Claim 1 of the main request therefore reads as follows:

- "1. A hemostatic or tissue sealing material comprising:
- (a) a peptide having a sequence SEQ ID NO: 1 or an amino acid analog sequence thereof selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, and combinations thereof, wherein said peptide is conjugated to a polyethylene glycol, and
- (b) a hemostatic scaffold wherein said hemostatic scaffold is crosslinked gelatin in particle form with a liquid carrier."
- VII. The board issued a further communication pursuant to Article 15(1) RPBA, in which it maintained its opinion that claims 1 and 10 of the new main request (formerly auxiliary request 17) did not comply with the requirements of Article 123(2) EPC. The board also held that auxiliary requests 1 to 3 amounted to an amendment to appellant I's appeal case, the admittance of which was governed by Article 13(2) RPBA. The board was not

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convinced that it should admit and consider the auxiliary requests in the appeal proceedings.

- VIII. At the end of the oral proceedings, the Chair announced the decision of the board.
- IX. The arguments of appellant I, where relevant for the decision, can be summarised as follows:

Main request - claim 1 - added subject-matter

The first sentence of paragraph [023] of the application as filed served as a basis for the claimed material.

It was an implicit property of the "crosslinked gelatin in particle form with a liquid carrier" in the claim that it was a suitable scaffold for the recited peptide.

In its simplest form, the claim covered a material having only the scaffold and the peptide present. In fact, the claim did not cite any ingredients other than the peptide and the scaffold. Specifying that the scaffold was "for the peptide" was thus superfluous.

The universal meaning of the term "scaffold" was a "structure to support" and in the context of the claim this could only mean the scaffold was intended "to support" the recited peptide. Paragraph [047] of the application as filed described the nature of gelatin carriers and paragraph [060] of the same taught methods for incorporating peptides onto such carriers.

If the "crosslinked gelatin in particle form with a liquid carrier" was separate from the peptide in the

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claimed material, than it was not a "scaffold". The only proper construction of claim 1 was thus that the scaffold as defined in claim 1 was *for* the recited peptide.

Auxiliary requests 1 to 3 - admittance

The opposition division held that auxiliary request 4 did not to relate to added subject-matter and that it was allowable.

If a patent proprietor were to file requests as fallback positions for every objection raised by an opponent, the number of required auxiliary requests would be enormous, making the burden on the boards and parties much greater. This could not have been the intent of the Rules of Procedure of the Boards of Appeal.

The amendments to claim 1 of auxiliary requests 1 and 3 limited the claimed subject-matter and were straightforward in nature. Furthermore, the remaining matters at issue in the appeal proceedings were unaffected. Thus, these requests i) were not detrimental to procedural economy in the case at hand, but in fact improved it since they overcame existing objections to claim 1 of the main request, and ii) did not adversely affect the opponent.

In such circumstances, boards had previously held that where the "change of case" served the purpose of procedural economy and was not contrary to the principle of fair proceedings, the requirement of exceptional circumstances within the meaning of Article 13(2) RPBA was met.

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The board should therefore admit and consider these requests in the appeal proceedings.

X. The arguments of appellant II, where relevant for the decision, can be summarised as follows:

Main request - claim 1 - added subject-matter

The claim did not require that the claimed material comprised "a scaffold for said peptide". Thus, the first sentence of paragraph [023] of the application as filed could not serve as a basis for the claimed material.

Auxiliary requests 1 to 3 - admittance

The argument to which the amendment to claim 1 of auxiliary requests 1 and 3 was the response had been submitted by the opponent for the first time during the oral proceedings before the opposition division and had been reiterated in appellant II's statement of grounds of appeal. The requests were not, but should have been, filed with appellant I's reply to the appeal of appellant II. Since appellant I had not filed any auxiliary requests as fallback positions at that stage in the proceedings, appellant II had not expected such requests to be filed at a later stage in the proceedings.

Appellant I filed these requests only after the parties had been summoned to oral proceedings and after the board had expressed its opinion that claim 1 of the main request related to added subject-matter. When filing the requests, appellant I had not provided cogent reasons for them being filed at that point in time. Furthermore, as a result of the amendment,

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claim 1 lacked clarity. Hence, it was inconceivable how the admittance and consideration of these requests in the appeal proceedings could improve the procedural economy of the proceedings.

Claim 1 of auxiliary request 2 was identical to the same claim of the main request and therefore did not overcome the deficiencies under Article 123(2) EPC. Thus, this request should not be admitted into the proceedings.

XI. Appellant I requested that the appeal of the opponent be dismissed (main request, i.e. that the patent be maintained with the set of claims of auxiliary request 17 filed with the statement of grounds of appeal and re-submitted as main request with letter dated 23 June 2023, being identical to the set of claims which was considered by the opposition division to comply with the EPC), or alternatively, that auxiliary requests 1 to 3, filed with the submissions dated 23 June 2023, be admitted into the proceedings, that the decision under appeal be set aside, and the patent be maintained upon the basis of one of these auxiliary requests.

Appellant II requested that the decision under appeal be set aside and the patent revoked. It further requested that auxiliary requests 1 to 3 not be admitted into the proceedings.

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Reasons for the Decision

Main request - claim 1 - added subject-matter

- 1. Claim 1 of the main request is identical to claim 1 of auxiliary request 4 considered in the decision under appeal and claim 1 of auxiliary request 17 filed with the statement of grounds of appeal (see section VI. above). The opposition division held that this claim met the requirements of Article 123(2) EPC. In reply to appellant II's objections in the grounds of appeal, appellant I referred to paragraphs [023] to [025].
- 2. The relevant parts of paragraph [023], under the section "Summary of the invention", spanning pages 7 and 8 of the application as filed, read as follows:
 - "[023] The present invention is directed to a hemostatic or tissue sealing material having (a) a peptide having a sequence SEQ ID NO: 1 or an amino acid analog sequence thereof, and (b) a scaffold for said peptide or amino acid analogue sequence. The scaffold is preferably hemostatic, such as a natural or genetically engineered absorbable polymer, a synthetic absorbable polymer, or combinations thereof. The natural or genetically engineered absorbable polymers can be selected from the group consisting of a protein, a polysaccharide, or combinations thereof. The protein can be selected from the group consisting of ... gelatin ..., or combinations thereof. The polysaccharide can be selected from ... The synthetic absorbable polymer can be an aliphatic polyester polymer, an aliphatic polyester copolymer, or combinations thereof" (emphasis added by the board).

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- 3. In the statement of grounds of appeal, appellant II reiterated the argument that contrary to the disclosure in paragraph [023] of the application as filed, claim 1 did not require that the claimed material comprised "a scaffold for said peptide or amino acid analogue sequence" (emphasis added). Without the functional relationship disclosed in paragraph [023] between the scaffold and the peptide, the scaffold could serve a purpose other than being for the peptide recited in the claim. The claimed material could also contain a further ingredient. The claim thus related to added subject-matter.
- 4. The opposition division had dismissed this argument by holding that the feature in paragraph [023] according to which the scaffold was for said peptide or amino acid analogue sequence was "an implicit property of the scaffold in the claimed hemostatic or sealing material comprising the peptide or amino acid analog sequence thereof", which therefore did not need to be specified in the claim (see the appealed decision, page 9, second paragraph, in the context of what was then the main request).
- 5. The board notes that due to the "comprising" formulation, it is not excluded that the claimed material contains further ingredients, in addition to the specified scaffold and peptide. Appellant I has not contested this construction of the claim and indeed confirmed that the exclusive presence of the two specified components is only a construction in the simplest form of the claim.
- 6. In this context, the board agrees with appellant II's argument that because the claim does not specify that

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the "crosslinked gelatin in particle form with a liquid carrier" scaffold is *for* the recited peptide, the scaffold may also be construed to serve another purpose, e.g. serving as a scaffold for an ingredient other than the recited peptide.

- 7. The counterargument of appellant I, according to which the only proper construction of claim 1 was that the scaffold as defined in claim 1 was for the recited peptide since the universal meaning of the term "scaffold" was a "structure to support" which in the context of claim 1 meant to support the recited peptide, must therefore fail.
- 8. Moreover, the fact that paragraphs [047] and [060] of the application as filed describe gelatin carriers and methods for incorporating peptides into such carriers, respectively, cannot call into question the board's construction of claim 1.
- 9. The board therefore concludes that the claimed subject-matter is not disclosed in the application as filed and that the claim thus fails to meet the requirements of Article 123(2) EPC.

Auxiliary requests 1 to 3 - admittance

10. Auxiliary requests 1 to 3 were filed by appellant I after the board had summoned the parties to oral proceedings, in response to the subsequent communication of the board expressing its opinion that contrary to the conclusions of the opposition division, claim 1 of the main request (then auxiliary request 17) related to added subject-matter and therefore contravened the requirements of Article 123(2) EPC (see

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section V. above). Appellant II requested that these requests not be admitted in the proceedings.

- 11. It is undisputed that the auxiliary requests constitute an amendment to appellant I's appeal case within the meaning of Article 13 RPBA (see also decision J 14/19, Reasons 1.1 to 1.5). The admittance of these claim requests is governed by Article 13(2) RPBA, which imposes the most stringent limitations on a party wishing to amend its appeal case at an advanced stage of the proceedings and stipulates that any amendment to a party's appeal case made at this stage of the proceedings will, in principle, not be taken into account unless there are exceptional circumstances which have been justified with cogent reasons by the party concerned.
- 12. Appellant I argued that cogent reasons needed not be submitted by the party if the board, of its own motion, considered the circumstances exceptional in view of the very purpose of the convergent approach, taking into account i) that the admittance of the amendment to the party's appeal case was not detrimental to the procedural economy of the appeal proceedings and ii) provided the amendment did not adversely affect any other party (see, for example, T 1294/16, Reasons 18.1 to 18.3, and T 1598/18, Reasons 25.1, and Case Law of the Boards of Appeal of the EPO, "CLBA", 10th ed., 2022, V.A.4.5.1 and V.A.4.5.5). These principles applied to auxiliary requests 1 and 3.
- 13. In the case in hand, the argument concerning the feature "scaffold for said peptide" (see point 3. above), which the amendment to claim 1 of auxiliary requests 1 and 3 was intended to address, had already been submitted by the opponent in the opposition

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proceedings, was dealt with in the decision under appeal and had been reiterated in appellant II's statement of grounds of appeal. Appellant I (as respondent to appellant II's appeal) chose, however, not to submit any auxiliary requests as defensive fallback positions with the reply to the appeal; instead it restricted itself to defending the decision under appeal in respect of appellant II's objections against auxiliary request 4 (re-submitted as auxiliary request 17 with its own statement of grounds of appeal and now the main request).

- 14. The board agrees with appellant II that a set of claims of an auxiliary request submitted in response to the objection concerning the feature "scaffold for said peptide" not only could, but in fact should, have been filed with appellant I's reply to the appeal of appellant II.
- 15. Appellant I submitted in this respect that filing fallback positions for every objection raised by appellant II would result in an *enormous* amount of auxiliary requests, making the burden on the parties and the board much greater, and that this could not have been the intent of the Rules of Procedure of the Boards of Appeal.
- 16. The board notes, however, that appellant I did not file any auxiliary requests with its reply to the appeal of appellant II. The board thus has sympathy for appellant II's argument that since no auxiliary requests at all were filed, it had assumed that appellant I would not be filing such auxiliary requests at a later stage in the proceedings. Accordingly, the board fails to see that there were exceptional circumstances, justified by cogent reasons, for the

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submission of such requests only after the parties had been summoned to oral proceedings and after the board had expressed its opinion that claim 1 of the main request related to added subject-matter. Moreover, in the view of the board, the admittance of such requests would not contribute to the procedural economy of the appeal case.

- 17. Furthermore, the board notes that the amendment to claim 1 of auxiliary requests 1 and 3 is not limited to the mere deletion of claims or to the incorporation of subject-matter of a dependent claim, but rather concerns the introduction of a new feature disclosed in the description. Accordingly, the amendment is open to objections under Article 84 EPC and appellant II did in fact also formulate such an objection. The board considers this a further reason for holding that admitting auxiliary requests 1 and 3 into the appeal proceedings would not contribute to the procedural economy of the appeal case.
- 18. In view of the above considerations, the board holds that the admittance of auxiliary requests 1 and 3 would be detrimental to the procedural economy of the appeal proceedings (see point 12. above).
- 19. Finally, since these appeal proceedings are *inter* partes proceedings, appellant II, which requested that auxiliary requests 1 and 3 not be admitted into the appeal proceedings, would have been adversely affected by the admittance and consideration thereof (see also point 12. above).
- 20. In conclusion, the board has decided, having taking into account the above considerations, that there were no exceptional circumstances justifying the admittance

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of auxiliary requests 1 and 3 into the appeal proceedings (Article 13(2) RPBA).

- 21. As regards auxiliary request 2, claim 1 of this request is identical to the same claim of the main request and therefore does not overcome the deficiencies under Article 123(2) EPC (see point 9. above).
- 22. The board has therefore decided not to admit auxiliary request 2 into the appeal proceedings either (Article 13(2) RPBA).

Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The patent is revoked.

The Registrar:

The Chair:



L. Malécot-Grob

T. Sommerfeld

Decision electronically authenticated