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**Datasheet for the decision
of 25 July 2024**

Case Number: T 1547/22 - 3.2.08

Application Number: 17159404.7

Publication Number: 3272312

IPC: A61F2/07

Language of the proceedings: EN

Title of invention:

DEVICE FOR AORTIC BRANCHED VESSEL REPAIR

Patent Proprietor:

Bolton Medical, Inc.

Opponent:

Cook Medical Technologies LLC

Relevant legal provisions:

EPC Art. 56

RPBA 2020 Art. 13(2), 11

Keyword:

Inventive step - (no)

Amendment after summons - exceptional circumstances (no)

Remittal to first instance - no



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Case Number: T 1547/22 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 25 July 2024

Appellant: Bolton Medical, Inc.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 7 April 2022
revoking European patent No. 3272312 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairwoman P. Acton
Members: G. Buchmann
C. Schmidt

Summary of Facts and Submissions

- I. The opposition division revoked European patent No. 3 272 312. The opposition division held that the subject-matter of claim 1 according to the then valid main request was not novel and the subject-matter of claim 1 of auxiliary requests 1-9 and 7'-9' did not involve an inventive step.
- II. The patent proprietor filed an appeal against this decision.
- III. Oral proceedings took place before the Board in the form of a videoconference on 25 July 2024.
- IV. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted or on the basis of one of the auxiliary requests MR(a), MR', 1 to 9, 2' and 7' to 9', all (re-)filed with letter dated 15 November 2023, or on the basis of auxiliary request 10, filed on 10 May 2024.

It also requested that, should the Board maintain its opinion that the subject of claim 1 was novel, the case be referred back to the opposition division for further consideration, in particular with regard to the question of inventive step of the claimed invention.
- V. The respondent (opponent) requested that the appeal be dismissed.

VI. In the present decision, reference is made to the following documents:

- D2 WO 2010/105195 A2
- D4 WO 2010/024879 A1
- D6 Declaration of Samuel Arbefeuille;
- D7 Bolton Medical Thoracic Branch Graft Case Presentation, April 2011;

VII. Claim 1 of the main request reads as follows. The numbering of the features has been added by the Board.

1.1

"An aortic graft assembly (10), comprising:

1.2

a) a tubular aortic component (12) that defines a tunnel lumen and includes a proximal end (14) and a distal end (16) connected by a wall (18) of the tubular aortic component,

1.3

the wall defining a wall aperture (20) that is between the proximal (14) and distal (16) ends,

1.4

the wall aperture having a proximal end (22) and a distal end (26), the proximal end of the wall aperture extending perpendicular to a major longitudinal axis (24) of the tubular aortic component when viewed orthogonally to the major longitudinal axis;

1.5

b) a tunnel graft (28)

1.6

connected to the wall of the tubular aortic component

1.7

and extending from the wall aperture and within the tunnel lumen of the tubular aortic component toward the proximal end of the tubular aortic component, the

tunnel graft having a proximal end (30) and a distal end (32), the distal end of the tunnel graft (28) being at the wall aperture of the tubular aortic component (12), the tunnel graft (28) further including

1.8

an open portion (84) at the wall aperture (20), the open portion (84) defining the distal end (32) of the tunnel graft; and

1.9

two tubular portions (100, 102) extending proximally from the proximal end of the open portion (84), the tubular portions (100, 102) each defining a proximal end (106) and a distal end (104) at the proximal end of the open portion (84);

1.10

c) a proximal stent (34) that supports the proximal end (14) of the tubular aortic component (12); and

1.11

d) a distal stent (36) that supports the distal end (16) of the tubular aortic component (12), [sic] "

VIII. Auxiliary requests

(a) Claim 1 of auxiliary requests MR(a), MR' and 1 is identical to claim 1 of the main request.

(b) Auxiliary request 2:

Claim 1 according to auxiliary request 2 differs from claim 1 as granted in the addition of Feature 1.12 according to which the graft assembly comprises

"a clasping stent (56) at the proximal end of the tubular aortic component (12), the clasping stent attached to an interior wall of the tubular aortic component (12) and including at least two exposed

proximal apices (58) proximate to the proximal end (14) of the tubular aortic component (12)."

(c) Claim 1 of auxiliary requests 3-9 and 2' and 7'-9' is identical to claim 1 of auxiliary request 2.

(d) Auxiliary request 10:

Claim 1 according to auxiliary request 2 differs from claim 1 as granted in the addition of the features of claim 12 as granted, according to which "one of the tubular portions is of about equal length to the other tubular portion; one of the tubular portions is parallel to the other tubular portion; the two tubular portions are each distinct and integrally complete tubular portions; the tubular portions share a common wall of a first graft material (108) that partition a conduit of a second graft material (110), the first and second graft materials defining, at least in part, the tubular portions."

IX. The arguments of the appellant can be summarised as follows:

Inventive Step - Article 56 EPC

The subject-matter of claim 1 of the main request and of auxiliary requests 1 - 9, 2' and 7' - 9' involved an inventive step.

Auxiliary request 10 - admittance

Auxiliary request 10 should be admitted to the proceedings because the issue of inventive step was

mentioned for the first time in the communication of the Board. This constituted exceptional circumstances in the sense of Article 13(2) RPBA 2020.

- X. The arguments of the respondent can be summarised as follows:

Inventive Step - Article 56 EPC

The subject-matter of claim 1 of the main request and of auxiliary request 1 was not inventive starting from D7 in combination with D4.

The subject-matter of claim 1 of auxiliary requests 2 - 9, 2' and 7' - 9' was not inventive starting from D7 in combination with D4 and D2.

Auxiliary request 10 - admittance

Auxiliary request 10 should not be admitted into the proceedings because it was filed after the point in time mentioned in Article 13(2) RPBA 2020. No exceptional circumstances were present.

Reasons for the Decision

1. Main request - inventive step
- 1.1 The respondent argued that the subject-matter of claim 1 did not involve an inventive step when starting from D7 in combination with D4.

- 1.2 It was undisputed that D7 discloses Features 1.1-1.8 and 1.10-1.11 of claim 1 of the main request. The availability to the public of the content of D7 prior to the effective date of the patent was proven by D6.

The subject-matter of claim 1 differs from D7 in Feature 1.9 according to which
"two tubular portions (100, 102) [are] extending proximally from the proximal end of the open portion (84), the tubular portions (100, 102) each defining a proximal end (106) and a distal end (104) at the proximal end of the open portion (84)."

- 1.3 The problem to be solved by Feature 1.9 may be regarded as providing an aortic graft assembly which is adapted to be connected to more than one tubular branch component.

- 1.4 D4 discloses an aortic graft assembly which differs from the assembly of claim 1 only in Feature F1.4, i.e. the shape of the aperture in the wall of the aortic component.

D4, page 3, lines 18-26 explains that the division of the internal tube (which corresponds to the tunnel graft of claim 1) into two smaller internal tubes 34, 36 allows extensions for two great arteries. Therefore,

D4 gives the skilled person an indication of the solution of the problem posed, by providing two tubular portions extending proximally from the opening (Feature 1.9).

Hence, Feature 1.9 does not contribute to an inventive step.

- 1.5 The appellant argued that D7 described a migration of the ascending graft which partially covered the innominate artery. This had forced the surgeons in the described operation to change the treatment plan and to insert the branch graft from the left common carotid artery instead of the brachio-cephalic artery. According to the appellant, such a flexibility of the treatment plan was not possible with a tunnel graft which had two internal tubes, because such a tunnel graft was useless after having migrated. Therefore, the skilled person would not have modified the tunnel graft of D7 by providing two internal tubes.

However, the skilled person would recognise that the problem which required the flexibility in the treatment plan of D7 arose from an insufficient fixation of the ascending graft in the individual situation. This would not prevent the skilled person who is trying to solve the problem posed from transferring the solution regarding the connection of the graft to more than one tubular branch suggested in D4 to the graft assembly of D7.

The appellant further argued that even if the skilled person had taken the solution disclosed in D4 into consideration, they would not have transferred just the number of internal tubes but also the shape of the aperture 30 in the wall of the aortic component at the

distal end of the internal tubes. Since the proximal end of the wall aperture 30 of D4 did not extend perpendicular to a major longitudinal axis of the tubular aortic component as required by Feature 1.4 the resulting graft assembly would therefore not comprise all features of claim 1.

The skilled person would, however, keep the perpendicularly extending proximal end of the wall aperture as disclosed in D7 because they would recognise the advantages of this shape of the opening, i.e. the increasing size of the aperture when bending the aortic component. The appellant itself had argued that this advantage was evident from the patent (Figure 23a) even if it was not explicitly mentioned. Therefore, the Board concludes that this advantage was also evident for the skilled person from D7.

1.6 Therefore, the skilled person would have arrived at the subject-matter of claim 1 of the main request without performing an inventive step.

2. Auxiliary requests MR(a), MR' and 1

Since claim 1 of each of auxiliary requests MR(a), MR' and 1 is identical to claim 1 of the main request, also the subject-matter of claim 1 of these requests does not involve an inventive step.

3. Auxiliary request 2 - inventive step

3.1 Claim 1 according to auxiliary request 2 differs from claim 1 as granted in the addition of the features of claim 12 as granted according to which the graft assembly comprises
"a clasping stent (56) at the proximal end of the

tubular aortic component (12), the clasping stent attached to an interior wall of the tubular aortic component (12) and including at least two exposed proximal apices (58) proximate to the proximal end (14) of the tubular aortic component (12)."

3.2 Claim 1 of auxiliary request 2 therefore differs from the prior art according to D7 in Features 1.9 and 1.12.

3.3 Feature 1.12 allows clasping of the tunnel graft by an insertion instrument and thereby a controlled insertion and deployment at the correct place.

3.4 The problem to be solved by Feature 1.12 may therefore be regarded as improving the correct placement of the graft assembly of D7.

Since the Features 1.9 and 1.12 solve different, technically independent problems, the problem solution approach may be applied using the combination of D7 with two different documents, D4 and D2.

The lack of inventive step regarding Feature 1.9 which results from the combination with D4, has been discussed above in view of the main request.

3.5 D2 describes a stent graft 1 for treating an aneurysm in the aorta and a corresponding delivery system.

The graft assembly comprises a clasping stent 72 at the proximal end of the graft, having exposed apices 73, 75 which can be engaged by tines 42 of the apex clasp 40 of an insertion instrument (page 14, lines 6-15, Figure 7D), i.e. D2 discloses Feature 1.12. This allows controlled release of the graft (page 12, lines 25-29) and avoids the formation of a "bird's beak" which is

exemplary shown in Figure 4 of D2 (page 17, line 21 - page 18, line 2). Therefore, the skilled person would recognise that Feature 1.12 as disclosed in D2 facilitates the correct placement of the graft assembly, and would add this feature to the graft assembly of D7 without performing an inventive step.

- 3.6 The appellant argued that Features 1.9 and 1.12 had a synergistic effect and could not be treated separately in the assessment of inventive step. The synergistic effect arose from the fact that for a correct alignment of the aperture for the two tubular portions, an exact positioning of the tunnel graft was required.

However, the number of the tubular portions is not correlated with the need to align the aperture of the tunnel graft with the branching off arteries. On the contrary, the controlled positioning is an issue which is important for any endovascular graft.

Therefore, Features 1.9 and 1.12 can be treated independently from each other in the assessment of inventive step.

The appellant's argument that D2 showed a graft without an opening, and was therefore not to be taken into consideration for a tunnel graft with side openings, is also not valid. Even if the placement of the tunnel graft of claim 1 needed a more correct placement than the graft of D2, there would be no reason to disregard the advantageous function of the clasping stent as disclosed in D2.

- 3.7 For the above reasons, the subject-matter of claim 1 of auxiliary request 2 does not involve an inventive step

starting from D7 in combination with D4 and D2.

4. Auxiliary requests 3-9 and 2' and 7'-9'

Since claim 1 of auxiliary requests 3-9, 2' and 7'-9' is identical to claim 1 of auxiliary request 2, also the subject-matter of claim 1 of these requests does not involve an inventive step.

5. Auxiliary request 10

Auxiliary request 10 was filed on 10 May 2024 which was after notification of a communication under Article 15(1) RPBA. Furthermore, the addition of the subject-matter of claim 12 as granted into claim 1 constitutes undisputedly an amendment of the appellants appeal case.

In such a case, Article 13(2) RPBA 2020 requires exceptional circumstances justified by cogent reasons for the admittance of the newly filed request.

The appellant argued that the inventive step attack had been dealt with for the first time in the Board's preliminary opinion and that it had reacted as soon as possible (one month after the Board's communication) to this objection.

However, the decision of the opposition division already stated that the subject-matter of claim 1 of auxiliary request 2 lacked an inventive step in view of D2.

Additionally, in its reply to the appeal, page 8, the respondent raised an objection concerning lack of inventive step of claim 1 of the main request by

referring to the notice of opposition, pages 10-14. The notice of opposition included an objection starting from D7 in combination with D4. Furthermore, in the reply to the appeal, page 10, the respondent argued that D2 rendered Feature 1.12 (of claim 1 of auxiliary request 2) obvious.

Therefore, the Board's communication was not the first time the appellant was confronted with the inventive step objection. Hence, no exceptional circumstances exist which would justify the admittance of auxiliary request 10, and the Board decided not to admit auxiliary request 10 into the proceedings.

6. Remittal

The appellant requested remittal of the case for examination of inventive step in case the Board came to the conclusion that the subject-matter of claim 1 as granted was novel.

They argued that the question of inventive step had not been completely discussed during the opposition proceedings and that it was not part of the opposition decision. Article 11 RPBA 2020 allowed the Board to remit the case to the first instance if special reasons present themselves for doing so.

The Board notes, however, that the question of inventive step was already raised in the notice of opposition and the opposition decision also treated inventive step of auxiliary request 2 (pages 20-24, point 3).

Furthermore, the Board of Appeal may exercise any power within the competence of the department which was

responsible for the decision appealed (Article 111(1) EPC, second sentence).

In the absence of special reasons, the Board decided not to remit the case to the opposition division.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated