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**Datasheet for the decision
of 15 November 2016**

Case Number: T 2168/14 - 3.3.10
Application Number: 04795047.2
Publication Number: 1682189
IPC: A61L2/26, A61B19/02, D04H13/00,
A61L2/28
Language of the proceedings: EN

Title of invention:
STERILIZATION WRAPS AND METHODS FOR STERILIZING ARTICLES

Applicant:
Allegiance Corporation

Headword:

Relevant legal provisions:
EPC Art. 123(2), 84, 54(2), 56

Keyword:
Amendments - allowable (yes)
Inventive step (yes) - after amendment

Decisions cited:

Catchword:



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Case Number: T 2168/14 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 15 November 2016

Appellant: Allegiance Corporation
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McGaw Park, IL 60085 (US)

Representative: Prock, Thomas
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 6 June 2014
refusing European patent application No.
04795047.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: R. Pérez Carlón
F. Blumer

Summary of Facts and Submissions

- I. The appellant lodged an appeal against the decision of the examining division to refuse European patent application No. 04 795 047.2.
- II. The examining division concluded that the claims of the requests before it were not clear, contained added subject-matter, or were not inventive.
- III. The documents forming part of the examination proceedings included the following:

D3: EP 0 754 796 A1
D7: US 3,780,857
D8: US 5,635,134

- IV. During the oral proceedings before the board, which took place on 15 November 2016, the appellant made the request filed as "new auxiliary request 2" under cover of a letter dated 8 July 2016 its main request. Claim 1 reads as follows:

"A sterilization wrap for wrapping an article (36) to be sterilized, comprising:

at least a first panel of sterilization material (32,48) comprising fibrous or non-fibrous material that is capable of inhibiting pathogens from passing therethrough;

wherein said first panel of sterilization material has two sides; one side of said first panel of sterilization material having a central portion; and

a panel (34,52) of absorbent material being bonded to the central portion of said first panel; the perimeter of said panel of absorbent material being smaller than the perimeter of said first panel; wherein said panel of absorbent material is adapted to receive the article (36) to be sterilized thereon; said panel of absorbent material (a) providing sterility protection for the article in addition to said first panel of sterilization material, and (b) wicking moisture away from the article after sterilization has taken place;

wherein the first panel and the panel of absorbent material permit sterilant to pass therethrough, but inhibit pathogens from passing therethrough; said sterilization wrap further including a second panel of sterilization material (46); said second panel of sterilization material bonded to said first panel (48) of sterilization material, and wherein said first and second panels of sterilization material (46, 48) are made of a three-ply laminate consisting of a layer of melt blown polypropylene sandwiched between two layers of spun bond polypropylene (SMS)."

- V. The arguments of the appellant relevant for the present decision were the following:

The claims of the main request did not contain any added subject-matter. Claim 1 found a basis in the combination of claims 1, 2, 7, 9, 10, and the passage on page 9, lines 4-7, of the description as originally filed. Dependent claims 2 to 10 found a basis in claims 5, 6, 8, 11-14, 17 and 15, respectively.

Document D8 related to a sterilisation wrap consisting of two layers of "SMS", wherein SMS indicated a layer of melt-blown polypropylene between two layers of spun-

bond polypropylene. It shared more features with claim 1 than any other document on file and was thus the closest prior art. The problem underlying the claimed invention was providing a sterilisation wrap which made it possible to improve long-term sterile packaging, and the solution, which was characterised by a further panel of absorbent material having a perimeter smaller than the first SMS panel bonded to its central portion, was inventive having regard to the prior art.

VI. The final requests of the appellant were that the decision under appeal be set aside and that a patent be granted on the basis of the main request, filed as new auxiliary request 2 with letter dated 8 July 2016, or, subsidiarily, on the basis of any of auxiliary requests 1 to 7, auxiliary request 1 filed as new auxiliary request 3 with letter dated 8 July 2016, auxiliary requests 2 to 7 filed as main request and auxiliary requests 1 to 5 with the statement setting out the grounds of appeal.

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

Reasons for the Decision

1. The appeal is admissible.

Amendments

2. Claim 1 of the main request finds a basis in the combination of claims 1, 2, 7, 9 and 10 as originally filed, and the passage of the description on page 9, lines 4-7.

Claim 10 as originally filed, which required the first and second panel to be made of melt-blown polypropylene sandwiched between two layers of spun-bond polypropylene (SMS), was not dependent on claims 7 or 9. The question thus arises whether the features of these claims were disclosed in combination in the application as originally filed.

SMS is the sole material disclosed in the application regarding the first and second layers. The skilled person would consider this preferred embodiment to be combined with any other feature of the claimed invention, and thus also with the features of claim 7, which requires the perimeter of the panel of absorbing material to be smaller than that of the first panel, and of claim 9, requiring the panel of absorbing material to be bonded to the central portion of the first panel.

The passage on page 9, lines 4-7, discloses that the first panel required by claim 1 can be made of fibrous or non-fibrous material which inhibits the passage of pathogens whilst permitting that of sterilant. Although this passage refers to figure 2, these properties are inevitably required by every panel forming part of a sterilisation wrap. This was also acknowledged by the appellant during the oral proceedings. Thus, the skilled reader would consider these properties of the first panel to apply to every embodiment according to the claimed invention, and thus not to be restricted to the embodiment represented by figure 2.

3. Dependent claims 2 to 10 find a basis, respectively, in original claims 5, 6, 8, 11-14, 17 and 15, in combination with the passages already mentioned with

respect to claim 1.

4. For these reasons, it is concluded that claims 1-10 of the main request do not contain added subject-matter, as required by Article 123(2) EPC.

Clarity

5. The feature "SMS" objected to under Article 84 EPC in the decision under appeal has been completed by its definition in claim 1.

Novelty

6. Novelty was already acknowledged by the examining division, and the board has no reason to differ, as document D3 does not disclose a wrap having two SMS layers, and neither D7 nor D8 discloses a wrap having absorbent material. For this reason alone, the subject-matter of claim 1 is novel, as required by Article 54 EPC.

Inventive step

7. Claim 1 relates to a sterilisation wrap containing three panels: first and second SMS panels, and a further panel of absorbent material, whose perimeter is smaller than that of the first panel, and is bonded to its central portion.
8. Closest prior art

Document D3 discloses a three-layer sterilisation wrap, intended as a single wrap, comprising a spun-bonded thermoplastic layer (14), a non-woven fibrous web layer (12) and a further layer (16) which can be made either

of spun-bonded thermoplastic filaments or of absorbing fibres (page 2, line 53 to page 3, line 18; figure I). Thus, document D3 discloses an SMS wrap (spun-bonded/non-woven/spun-bonded), and a wrap having absorbing/non-woven/spun-bonded layers.

Document D7 discloses a wrap that does not have an absorbing layer, as cardboard mat (11) is made of coated cardboard in order to avoid absorbing any steam during autoclaving (column 3, lines 36-39). Neither wrap (10) nor additional pouch (30) are made of SMS.

Document D8 discloses a double wrap consisting of two SMS layers (column 7, lines 31-61) which are joined to one another (column 3, lines 52-56; figure I).

Document D8 discloses more features required by claim 1 than D3 and D7 and is thus the closest prior art.

9. Technical problem underlying the invention

The appellant defined the technical problem underlying the claimed invention as providing a sterilisation wrap which made it possible to improve long-term sterile packaging.

10. Solution

The solution to this technical problem is the claimed sterilisation wrap, characterised in that it has a further panel of sterilisation material which is made of absorbent material and, hence, can wick moisture away after sterilisation has taken place, is bonded to the central portion of the first panel, and whose perimeter is smaller than that of the first panel.

11. Success

There is no reason to doubt that the presence of an additional panel enhances the long-term packaging properties of a sterilisation wrap and thus that the problem as defined above is credibly solved by the sterilisation wrap of claim 1.

12. It thus remains to be decided whether or not the proposed solution to the objective problem defined above is obvious in view of the state of the art.

Document D3 is the sole prior-art disclosure which refers to a layer of absorbent material. D3 discloses an absorbing layer as part of a sterilisation wrap having absorbing/non-woven/spun-bonded layers, intended for single wrapping. This three-layered wrap is an alternative to an SMS panel. Document D3 is silent on the role of said layer. D3 thus hints at replacing one of the three layers of one or more of the SMS panels of D8 with an absorbent layer, but not at the claimed solution.

The skilled person, confronted with document D8 and trying to provide a sterilisation wrap which made it possible to improve long-term sterility could add a further layer of sterilisation material. However, there is no indication in the prior art which would have led the skilled person to add a layer of absorbent material having a perimeter smaller than that of the SMS first panel and attached to its central part. In the absence of such indications, the board concludes that the sterilisation wrap of claim 1 is inventive, as required by Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to grant a patent on the basis of the claims of the main request, filed as new auxiliary request 2 with letter dated 8 July 2016, and a description and drawings to be adapted thereto.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated