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**Datasheet for the decision  
of 3 November 2023**

**Case Number:** T 3250/19 - 3.2.06

**Application Number:** 11839057.4

**Publication Number:** 2638194

**IPC:** D04H1/08, D04B21/00, D04H1/46,  
D06C15/00, D01G15/00

**Language of the proceedings:** EN

**Title of invention:**  
A RESORBABLE LAPAROSCOPICALLY DEPLOYABLE HEMOSTAT

**Patent Proprietor:**  
Ethicon LLC

**Opponent:**  
Baxter International Inc.

**Headword:**

**Relevant legal provisions:**  
EPC Art. 123(2)

**Keyword:**  
Amendments - extension beyond the content of the application  
as filed (yes)

**Decisions cited:**

**Catchword:**



**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 3250/19 - 3.2.06

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.06**  
**of 3 November 2023**

**Appellant:** Ethicon LLC  
(Patent Proprietor) 475 Street C, Suite 401  
Los Frailes Industrial Park  
00969 Guaynabo (PR)

**Representative:** Carpmiels & Ransford LLP  
One Southampton Row  
London WC1B 5HA (GB)

**Appellant:** Baxter International Inc.  
(Opponent) One Baxter Parkway  
Deerfield, IL 60015 (US)

**Representative:** SONN Patentanwälte GmbH & Co KG  
Riemergasse 14  
1010 Wien (AT)

**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
11 October 2019 concerning maintenance of the  
European Patent No. 2638194 in amended form.**

**Composition of the Board:**

**Chairman** M. Harrison  
**Members:** T. Rosenblatt  
W. Ungler

## **Summary of Facts and Submissions**

- I. The appellants (patent proprietor and the opponent) filed appeals against the interlocutory decision of the opposition division, in which it found that European patent No. 2 638 194 in an amended form met the requirements of the EPC.
- II. The parties were summoned to oral proceedings before the Board. With a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA 2020) the parties were informed of the Board's provisional opinion. The subject-matter of claim 1 according to the appellant-proprietor's main request was considered as extending beyond the content of the application as filed. The Board also opined that the underlying problem could apparently not be remedied by any of the amendments to claim 1 of the auxiliary requests 1 to 14 submitted so far by the appellant-proprietor.
- III. With a subsequent letter dated 30 October 2023, the appellant-proprietor submitted auxiliary requests 15 to 18.
- IV. Oral proceedings before the Board were held on 3 November 2023.
- V. The appellant-proprietor requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or one of auxiliary requests 1 to 8 filed with the statement of grounds of appeal, or the patent be maintained on the basis of one of auxiliary requests 9 to 14 filed with letter of 8

July 2020 or on the basis of one of auxiliary requests 15 to 18 filed with letter of 30 October 2023.

VI. The appellant-opponent requested that the decision under appeal be set aside and the patent be revoked.

VII. Claim 1 of the appellant-proprietor's main request reads as follows:

"A flexible resorbable hemostatic dressing comprising a single layer of three-dimensionally entangled nonwoven felt that is not separable into distinct layers by hand consisting essentially of oxidized cellulose fibers, wherein the felt is deployable laparoscopically wherein said felt has:  
i) a basis weight of from 70 to 200 grams per square meter;  
ii) a tensile strength of more than 0.89 newtons, wherein said tensile strength is determined according to the method in the description;  
iii) a tear strength of greater than 0.22 newtons, wherein said tear strength is determined according to the method in the description."

Claim 1 of each of auxiliary requests 1 to 5 and 15 has the same wording.

Compared to claim 1 of the main request, claim 1 of auxiliary request 6 comprises the following amendment (underlining added by the Board):

"wherein the felt retains its structural integrity when deployed laparoscopically"

Claim 1 of auxiliary requests 7, 8 and 16 has the same wording as in auxiliary request 6.

Compared to claim 1 of the main request, claim 1 of auxiliary request 9 comprises the following amendment (underlining added by the Board):

"wherein the felt is flexible and retains its structural integrity when deployed laparoscopically"

Claim 1 of auxiliary requests 10, 11 and 17 has the same wording as in auxiliary request 9.

Compared to claim 1 of the main request, claim 1 of auxiliary request 12 comprises the following amendment (underlining added by the Board):

"wherein the felt has sufficient mechanical strength and flexibility to retain its structural integrity when deployed laparoscopically"

Claim 1 of auxiliary requests 13, 14 and 18 has the same wording as in auxiliary request 12.

The claim sets of all requests also comprise a second independent method claim, the wording of which is not relevant for the present decision.

The main request and several of the auxiliary requests also comprise amendments to some dependent claims and to the description, which are also not relevant to the present decision.

VIII. The arguments of the appellant-opponent may be summarised as follows.

*Main request - Article 123(2) EPC*

The insertion of the features "wherein said tensile strength is determined according to the method in the

description" and "wherein said tear strength is determined according to the method in the description" in features ii) and iii) of claim 1 had no basis in the application as filed. The minimum values for the tensile strength and the tear strength defined in claim 1 were disclosed in the application as filed without any indication of a method for determining them. It was not disclosed in the application as filed that the methods employed in Examples 4 and 5 should be applied. The values measured in these Examples were uncorrelated to the claimed lower limit values and it was unknown whether for example the method described for Example 4, indicating values with the unit of a mass instead of a force, could be performed in the same way at the lower limit values given in the claim as for the examples reported. Moreover, in regard to the determination of the tear strength according to Example 4, at least two methods were disclosed, so that a skilled person turning to this Example would not find a single unambiguous method disclosed.

IX. The arguments of the appellant-proprietor may be summarised as follows.

*Main request - Article 123(2) EPC*

The opposition division correctly rejected the appellant-opponent's objection directed to the references in claim 1 for the measurement methods. The dependent claims and paragraph 19 of the application as filed disclosed the broadest ranges for the claimed parameters tear strength and tensile strength, without indeed any indication of a measurement method. The skilled person would find the information for the measurement method to be applied for determining, for example, the tear strength, in paragraph 57 of the

application as filed. This paragraph contained the disclosure for a measurement method. It referred specifically to the application of the method on a nonwoven felt "of the present invention", from which reference the skilled person would have concluded that this method applied to the application as whole. The perceived large discrepancy between the values in the Examples and those in claim 1 just confirmed that the invention could be carried out, rather than providing substantiated doubts as to the applicability of the method to values also including the lower limit values given in claim 1. The Board's written comment "that it cannot see that the application as filed discloses 'a single and specific method for determining the tensile strength according to feature ii) of claim 1'" seemingly required two conditions ("single" and "specific") for a method to be met in order to be considered to be disclosed, for which notably the second condition referred rather to the requirement of clarity, Article 84 EPC, instead of the requirement of Article 123(2) EPC; no such requirement existed.

## **Reasons for the Decision**

### *Main request - Article 123(2) EPC*

1. The subject-matter of claim 1 of the main request extends beyond the content of the application as filed, contrary to the requirement of Article 123(2) EPC.
- 1.1 When referring to the application as filed, reference is made to the publication of the international

application underlying the patent in suit,  
WO 2012/064687 A2.

- 1.2 It has to be examined whether claim 1 of the main request, which is identical to claim 1 of the patent as granted, is directed to subject-matter which is directly and unambiguously derivable by a skilled person, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the documents as filed (see e.g. Reasons 4.3 in the Decision of the Enlarged Board of Appeal G 2/10, OJ EPO 2012, 376)
  
- 1.3 Claim 1 of the main request defines in features ii) and iii) lower limit values for the tensile strength and tear strength of the felt of the claimed dressing. The Board considers that the expression "is determined according to the method in the description", added before the grant of the patent, in regard to the lower limit values defined by features ii) and iii) leads to subject-matter which is not directly and unambiguously derivable from the application as filed. In particular, the Board cannot see that the description of the application as filed discloses a single and specific (i.e. "the") method for determining the tear strength or tensile strength.
  - 1.3.1 Literal basis for the two lower limit values according to features ii) and iii) is found in paragraph 19 and dependent claims 3 and 5 of the application as filed, without however any reference to a method for their determination, let alone an indication that any method used may be indicated elsewhere in the application as filed.

