

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

D E C I S I O N
of 16 November 2001

Case Number: T 0490/01 - 3.2.2

Application Number: 94918102.8

Publication Number: 0702529

IPC: A61B 17/12

Language of the proceedings: EN

Title of invention:
Universal Gastric Band

Applicant:
INAMED DEVELOPMENT COMPANY

Opponent:

-

Headword:

-

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty and inventive step: yes, after amendments"

Decisions cited:

-

Catchword:

-



**Europäisches
Patentamt**

**European
Patent Office**

**Office européen
des brevets**

Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 0490/01 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 16 November 2001

Appellant: INAMED DEVELOPMENT COMPANY
1035-B Cindy Lane
Carpinteria
CA 93013 (US)

Representative: VOSSIUS & PARTNER
Siebertstrasse 4
D-81675 München (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 5 December 2000
refusing European patent application
No. 94 918 102.8 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
R. T. Menapace

Summary of Facts and Submissions

I. The appellant (applicant) filed an appeal against the decision of the Examining Division to reject the application for lack of novelty on the basis of document:

D1: US-A-5 074 868.

II. The following further document cited in the Search Report is relevant for the decision:

D3: US-A-5 207 694.

With letter of 12 June 2001 a third party filed observations under Article 115(1) EPC citing in particular the document:

D4: EP-A-611 651.

III. Following a request of the appellant, oral proceedings have been held on 16 November 2001.

IV. Claim 1 as submitted during the oral proceedings reads as follows:

"A gastric band (10) for treatment of morbid obesity, comprising a body portion (11) having a head end (12) and a tail end (13) and an inner stomach-facing surface (15) therebetween, said tail end (13) comprising an elongate tubular member (14) capable of fluid tight connection to an injection reservoir, said head end (12) comprising means (19) for receiving said tail end (13) and for locking said gastric band (10) non-adjustably into a circle having an inner circumference,

an inflatable member (16) on the inner surface (15) being in fluid communication with said tubular member (14), the inflatable member (16) being substantially coextensive with said inner surface (15) of said body portion (11) when said gastric band (10) is non-adjustably locked into said circle, said gastric band (10) being adapted for laparoscopic placement around the stomach of a patient."

V. At the end of the oral proceedings the appellant's requests were that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 and 2 as submitted during the oral proceedings.

VI. The appellant argued essentially as follows:

The band of document D1 was not suitable for laparoscopic treatment, but it had to be put in place by means of major surgery, being not self-locking like the claimed band and needing a suture for fixation. The buckle of the device according to document D1 had only a guiding and not a fixing function.

The tie of document D3 belonged to a different field of surgery being directed to the replacement of the usual clamps for performing a total occlusion of internal vessels.

Reasons for the Decision

1. The appeal is admissible.

2. *Formal matters*

The new claim 1 corresponds substantially to claim 1 as originally filed and therefore complies with Article 123 EPC. Claim 2 is based on the original description, page 2, lines 19 to 22.

3. *Novelty*

3.1 Document D1 discloses a gastric band (20) for treatment of morbid obesity, comprising a body portion having a head end (buckle portion 13) and a tail end (12) and an inner stomach-facing surface therebetween, said tail end comprising an elongate tubular member capable of fluid tight connection to an injection reservoir, said head end (13) comprising means (14) for receiving said tail end (17) and for forming said gastric band into a circle having an inner circumference. This known device further comprises an inflatable member (15) on said inner surface being in fluid communication with said tubular member (17), the inflatable member being substantially coextensive with said inner surface of said body portion when said gastric band (20) is formed into a circle and fixed in position by suturing the tail end to the head end.

The suturing step is facilitated by a suture hole (18) located on the tail end (12). The receiving means (14) on the head end is no longer needed when the band is secured in a circle by the application of sutures (32) or by a cotter-type of pin (column 6, lines 1 to 4) and

may be cut away (see D1, column 4, lines 48/49). That means that this constructional element on the head end has no locking function.

This known gastric band is said to be **removable** without the need for major surgery. Document D1 is silent about the band being adapted for laparoscopic placement. Considering the fact that the method of placing the known gastric band comprises steps which a skilled surgeon may be capable to execute by laparoscopy, the feature of claim 1 which refers to "being adapted for laparoscopic placement" is not considered to distinguish its subject-matter from the disclosure of document D1.

Consequently, the subject-matter of claim 1 differs from this known gastric band in that the receiving means on the head end is designed for locking the gastric band non-adjustably into a circle.

Accordingly the subject-matter of claim 1 is novel against the disclosure of document D1 and distinguishes therefrom by the feature cited above.

- 3.2 Document D4 - which is a document to be considered only within the meaning of Article 54(3) EPC - discloses a gastric band (10) for treatment of morbid obesity, comprising a body portion (12a) having a head end (20) and a tail end (12c) and an inner stomach-facing surface (24) therebetween, said tail end comprising an elongate tubular member (26) capable of fluid tight connection to an injection reservoir, said head end comprising means (20) to be inserted into said tail end and for locking said gastric band non-adjustably into a circle having an inner circumference, and an inflatable

member (24) in fluid communication with said tubular member, the inflatable member being substantially coextensive with said inner surface of said body portion when said gastric band is non-adjustably locked into said circle, said gastric band being adapted for laparoscopic placement around the stomach of a patient.

The subject-matter of claim 1 differs therefrom in that the head end comprises means for receiving the tail end. On the contrary, in the device according to document D4, as can be seen in particular in Figures 2a, 2b and 4, the locking element on the head end (20) is inserted in a recess (22) on the tail end and then the two ends are screwed together by a bolt (30).

Accordingly, the subject-matter of claim 1 is also novel against the disclosure of document D4. As documents D1 and D4 are the only documents cited against novelty it follows that the subject-matter of claim 1 is novel having regard to the whole cited prior art.

4. *Inventive step*

- 4.1 According to document D1 (see the paragraph bridging columns 4 and 5), the placement of this known gastric band includes the following steps: The band is first wrapped around the stomach and the guide tab (11) on the tail end passed through the slot (14) in the buckle (13) on the head end and cinched tight until a calibrating apparatus in the stomach indicates the stoma opening is the correct size. The loose end of the band (the end of the band that has been passed through the slot in the buckle) is then sutured to the band distal to the buckle through the suture guide hole (18)

thereby anchoring the band around the stomach. The protruding portions of the buckle may then be cut off and removed.

The sequence of surgery steps enumerated above may be the source of errors and therefore calls for an experienced surgeon even when executed as major surgery. In particular, the adjustment of the gastric band in relation to the calibrating apparatus, the fixation of the band's position during the sewing step and the recovery of the cut away portion of the buckle are prone to inadvertent negligence. This may be the reason that document D1 mentions the avoidance of major surgery only in connection with the removal of the gastric band and is silent about the method used for its placement.

4.2 Starting from the teaching of document D1 the technical problem to be solved by the invention is therefore to provide a gastric band which can easily and reliably be put in place even by an unexperienced surgeon using laparoscopic instruments, ie without major surgery and without the use of calibrating tools.

4.3 This problem is solved by the differentiating features mentioned at the end of paragraph 3.1 above. The feature that the means (19) is designed to simultaneously perform the functions of receiving the tail end and non-adjustably lock it in a position, which may be defined before the placement of the band, eliminates the need for a calibrating instrument and for a relatively complicated suturing step.

4.4 Document D3 is concerned with a tie having a retaining head (101) on one end, in which locking cones (107),

located in an intermediary portion (04) of the tie, engage, and it is intended to perform occlusion of vessels on each side of a tissue area to be surgically operated. Document D3 is not in particular directed to achieve a fixed encircling position during placement of the tie.

- 4.5 The further available documents of the state of the art are farther away from the claimed invention. Thus the available state of the art does not contain sufficient hints which can lead the person skilled in the art to the claimed invention without any inventive skill being involved and the subject-matter of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division with the order to grant a patent on the basis of claims 1 and 2 as submitted during the oral proceedings and a description yet to be adapted.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß