Deckblatt Übersetzung

Daten der Übersetzung:

Court/Gericht:	Bundesgerichtshof
Date of Decision / Datum der Entscheidung:	2020-08-04
Docket Number / Aktenzeichen:	X ZR 38/19
Name of Decision / Name der Entscheidung:	Mitralklappenprothese

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FEDERAL COURT OF JUSTICE

IN THE NAME OF THE PEOPLE

JUDGMENT

X ZR 38/19

Pronounced on:
4 August 2020
Zöller
Judicial Secretary as
Clerk of the Court
registry

in the matter

Mitralklappenprothese/
Mitral valve prosthesis

Patent Act Sec. 8

Whether and, if so, to what extent there has been an unlawful taking can be reliably assessed in the overall view to be taken for this purpose only on the basis of established similarities between the teaching claimed to have been taken and the teaching applied for (confirmation of Federal Court of Justice, judgment of 20 October 2015 - X ZR 149/12, GRUR 2016, 265 marginal no. 22 - Kfz- Stahlbauteil).

Federal Court of Justice, judgment of 4 August 2020 - X ZR 38/19 –
Higher Regional Court of Munich
Regional Court of Munich I

ECLI:DE:BGH:2020:040820UXZR38.19.0

The X. Civil Senate of the Federal Court of Justice, following the oral hearing on 4 August 2020, attended by the presiding judge Dr. Bacher, the judges Dr. Grabinski, Hoffmann and Dr. Deichfuß and the judge Dr. Rombach

ruled that:

On appeal by the plaintiff, the judgment of the 6th Civil Senate of the Munich Higher Regional Court of 21 March 2019 is set aside.

The case is referred back to the Court of Appeal for a new hearing and decision, including on the costs of the appeal proceedings.

By operation of law

Facts of the case:

1 The parties are in dispute over the rights to European patent application 2 566 416 (the application in dispute), which relates to a mitral valve prosthesis.

2 The plaintiff is a medical technology company based in the USA. Until 2008, it was primarily involved in the development of a system for replacing the aortic valve. In August 2008, it began developing a catheterizable mitral valve prosthesis. Such a prosthesis consists of a frame into which a valve is sewn.

3 Defendants' parent company, N.Inc. ("hereinafter: N.), is based in Canada and is involved, among other things, in the provision of biological material for valve prostheses.

4 In June 2009, business relations were established between the plaintiff and N. and a non-disclosure agreement was concluded. The plaintiff entrusted N. with the task of equipping metal frames developed by it with flaps made of biological material. For this purpose it submitted Design documents for several prototype mitral valve prosthesis frames it developed, designated as revisions (Rev.) B, C, D and E. The collaboration ended in April 2010.

5 In May, October and November 2010, N. filed three US patent applications. It claimed priority of these applications for the international patent application WO 2011/137531 of 4 May 2011 (HE1). This application gave rise to the application in suit published on 13 March 2013, which was rewritten to the defendant with effect from 2 October 2013.

6 The plaintiff claimed the defendant for assignment of the application for dispute and consent to its transcription to itself, or in the alternative for a grant of joint entitlement.

7 The Regional Court sentenced the defendant on the alternative claim.

8 On appeal by the defendant, the Higher Regional Court dismissed the action. In its appeal, which was allowed by the Senate and which the defendant seeks to have dismissed, the plaintiff continues to pursue its motion

to dismiss the defendant's appeal.

Grounds of the decision:

9 The plaintiff's appeal is successful. It leads to the judgment under appeal being set aside and the case being referred back to the Court of Appeal.

10 I. The application in dispute concerns the treatment of heart valve insufficiency, in particular mitral valve insufficiency, by means of a prosthesis.

11 The mitral valve is located between the left atrium and the left ventricle. It opens during diastole to allow oxygenated blood to flow from the left atrium into the left ventricle. It closes during systole to ensure that blood flows into the aorta but not back into the left atrium. The mitral valve has two valve leaflets called the anterior and posterior leaflets. The valve leaflets are attached to a connective tissue mitral valve ring (mitral valve annulus). At their free end, very stable chordae tendineae attach to prevent the leaflets from being pushed too far into the left atrium during systole.

12 A dysfunction of the mitral valve can be treated, inter alia, by implantation of a mitral valve prosthesis. According to the application in dispute, it was already known in the state of the art to insert such prostheses into the heart via a catheter. However, the insertion of the prostheses was sometimes difficult, their manufacture was expensive and they were not suitable for every patient.

13 The publication of International Application WO 2008/103722 (HE3), from which Figures 1, 22 and 26G are reproduced below, discloses a catheter-insertable mitral valve prosthesis comprising a flexible and resilient ring 106, a plurality of leaflets 108 attached thereto, and a plurality of tissue-engaging positioning elements 120 movably attached to the ring and engaging the anatomical structures of the valve ring, the (natural) leaflets or the heart wall. Further, portions (barb portions 2114) with barbs (2150) that pierce the tissue could be provided, and a skirt (2206) attached to the ring could be provided to seal the periphery of the prosthesis.

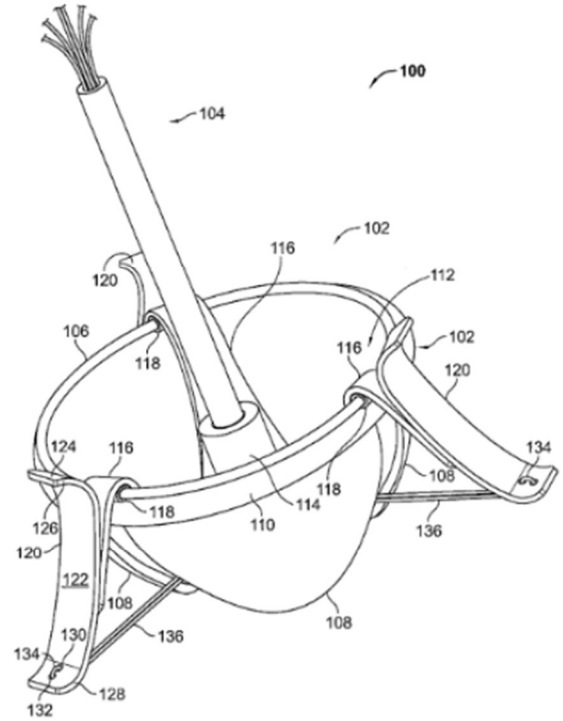

FIG. 1

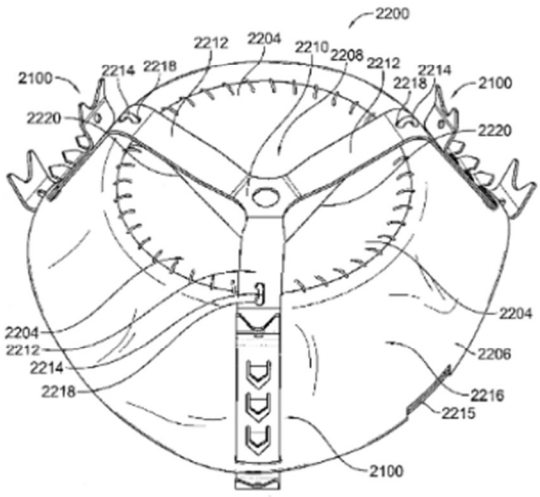

FIG. 22

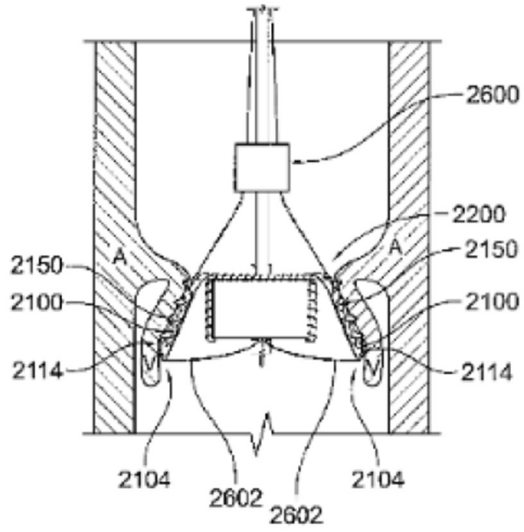

FIG. 26G

14 The publication of international application WO 2009/134701 (HE4) describes a prosthesis with an external support frame which expands upwards - towards the atrium - and tapers downwards - towards the ventricle. The device could expand during insertion to achieve an interference fit with the heart tissue.

15 Figures 1 and 4 of H4 show a frame and its position after insertion:

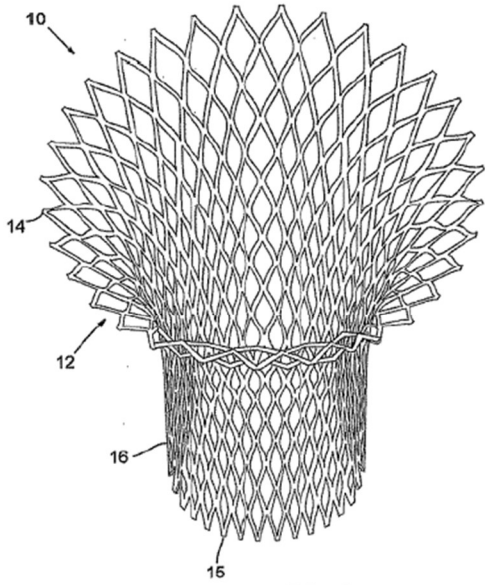

FIG. 1

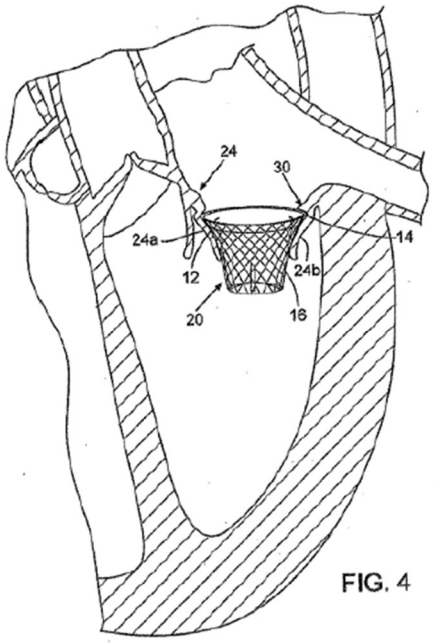

FIG. 4

16 The US patent application 2007/0016286 (HE5), from which Figure 6 is reproduced, shows a device which is attached to the surrounding heart tissue (32) by means of at least two staples (18).

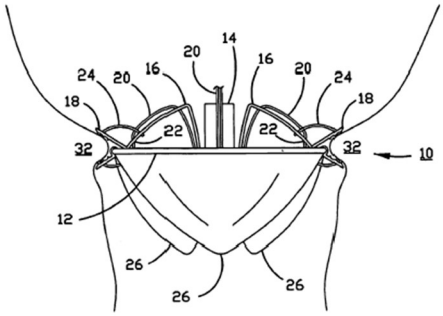

Fig. 6

17 2. A task is not expressly stated in the application in dispute. Against the background explained, the technical problem can be described as providing an improved valve prosthesis in which, in particular, a secure fit with a low stress on the natural tissue and a safe function of the valve are ensured.

18 3. To address this problem, the dispute application provides transcatheter mitral valve prostheses and methods and systems for their use.

19 The prosthesis comprises a tissue-like disposable valve structure having a plurality of leaflets secured within a self-expanding or expandable anchor or frame portion. This has a geometry that fans out into a low-profile atrial skirt region, an annular region sized to substantially match the natural mitral valve annulus, and a ventricular skirt region that displaces the natural mitral valve leaflets.

20 In preferred embodiments, the frame portion may be asymmetric along the longitudinal axis, wherein the atrial skirt region, the annular region, and/or the ventricular skirt region may be configured differently anteriorly and posteriorly to provide a good fit with the asymmetric contours and features of a typical natural mitral valve (para. 12).

21 When deployed, the atrial skirt region extends substantially radially outward so that it lies flat against and covers the atrial surface of the natural mitral valve annulus and supports the prosthesis against at least a portion of the adjacent atrial surface of the heart. In this case, the axial profile is low, extending only slightly into the atrium, to minimize thrombogenic turbulence in blood flow. In preferred embodiments, this region is covered with biological or synthetic tissue to seal it from the atrial surface. In some embodiments, the atrial skirt region may have hooks or spines to facilitate anchoring to the atrial surface (para. 16, para. 38).

22 The annular portion of the prosthesis is sized to substantially match the natural mitral valve annulus and to bear against it after deployment. Preferably, the annular portion has a D-shape in the deployed state and is covered with biological or synthetic material to provide a seal against the mitral valve annulus. The struts of the frame in the annular region may have suture holes (para. 17, para. 39).

23 The ventricular apron area, when deployed, extends essentially radially outward against the natural mitral valve, but not so far as to contact the ventricular wall or obstruct left ventricular outflow. To support it against the

displaced natural valve leaflets, the prosthesis is slightly larger than the natural valve when deployed. Preferably, the ventricular apron area has hooks or spikes for better anchoring. Particularly preferably, the frame in the ventricular apron region has an asymmetric shape and the hooks comprise two anchoring tabs located in the anterior region of the apron and serving to support the prosthesis against the fibrous trigones on either side of the natural anterior valve leaflet, further a posterior anchoring tab located in the posterior region of the apron and serving to provide support over the posterior leaflet (paras. 18, para. 40 f.). The area of the ventricular apron may also be covered with biological or synthetic material to provide a seal against the displaced natural sail (para. 19).24 This combined three-zone anchorage against the atrial surface, the mitral valve annulus and the natural leaflets pushed aside, completed in preferred embodiments in the region of the ventricle by trigonal anterior and posterior flaps forming a fourth anchorage zone, prevents the prosthesis from shifting when the atrium or ventricle contracts. In addition, less anchorage pressure is required in each case than if anchorage is made in only one zone or in a combination of two of the three or four zones mentioned. The consequent reduction in the radial forces exerted on the natural structures in each zone reduces the risk of blockage of or collision with the nearby aortic valve or the aortic root due to displacement of the natural valve apparatus. The three- or four-zone design also facilitates positioning of the prosthesis (para. 20 and para. 140).

25 If the prosthesis has the aforementioned anchoring flaps, the sheath is initially retracted only enough to allow these flaps to unfold during catheter insertion, while the rest of the ventricular apron remains sheathed. The posterior flap is aligned with the center of the posterior leaflet, where there are no chordae tendineae, and passed over the leaflet so that it sits between the leaflet and the ventricular wall. The two trigonal anchoring flaps are positioned on either side of the anterior leaflet with the heads against the trigona fibrosa (para. 25).

26 When the sheath is retracted further to expose the ventricular apron, the trigonal flaps anchor to the fibrous trigones and trap the anterior leaflet between themselves and the anterior surface of the prosthetic valve. The

posterior flap anchors itself between the ventricular wall and the posterior surface of the prosthetic valve. valve (see also para. 33). The remaining portion of the ventricular apron expands against the natural leaflets and surrounding anatomy. Thus, a sealed tunnel is created between the natural leaflets. These are displaced to avoid obstructing the function of the prosthetic valve. (para. 26).

27 Figure 7 (para. 86 f.) shows an example of a frame according to the teaching of the application in dispute, with atrial apron 18, annular region 20 and ventricular apron 22:

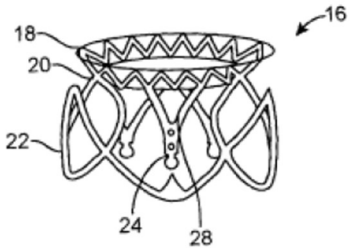

FIG. 7

28 Figures 8A and 8B (paras. 88 et seq.) show another embodiment with an asymmetrical frame from the side (8A) and from above (8B):

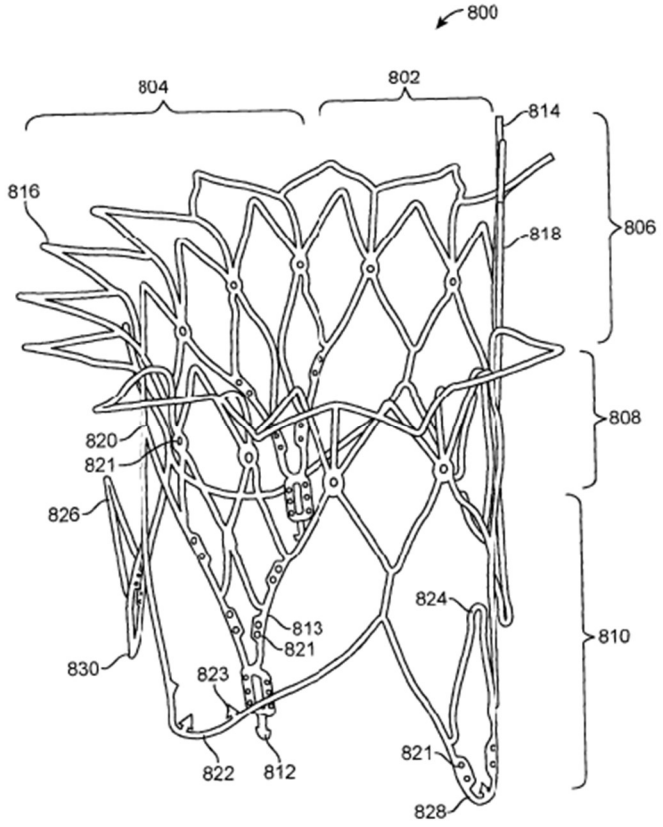
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FIG. 8A

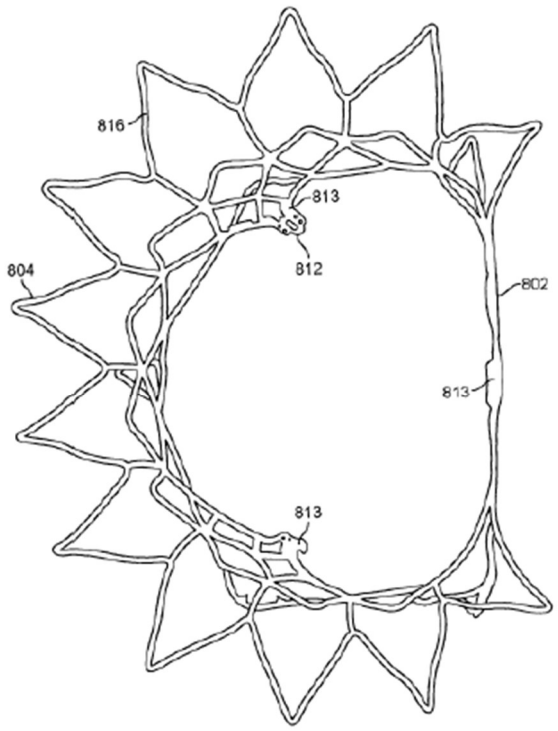
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FIG. 8B

29 Figure 8B shows the aforementioned D-shape of the frame.

30 Figure 8A shows the atrial region 806, the annular region 808, and the ventricular region 810 of the frame. In the atrial region, an atrial apron 816 is formed comprising triangular fingers that are curved radially outward. In the ventricular region, posterior flap 826 and one of two trigonal anterior flaps 824 can be seen.

31 Figure 24 (para. 140) shows an inserted prosthetic flap:

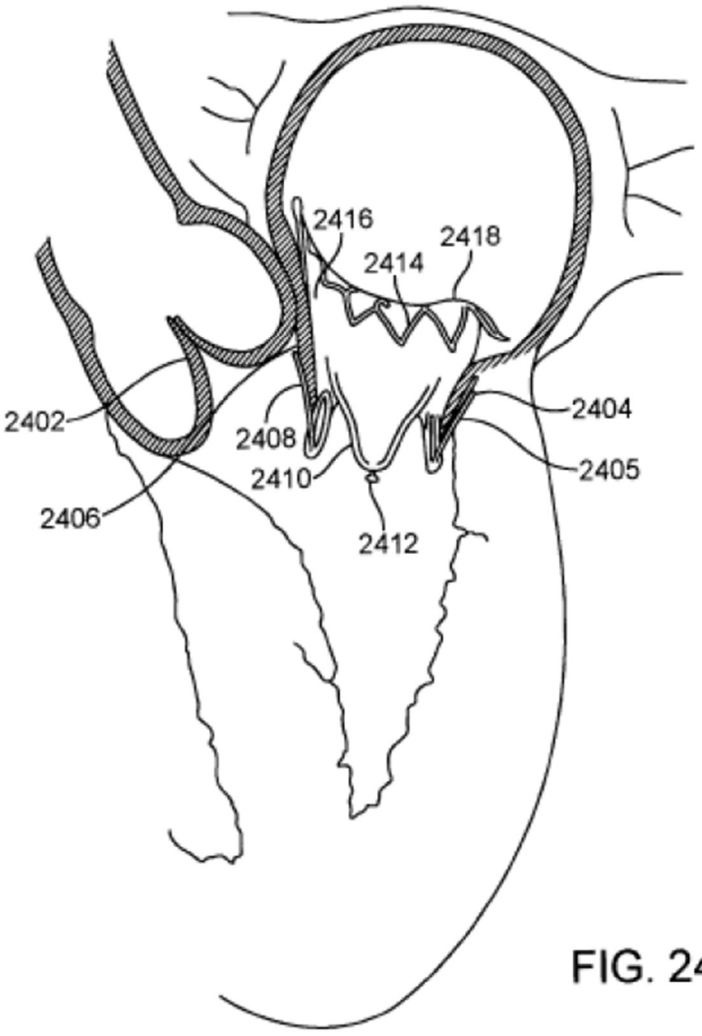


FIG. 24

32 One of the two anterior trigonal processes 2408, which reaches behind the natural anterior leaflet 2406, can be seen, as well as the posterior leaflet 2405, which reaches behind the natural posterior leaflet 2404. The sails are thus each trapped between the flap (the process) and the ventricular apron 2410. The annular area 2416 extends radially outward and abuts the mitral valve

annulus. The atrial portion expands outwardly to form a collar that rests against the anterior tissue in the region of the natural mitral valve. The prosthesis is thus anchored in four places.

33 II. The Court of Appeal gave the following main reasons for its decision:

34 According to the understanding of the skilled person, the geometry described in the contested application defines a transcatheter mitral valve prosthesis which has three specifically designed anchoring zones, namely against the atrial surface, the native valve annulus and in the ventricular space against the displaced native leaflets. The skilled person would take from the application in dispute the concept of a mitral valve prosthesis which is designed to ensure a two-dimensional anchoring against the respective native tissue in three defined zones by exploiting the radial forces occurring during the expansion of the prosthesis. The flat contact pressure of the prosthesis is achieved by covering the metal frame with biological or synthetic tissue, so that the entire outer skin of the prosthesis can be in pressure contact with the native tissue.

35 In preferred embodiments, a fourth anchoring zone is added to the structure. This is formed by two anterior anchoring processes and one posterior anchoring process attached to the ventricular apron. In the procedure described in the application in suit, the anterior processes anchored to the fibrous trigones and captured the native anterior leaflet between the processes and the anterior surface of the prosthesis. The posterior process anchors between the ventricular wall and the posterior leaflet so that the leaflet is captured between the process and the posterior surface of the prosthesis.

36 Anchoring in three or four zones reduces the anchoring pressure compared to prostheses anchored in fewer zones. This reduces the radial force to be exerted on the natural structures and the risk of obstruction of the aortic valve or aortic root.

37 It could not be established that the plaintiff had made a creative contribution to the subject matter of the application in dispute thus determined.

There had been no reference to a three-zonal flat anchoring in the correspondence with the defendant. However, this idea was also not embodied in the prototypes provided to the defendant. The prototype according to Rev. E, with two rings of twelve equally spaced hooks arranged in opposite directions, with their tips pointing towards each other, neither showed the concept of an anchorage in three specific zones nor was it suitable for securing a planar anchorage in each of the three zones caused by radial forces. The upper hook rim could not be considered an atrial apron within the meaning of the application in dispute. Since it is exposed without a tissue cover, it lacks the suitability to lie flat against the native mitral valve annulus, to cover it, and to anchor the prosthesis to at least a section of the adjacent atrial surface. Rev. E also does not show a ventricular apron in the sense of the application in dispute, with which a planar anchorage can be produced. Rather, anchorage was effected by the inferior hooked rim, which embraced the ventricular end of the annulus, including the native leaflets, and clamped it between itself and the ventricular apron. The lower hook ring could also not be regarded as the equivalent of the three anchoring processes optionally provided for in the application in dispute, because a specific alignment with certain specifically designated positions on the native cardiac tissue was not apparent. Finally, it was not apparent that the plaintiff's prototypes specifically used radial forces; rather, they were primarily fixed by forces acting axially. Accordingly, it could be left open whether the plaintiff had been in possession of the invention, how the information conveyed to N. in the course of the cooperation was to be classified in relation to the state of the art, and whether the plaintiff had effectively acquired the rights of the co-inventors.

38 III. This assessment does not stand up to review under the law of review in all points.

39 1. A person who has made a creative contribution to the subject matter of the invention applied for shall be entitled to the grant of a joint right to a patent application. A contribution is creative in this sense if it goes beyond mere constructive assistance in the realization of the invention. It is not necessary that the contribution is to be evaluated as an independent inventive achievement. Not sufficient are only those contributions which have not

influenced the overall success, i.e. are insignificant in relation to the solution, as well as those which have been created on the instructions of an inventor or a third party (cf. only Federal Court of Justice, judgment of 17 May 2011 - X ZR 53/08, GRUR 2011, 903 marginal no. 14 - Atemgasdrucksteuerung).

40 In order to answer the question whether there is a creative contribution, it is first necessary to determine the subject matter of the application in dispute, then to examine whether the claimed contribution has contributed to it, and finally to weigh the weight of the contributions in relation to each other and to the overall inventive achievement (Federal Court of Justice, GRUR 2011, 903 marginal no. 16 - Breathing gas pressure control).

41 In the examination required thereunder, the comparison of the teaching applied for a patent with the teaching whose unlawful taking is asserted must first of all be examined as to what extent the two teachings coincide. Whether and, if so, to what extent there is an unlawful taking can be reliably assessed in the overall view to be taken for this purpose only on the basis of established correspondences between the teaching claimed to have been taken and the teaching applied for (Federal Court of Justice, judgment of 20 October 2015 - X ZR 149/12, GRUR 2016, 265 marginal no. 22 - Kfz-Stahlbauteil).

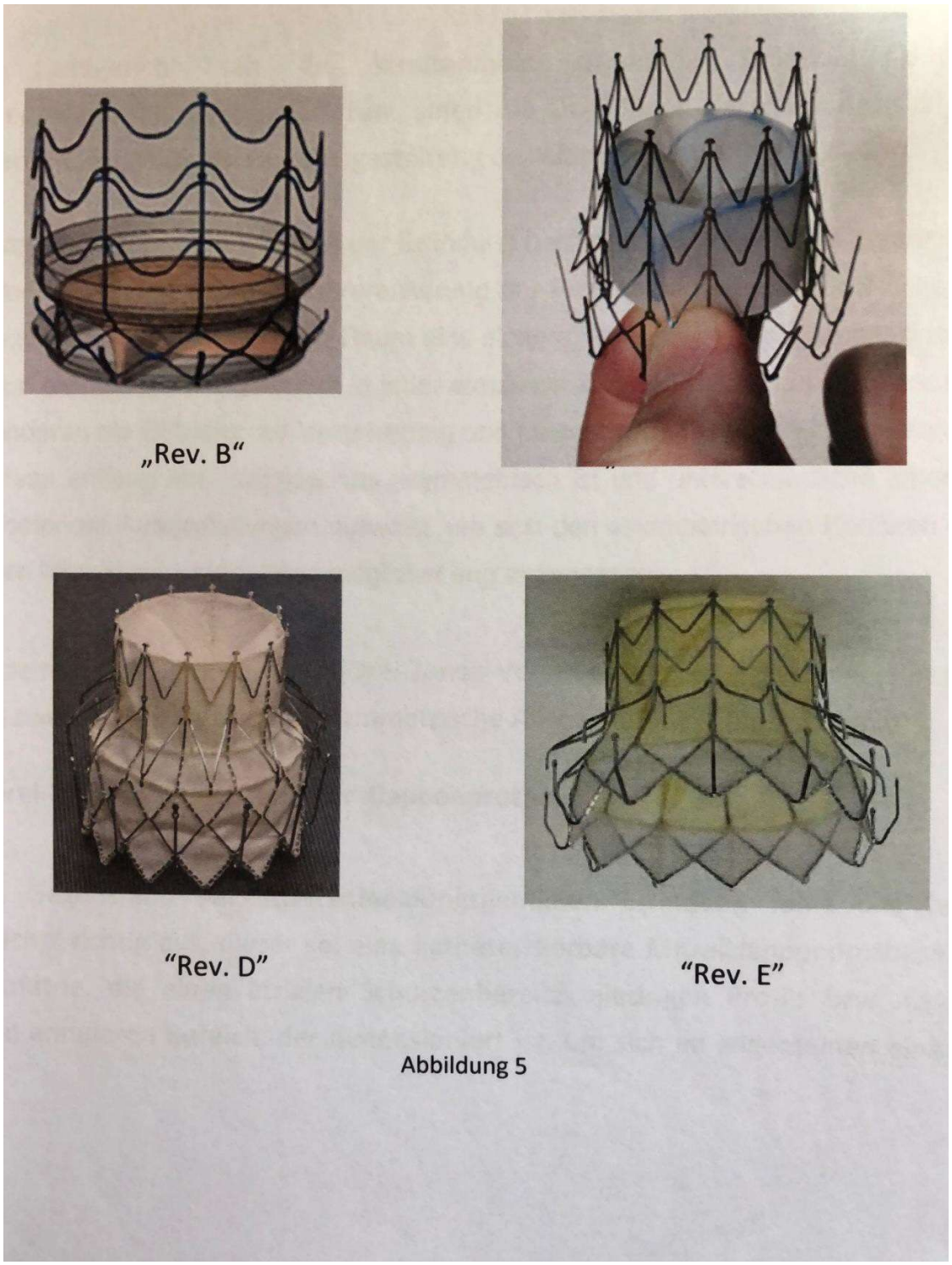
42 2. The judgment under appeal does not in all respects satisfy the requirements arising therefrom.

43 a) Contrary to the view of the Court of Appeal, the subject matter of the application in dispute is not characterized by the fact that the metal frame is covered with biological or synthetic tissue-like material in order to ensure a flat anchorage of the prosthesis against the native tissue in each of the three zones and to achieve a better seal.

44 aa) The application in dispute provides for covering the various parts of the frame with fabric only as an option.

45 In the light of the foregoing, the mere fact that the prototypes provided by the plaintiff do not have a fabric-covered frame does not mean that the plaintiff creative contribution cannot be denied.

46 bb) Irrespective of this, the Court of Appeal failed to take into account the fact that some of the prototypes provided by the plaintiff, such as those shown in the photographs reproduced below, have the frame covered with fabric.



47 cc) Whether a flat anchoring of the prosthesis was the subject of the correspondence between the plaintiff and N. is irrelevant in view of all this.

48 Even if the contracting parties had not addressed this aspect, this would not prevent the assumption of their own creative contribution, if only because the prototypes provided by the plaintiff are at least suitable for such an anchoring.

49 b) In addition, the Court of Appeal failed to take account in its assessment of essential aspects which speak in favor of correspondences between the doctrine of the application in dispute and the plaintiff's contributions and therefore in favor of a creative contribution by the plaintiff.

50 The Court of Appeal saw that the ventricular hook ring in the plaintiff's prototypes had a similar function to the fourth anchoring zone in the form of three anchoring tabs optionally provided for in the application in dispute. It considered this to be insufficient because the hook ring provided for in the prototypes did not allow the hooks to be directed at specific points in the native tissue, in particular at the fibrous triangles.

51 These considerations are insufficient because the plaintiff has argued that a creative contribution can already be seen in the fact that the prototypes according to Rev. D and E have anchoring processes at all, which are capable of reaching through the chordae tendineae behind the native valve leaflets, displacing them and fixing them between the process and the ventricular region of the frame.

52 The Court of Appeal did not make any findings as to whether the plaintiff's submission was correct. In the appellate instance, the submission must therefore be regarded as correct in favor of the plaintiff.

53 In this initial situation, a creative contribution by the plaintiff cannot be denied, contrary to the view of the Court of Appeal, because the application in dispute provides for a fastening of the type referred to only in three areas specifically selected for that purpose. It is true that such an arrangement develops and refines the fixing method proposed by the plaintiff, according to its submissions. Nevertheless, the proposal to use that method at all constitutes a contribution which, in any event, cannot be classified as wholly insignificant without a detailed assessment of the facts by the court.

54 Nor can the contribution relied on by the plaintiff be regarded as immaterial without further ado because, according to the defendant's submissions, anchoring continuations of the kind in question were known in the state of the art, for example, from US patent application 2008/0071366 (PM38). As already explained above, a contribution may be considered creative even if it is not self-inventive. The fact that the contribution arises in a constructive detail, the realization of which does not go beyond a mere assistance in the realization of the invention, does not result from the factual findings made so far.

55 3. The Senate cannot decide conclusively on the merits of the case.

56 On reopened appeal, the Court of Appeals will have to make the requisite searching comparison of the doctrine of the application in controversy with that of the wrongful taking alleged, in light of the considerations discussed above.

57 If the Court of Appeal finds that the plaintiff has made a substantial contribution to the subject matter of the application in suit, it will have to make findings on the plaintiff's assertion that the inventors of the plaintiff's prototypes assigned their rights to the invention to it.

Judge at the Federal Court of Justice Hoffmann is unable to sign due to absence on vacation

Bacher Grabinski Bacher

Deichfuß Rombach

Previous instances:
Regional Court of Munich I, judgment of 16 June 2016 - 21 O 19141/14 –
Higher Regional Court of Munich, judgment of 21 March 2019 - 6 U 2408/17 -