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Datasheet for the decision of 9 February 2010

Case Number: T 1797/07 - 3.2.02

Application Number: 03728398.3

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Language of the proceedings: EN

Title of invention:
Clip device with flushing feature

Applicant:
Wilson-Cook Medical Inc.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 54

Relevant legal provisions (EPC 1973):
-

Keyword:
"Novelty (yes, after amendments)"

Decisions cited:
G 0002/88

Catchword:
-

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Case Number: T 1797/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 9 February 2010

Appellant: Wilson-Cook Medical Inc.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 6 June 2007 refusing European patent application No. 03728398.3 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: M. Noël
Members: D. Valle
M. J. Vogel

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal on 3 August 2007 against the decision of the Examining Division posted on 6 June 2007 to refuse the European patent application. The fee for appeal was paid at the same time and the statement setting out the grounds for appeal was received on 16 October 2007, along with amended claims.

II. The application was refused for lack of novelty of the subject-matter of claim 1, having regard to the disclosure of document:

D1 = EP - A - 0738 501.

III. Oral proceedings took place on 9 February 2010.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the sets of claims according to either the main request or the first auxiliary request in the versions as refused by the Examining Division or according to a second auxiliary request filed on 16 October 2007 or according to a third auxiliary request filed with the letter of 7 January 2010.

IV. Claim 1 of the various requests reads as follows:

Main request

"A haemostatic clip delivery system for use in endoscopic medical procedures comprising:

(a) a delivery apparatus comprising an operating wire, an inner sheath, an outer sheath and a handle, the operating wire being slidably disposed within the inner sheath, and the inner sheath being slidably disposed within the outer sheath; and

(b) a haemostatic clip comprising a first retainer, a plurality of arms extending distally from the first retainer, and a sliding ring disposed about the plurality of arms, said arms being formed of a resilient material and shaped so that the arm tend to be spaced apart from each other, said sliding ring being configured to engage and close said arms together, wherein the handle includes a flushing port that is in fluid communication with an interior volume of the delivery apparatus, and wherein the flushing port is in fluid communication with a cavity between the inner sheath and the outer sheath, the flushing port being configured to permit the ingress or egress of fluid from near the clip via the cavity between the inner sheath and the outer sheath."

First auxiliary request

Claim 1 of the first auxiliary request comprises the content of claim 1 of the main request and the following additional feature (in italics) incorporated in the last portion of the claim:

"the flushing port being *connected to a source of fluid or to a vacuum and being* configured ...".

Second auxiliary request

Claim 1 of the second auxiliary request comprises the content of claim 1 of the main request, wherein the last feature has been amended (in italics) in the following manner:

"the *system* being configured to permit the ingress or egress of fluid from near the clip via the cavity between the inner sheath and the outer sheath *and via the flushing port*."

Third auxiliary request

Claim 1 of the third auxiliary request reads as follows:

"A haemostatic clip delivery system for use in endoscopic medical procedures comprising:

(a) a delivery apparatus comprising an operating wire, an inner sheath, an outer sheath and a handle, the operating wire being slidably disposed within the inner sheath, and the inner sheath being slidably disposed within the outer sheath; and

(b) a haemostatic clip comprising a first retainer, a plurality of arms extending distally from the first retainer, and a sliding ring disposed about the plurality of arms, said arms being formed of a resilient material and shaped so that the arms tend to be spaced apart from each other, said sliding ring being configured to engage and close said arms together,

wherein the handle includes a flushing port that is in fluid communication with an interior volume of the delivery apparatus, and

wherein the flushing port is in fluid communication with a cavity between the inner sheath and the outer sheath, the flushing port being configured to permit the egress of flushing fluid from near the clip, the cavity between the inner sheath and the outer sheath containing an amount of the flushing fluid."

Claim 2 to 9 are dependent claims.

V. The appellant argued essentially that at the distal end of the clip device according to Figures 1 to 6 of D1 there was no cavity between the inner sheath 28, 32 and the outer sheath 3, that the through hole 12 inside the operating unit 5 was preferably in communication with the external atmosphere through a slit 11 and that therefore it was impossible for the port 14 provided on said operating unit to establish a fluid communication through a cavity between the inner and outer sheaths, and to permit ingress or egress of fluid as required by the last features of claim 1. Besides, there was no disclosure in D1 of any injection of flushing fluid or any other fluid through the port 14. A cleaning tube for supplying a cleaning liquid was provided in another embodiment according to Figure 28, however without any relation to the port 14 of the embodiment of Figure 6. The subject-matter of claim 1 of the main request was therefore novel.

The claims of the auxiliary requests were further distinguished over D1 by the incorporation of additional or more limiting features. In particular, a flushing port connected to a source of fluid or to a vacuum, or a clip delivery system adapted as a whole for permitting the ingress or egress of fluid via both the cavity and the port, was not directly and unambiguously disclosed by D1. Accordingly, the claims of the various auxiliary requests were also novel.

Reasons for the Decision

1. The appeal is admissible.

2. Main request

D1 (see in particular the embodiment of Figures 1 to 6 and 16) discloses a haemostatic clip delivery system suitable for use in endoscopic medical procedures comprising:

a delivery apparatus comprising an operating wire 33, an inner sheath 28, 31, 32, an outer sheath 3 and a handle 5, 6, the operating wire being slidably disposed within the inner sheath, and the inner sheath being slidably disposed within the outer sheath; and

a haemostatic clip 2 comprising a first retainer 30, 37, a plurality of arms 45 extending distally from the first retainer, and a sliding ring 46 disposed about the plurality of arms, said arms being formed of a resilient material and shaped so that the arms tend to be spaced apart from each other (see Figure 5), said

sliding ring being configured to engage and close said arms together, wherein the handle 5 (operating unit proper) includes a port 14 that is in fluid communication with an interior volume 12 (through hole) of the delivery apparatus, and in fluid communication with a cavity (gap) arranged between the inner sheath and the outer sheath (see column 6, lines 49 to 54 and column 7, lines 15 to 19). As a consequence, the port is configured to permit the ingress of fluid via the cavity between the inner sheath and the outer sheath.

The appellant argued that D1 did not disclose a port in fluid communication with a cavity between the inner sheath and the outer sheath, since such cavity was apparently filled by the inner tube. However, the port 14 shown in Figures 6 and 16 is clearly in communication with the through hole 12, which, according to column 6, lines 51 to 54, communicates with the inner hole of the lead tube 3 forming the outer sheath. Such hole has a reduced diameter portion 12a at its forward end for receiving the outer sheath 3 (compare column 6, lines 51 to 54 and column 7, lines 7 to 8). As can also be seen in Figures 1A, 1B, there is a gap or cavity between the inner hole of the outer sheath 3 and the outer diameter of the inner sheath 28, which is sufficient for establishing a fluid communication between the port and said cavity.

The reference number 11 in Figure 6 of D1 refers to the base-end opening of the through hole 12 (see column 6, line 51), whereas the slider 13 must closely match said opening of the operating unit 5 on which the slider is mounted (column 6, lines 44 to 46). That means that in use, practically, there cannot be any significant fluid

communication other than leakage, if any, between the cavity, the interior volume 12 and the base-end opening 11. On the other hand, the relevant cited passage at column 6, lines 49 to 54, clearly shows that the port 14 is perfectly appropriate for allowing a flow of fluid from the injection port through the cavity between the inner sheath and the outer sheath via the through hole 12.

D1 does not directly mention that a fluid is flowing through a gap between the inner and outer sheaths. However, the port 14 of D1 (here lock socket) is provided for removably connecting an injection cylinder (see column 7, lines 15 to 16) likely to be used for injecting a cleaning liquid as mentioned in claim 16 of D1. Therefore, the port of D1 can qualify as a flushing port within the meaning of the present application, the more so since the nature of the fluid injected is irrelevant to the structure of the claimed device. Since, moreover, the egress of fluid from near the clip is presented in claim 1 at issue only as an option ("or"), this feature can be ignored when assessing the novelty of the claimed subject-matter.

It results therefrom that the subject-matter of claim 1 of the main request lacks novelty over the disclosure of D1.

3. First auxiliary request

Claim 1 of the first auxiliary request differs from the main request in that the flushing port is "*connected to a source of fluid or to a vacuum".* Besides the fact that the expression "or to a vacuum" can also be

regarded as optional and, therefore, ignored, a port "connected to a source of fluid" is disclosed in D1 (column 7, lines 15 to 17) as mentioned above. Consequently, the amendments brought to claim 1 of the first auxiliary request do not confer novelty on the subject-matter of this claim.

4. Second auxiliary request

Claim 1 of the second auxiliary request differs from the main request in that the "*system*" is configured to permit the ingress or egress of fluid. However, there is no basis or justification in the application as filed for replacing the expression "flushing port" by the broader term "system". It is also not clear from the application as filed with what means and how the system should be configured for the claimed fluid flows to be achieved. Therefore, the introduction of the word "system", which is already used to define the subject-matter of the claim as a whole (first line of claim 1), introduces unclarity into claim 1 and extends its subject-matter contrary to the requirements of Articles 84 and 123(2) EPC.

5. Third auxiliary request

Claim 1 of the third auxiliary request differs from the main request in that only the egress of flushing fluid from near the clip is permitted and in that an amount of flushing fluid is contained in the cavity between the inner and the outer sheaths.

The egress of flushing fluid from near the clip with the view to remove blood or bloody fluids is achieved

by application of a vacuum to the flushing port so as to create suction within the cavity as explained and supported by paragraph [97] of the application as filed. This directional (egress) flow of fluid from the part to be treated near the clip towards the flushing port is neither explicitly nor implicitly disclosed by D1, which is clearly restricted to the injection of cleaning fluid. While this distinguishing feature over D1 represents a functional feature related to the use of the apparatus, said feature must be regarded as an essential feature of the delivery system as claimed, having in mind that such a system belongs to a category of hybrid claims, i.e. those including features relating to both physical entities and physical activities (see G 2/88, OJ 1990, point 2.2).

Therefore, the subject-matter of claim 1 of the third auxiliary request is novel, in accordance with the requirement of Article 54 EPC.

6. Remittal

Since the decision under appeal is concerned only with novelty, the Board considers it appropriate to remit the case to the Examining Division for further prosecution on the basis of the third auxiliary request in order to give the applicant the benefit of two instances of jurisdiction.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution on the basis of claims 1 to 9 of the third auxiliary request filed on 7 January 2010.

The Registrar: The Chairman:

D. Sauter M. Noël