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Datasheet for the decision of 12 August 2014

Case Number: T 0828/11 - 3.2.02

Application Number: 06253277.5

Publication Number: 1736197

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Language of the proceedings: EN

Title of invention:
Implantable medical device with simultaneous attachment mechanism

Patent Proprietor:
ETHICON ENDO-SURGERY, INC.

Opponent:
withdrawn

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - first and third auxiliary requests (no)
Inventive step - fifth auxiliary request (yes)

Decisions cited:

Catchword:

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Case Number: T 0828/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 12 August 2014

Appellant: (Patent Proprietor)	ETHICON ENDO-SURGERY, INC. 4545 Creek Road Cincinnati, Ohio 45242 (US)
Representative:	Tunstall, Christopher Stephen Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Opponent)	withdrawn
Representative:	
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 4 February 2011 revoking European patent No. 1736197 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
C. Körber

Summary of Facts and Submissions

I. The patent proprietor has appealed the Opposition Division's decision, dispatched on 4 February 2011, to revoke European patent No. 1 736 197.

II. The Opposition Division revoked the patent on the grounds that the subject-matter of claim 1 of the main request was not novel, the subject-matter of claim 1 of each of the first to third auxiliary requests extended beyond the contents of the application as originally filed, and the fourth auxiliary request was not admitted into the proceedings.

III. The notice of appeal was received on 12 April 2011 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 14 June 2011.

IV. After having replied to the statement setting out the grounds of appeal, the then respondent withdrew the opposition on 11 December 2012.

V. The Board summoned the appellant to oral proceedings and provided its provisional opinion in a communication dated 13 May 2014.

VI. In response to the Board's communication, the appellant filed a main request and first to fifth auxiliary requests with letter dated 11 July 2014.

VII. Oral proceedings took place on 12 August 2014. During the oral proceedings the appellant withdrew the main request and the second and fourth auxiliary requests and filed a new fifth auxiliary request.

VIII. The appellant's final requests were that that the decision under appeal be set aside and that the patent be maintained on the basis of the first auxiliary request, filed with letter dated 11 July 2014, or, in the alternative, of one of the third auxiliary request, filed on the same date, and the fifth auxiliary request, filed during oral proceedings.

IX. The following documents are mentioned in the present decision:

D1: WO-A-2005/037055;
D7: WO-A-2004/026152;
D8: US-A-5,688,247;
D9: EP-A-1 736 198.

X. Claim 1 of the first auxiliary request reads as follows:

"A surgically implantable device (2) comprising:

(a) an injection port (2) for performing a therapeutic function;

(b) an attachment mechanism comprising at least two fasteners (10) integral to said injection port for attaching said injection port to a body, said fasteners (10) having a deployed position and an undeployed position;

characterized by:

(c) an actuator (12) for simultaneously moving said at least two fasteners (10) from said undeployed position to said deployed position, wherein said actuator is also capable of moving said at least two fasteners (10) from said deployed position to said undeployed position simultaneously."

XI. Claim 1 of the third auxiliary request reads as follows (compared to claim 1 of the first auxiliary request, additions are underlined by the Board):

"A surgically implantable device (2) comprising:

(a) an injection port (2) for performing a therapeutic function;

(b) an attachment mechanism comprising at least two fasteners (10) integral to said injection port for attaching said injection port to a body, said fasteners (10) having a deployed position and an undeployed position;

characterized by:

(c) an actuator (12) for simultaneously moving said at least two fasteners (10) from said undeployed position to said deployed position, wherein said actuator is also capable of moving said at least two fasteners (10) from said deployed position to said undeployed position simultaneously, and wherein each of said at least two fasteners (10) is configured to rotate about a respective axis as it moves from said undeployed position to said deployed position."

XII. Claim 1 of the fifth auxiliary request reads as follows (compared to claim 1 of the third auxiliary request, additions are underlined, deletions are struck through by the Board):

"A surgically implantable device (2) comprising:

(a) a medical implant being an injection port (2) for performing a therapeutic function;

(b) an attachment mechanism comprising at least two fasteners (10) integral to said implant ~~injection port~~ for attaching said implant ~~injection port~~ to a body, said fasteners (10) having a deployed position and an undeployed position; and

~~characterized by:~~

(c) an actuator (12) capable of ~~for~~ simultaneously moving said at least two fasteners (10) from said undeployed position to said deployed position, wherein said actuator is also capable of moving said at least two fasteners (10) from said deployed position to said undeployed position simultaneously, ~~and~~ wherein each of said at least two fasteners (10) is configured to rotate about a respective axis as it moves from said undeployed position to said deployed position, and wherein said actuator (12) is configured to rotate about a respective axis and comprises an associated surface for each of said at least two fasteners (10), each said surface configured to exert a rotational force on each associated fastener (10) when said actuator (12) is rotated in a deploying direction, thereby moving each of said at least two fasteners (10) from said undeployed position to said deployed position."

XIII. The appellant's arguments are summarised as follows:

a) First auxiliary request

In the impugned decision, the Opposition Division had held that document D7 disclosed a surgically implantable device comprising an injection port, because it concerned a device which was "at least temporally *(sic)* introduced into a blood vessel, organ or cavity" (point 5.2 of the Reasons). However, in claim 1 the term "surgically implantable device" in conjunction with the definition of an injection port as being part of the implantable device should be construed to mean a device that was wholly implanted into a patient. The whole disclosure of the patent was directed to

devices which were wholly implantable into a patient. Document D7 related to a device for subcutaneously anchoring indwelling catheters. These catheters and their mechanism for controlling the anchor mechanism would not function if the whole device was implanted. Hence, document D7 did not disclose a surgically implantable device within the meaning of claim 1.

Document D8 did not disclose an actuator for simultaneously moving two fasteners from an undeployed position to a deployed position as required by claim 1. It rather disclosed a string, which, when released, allowed anchoring loops to move to their deployed position by virtue of their own resilience. This was in direct contrast to the requirement of the invention as defined in claim 1, in which the actuator was responsible for actively moving the fasteners.

Document D8 represented the closest prior art for the assessment of inventive step. The surgically implantable device which it disclosed operated perfectly well. Any modification to it would be entirely superfluous. Hence, the skilled person would have no motivation to provide an actuator which actively moved the fasteners, as required by claim 1. Moreover, it was not possible to combine the teachings of D8 and D7, especially because of the different nature of the fastening mechanisms disclosed in the respective document. The fastening mechanism of document D7 required very specific deployment ports. Implementing it in the device of document D8 would involve an unnecessarily complex modification.

It followed that the subject-matter of claim 1 of the first auxiliary request was novel and inventive.

b) *Third auxiliary request*

In addition to the arguments presented with respect to the first auxiliary request, document D8 did not disclose fasteners configured to rotate about a respective axis as they moved from the undeployed position to the deployed position. The fasteners of document D8 were made up of a single endless wire, which, as a whole, did not rotate while it was deployed. Moreover, the respective arms of the wire which anchored the surgically implantable device of document D8 were wrapped and held in the undeployed position, from which they splayed out when the string was released. They simply projected themselves outwardly. That was not a rotation about a respective axis, in a wheel-like fashion, as was the case in the claimed invention. At most, there was some kind of arcuate movement of individual points of the anchoring loops that corresponded to the fasteners of claim 1. Such a rotation was also not taught by document D7. Hence the subject-matter of claim 1 of the third auxiliary request was novel and inventive.

c) *Fifth auxiliary request*

Claim 1 of the fifth auxiliary request was based on claims 3, 4, 7 and 8 and paragraphs [0003], [0044] and [0050] of the application as originally filed. Therefore it satisfied the requirements of Article 123(2) EPC. At least for the reasons

presented in relation with the first and the third auxiliary requests the subject-matter of claim 1 of the fifth auxiliary request was also novel and inventive.

Reasons for the Decision

1. The appeal is admissible.

2. Documents D7, D8 and D9 were filed by the opponent before it withdrew the opposition, after the period specified in Article 99(1) EPC.

More particularly, document D7 was filed in the proceedings before the first instance and was admitted by the Opposition Division exercising its discretion under Article 114(2) EPC, after an examination as to the relevance of that document. Document D7 is to be considered in the appeal proceedings, too.

Documents D8 and D9 were filed in the appeal proceedings, in response to the statement setting out the grounds of appeal. Prima facie, as is apparent from the examination of patentability below, the Board considers these documents relevant for the assessment of novelty and inventive step of the appellant's requests as presented in the appeal proceedings. It therefore admits these documents into the proceedings under Article 114(2) EPC.

The appellant did not present to the Board any objections as to the admissibility of these documents.

3. First auxiliary request

3.1 Claim 1 of the first auxiliary request relates to a surgically implantable device comprising an injection port and an attachment mechanism. The injection port is intended to perform a therapeutic function, for example in connection with a gastric band for treating obesity. Such a gastric band is normally implanted around a patient's stomach. By inflating it, the gastric band is tightened around the stomach in order to reduce the size of the latter. The amount of food that the patient can eat is thereby reduced. By introducing or removing fluid through a needle from the injection port, which may suitably be placed in a subcutaneous position, the size of the gastric band and, hence, of the patient's stomach, can be adjusted.

In particular, it is proposed to have at least two fasteners movable between a deployed position and an undeployed position, and an actuator as claimed. Their presence should assist in the surgical procedure for the implantation of the device.

3.2 Document D8 relates to an implantable port catheter designed to be implanted by puncturing. It is undisputed that it is the closest prior art.

More particularly, document D8 discloses a surgically implantable device (column 1, lines 4 to 13) comprising an injection port (cylindrical casing 1 and membrane 4 in figures 7 and 8) for performing a therapeutic function, an attachment mechanism comprising two fasteners (anchoring loops 9 and 10 in figures 7 and 8) integral to said injection port for attaching said injection port to a body (column 1, lines 34 to 37), said fasteners having a deployed position (shown in

figure 8) and an undeployed position (shown in figure 7), and an actuator (string 31, in figures 7 and 8) capable of moving said two fasteners from said deployed position to said undeployed position simultaneously (column 5, lines 17 to 22).

The appellant argued that document D8 did not disclose an actuator for simultaneously moving the two fasteners from the undeployed position to the deployed position.

The Board is of the opinion that string 31 of document D8 can be considered an actuator, at least because it actively moves the fasteners from the deployed position to the undeployed position when it is pulled. However, it may be argued, as the appellant does, that string 31 is not for moving the fasteners from the undeployed position to the deployed position, since that movement is not actively caused by the string. Rather, it is due to the elasticity of the anchoring loops, which, when freed from the undeployed position using the string, can simultaneously unfold themselves (column 4, lines 62 to 63).

Following this argument the subject-matter of claim 1 of the first auxiliary request would differ from the disclosure of document D8 in that the actuator is not for moving the two fasteners from the undeployed position to the deployed position.

3.3 With an actuator for (actively) moving the two fasteners between the undeployed and the deployed position in both directions, the securement of the device on its intended implantation site would not have to rely (only) on the intrinsic elastic properties of the fasteners. These may cause an uncontrolled fixation due to a sudden release of energy, possibly affected by

the fact that the fasteners would need to be kept in a condition of relatively high stress in the undeployed storage position.

The objective technical problem solved is therefore a way of ensuring a more effective and reliable anchoring action of the surgically implantable device.

3.4 Document D7 discloses a sutureless retention device for anchoring an indwelling catheter subcutaneously, hence under the same conditions as for the port catheter of document D8. The skilled person would therefore consider the details of the retention device of document D7.

With particular reference to figures 10, 10a and 11, the retention device is shown to comprise two fasteners (tines 18a) made of a shape memory material with a transition temperature at human body temperature (page 14, lines 19 to 21), which are actively moved from an undeployed position (shown in figure 10) to a deployed anchoring position (shown in figure 10a) by means of an actuator comprising control rod 18b and handle 40 (page 17, lines 4 to 12). Hence, document D7 discloses an actuator for moving the two fasteners from the undeployed position to the deployed position within the meaning of claim 1.

Document D7 also explains the importance of avoiding an excessive stress of the fasteners in the storage position (page 14, lines 21 to 24), and of having a controllable deployment (page 15, lines 2 to 3 and lines 23 to 25, page 16, lines 6 to 9).

Faced with the objective technical problem mentioned above, the skilled person would therefore apply the

teaching of document D7 to the device of document D8 and arrive at the subject-matter of claim 1 of the first auxiliary request in an obvious way.

3.5 The appellant's argument that the device of document D8 operated perfectly well and thus any modification to it would be entirely superfluous is not convincing. Following the problem-solution approach, as is the established case law of the boards of appeal, the question of whether the skilled person would be prompted to look for and adopt a modification of the device of the closest prior art should be answered with regard to the technical problem solved by this modification, in the light of all prior art at hand. As explained in point 3.4 above, the disclosure of document D7 prompts the skilled person to a solution of that technical problem, even if document D8 may be considered as working well in other respects.

The argument that a combination of the respective fastening means of documents D7 and D8 would be too complex also fails. From the disclosure of document D7, the skilled person mainly derives the teaching that an actively controlled deployment of the fasteners by means of an actuator as claimed in claim 1 addresses the objective technical problem posed. The implementation of such an actuator to the particular fasteners of document D8 is within the competence of the skilled person. With respect thereto, the specific configuration as shown in document D7 is not necessary. Document D8 itself discloses different kinds of actuators (figures 5 and 9, for example), showing that the specific form of any of them is not decisive for its purposes.

3.6 It follows that the first auxiliary request cannot be allowed due to lack of inventive step (Article 56 EPC) of the subject-matter of claim 1.

4. Third auxiliary request

4.1 The subject-matter of claim 1 of the third auxiliary request additionally defines that each of the two fasteners is configured to rotate about a respective axis as it moves from the undeployed position to the deployed position.

First, the Board notes that this additional feature is drafted in very broad terms, since neither the position of the rotation axis with respect to the fasteners, nor any further limitation to the actual movement of the fasteners while they deploy is specifically defined. Hence, the only limitation of the additional feature is regarded as being that the deployment movement of the fasteners should comprise some rotational component. The Board concludes that this is anticipated by the spreading movement of the fasteners of document D8, from the configuration shown in figure 7 to the configuration shown in figure 8. This movement involves a rotation of fasteners 9 and 10, also shown in figure 4, around an axis on the surface of casing 1, parallel to its central axis.

It follows that the additional feature does not contribute to inventive step.

4.2 The appellant's argument that the single endless wire from which the fasteners of document D8 were made did not rotate as a whole while it was deployed is of little relevance. It is not the whole wire which is to be considered as "the fasteners" within the meaning of

claim 1, but rather its anchoring loops 9 and 10, which actually perform the anchoring action.

As regards the nature of the movement which they undergo upon deployment, it is agreed that they splay out from a folded condition without rotating in a "wheel-like" fashion. However, such a rotation is not defined in claim 1, which merely requires a rotation "about a respective axis".

Still, due to the elastic properties of the endless wire, each individual fastener 9 and 10, upon deployment, will perform a movement comprising a rotation of the fastener around an axis on the surface of casing 1, parallel to its central axis, before it has reached a straight configuration as in figure 4.

4.3 It is therefore concluded that the third auxiliary request cannot be allowed either, due to lack of inventive step (Article 56 EPC) of the subject-matter of claim 1.

5. Fifth auxiliary request

5.1 The subject-matter of claim 1 of the fifth auxiliary request is based on the combination of originally filed claims 3, 4, 7 and 8, which corresponds to the combination of claims 1, 3, 4, 7 and 8 of the patent as granted, with the further addition that the medical implant is an injection port, for which there is a basis in paragraph [0002] of the application as originally filed. The other claims are dependent claims based on respective dependent claims as originally filed.

The Board is satisfied that the requirements of

Article 123(2) and (3) EPC are met.

5.2 Compared to claim 1 of the third auxiliary request, claim 1 of the fifth auxiliary request further defines that the actuator is configured to rotate about a respective axis and comprises an associated surface for each of the fasteners, each surface configured to exert a rotational force on each associated fastener when the actuator is rotated in a deploying direction, thereby moving each fastener from the undeployed position to the deployed position.

This feature specifically makes it possible to control the force by which the fasteners are deployed, which can therefore be adjusted according to the particular tissue to be pierced. Hence, it further contributes to solving the objective technical problem of ensuring a more effective and reliable anchoring action of the surgically implantable device.

Neither document D8 nor document D7 discloses the specific actuator as claimed in claim 1.

Document D1 discloses an actuator which acts on fasteners of an implantable injection port, the actuator and the fasteners comprising respective surfaces for transmitting a rotational force as claimed in claim 1 (rotating disc with arms 525 in figures 58 to 62 and paragraph bridging pages 17 and 18). However, this arrangement does not enable a simultaneous movement from the deployed position to the undeployed position as required by claim 1. On the contrary, document D1 discloses that this movement should preferably be prevented (page 17, last two full sentences). Moreover, the specific arrangement of the fasteners and the actuator of document D1 cannot be

applied to the fasteners and the port catheter of document D8 without substantial mechanical modification.

Hence, the skilled person would not arrive at the subject-matter of claim 1 without exercising an inventive activity. The same applies to dependent claims 2 to 5, which relate to preferred embodiments.

5.3 Before withdrawing the opposition, the then respondent contended that the subject-matter now claimed in claim 1 of the fifth auxiliary request could not validly claim priority. It followed that document D9 enjoyed a priority date earlier than the relevant date of claim 1, i.e. it was part of the state of the art for assessing novelty, and was novelty-destroying.

The Board is however of the opinion that the priority document provides a basis for the subject-matter of claim 1 of the fifth auxiliary request, principally in claims 2, 5 and 6. In this combination of claims the simultaneous movements from and to the undeployed position are not defined. However, the description of the embodiments of the invention, which is identical to that of the application as originally filed, provides a disclosure of these simultaneous movements in paragraphs [0050], [0054] and [0055] and, clearly, in figures 8 to 11. Moreover, the simultaneous movements are also implicit from the "associated surface" of the fasteners and the exertion of "a rotational force on each associated fastener when said actuator is rotated" as claimed in claim 6 of the priority document. Hence, also for the invention disclosed in the priority document, it is the presence of the simultaneous movements, not the structural details of the particular embodiments which allow them, which is technically

significant. Therefore, extracting only the features of the simultaneous movements from the embodiments as originally filed in the priority document does not extend the subject-matter of the latter.

It follows that the priority claim is valid for the subject-matter of claim 1 of the fifth auxiliary request. In view thereof, document D9 does not belong to the state of the art and does not need to be considered.

5.4 The Board therefore concludes that the fifth auxiliary request satisfies the requirements of the 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 maintain the patent on the basis of:

   - claims 1 to 5 of the fifth auxiliary request filed during oral proceedings;

   - description pages 2, 2a and 3 to 8 filed during oral proceedings; and

   - figures 1 to 29 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated