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Datasheet for the decision of 26 March 2015

Case Number: T 0851/11 - 3.3.10

Application Number: 06786762.2

Publication Number: 1907025

IPC: A61L29/06, A61L29/14

Language of the proceedings: EN

Title of invention:
MEDICAL DEVICE BALLOON

Applicant:
ABBOTT LABORATORIES

Headword:

Relevant legal provisions:
EPC Art. 56, 123(2)

Keyword:
Main request: Amendments (not allowable) - added-subject-matter
First auxiliary request: Inventive step (yes)

Decisions cited:
T 0013/84, T 0039/93, T 0440/91

Catchword:

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Case Number: T 0851/11 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 26 March 2015

Appellant: (Applicant)	ABBOTT LABORATORIES Abbott Vascular Devices 400 Saginaw Drive Redwood City, CA 94063 (US)
Representative:	Boult Wade Tennant Verulam Gardens 70 Gray's Inn Road London WC1X 8BT (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 23 November 2010 refusing European patent application No. 06786762.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	P. Gryczka
Members:	J. Mercey
	C. Schmidt

Summary of Facts and Submissions

I. The appeal lies from the decision of the Examining Division refusing European patent application No. 06786762.2 with the European publication No. 1 907 025 and International publication No. WO 2007/008784.

II. Claim 1 of the set of claims underlying the contested decision (and present main request) reads as follows:

"A balloon catheter (10,110) comprising:
an elongated shaft (20,120) having a proximal end (22) and a distal end (24);
a bioabsorbable balloon (40,140) having a proximal portion (46,146) and a distal portion (50,150) and being disposed adjacent the distal end (24) of the elongated shaft (20,120); and
a marker band (60,160) to attach the proximal portion (46,146) and/or the distal portion (50,150) of the balloon (40,140) to the elongated shaft (20,120)."

III. *Inter alia* the following documents were cited in the examination proceedings:

(2) EP-A-560 984 and
(4) US-A-5 718 861.

In the decision under appeal, the Examining Division considered that document (2) represented the closest prior art and indicated that the objective technical problem to be solved by the invention might be formulated as to modify the balloon catheter of document (2) to make it detectable. The Examining Division also indicated that reformulation of the technical problem in this manner was not allowable as

said problem was not derivable from the application as filed. It was obvious for the person skilled in the art to use radiopaque markers to make medical devices visible by fluoroscopy or X-ray, since document (4) taught the application of a radiopaque marker band to a balloon catheter, said band also aiding in the attachment of the balloon to the shaft by being positioned in between the two. Therefore, the claimed subject-matter did not involve an inventive step.

IV. In a communication dated 23 October 2014 pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal, the Board indicated that there would appear to be no basis in the application as filed for the amendment "marker band" in claim 1 of the main request, but only for "radiopaque marker band". It also indicated that it might need to be discussed whether the feature "to attach the proximal portion (46,146) and/or the distal portion (50,150) of the balloon (40,140) to the elongated shaft (20,120)" was indeed limiting, or whether it merely defined the purpose of the marker band.

V. With letter dated 26 February 2015, the Appellant filed three auxiliary requests and with letter dated 18 March 2015, the Appellant indicated that it would not be attending the oral proceedings to be held on 26 March 2015.

VI. With letter dated 24 March 2015, the Appellant filed a first auxiliary request, replacing the first auxiliary previously on file. Claim 1 of said request reads as follows:

"A balloon catheter (10,110) comprising:

an elongated shaft (20,120) having a proximal end (22) and a distal end (24);
a bioabsorbable balloon (40,140) having a proximal portion (46,146) and a distal portion (50,150) and being disposed adjacent the distal end (24) of the elongated shaft (20,120); and
a radiopaque marker band (60,160) attaching the proximal portion (46,146) and/or the distal portion (50,150) of the balloon (40,140) to the elongated shaft (20,120)."

VII. The Appellant argued that the feature "marker band" on claim 1 of the main request did not offend against Article 123(2) EPC, since this term was used in the application as filed as a shorthand for the longer term "radiopaque marker band", citing page 6, lines 24 to 34, page 9, lines 16 to 21 and 27, and Figures 1A and 4 to support its arguments. The Appellant argued that the subject-matter of all requests was inventive, the objective technical problem in the light of document (2) as closest prior art being provision of a balloon catheter which was detectable. The reformulation of the technical problem in this manner was allowable, since detectability was derivable from the application as filed, since it was immediately apparent to the skilled person that the provision of marker bands constructed of materials that facilitate or provide radiopacity was to enable the balloon catheter to be detectable under fluoroscopy. The solution, namely a radiopaque marker band which attaches the balloon to the shaft, was not suggested by document (4), since although this document did indeed teach the application of a radiopaque marker ring to a balloon catheter, this marker ring occupied a position between the balloon sleeve and the lumen tube and did not assist in attaching the two together.

VIII. The Appellant requested in writing that the decision under appeal be set aside and a patent be granted on the basis of the main request as filed with letter dated 20 January 2010, which corresponds to the main request on which the contested decision was based, or, alternatively, on the basis of the first auxiliary request filed with letter dated 24 March 2015, or on the basis of the second and third auxiliary requests filed with letter dated 26 February 2015.

IX. At the end of the oral proceedings, which were held in the absence of the Appellant, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. Amendments (Article 123(2) EPC)

2.1 Claim 1 is based on original claim 1, wherein the balloon (40,140) is defined as having a proximal portion (46,146) and a distal portion (50,150) as in the description of Fig. 1A on page 6, line 15 of the application as filed. The Appellant submitted that basis for a marker band (60,160) to attach the proximal portion (46,146) and/or the distal portion (50,150) of the balloon (40,140) to the elongated shaft (20,120) was to be found in the description of Fig. 1A at page 6, lines 27 to 29 of the application as filed.

2.2 However, this passage at page 6, lines 27 to 29 in fact discloses "a band 60, such as a **radiopaque** marker band"

to attach the proximal portion and/or the distal portion of the balloon to the elongated shaft (emphasis added), but not that a "marker band" may be used for this purpose.

2.3 The Appellant argued that the term "marker band" was used in the application as filed as a shorthand for the longer term "radiopaque marker band", citing page 6, lines 24 to 34 and page 9, lines 16 to 27 in combination with Figures 1A and 4 of the application as filed, respectively, to support its arguments.

However, the term "marker bands" used at page 6, line 30 of the application as filed is in the context of **additional** radiopaque markers or marker bands which may be secured to the outer surface of the of the elongated tubular member at any position along its length, these markers thus not being the same as the band 60 referred to at page 6, line 27, the band 60 being to attach the balloon to the tubular member 20, the additional radiopaque markers or marker bands not having this additional function. Furthermore, page 6, lines 33 to 34 indicates that "The marker bands **can** be constructed of materials that facilitate or provide radiopacity" (emphasis added), such that said marker bands do not necessarily have to be radiopaque, which contradicts the argument of the Appellant that in the application as filed, the term "marker band" is used merely as a shorthand for "radiopaque marker band".

With regard to the passage on page 9, lines 16 to 27 of the application as filed, this does indeed refer to a "marker band 160", but this is in the context of the description of Figure 4, such that this marker band is disclosed only in combination with the other essential features of this figure, namely that it is upon a

portion of each of the shoulders 152 and 154, said shoulders, however, not being features of present claim 1.

2.4 The Board thus concludes that claim 1 of the main request extends beyond the application as filed, contrary to the requirements of Article 123(2) EPC. This request is thus not allowable.

First auxiliary request

3. Amendments (Article 123(2) EPC)

3.1 Claim 1 of this request differs from claim 1 of the main request in that the marker band is now defined as a radiopaque marker band, such that the passage at page 6, lines 27 to 29 of the application as filed referred to above in point 2.1 does now indeed provide a basis for this amendment.

3.2 Furthermore, in response to the communication of the Board (see point IV above) the term "to attach" was replaced by "attaching", it being implicit to the skilled reader that an element "which may be utilized to attach" (see page 6, line 28 of the application as filed) two elements together does indeed attach the two elements together when put into practice as in, for example, Figs. 1 and 4, such that this amendment also finds a basis in the application as filed.

3.3 Dependent claims 2 to 20 are based on original claims 2 to 20, respectively.

3.4 Therefore, the amendments made to the claims do not generate subject—matter extending beyond the content of

the application as filed and the Board concludes that the requirements of Article 123(2) EPC are satisfied.

4. Inventive Step

4.1 The Examining Division considered document (2), which discloses biodegradable balloon catheters made of *inter alia* poly(3- or 4-hydroxybutyrate) (see page 2, lines 53 to 58, page 3, lines 51 to 58 and page 10, lines 19 and 24) to represent the closest prior art and the Appellant also argues starting from this document.

4.2 In view of this state of the art, the Appellant submitted that the problem underlying the present application was the provision of a balloon catheter that was detectable.

4.2.1 In the decision under appeal, the Examining Division did not accept the formulation of the technical problem in this manner, since there was no indication in the application as filed that this was indeed the problem which the invention attempted to solve, this having been originally defined on page 2, lines 1 to 5 as "to have a dilatation balloon exhibiting the combined characteristics of softness, abrasion and puncture resistance, hoop strength, and the ability to maintain a preselected diameter as the internal pressure within the balloon is increased", there being no mention that the problem to be solved was the visualisation of the device.

4.2.2 According to the well established case law of the Boards of Appeal, the technical problem has to be determined on the basis of objectively established facts, since for the determination of the objective technical problem, only the effect actually achieved

vis-à-vis the closest prior art should be taken into account (see T 13/84, Headnote I and points 10 and 11, OJ EPO 1986, 253 and T 39/93, points 5.3.1 to 5.3.4, OJ EPO 1997, 134). In this connection, any effects may be taken into account, so long as they concern the same field of use and do not change the character of the invention (see T 440/91, points 4.1 and 4.2, not published in OJ EPO).

4.2.3 In the present case, it is indicated in the application as filed (see page 6, line 27 to page 8, line 6) that the band 60 may radiopaque. It would thus be immediately apparent to the skilled person that the provision of radiopaque marker bands was to enable the balloon catheter to be detectable, such that the formulation of the technical problem to be solved as the provision of a balloon catheter that was detectable is thus based on an effect which is clearly derivable from the application as filed. As a consequence, the Board does not agree with the conclusions of the Examining Division regarding the formulation of the technical problem and thus allows the definition given under point 4.2 above.

4.3 As the solution to this problem, the application proposes a radiopaque marker band attaching the proximal portion and/or the distal portion of the balloon to the elongated shaft.

4.4 Finally, it remains to be decided whether or not the proposed solution to this objective problem is obvious in view of the state of the art.

4.5 When starting from the balloon catheter of document (2), it is a matter of course that the person skilled in the art seeking to provide a detectable balloon

catheter would turn his or her attention to that prior art addressing other balloon catheters which provide improved imaging capabilities, for example, document (4) (see col. 4, lines 13 to 16). This document (see col. 10, lines 5 to 23 and Fig. 6) teaches the application of a radiopaque ring 94 to the outer lumen 12 in a position to be adjacent the proximal end of the balloon 18 in the final assembly in order to permit the user to readily determine the location of the balloon by fluoroscopy or X-ray.

4.5.1 However, the radiopaque marker band of the present invention additionally attaches the proximal and/or the distal portion of the balloon to the elongated shaft, this additional function of the band not being suggested by document (4).

4.5.2 The only type of attachment described in document (4), which is also concerned with improved techniques for joining the balloon to the distal end of the outer lumen (see col. 4, lines 5 to 10), is a gas-tight solvent bond connection between an end sleeve section of the balloon and the outer surface of the outer lumen (see col. 5, lines 8 to 11). Said solvent and pressure-bonding technique is further described at col. 7, line 63 to col. 8, line 13, wherein it is indicated that said binding is facilitated by forming at least the outer surface of the outer lumen and and the balloon of the same types of material, preferably polyurethane, so that pressure-bonding with radiofrequency heating to the melting temperature of the materials further enhances the bond. There is no disclosure in document (4) of these two parts of the ballon catheter being attached by a band, let alone a radiopaque band.

4.5.3 On the contrary, the sole purpose of the marker ring 94 in document (4) is to enable the user to locate the balloon by fluoroscopy or X-ray (see col. 10, lines 7 to 10). Document (4) does not explicitly disclose that the ring attaches parts of the balloon catheter together, let alone one or more ends of the balloon 18 to the outer lumen 12, the latter being equivalent to the elongated shaft (20/120) of present claim 1. Nor does this document implicitly disclose such a method of attachment. This is because the position of the ring 94 is described as being "**in**" (emphasis added) the outer lumen 12 (see col. 10, line 19) and the sleeve of the balloon 21 as being bonded over the outer lumen 12 (see col. 10, line 21, col. 5, lines 8 to 11 and col. 7, line 63 to col. 8, line 13). Since it is also stated that the compression of the lumen holds the ring 94 in place (see col. 10, line 20) and the ring 94 is preferably made of the same material as the inner lumen 14 to avoid problems of incompatibility of dissimilar materials (see col. 10, lines 10 to 15), this would seem to confirm that the ring 94 is indeed **inside** the outer lumen 12 in close contact with the inner lumen 14, since otherwise compression of the outer lumen 12 could not hold it in place and compatibility of the materials of the ring 94 and the inner lumen 14 would be irrelevant if they did not potentially come into contact with each other. Furthermore, since at least the outer surface of the outer lumen 12 and the balloon 18 are preferably made of the same types of materials in order to facilitate solvent and pressure-bonding (see point 4.5.2 above), this would seem to confirm that the balloon sleeve 21 is attached directly to the outer lumen 12, with no ring in between. The Board interprets the statement in document (4) that the sleeve 21 of the balloon is preferably "over" the marker ring 94 (see col. 10, lines 21 to 22) as meaning

the sleeve is bonded over the outer lumen 12 at a position such that it is also over the marker ring 94, since the position of the marker ring is described as being adjacent the proximal end of the balloon in the final assembly (see col. 10, lines 5 to 7). Thus, in contrast to the findings of the Examining Division, it would appear that starting from the outer layer, the order of the four catheter components is balloon sleeve 21, outer lumen 12, marker ring 94, followed by inner lumen 14. It thus cannot be seen how in this configuration the marker ring serves any function in attaching the balloon sleeve to the outer lumen.

4.5.4 Even if document (4) were to describe an embodiment wherein the marker ring 94 was between the balloon sleeve 21 and the outer lumen 12, as found by the Examining Division and submitted by the Appellant, there is no teaching that the marker ring 94 in this position aids in attaching the balloon to the lumen 12, the Examining Division not having indicated why this should be the case. Indeed to the contrary, since the ring 94 is preferably made of the same material as the **inner** lumen 14, such as nitinol (see col. 10, lines 10 to 12), if it were positioned between the outer lumen and balloon sleeve, it might in fact be detrimental to the attachment between the balloon and the outer lumen, since these are described as being preferably made of the same material in order to facilitate pressure-bonding between the two (see point 4.5.2 above).

4.5.5 The Examining Division also indicated that it would appear that the position of the radiopaque marker as defined in the claimed invention and as described in document (4) was identical, so that it could be assumed that they had the same function. However, the position of the band in present claim 1 is defined only in terms

of its function, namely attaching the proximal portion and/or the distal portion of the balloon to the elongated shaft, the band of document (4) not having this function at the position(s) disclosed for it. Indeed, a possible position for the band (60/160) of the invention would be **over** the balloon sleeve (50/150) and/or (46/146) to hold the balloon (40/140) to the shaft (20/120), as would appear to be shown in Figs. 1A, 4 and 5 of the application in suit, such a position not being disclosed in document (4).

4.5.6 Hence, the Board holds that the radiopaque marker ring in document (4) serves no function in attaching parts of the balloon catheter together, let alone one or more ends of the balloon 18 to the outer lumen 12, nor does it suggest the use of a marker ring for such a purpose, the only function for the marker ring described in document (4) being to provide detectability. Document (4) also does not suggest any alternative to the solvent bond connection between the end sleeve section of the balloon and the outer surface of the outer lumen described variously at col. 5, lines 8 to 11 and col. 7, line 63 to col. 8, line 13.

4.5.7 Nor does the closest prior art document (2) suggest the claimed solution, since it discloses neither a marker band, nor how the balloon of the balloon catheter is attached to the shaft.

4.6 Accordingly, there is no suggestion in either of documents (2) or (4) to use a radiopaque marker band to attach the proximal portion and/or the distal portion of the balloon to the elongated shaft of a balloon catheter.

4.7 For these reasons, the Board concludes that in the light of the prior art cited by the Examining Division, the balloon catheter according to claim 1, together with the subject-matter of dependent claims 2 to 20, involves an inventive step within the meaning of Articles 52(1) and 56 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 grant a patent on the basis of claims 1 to 20 of the first auxiliary request filed with letter dated 24 March 2015 and a description yet to be adapted.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated