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**Datasheet for the decision
of 24 January 2018**

Case Number: T 0578/13 - 3.2.02

Application Number: 03794433.7

Publication Number: 1551715

IPC: A61M25/00, B65D1/00

Language of the proceedings: EN

Title of invention:

APPARATUS FOR PACKAGING ELONGATE SURGICAL DEVICES

Patent Proprietor:

Clean Cut Technologies LLC

Opponent:

SP Medical A/S

Headword:

Relevant legal provisions:

EPC Art. 111(1), 113(1), 114(1), 114(2)

EPC R. 103(1)(a), 111(2)

RPBA Art. 11

Keyword:

Substantial procedural violation - appealed decision reasoned
(no) - violation of the right to be heard (yes) - Late-filed
documents not admitted
Remittal to the department of first instance
Reimbursement of appeal fee

Decisions cited:

J 0007/82, T 0736/14

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0578/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 January 2018

Appellant: SP Medical A/S
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on
21 December 2012 rejecting the opposition filed
against European patent No. 1551715 pursuant to
Article 101(2) EPC**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
M. Stern

Summary of Facts and Submissions

- I. The opponent has appealed the Opposition Division's decision, dispatched on 21 December 2012, to reject the opposition against European patent No. 1 551 715.
- II. The patent was opposed on the grounds of lack of novelty and inventive step.

In the impugned decision the Opposition Division held that the subject-matter of claims 1 and 17 was novel and inventive. In particular, it referred to alleged prior uses supported by the following evidence filed by the opponent with the notice of opposition:

- E0: Declaration by Mr Egon Johannes Nielsen, dated 10 May 2010;
- E1: Fax from Mr Bent Thorning Bensen (1 page, 1 figure), dated 7 November 1994;
- E2: Drawings from Porges S.A., dated 5 September 1994;
- E3: Fax from Mr Gérard Torchio (Porges S.A.), dated 16 December 1998, including a drawing;
- E4: Fax from Ms Grethe Bensen (MEE-DAN A/S), dated 7 January 1999, in reply to fax E3;
- E5: Manufacturer/supplier quality agreement for Guide wire between MEE-DAN A/S (now Acccoat Medical) and PORGES-SYNTHELABO, signed on 25 October 1999 together with enclosures in the form of "PRODUCT SPECIFICATION" (1 page) and "Controls' Balance Sheet of the past year" (2 pages of 20);
- E6: Three drawings of different oval welded dispensers from Acccoat Medical, dated 20 August 2001;
- E7: Order for welded oval dispensers from PORGES S.A., dated 19 October 2000, order confirmation

- from Acccoat Medical, dated 23 October 2000, delivery note and invoice from Acccoat Medical, dated 8 November 2000, together with internal production papers (13 pages);
- E8: Reports and summary of development project U.03 in the period from 28 February 2000 to 19 December 2000 relating to a machine for manufacturing round welded dispensers (16 pages);
- E9: Order from MEE-DAN A/S, dated 19 April 2000, for a machine for manufacturing round welded dispensers, including a project description (16 pages);
- E10: Drawing from H H Engineering ApS (a producer of machines for manufacturing round welded dispensers), dated 27 May 2000 (1 page);
- E11: Declaration of conformity of a machine for manufacturing round welded dispensers according to EU Directive 89/392 from H H Engineering ApS and side labels for the machine, all dated 10 October 2001 (2 pages);
- E12: Fax from Acccoat Medical, dated 18 January 2001, including drawings of an oval welded dispenser (3 pages);
- E13: Declaration of Mr Gorm Gerved, dated 7 May 2010, relating to the properties of a welded dispenser;
- E14: Fax order for welded dispensers from ENDOTECH S.p.A., dated 12 February 2002, order confirmation from Acccoat medical, dated 15 February 2002, delivery note and invoice from Acccoat medical, dated 8 March 2002, together with internal production papers (12 pages);
- E15: Drawing of a round welded dispenser from Acccoat Medical, dated 6 September 2001, and production list for round welded dispensers (2 pages);
- E16: Extract from the 2001 annual report of the SP

Group (cover page and page 21);

- E17: Leaflet illustrating Accoat products (pages 1 to 7) and an enlarged picture showing the producer of the leaflet;
- E18: Invoice from Bureau2 (producer of leaflet E17), dated 25 November 2002;
- E19: Video illustrating the functional principle of an oval welded dispenser;
- E20: Video illustrating the functional principle of a round welded dispenser;

and the following evidence filed after expiry of the opposition period:

- E7A: English translation of E7;
- E8A: English translation of E8;
- E9A: English translation of E9;
- E10A: English translation of E10;
- E11A: English translation of E10;
- E14A: English translation of E14;
- E15A: English translation of E15;
- E16A: English translation of E16;
- E18A: English translation of E18.

It further referred to the following documents filed with the notice of opposition:

- D1: US-A-6,053,313
- D2: US-A-4,607,746
- D3: US-A-5,848,691.

The Opposition Division did not admit into the proceedings the following evidence filed after expiry of the opposition period:

- E21: Picture illustrating an oval welded dispenser,

- taken after 3 September 2002;
- E22: Picture illustrating a round welded dispenser;
- E23: Additional statement by Mr Gorm Gerved, dated 18 September 2002, to complement E13;
- E24: Statement by Mr Hugo Schak Hansen of H H Engineering ApS, dated 18 September 2012;
- E25: Fax from Porges S.A., dated 23 December 1994 (2 pages);
- E26: Full version of the Manufacturer/Supplier Quality Agreement for Guide wire of E5;
- E27: Invitation to an ordinary general meeting of SP Group A/S to be held on 14 May 2002 at 2 pm;
- E27A: English translation of E27;
- E28: Statement by Mr Aldo Pagani, President and CEO of EndoTech s.r.l., dated 4 September 2012;
- E29: Statement by Mr Erik Othel-Jacobsen, CEO of Pnn Medical A/S, dated 19 September 2012, together with an order dated 14 January 2002, an order confirmation dated 15 January 2002 and an invoice dated 1 February 2002;
- E30: Statement by Mr Zia Ul Islam, partner of Noor International, dated 21 September 2012, together with an order dated 30 January 2001, a delivery note and an invoice dated 5 March 2001;
- E31: Statement by Mr Cheson Yeh, president of China Hosmed International Inc., dated 19 September 2012, together with an order dated 13 November 2001, an order confirmation dated 16 November 2001 and an invoice dated 17 December 2001;
- E32: Statement by Mr Johannes Schrama, head of procurement at Coloplast Manufacturing France (PORGÉS), dated 20 September 2012, together with an order dated 18 January 1999 and a delivery note and an invoice dated 17 June 1999;

- E33: Statement by Mr Pavel Krbec, managing director of Bohemia Medical s.r.o., dated 6 September 2012;
- E34: Statement by Mr James Wong, director of Ritz Medical, dated 20 September 2012, together with an order dated 13 May 2002, an order confirmation dated 17 May 2002 and an invoice dated 4 July 2002;
- D4: GB-A-2 090 231.

- III. Notice of appeal was received on 20 February 2013. The appeal fee was paid the same day. The statement setting out the grounds of appeal was received on 29 April 2013.
- IV. In the statement of grounds the appellant requested that the decision under appeal be set aside and that the patent be revoked. It also requested oral proceedings as an auxiliary measure.
- V. With letter dated 6 September 2013 the respondent requested that the appeal be dismissed or, in the alternative, that the patent be maintained on the basis of the first to fourth auxiliary requests filed with letter dated 22 November 2010. It further requested oral proceedings "in case the Board of Appeal questions rejecting the opposition in its entirety and maintaining the patent...".
- VI. With communication dated 18 October 2017 the parties were summoned to oral proceedings. In the annex to the summons the Board expressed its preliminary opinion that the impugned decision was tainted by several substantial procedural violations and that, in view of this, the case should be remitted to the Opposition

Division for further prosecution.

VII. In response to the summons both parties withdrew their requests for oral proceedings without any further substantive comments. The oral proceedings were then cancelled by the Board.

VIII. Independent claims 1 and 17 of the patent as granted read as follows:

"1. A package for an elongate surgical device (12), comprising:

an elongate tube (14) having walls defining a lumen (16) between a first end (18) and a second end (21) of the tube (14);

the tube (14) being formed into a coiled configuration (23) with a first coiled portion (28) disposed adjacent to a second coiled portion (29); characterised by

a weld (30, 32, 34, 36) bonding the first coiled portion (28) to the second coiled portion (29) in a fixed relationship, the weld (30, 32, 34, 36) being of sufficient strength to prevent peeling the first coiled portion (28) from the second coiled portion (29) to maintain the coil configuration (23) of the tube (14)."

"17. A method for making a package for an elongate surgical device (12), the steps:

providing an elongate tube having walls defining a lumen (16) between a first end and a second end of the tube;

characterised by the steps of attaching the first end of the tube to a fixture

having at least one heating station (96, 98) and a turntable (94) rotatable relative to the heating station (96, 98); rotating the turntable (94) to form the tube into at least one coil having adjacent coiled portions; and bonding the adjacent coiled portions as they rotate by the heat station."

- IX. The appellant's arguments, as far as they are relevant for the present decision, may be summarised as follows:

It had been very surprising for the appellant that the Opposition Division had considered the prior uses not sufficiently proven, without arguing in detail. The Opposition Division had not paid enough attention to the true content of the items of evidence submitted, when considered in combination.

- X. The respondent's arguments, as far as they are relevant for the present decision, may be summarised as follows:

E0 to E20 failed to prove the alleged prior uses. E21 to E34 had been evaluated with respect to their probative value and not admitted by a qualified decision that lay within the discretion of the Opposition Division.

Reasons for the Decision

1. The appeal is admissible.
2. *The invention*

The invention relates to a package for an elongate surgical device and a method for making such a package,

as set forth in independent claims 1 and 17 of the patent as granted.

The package, as shown for example in figures 1 and 2 of the patent reproduced below, is in the form of a coiled tube (14) into which the surgical device (12), typically in the form of a guide wire or a catheter, can be loaded without being kinked or distorted.

According to the invention the coils of the tube are kept together in a fixed relationship by means of a weld (30, 32, 34, 36). This is stated to be advantageous over other known means used for the same purpose, such as mechanical clips (paragraphs [0005] and [0006] of the patent).

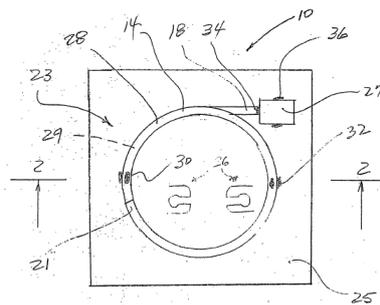


Fig. 1

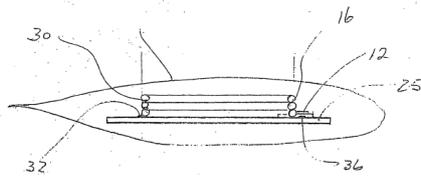
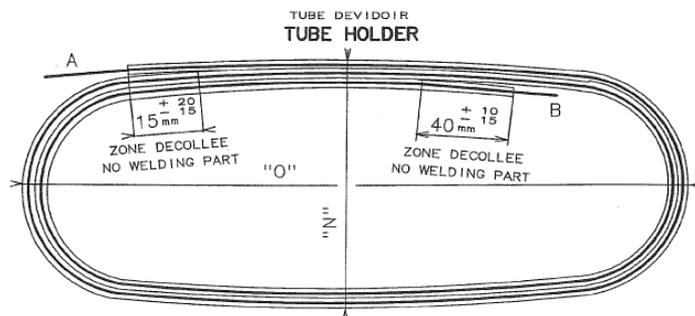


Fig. 2

3. *Non-admission of E21 to E34 and D4 at first instance*

3.1 In the first-instance proceedings the appellant argued that the subject-matter of claims 1 and 17 lacked novelty over its own prior uses of welded dispensers

for packing guide wires, illustrated by E0 to E34. For example, E2 comprises the following drawing.



The appellant further relied on documents D1 to D4.

D4 and E21 to E34 were filed after expiry of the opposition period, with letter dated 21 September 2012. In that letter the appellant argued that the filing was in response to the respondent's filing of auxiliary requests and to the Opposition Division's preliminary opinion expressed in an annex to the summons to oral proceedings. The appellant reaffirmed this in the subsequent oral proceedings before the Opposition Division (minutes, point 4.2). More particularly, it argued that E21 to E34 served "only to give further documentation for the arguments and facts earlier submitted", i.e. to support evidence items E0 to E20. The Board notes that several items of evidence filed after expiry of the opposition period are solemn declarations by various customers of the appellant, confirming that they had bought the appellant's products constituting the objects of the alleged prior uses. Moreover, in the letter dated 21 September 2012 the appellant explained in detail (pages 4 to 20 and 23 to 26) why it considered that E21 to E34 and D4 were relevant to its case.

3.2 As far as the admissibility of D4 and E21 to E34 is concerned, in the impugned decision the Opposition Division merely stated the following (point 2 of the reasons):

"The Opposition Division notes that the additional documents introduced with letter of 21.09.2012 have been filed after the nine-month time limit mentioned in Article 99(1) EPC. As they are prima facie not considered more relevant than the documents presented earlier there is no reason to take them into account in the proceedings. Following Article 114(2) these documents - with the exception of the translations into an official language E7A-E11A, E14A-E16A, E18A - are not admitted therefore in the proceedings."

3.2.1 In the Board's view such a statement does not provide sufficient reasoning for not admitting the evidence concerned.

It is established jurisprudence that, when exercising its discretionary power to decide on the admissibility of late-filed evidence, a department of first instance should perform a *prima facie* analysis of its content. If, on that basis, the evidence is not considered relevant, then that department may decide not to admit it.

In order for that decision to be adequately reasoned, however, the reasons **why there is no prima facie relevance** should be explained. These are clearly absent in the impugned decision. It follows that the Opposition Division exercised its discretion in an unreasonable way, hence exceeding the proper bounds of its discretion.

This lack of reasoning amounts to a substantial procedural violation, as it contravenes Rule 111(2) EPC.

- 3.2.2 The Board further notes that the appellant's arguments concerning why it filed D4 and E21 to E34 after expiry of the opposition period and why they were prima facie relevant were not addressed in the impugned decision.

Ignoring those arguments infringes Article 113(1) EPC, as there is no indication that they were heard at all by the Opposition Division. This constitutes a further substantial procedural violation.

4. *Analysis of the admitted evidence about the prior uses*

- 4.1 The reasons given in the impugned decision as to why the novelty objections based on evidence items E0 to E20 were not successful (point 3 of the reasons) do not meet the requirements of Rule 111(2) EPC either.

For example, it is not explained why the Opposition Division considered that the appellant had failed to prove any correlations between E0 and E1 to E20, or why the mere fact that the various declarations seemed to be from employees or customers of the appellant "having an own vested interest in having the patent revoked" should make these declarations of "uncertain" probative value, or why evidence of a sale to an "end-consumer" should be presented. In relation to this latter aspect, the Board observes that for the assessment of whether an item of evidence forms part of the state of the art the EPC does not require availability to end-consumers, but more general availability to the public (Article

54(2) EPC).

4.2 The Board sees a further contravention of Article 113(1) EPC in relation to the Opposition Division's mere statement that in E0, E1 to E12 and E14 to E18 "**the kind**" of the weld was not defined. The appellant extensively argued in its letter dated 21 September 2012 (section titled "Re: Weld" on pages 2 and 3) that **any weld** fell under the definition of claims 1 and 17. This argument of the appellant was ignored in the decision.

5. According to Article 111(1) EPC, when examining an appeal "the Board of Appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution".

Under Article 11 RPBA "a Board shall remit a case to the department of first instance if fundamental deficiencies are apparent in the first instance proceedings, unless special reasons present themselves for doing otherwise".

In view of the substantial procedural violations established above, since the parties have not pointed out any special reasons against a remittal and the Board does not see any either, the case should be remitted to the Opposition Division for further prosecution.

6. Under Rule 103(1) (a) EPC the appeal fee is to be reimbursed in full if the Board "deems an appeal to be allowable, if such reimbursement is equitable by reason of a substantial procedural violation".

Since the case is to be remitted, the decision under appeal is set aside and the appeal is allowed. The established substantial procedural violations, which made the appeal necessary in order for the appellant to safeguard its rights under the EPC, render reimbursement of the appeal fee equitable. The Board notes that the appellant has not requested such reimbursement. According to established jurisprudence, however, the Board may examine ex officio whether reimbursement is equitable and order it within its powers under Article 114(1) EPC (for example J 7/82, Reasons 6, also cited in T 736/14, Reasons 5.1).

In view of the above it is concluded that the appeal fee should be reimbursed in full.

7. Since the case is to be remitted, there is no need for the Board to decide on the admissibility of E21 to E34, D4 or the other evidence filed by the appellant in the appeal proceedings.

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 for further prosecution.
3. The appeal fee is to be reimbursed in full.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated