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**Datasheet for the decision
of 10 October 2013**

Case Number: T 1666/11 - 3.2.08

Application Number: 04021323.3

Publication Number: 1514572

IPC: A61F2/00, A61F5/445,
A61F5/448, // A61M31/00,
A61M25/01

Language of the proceedings: EN

Title of invention:
Fecal management appliance and method

Patent Proprietor:
ConvaTec Technologies Inc.

Opponent:
Hollister Incorporated

Headword:

Relevant legal provisions:
EPC Art. 100(b)

Keyword:
Sufficiency of disclosure - (yes)

Decisions cited:

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 1666/11 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 10 October 2013

Appellant:
(Patent Proprietor)

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Respondent:
(Opponent)

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Representative:

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 17 May 2011
revoking European patent No. 1514572 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman: M. Alvazzi Delfrate
Members: P. Acton
D. T. Keeling

Summary of Facts and Submissions

- I. The appellant (patent proprietor) filed a notice of appeal received at the EPO on 27 July 2011 against the opposition division's decision posted on 17 May 2011 revoking European patent EP 1 514 572. The appeal fee was paid simultaneously and the statement of grounds was received on 22 September 2011.
- II. The Opposition Division had come to the conclusion that the European Patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- III. The appellant requested that the decision under appeal be set aside and the case be remitted to the Opposition Division to consider the issues of novelty and inventive step on the basis of the patent as granted or, in the alternative, of auxiliary requests 1 to 9 filed with letter of 22 September 2011.

The respondent (opponent) requested that the appeal be dismissed.

- IV. Third party observations relating to sufficiency of disclosure were filed on 9 August 2013 and communicated to the parties on 16 August 2013.
- V. Independent claim 1 according to the main request reads:

"A waste management appliance for the rectum or stoma comprising an elongated tubular element (A) having a distal end (10) and a proximal end (12); an inflatable balloon (14) surrounding said distal end of said elongated tubular element (A); an externally accessible

inflation lumen (16) operably connected to said balloon; a waste collection receptacle (B); and means (C) for detachably mounting said receptacle to said proximal element end of said elongated tubular element (A), characterized in that said distal element end of said elongated tubular element (A) is formed entirely of soft, compliant material."

The further independent claims 40 and 45 have not been contested under Article 100(b) EPC.

The auxiliary requests are not relevant for the present decision.

VI. The following document played a role for the present decision.

Declaration of W. Woinowski concerning the Sufficiency of the Patent in Suit, dated 20 September 2011.

VII. The respondent's arguments can be summarised as follows:

Claim 1 as granted covered waste management appliances which needed a separate introduction tool as well as appliances which could be introduced on their own. In the latter case the distal end of the claimed appliance needed some sort of rigidity, so that it could be introduced into the rectum.

The claim itself did not define how soft and compliant the material of the distal end had to be.

The description stated in paragraph [0018] that any device according to the invention must be such that it is "incapable of causing any injury to the tissue".

This was irrespective of the use of a separate introduction tool. However, no material fulfilling these requirements was disclosed.

It was correct that silicone was cited in paragraph [0055] as a soft and compliant material which could be used for the distal end of the appliance. However, not all types of silicone complied with the requirements of softness and compliance which are necessary in order to assure that no injury is caused to the tissue surrounding the appliance. The declaration of W. Woinowski stated that the material should have a Durometer Shore A of 50 or less. However, the patent was silent on this condition.

Moreover, paragraph [0055] related only to an embodiment in which the appliance is used together with a separate introduction apparatus. Therefore, paragraph [0055] did not disclose a suitably soft and compliant material to be used for an appliance according to the invention, which is applied without the need of an insertion tool. Accordingly, the European patent did not enable a person skilled in the art to carry out the invention over the whole scope of the claim, because it did not disclose how soft and compliant the material had to be.

Therefore, the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

VIII. The appellant's arguments can be summarised as follows:

Generally, an objection of lack of sufficient disclosure presupposed that there were serious doubts as to the possibility to carry out the invention. The

burden of proof being upon the opponent to establish that a person skilled in the art, using common general knowledge, would be unable to carry out the invention. In the present case, the respondent was not able to submit any proof in this respect.

Article 100(b) EPC referred to the patent as a whole, including description and drawings. Normally the disclosure of one embodiment showing a way to carry out the invention, in the present case the use of silicone, was sufficient to assure compliance with this article.

Finally, the functional feature according to which the material has to be so soft and compliant that it is incapable of causing injury gave the skilled person enough information for choosing the appropriate material without any undue burden.

Therefore, the invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The appellant's objection relating to the lack of definition of the degree of softness was rather a disguised clarity objection.

Reasons for the Decision

1. The appeal is admissible.
2. Article 100(b) EPC
 - 2.1 Sufficiency of disclosure must be assessed on the basis of the patent as a whole - including the description and drawings - and not of the claims alone. Moreover, an invention is in principle sufficiently disclosed if

at least one way is clearly indicated enabling a person skilled in the art to carry out the invention (Case Law of the Boards of Appeal of the European Patent Office, 7th edition 2013, II.C.4.2).

2.2 In the present case, the patent discloses in the description and in the drawings an appliance which is to be used together with an introduction tool, with all its geometrical and physical characteristics. In paragraph [0055] it is stated that silicone can be used as a material of the distal end, in order to ensure that body tissue is not injured. It is correct that not all silicones fulfil these requirements of softness and compliance (see declaration of W. Woinowski), however, choosing amongst silicones those which do not cause any injury does not amount to an undue burden on a person skilled in the art. Therefore, such a person is able to build the appliance on the basis of this embodiment.

2.3 It is correct that claim 1 also encompasses appliances which can be inserted without the need of an introduction tool, while paragraph [0055] relates to a device which is to be inserted via an introduction tool.

Nevertheless, since the patent suggests the use of silicone for a specific embodiment of the appliance according to the invention, it is evident for the skilled person that this material can be used for the further embodiments of the device as well. Furthermore, it is a matter of routine to select from the number of commercially available biocompatible silicones those which are both rigid enough to allow the use of the appliance without any insertion tool and which do not cause any injury to the body tissue, as required by paragraph [0018].

2.4 It is true that claim 1 does not define how soft and compliant a material needs to be. However, the determination of the scope of the claim is a matter which concerns the requirements of Article 84 EPC, which is not a ground of opposition.

As a matter of fact, the respondent did not provide a single example of an appliance in accordance with claim 1 which could not be realised. Accordingly, there is no reason to conclude that the invention cannot be carried out over the whole scope of the claim.

2.5 Hence the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and complies with the requirements of Article 100(b) EPC in combination with Article 83 EPC.

3. For the reasons above, the ground of opposition under Article 100(b) EPC does not justify the revocation of the patent as granted. Under these circumstances, the Board deems it appropriate, exercising its powers under Article 111(1) EPC, to remit the case to the opposition division for further prosecution so that it can decide on the grounds of opposition under Article 100(a) EPC, which relate to separate requirements from those of Article 100(b) EPC, and which were also raised during the opposition proceedings but not dealt with in the decision under appeal.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division for further prosecution.

The Registrar:

The Chairman:



V. Commare

M. Alvazzi Delfrate

Decision electronically authenticated