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**Datasheet for the decision
of 19 February 2008**

Case Number: T 1240/05 - 3.2.02

Application Number: 94918102.8

Publication Number: 0702529

IPC: A61B 17/12

Language of the proceedings: EN

Title of invention:
Universal Gastric Band

Patentee:
ALLERGAN, INC.

Opponents:
AMI Agency for Medical Innovations GmbH
Johnson & Johnson Ethicon Endo-Surgery, Inc.
COMPAGNIE EUROPEENNE D'ETUDE ET DE RECHERCHE DE DISPOSITIFS
POUR L'IMPLANTATION PAR LAPAROSCOPIE
Medical Innovation Developpement
Hospimedical GmbH

Headword:

-

Relevant legal provisions:
EPC Art. 123

Relevant legal provisions (EPC 1973):
EPC Art. 54, 56, 87(1)

Keyword:
"Priority (valid)"
"Novelty and inventive step (yes, after amendments)"

Decisions cited:
G 0002/98

Catchword:

-



Case Number: T 1240/05 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.0
of 19 February 2008

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 20 July 2005
revoking European patent No. 0702529 pursuant
to Article 102(1) EPC 1973.**

Composition of the Board:

Chairman: T. Kriner
Members: M. Noel
A. Pignatelli

Summary of Facts and Submissions

- I. European patent No. 0 702 529 was revoked by decision of the opposition division dated 20 July 2005.
- II. The appellant (patentee) lodged an appeal against this decision by notice received on 23 September 2005. The appeal fee was paid on the same day. A statement setting out the grounds of appeal was filed on 30 November 2005.
- III. At the oral proceedings held on 19 February 2008, only the appellant was represented.

Opponents 1, 2, 4 and 5 withdrew their oppositions by the letter of 15 February 2008, on 6 July 2005, and by the letters of 13 February 2008 and 14 February 2008, respectively.

Opponent 3 informed the Board by the letter dated 21 September 2007 that he would not take part any more in the appeal proceedings.

- IV. At the oral proceedings the appellant filed a new set of claims and requested that the decision under appeal be set aside and that the patent be maintained on the basis of the following documents:

Claims 1 to 2 filed during the oral proceedings,
Description columns 1 to 5 as granted,
Figures 1 and 2 as granted.

- V. At the oral proceedings the appellant submitted that the expression "non-adjustably" present in claim 1 was

implicity disclosed in the priority document and that, therefore, the priority date was validly claimed. Further, by deleting the word "substantially" before the word "coextensive", full coextension was provided which distinguished the claimed subject-matter from the closest prior art document D10 (US-A-5 152 770).

VI. Claim 1 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 thereon a buckle (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 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."

Reasons for the Decision

The Board draws the attention of the parties to the fact that this decision is issued after the entry into force of the EPC 2000. When Articles of the old version of the EPC (1973) are cited, the year is indicated in parentheses. The transitional provisions according to Article 7 of the Act revising the EPC of 29 November 2000 and the Decisions of the Administrative Council of 28 June 2001 and of 7 December 2006, Article 2, have been applied.

1. The appeal is admissible.

2. *Priority*

The question to be answered is whether the claimed expression "**non-adjustably**" which characterises the locking of the gastric band into a circle was originally disclosed by the US priority application US Serial No. 08/068411 filed on 27 May 1993, and whether the present claim 1 is entitled to this priority date.

In accordance with Article 87(1) EPC 1973 a European patent application is only entitled to priority in respect of "the same invention" as was disclosed in the previous application. The Enlarged Board of Appeal stated in G 2/98 that the concept of "the same invention" was to be interpreted narrowly and equated with "the same subject-matter" in Article 87(4) EPC 1973. This interpretation means that priority of a previous application is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general

knowledge, from the previous application as a whole. Identical wording is not required (see also Case Law of the BOA, 5th edition, section IV. B.1.1).

In the present case, the US priority application states on page 5, lines 9 to 20: "In practice, the gastric band is placed in the circling position around the stomach as shown in Figure 2."..."The end of the fill tube 14 is passed around the stomach, and the tail 13 is attached to the buckle 19, so that the buckle and the tail are irreversibly affixed to one another. In this sense, the band is a "one-size-fits-all" device. That is, for a particular band there is **only one single position** in which the tail and buckle can be attached to one another." Further, on page 7, lines 14 to 15: "Since there is **only one locking position** for the band around the stomach..." and at the end of claim 5: "the band means, in use, forms **a circle of fixed circumference** around the stoma opening".

For a skilled person, it is clear that locking the band in only one single position and into a circle having a fixed circumference necessarily implies that the locking is not adjustable. Once the band is locked into a circle, the two complementary locking elements (buckle and tail end) are no longer capable of being changed and the size of the circle can no longer be altered ("one-size-fits-all"). This is, with other words, what the priority application discloses as constituting a first step or rough adjustment, the second step or fine adjustment being subsequently achieved by injecting a fluid into the inflatable member.

Therefore, the expression "non-adjustably" is directly and unambiguously derivable from the disclosure of the previous US application. As a consequence, the claimed subject-matter is entitled to the priority date of 27 May 1993, in accordance with the "same invention" requirement of Article 87(1) EPC 1973.

It results therefrom that, in particular, the alleged prior use introduced by the opponents of a presumably first laparoscopic adjustable gastric band used in Europe in September 1993, as well as the presentation of the first human laparoscopic adjustable gastric banding procedure performed on 1 September 1993 in Belgium or still the presentation of a video film during the Seventh International Symposium on Obesity Surgery, which took place from 8 to 11 November 1993 in Echuca, Australia, are not part of the prior art.

3. *Amendments*

With respect to the version as granted, claim 1 at issue has been amended as follows:

- the expression "comprising **means** (19) for receiving" was replaced by "comprising **thereon a buckle** (19) for receiving".
- In the next feature, the term "**substantially**" before the term "**coextensive**", was deleted.

The first feature mentioned above ("comprising thereon a buckle") is supported by the application as filed (version published as WO 94/27504). The term "buckle" is mentioned on page 4, lines 2 and 10 and the Figures

1 and 2 unambiguously show that the buckle 19 is placed on the head end 12. Moreover, the replacement of "means" by "a buckle", which is a more specific term, results in a restriction of the protection conferred.

The second feature ("coextensive" without "substantially") is to be found in the application as filed on page 11, lines 19 to 21 and lines 24 to 27. The adverb "substantially", therefore, is regarded as optional and can be left aside. Moreover, the deletion of such a relative term as "substantially" results in a further limitation of the protection since coextension of the inflatable member is even now given with respect to the entire surface of the body portion.

Therefore, the requirements of Article 123(2) and (3) EPC are satisfied.

4. *Novelty*

4.1 D10 (US-A-5 152 770) is considered as representing the closest prior art by reason of most structural and functional similarities between the device of this document and the subject-matter of claim 1. It discloses an implantable device for occluding a duct in the body of a living being, generally, but more specific applications are mentioned in the paragraph bridging columns 2 and 3, such as occluding the orifice of the stomach in obese patients. The device of D10, therefore, can be used as a gastric band for the treatment of morbid obesity.

The gastric band of D10, however, is not adapted for laparoscopic placement around the stomach of a patient

since such placement requires the use of laparoscopic cannula (trocar) to introduce the band and other special instruments in order to attach the band around the stomach (see present patent, paragraphs [7] and [16]). Having regard to the important width of the elongate strip portion or plate 1 of the device of document D10, which was demonstrated by the model presented during the oral proceedings, it appeared that the known band could hardly have been introduced laparoscopically into a tiny incision in the abdomen of a patient but, instead, only by laparotomy, i.e. by open surgery.

More specifically D10 discloses a gastric band comprising a body portion 1 having a head end and a tail end and an inner stomach-facing surface therebetween, the tail end comprising an elongate tubular member 8 capable of fluid tight connection 9 to an injection reservoir and the tubular member being in fluid communication with an inflatable member 4 provided on the inner surface of the body portion 1.

The head end comprises a perforation or slot 3 for receiving the tail end and for locking the band around the stomach of a patient. When using the device, the tubular member is passed through the perforation and the tail end or locking means 10 is forced through the perforation to ensure reliable and safe locking. In Figure 2, the smallest outer bulb 6 of the inflatable member is used as locking means. If only one bulb is used as locking means, the locking is made non-adjustably. However, once the device of D10 has been locked in place, the band cannot form an inner circumference having a continuous circle since the

complementary locking elements are presented at right angle each other for assembly.

Furthermore, the inflatable member of D10 is not coextensive with the inner surface of the body portion when considering that the term "coextensive" in the present patent is always associated with the surface of the body portion, i.e. in all directions with the inner stomach-facing surface of the band (see patent, column 3, lines 54-55; column 4, lines 32-33 and 42-43). Applying the same concept to the device of D10 it is clear from the Figures that the inflatable member covers only a part of the band surface.

4.2 It results therefrom that claim 1 at issue differs from the disclosure of D10 by the following, highlighted, features:

- the head end comprises **thereon a buckle**
- the gastric band is locked **into a circle having an inner circumference**
- the inflatable member is **coextensive** with the inner surface of the body portion, and
- the band is **adapted for laparoscopic placement.**

The subject-matter of the claim 1, therefore, is novel vis-à-vis the disclosure of D10. Since no other prior art document comes closer to the claimed subject-matter, the requirements of Article 54 EPC are satisfied.

5. *Inventive step*

5.1 With respect to D10 in which the gastric band can be non-adjustably fastened around the stomach, thereby avoiding the use of sutures for achieving initial "rough" tensioning of the band to approximate the desired stoma, the objective problem is to provide a gastric band which can be laparoscopically placed and easily locked into a circle around the stomach and presenting a smooth, continuous surface when the band is fastened into an encircling position and the inflatable member is inflated (see patent, paragraphs [8] to [18]).

5.2 The provision of a buckle on the head end of a band for receiving a tail end and for locking the band into a circle, is known per se from document D12a (US-A-4 632 114: see Figures 1 to 3) for a neighbouring application to an urethral sphincter. Also the provision of an inflatable member which is coextensive with the inner surface of the body portion of a gastric band may be suggested, in isolation, for example by document D1 (US-A-5 074 868: see Figure 4) or by document D2 (WO-A-86/04498: see Figures 1 to 3). However none of them does suggest the combination of the claimed features. In order to arrive at the subject-matter of claim 1 starting from D10 the skilled person has to combine at least three documents and to adapt the various designs and structures described therein in the manner as claimed. However, such an approach is based on hindsight and results in an ex-post facto analysis of the prior art.

In the Board's judgement, the inventive step of claim 1 resides in the combination of all its features, in particular in the fact that the buckle allows for a complete and continuous circle to be formed when the gastric band is locked into the encircling position, as shown in Figure 2, and in the coextension of the inflatable member with the inner stomach-facing surface when the gastric band is locked into said circle, which results in a continuous surface free of abrupt contours and discontinuities, thereby preventing squeezing of the tissue and the risk of necrosis, as repetitively emphasised in the contested patent (see column 3, lines 53 to 58; column 4, lines 47 to 52 and column 5, lines 27 to 36).

- 5.3 It results therefrom that the subject-matter of claim 1 involves an inventive step vis-à-vis the state of the art, within the meaning of Article 56 EPC 1973.

Claim 2 which depends thereon is also acceptable.

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 with the order to maintain the patent on the basis of the following documents:

Claims 1 and 2 as filed during the oral proceedings;
Description columns 1 to 5 as granted;
Figures 1 and 2 as granted.

The Registrar:

The Chairman:

V. Commare

T. Kriner