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Datasheet for the decision of 29 January 2013

Case Number: T 2442/11 - 3.2.06

Application Number: 03777601.0

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Title of invention:
MEDICAL DRESSING CONTAINING ANTIMICROBIAL AGENT

Applicant:
Covidien LP

Relevant legal provisions:
EPC Art. 56, 123(2)
RPBA Art. 13(1)

Keyword:
Inventive step - (no)
Auxiliary request filed during oral proceedings - not admitted

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Case Number: T 2442/11 - 3.2.06

D E C I S I O N
of the Technical Board of Appeal 3.2.06
of 29 January 2013

Appellant: (Applicant)	Covidien LP 15 Hampshire Street Mansfield, MA 02048 (US)
Representative:	Tomlinson, Edward James Frohwitter Patent- und Rechtsanwälte Possartstrasse 20 81679 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted 3 May 2011 refusing European patent application No. 03777601.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: M. Harrison
Members: G. de Crignis
W. Sekretaruk

Summary of Facts and Submissions

I. The Examining Division refused European patent application No. 03 777 601.0 holding that claim 1 of the main request and of auxiliary requests 1, 2, 3, 4, and 6 did not meet the requirement of Article 123(2) EPC, that claim 1 of the main request and of auxiliary requests 2 and 3 did not involve an inventive step and that claim 1 of auxiliary requests 2, 5 and 6 was not clear (Article 84 EPC) and also holding that the subject-matter of claim 1 of auxiliary requests 2 and 5 did not meet the requirements of Article 83 EPC.

II. The appellant (applicant) filed an appeal against this decision and together with its statement setting out the grounds of appeal filed an amended main request.

III. In a communication sent as an annex to a summons to oral proceedings the Board addressed various issues concerning admittance of the requests and clarity of the claims (Article 84 EPC). The Board also indicated that the subject-matter claimed did not involve an inventive step.

IV. With letter of 28 December 2012, the appellant filed an amended main request and an amended first auxiliary request.

V. Oral proceedings were held on 29 January 2013. During the oral proceedings the appellant filed a main request and an auxiliary request replacing all previous requests. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request or on the basis of the auxiliary request, each dated 29 January 2013.

VI. Claim 1 of the main request has the following text:

"A medical dressing comprising:
layered fabric characterized by consisting of:
an inner layer (B) of substantially hydrophilic material;
an outer layer (A,C) of substantially hydrophobic material on both sides of the inner layer; and
an antimicrobial agent contained in the inner layer,
wherein the antimicrobial agent is releasably impregnated into the hydrophilic material of the inner layer, and
wherein the antimicrobial agent is a biguanide."

Claim 1 of the auxiliary request has the following text:

"A medical dressing comprising:
a thermally bonded layered fabric characterized by consisting of:
an inner layer (B) of substantially hydrophilic material;
an outer layer (A,C) of substantially hydrophobic material on both sides of the inner layer; and
an antimicrobial agent contained in the inner layer,
wherein the antimicrobial agent is releasably impregnated into the hydrophilic material of the inner layer and is releasable from the fabric in a moist environment, and
wherein the antimicrobial agent is a biguanide."

VII. The appellant argued essentially as follows:

Claim 1 of the main request included the wording "substantially" linked to the hydrophilic and the hydrophobic material such as disclosed in originally filed claim 1 and in the description on page 12. Moreover, claim 1 was limited to the embodiment where the antimicrobial agent was releasably impregnated into the hydrophilic material of the inner layer such as disclosed in originally filed claim 2, and the alternatives were deleted concerning the coating of such material on the inner layer as well as the combination of coating and impregnation. Accordingly, the combination of features such as claimed in claim 1 was originally filed and the requirement of Article 123(2) EPC was met.

It was clear from the description as a whole and from the embodiment shown in Figure 1, that the layered fabric consisted only of an inner layer and two outer layers and that an antimicrobial was contained in the inner layer only (Article 84 EPC). This followed from the wording of the claim, due to the wording “consisting of” together with the expression “contained in the inner layer” which thereby excluded the presence of the antimicrobial agent in any other layer.

Such structure differed from the structure of the fabric disclosed in

D2: EP-A-0 531 096,

in that the dressing in D2 was produced by hydraulic entanglement through water jets which manufacturing process did not allow a structure to be obtained which consisted of an inner layer of hydrophilic material and a layer of hydrophobic material on each side thereof

because there were always transition regions present including intermingled material.

The skilled person considering the manufacturing process of D2 did not immediately arrive at the claimed structure, nor was a teaching present to do so. This was also clear from D2, which disclosed up to 5% of hydrophilic fibres at the hydrophobic surface of the composite fabric (col. 6, l. 53 - 56). Accordingly, the skilled person had no suggestion to avoid hydrophilic fibres in the hydrophobic layer, it being noted that the antimicrobial was present in the hydrophilic fibres. An inventive step was thus present, since there was no teaching to combine the layers in the way claimed. In particular, the choice of thermo-bonding as an appropriate manufacturing process allowed the structure in claim 1 to be obtained, for which there was no suggestion in D2.

The wording of claim 1 of the auxiliary request addressed the difference in the manufacturing process explicitly via the insertion of the reference to the "thermally bonded" layered fabric. Such fabric was disclosed on page 10, line 7 of the application in suit. Thus the claimed subject-matter was distinguished further from the dressing disclosed in D2 in that a completely different and specific manufacturing process was applied whereby no intermingling of the layers in the layered fabric was possible. Only via such a manufacturing process, could the object of the current invention be obtained in a manner so as to maintain the antimicrobial agent only in the inner layer, or in other words to "contain" it therein in accordance with the claim.

It was not necessary to further include the term "nonwoven" with regard to the "thermally bonded" fabric as the claimed embodiment was additionally based upon the teaching disclosed in US-A-4,211,227 - which was incorporated by reference as set out on page 10, lines 3 to 5 of the patent application, - and hence, the skilled person knew that only such material was to be considered. Hence, the request was *prima facie* allowable and should be admitted into proceedings.

Reasons for the Decision

1. *Main request - Admittance*

The main request was filed during the oral proceedings. According to Article 13(1) of the Rules of Procedure of the Boards of Appeal (RPBA), it lies within the discretion of the Board to admit any amendment to a party's case after it has filed its grounds of appeal. This main request is considered by the Board to at least *prima facie* overcome the objections raised against the previous requests under Article 84 EPC 1973 and Article 123(2) EPC. The Board thus exercised its discretion to admit this request into the proceedings.

2. *Main request - inventive step*

2.1 In claim 1, the medical dressing is defined by the structural features of a layered fabric consisting of an inner layer, two outer layers and biguanide as an antimicrobial agent contained in the inner layer.

2.2 Considering such medical dressing, the closest prior art is represented by D2. This was also not contested by the appellant.

2.3 D2 discloses a composite fabric used as a wound dressing (col. 1, l. 3-5).

2.3.1 The fabric is disclosed as having a symmetrical sandwich structure which consists of an inner layer of water-absorbent fibrous material and two outer hydrophobic layers which are formed by water-permeable fibrous material (col. 4, l. 39-41, col. 7, l. 1-3), which structure is illustrated in the sketch shown in Figure 3 therein.

2.3.2 The hydrophobic layers in D2 retain outer surfaces "that are substantially free from hydrophilic fibres" (col. 6, lines 51-53, col. 5, line 22-26). Thus, although it is disclosed in D2 that the "hydrophobic surface of the composite fabric after entanglement will comprise no more than 5% of hydrophilic fibres and usually no more than 1% of hydrophilic fibres" (col. 6, l. 53-56), D2 aims towards, and is to be understood as disclosing, an outer surface which is indeed "substantially free" from hydrophilic fibres and the presence of hydrophilic fibres in the outer layer.

2.3.3 D2 discloses that the water-absorbent inner layer 7 may be impregnated with an antimicrobial agent such as silver chloride or silver sulphadiazine (col. 8, lines 8-10).

2.4 The appellant considered the layered fabric of D2:

(a) not to be "consisting of" an inner layer of substantially hydrophilic material and an outer layer of substantially hydrophobic material on both sides of the inner layer;

(b) as not disclosing an inner layer "of substantially hydrophilic material" but disclosing an inner layer "substantially of hydrophilic material" - and the same applying for the outer layer and the substantially hydrophobic material;

(c) as not disclosing a structure "consisting of" ... an antimicrobial agent "contained in" the inner layer; and

(d) as not disclosing biguanide as antimicrobial agent.

2.5 The appellant's consideration (a) was based upon the understanding that the fabric in D2 was to be manufactured by water entanglement which necessarily leads to a transition region of intermingled fibers and therefore, no specific three-layer structure as defined in claim 1 could be present in the dressing according to D2, since the claimed structure allegedly required entirely distinct layers.

2.5.1 However, the symmetrical sandwich-structure in D2 can also only be understood as "consisting of" an inner layer of hydrophilic material and an outer layer of hydrophobic material on both sides of the inner layer because no other layers than these three layers are disclosed, and the existence of transition regions applies for any fibrous layered structure and thus also for both the one disclosed in D2 as well as for the claimed layered fabric.

2.5.2 Also, there is no feature concerning a structural limitation implied by any particular manufacturing method included in claim 1 (as was argued by the appellant to be implicitly present when interpreting the term "consisting of" as related to the three layers). Thus, technically inevitable transition

regions, which always occur upon the joining of layers of fibrous material, are in the scope of any sandwich composite in relation to any applied manufacturing technique. Such manufacturing techniques include water entanglement of the fibrous layers, thermo-bonding but also ultrasonic bonding or gluing. In none of these manufacturing processes can transition regions be avoided - albeit that these transition regions may extend to a greater or lesser extent throughout the layers: during water entanglement, an intermingling of the fibres in a transition area occurs; during thermo-bonding or gluing the neighbouring fibres are bonded by pressure and/or heat with or without adhesives which leads inevitably to a bonded area containing a mixture of fibres.

2.5.3 Additionally, the terminology "consisting of" as used in the claim, cannot be regarded as absolute (referring to 100% of hydrophilic/hydrophobic material) in the sense of excluding entirely the presence of any other material, due to the fact that the inner and outer layers are specified in the claim as consisting "substantially" of the defined materials, allowing thus other materials - albeit to a minor extent - to be included in these layers. Thus, the terminology "consisting of", with respect to the layers, does not distinguish the claimed subject-matter from the subject-matter disclosed in D2.

2.6 The appellant’s consideration (b) was mainly based upon the disclosure in D2 referring to a water entanglement process for manufacturing the composite which process leads to hydrophilic fibres being introduced into the outer layer and even extending into the surface thereof. For support of this argument, the disclosure in D2, cited under point 2.3.2 above was cited.

2.6.1 However, such disclosure is preceded by the wording in column 6, lines 46 to 53:
"The minimal penetration of fibres from the hydrophilic layer into the hydrophobic layer arises because it is the hydrophobic layer which faces the water jets in the entanglement process. As a result, even very thin hydrophobic layers ... retain outer surfaces that are substantially free from hydrophilic fibres."
As regards the aspect of thickness, D2 discloses (see citation above) that "even very thin hydrophobic layers … are substantially free from hydrophilic fibres" and that the fabric (see column 6, lines 34 to 36) may vary in the thickness range of 0.5 to 2.0 mm.

2.6.2 In this context, it has to be taken into account that the effective presence of hydrophilic fibres on the outer surface - and thus also within the outer layer - is, for a skilled person, evidently dependent on e.g. the manufacturing method, the thickness of the inner and outer layers, the materials applied, the position of the mesh belt when applying for example water jets and the pressure of such water jets, the application of a hydrophobic finish after the entangling step, and also other process conditions. Moreover, such disclosure in D2 is relates to the general aim to provide a surface which is "substantially free" from hydrophilic fibres and the process conditions would evidently necessarily be optimized in order to ensure this.

2.6.3 Moreover, with regard to the material of the layers, the application in suit defines with regard to the inner layer that:

- "in general, the inner layer material is "substantially hydrophilic" (page 12, lines 5, 6); and
- "the fibres used in the substantially hydrophilic inner layer" (page 12, line 22/23);

Thus, with respect to the correct interpretation of the subject-matter claimed, no distinction is to be made between whether the inner layer is of substantially hydrophilic material or whether the inner layer substantially is of hydrophilic material - and the same applies for the outer layer with respect to the substantially hydrophobic material. Thus, it is clear that the term "substantially" has been purposefully chosen to clarify that the inner layer and the outer layers have to differ substantially from each other in their kind of material, but it is not excluded that another material is present to a minor extent in the respective layers.

2.6.4 Thus, the terminology "substantially of" with respect to the hydrophilic and hydrophobic material of the inner and outer layers, does not distinguish the claimed subject-matter from the disclosure in D2.

2.7 The appellant’s consideration (c) was based upon the understanding that the antimicrobial was restricted in claim 1 to being only in the inner layer and nowhere else.

2.7.1 The Board finds this argument unconvincing, since, as explained *supra*, although the inner layer is of substantially hydrophilic material and the outer layer is of substantially hydrophobic material - the presence of minor amounts of hydrophilic materials in the outer layers cannot be excluded. In particular the release

function of the dressing with respect to the antimicrobial agent even necessitates such.

2.7.2 Consistently, the application in suit discloses with regard to the inner layer that "In general, the inner layer material is "substantially hydrophilic" such that wound exudate may be absorbed by the inner layer absorbent core and that the antimicrobial agent may be contained mostly within the absorbent core" (page 12, lines 6 to 8). Thus, the description does not define the antimicrobial agent being contained "only" in the inner layer but defines that it is contained "mostly" therein when defining the inner layer as being "substantially hydrophilic". The same paragraph (page 12, lines 10 - 12) specifies that when defining the outer layer as being "substantially hydrophobic", it "provides an antimicrobial barrier property and attenuates or reduces the release of antimicrobial agent away from the dressing". Thus, the barrier property of the outer layer is not for blocking the release but for attenuating or reducing the release of the antimicrobial agent. Hence, minor amounts of antimicrobial agent are to be considered as being present within such layer.

2.7.3 Likewise, whilst claim 1 defines that the antimicrobial agent is "contained in the inner layer" and also that it is "releasably impregnated into the hydrophilic material of the inner layer", the understanding of this feature (consistent with the aforegoing) can only be that the vast majority of the antimicrobial agent is contained in the inner layer. Therefore, the terminology "consists of" with respect to the inner and outer layers in combination with the terminology "contained in" does not limit the antimicrobial to being present only in the inner layer.

2.7.4 In D2 this feature is disclosed in that the water-absorbent layer may be impregnated with an antiseptic (col. 8, l. 8 -10). Accordingly, when applying the manufacturing method of water entanglement, the water jets are directed onto the surface of the hydrophobic layer and the entanglement leads to the composite dressing comprising small amounts of hydrophilic material in at least one of the hydrophobic layers. Such small amounts of hydrophilic fibres accordingly necessarily also include hydrophilic fibres which have been impregnated with an antiseptic and thus the release of the antiseptic function is possible and the same structure and effect is present as in the claimed dressing. Therefore no difference as regards this claimed feature can be recognised when compared to the disclosure in D2.

2.8 For these reasons, the only difference between the subject-matter of claim 1 and the disclosure in D2 concerns the feature that the antimicrobial agent is a biguanide (feature (d) as specified under point 2.4 above).

2.8.1 Biguanides are well-known antimicrobial agents which can be used whenever circumstances make it desirable. In the application, it is also noted that no particular advantage is set out for using this antimicrobial agent. Accordingly, when starting from the composite dressing of D2 and desiring to provide antimicrobial characteristics to the dressing, the choice of biguanide is one of several straightforward possibilities which the skilled person would select for achieving a desired antimicrobial activity.

2.8.2 D2 already suggests the impregnation of the hydrophilic inner layer using antiseptic agents (col. 4, lines 23 - 25; col. 8, lines 8 - 10). The selection of a different kind of antimicrobial agent cannot thus be considered as involving an inventive step (Article 56 EPC). Such view was already given in the annex to the summons of the oral proceedings before the Board; it also underlies the reasoning of the opposition division in the appealed decision. No argument to the contrary was presented by the appellant. Thus, when starting from D2 and wishing to solve the problem of providing a suitable alternative antimicrobial agent to those disclosed in D2, no inventive step is involved in the use of biguanide as the antimicrobial agent (Article 56 EPC).

The main request is therefore not allowable.

3. *Auxiliary request 1*

3.1 The request was filed during the oral proceedings, hence at the latest possible stage in the proceedings and, as already set out above, the Board needs to exercise its discretion as to whether the request should be admitted into proceedings in accordance with Article 13(1) RPBA. In order to be admitted, the aspect of procedural economy given in Article 13(1) RPBA should be considered, which implies at least that the request should clearly be allowable in the sense that it overcomes the objections raised without giving rise to new objections. This is however not the case for claim 1 of this request, for the following reasons.

3.2 Compared to claim 1 of the main request, the subject-matter of claim 1 additionally includes the feature concerning the layered fabric being "thermally bonded".

The appellant referred in this regard to the sole explicit disclosure of this feature on page 10, line 7 of the originally filed application.

3.3 The description on page 10, line 7 is related to "a medical dressing which is an antimicrobial drain sponge which is a thermally bonded nonwoven absorbent material, typically in the form of a square that is 2" x 2" or 4" x 4" and having a 6 ply thickness". Accordingly, with regard to the material which is thermally bonded, the only disclosure refers to a nonwoven absorbent material in combination with a drain sponge. These features are however not included in claim 1 under consideration.

3.4 The appellant's reference to the inventive medical dressing being further based, in part, upon the dressing disclosed in US-A-4,211,227 such as set out on page 10, lines 3 to 5 of the originally filed application (which document would refer to thermally bonding with regard to nonwoven materials), is not found persuasive. On the one hand it is not disclosed to which extent the application in suit is based upon the dressing disclosed in US-A-4,211,227, and on the other hand the claimed subject-matter is anyway not limited to the specific nonwoven materials disclosed therein nor to the particular method of thermal bonding which results in the structured material having a defined pattern as disclosed in US-A-4,211,227.

3.5 Moreover, no disclosure in the originally filed application is present or has been cited for the combination of a "thermally bonded" fabric having a biguanide as an antimicrobial agent contained in its inner layer.

3.6 Thus, no clear and unambiguous disclosure can be derived from the application as originally filed for the claimed combination of features. Consequently the subject-matter of claim 1 extends beyond the content of the application as originally filed contrary to Article 123(2) EPC.

3.7 Hence, the auxiliary request is *prima facie* not allowable at least for this reason. The Board thus exercised its discretion under Article 13(1) RPBA not to admit this request into the proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. H. A. Patin M. Harrison

Decision electronically authenticated