- 1.3.2 The only measurement methods for tensile and tear strength of nonwoven felts are found in the application as filed in the description of the exemplary embodiments. The values disclosed in this context are however entirely uncorrelated with the values in paragraph 19 and in the dependent claims of the application as filed. Paragraphs 57 to 59 of the application as filed relate to examples of felts, and these paragraphs disclose results of measurements of tear strength and tensile strength (tables 4 and 5) performed for a number of specific samples.
- 1.3.3 Paragraph 57 specifically relates to the measurement of "tear strength in machine direction cut of the resorbable hemostatic nonwoven felt of the present invention" and indicates an apparatus to be used. Details of the measurement method are described in paragraph 58, indicating, for example, sample dimensions, sample mounting details on the used apparatus, as well as test operation parameters, such as a machine cross head movement speed for propagating a tear along a sample. Results are summarised in table 4. In this table measured values are indicated for machine direction ("MD") tear strength and cross machine direction ("CD") tear strength. The respective (MD and CD) strength values are reported in units "lbs", which is a unit of mass, instead of the common unit of force, Newton [N], used in claim 1 of the main request, in originally filed claims 3 and 5 as well as in paragraph 19 of the application as filed. Measured values for MD tear strength range from 0.188 to 0.244 lbs, with an average over all samples of 0.215 lbs, whereas for CD tear strength a range of 0.098 to 0.279 lbs with an average of 0.19 lbs is reported. Accepting for the sake of argument and in favour of the appellant-proprietor that the unit "lbs" used in table

4 is an error and that the correct unit should have read "lbf" (as, for example, in Table 5 for the indication of the tensile strength) - the Board however notes that no decision on this aspect of the main request of the appellant-proprietor, directed to an amendment of the description in this sense, has been taken by the Board. This was not necessary since it was unrelated to the question of whether a disclosure for the added reference to "the method" in claim 1 leads to added subject-matter. The required consequential conversion of the anglo-american force unit "lbf" into the SI unit Newton [N] would lead to a MD tear strength range of 0.836 to 1.085 N and an average of 0.956 N (see also table 4 of the patent). These values are much higher than the lower limit value disclosed in paragraph 19 and in corresponding dependent claim 5 of the application as filed and defined in feature iii) of claim 1 of the main request, i.e. 0.22 N. The discrepancy with the claimed value is similar for converted CD tear strength values in table 4. It therefore cannot be directly and unambiguously derived that the comparatively low tear strength of a nonwoven felt as defined in claim 1 of the main request is to be determined by the method which is actually disclosed in paragraphs 57 and 58. For example, as also discussed in the oral proceedings before the Board, a felt with a low tear strength could require a modified, lower cross head movement speed than the speed indicated in paragraph 58 in order to prevent immediate rupture of the low tear strength felt. The method disclosed in paragraph 58, i.e. the specific test set-up and parametrisation disclosed therein, can only be unambiguously considered to be valid for the testing of the specific examples of nonwoven felts reported in table 4.

- 1.3.4 An even greater discrepancy exists for the average (MD or CD) tensile strength given in table 5 (averages ranging from 5.16 to 23.5 N) compared to the claimed lower limit value of 0.89 N.
- 1.3.5 In addition to the ambiguity arising from the discrepancy between the values reported in tables 4 and 5 and the values indicated in paragraph 19 and in dependent claims 3 and 5 of the application as filed, a further ambiguity arises from the disclosure of paragraph 59 relating to the determination of the tensile strength. In this respect it is only indicated that "tensile strength was measured in a similar test as described in the Example 4", complemented by an indication of the apparatus to be used, the measurement direction and sample dimensions. It is not specified in which way the method in paragraph 59 is "similar" or may comprise variations compared to the method described in the preceding paragraph 58. The information in paragraph 59 therefore cannot be construed to unambiguously disclose any method of determining a tensile strength, let alone "the method" in connection with the defined lower limit value of feature ii) as referred to in claim 1 of the main request.
- 1.3.6 In the absence of any other disclosure linking, unambiguously, the methods referred to in paragraphs 57 to 59 to the lower limit values for tear strength and tensile strength disclosed in paragraph 19 and dependent claims 3 and 5 of the application as filed, the Board concludes that the addition of the expression "determined according to the method in the description" to the claimed lower limit values for tear strength and tensile strength leads to subject-matter extending beyond the content of the application as filed.

1.4 One part of the reasons given by the opposition division for its contrary conclusion, and on which the appellant-proprietor also relied, is based on the expression "nonwoven felt of the present invention" used in paragraph 57 of the application as filed. The Board is, however, not convinced by this. The expression "of the present invention" does not establish the missing link between the method and the lower limit value in feature iii) of claim 1 of the main request. The Board can agree that, as argued by the appellant-proprietor, the skilled person could have understood the reference to the "nonwoven felt of the present invention" as referring in fact to a nonwoven felt of the resorbable hemostatic dressing defined by claim 1 of the application as filed. However, claim 1 of the application as filed, if understood as defining the invention referred to in paragraph 57, does not define the lower limit values of tear strength or tensile strength. The Board cannot unambiguously infer from the cited statement that this means that the precise method as further described in paragraph 58 is to be applied, without any modification, to any nonwoven felt in a claimed dressing. It is rather to be understood in the limited context of the exemplary nonwoven felts tested by that method, which exemplary nonwoven felts are nevertheless felts of a dressing according to claim 1.

In view of the above, the appellant-proprietor's argument that only a single method is disclosed in the description for either lower limit value in claim 1 respectively, with the consequence that only these particular methods would be understood as applicable to the respective values in claim 1, also fails.

- 1.5 The Board is also not convinced by the appellant-proprietor's argument that the identified large discrepancy between the low minimum value of the strength ranges and the actually measured values for the exemplary nonwoven felts was evidence that the invention could be carried out over a broad range of the claim where the tested examples just constituted the best modes of the invention. This argument appears to relate in essence to the requirement of sufficiency of disclosure (Article 83 EPC), rather than to the present objection of extension of subject-matter. More importantly, the absence of any measured values closer to the claimed low minimum value cannot be seen as representing a disclosure for a link of the claimed values and the measured values and measurement methods.
- 1.6 As to the appellant-proprietor's argument that the Board had set two conditions to be met for a method to be considered as disclosed, this is apparently based on a misunderstanding of the Board's communication pursuant to Article 15(1) RPBA 2020. In the second paragraph of point 2.1 thereof, the Board stated that it 'cannot see that the description of the application as filed discloses a single and specific ("the") method for determining the tensile strength according to feature ii) of claim 1'. The expression in parenthesis ('"the"') in this quotation from the Board's communication, which was omitted by the appellant-proprietor in their counter-argument, refers back to the expression used in claim 1 of the main request, relating to "the method in the description". The question raised by the Board as to whether there is such a single and specific (i.e. "the") method disclosed in the description does not relate to the clarity requirement of Article 84 EPC, since it does

not address the clarity of the wording of claim 1. To the contrary, it goes to the heart of the question as to whether the application as filed discloses such a single and specific method as suggested by the added claim wording ("the method") in the context of the claimed lower limit values for tear strength and tensile strength, i.e. whether such a method could be derived directly and unambiguously from it. Notably, in view of the reference in paragraph 59 to "a similar method" - notwithstanding the absence of any link in this statement between such "similar method" used to measure tensile strength for the exemplary nonwoven felts and the low limit value indicated in paragraph 19 or claim 3 of the application as filed - it remains entirely unclear in which sense such method should be "similar" or at variance with the method mentioned before in paragraph 58, so that there cannot be an unambiguous disclosure of "the method". In this context it is thus not questioned whether the expression "similar method", when hypothetically inserted in a claim could render its subject-matter unclear under Article 84 EPC, as suggested by the appellant-proprietor.

2. Since the subject-matter of claim 1 of the main request does not meet the requirement of Article 123(2) EPC, the appellant-proprietor's request to maintain the patent in this form cannot be allowed.

*Auxiliary requests 1 to 18 - Article 123(2) EPC*

3. As already indicated in the Board's preliminary opinion in regard to the pending auxiliary requests 1 to 14, the objection under Article 123(2) EPC directed to the addition of "the method in the description" cannot be remedied by any of the amendments to claim 1 of these

auxiliary requests 1 to 14, not least since these fail to overcome the issues identified above as to why the main request is not allowable. In fact, in as far as the amendments to the respective independent claim 1 are concerned (see above point VII.), these are essentially directed to remedy another objection raised by the appellant-opponent under Article 123(2) EPC against claim 1 of the main request, notably against the expression "wherein the felt is deployable laparoscopically". Similarly, amendments to dependent claims as well as the different amendments to the description in these requests were submitted to, again, address objections unrelated to the above issue. It was also not argued that the respective amendments could have an impact on that issue. The same applies for auxiliary requests 15 to 18 submitted in reply to the Board's preliminary opinion. The appellant-proprietor also did not submit any comments or arguments in this regard during the oral proceedings before the Board. Maintenance of the patent in amended form according to auxiliary requests 1 to 18 therefore cannot be allowed.

4. Absent any set of claims meeting the requirements of the EPC, the Board can only accede to the appellant-opponent's request that the patent be revoked.

**Order**

**For these reasons it is decided that:**

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

The Registrar:

The Chairman:



D. Grundner

M. Harrison

Decision electronically authenticated