Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Central Division

Paris Seat

DECISION
of the Court of First Instance of the Unified Patent Court
Central division - Paris seat
issued on 19 July 2024
in the revocation action No. ACT_551308/2023
UPC_CFI_255/2023
and in the counterclaims for revocation No. CC_584916/2023 and CC_585030/2023
UPC_CFI_15/2023

HEADNOTES:

KEYWORDS:

REFERENCE CODE ECLI:

CLAIMANT:

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assisted by Jean-Robert Callon de Lamarck and Anne Seibel, Cabinet Regimbeau
and Jonathan Stafford and Gregory Carty-Hornsby, Marks & Clerck LLP

COUNTERCLAIMANTS:

Meril GmbH - Bornheimer Straße 135-137, 53119, Bonn, Germany

Meril Life Sciences Pvt Ltd - M10M2, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396 191, Gujarat, India

both represented by Andreas von Falck, Hogan Lovells International LLP

DEFENDANT:

Edwards Lifesciences Corporation - 1 Edwards Way, 92614, Irvine, California, USA,

represented by Boris Kreye and Elsa Tzschoppe, Bird & Bird LLP,
Bernhard Thum und Jonas Weickert, Thum & Partner
and Siddharth Kusumakar, Tessa Waldron and Bryce Matthewson, Powell Gilbert (Europe) LLP

PATENT AT ISSUE:

European patent n° EP 3 646 825

PANEL:

Panel 2

Paolo Catallozzi	Presiding judge and judge-rapporteur
Tatyana Zhilova	Legally qualified judge
Stefan Wilhelm	Technically qualified judge

SUMMARY OF FACTS AND PARTIES' REQUESTS

The revocation action.

1. On 4 August 2023, Meril Italy Srl filed a revocation action against Edwards Lifesciences Corporation concerning the patent at issue (EP '825) before this Central Division, registered as No. ACT_551308/2023 UPC_CFI_255/2023.

2. The patent at issue was filed on 16 July 2012, as a divisional application of EP 3 205 309 (parent application), which in turn had been filed as a divisional application of EP 2 731 552 (grandparent application); the grandparent application was filed as an international application WO 2013/012801 (WO '801). The patent at issue claims priority from two patent applications of 15 July 2011 (US 201161508456 P) and 13 July 2012 (US 201213549068).

3. The patent relates to embodiments of a prosthetic heart valve having a sealing mechanism to prevent or minimize perivalvular leakage. Its independent claim 1 reads as follows:
"A system comprising:
a prosthetic valve (100) comprising:
a collapsible and expandable annular frame (102), configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body;
wherein the frame (102) comprises a plurality of rows (112a, 112b, 112c, 112d) of angled struts (114), the angled struts (114) joined to each other so as to form a plurality of rows of hexagonal cells,

wherein the frame (102) is made up entirely of hexagonal cells, and wherein each of the hexagonal shaped cells is defined by six struts (144, 146, 148), including:

two opposing side struts (144) extending parallel to a flow axis of the valve (100),

a pair of lower angled struts (146), extending downwardly from respective lower ends of the side struts (144) and converging toward each other, and

A pair of upper angled struts (148) extending upwardly from respective upper ends of the side struts (144) and converging toward each other; and

a delivery catheter comprising an inflatable balloon;

wherein the prosthetic valve (100) is crimped in its radially compressed state on the balloon of the delivery apparatus, and wherein the balloon is configured to be inflated to expand to radially expand the prosthetic valve (100) at the desired deployment location, preferably within a native aortic valve.'

4. The claimant argues that the patent is not valid for several reasons: the extension of its subject matter beyond the content of the application as originally filed; the lack of enabling disclosure; the lack of novelty of claim 1 in view of WO 2012/48035 ('Levi'), WO 2011/109801 ('Benichou') and WO 01/28459 ('Dimatteo'); the lack of inventive step, assuming as closest prior art Levi or a combination of the Melody valve and its Ensemble transcatheter delivery system and the stent disclosed in Fontaine article.

5. On 14 September 2023, the defendant lodged a Preliminary objection pursuant to Rules 19 (1) (b) and 48 of the Rules of Procedures ('RoP'), challenging the competence of this Division on the ground of Article 33 (2) of the Unified Patent Court Agreement ('UPCA') as an infringement action between the same parties on the same patent was already pending before the Munich Local Division.

6. By order issued on 13 November 2023, the judge-rapporteur rejected the Preliminary objection, as well as the request for security for the legal costs submitted by the defendant, on the ground that the claimant cannot be considered the same party as those sued before the Munich Local Division and, therefore, Article 33 (2) 'UPCA' does not apply. The order was not appealed.

7. In the meantime, on 31 October 2023 the defendant lodged a statement of defence which included a conditional application to amend the patent based on 9 conditional amendments and 84 auxiliary requests. The claimant argued that the application was inadmissible as it disregarded the structure and content requirements of an application to amend a patent as set by Rules 30 (1) and 50 (2) 'RoP'. The judge-rapporteur rejected the objection, stating that it was not appropriate to address the issue during the written procedure, and deferred it to the oral hearing (see order of 21 December 2023).

8. On 22 January 2024 the defendant filed a second request to amend the patent, consisting of 41 auxiliary requests based on 9 individual amendments. The request was rejected by the panel as not reasonably justified (see order of 28 February 2024) and the Court of Appeal denied the defendant's request for discretionary review of the order.

9. After the closure of the written procedure and following the interim conference, the defendant filed a new request to amend the patent on 12 April 2024, proposing one unconditional amendment and six auxiliary requests. The panel admitted this request to amend the patent into the proceedings and, at the same time, granted the claimant a time period to submit an additional defence (see order 30 April 2024).

10. Finally, the oral hearing was held on 7 June 2024.

***The counterclaims for revocation*.**

11. On 2 November 2023 Meril GmbH and Meril Life Sciences Pvt Ltd filed separate counterclaims for revocation of the patent at issue – identical in their content – in the infringement action brought against them on 1 June 2023 by Edwards Lifesciences Corporation before the Munich Local Division, registered, respectively, as No. CC_584916/2023 and No. CC_585030/2023 UPC_15/2023.

12. The counterclaimants raised similar grounds of invalidity to those on which the revocation action filed by the claimant was based; they also challenged the patent for lack of novelty in view of WO 2009/149462 ('Hariton') and for lack of inventive step based on the prosthetic 'Colibri' heart valve.

13. By order issued on 28 March 2024, the Munich Local Division decided to refer the counterclaims for revocation to this Central Division for decision pursuant to Article 33 (3) (b) 'UPCA' and 37 (2) 'RoP'.

The consolidation of the proceedings.

14. After the counterclaims were assigned to this panel, the judge-rapporteur held the interim conference and then ordered, pursuant to Rule 302 'RoP', the consolidation of these counterclaims for revocation with the revocation action.

15. Therefore, a single oral hearing for both the revocation action and the counterclaims for revocation was held on 7 June 2024.

GROUNDS FOR THE DECISION

Parallel proceedings.

16. It may be useful to point out that in the present case there was a situation of concurrent pendency before different divisions of the Unified Patent Court ('UPC'). On the one hand, there is a revocation action, and on the other a counterclaim for revocation of the same patent, a situation which appears to arise frequently.

17. This situation can occur in two scenarios. First, when the patent proprietor files an infringement action and the defendant responds with a counterclaim for revocation, while a third party also challenges the same patent with a separate revocation action. Second, when a party files a revocation action and then a counterclaim for revocation of the same patent in response to an infringement action subsequently brought against it.

18. With regard to the first scenario, Article 33 (3) 'UPCA' states that when a counterclaim for revocation is brought in an infringement action, the local or regional division concerned has the discretion either to proceed with both the action for infringement and with the counterclaim for revocation, refer the counterclaim for revocation to the central division for decision or, with the agreement of the parties, refer the entire case to the central division for decision.

19. The decision of the local or regional division on whether or not to proceed with both the action for infringement and with the counterclaim for revocation, and the decision of the central division on whether or not to stay its proceedings, should be taken on a case-by-case basis. In exercising its discretionary power, the Court must take into account the principle of efficiency of the proceedings, which can be undermined by unnecessary procedural activities, duplication of these activities, and by irreconcilable decisions. Additionally, the Court must weigh up the interest in issuing expeditious decisions, which are important for enhancing legal certainty regarding the validity and enforcement of the patents.

20. In this regard, it may be relevant – as it appears in the current case – that there is likely to be a significant time difference between the decisions of the involved divisions. Additionally, the similarity of grounds for invalidity in both proceedings and the multiplicity of infringement actions in which counterclaims against the same patent are filed are relevant considerations.

21. Coordination of the revocation action and counterclaims for revocation of the same patent through consolidation of proceedings before the local division, pursuant to Rule 340 'RoP', as originally requested by the defendant, is not possible. Indeed, said Rule 340 'RoP' requires that 'Article 33 of the Agreement shall be respected', which means that the competence of the central division, as established by Article 33(4) 'UPCA' cannot be derogated by virtue of the joinder of the proceedings.

22. The Munich Local Division's order of 28 March 2024, issued in the counterclaim proceedings, suggests interpreting Rule 340 'RoP' to require a joint hearing for the revocation proceedings before a panel comprising all judges from both the central and local divisions. However, this interpretation lacks a legal basis in the 'UPCA' and the 'RoP', nor is it supported by EU law principles. Additionally, the argument that Rule 340 (2) 'RoP', which states that "the actions may subsequently be disjoined", is otherwise 'obsolete' or 'not clear' neglects the fact that this provision allows for the disjoining of consolidated actions in situations where one (or more) of the actions is ready to be decided while others are not, thereby justifying different timeframes for their resolution.

23. Joining the revocation action and the counterclaims for revocation does not result in a true merger of the claims. These claims retain their distinct legal identities and must be adjudicated independently, even if a single decision is ultimately issued.

The admissibility of the amendment of the patent.

24. As previously noted, the defendant filed an initial application to amend the patent with its defence to revocation. The claimant argues that this amendment is inadmissible as it does not contain an operative part and does not explain why the proposed amendments satisfy the

requirements of Articles 84 and 123 (2) (3) of the European Patent Convention ('EPC'). The claimant also submits that the number of conditional auxiliary requests is not reasonable.

25. The claimant argues that the second request to amend the patent, filed on 22 January 2024, contained the same procedural errors as the first request and that the panel correctly refused to admit this request into the proceedings.

26. However, the claimant asserts that the panel incorrectly admitted the final request to amend the patent, filed on 12 April 2024. This request consists of one main request and six auxiliary requests, all of which were already included in the previous submissions. The claimant contends that allowing this final amendment contradicts the panel's earlier decision and represents an improper attempt to rectify the procedural issues affecting the previous requests.

27. The issue of the admissibility of the initial amendment application, regarding the procedural errors promptly raised by the claimant, was not clearly addressed by either the judge-rapporteur during the written procedure or by the panel in its order of 30 April 2024, which admitted the subsequent amendment request filed on 12 April 2024. Therefore, the panel finds it appropriate to consider the issue raised by the claimant.

28. In this regard, it should be noted that according to Rules 30 and 50 'RoP', the defendant in a revocation action is entitled to amend the patent, provided that the relevant application is included in the statement of defence (or, in any event, meets the filing deadline for this application) and contains the information referred to in Rule 30 (1) (a) (c) 'RoP'. This includes the language of the application, an indication of whether the amendments are conditional or unconditional, and an explanation of how the amendments comply with Articles 84 and 123 (2) (3) 'EPC' and why the proposed amended claims are valid.

29. Furthermore, Rule 30 (2) 'RoP' allows for a subsequent request to amend the patent, provided that such request is admitted into the proceedings with the permission of the Court. The term 'subsequent' must be interpreted as referring to a request which follows a previous one, making it sufficiently clear that the term refers to any request that amends the original application to amend the patent.

30. This panel agrees with the claimant that if an application to amend the patent is found to be inadmissible, any subsequent request to amend the patent must also be considered inadmissible. This is because a subsequent request inherently presupposes that a previous request was validly submitted. Amending an invalid previous request could be seen as an inadmissible circumvention of the procedural provisions for amending the patent.

31. However, in this case, the defendant has submitted a timely application to amend the patent, included in its defence to revocation, and its content meets the requirements set forth in Rule 50 'RoP'.

32. Indeed, contrary to claimant's argument, the defendant's initial application to amend the patent contains an explanation of why the proposed amendments satisfy the requirements of Articles 84 and 123 (2) (3) 'RoP' and are valid. Moreover, it allows for an understanding of the specific amendments proposed. While a complete lack of explanation in an amendment request can render it inadmissible, an insufficient explanation does not necessarily have the

same effect. In the latter case, the application may be unsubstantiated but not inadmissible. This unsubstantiated nature would not prevent the defendant from filing a subsequent, compliant request to amend the patent under Rule 30 (2) 'RoP'.

33. Moreover, while this panel considers the number of the amendments originally filed to be extremely high, potentially hindering the efficiency of the 'UPC' proceedings and the goal of delivering expeditious decisions, it does not appear that that number is 'unreasonable', considering the extreme complexity of the case (in particular, the number of grounds of invalidity raised), the importance of the patent at issue and the interrelationship with other proceedings, both judicial and administrative, concerning related patents of the same family. The lack of a consistent interpretation of the expression 'reasonable in number' also suggests a less strict interpretation of this relevant provision.

34. Since the initial application to amend the patent is admissible, the defendant could file a subsequent request to amend the patent, as no derivative invalidity applies in this case. Therefore, the panel's order admitting into the proceedings the subsequent request to amend the patent, lodged on 12 April 2024, must be confirmed.

The patent at issue.

35. The patent at issue contains 13 claims of which claim 1 is an independent claim and claims 2 to 13 are dependent on claim 1. Claim 1 relates to a system comprising a prosthetic valve and a delivery catheter.

36. According to the description of the patent prosthetic cardiac valves have been used for many years to treat cardiac valvular disorders and while traditionally the definitive treatment for such disorder was the surgical repair or replacement of the valve during open heart surgery, more recently a transvascular technique has been developed for introducing and implanting a prosthetic heart valve using a flexible catheter in a manner that is less invasive than open heart surgery (para. [0002]).

37. Based on this new technique, a prosthetic valve is mounted in a crimped state on the end of a flexible catheter and advanced through a blood vessel of the patient until it reaches the implantation site where it is expanded to its functional size by inflating a balloon on which the prosthetic valve is mounted or by a self-expanding frame (para [0003]).

38. As the native valve annulus in which the expandable prosthetic valve is deployed typically has an irregular shape, mainly due to calcification, small gaps may exist between the expanded frame of the prosthetic valve and the surrounding tissue and these gaps can allow for regurgitation (leaking) of blood flowing in a direction opposite of the normal flow of blood through the valve. To minimise the perivalvular leakage, various sealing devices have been developed (para. [0004]).

39. Bearing that in mind, one of the objectives addressed by the disputed patent is to provide a prosthetic valve that does not contribute significantly to its the overall crimp profile. This is achieved through the honeycomb structure of the frame, which 'provides stability during crimping and subsequent expansion, is less sensitive to variations in strut width, and provides increased radial strength' (para. [0039]).

40. According to claim 1 of the patent at issue in the version of the main request (with the features added compared to the granted version shown in bold) and following, for convenience, the construction of the claim proposed by the claimant, which was not objected to by the defendant for this purpose, this problem is to be solved by the following system:
    1. A system comprising:
    (1.1) a prosthetic **heart** valve (100) comprising:
    (1.2) a collapsible and expandable annular frame (102), configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body;
    (1.3) wherein the frame (102) comprises a plurality of rows (112a, 112b, 112c, 112d) of angled struts (114),
    (1.4) the angled struts (114) joined to each other so as to form a plurality of rows of hexagonal cells
    (1.5) wherein the frame (102) is made up entirely of hexagonal cells, and
    (1.6) wherein each of the hexagonal shaped cells is defined by six struts (144, 146, 148), including:
    (1.7) two opposing side struts (144) extending parallel to a flow axis of the valve (100),
    (1.8) a pair of lower angled struts (146), extending downwardly from respective lower ends of the side struts (144) and converging toward each other, and
    (1.9) a pair of upper angled struts (148) extending upwardly from respective upper ends of the side struts (144) and converging toward each other; and
    (1.10) a delivery catheter comprising an inflatable balloon;
    (1.11) wherein the prosthetic **heart** valve (100) is crimped in its radially compressed state on the balloon of the delivery apparatus, and wherein the balloon is configured to be inflated to expand to radially expand the prosthetic **heart** valve (100) at the desired deployment location, preferably within a native aortic valve.

41. With regard to the interpretation of the claims, the following must be borne in mind: the patent claim is not only the starting point, but the decisive basis for determining the protective scope of the European patent; the interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used, as the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim, but this does not mean that the patent claim serves only as a guideline and that its subject-matter may extend to what, from a consideration of the description and drawings, the patent proprietor has contemplated (see order of Court of Appeal issued on 26 February 2024, case UPC_CoA_335/2023).

42. The relevant assessment must be carried out from the point of view of a person skilled in the art, which, in the present case, may be identified as a group consisting of a medical device engineer with an interest in prosthetic heart valves and an interventional cardiologist.

43. The parties debated the meaning of the term ‘strut’. According to this Court, the term must be understood, in line with the common general knowledge, to mean a single, unitary elongated piece that connects the neighbouring struts. This definition is not explicitly disclosed in EP ‘825 but is implied by the claims, which require that each hexagonal cell is defined by six struts (feature 1.6.) including two opposing side struts extending parallel to a flow axis of the valve

(feature 1.7), a pair of lower and upper angled struts angled struts extending downwardly or upwardly from respective lower or upper ends of the side struts, respectively, and converging toward each other (features 1.8 and 1.9.) with the angled struts being joined to each other so as to form a plurality of rows of hexagonal cells (feature 1.4.). Reference can also be made to Fig. 6 which shows that neighbouring struts are joined at apices 150 and 152 at the topmost and lowermost row of angled struts, respectively, and in correspondingly shaped connecting portions such as welding points or nodes at intermediate rows of angled struts.

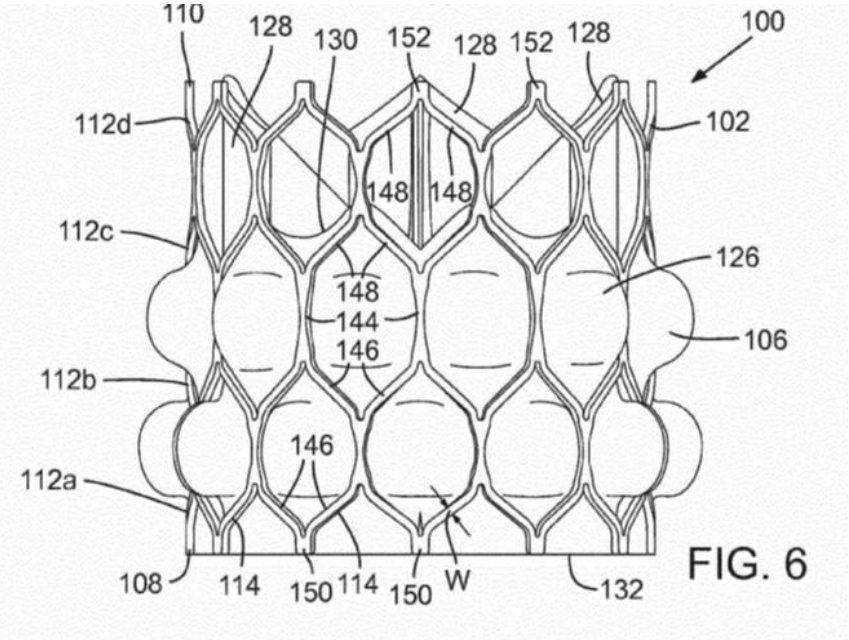


FIG. 6

44. There is also disagreement between the parties regarding the meaning of the terms ‘cell’ and ‘opening’. The claimant argues that they should be understood as synonyms. However, the panel holds the opposing view that ‘cell’ refers to the entity defined by the struts, while ‘opening’ refers to the open space within the cell, as evident from the content of paras. [0040] and [0041], where the term ‘opening’ is clearly used to refer specifically to an opening within the cell.

Extension beyond the content of patent application: a) prosthetic valve in combination with a delivery catheter and an inflatable balloon.

45. The claimant argues that the patent describes a system in which the prosthetic valve is crimped on the balloon and the balloon is configured to be inflated to expand the prosthetic valve radially at the desired deployment location (see features 1.1, 1.10 and 1.11) while WO ’801 (Gide 5), the parent application, does not disclose the prosthetic valve in combination with a delivery catheter with an inflatable balloon, nor does it disclose the valve being effectively crimped in its radially compressed state on the balloon. It merely indicates that the prosthetic valve can be crimped or is configured to be crimped, essentially describing a capability. For this reason, the claimant contends that the subject-matter of claim 1 of EP ‘825 cannot be derived directly and unambiguously from the content of WO ‘801 as filed.

46. The panel disagrees with the claimant on this point.

47. The contested features are disclosed in WO ‘801, in particular in para. [013], which states that “… a prosthetic heart valve comprises a collapsible and expandable annular frame that is configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body”.

48. Moreover, WO ’801 discloses that the frame can be made of plastically-expandable materials, in addition to self-expending materials, and that in this case “the frame (and thus the prosthetic valve) can be crimped to a radially collapsed state on a delivery catheter and then expanded inside a patient by an inflatable balloon …” (para. [036]).

49. The prosthetic valve “can be crimped to a radially compressed state on a balloon … of a delivery apparatus” (para. [043] and the drawing it relies on). Similarly, it discloses that in such embodiment, “when the prosthetic valve is positioned at the desired deployment location (e.g., within the native aortic valve), the balloon of the delivery apparatus is inflated to radially expand the prosthetic valve” (para. [044]).

50. Therefore, WO ‘801 clearly and unambiguously discloses feature 1.11 in combination with features 1.1 and 1.10.

Extension beyond the content of the patent application: b) intermediate generalization due to isolation of features 1.3, 1.4 and 1.5.

51. The claimant submits that “[t]he only possible basis for these features in WO ‘801 may be found in paragraphs [053] and [054] and in Figures 5 and 6” (para. 113 of the statement for revocation), however it points out that the disclosure in paragraphs [053] and [054] and Figures 5 and 6 of WO ’801 is not limited to features 1.3, 1.4 and 1.5 alone and that the additional features intrinsically linked to these are omitted, leading to an unallowable intermediate generalization.

52. In particular, WO ‘801 purportedly also discloses that the frame has exactly four rows of angled struts that define exactly three rows of hexagonal cells and other features concerning the shape and the intersection of angle and side struts. Additionally, it mentions the presence of a sealing device inside the frame, the presence of a valvular structure comprising exactly three leaflets and the lack of a full definition for the expression ‘homogeneous pattern of hexagonal cells’.

53. This ground of revocation may be addressed by considering the isolation of features 1.3, 1.4 and 1.5 separately. It is unfounded in terms of the isolation of the first two features but well-founded in terms of the isolation of feature 1.5.

54. It is worth noting that, pursuant to Articles 76 (1) and 123 (2) ‘EPC’ a European divisional application may only be filed in respect of subject-matter which does not extend beyond the content of the earlier application as filed. Such an extension occurs if the subject-matter cannot be directly and unambiguously deduced from the earlier application by a person skilled in the art. An undue extension may result from an amendment to the claims or the description consisting of an intermediate generalisation, i.e. by extracting one or more isolated features which, in the initial application, were disclosed only in combination with other features, thereby extending the claimed subject matter, which is no longer limited to this initial combination of features.

55. With regard to the alleged isolation of feature 1.3, based on the purported omission of the feature describing the frame as having exactly four rows of angled struts, it should be noted that para. [013] of WO ’801 discloses that the frame “comprises a homogenous pattern of hexagonal cells”. Para. [053] adds that the frame “can comprise a plurality of rows” and refers to the rows designated in Fig. 6 as 112a-112d. Additionally, the next-to-last line of para. [053] uses the term ‘fourth row 112d’.

56. This panel understands that the feature at hand indicates that the number of rows is optional, as suggested by the use of the word ‘plurality’, and that the reference to the ‘forth row’ constitutes one of the possible implementations of the invention.

57. This interpretation is supported by the explanation provided in para. [071], which clarifies that the term ‘plurality’ refers to “two or more of the specified elements”.

58. It may be added that para. [055] indicates the technical advantages of using a frame having a ‘honeycomb’ structure but does not describe a specific number of hexagonal rows as specifically advantageous. It follows that a specific number of four rows is not intrinsically linked to the hexagonal structure of a frame.

59. Moreover, providing reference numbers 112a-112d in the claim is illustrative but not restrictive.

60. With regard to the isolation of feature (1.4), the claimant argues that the term ‘angled struts (114) joined to each other’ is not congruent with the term ‘intersect’ disclosed in paragraph [053] of WO ‘801 in which it is also disclosed that the angled struts intersect in the bottom and top row, respectively, to form apices 150 and 152.

61. The panel concurs with the defendant that the omitted feature is implicit in claim 1, as it states that “the angled struts (114) [are] joined to each other so as to form a plurality of rows of hexagonal cells” and that “the frame (102) is made up entirely of hexagonal cells”. Indeed, as also disclosed in para. [013], the conjunction of the lower angled struts with the upper angled struts clearly constitutes a situation of ‘intersection’.

62. The allegation of intermediate generalisation related to feature (1.5) relates to the incomplete disclosure of the feature regarding the homogeneous pattern of the hexagonal cells which constitute the frame of the system.

63. In this regard, the panel notes that para. [013] of WO ‘801 indicates that “the frame comprises a homogeneous pattern of hexagonal cells” and para. [054] provides for a definition of the expression ‘homogeneous pattern’ in the context of the frame, explaining that a ‘homogenous pattern’ of hexagonal cells means that “the frame is made up entirely of hexagonal cells and does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from the inflow end or outflow end for mounting the frame to a delivery apparatus”.

64. Based on common general knowledge and the usual meaning of the term ‘homogenous’ the person skilled in the art would understand the term ‘homogenous pattern of hexagonal cells’ disclosed in para. [013] to mean that the hexagonal cells are somehow uniformly arranged. This general understanding deviates from the definition provided in paragraph [054] of WO

‘801, and therefore the person skilled in the art would not understand the term on the basis of this latter definition.

65. In feature (1.5) of the patent at issue, the term ‘homogeneous pattern of hexagonal cells’ of para. [013] of WO ‘801 is not present and only the first part of the definition of the term ‘homogenous pattern of hexagonal cells’ of para. [0054] is included in the claim.

66. Hence, the presence of the feature in claim 1 stating that “the frame is made up entirely of hexagonal cells”, while omitting the feature that “the frame does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from the inflow end or outflow end for mounting the frame to a delivery apparatus”, constitutes an extension of the subject-matter beyond the content of the earlier application by intermediate generalisation as a consequence of the isolation of a non-optional feature that was originally disclosed only in combination with the others in the earlier application.

67. This conclusion is supported by the decision of the Opposition Division of the European Patent Office (‘EPO’) issued on 15 December 2022 (Gide 16), concerning EP '920, a patent from the same family, which states that the feature "the frame is made up entirely of hexagonal cells" adds subject matter extending beyond the content of the earlier application as filed.

Extension beyond the content of patent application: c) missing of a "collapsible and expandable valve structure".

68. The counterclaimants argue that claim 1 is also inadmissibly extended compared to WO '801 because it does not contain the essential feature of a collapsible and expandable leaflet structure.

69. The panel notes that para. [013] of WO ‘801, which forms the basis of claim 1, does not comprise the term of a collapsible and expandable valve member, but requires that the prosthetic heart valve has a frame that is configured to be radially collapsed in the crimped stated and radially expanded when implanted. Since the prosthetic heart valve intrinsically also comprises a valve member the prosthetic heart valve including the frame and the valve member are collapsible and expendable.

70. Therefore, the panel is of the opinion that that the feature of a collapsible and expandable valve member is implicitly comprised in feature 1.1 of claim 1, as amended by the main request.

71. Since the ground of invalidity concerning the violation of Articles 76 (1) and 123 (2) ‘EPC’ is upheld, it is unnecessary to examine the other grounds of invalidity raised with regard to the patent as unconditionally amended. The Court will instead examine the grounds of invalidity raised against the patent as amended by the auxiliary requests, including those raised by the counterclaimants.

Auxiliary request I.

72. The amendment proposed with the auxiliary request I differs substantially from the one submitted with the main request only in that dependant claims 2-4, 7-9 and 12 are deleted.

73. It follows that the ground of invalidity previously assessed with regard to the claim 1 of the main request is not superseded.

Auxiliary request II: lack of clarity.

74. Claim 1 as amended in the auxiliary request II reads as follows (the features added compared to the granted version are in bold):

"1. A system comprising:
a prosthetic **heart** valve (100) comprising:
a collapsible and expandable annular frame (102), configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body;
wherein the frame (102**) is made of a nickel-cobalt-chromium-molybdenum alloy and** comprises a plurality of rows (112a, 112b, 112c, 112d) of angled struts (114), the angled struts 10 (114) joined to each other so as to form a plurality of rows of hexagonal cells, wherein the frame (102) is made up entirely of hexagonal cells, and wherein each of the hexagonal shaped cells is defined by six struts (144, 146, 148), including:
two opposing side struts (144) extending parallel to a flow axis of the valve (100),
a pair of lower angled struts (146), extending downwardly from respective lower ends of the 15 side struts (144) and converging toward each other, and
a pair of upper angled struts (148) extending upwardly from respective upper ends of the side struts (144) and converging toward each other; and
a delivery catheter comprising an inflatable balloon;
wherein the prosthetic **heart** valve (100) is crimped in its radially compressed state on the 20 balloon of the delivery apparatus, and wherein the balloon is configured to be inflated to expand to radially expand the prosthetic **heart** valve (100) at the desired deployment location, preferably within a native aortic valve,
wherein the frame (102) of the prosthetic heart valve (100) does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from an inflow end (108) or an outflow end (110) of the frame (102) for mounting the frame (102) to the delivery catheter."

75. The claimant contends that the wording of claim 1 of auxiliary request II is not clear and therefore does not comply with Article 84 'EPC', which states that the claims "shall be clear and concise and be supported by the description". In particular, it purportedly does not provide any guidance on the requirements for a strut to be suitable "for mounting the frame to the delivery catheter".

76. The argument is unfounded. The panel points out that nickel-cobalt-chromium-molybdenum alloys are suitable plastically-expandable materials that can be used to form the frame (see, para. [037]) and that this explanation is sufficiently clear.

77. The counterclaimants argue that a lack of clarity also arises from the fact that the amendment does not indicate which axial struts do not form part of the hexagonal cells as they serve to attach the frame to the delivery catheter.

78. Similarly, this argument is not convincing. The skilled person is able to understand which axial struts do not form part of the hexagonal cells because, as indicated in the wording of the claim, they are the ones which extend axially away from an inflow end (108) or an outflow end (110) of the frame for mounting the frame to the delivery catheter.

79. Therefore, the auxiliary request II is not ambiguous with respect to the contested points and to that extent does not contravene Article 84 'EPC'

Auxiliary request II: added matter.

80. The claimant argues that the amendment filed by the defendant does not overcome the added matter objections raised under Articles 76 (1) and 123 (2) 'EPC' against claim 1 of EP '825 as granted.

81. As previously noted, the added matter ground of invalidity raised by the claimant against the main request has been deemed founded only with regard to the intermediate generalization of feature (1.5), as a consequence of the omission of the complete definition of the 'homogeneous pattern of hexagonal cells'.

82. Auxiliary request II overcomes this deficiency by reproducing the wording of para. [054] of WO '801. The replacement of the original definite article 'the' with the indefinite article 'a' in relation to the inflow end and the outflow end does not seem to be relevant, as it is clear that the valve comprises only one inflow end and outflow end.

Auxiliary request II: validity of the priority claim.

83. The claimant argues that the priority indicated in the patent at issue, namely P1, filed on 15 July 2011 (Gide 6), and P2, filed on 13 July 2012 (Gide 7), cannot be validity claimed for the following reasons: firstly, the proprietor was not entitled to claim priority from these earlier applications, and secondly, the subject-matter claimed by the patent at issue is not directly and unambiguously derivable from priority application P1.

84. It is clear that the assessment of the disputed claimed priority is crucial to identify correctly the relevant state of the art for examining the grounds of invalidity based on lack of novelty and lack of inventive step.

85. With regard to the first argument, the claimant notes that P1 was filed jointly in the names of four individuals as applicants, and that the same is true for P2 which added a fifth applicant (also an individual), while in WO '801 the applicants were listed as Edwards Lifesciences Corporation (the defendant), for all states except the United States, and the five applicants from P2 (individuals) for the United States only. As the five applicants had assigned only their rights in these applications to the defendant, but not the priority rights attached to them, the defendant would not be entitled to claim priority from P1 or P2.

86. The defendant objects, arguing that there is a rebuttable presumption that the applicant claiming priority in accordance with Article 88 (1) 'EPC' is entitled to do so, even when the priority applicants are not identical to the subsequent applicants and that the claimants have not provided specific facts to support serious doubts about the subsequent applicant's entitlement to priority. The defendant bases its argument on the decision of the Enlarged Board of Appeal of the 'EPO', issued on 10 October 2023 (cases G-1/22 and G-2/22).

87. The panel is aware that, pursuant to Article 4 of the Paris Convention for the Protection of Industrial Property and Article 87 (1) 'UPC', the right to claim the priority of a patent belongs to the applicant of the initial application or to his successor in title. The panel recognizes that the priority right is distinct from the right to the subsequent patent application and, as such, it is not automatically transferred with the transfer of the right to the title, but requires a specific dispositive act.

88. Nevertheless, as also pointed out by the Enlarged Board of Appeal of the 'EPO' in the abovementioned decision, it is a fact that agreements under which the subsequent applicant acquires the title to the subsequent application and the right of priority usually fail to distinguish between the two rights. The priority right is rarely addressed in these agreements, in which it is implicitly treated as a mere ancillary right to the right to the subsequent application.

89. It may also be noted that, under normal circumstances, any party transferring the right to a subsequent application intends for the subsequent applicant to benefit from the priority right, and that in most European national legislation formal requirements for transferring priority rights do not exist.

90. All these facts establish a rebuttable presumption of the entitlement to priority in favour of the subsequent applicant, provided the latter can demonstrate the acquisition of the right to the title.

91. Therefore, since the claimant has not provided any evidence to suggest that the priority rights were the subject of a separate dispositive act in favour of third parties or that the original applicants intended to retain them instead of transferring them along with the rights to the title, the presumption is not rebutted.

92. With regard to the second argument, the claimant asserts that the patent at issue may not validly claim priority from P1 because certain features disclosed therein as required to solve the technical problem are not claimed in auxiliary request II of EP '825. Consequently, the subject-matter of claim 1 in this request is not directly and unambiguously derivable from P1.

93. In particular, the claimant notes that claim 1 of auxiliary request II at issue does not necessarily include a valvular/leaflet structure nor a sealing device, which are required to solve the technical problem that P1 is supposed to solve; does not claim the constitutive material of the frame, which according to P1 is not constructed of a plastically-expandable material; encompasses a system in which, differently from the one disclosed in P1, the prosthetic valve and the delivery catheter are assembled; requires that the prosthetic valve is crimped on the balloon of the delivery apparatus, while P1 does not disclose this feature; discloses features (1.5) to (1.9) which define the structure of the frame (being entirely made up of hexagonal cells), the number of struts and the geometry of the angled struts and the side struts, which are not disclosed in P1 where the only occurrence of 'hexagonal' cells is found.

94. The claimant's argument is well-grounded.

95. According to Article 87(1) EPC, a subsequent European patent application can validly claim the priority of an earlier application only insofar as the invention claimed in the later application covers the 'same invention' as that described in the earlier application. For this purpose, the

subject matter of the later application must be directly and unambiguously included as a technical teaching in the priority document. This interpretation of Article 87 (1) 'EPC' is supported by the case law of national jurisdictions as well as by the Enlarged Board of Appeal of 'EPO' (see decision issued on 31 May 2001, case G-2/98).

96. This panel first point outs that P1 does not include the equivalent of para. [0013] of EP '825. In particular, P1 does not disclose that the frame is made up entirely of hexagonal cells but merely discloses a frame which is made of "a plurality of hexagonal or 'honeycomb' shaped cells" (para. [010] of P1); this feature is also not directly and unambiguously disclosed by Figs. 3-7. Furthermore, P1 does not include para. [054] of WO '801, which provides a definition of the term 'homogenous'.

97. Additionally, P1 relates to a prosthetic heart valve which "includes a frame, or stent, 102, a leaflet structure comprising a plurality of leaflets 104 (e.g., three leaflets 104 as shown), and a sealing device in the form of a skirt 106" (para. [009]). According to this passage, the presence of a leaflet structure and a sealing device is mandatory, not optional, as confirmed by Figs. 3-7. Para. [013] of P1 only specifies that it is not required to use sealing skirts that reduce the pushing force but does not specify that the skirt can be omitted altogether. In contrast, claim 1 of auxiliary request II does not require the presence of a leaflet structure and/or a sealing skirt.

98. For these reasons – though non-exhaustive – the priority of P1 is not validly claimed relative to claim 1 of auxiliary request II. Consequently, the relevant date for this purpose is 13 July 2012.

Auxiliary request II: lack of novelty in view of 'Levi'.

99. 'Levi' (Gide 47) is a patent application which discloses embodiments of a prosthetic heart valve and delivery systems for implanting heart valves, filed on 5 October 2011 and claiming the priority of earlier applications filed on 5 October 2010 and 15 July 2011, respectively. As such, 'Levi' is relevant as prior art for the purpose of evaluating the novelty requirement pursuant to Article 54 'EPC' due to its earlier priority claim date compared to the defendant's validly claimed date.

100. The claimant argues that 'Levi' discloses all features of claim 1 of auxiliary request II of the patent at issue, in particular, a prosthetic heart valve which includes a collapsible and expandible annular frame which can be crimped to a radially compressed state on a delivery catheter and then expanded inside a patient by an inflatable balloon (see para. [052]), where the frame comprises a plurality of angled struts and these angled struts are joined to each other (see also para. [054]) to form hexagonal cells so that the frame only comprises hexagonal cells. The frame disclosed in Fig.5, for example, purportedly comprises five rows of angled struts, whereby the topmost and the bottom-most rows of cells are hexagonal in shape and comprise side struts extending parallel to a flow axis of the valve. 'Levi' also discloses the use of a nickel-cobalt-chromium-molybdenum alloy as a suitable material to form the frame (para. [053]).

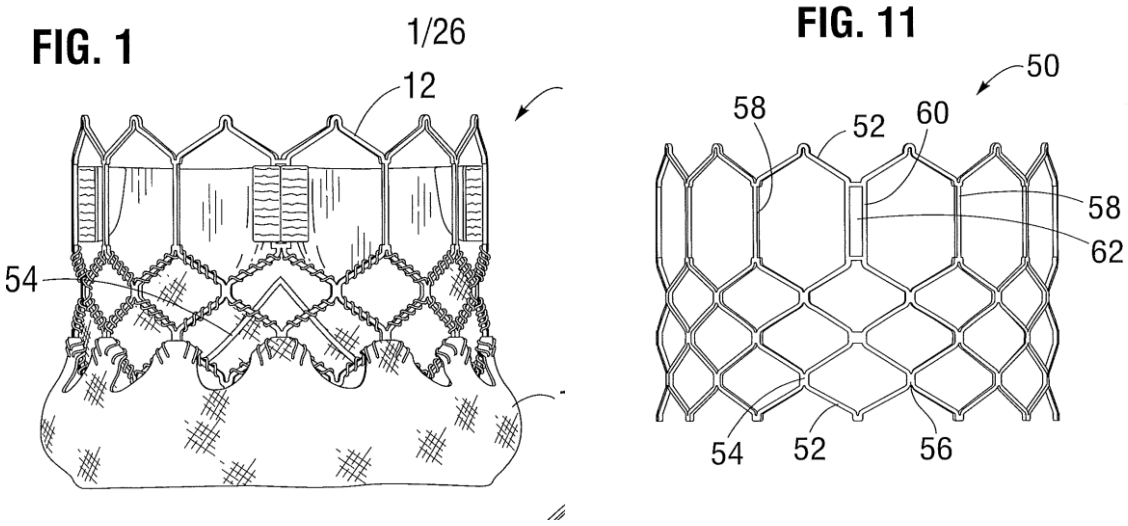
101. The defendant denies that 'Levi' discloses a frame that is made up entirely of hexagonal cells, pointing out that, as evident from the drawings, the cells of the inflow and outflow rows are each defined by six struts, forming hexagonal cells, whereas the cells of the two intermediate rows are each defined by four struts, forming diamond shaped cells.

102. To address the debated issue, it is necessary to interpret feature (1.5), which requires that "the frame of the prosthetic heart valve is made up entirely of hexagonal cells".

103. Claim 1 as amended in the auxiliary request II of the patent at issue clarifies that "[e]ach hexagonal cell is defined by six struts including two opposing side struts extending parallel to a flow axis of the valve, a pair of lower angled struts extending downwardly from respective lower ends of the side struts and converging towards each other, and a pair of upper angled struts extending upwardly from respective upper ends of the side struts and converging towards each other" [features (1.6), (1.7), (1.8) and (1.9)]. It further specifies that the angled struts are joined to each other to form a plurality of hexagonal cells [feature (1.4)].

104. The wording of 'Levi''s claims and description does not disclose this feature. Additionally, contrary to the claimant's argument, the drawings are not conclusive. In fact, they show a distinction between hexagonal cells with side struts and cells without side struts (rhombic or diamond-shape cells) in which the connections between lateral portions must be considered welding nodes and do not consist of separate struts.

105. It follows that it is not possible to assert that 'Levi' discloses a prosthetic heart valve with a valve made entirely of hexagonal cells.



106. The claimant relies on an opinion delivered by Mr. [redacted] (Gide 48) in a different judicial proceeding related to a patent of the same family (EP '928). Mr. [redacted] reportedly stated that a skilled person would consider the intermediate rows to be hexagonal cells, not diamond-shaped. However, for the reasons explained above, this opinion is not convincing and fails to sustain the claimant's ground of invalidity.

Auxiliary request II: lack of novelty in view of 'Benichou'.

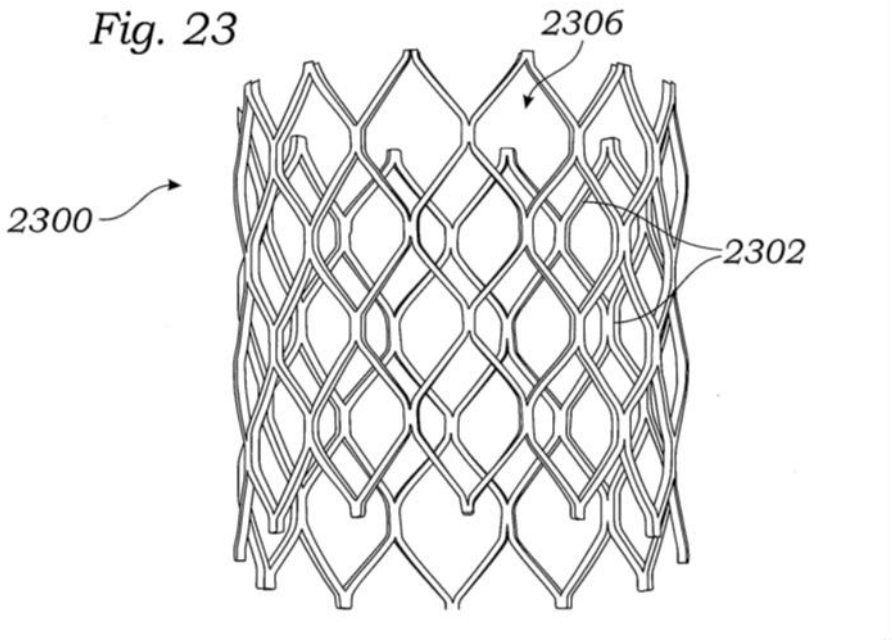
107. 'Benichou' (Gide 52) is a patent application which relates to devices and methods for implantation of a prosthetic heart valve (para. [001]).

108. The claimant argues that the teaching of 'Benichou' includes an annular frame which can be configured to be radially collapsible to a collapsed or crimped state for introduction into the body on a delivery catheter and radially expandable to an expanded state for implanting the valve at a desired location in the body (e.g., the native aortic valve) (para. [073]). The claimant

also submits that ‘Benichou’ discloses a frame comprising a plurality of (five) rows of angled struts, with the angled struts joined to each other by vertical blue struts to form a plurality of (four) rows of hexagonal cells (in green) and the frame comprised exclusively of hexagonal cells. Therefore, ‘Benichou’ discloses all features of claim 1 of the auxiliary request II.

109. Similar to ‘Levi’, ‘Benichou’'s claims and description do not disclose a frame made entirely of hexagonal cells, nor do they mention the types of struts which form the cells. While ‘Benichou’ mentions a "wire mesh of cells 2302 arranged in, for example, a substantially cylindrical tube" (para. [0122]), it does not explicitly mention side struts. Additionally, the figures lack a clear depiction of side struts; instead, it appears that the wire mesh is connected by connecting portions or welding nodes that differ from side portions based on the provided claim interpretation.

110. Furthermore, it may be noted that the frame illustrated in Fig. 23 is not a valve but a frame portion that only forms a valve in combination with the valve portion of Fig. 22. Hence, even if it were demonstrated that the portion of Fig. 23 is exclusively made of hexagonal cells, Fig. 23 alone would not be novelty-destroying.

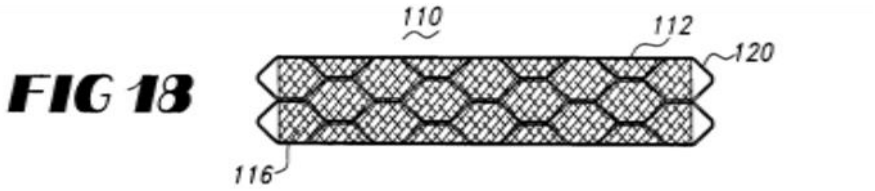


Auxiliary request II: lack of novelty in view of ‘Dimatteo’.

111. ‘Dimatteo’ (Gide 54) is a patent application which discloses an invention in “the field of implantable prostheses. More specifically, the present invention relates to implantable prosthetic cardiac, aortic, and venous valves” (page 1, lines 3-4).

112. The claimant relies on the description contained in page 22, lines 24-26 and on Figs. 18-21, that depict an embodiment “in which the valve leafs of an implantable prosthetic valve 110 are attached to the interior lumenal surface 114 of a second radially collapsible tubular fluid conduit 112” and, therefore, disclose a collapsible and expandable frame. The claimant adds that in ‘Dimatteo’ the frame may be formed to permit radial expansion at a desired location by a delivery balloon. Furthermore, the claimant points out that ‘DiMatteo’ discloses feature (1.5), as each cell has a hexagonal shape.

113. The panel considers that a person skilled in the art would understand that 'Dimatteo' discloses two embodiments, depicted in Figs. 1-21 and Figs. 22-29, respectively. The first embodiment (and the related drawings), referred to by the claimant, discloses a venous valve rather than a heart valve. This can be inferred from page 22, lines 27-28 where it is stated that the "[S]econd conduit 112 further maintains the patency of the body lumen to either side of the valve ….". Also, the size of the second conduit and the arrangement of the leaflets 40 within the conduit support the view that the prosthetic valve shown is designed for venous valve replacement. Therefore, it would be unsuitable for the purpose of replacing a heart valve, as asserted by the defendant (see para. 226 of the defence to revocation).



114. The claimant argues that a person skilled in the art would consider the device of Figs. 18-20 to be a prosthetic heart valve and supports this argument by referring to the declaration of Prof. [redacted] (Gide 74). However, this evidence is not convincing.

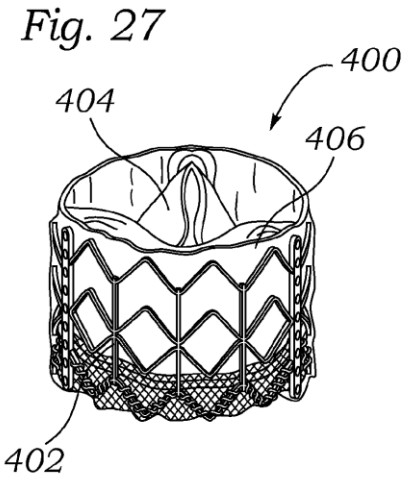
115. Moreover, 'Dimatteo' does not disclose the nickel-cobalt-chromium-molybdenum alloy as a frame material (as required in claim 1 of auxiliary request II), nor does it offer any information in this regard.

Auxiliary request II: lack of novelty in view of 'Hariton'.

116. 'Hariton' (HLNK 50) is a patent application which "relates to implantable devices and, more particularly, to valve prosthetics for implantation into body ducts, such as native heart valve annuluses" (para. [001]).

117. 'Hariton' discloses several features of the patent at issue: in particular, the use of the nickel-cobalt-chromium-molybdenum alloy as a preferred plastically expandable material (para. [055]) and the fact that the prosthetic valve is crimped on a balloon catheter (see fig. 23). However, it does not disclose either that the frame comprises hexagonal cells or that it is made up entirely of hexagonal cells.

118. In this latter regard, the counterclaimants rely on Fig. 27. However, it is clear from this figure, reproduced below, that feature (1.5) cannot be derived directly and unambiguously from 'Hariton'.



Auxiliary request II: lack of inventive step. Technical effect.

119. According to para. [0039] of EP '825 the 'honeycomb' structure of the frame "reduces the crimping profile of the valve" and at the same time "provides stability during crimping and subsequent expansion, is less sensitive to variations in struth width, and provides increased radial strength". Claim 1 does not comprise the term 'honeycomb' but uses the terms 'hexagonal' and 'honeycomb' synonymously (see para. [0037]).

120. The claimant argues that the combination of features in claim 1 of auxiliary request II does not offer any discernible technical effect vis-à-vis the prior art and therefore is a mere obvious alternative and that, furthermore, it lacks inventive step over Levi and, in the alternative, over the combination of the Melody® valve with Fontaine. In its additional defence to Edwards' final subsequent request to amend the patent, lodged on 30 May 2024, the claimant also challenges auxiliary request II for lack of inventive step citing 'Benichou' or 'Dimatteo'.

121. The counterclaimants contend that the patent at issue also lacks inventive step citing the prosthetic 'Colibri' heart valve and US '313 ('Alon').

122. With regard to the first argument, the claimant asserts that EP '825 lacks data regarding the radial strength, stability during crimping and subsequent expansion, or the crimping profile of the valve claimed and that, furthermore, there is no overall technical effect throughout the whole claim 1, but at most with regard to the embodiment described in paras. [0027] to [0042].

123. The claimant relies on the declaration provided by Prof. [redacted] (Gide 56), according to which the mere fact of having a frame entirely made up of hexagonal cells, as described in features (1.6) to (1.9), is not sufficient to achieve the technical effects mentioned in para. [0039], as other parameters might also affect the crimping profile and the radial strength of the frame. This view is also stated in the declaration of Prof. [redacted] (Gide 50), who furthermore contends that not all hexagonally shaped cells yield the same technical effect.

124. This panel agrees that, based on the ordinary distribution of the burden of proof, the claimant must present evidence for the alleged lack of a technical effect. The party asserting

the invalidity of the patent must prove the relevant constituent facts in order to rebut the presumption of validity accorded to the granted patent.

125. The claimant fails to provide such evidence and the reported declarations do not appear to be conclusive as the reference to Prof. [redacted] declaration seems to be generic, lacking a specific indication of the relevant passage. Nevertheless, the fact that a feature is not sufficient for achieving a specific technical effect does not mean that this feature is not relevant.

126. Moreover, when commenting on four different shapes of hexagonal cells described in the Prof. [redacted] declaration, Prof. [redacted] clarifies that "the skilled engineer would recognise that feature group 1.2 of claim 1 is not limited to perfectly geometric hexagons, but the skilled engineer would also read this claim in a sensible way and would not understand this to extend to all possible forms of hexagonal shapes".

127. Additionally, both Prof. [redacted] and Dr. [redacted] (Gide 57) acknowledge that the skilled engineer would understand that several features (e.g. the angle between connecting angled struts, the thickness of these struts, and their number) impact the relative diameter and strength of the crimped valve. However, this acknowledgement does not lead to the conclusion that a frame entirely made up of hexagonal cells lacks a technical effect.

128. It must be added that the skilled person would understand the technical effect conferred by the honeycomb structure of the frame described in para. [0038] to be a general teaching which applies generally to such structures and, hence, such skilled person would not consider the technical effect of the honeycomb structure to be limited to the frame dimensions of the specific embodiment described therein.

Auxiliary request II: lack of inventive step. Hexagonal cells in heart valves.

129. The claimant points out that EP '825 discloses an obvious and alternative solution to the technical problem, citing the use of frames made up entirely of hexagonal cells, which were already known (see, in particular, 'Dimatteo' and the 'Fontaine's stent') and, in addition, 'Levi' would have encouraged the skilled person to obtain hexagonal cells also in the intermediate rows of the frame and not only in the upper and lowermost row. The counterclaimants note that also 'Colibri' valve discloses a frame of a prosthetic heart valve 'predominantly' consisting of hexagonal cells.

130. The assessment of the inventive step must be carried out in accordance with Article 56 'EPC', which states that '[a]n invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art'. Hence, it is necessary to determine whether, given the state of the art, a person skilled in the art would have arrived at the technical solution claimed by the patent using their technical knowledge and carrying out simple operations. Inventive step is assessed in terms of the specific problem encountered by the person skilled in the art (see Decision of the Paris Local Division issued on 3 July 2024, case UPC_CFI_230/2023).

131. Both the claimant and the counterclaimants argue that using a frame geometry exclusively made of hexagonal cells would have been an obvious alternative based on the established prior art demonstrating that hexagonal cells had already been used in heart valves and that it would be a mere design choice to extend the length of the side struts (or rather connection

portions) without requiring any inventive step. The prior art would sufficiently motivate this approach because it would have been known that hexagonal cells have a low foreshortening and provide a low crimping profile.

132. As previously indicated, frames of heart valves that comprise hexagonal cells were disclosed at the time of the application of the patent at issue but were only used in combination with (intermediate) rhombic cells.

133. However, the mere use of hexagonal cells in the frame of heart valves does not lead to the conclusion that for the person skilled in the art it would be obvious to employ a frame entirely made of hexagonal cells to address the problem of reducing the crimping profile of a prosthetic heart valve.

134. In fact, the teachings of the prior art disclose various solutions for reducing the crimping profile of a valve, but do not suggest that modifying the geometry of the frame as claimed in claim 1 of auxiliary request II would be an obvious approach to address this problem. One the underlying objectives of 'Levi' is to reduce the crimping profile of the valve (para. [006]) and for this purpose 'Levi' discloses several hybrid frames that each comprise hexagonal cells and intermediate rhombic cells. 'Levi' is thus aware of hexagonal cells but deliberately chooses also to use intermediate rhombic cells in order to provide a structure for the collapsed frame that tapers from the outflow end to the inflow end (see para. [061] and Figs. 53 and 54). The advantage of this solution is that a homogenous crimping profile is obtained when an outer skirt is added at the inflow end (see para. [085] and Fig. 56).

135. Thus, replacing the intermediate rhombic cells with hexagonal cells would not be consistent with the teaching of 'Levi' and, therefore, would not be considered obvious by the person skilled in the art when addressing the problem of reducing the crimping profile of the frame of a heart valve.

136. Additionally, it should be noted that 'Levi' is also aware of the fact that larger angles between struts, as present in hexagonal cells, tend to increase the force required to expand the frame and thus the radial strength (para. [058] and Figs. 15A and 15B). However, 'Levi' does not consider converting all cells to a hexagonal shape based on this feature, but instead utilizes it in the topmost row – where a hexagonal cell is present – to control the expansion of the frame.

137. The counterclaimants rely on the expert opinion provided by Prof. [redacted] (HLNK 38), Prof. [redacted] (HLNK 38a) and Prof. [redacted] (HLNK 38b). However, these declarations do not appear conclusive, as they fail to convincingly demonstrate that it would be obvious for a person skilled in the art to achieve a favourable crimping profile of the frame by making this frame entirely of hexagonal cells.

138. In conclusion, the prior art teachings on heart valves and, in particular, concerning the structure of the frame do not provide any motivation to alter the shape of (some of) the cells to an all-hexagonal configuration.

Auxiliary request II: lack of inventive step. Hexagonal cells in stents.

139. The claimant points out that catheter-based prosthetic valves were developed by combining the technology of valves with leaflets with the frame technology used in vascular stents. It submits that both stents and prosthetic valve frames require similar properties, such as a small crimping profile, good radial strength and stability during crimping and expansion. and asserts that several stents were entirely made of hexagonal cells and demonstrated excellent radial strength and minimal crimping profile. The claimant argues that these facts were common general knowledge in respect of heart valves at the priority date (and even more so at the filing date) of EP '825.

140. The claimant relies, in particular, on the stent disclosed by Fontaine in an article entitled "Vascular Stent Prototype: Results of Preclinical Evaluation", published in the January 1996 edition of the Journal of Vascular and Interventional Radiology (Gide 35) and argues that the person skilled in the art would have been aware of this paper as either common general knowledge or prior art in the closely related technical field of vascular stents.

141. Both parties agree that transcatheter aortic valve replacement (TAVR) (also referred to as transcatheter aortic valve implantation (TAVI) or percutaneous aortic valve replacement (PAVR) was originally developed by combining vascular stent technology with the surgical leaflet valve technology developed for surgical aortic valve replacement (SAPR).

142. In view of this, despite the significant evolution of TAVRs and the distinct requirements for crimping on a balloon of a delivery device and deployment at the implantation site within the heart, which differentiate TAVRs from stents as separate fields, the person skilled in the art would be aware of the vascular stent prior art. This includes in particular familiarity with the relevant references and commercial products in the stent field. However, such person would always bear in mind that stents and heart valves are very different devices with very different requirement profiles. Therefore, a reference to the prior art in the stent field would require careful consideration and a strong motivation for application to heart valve technology.

143. However, even when considering the prior art in the stent field, it would not be obvious for the person skilled in the art and versed in both technologies to solve the technical problem of reducing the crimping profile of the heart valves by using a frame made up entirely of hexagonal cells.

144. Paying particular attention to Fontaine's article, the study aimed to develop a prototype balloon-expandable stent intended for vascular and biliary applications which combined "the profile and flexibility of the Wallstent device with the radial hoop stent of the Palmaz stent", exhibiting excellent radiopacity and whose "proprietary design minimizes profile and maximizes expansion ratio".

145. The honeycomb design pattern is not explicitly described therein, and its use appear to focus on its capability to provide light weight, flexibility and, particularly, high stress loading (see page 32).

146. It follows that the technical problem addressed by Fontaine's study differs from the one solved by the patent at issue. Fontaine aimed to develop a device that is both flexible and radially resistant, while the patent focuses on a smaller crimping profile.

147. In fact, the Fontaine stent exhibits high flexibly, in particular in the partially expanded state (Fig. 7), allowing for “an almost 180° bend” (page 31). Such flexibility is not required for heart valves which are introduced through the femoral artery and would in fact be considered disadvantageous because high flexibility may impede a safe anchoring of the valve in the aortic annulus.

148. Furthermore, radial strength plays different roles in vascular stents and in aortic valves: in the former devices, it fulfils the technical function of maintaining the opening of the vessel and preventing restenosis, while in the latter, it ensures tight closure and prevents blood reflux. Therefore, achieving a very high radial strength, which in the Fontaine stent is obtained upon full expansion of the stent so that the hexagonal cells “assume a boxlike configuration, with two vertical and two nearly horizontal struts (Fig. 6)”, would be undesirable for heart valves as it might damage the valve’s leaflet structure and prevent the device from properly fulfilling its function. Hence, Fontaine’s article demonstrates how the honeycomb pattern allows for an increase in the device’s capability to maintain the opening of the vessel, but there is no indication – neither in this document nor in the prior art – of whether the teaching is also applicable to heart valves.

149. The claimant argues that the Fontaine stent discloses a device with a low crimping profile and, therefore, provides for a solution to the technical problem of the patent at issue. The claimant specifically refers to Fig. 8 of Fontaine's article, which illustrates the stent's expansion ratio and shortening in its nominal form compared to its expanded form.

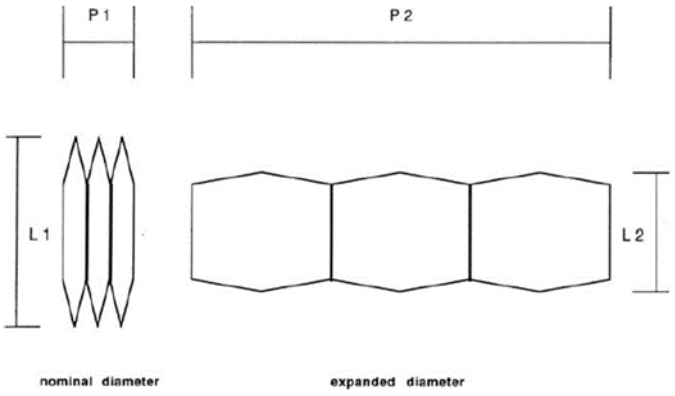


Figure 8. Diagram demonstrates the prototype cell shape in nominal format (left) and expanded format (right). The expansion ratio (P1:P2) is approximately 6:1, and the shortening ([L1 – L2]/L1) is approximately 35%.

150. However, this panel notes that in Fontaine stent the lower crimping profile is derived from the use of a new “proprietary design” (see pages 29 and 32) and not explicitly from the use of a honeycomb pattern itself. The terms ‘proprietary design’ and ‘honeycomb pattern’ cannot be understood as having the same meaning. In fact, design encompasses a combination of a plurality of features (such as, for example, the overall shape of the product, the material used, etc.), so the geometry of the external walls of the product is only one of these.

151. However, this panel notes that in Fontaine stent, the reduction of the crimping profile is derived from the use of a new “proprietary design” (see pages 29 and 32) and not explicitly from the use of a honeycomb pattern alone. The terms ‘proprietary design’ and ‘honeycomb pattern’ cannot be considered synonymous. In fact, design encompasses a combination of a plurality of features (such as, for example, the overall shape of the product, the material used, etc.), where the geometry of its external walls is only one of such features.

152. It follows that it cannot be assumed that the effect resulting from the use of a specific design is necessarily attributable to the use of a certain geometry for the external walls. Therefore, Fontaine's article does not teach that the reduced crimping profile of the device derives from the use of a frame made up entirely of hexagonal cells.

Auxiliary request II: lack of inventive step. Final remarks.

153. The panel is aware that in order to assess the inventive step challenge, the 'EPO' and some national jurisdictions apply the so-called 'problem-solution approach'. Under this approach, the judge determines the 'closest prior art', then defines the 'objective technical problem' to be solved and finally considers whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person. This test is not explicitly provided for in the 'EPC' and, therefore, does not appear to be mandatory.

154. Regardless, applying the "problem-solution approach" to the present proceedings would not lead to a different conclusion.

155. Indeed, the panel identifies 'Levi' as the closest prior art because it addresses the same technical problem as the patent at issue and falls within the same field as the claimed invention. The same considerations regarding the alleged lack of inventive step due to the disclosure of hexagonal cells in heart valves are equally applicable.

Conclusions.

156. For these reasons, the grounds of invalidity raised by both the claimant and the counterclaimants against the patent at issue, as amended by the auxiliary request II submitted on 12 April 2024, are unfounded and any arguments of the parties which have not been specifically addressed must be deemed absorbed.

157. Therefore, the patent EP '825 shall be maintained in the amended version (Auxiliary request II), which reads as follows:

"1. A system comprising:
a prosthetic heart valve (100) comprising:
a collapsible and expandable annular frame (102), configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body;
wherein the frame (102) is made of a nickel-cobalt-chromium-molybdenum alloy and comprises a plurality of rows (112a, 112b, 112c, 112d) of angled struts (114), the angled struts 10 (114) joined to each other so as to form a plurality of rows of hexagonal cells, wherein the frame (102) is made up entirely of hexagonal cells, and wherein each of the hexagonal shaped cells is defined by six struts (144, 146, 148), including:
two opposing side struts (144) extending parallel to a flow axis of the valve (100),
a pair of lower angled struts (146), extending downwardly from respective lower ends of the 15 side struts (144) and converging toward each other, and
a pair of upper angled struts (148) extending upwardly from respective upper ends of the side struts (144) and converging toward each other; and
a delivery catheter comprising an inflatable balloon;

wherein the prosthetic heart valve (100) is crimped in its radially compressed state on the 20 balloon of the delivery apparatus, and wherein the balloon is configured to be inflated to expand to radially expand the prosthetic heart valve (100) at the desired deployment location, preferably within a native aortic valve,
wherein the frame (102) of the prosthetic heart valve (100) does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away 25 from an inflow end (108) or an outflow end (110) of the frame (102) for mounting the frame (102) to the delivery catheter.

2. The system (100) of claim 1, further comprising a leaflet structure comprising a plurality of leaflets (104), and a sealing skirt (106).

3. The system (100) of claim 2, wherein each leaflet (104) has a scalloped lower edge portion (134) that is secured to the frame (102) and/or the skirt (106) by sutures.

4. The system (100) of any of claims 2 to 3, wherein each leaflet (104) has a tab portion (116) adjacent an upper free edge of the leaflet (104).

5. The system (100) of any of claims 2 to 4, wherein the skirt (106) is made of a fabric, the fabric preferably made of PET or UHMWPE."

***Costs*.**

158. As the revocation action was dismissed solely because the defendant submitted a limitation of the patent during the proceedings, the panel deems it appropriate that the costs of the Court and of the parties shall be borne by the claimant and by the counterclaimants, jointly, in the amount of 60%, and by the defendant in the amount of 40%.

159. The panel notes that during the interim conference, the value of the revocation action for the purpose of applying the scale of ceilings for recoverable costs is set at 8,000,000 euros. The same valuation has been applied to the counterclaims for revocation, collectively considered.

DECISION

The Court,

a) rejects the revocation action filed by Meril Italy Srl on 4 August 2023 and the counterclaims for revocation filed by Meril GmbH and Meril Life Sciences Pvt Ltd on 2 November 2023;

b) maintains EP '825 as amended by auxiliary request II submitted on 12 April 2024;

c) orders that the Registry shall send a copy of this decision to the European Patent Office and to the national patent office of any Contracting Member States concerned, after the deadline for appeal has passed;

d) orders that the costs of the proceedings shall be borne by the claimant and the counterclaimants, jointly, in the amount of 60%, and by the defendant for the remaining fraction.

Issued on 19 July 2024.

Paolo Catallozzi	Presiding judge and judge-rapporteur	Paolo Catallozzi Firmato digitalmente da Paolo Catallozzi Data: 2024.07.19 16:05:38 +02'00'
Tatyana Zhilova	Legally qualified judge	Tatyana Zhilova Signature numérique de Tatyana Zhilova Date : 2024.07.19 14:47:12 +02'00'
Stefan Wilhelm	Technically qualified judge	Stefan Maria Wilhelm Digitally signed by Stefan Maria Wilhelm Date: 2024.07.19 15:11:48 +02'00'
Margaux Grondein	Clerk	Unified Patent Court Einheitliches Patentgericht Juridiction unifiée du brevet Signature numérique de MARGAUX MARIE-ANGE GRONDEIN Date : 2024.07.19 15:20:00 +02'00' Paris Central Division Local Coordinator & Clerk

ORDER DETAILS

Order no. ORD_598365/2023 in ACTION NUMBER: ACT_551308/2023
UPC number: UPC_CFI_255/2023
Action type: Revocation Action
Related proceeding no. Not provided Not provided
Not provided Not provided