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**Datasheet for the decision
of 4 June 2024**

Case Number: T 2043/22 - 3.2.01

Application Number: 18210929.8

Publication Number: 3494930

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

LEAFLET ATTACHMENT FRAME FOR A PROSTHETIC VALVE

Patent Proprietor:

Edwards Lifesciences Corporation

Opponent:

Meril GmbH

Headword:

Relevant legal provisions:

EPC Art. 54

Keyword:

Novelty - all requests (no)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2043/22 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 4 June 2024

Appellant: Meril GmbH
(Opponent 1) Bornheimer Straße 135-137
53119 Bonn (DE)

Representative: Klicznik, Alexander
Hogan Lovells International LLP
Kennedydamm 24
40476 Düsseldorf (DE)

Respondent: Edwards Lifesciences Corporation
(Patent Proprietor) One Edwards Way
Irvine, CA 92614 (US)

Representative: Thum, Bernhard
Thum & Partner
Thum Mötsch Weickert
Patentanwälte PartG mbB
Siebertstr. 6
81675 München (DE)

Intervener: Meril Life Sciences Pvt Ltd.
M1-M2, Meril Park, Survey No 135/2/B & 174/2
Muktanand Marg
Chala
Vapi - 396 191, Gujarat (IN)

Representative: Klicznik, Alexander
Hogan Lovells International LLP
Kennedydamm 24
40476 Düsseldorf (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 22 August 2022
rejecting the opposition filed against European**

patent No. 3494930 pursuant to Article 101(2)
EPC.

Composition of the Board:

Chairman G. Pricolo

Members: A. Wagner
 A. Jimenez

Summary of Facts and Submissions

- I. The appeal of the opponent lies against the decision of the opposition division to reject the opposition filed against the European patent No. 3 494 930.
- II. In its decision, the opposition division held that none of the grounds of opposition raised by the opponents under Article 100(a), (b), (c) EPC was prejudicial to the maintenance of the patent as granted. Among others, it was found that the subject-matter of claim 1 as granted was new over US 2004/0186563 A1 (D4).
- III. On 15 September 2023, Meril Life Sciences Pvt Ltd. filed a notice of intervention.
- IV. Oral proceedings were held before the Board on 4 June 2024.
- V. The appellant (opponent) requested that the decision be set aside and the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed. As an auxiliary measure, the respondent requested that the patent be maintained on the basis of one of the auxiliary requests 1 to 20 filed with the reply to the opponent's statement of grounds of appeal, or on the basis of one of the corrected auxiliary requests 5, 9, 16, 18 to 20 or one of the auxiliary requests 5', 9', 16', 18' to 20', all filed with letter dated 22 December 2023.

The intervention was withdrawn.

VI. The **main request** corresponds to the patent as granted. Claim 1 reads as follows (feature numbering as used in the impugned decision):

1. An assembly, comprising:

1.1 a balloon catheter comprising an inflatable balloon (110); and

1.2 a balloon-expandable prosthetic aortic heart valve (100), comprising:

1.2.1 a radially collapsible and expandable annular frame (104);

1.2.2 a leaflet assembly (102) positioned within the frame (104), the leaflet assembly comprising a plurality of leaflets (106) that are connected to each other to form commissures of the leaflet assembly (102);

1.2.3 wherein the frame (104) comprises a pair of struts (404, 406) adjacent to each of the commissures, the struts of each pair being spaced apart from each other so as to define an opening (420) therebetween;

1.2.4 wherein at each commissure, two adjacent leaflets (106a, 106b) are positioned between an adjacent pair of struts (404, 406), with one of the leaflets (106a) wrapping around at least a portion of one of the struts (404) and the other leaflet (106b) wrapping around at least a portion of the other strut (406);

1.2.5 wherein a cloth portion (304) is attached to a portion (408, 410) of one leaflet (106a, 106b) that extends radially outside of the frame, the cloth

portion (304) being wrapped around one of the struts (404, 406) and

1.2.6 wherein another cloth portion (304) is attached to a portion (408, 410) of the other leaflet (106a, 106b) that extends radially outside of the frame, the cloth portion (304) being wrapped around the other strut (404, 406),

1.2.7 characterized in that the struts (404, 406) are orientated vertically and

1.2.8 that the leaflets (106a, 106b) of the leaflet assembly (102) are attached to the frame without suturing the leaflets (106a, 106b) at the commissures directly to the struts (404, 406).

In the **auxiliary requests**, several amendments are made and differently combined. The individual amendments are:

Amendment **A1** concerns feature 1.2.2:

"a leaflet assembly (102) mounted on and positioned within the frame (104), [...]"

Amendment **A2** also concerns feature 1.2.2:

"[...] a plurality of leaflets (106) that are connected to each other at commissure tabs to form commissures of the leaflet assembly (102);"

Amendment **A3** adds the following feature between features 1.2.6 and 1.2.7:

"each of the cloth portions (304) being sutured to a third cloth portion (440) and one of the leaflet portions (408, 410) that are radially outside of the frame to attach the leaflets to the frame;"

Amendment **A4** concerns feature 1.2.1:

"a radially collapsible and expandable, generally cylindrical annular frame (104);"

Amendment **A5** concerns feature 1.2.3:

"wherein the frame (104) comprises a pair of struts (404, 406) adjacent to each of the commissures, the vertical struts being arranged at an upper area between two frame sections and the struts of each pair being spaced apart from each other so as to define an opening (420) therebetween;"

Additionally dependent claim 6 as granted is deleted.

Corrected amendment A5 is based on A5 and submitted as an alternative to A5. It also concerns feature 1.2.3:

"wherein the frame (104) comprises a pair of vertical struts (404, 406) adjacent to each of the commissures, the vertical struts being arranged at an upper area between two frame sections and the struts of each pair being spaced apart from each other so as to define an opening (420) therebetween;"

Additionally dependent claim 6 as granted is deleted.

Amendment **A5'** is based on corrected amendment A5 and also submitted as an alternative to A5. It concerns features 1.2.3 to 1.2.8 as follows:

1.2.3 wherein the frame (104) comprises a plurality of frame sections and a pair of vertical struts (404, 460) adjacent to each of the commissures, the vertical struts being arranged at an upper area between two frame sections and the vertical struts of each pair being spaced apart from each other so as to define an

opening (420) therebetween;

1.2.4 wherein at each commissure, two adjacent leaflets (106a, 106b) are positioned between an adjacent pair of vertical struts (404, 406), with one of the leaflets (106a) wrapping around at least a portion of one of the vertical struts (404) and the other leaflet (106b) wrapping around at least a portion of the other vertical strut (406);

1.2.5 wherein a cloth portion (304) is attached to a portion (408, 410) of one leaflet (106a, 106b) that extends radially outside of the frame, the cloth portion (304) being wrapped around one of the vertical struts (404, 406) and

1.2.6 wherein another cloth portion (304) is attached to a portion (408, 410) of the other leaflet (106a, 106b) that extends radially outside of the frame, the cloth portion (304) being wrapped around the other vertical strut (404, 406),

1.2.7 characterized in that the vertical struts (404, 406) are orientated vertically and

1.2.8 that the leaflets (106a, 106b) of the leaflet assembly (102) are attached to the frame without suturing the leaflets (106a, 106b) at the commissures directly to the vertical struts (404, 406).

Additionally claims 2, 3, 6 and 11 to 14 as granted are deleted.

Auxiliary request 1 includes amendment A1.
Auxiliary request 2 includes amendment A2.
Auxiliary request 3 includes amendment A3.

Auxiliary request 4 includes amendment A4.
Auxiliary request 5 includes amendment A5.
Auxiliary request 6 includes amendments A1 and A2.
Auxiliary request 7 includes amendments A1 and A3.
Auxiliary request 8 includes amendments A1 and A4.
Auxiliary request 9 includes amendments A1 and A5.
Auxiliary request 10 includes amendments A1, A2 and A3.
Auxiliary request 11 includes amendments A1, A3 and A4.
Auxiliary request 12 includes amendments A1, A2, A3 and A4.
Auxiliary request 13 includes amendments A2 and A3.
Auxiliary request 14 includes amendments A2 and A4.
Auxiliary request 15 includes amendments A2, A3 and A4.
Auxiliary request 16 includes amendments A2, A3, A4 and A5.
Auxiliary request 17 includes amendments A3 and A4.
Auxiliary request 18 includes amendments A3, A4 and A5.
Auxiliary request 19 includes amendments A4 and A5.
Auxiliary request 20 includes amendments A1, A2, A3, A4 and A5.

Corrected auxiliary request 5 includes corrected amendment A5.
Corrected auxiliary request 9 includes amendment A1 and corrected amendment A5.
Corrected auxiliary request 16 includes amendments A2, A3, A4 and corrected amendment A5.
Corrected auxiliary request 18 includes amendments A3, A4 and corrected amendment A5.
Corrected auxiliary request 19 includes amendment A4 and corrected amendment A5.
Corrected auxiliary request 20 includes amendments A1, A2, A3, A4 and corrected amendment A5.

Auxiliary request 5' includes amendment A5'.
Auxiliary request 9' includes amendments A1 and A5'.

Auxiliary request 16' includes amendments A2, A3, A4 and A5'.

Auxiliary request 18' includes amendments A3, A4 and A5'.

Auxiliary request 19' includes amendments A4 and A5'.

Auxiliary request 20' includes amendments A1, A2, A3, A4 and A5'.

VII. The appellant's (opponent's) arguments relevant to the present decision may be summarized as follows:

Novelty over D4 - main request

The opposition division erred in concluding that features 1.2.7 and 1.2.8 were not disclosed in D4.

The wording "vertically oriented" in feature 1.2.7 was to be understood in a broader manner than "perfectly vertical and parallel to each other". A strut with an angle from the vertical up to +/- 45° was "vertically oriented". Furthermore D4 literally disclosed vertically oriented struts in paragraphs [0058] and [0067].

Feature 1.2.8 required that the attachment of the leaflets only "at the commissures" was without suturing the leaflets directly to the struts.

According to feature 1.2.2 the commissure was the area where the leaflets are connected to each other.

Consequently, only the connection areas between the leaflets were to be considered as commissures, not additionally the leaflet portions (408, 410) that extended radially outside of the frame.

D4 disclosed in figure 10 a very similar attachment of the leaflets as figure 9B of the patent in suit. In D4,

no sutures were shown at the commissures, i.e. in between the two struts.

The opposition division was correct in finding that features 1.1 and 1.2 were disclosed in D4. In paragraph [0070] of D4, it was described that the valve 22 was "*expanded with or without assistance of a balloon.*" A balloon catheter according to feature 1.1 was mentioned in paragraph [0091].

Novelty over D4 - all auxiliary requests

None of the amendments to claim 1 could overcome the lack of novelty over D4. The leaflet assembly in D4 obviously was also "mounted on" the frame as shown in figure 10 (amendment A1). The leaflets were connected to each other at commissure tabs 100 as shown in figures 7 and 8 (amendment A2). Furthermore D4 disclosed in figure 10 a third cloth portion 54 at the outside of the frame and sutures 122 between the cloth portions 114, the leaflets portions 100 and the third cloth 54 (amendment A3). Figures 2B and 3B showed that the frame 50 was generally cylindrical (amendment A4). D4, figures 5 and 8 disclosed vertical struts arranged at an upper area between two frame sections (amendments A5, corrected A5, A5').

- VIII. The respondent's (patent proprietor's) arguments relevant to the present decision may be summarised as follows:

Novelty over D4

The opposition division correctly found that D4, figure 5 and paragraph [0082], disclosed only slanted struts - contrary to feature 1.2.7. These struts did not fall

under the wording "vertically oriented" which required the pair of struts being in parallel arrangement.

Also with regard to feature 1.2.8, the opposition division was right in finding that the sutures 120 in D4, figure 10, attached the leaflets at the commissures directly to the struts. The term "commissure" was interpreted too narrowly by the appellant (opponent). The commissures included the connected portions and the portions 408, 410 of the leaflets that were external to the struts. There could be no doubt that in D4 there was a direct connection between the leaflet tabs 100 and the frame flanges 106 via the sutures 120 - contrary to the requirement of feature 1.2.8.

Additionally the opposition division erred in concluding that D4 disclosed features 1.1 and 1.2. The heart valve of D4 was self-expanding and not balloon expandable. D4 disclosed in paragraph [0070] that the valve 22 *"is merely expelled from the end of the delivery tube 20"*. The skilled person clearly distinguished between a self-expandable valve that acted as a spring and a balloon-expandable valve that was plastically deformed.

Novelty over D4 - all auxiliary requests

In particular the corrected amendment A5 (alternatively amendment A5'), and the amendments A2 and A4 included features which were not disclosed in D4.

Amendment A5' (and corrected amendment A5) clearly defined the struts as being vertical and not somehow slanted or tapered as shown in D4.

Amendment A2 specified that the leaflets were connected

at commissures tabs. It was thus clarified that the leaflets must be attached to the frame without direct sutures between the leaflets and the frame along the complete tab. However, in D4, the sutures 120 between the leaflets and the frame were provided at the tabs 100 (figure 10).

Amendment A4 required a generally cylindrical frame. However D4 (figure 5) disclosed a frame with two opposing cones. The first cone was the cusp regions 74 extending outwards from the inflow end to the outflow end of the valve. The second cone was the commissure regions 76 extending inwards from the inflow end to the outflow end. This was supported by paragraph [0058], second sentence, reciting that the shape of the frame "*describes a conical surface of revolution*".

Therefore at least auxiliary request 16' incorporating the amendments A2, A3, A4 and A5' into claim 1 met the requirements of Article 54 EPC.

Reasons for the Decision

1. Main request - novelty over D4

1.1 The assembly as defined in claim 1 as granted is not new over D4.

1.2 The respondent (patent proprietor) disputed the disclosure of features 1.1, 1.2, 1.2.7 and 1.2.8.

1.3 Features 1.1, 1.2

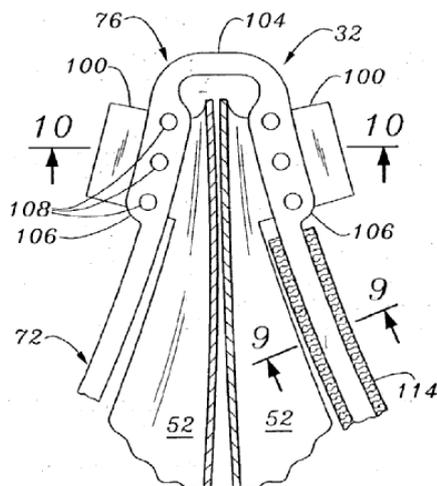
1.3.1 The Board confirms the opposition division's opinion that feature 1.1 (a balloon catheter) and feature 1.2 (a balloon-expandable prosthetic aortic heart valve)

are disclosed in D4 (impugned decision, point 24.1).

- 1.3.2 D4 discloses in paragraph [0028] that *"the valve is permitted to self-expand to a first diameter, and then the valve is assisted with a physical expander such as a balloon to further expand to a second diameter."* Paragraph [0095] further describes that *"the heart valve 22 may be loaded around an inflation balloon, but for the sake of a small profile the balloon is used after expulsion of the valve from the tube at the implantation site."* D4 then summarizes in paragraph [0095] that the expansion *"is unlike a self-expanding device that relies solely on the outward radial force of the device to achieve its desired diameter. It is also unlike balloon expanded devices that rely on a balloon to plastically deform the device into the desired diameter."*
- 1.3.3 Therefrom it is concluded that, to allow the heart valve to be loaded around the balloon or to allow the balloon to be used after expulsion of the heart valve at the implantation site, a balloon catheter is necessary. Feature 1.1 is thus disclosed.
- 1.3.4 Furthermore, from paragraphs [0028] and [0095] cited above, it is apparent that the prosthetic heart valve described in D4 is balloon-expandable. The respondent (patent proprietor) might be right that D4 does not disclose a typical balloon-expandable heart valve which is expanded primarily by the balloon, however, as the balloon assists the final expansion, the prosthetic heart valve of D4 is at least partly balloon-expandable. A balloon-expandable heart valve as described in D4 is not excluded by the wording of claim 1.

1.4 Feature 1.2.7

1.4.1 It is undisputed that the pair of struts as defined in feature 1.2.3 is disclosed in D4 by the commissure region 76 with the attachment flanges 106 as shown in figure 8 (reproduced below).



1.4.2 Feature 1.2.7 of claim 1 then further defines the struts as being orientated vertically.

1.4.3 Contrary to the respondent's opinion, the wording "vertically orientated" does not imply a perfect vertical orientation resulting in the pair of struts being parallel. Instead, the skilled person understands the wording "vertically orientated" in its broadest technical meaning including generally or substantially vertical orientations.

1.4.4 The argument of the respondent that D4 described in paragraph [0081] with reference to figure 8 clearly non-vertical struts because "*the commissure region 76 of the leaflet frame 72 tapers down in the outflow direction to a tip 104*" is not convincing. A commissure region that tapers down to a tip is not in contradiction to struts being (substantially)

vertically oriented.

1.4.5 Furthermore, in the general part of the description, D4 discloses in paragraph [0058] that the frame has "*three upstanding and generally axially-oriented arcuate or U-shaped commissure regions on the outflow end*". The skilled person understands the wording "*upstanding and generally axially-oriented arcuate or U-shaped*" as falling under "vertically orientated" - even if the commissure region is slightly tapering in the outflow direction to a tip 104 as shown in figure 8 of D4.

1.4.6 Consequently, the attachment flanges 106 of the frame adjacent to the leaflet tabs 100 can be considered as a pair of struts being "vertically orientated" according to feature 1.2.7.

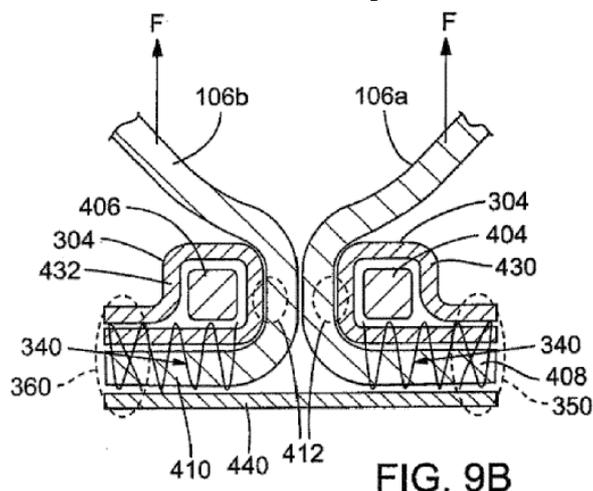
1.5 Feature 1.2.8

1.5.1 Feature 1.2.8 requires that the leaflets are attached to the frame without suturing the leaflets at the commissures directly to the struts.

1.5.2 The commissures are defined in features 1.2.2 and 1.2.4. According to feature 1.2.2, the leaflets "*are connected to each other to form commissures*". Feature 1.2.4 then requires that at each commissure, the two adjacent leaflets are positioned between an adjacent pair of struts.

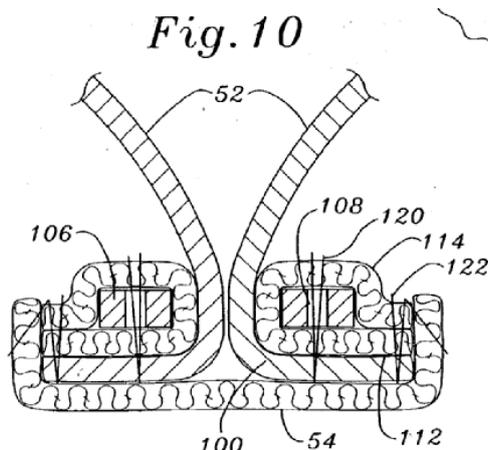
1.5.3 According to this claim wording of the patent in suit, the commissures can thus validly be regarded each as the part of adjacent leaflets at which they are connected to or in contact with each other, and that lies between the pair of struts (see figure 9B of the patent in suit reproduced below).

This understanding of features 1.2.2 and 1.2.4 is also supported by paragraph [0042] of the patent in suit. Therein it is described that the commissure is the area "where two leaflets come together".



1.5.4 Following this interpretation, the portions 408, 410 of the leaflets that wrap around the struts at the outside of the frame do not belong to the commissures - contrary to the opinion of the respondent (patent proprietor).

1.5.5 Having identified the meaning of the feature "commissures" in claim 1, it is apparent that D4, figure 10 (reproduced below), discloses feature 1.2.8 because the leaflets 52 are attached to the frame flanges 106 without suturing the leaflets 52 at the commissures, i.e. the area between the struts in circumferential direction, to the frame. The sutures 120 that attaches the leaflets to the frame flanges 106 are away from the commissure and not "at the commissure".



1.5.6 Consequently, feature 1.2.8 is disclosed in D4.

2. Auxiliary request 16' - novelty over D4

2.1 In auxiliary request 16', the amendments A2 to A4 and A5' are included in claim 1. Amendment A5' incorporates amendment A5 and corrected amendment A5.

2.2 The subject-matter of claim 1 of auxiliary request 16' is not new over D4.

2.3 The respondent disputed that in D4 the frame was generally cylindrical (A4). Instead, D4 disclosed a conical frame. Furthermore, with amendment A5', it was clarified that the struts had to be perfectly vertical and not tapered as in D4. Finally, amendment A2 was specifying that the commissure tabs were part of the commissure. In D4, figure 10, the sutures 120 were provided at the commissure tabs 100. This arrangement was now excluded by the claim wording of auxiliary request 16'.

2.4 The Board is not convinced. None of the amendments made to claim 1 overcomes the lack of novelty over D4.

2.4.1 Vertical struts (A5')

The definition of "vertical struts" does not change the conclusion of point 1.4 above. In fact, defining that the struts are vertical does not restrict the term "orientated vertically" of feature 1.2.7 in any manner. In the broadest technically sensible meaning "vertical struts" include struts that are *"upstanding and generally axially-oriented arcuate or U-shaped"* as disclosed in paragraph [0058] of D4. Contrary to the respondent's opinion, a perfectly vertical orientation is still not implicitly required.

The disclosure of the further features included by amendment A5' that the frame comprises a plurality of frame sections and that the struts are arranged at an upper area between two frame sections is not disputed by the respondent (patent proprietor). Indeed, these features are shown in D4, figure 5, as argued by the appellant (opponent).

2.4.2 Generally cylindrical frame (A4)

D4, figure 5, discloses a generally cylindrical frame. The Board agrees with the appellant (opponent) that a frame for a prosthetic heart valve as shown in D4 inherently has to be generally cylindrical to follow the natural anatomy of the implantation site as shown e.g. in figure 2B of D4.

Furthermore, a generally cylindrical frame does not need to have a perfectly cylindrical shape. Even if in D4, according to paragraph [0058], the frame is described as having a conical surface of revolution because the three commissures regions 75 on the outflow end of the valve are closer together than the three

cuspid positioners 42 as shown e.g. in figures 3B and 3C, the frame can still be regarded as being "generally cylindrical".

Finally, D4 discloses also in paragraph [0058] an alternative frame with a tubular surface manufactured by bending a two-dimensional blank around a cylindrical mandrel (paragraph [0072]). In this embodiment which is not shown in the figures, the commissure regions 75 on the outflow end of the valve would not be closer together than the three cuspid positioners 42.

The feature introduced with amendment A4 is thus known from D4.

2.4.3 Leaflets connected to each other at commissure tabs (A2)

Contrary to the respondent's (patent proprietor's) opinion, the wording that the leaflets "*are connected to each other at commissure tabs to form commissures*" does not define that the commissure tabs are part of the commissures. It is rather the other way around, namely that the commissures - defined as the part of the leaflets where they come together (see point 1.5 above) - are provided at commissure tabs of the leaflets.

Also D4, figures 8 and 10, discloses leaflets which "*come together in the commissure regions 76 and the tabs 100 thereof are folded away from each other on the exterior of the flanges 106*" (paragraph [0082], last sentence). Thus, in D4, the leaflets 52 are connected at leaflet tabs 100 to form commissures. However the commissure itself is still the part at the leaflet tabs

located between the struts where the leaflets are in connection.

2.4.4 Amendment A3

With amendment A3, claim 1 further requires a third cloth portion 440 and a suture 340 between the cloth portions 304 of features 1.2.5 and 1.2.6, the third cloth portion 440 and the leaflet portions 408, 410 which extend at the outside of the frame (see figure 9B above). The respondent (patent proprietor) did not dispute the disclosure of these features in D4. Indeed, figure 10 of D4 shows a third cloth portion 54 and sutures 122 according to the features defined by amendment A3.

3. Auxiliary request 20'

- 3.1 Claim 1 of auxiliary request 20' is based on auxiliary request 16' with the additional (and last remaining) amendment A1, defining in feature 1.2.2 that the leaflet assembly is not only positioned within but also mounted on the frame.
- 3.2 Auxiliary request 20' does not meet the requirements of Article 54 EPC for the same reasons as auxiliary request 16'.
- 3.3 The respondent (patent proprietor) has not put forward any additional arguments in respect of auxiliary request 20' to those already submitted in respect of the previous requests. Actually, the respondent acknowledged during oral proceedings that amendment A1 is not suitable to overcome the novelty objection with regard to D4.

4. All other auxiliary requests

4.1 In claim 1 of all other requests (auxiliary requests 1 to 20, corrected auxiliary requests 5, 9, 16, 18 to 20 and auxiliary requests 5', 9', 18' and 19') the amendments A1 to A5 (alternatively corrected amendment A5 or amendment A5') are combined in various ways. The subject-matter of claim 1 of all of these auxiliary requests is broader than the subject-matter of claim 1 of auxiliary request 20'. As auxiliary request 20' does not meet the requirements of Article 54 EPC, also all other auxiliary requests are not allowable for the same reasons as set out in points 2 and 3 above.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



M. Schalow

G. Pricolo

Decision electronically authenticated