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Datasheet for the decision of 26 February 2019

Case Number: T 2455/17 - 3.2.08

Application Number: 14161991.6

Publication Number: 2749254

IPC: A61F2/01, A61F2/24

Language of the proceedings: EN

Title of invention:
Repositionable heart valve

Patent Proprietor:
Boston Scientific Scimed, Inc.

Opponents:
Medtronic CV Luxembourg S.à.r.l./
Medtronic Vascular Galway

Headword:

Relevant legal provisions:
EPC Art. 100(c), 100(b), 100(a), 54, 56, 123(2), 84
RPBA Art. 12(2), 12(4)

Keyword:
Grounds for opposition - insufficiency of disclosure (no) - subject-matter extends beyond content of earlier application (no) - added subject-matter (no) - clarity in opposition appeal proceedings
Novelty - (yes)
Inventive step - (yes)
Amendments - allowable (yes) - intermediate generalisation - added subject-matter (no)
Claims - support in the description (yes)

Decisions cited:
G 0003/14, T 1903/13

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2455/17 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 26 February 2019

Appellant: (Patent Proprietor)	Boston Scientific Scimed, Inc. One Scimed Place Maple Grove, MN 55311-1566 (US)
Representative:	Peterreins Schley Patent- und Rechtsanwälte Hermann-Sack-Strasse 3 80331 München (DE)
Appellant: (Opponent 3)	Medtronic CV Luxembourg S.à.r.l./ Medtronic Vascular Galway 102 rue des Maraichers/Parkmore Business Park West 2124 Luxembourg/Galway, IE (LU)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 19 October 2017 concerning maintenance of the European Patent No. 2749254 in amended form.**

Composition of the Board:

Chairwoman	P. Acton
Members:	C. Herberhold
	Y. Podbielski

Summary of Facts and Submissions

I. By decision posted on 19 October 2017 the Opposition Division decided that European patent No. 2 749 254 as per the first auxiliary request then on file, and the invention to which it related, met the requirements of the EPC.

II. The patent proprietor (appellant 1) and opponent 3 (appellant 2) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.

III. Opponents 1 and 2 had withdrawn their oppositions during the proceedings before the opposition division and were thus not party to the appeal proceedings.

IV. Oral proceedings before the Board were held on 26 February 2019.

At the end of the oral proceedings the requests of the parties were as follows:

Appellant 1 requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request, filed as auxiliary request 7a with letter dated 17 January 2019.

Appellant 2 requested that the decision under appeal be set aside and that the patent be revoked.

V. Claim 1 of the main request reads as follows:

"Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an expandable anchor (30) supporting a replacement valve (20), the anchor having a delivery configuration and a deployed configuration, characterized by

a fabric seal extending from the distal end of the valve (20) proximally over the anchor in the delivery configuration, wherein the seal is bunched up in the deployed configuration,

wherein the apparatus is configured such that during deployment, the expandable anchor (30) foreshortens and the fabric seal bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets (382)."

VI. The following documents played a role in the present decision:

BB2: WO-A-2005/062980;
BB3: WO 98/29057;
BB6: WO 03/047468;
D9: US 5,855,601.

VII. The essential arguments of appellant 2 can be summarised as follows:

Admission of the main request into the proceedings

The main request had been filed as auxiliary request 7a only with letter dated 17 January 2019. It was to some extend based on an auxiliary request filed - but never admitted - during opposition proceedings. The subject-matter of the set of requests from which the present main request originated was of divergent scope. It was furthermore extremely late filed and should thus not be

admitted. In this context, the Board's communication could not be considered an invitation to file further requests. Moreover, T 1903/13 had made clear that requests submitted but not examined in opposition were not necessarily to be admitted in appeal.

Original disclosure

While the earlier application as filed (BB2) disclosed on page 34, lines 26-31, page 85, lines 26-34, page 86, lines 22-32 and Figures 32-34, a fabric seal which bunches up to create fabric flaps and pockets, said disclosure was in the context of further features with which the presently claimed features were inextricably linked and from which they could not be isolated.

In particular, the foreshortening of the anchor and the bunching up of the fabric seal were not only co-occurring, but the foreshortening was required to be causal for the bunching up. For that causal relationship to take place, the foreshortening needed to be significant, as could be appreciated in Figures 32 to 34 of the earlier application as filed. It was also an essential feature that the foreshortening was imposed on the anchor by an external non-hydraulic or non-pneumatic force, possibly in addition to self-expansion of the anchor, which, however, taken alone was not sufficient. The foreshortening furthermore needed to be maintained, i.e. the mechanism required a locking mechanism in order to keep the anchor in the foreshortened state. Likewise, such a locking mechanism was required for radial strength and stability. While shape memory alloys were indeed mentioned, this was, however, in an embodiment having locking means. Moreover, the drastic foreshortening required a certain construction of the valve assembly in order to survive

the significant length changes between the delivery configuration and the deployed configuration, such that the valve had to be attached to the frame via constant length posts. Furthermore, leaflet engagement elements were disclosed as essential for locking the device in place. Lastly, as became apparent from the overall disclosure, repositionability of the apparatus was a further essential feature.

As claim 1 of the present request did not define the above-mentioned features, its subject-matter amounted to an unallowable intermediate generalisation.

Additionally, several dependent claims defined subject-matter which was not originally disclosed. In particular claims 1 to 4 defined in combination a fabric seal which bunched up to create fabric flaps and pockets, said seal further bunching up to create pleats, said seal further comprising a pleated seal, the pleating creating a seal around the replacement valve. Such a combination of features was nowhere to be found in the original disclosure. Furthermore, claim 11 in combination with claim 1 defined a seal having flaps and pockets and additionally being adapted to be captured between native valve leaflets and a wall of the patient's heart, whereas the allegedly supporting passage of the description in this respect related to two different seals.

Article 84

Claim 1 of the main request was furthermore not clear: It defined the created flaps and pockets to extend into spaces formed by the native valve leaflets. This was nothing more than a definition of the result to be achieved. Even if one accepted it to be a functional

feature, there was no support in the description of how this feature was to be put into practice. While the term flaps and pockets had indeed been part of claim 2 as granted, the feature was objectionable under Article 84 because it had been functionally combined with a further feature from the description rendering it unclear.

A further lack of clarity was present in dependent claim 5. As the flaps and pockets extended into spaces formed by the native valve leaflets, it was not clear how they could at the same time bunch up in response to backflow blood pressure.

Novelty

BB3 uncontestedly disclosed, see Figure 6d, an expandable anchor supporting a replacement valve, the anchor having a delivery configuration and a deployed configuration, with a seal extending from the distal end of the valve proximally over the anchor, in the delivery configuration as well as in the deployed configuration. It was further uncontested that upon expansion the anchor foreshortened to some extent.

BB3 disclosed the seal to be made from Dacron, which was a long-established, well-known trademark for a fiber made from PET. It was thus implicitly disclosed that the seal was a fabric material, because the only way in which a structure as the one in Figure 6d could be made was by using a Dacron fiber as starting material.

Furthermore, it was inevitable for the skilled person that the seal shown in Figure 6d had to be attached to the anchor with sufficient slack. As evidenced by BB6,

page 23, line 5-16, in all these expandable devices, the change in dimension of the support structure upon crimping must be taken into consideration by leaving slack material when attaching the valve assembly in the deployed configuration. With the valve assembly - including the part extending proximally over the anchor in Figure 6d - being necessarily mounted with sufficient slack, it was inevitable that upon deployment the fabric seal bunched up to create fabric flaps and pockets, which - when implanted into the heart - inevitably extended into spaces formed by the native valve leaflets.

Thus all features of claim 1 were disclosed in BB3 and the claimed subject-matter was not novel.

Also D9 disclosed, see in particular Figures 1-4, a stent comparable to the one of BB3. Again, uncontestedly, it somewhat foreshortened upon deployment and it exhibited a "cuff portion", see no. 25, 37 in the figures, which extended from the distal end of the valve proximally over the anchor. For the same reasons as discussed in the context of BB3, the "cuff" portion had to be attached to the anchor with a certain slack, such that, in the deployed state a bunching up to create flaps and pockets inevitably occurred. Indeed, the slack was even represented in the drawings by hatching. With the cuff material being disclosed to be made from polyester, i.e. from a fiber material, it was again implicit that said fiber material had to be made into a fabric in order to form a cuff as shown.

Therefore, D9 disclosed all the features of claim 1 as well.

Inventive step

Even if one considered the seal being made of fabric and the creation of fabric flaps and pockets not directly and unambiguously disclosed in BB3 or D9, clearly no inventive activity was involved in reaching the claimed subject-matter. These two alleged differences related to different partial problems and were thus to be addressed individually.

As to the use of a fabric material, the problem amounted to nothing more than to finding a way for creating the cover / cuff from the disclosed Dacron or polyester fibers. For this task, indeed, nothing else than forming a fabric out of the fibers could be envisaged.

On the other hand, the creation of flaps and pockets according to the patent specification solved the technical problem to form an improved seal. The skilled person starting from the disclosure of BB3 and aiming to solve the problem to improve sealing of the apparatus would realise that in order to seal the valve to the irregularly surfaced native valve leaflets, a not so smooth outer cover was preferable. BB3 itself disclosed on page 14, line 8 et seq. a frame which underwent significant foreshortening upon deployment. The skilled person would realize that in case of an outer cover as the one of BB3, Figure 6d, such a change of dimension upon deployment would result in bunching up and thus in a better sealing due to the resulting irregular shape. This would bring the skilled person in an obvious manner to an apparatus in which - during deployment - the anchor foreshortened and the fabric seal bunched up to create fabric flaps and pockets,

which then - upon implantation - inevitably extended into spaces formed by the native valve leaflets.

Consequently, the subject-matter of claim 1 did not involve an inventive step over BB3 in combination with the common general knowledge.

D9, on the other hand, disclosed a valve replacement adapted to be implanted after resection of the natural valve leaflets. The person skilled in the art would strive for implanting the D9 device also with the native leaflets having been left in place. With this aim in mind, the person skilled in the art would again recognize that for sealing to an irregularly surfaced structure, a smooth outer seal was not very efficient. This would lead them again towards providing more fabric material, which would result in the creation of the fabric flaps and pockets as claimed.

Therefore, the subject-matter of claim 1 was also not inventive over D9 combined with the common general knowledge.

Sufficiency of disclosure

Figures 22-24 and paragraphs [0062], [0103] of the patent specification disclosed a fabric seal which bunched up to create fabric flaps and pockets. It was, however, not discernible from these parts of the disclosure, how the fabric was to be attached to the anchor in order for the fabric to behave as claimed. In particular, Figures 23 and 24, although allegedly relating to the very same device, showed a fabric behaving in a completely different manner. From the information available, the person skilled in the art could not build a device which looked at the same time

like the one shown in Figures 23 and 24. Moreover, in particular figure 29C, although according to paragraph [0099] showing a device with a fabric which bunched up upon deployment, did not exhibit any fabric flaps or pockets. Without further information as to the type of fabric and as to its connection with the anchor, the skilled person was at a loss how to manufacture the device claimed. As disclosed in paragraph [0097], penultimate sentence, any means known in the art to attach the seal to the anchor was conceivable. However, together with the possible different fabrics this amounted to an enormous number of possibilities which had to be examined in order to find one which showed the claimed behaviour. Moreover, the fabric had to be connected to the anchor in a way different from the prior art, because the usual attachment would result in a deployed state as the one shown in BB3 and D9, which had been found not to bunch up as claimed. Thus, not only was there an undue burden for the skilled person to put the invention into practice, but the necessary information was missing exactly for what made up the invention.

The claimed invention was thus not disclosed sufficiently clear for it to be carried out in practice.

VIII. The essential arguments of appellant 1 can be summarised as follows:

Admission of the main request into the proceedings

The wording of the present main request had been only minimally changed with respect to auxiliary request 7 already submitted in opposition proceedings. Said request originated from a set of requests all directed

to the sealing aspect and all dealing with features objected to by the opponent as missing. The additional wording had likewise been on record during the first instance proceedings. Thus, the filing of the request cannot have caused any surprise or undue burden for appellant 2. It was furthermore an appropriate reaction to the course of the proceedings and should thus be admitted.

Original disclosure

Whereas the original disclosure related to a plurality of different individual inventions or inventive aspects, claim 1 of the main request focused on only one particular of these inventions, i.e. on the sealing aspect. There was thus no need to include all the technical features of the other inventive aspects into the claim.

In particular, there was no need for a limitation to a particular type of anchor, as long as the anchor foreshortened and the fabric seal bunched up to create flaps and pockets. Said feature was defined in the claim, exactly as it was worded in the original disclosure on page 86, lines 25-27 of BB2. If a causal relationship between foreshortening and bunching up was to be derived from said part of the description, it was - due to the identical wording - inevitably part of the claimed subject-matter. That sealing aspect could be put into practice by use of a self-expanding anchor, an anchor being balloon expandable, an anchor being partially-self-expanding or an anchor being foreshortenable by external force. As the description disclosed all those options, there was no need to restrict the subject-matter to only one thereof. Likewise, with the claim defining the structural

features of the sealing functionality and their functional relationship, including the formation of fabric flaps and pockets that extended into spaces formed by the native valve leaflets, it was not necessary to define the exact degree of foreshortening. As to repositionability, locking means, leaflet engagement elements and the details of connecting the valve to the anchor, these were - as clearly indicated by the word "may" in the disclosure - optional features, which were not essential for the sealing function.

Thus, the subject-matter of claim 1 was not generalized over the original disclosure in an unallowable manner.

There was also no extension of subject-matter in the dependent claims. Although claims 1-4 were basically redundant, all the features defined therein had been originally disclosed. Likewise the last sentence of page 86 disclosed the subject-matter of claim 11, it being clear from the context that said sentence referred to seal 380 which had been discussed throughout the whole paragraph.

Article 84

Claim 1 clearly defined the structural features, i.e. the flaps and pockets created in the fabric seal, with the objected term "that extend into spaces formed by the native leaflets" only adding the behaviour of these already structurally defined features.

As to the term "flaps and pockets", it had been present in claim 2 as granted and was therefore not objectionable under Article 84 according to decision G 3/14. Nevertheless it was pointed out that the term had

to be understood as defining a single thing by two words. Whereas the flaps or pleats formed the structure protruding towards and into the spaces of the native valve leaflets, the pockets essentially formed on the aortic side of said flap/pleat upon bulging of the flaps/pleats in response to the backflow blood pressure.

Also the further subject-matter objected to as unclear had been part of granted claims and could thus not be objected to under Article 84 EPC.

Novelty

Neither document BB3 nor D9 showed all the features of claim 1 in combination.

Firstly neither the terms Dacron nor polyester were exclusively used for fibers. The term Dacron could well relate to an extruded film. The same applied to the term polyester. There was thus no direct and unambiguous disclosure of the seal being a fabric seal as claimed.

Moreover, both documents showed in their figures the apparatus in the deployed state. As was apparent from Figures 1-4 of D9 and Figure 6d of BB3, the respective seal was smooth, without any indication of a bunching up creating flaps or pockets that extended into spaces formed by the native valve leaflets.

With respect to D9, which referred to an apparatus to be implanted after removal of the native valve leaflets, there was no need for any structure extending into the spaces formed by the native valve leaflets. Indeed, the cuff was intended to prevent through-the-valve leakage, not paravalvular leakage. For both the

valve apparatuses as disclosed in D9 and in BB3, there were several technical solutions to provide a smooth, i.e. not bunched up seal in the deployed state, such as e.g. the use of an inherently elastic material, the use of an elastic fabric or of an attachment via sliding suture loops. It could thus not be derived from the Figures, that bulging up - although clearly not shown - nevertheless had to be implicitly present.

Thus, none of the documents directly and unambiguously disclosed the subject-matter claimed.

Inventive step

It was agreed that BB3 might be regarded as a possible closest prior art.

D9 on the other hand was not even a suitable starting point in that the apparatus disclosed therein was to be used after removal of the native valve leaflets.

Even if, when starting from D9, improvement of the seal was an issue, there was no reason and no indication to provide sealing to the irregular surface of the native valve's leaflets. Appellant 2's arguments in this respect were clearly hindsight driven.

As to BB3, the document did not address paravalvular leakage but through the frame leakage. Even if paravalvular leakage was an issue, there was no disclosure how to address it, let alone to employ a bunching up of the seal and the resulting fabric flap and pocket formation for that purpose. Indeed, at the time when BB3 was drafted, paravalvular sealing was typically addressed by oversizing of the implant and by increasing its radially outward expanding force. Thus,

even if in BB3 a frame with a more prominent change in dimension were to be used, this would rather lead to a circumferential stretch of the seal than to a bunching up.

The subject-matter of claim 1 was thus clearly inventive over each of BB3 or D9 even if the common general knowledge was to be taken into account.

Sufficiency of disclosure

The passages mentioned by appellant 2 provided the skilled person with sufficient information to put the invention into practice. Indeed, the basic function of the seal bunching up upon deployment and the formation of the fabric flaps and pockets that extend into spaces formed by the native valve leaflets was clearly derivable from the schematic drawings 22 and 23. Means of connecting a fabric to a support structure were well known in the art and the person skilled in the art would have no difficulty to attach the fabric such that it forms the flaps and pockets in the deployed configuration, whereas in the elongated form of the anchor, the fabric was smoothed out. Figure 24 was also in accordance with Figures 22 and 23 and indicated the flaps and pockets by the plurality of concave lines close to the leaflets. It furthermore illustrated in the upper part of the seal the seal bunching up in response to the backflow blood pressure. There was thus no contradiction between the drawings. As to Figure 29C, the disclosure in paragraph [0099] clearly described the bunched up seal, even if it was not clearly shown in the drawing due to its schematic nature.

The invention was thus disclosed sufficiently clear and complete for it to be carried out by a person skilled in the art.

Reasons for the Decision

1. Admission of the main request into the proceedings

The main request has been filed as auxiliary request 7a with letter dated 17 January 2019. Apart from the last subordinate clause of claim 1, which was added only with the version of 17 January 2019 and which further defines the flaps and pockets to "extend into spaces formed by the native valve leaflets", auxiliary request 7a is identical to auxiliary request 7, submitted together with the grounds of appeal and identical to an auxiliary request already submitted during opposition proceedings (even though it had not been examined by the Opposition Division). The very same amendment had likewise been performed in the request based on which the opposition division had decided to maintain the patent (refiled as auxiliary request 10 with the statement setting out the grounds of appeal).

It furthermore takes into account the remark in point 4.1.3, second paragraph, of the board's preliminary opinion. The filing of auxiliary request 7a is thus an appropriate and commensurate reaction which does not cause new or surprising issues, with which the Board or the other party could not deal. The Board thus decided to exercise its discretion in accordance with Article 13 RPBA such as to admit the request.

This is not in contradiction with the fact that a different Board in case T 1903/13 did not admit requests which had already been filed - but not

examined - in opposition proceedings. Such decisions are discretionary and largely depend on the particular facts of the case. In this respect, every case is unique and needs to be decided based on its particular circumstances.

It is further pointed out that in the context of amendments aiming at overcoming an objection as to an unallowable intermediate generalization, an alleged divergence of the requests is normally of low importance. Typically such requests add particular features from the context of the original disclosure, which the opponents had been criticised as missing. Hence, their addition can hardly be surprising to the opponents.

2. Original disclosure

2.1 The patent was granted on a divisional application. The parent as originally filed has been published as WO-A-2005/062980 (BB2).

The application is essentially identical to the earlier application, with the originally filed claims having been transformed into "embodiments" 1-441, and claims 1-15 having been newly drafted.

It is thus sufficient for examining whether the requirements of Article 100(c) EPC prejudice the maintenance of the patent or not, to verify that the claimed subject-matter is clearly and unambiguously disclosed in BB2.

2.2 The invention relates to an apparatus for endovascularly replacing a patient's heart valve having a particular fabric seal extending from the distal end

of the valve proximally over the anchor in the delivery configuration. During deployment, the expandable anchor foreshortens and the fabric seal bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets. The most relevant disclosure in this respect can be found in BB2 on page 34, lines 26-31, page 85, lines 26-34, page 86, lines 22-32 and in Figures 32-34 (Figures 32 and 33 are reproduced below).

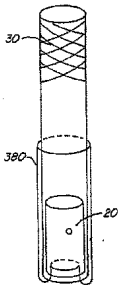

FIG. 32

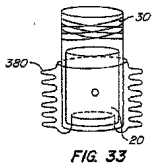

FIG. 33

2.3 As becomes clear from page 34, line 26 and page 86, lines 22-23, the respective disclosures focus on the process of forming a pleated seal around the replacement valve to prevent leakage, i.e. they focus on sealing. The sealing process is also the focus of schematic drawings 32 to 34. The Board agrees with appellant 1 that the person skilled in the art would recognize from said disclosures that the sealing functionality forms a particular invention which is an individual part of the originally filed disclosure. A claim directed to said individual invention thus does not add subject-matter with respect to the original disclosure unless features structurally and functionally inextricably linked with said invention have been omitted.

2.4 Independent claim 1

Claim 1 of the main request defines that "during deployment, the expandable anchor (30) foreshortens and the fabric seal bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets (382)". The skilled person would understand the active language to imply the foreshortening as being causal for the bunching up, in particular as the original disclosure gives no indication whatsoever to any additional mechanism effectuating simultaneous foreshortening of the anchor and bunching up of the seal, without the latter being causal for the former. It is further pointed out that the respective wording of the claim is disclosed essentially verbatim on page 86, lines 25-27. Thus, even if said wording included co-occurrence of foreshortening and bunching up without a causal relationship between the two (which it does not), due to the identical disclosure in the description, the feature would still need to be considered originally disclosed.

By not only defining the structural features (i.e. the expandable, foreshortenable anchor and the seal extending from the distal end of the valve proximally over the anchor in the delivery configuration), but also the way in which they functionally cooperate (i.e. the anchor foreshortens and the fabric seal bunches up to create fabric flaps and pockets) as well as the effect thereof (the apparatus is configured such that the flaps and pockets extend into spaces formed by the native valve leaflets), the claim comprises all features required for the sealing effect.

For the effect to occur, the claimed subject-matter thus implies a certain degree of foreshortening. There is, however, no need to restrict that degree to a particular value of e.g. 50%. It is sufficient that the apparatus is configured in such a way that the seal bunches up to create flaps and pockets which extend into spaces formed by the native valve leaflets.

It is also not decisive how the foreshortening is brought about or how it is maintained. Indeed the anchors described in the original disclosure may be fabricated by using self-expanding patterns (page 22, line 21, page 86, lines 18, 19) and undergo a dynamic self-expansion from a constrained delivery configuration within a delivery sheath (page 24, lines 3-5). According to page 49, lines 20-24, if the anchor is composed of shape memory material, it may self-expand to ... its 'at rest configuration'. The at rest configuration of the braid can be, in particular, its expanded configuration. The person skilled in the art thus understands that the self-expansion per se (and the foreshortening resulting therefrom) can allow and maintain the creation of the seal. Even if - in preferred embodiments (page 49, lines 24-26) - the self-expansion is augmented by hydraulic or non-hydraulic actuator action and maintained by locking means, such actuator action and locking means are optional for the sealing effect to occur.

As emphasized above, the invention defined in the claims deals with the concept of creating a seal. The replacement valve structure itself - although necessary for an apparatus for endovascularly replacing a patient's heart valve - forms a further individual aspect of the apparatus.

It is correct that the valve itself needs to be present. However, many different valve designs are known which may or may not be affected in their connection to an anchor by its foreshortening. As mentioned by appellant 1, for a conical valve connected to the anchor in a single transversal plane only, there is no need for an attachment via constant length posts. Since the detailed features of the valve are not functionally or structurally inextricably linked with the sealing functionality, there is no requirement for the claim to include further details of the valve or of its connection to the frame.

Appellant 2 has further argued that leaflet engagement elements were essential for locking the device in place. It is true that BB2 mentions leaflet engagement elements, e.g. on page 85, line 26 et seq. However, the skilled person learns from the overall disclosure that leaflet engagement elements are facultative ("in preferred embodiments", see page 79, last paragraph) and may be provided either on the delivery system or on the anchor (page 83, lines 18-23). There is thus no need to include the leaflet engagement elements into the subject-matter of claim 1.

Lastly, while the title of the application indeed relates to a "repositionable heart valve", with respect to the sealing aspect it is of no importance whether or not the device is repositionable and consequently this need not be defined in the independent claim.

2.5 Dependent claims

Dependent claims 2-4 each depend on any of the preceding claims, i.e. the claimed subject-matter includes an apparatus with a fabric seal which exhibits

all properties claimed in these claims in combination. Appellant 1 concedes that these properties are essentially redundant. Redundancy or lack of conciseness is, however, a question of Article 84, which in the present context cannot be examined because the objected combination essentially corresponds to granted claims. As to original disclosure, the different properties claimed are disclosed on page 86, line 27 et seq. The sentence in lines 27-29 follows the one disclosing that the seal bunches up to create fabric flaps and pockets. It states that the "bunched up fabric or pleats occur, in particular, when the pockets are filled with blood in response to backflow blood pressure" and thus discloses that the bunched up seal creates pleats (as defined in claim 2, possibly in response to backflow blood pressure, as defined in claim 5). From this it follows that the flaps and pockets can also be called "pleats". A seal comprising pleats is a "pleated seal", just as defined in claim 3. The next sentence (page 86, lines 29, 30) states that the pleating "can create a seal around the replacement valve", i.e. it discloses the subject-matter of claim 4. The subject-matter of dependent claims 2-4 is thus originally disclosed.

Dependent claim 11 defines that at least a portion of the seal (i.e. of the same seal which bunches up to create fabric flaps and pockets) is adapted to be captured between native valve leaflets and a wall of the patient's heart when the anchor and replacement valve are fully deployed. According to appellant 2, such a seal was not originally disclosed, as the allegedly supporting sentence (page 86, lines 31, 32) referred to a seal, i.e. to an additional seal as having those properties. In other words, in order to provide disclosure for claim 11, the sentence would

have to relate to the seal as having the claimed properties instead of to a seal. The Board finds this argument overly academic. The relevant sentence is the last one of a single paragraph which relates to the process of forming a pleated seal. The whole paragraph mentions and defines only one seal. Also in the accompanying Figures, only one such seal is shown. The person skilled in the art would thus understand also the last sentence of the paragraph to relate to the very same seal which was under discussion before. Consequently, the subject-matter of claim 11 has to be considered originally disclosed.

3. Article 84

Claim 1 defines that the apparatus is configured such that during deployment, the expandable anchor foreshortens and the fabric seal bunches up to create fabric flaps and pockets **"that extend into spaces formed by the native valve leaflets"**. The part represented in bold has been taken from the description, whereas the rest of the feature had been part of claims 1 and 2 as granted. Appellant 2 argues that due to the amendment, the complete feature became unclear which would - in accordance with G 3/14 - warrant examination of the requirements of Article 84 EPC.

The added feature according to which fabric flaps and pockets "extend into spaces formed by the native valve leaflets" cannot be considered in isolation, but has to be evaluated in the context of the claim. It thus does not just define the result, i.e. that the flaps and pockets extend into spaces formed by the native valve leaflets, but indicates the structural features (i.e. the fabric seal and the foreshortenable anchor to which

it is connected), which result upon deployment of the device in the formation of the flaps and pockets in the fabric seal. With respect to the flaps and pockets, the Board accepts the interpretation put forward by appellant 1 that these terms describe two aspects of one and the same structure: the folding forms flaps, which on the aortic side thereof may be indented by the blood's backflow pressure such as to form a "top" pocket in the respective flap. It is true that these terms are overlapping or even redundant. This had, however, likewise been the case in the claim as granted and is thus not objectionable under Article 84 EPC according to G 3/14. The amendment only further elucidates the sealing function of these flaps and pockets formed by the bunched up fabric seal, which occurs upon implantation of the device into the body. The added feature is thus merely further explanatory information with respect to the structural and functional definition already present in the claim. With the claimed structural features and their functional inter-engagement, the claim defines clearly more than just a result to be achieved. The respective objection is thus not convincing.

As to the objection that the description did not indicate how to put the invention into practice, such that the there was no support of the claim in the description, this is rather an objection under Article 100(b) EPC (see below) than 84 EPC. Indeed, the passages indicated in point 2.2 and 2.3 above provide sufficient "support" within the meaning of Article 84 EPC.

As to the alleged lack of clarity of claim 5 of the present main request, there is no reason why a flap should not extend into spaces formed by the native

valve leaflets and at the same time - e.g. in the parts of the flap being closest to the foreshortenable anchor - being additionally further dented and bunched up in reaction to the backflow blood pressure.

The objections of appellant 2 under Article 84 against the claims of the main request are thus not convincing.

4. Novelty

According to established case law, a prior art document anticipates the novelty of claimed subject-matter if the latter is directly and unambiguously derivable from the document, including any features implicit to a person skilled in the art. However, an alleged disclosure can only be considered "implicit" if it is immediately apparent to the skilled person that nothing other than the alleged implicit feature forms part of the subject-matter disclosed (Case Law of the Boards of Appeal, 8th edition 2016, I.C.4.3).

Claim 1 of the main request defines the apparatus to have a fabric seal extending from the distal end of the valve proximally over the anchor in the delivery configuration,
wherein the seal is bunched up in the deployed configuration and
wherein the apparatus is configured such that during deployment, the expandable anchor foreshortens and the fabric seal bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets.

It is uncontested that the anchors disclosed in both, BB3 and D9 foreshorten upon deployment. It is also uncontested that both documents disclose a seal

extending from the distal end of the valve proximally over the anchor in the delivery configuration (BB3, Figure 6d, **19**, **19''**; D9, Figures 1-4, **25**, **37**).

Appellant 2 was of the opinion that said seals had to be connected to the anchor frame with some slack, such that in the deployed state inevitably a bunching up to create flaps and pockets occurred.

However, the respective drawings (BB3, Figure 6d and D9, in particular Figure 4), which uncontestedly show the apparatus in the deployed configuration, do not clearly and unambiguously disclose a seal bunched up to create fabric flaps and pockets.

Indeed, the seal **19**, **19''** in BB3, Figure 6d is shown to smoothly adapt to the form of the anchor/stent **10**, without any indication of bunching up, let alone of pocket and flap creation. This representation is in accordance with the description page 22, lines 25, 26 which discloses a tight connection between the seal and the bars of the stent ("The internal and external cover are molded, glued or soldered to the bars of the stent").

Also Figures 1 and 4 of D9 do not clearly and unambiguously disclose a deployed configuration with the seal bunched up to create fabric flaps and pockets. The "hatching" mentioned by appellant 2 (see e.g. the curved lines on the seal in-between the regions next to reference numerals 33 and 34) might indicate a slightly concave form of the seal between the stent struts. It does, however, not indicate any bunching up to create flaps and pockets.

Appellant 2 has further relied on a statement in document BB6 (page 23, lines 9-16), which teaches that in prior art implantable valve devices (such as - according to appellant 2 - the ones disclosed in documents BB3 and D9), "the entire support structure changes it dimensions from its initial first crimped position and final deployed position, and this means that in the attachment of the valve assembly to the support structure one must take into consideration these dimension changes and leave slack material so that upon deployment of the device the valve assembly does not tear or deform". Because of this slack material, according to appellant 2, bunching up and flap/pocket formation inevitably occurred, even if it were not considered to be shown in the drawings of BB3 and D9. However, as pointed out by appellant 1, there are other means of taking the dimensional change of the anchor into account in order to prevent destruction of the valve assembly upon deployment, such as a certain elasticity of the seal material or a connection by suture loops which allow for a certain amount of sliding of the connection. Furthermore, even if some slack was present, this does not necessarily result in a bunching up of the seal to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets. Instead, it may result in only a slight concave bulge of the seal between the stent struts.

It is thus not immediately apparent to the skilled person that the BB3 or D9 devices exhibit upon deployment nothing other than a seal bunching up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets.

With at least this feature not being disclosed in either BB3 or D9, the subject-matter of claim 1 is novel over the disclosure in each BB3 and D9.

It can thus be left open whether any of BB3 or D9 disclose a seal which actually qualifies as a fabric seal.

5. Inventive step

5.1 BB3 as closest prior art

BB3 discloses an apparatus for endovascularly replacing a patient's heart valve with the native heart valve leaflets left in place. As discussed above, said apparatus comprises an expandable anchor, which foreshortens during deployment and a seal extending from the distal end of the valve proximally over the anchor in the delivery configuration.

The subject-matter of claim 1 differs from the disclosure of document BB3 at least in that:

- the seal is bunched up in the deployed configuration

- the apparatus is configured such that during deployment (and foreshortening of the anchor) the fabric seal bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets.

The technical effect of the differing features is a tight sealing connection between the outside of the apparatus and the native valve leaflets left in place.

This solves the technical problem to improve the (paravalvular) seal between the apparatus and the body at the implantation site.

Starting from the disclosure of BB3 the person skilled in the art would thus strive to improve the apparatus' (paravalvular) seal.

So far the analysis is essentially as put forward by appellant 2.

Appellant 2 then argued that BB3 itself comprised on page 14, line 8 et seq., an embodiment with a frame undergoing upon deployment a significant foreshortening. Allegedly the skilled person would realize that - if provided with an outer cover such as in BB3, Figure 6d, such a change in length would result in bunching up and thereby in better sealing to the irregularly shaped natural valve leaflets, an approach which would make the invention obvious.

This argumentation is, however, hindsight driven.

While the internal cover **19, 19''** shown in BB3, Figure 6d is provided in order to avoid any risk of leaks (page 22, lines 11-14), this is in the context of trans-frame leakage, i.e. in the context of blood passing through the spaces between the metallic frame bars of the stent/ anchor structure (see the foregoing sentence, page 22, lines 8-10). There is no mention of the cover bunching up and forming flaps and pockets. Nor is there any teaching that slack, let alone that bunching up and pocket/flap creation may be favourable in order to solve the problem to improve para-valvular leakage.

The skilled person thus had - without knowledge of the invention - no reason to consider that bunching up and pocket / flap formation occurred at all and that it was furthermore in any way beneficial for solving the problem posed. Consequently, there was no reason to combine the embodiment of BB3, Figure 6d with the frame disclosed on page 14, line 8 et seq. in order to solve the problem posed.

The argument that the claimed subject-matter was obvious over BB3 in view of the common general knowledge is thus not convincing.

5.2 D9 as closest prior art

D9 likewise discloses an apparatus for endovascularly replacing a patient's heart valve, however, after the native valve has been excised (D9, summary of invention: "a cutting mechanism is used to remove the diseased or defective heart valve").

As discussed in point 5 above, also D9 does at least not disclose that the seal extending from the distal end proximally over the anchor in the delivery configuration, during deployment bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets.

The claim feature according to which the flaps and pockets created extend into spaces formed by the native valve leaflets implies that the problem solved by the invention is an improvement of the seal between the apparatus and native valve structure, i.e. with the native valve being still present at the implantation site.

As according to D9 the native valve is excised before implantation of the apparatus, the D9 valve does not need to be sealed with respect to the native valve leaflets left in place. The problem the invention strives to solve with the differing feature thus does not arise in D9. Therefore, D9 does not form the closest prior art for solving said problem.

Already for this reason, the inventive step attack starting from D9 as closest prior art is not convincing.

Appellant 2 has further put forward that the person skilled in the art would strive for implanting the D9 device also with the native leaflets having been left in place. There is, however, no reason, why the person skilled in the art would indeed be prompted to do so.

Even if this was the aim, there is no teaching whatsoever that for sealing against an irregularly surfaced structure, an irregularly surfaced structure could be beneficial. There is furthermore no teaching that this irregular structure could be provided by bunching up of the fabric material such as to create flaps and pockets that extend into spaces formed by the native valve leaflets.

Again, appellant 2's attack is clearly hindsight driven and not convincing.

5.3 The subject-matter of claim 1 of the main request thus involves an inventive step over the disclosure of BB3 or D9 when combined with the common general knowledge, even if one considered it obvious to use a fabric material for the seal of BB3 or D9.

6. Sufficiency of disclosure

Appellant 2 was of the opinion that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In particular, there was not sufficient disclosure with respect to the type of fabric and to its connection to the anchor.

The process of forming a pleated seal around the replacement valve to prevent leakage is illustrated in schematic Figures 22-24 (corresponding to Figures 32-34 of the earlier application as filed). Figures 22 and 23 show that during deployment the anchor foreshortens and the fabric seal bunches up to create fabric flaps and pockets. Bunching up and flap creation of a tubular fabric is an effect well-known from everyday life, for example when pushing up the sleeves of a pullover. It is thus common general knowledge that an excess length of tubular fabric material with respect to the carrying structure results in bunching up and flap creation. That is exactly what is illustrated in Figures 22 and 23. In view of such a well-known behaviour of a fabric, the person skilled in the art immediately understands from the schematic drawings 22 and 23 that foreshortening of the anchor may lead to bunching up and flap creation if the fabric is sufficiently pliable and if the connections between fabric and anchor do allow it. It being furthermore well known (see in this respect paragraph [0097]) how to establish connections between a fabric and an underlying supporting anchor structure, the person skilled in the art will have no difficulty to establish connections which allow flap creation as represented schematically in Figure 23, i.e. connections which are essentially at the sites where the resulting pleats fold back from inwards to

outwards and which are closest to the anchor. It is true that there exists a large variety of possible fabrics and types of connections between fabric and anchor. However, from these the skilled person does not have to identify a one and only single working combination. Instead, there are numerous possibilities to create a fabric seal according to the invention, which are all within the capabilities of the person skilled in the art. Putting the invention into practice is thus not unduly burdensome. In this context, sufficiency of disclosure merely requires it to be not unduly burdensome to put the invention into practice (and not to be not unduly burdensome to put each and every possible embodiment of the invention into practice).

The Board also does not see a contradiction between Figures 22, 23 and Figure 24. Firstly, obviously the reference number 382 has erroneously been given twice to two different structures. It is, however, immediately obvious to the skilled person that only the structure referred to by the lower reference represents the native valve leaflets, whereas the other represents the fabric seal, to which also the accompanying part of the description explicitly refers (paragraph [0103] of the specification). Figure 24 shows three essentially concave lines on the fabric in the region of contact with the native valve leaflets, which are fully in accordance with the pleats created. Figure 24 further shows a cuff-like end of the fabric seal, which is, however, not in contradiction to Figures 22 and 23. As pointed out by appellant 1 it may well represent the effect of the backflow blood pressure which only occurs when implanted and which is accordingly not present in the non-implanted apparatus schematically represented in Figures 22, 23.

With respect to Figure 29C (corresponding to Figure 107C of the earlier application), it is true that the pleated seal is not shown. In view of the schematic character of the drawings this does, however, not hinder the person skilled in the art, who has the necessary information available in Figures 22-24 (as discussed above) and in the description, paragraphs [0092],[0099] and [0103], from putting the invention into practice.

Article 100(b) EPC thus does not prejudice maintenance of the patent according to the main request.

7. Adaptation of the description

Both parties agree that no amendment of the specification allowable in view of Rule 80 EPC was required additionally to the amendment performed in the oral proceedings before the Opposition Division. The Board sees no reason to deviate from this common understanding of the parties.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent as amended in the following version:

Claims 1-11 of the main request filed as auxiliary request 7a with letter dated 17 January 2019,

Columns 1, 2, 5-26 of the patent specification, and columns 3 and 4 as filed during the oral proceedings on 11/12 September 2017,

Figures 1A-31B of the patent specification.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated