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**Datasheet for the decision
of 27 November 2023**

Case Number: T 0044/19 - 3.2.08

Application Number: 09741126.8

Publication Number: 2370028

IPC: A61F2/97, A61F2/24, A61F2/966

Language of the proceedings: EN

Title of invention:

DELIVERY SYSTEM FOR DEPLOYMENT OF MEDICAL DEVICES

Applicant:

Medtronic CV Luxembourg S.à r.l.

Relevant legal provisions:

PCT Article 17(3)(a) , Article 15(3) , International Search
and Preliminary Examination Guidelines of 2004
EPC Art. 113(1)
EPC R. 103(1)(a), 164(2)(a), 164(5)

Keyword:

Unity of invention - invitation to pay further fees justified
(no)
Right to be heard - substantial procedural violation (yes)
Reimbursement of appeal fee - (yes)



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Case Number: T 0044/19 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 27 November 2023

Appellant: Medtronic CV Luxembourg S.à r.l.
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 3 July 2018
concerning the refusal for refund of the
second search fee of European Patent
Application No. 09741126.8**

Composition of the Board:

Chairwoman P. Acton
Members: A. Björklund
F. Bostedt

Summary of Facts and Submissions

- I. The appeal was filed by the applicant (appellant) against the interlocutory decision of the examining division to refuse the request for refund of the second search fee.
- II. The Appellant requests that the decision under appeal be set aside and that the paid additional search fee be refunded. In addition, the appellant requests reimbursement of the appeal fee because of a substantial procedural violation allegedly committed by the Examining Division.
- III. The relevant claims on file during the search read as follows (the most relevant portions of the claims for the decision are marked in **bold**):

Claim 1: "An apparatus for minimally invasively delivering a medical device to a target site within a patient, the apparatus comprising:
a first tube having an outside surface suitable for accepting a medical device collapsed thereon in a stationary position; and
a sheath comprising first and second portions that may be moved axially relative to each other and with respect to the first tube, the sheath portions configured so as to enclose a medical device collapsed onto the first tube when brought together, and configured to expose the medical device when directed away from each other, **the first sheath portion comprising a section that is normally biased radially inwardly so as to maintain a low profile.**"

Claim 2: "The apparatus of Claim 1, wherein the first tube comprises a **hub.**"

Claim 3: "The apparatus of Claim 2, wherein **the first sheath portion is configured so as to enclose at least a portion of the hub.**"

Claim 5: "An apparatus for minimally invasively delivering a medical device to a target site within a patient, the apparatus comprising:
a first tube having an outside surface suitable for accepting a medical device collapsed thereon in a stationary position, **the first tube comprising a hub for retaining at least a portion of a medical device on the first tube, wherein the hub comprises a generally extended non-tapered portion;** and
a sheath comprising first and second portions that may be moved axially relative to each other and with respect to the first tube, the sheath portions configured so as to enclose a medical device collapsed onto the first tube when brought together, and configured to expose the medical device when directed away from each other;
wherein, during operation, the first sheath portion may be moved in a direction sufficient to expose the medical device while said first sheath portion still covers at least a part of the extended non-tapered portion of the hub."

Claim 6: "An apparatus for delivering a medical device to a target site within a patient via a body lumen, the apparatus comprising:
an inner tube;
a distal sheath portion attached to the inner tube;
an intermediate tube, moveable over the inner tube and at least partially into the distal sheath portion;

an outer tube, moveable over the intermediate tube;
a proximal sheath portion attached to the outer tube,
so that, in use, the proximal sheath portion and the
distal sheath portion can be moved together to
substantially cover a medical device mounted on the
intermediate tube and moved apart to deploy the medical
device;

**the distal sheath portion having a proximal end portion
configured to extend away from the walls of the body
lumen** when, in use, the sheath portions are apart and
the distal sheath portion is moved proximately."

Claim 10: "An apparatus for delivering a medical device
to a target site within a patient via a body lumen, the
apparatus comprising:

an inner tube;

a distal sheath portion attached to the inner tube;
an intermediate tube, moveable over the inner tube and
at least partially into the distal sheath portion, **the
intermediate tube having a hub at its distal end and
having a region on the intermediate tube proximal of
the hub for mounting the medical device;**

an outer tube, moveable over the intermediate tube;
a proximal sheath portion attached to the outer tube,
so that, in use, the proximal sheath portion and the
distal sheath portion can be moved together to
substantially cover a medical device mounted on the
intermediate tube and moved apart to deploy the medical
device;

**the hub having an axial length sufficient to permit the
medical device to be deployed while the distal sheath
portion covers at least part of the hub."**

Claim 11: "The apparatus for delivering a medical
device of Claim 10, wherein the hub comprises a
substantially cylindrical outer surface over which the

distal sheath portion can reside until the medical device is deployed."

- IV. The appellant's arguments relevant to the decision can be summarised as follows:

Dependent claims 2 and 3, which were part of the "first invention" in claims 1 to 4 and 6 to 9 according to the search division, defined that the first tube of the apparatus comprises a hub. The search division had defined the hub as the special technical feature of the "second invention" in claims 5 and 10 to 11.

Consequently, the search for the first invention had completely covered the second invention. The request for an additional search fee was therefore not justified, irrespective of whether the searched claims lacked unity or not. For this reason, the examining division should have refunded the additional search fee.

Furthermore, the appellant had repeatedly argued that the search for the "first invention" already covered the "second invention".

Reasons for the Decision

1. History of the case
 - 1.1 The application was filed as an international application.

The search examiner of the EPO, acting as International Search Authority, found that the originally filed claims did not fulfil the requirements of unity of invention but contained two inventions.

The applicant was thus invited to pay one additional search fee according to Article 17(3) (a) PCT, which they did not do in the international phase of the application.

- 1.2 The search examiner stated that the common matter of both inventions was an apparatus for delivering a medical device to a target site within a patient, comprising a tube suitable for accepting a medical device mounted on it, and a sheath comprising proximal and distal portions axially movable relative to each other and with respect to the tube on which is mounted the medical device, to cover the medical device when brought together, and to expose it when moved apart. Said matter was considered not novel over the general knowledge in the considered technical field and to be disclosed in several documents cited in the partial international search report sent with the invitation to pay one additional search fee.

The search examiner considered claims 1 to 4 and 6 to 9 to define a first invention, which addressed the objective technical problem of "providing an apparatus for delivering a medical device which minimize the risk of damaging the walls of the body lumen during retrieval or repositioning". This problem was solved by the configuration of the sheath portion extending away from the walls of the body lumen as defined in claims 1 to 4 and 6 to 9.

The search examiner considered claims 5 and 10 to 11 to define a second invention, which addressed the objective technical problem of "providing an apparatus for delivering a medical device better retaining the

medical device on the tube". This problem was solved by the hub defined in claims 5 and 10 to 11.

- 1.3 After the entry of the application into the regional phase before the EPO, the examining division sent a communication under Rule 164(2)(a) EPC. In this communication the examining division stated that they agreed with the finding of lack of unity in the International Preliminary Report on Patentability (IPRP), repeated the reasoning for the lack of unity of the IPRP and invited the applicant to pay an additional search fee for the second invention.

The applicant paid an additional search fee for the second invention. An additional search for the second invention was then carried out.

- 1.4 The applicant requested a refund of the second search fee under Rule 164(5) EPC in several replies during the examination proceedings. The applicant put forward that even if the claims as filed did not comply with the requirements of unity of invention, the subject matter of claims 2 and 3 which according to the search division belonged to the first invention comprised the hub which was the special technical feature of the second invention. The search for the first invention therefore fully encompassed the second invention. The invitation to pay an additional search fee was therefore not justified and the additional search fee should be refunded.

- 1.5 At the end of the examination proceedings, the examining division issued a decision not to refund the search fee for the second invention.

2. Refund of second search fee

2.1 As can be seen in the partial international search report sent together with the invitation to pay an additional search fee, the search examiner found prior art which was highly relevant to the question of novelty and/or inventive step of the subject-matter of claim 1. The search thus had to be extended to prior art relevant to at least dependent claim 2. This was done as can be seen from the international search report which cited prior art relevant to both claims 2 and 3.

2.2 According to Article 15(3) PCT, the "international search shall be made on the basis of the claims, with due regard to the description and the drawings (if any)".

The hub of dependent claims 2 and 3 has the function of retaining the medical device on the tube, as described in page 8, paragraph 3 of the description of the published international application. As a result, the medical device is better retained on the tube. The hub of claims 2 and 3 thus has the same function and addresses the same technical problem as the hub of the second invention identified by the objection to lack of unity raised by the search examiner.

Consequently, during the search for the first invention and having due regard to the description and drawings, the search examiner already had to search for a hub according to the second invention. Furthermore, in the present application there are two embodiments, the first embodiment relating to the first invention and the second embodiment relating to the second invention. These embodiments are conceptually very closely linked

to each other and differ essentially in whether the distal sheath moves distally past the hub or its proximal end remains on a straight portion of the hub during deployment of the medical device, and in the extent to which the proximal end of the distal sheath is biased radially inwardly. It is also noted that in the invitation to pay additional fees, the search examiner did not identify any particular functions or effects which relate to the slight differences of the geometry of these hubs. Thus, in fact, the search examiner by searching prior art for claims 2 and 3 also covered the second invention.

- 2.3 In the particular circumstances of the case, it is irrelevant whether the examining division correctly considered that there was a lack of unity. This is so since the examining division may only ask for the payment of an additional search fee if it "considers that in the application documents which are to serve as the basis for examination an invention, or a group of inventions within the meaning of Article 82, is claimed **which was not searched** by the European Patent Office in its capacity as International Searching Authority" (Rule 164(2) EPC, emphasis added). However, for the reasons set out in point 2.2 above, the search examiner covered the second invention with the prior art search for claims 2 and 3, so that this invention was in fact searched. The communication under Rule 164(2)(a) EPC, and thus the request for an additional search fee, was therefore not justified and the additional search fee should have been refunded by the examining division under Rule 164(5) EPC.

3. Reimbursement of the appeal fee

3.1 The right to be heard under Article 113(1) EPC requires that the party to the proceedings be given an opportunity not only to present comments but also to have those comments considered, that is, reviewed with respect to their relevance for the decision on the matter. In the present case, this right was not respected.

3.2 In its decision, the examining division essentially repeated the reasons given for the lack of unity raised by the search examiner. The decision does however not deal with the argument that the search for the first invention already covered the second invention and that an additional search fee was not justified for this reason. This argument had been put forward by the appellant during the examination proceedings in its submissions (see letter of 16 February 2012, point II.2, letter of 1 June 2017, point II.1. and letter of 3 November 2017, point II.1.).

Disregarding this argument of the applicant, which was clearly central to their case, is a violation of the applicant's right to be heard under Article 113(1) EPC and constitutes a substantial procedural violation.

Consequently, a reimbursement of the appeal fee under Rule 103(1)(a) EPC is equitable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The additional search fee is to be refunded.
3. The appeal fee is to be reimbursed.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated