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 20 October 2025
in the revocation action No. ACT_22275/2024
UPC_CFI_189/2024
and in the counterclaim for infringement No. CC_43159/2024
UPC_CFI_434/2024

HEADNOTES:

1. The assessment of the inventive step requires: first, the identification of the objective problem underlying the claimed invention, which must be carried out in light of the patent's specification; second, the identification of the state of the art at the time of the claimed invention, which can be represented by one or more realistic starting points and is left to the initiative of the parties; and, finally, whether it would have been obvious for the person skilled in the art to arrive at the claimed solution.

2. For the assessment of the inventive step, a "holistic approach" – that is, a broader way of assessing non-obviousness by considering the invention as a whole, rather than just focusing upon isolated distinguishing features – appears, in general, to be more appropriate.

3. A realistic starting point is a document "of interest" for solving the objective problem. In this regard, it may be assumed that realistic starting points, in general, are the pieces of evidence which disclose the main relevant features as those of the challenged patent and for that reason have constituted the basis for the developing of the inventive idea and/or which address the same or a similar underlying problem.

4. While a general injunction to restrain future infringements is the normal remedy for the patentee where its patent is infringed, the Court has a discretionary power and must refuse granting an injunction or issuing corrective measures where it would be disproportionate or unreasonably detrimental to the interests of third parties.

5. Excluding a certain product from the range of those available to medical practitioners for the performance of certain procedures does not engage in itself a relevant public interest, because it

does not necessarily carry with it the implication that, should the choice not been available, all the patients could not be treated adequately with the remaining products.

KEYWORDS: inventive step; injunction relief; public interest.

CLAIMANTS, DEFENDANTS IN COUNTERCLAIM:

Meril Life Sciences Private Ltd. - M1-M2, Meril Park, Survey No.135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396191, India

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

Meril Italy S.r.l. - Piazza Tre Torri 2, 20145 Milano, Italy

all represented by Emmanuel Larere and Jean-Hyacinthe de Mitry, Cabinet Gide Loyrette Nouel AARPI, and by Jonathan Stafford and Gregory Carty Hornsby, Marks & Clerck LLP

DEFENDANT, CLAIMANT IN COUNTERCLAIM:

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

represented by Siddharth Kusumakar, Tessa Waldron and Bryce Matthewson, Powell Gilbert (Europe) LLP, by Adam Rimmer, Powell Gilbert LLP, and by Jonas Weickert and Bernhard Thum, Thum & Partner

PATENT AT ISSUE:

European patent n. 4 151 181 B1

PANEL:

Panel 2

Paolo Catallozzi	Presiding judge and judge-rapporteur
Tatyana Zhilova	Legally qualified judge
Elisabetta Papa	Technically qualified judge

DECIDING JUDGE:

This decision has been issued by the panel.

SUMMARY OF FACTS:

1. On 15 May 2025 Meril Life Sciences Private Ltd., Meril GmbH and Meril Italy s.r.l. filed a revocation action against Edwards Lifesciences Corporation before this Central Division, registered as No. ACT_22275/2024 UPC_CFI_189/2024, requesting that the Court orders the revocation of EP 4 151 181 B1 ('EP 181') in its entirety with effect in all territories of those Contracting Member States for which 'EP 181' has effect and issues the consequences statements with regard to the publishing of the decision, its registration to the European Patent Office registry and the costs of the proceedings.

2. The patent at issue was filed on 5 October 2011, as a third-generation divisional application originating from EP 3 960 126 A1, which in turn had been filed as a divisional application of EP 3 669 829 B1, which in turn had been filed as a divisional application of the parent application EP 2 624 785 B1. This patent application was filed as an international application WO 2012/048035 A2 (WO '035). The patent claims priority from two patent applications of 5 December 2010 (US 39010710 P) and 15 July 2011 (US 2011/61508513 P). The date of publication and mention of the grant of the patent is 28 February 2024.

3. The patent relates to a prosthetic heart valve and to a delivery assembly including the valve and has 13 claims, one of which is independent, and the remaining are dependent.

4. Its independent claim 1 reads as follows:
"An implantable prosthetic valve (10) that is radially collapsible to a collapsed configuration and radially expandable to an expanded configuration, the prosthetic valve (10) comprising:
an annular frame (12);
a leaflet structure (14) positioned within the frame (12); and
an annular outer skirt (18) positioned around an outer surface of the frame (12), the outer skirt (18) comprising an inflow edge (160) secured to the frame (12) at a first location, an outflow edge (162) secured to the frame (12) at a second location, and an intermediate portion between the inflow edge (160) and the outflow edge (162);
wherein when the valve is in the expanded configuration, the intermediate portion of the outer skirt (18) comprises slack in the axial direction between the inflow edge (160) of the outer skirt (18) and the outflow edge (162) of the outer skirt (18), and when the valve is collapsed to the collapsed configuration, the axial distance between the inflow edge (160) of the outer skirt (18) and the outflow edge (162) of the outer skirt (18) increases, reducing the slack in the outer skirt (18) in the axial direction".

5. In the statement for revocation the claimants argue that the patent is not valid because its subject matter extends beyond the content of the earlier application as initially filed, lacks novelty and lacks inventive step.

6. On 17 July 2024 the defendant lodged the defence to revocation. The defendant requested that: I) the revocation claim be dismissed; II) 'EP 181' be maintained: a) as granted; or b) in the alternative, based on one of the proposed amendments of the claims (Auxiliary Requests 1 to 9 and 1' to 8'); or c) further in the alternative, in part based on the independent validity of one or more of its dependent claims in combination with independent claim 1 as granted according to the dependencies of the claims as granted and insofar as 'EP 181' is maintained as such; d) yet further in the alternative, in part based on the independent validity of one or more of its dependent claims in combination with independent claim 1 of one of the auxiliary requests

according to the dependencies of the claims of the respective auxiliary request and insofar as 'EP 181' is maintained as such.

7. With separate written pleadings the defendant filed an application to amend the patent and a counterclaim for infringement of the patent at issue by offering and selling 'Octacor THV' together with 'Navigator Inception' in countries where the Unified Patent Court Agreement ('UPCA') is in force, requesting an injunction against the claimants as well as the other consequential relief measures.

8. With its reply to defence to revocation and defence to the application to amend the patent, filed on 30 September 2024, the claimants requested that the Court rejects this application to amend the patent as inadmissible or as the Auxiliary Requests are not allowable, and reiterated its request to revoke the patent at issue in its entirety for all the territories of the Unified Patent Court ('UPC') Contracting Member States for which the patent has effect.

9. With separate brief the claimants requested the Court to dismiss the counterclaim for infringement as none of the claims of the patent is infringed. In the alternative, they requested the Court to reject Edwards' request for an injunction pursuant to Article 63 'UPCA' as it would be disproportionate and, further in the alternative, to refer the issue on the interpretation of Article 3, para. 2, of the Directive (EC) 2004/48 on the enforcement of intellectual property rights ('Enforcement Directive') to the Court of Justice of the European Union for a preliminary ruling, to exclude any injunction in return for a reasonable compensation of payment under the circumstances of the case and the economic value of a hypothetical license and, in the utmost alternative, to exclude from such injunction the 'Octacor' system in the sizes in which other self-expandable valves are not available, to grant a grace period, a stay of the injunction for at least 12 months, and an exception for particular patient groups for whom the 'Octacor' system is the only suitable device, and to deny to grant Edwards Lifesciences Corporation a penalty for each violation of the Court's decision.

10. After the parties submitted the remaining written pleadings provided by the written procedure, Edwards Lifesciences Corporation requested, under Rule 263 (1) of the Rules of Procedure ('RoP'), leave to amend its counterclaim in the way that it explicitly extends it to the new product Myval Octapro THV ('Octapro THV') and the Navigator Pro THV delivery system ('Navigator Pro'), together, the 'Octapro System'. The judge-rapporteur granted the request, allowing the parties to exchange further written pleadings on this matter.

11. After the closure of the written procedure an interim conference was held on 17 April 2025 in which the judge-rapporteur took several decisions, in particular on late filed grounds of invalidity and documents which were debated by the parties during the written procedure and ordering the producing of samples of 'Octator' valve, took note of the defendant's withdrawal of request II d), and identified certain main issues that needed to be addressed at the oral hearing with particular attention.

12. Finally, the oral hearing was held on 11 September 2025.

GROUNDS FOR THE DECISION:

Opposition proceedings before the 'EPO'.

13. On 2 July 2025 – that is, after the written procedure was closed and the interim conference held – the defendant informed the Court of the issuance of the European Patent Office ('EPO') Opposition Division's preliminary opinion regarding the validity of the patent at issue and submitted the relevant document, issued the day before (EDW-EPO-01). The Court had not been previously informed of the existence of opposition proceedings before the 'EPO', despite the applicant having stated in its originating application that the relevant deadlines had not yet expired, since neither party had highlighted this circumstance in their written submissions.

14. Rule 295 (a) 'Rop' states that the Court may stay proceedings where it is seized of an action relating to a patent which is also the subject of opposition proceedings or limitation proceedings (including subsequent appeal proceedings) before the European Patent Office or a national authority where a decision in such proceedings may be expected to be given rapidly.

15. As pointed out in the order of the Court of Appeal of 28 May 2024, UPC_CoA_22/2024, "the mere fact that the revocation proceedings before the UPC relate to a patent which is also the subject of opposition proceedings before the EPO is not sufficient to allow an exception to the principle that the Court will not stay proceedings. The Convention on the Grant of European Patents and the UPCA allow third parties to challenge the validity of a patent in both opposition and revocation proceedings and allow them to initiate revocation proceedings while opposition proceedings relating to the same patent are pending". This order further stated that "The term 'may' in Article 33(10) UPCA and Rule 295(a) RoP means that the Court has a discretionary power to stay the proceedings when a rapid decision may be expected from the EPO. Whether or not a stay is granted depends on the balance of the interests of the parties."

16. In the present case, neither party has requested a stay of the proceedings, thus implicitly demonstrating their interest in a prompt decision by the Court. Furthermore, at the time the Court was informed of the pending opposition proceedings before the 'EPO', the proceedings were already at an advanced stage, with the written phase concluded, the interim conference held, and the oral hearing imminent. Lastly, the Court observes that any stay of the proceedings would have the effect of postponing the decision on the infringement action – which is also ready to be decided – thereby frustrating the patent proprietor's interest in a swift protection of its exclusive right.

17. The balance of the interests of the parties – as assessed from the aforementioned factual circumstances – leads this Court to exercise its discretion against a stay, and thus not to consider the conditions met for an exception to the principle that the Court will not stay revocation proceedings pending opposition proceedings.

Claimants' Rule 9 'RoP' application dated 12 November 2024.

18. On 12 November 2024, the plaintiffs filed an application, pursuant to Rule 9 'RoP', in which they commented on the rejoinder to the revocation filed by the opposing party. Specifically, with that filing, they requested that the Court dismiss Edwards' request not to admit certain documents submitted by the claimants in the Reply to the Defence to the Statement for Revocation and not to admit added matter arguments raised by the therein (Req. 4 of the Rejoinder), as well as to

state that new arguments filed by the defendant in its Rejoinder are not admissible as they are not responsive to the claimants' Reply.

19. With regard to the latter issue, they requested that the Court, should it find that those arguments raised by the defendant were validly introduced into the proceedings, rule them to be unfounded and, for that purpose, they set out the reasons that would demonstrate such a lack of merit.

20. At the oral hearing, the defendant raised the issue of the inadmissibility of that filing, arguing that it amounted to a further round of pleadings not permitted under the Rules of Procedure, in the absence of a prior authorisation from the judge-rapporteur.

21. In this regard, this Court acknowledges that, while a party may at any time, if necessary by way of an application pursuant to Rule 9 'RoP', ask the judge to take a position on the admissibility of specific arguments, factual allegations, and document productions by the opposing party and, more generally, urge the exercise of case management powers, a party may not file written pleadings in which it further develops defensive arguments other than those specifically provided for in the Rules of Procedure, unless it has made a reasoned request to the judge-rapporteur pursuant to Rules 36 or 58 'RoP' and the judge-rapporteur has assented to it in the manner specified therein.

22. This, however, does not preclude the parties from elaborating their legal arguments and responding to the opposing party's arguments in detail during the oral hearing.

23. It follows that the application of 12 November 2024 is admissible in the part in which it prompts the judge's decision to assess the admissibility of certain allegations on the grounds of their timeliness and, following that interpretation, the judge-rapporteur correctly proceeded with that assessment during the interim conference.

24. However, it is not admissible in the part in which it provides a further elaboration and development of the defensive arguments already set out in the previous written submissions and, specifically, in the part in which it contests the arguments set out by the defendant in the Rejoinder regarding claim construction and the skilled team: to this extent the application of 12 November 2024 is excluded from consideration.

Late filed grounds of invalidity: added subject-matter in claim 7.

25. The defendant complains that only in their Reply (para. 60-61) the claimants raised, with reference to claim 7, a new line of attack for invalidity of the patent for infringement of Article 123 (2) of the European Patent Convention, in relation to the omission of the features consisting of "the suturing of the lower edge of the outer skirt to the lower edge of the inner skirt". The claimants object that it added only new arguments to the ground of invalidity already filed and, anyway, that the defendant replied on the issue, so no unfairness came from these new allegations.

26. In the interim conference (see order issued pursuant to Rule 105 'RoP') the judge-rapporteur noted that in revocation actions the claimant is required to specify in detail the grounds of invalidity and the underlying facts that allegedly affect the contested patent, as well as the prior art documents relied upon to support any allegation of lack of novelty or inventive step, in the

initial Statement for Revocation under Rule 44 'RoP'. This defines the subject matter of the dispute and enables the defendant to understand the allegations made against it and to prepare an adequate defence, as well as allowing the Court to determine the scope of its jurisdiction in relation to the claim. Consequently, the claimant cannot introduce new lines of attacks as this would result in a broadening or, in any case, a modification of the subject matter of the dispute, constituting an amendment of the case and falling within the scope of Rule 263 'RoP'.

27. From these principles the judge-rapporteur stated that the issue concerning the added matter in claim 7 should have filed with the statement for revocation as it constitutes a new and autonomous line of attack and, therefore, it must be excluded from the subject-matter of the proceedings.

28. The Court confirms this assessment and its reasoning, which is consistent with 'UPC' case-law that the in revocation claims new grounds of invalidity of the attacked patent cannot be introduced after lodging the first written submission of the written procedure (see LD Hamburg, 30 April 2025, UPC_CFI_278/2023; LD Dusseldorf, 7 March 2025, UPC_CFI_459/2023; CD Paris, 21 January 2025, UPC_CFI 311/2023; LD Paris, 11 December 2024, UPC_CFI_395/2023).

29. This because Rule 44 'RoP' states that the statement for revocation shall contain "… (e) one or more grounds for revocation, which shall as far as possible be supported by arguments of law, and where appropriate an explanation of the claimant's proposed claim construction; (f) an indication of the facts relied on; (g) the evidence relied on, where available, and an indication of any further evidence which will be offered in support …". Similar requirements are requested in the statement of claim as Rule 13 'RoP' provides that this written pleading shall contain "an indication of the facts relied on" [lett. (l)], "the evidence relied on" [lett. (m)] and "the reasons why the facts relied on constitute an infringement of the patent claims, including arguments of law and where appropriate an explanation of the proposed claim interpretation" [lett. (n)]. In general, the parties are under an obligation to set out their full case as early as possible (Preamble 'RoP', para. 7, last sentence).

30. This legal framework introduces the so-called 'front loaded' procedural system whereby a claimant is required to concretely elaborate their arguments and evidence in their first written pleading (see, on this issue, Paris CD, decision issued on 29 July 2024, UPC_CFI_263/2023; Brussels LD, order issued on 8 July 2024, UPC_CFI_376/2023). The *rationale* behind these provisions is to ensure that the defendant is aware of the factual elements and grounds upon which the claim against them is based, as well as the evidence available to the claimant, thereby enabling them to prepare an adequate defence, and, at the same time, to expedite the proceedings. This is one of the primary objectives of the Court, which would be undermined if the claimant were permitted to gradually introduce new factual circumstances, new legal arguments, or new evidence into the proceedings.

Late filed argument: identification of the person skilled in the art and claim construction.

31. The claimants argue that the arguments developed by the defendant in its rejoinder regarding the identification of the skilled team (paras. 40-57) and the claim construction (paras. 75-110) are not admissible as they do not respond to the matters raised in the reply and did not appear in its initial defence, making them entirely new. The defendant objects to this.

32. In the interim conference, the judge-rapporteur found that these arguments were timely filed and, as such, admissible, as they constituted a response to the new arguments and new evidence adduced in the proceedings by the claimants with their reply.

33. The Court agrees with the judge-rapporteur.

34. Pursuant to Rule 52 'RoP', with the Rejoinder the defendant may (only) respond to the matters raised in the Reply. This provision allows the defendant, in light of the principle of fairness, to raise new arguments, facts, and documents, insofar as they are considered capable of supporting their stances, which were already timely taken and disputed by the claimant. The admissibility of these late filed arguments extends also to arguments that, while not constituting a direct response to the defendant's arguments, are closely related to them (see CD Paris, 27 November 2024, UPC_CFI_308/2023).

35. Furthermore, it must be borne in mind that in the assessment on whether an argument is newly introduced or is raised as a mere reaction to previously filed arguments a generous standard is to be applied (see CD Paris, 28 February 2025, UPC_CFI_312/2023).

36. All this is consistent with the principles set by the Court of Appeal in the decision of 21 November 2024, UPC_CoA_456/2024, according to which while the parties are required to set out their case as early as possible in the proceedings, nevertheless specific new arguments may be admitted into the proceedings in consideration of specific circumstances of the case.

37. With regard to the first issue, the Court points out that with the rejoinder, the defendant did not propose a different figure for the person skilled in the art from the one identified in the defence to revocation, which was a specialist team comprising a medical device engineer with an interest in prosthetic heart valves and an interventional cardiologist familiar with catheter-based cardiac procedures, wherein both specialists have average knowledge and ability in the field of delivery catheters. The defendant merely, in relation to the production of the opinion of [redacted] (Gide [redacted] and its reliance on by the claimants, noted its inconclusiveness as it came from a biomedical engineer in circumstances in which it is the interventional cardiologist in the skilled team rather than the biomedical engineer who is responsible for identifying the clinical parameters by which the transcatheter heart valves – that is, the embodiments disclosed by the patent – should be designed and for directing the latter as to the critical factors which impact upon the safety, durability and functionality of these valves.

38. This does not constitute a new identification of the figure of the skilled person in the art, but rather a clarification of the role of the team members who define it, imposed by the need to reply to the new document filed by the opposing party in the immediately preceding submission.

39. With reference to the arguments developed in the rejoinder regarding claim construction, the defensive arguments set out in the rejoinder constitute a reaction to the content expressed in para. 29 of the Reply and a clarification of its interpretation of the contested features, and for that reason must be considered permitted in light of the aforementioned legal framework.

Late filed documents.

40. The defendant requested the Court not to admit into the proceedings, as late filed, the documents submitted by the claimant with its reply as Gide 94 to 98. The claimants objected to

this, highlighting that the necessity to file these documents arose from the defendant's defence. Additionally, the defendant requested that [redacted] declaration [redacted] as enclosed in their Rejoinder, is admitted into the proceedings as well.

41. In the interim conference the judge-rapporteur considered that although in the revocation actions the claimant is required to concretely elaborate their arguments and evidence in its first written pleadings according to Rule 44 'RoP', in certain situations, following the defence raised by the defendant, the claimant may need to allege new facts and to produce new evidence, insofar as they are considered capable of supporting the main facts already timely alleged and disputed by the defendant.

42. The judge-rapporteur thus concluded that the documents submitted by the claimants in their reply, consisting of an expert opinion released by [redacted] on 13 September 2024 (Gide [redacted] the Edwards Lifesciences 2010 Annual Report (Gide 95) and academic/scientific papers (Gide 96 and 97), seemed to contain arguments and evidence regarding the claim construction of the patent in suit and the cited prior art, as well as the identification of the common general knowledge which were intended to contrast and react to the arguments raised by defendant in its defence to revocation. To this extent, they should not be excluded from the proceedings. The same applied to said expert declaration of [redacted] filed by the defendant.

43. The panel confirms the judge-rapporteur's assessment, fully agreeing with his reported reasoning.

44. In this regard, the panel refers to the decisions issued by this Central Division on 21 January 2025, UPC_CFI_311/2023, and 27 November 2024, UPC_CFI_308/2023, which affirmed that, following the defence raised by the defendant, the claimant may need to produce new evidence which disputes the facts alleged by the claimant or the probative value of the evidence already filed in Court. Similarly, the defendant may submit new evidence in reaction to facts or evidence produced by the claimant in its reply.

Presentations during oral hearing.

45. Consistent with the established practice of this Division, as well as others, the parties were authorized to supplement their oral submissions with a multimedia presentation projected on a screen, in order to better clarify the arguments presented.

46. During the oral hearing, however, the claimants objected that the slides used on behalf of the defendant contained arguments that were additional to those presented during the written proceedings and, as such, were inadmissible because they were late, being contrary to the right to a fair trial and the front-loaded character of the 'UPC' proceedings. In particular, they argued that the notions of 'stress-free reservoir' to interpret the concept of slack and of 'reinforcing strip' to demonstrate the alleged infringement of Auxiliary Request 4, as well as a few drawings which were included in the presentation, had never been introduced before into the proceedings and should be disregarded by the Court as they contained new subject matter.

47. The Court intends to dismiss this request.

48. The purpose of the oral hearing is to allow the parties to explain, clarify and expand upon the arguments made in writing. To this extent, the parties have been permitted to use pleadings

tools for the purpose of a better illustration of their arguments (see order of 17 April 2025, ORD_69231/2024).

49. Against this background, the content of the presentation used by the defendant (as well as the one used by the claimants) does not introduce new arguments but merely served to strengthen the arguments already introduced into the proceedings during the written procedure. Indeed, the use of new terms or illustrations does not give rise to the presentation of new arguments and, therefore, does not constitute an inadmissible extension of the scope of the proceedings where, as in the present case, such terms and illustrations are used as further means to explain with greater immediacy technical aspects already sufficiently illustrated in the written pleadings.

The patent at issue.

50. As previously mentioned, the invention claimed concerns embodiments of a prosthetic heart valve and delivery systems for implanting heart valve (para. [0001] of 'EP 181').

51. The patent explains that the human heart can suffer from various valvular diseases which can require replacement of the native valve with an artificial one and that due to the drawbacks associated with conventional open-heart surgery, percutaneous and minimally invasive surgical approaches, as the implantation of a prosthetic valve by way of catheterization, are garnering intense attention (paras. [0002]-[0005]). In order for the valve to be able to follow the intra-vessel pathway from the point of insertion in the body up to the delivery site at the heart, its dimensions need being temporarily reduced. In particular, the valve needs be brought from an expanded configuration to a collapsed, or crimped, one. In this collapsed configuration, the valve is deformed so that its diameter decreases and its axial length increases.

52. In this regard, an important design parameter of a transcatheter heart valve is the diameter of the folded or crimped profile, as it directly influences the physician's ability to advance the transcatheter heart valve through the insertion artery or vein (para. [0010]).

53. As suggested by the claimants, the features of claim 1 of the patent at issue may be broke down as follows:

(1a) An implantable prosthetic valve (10) that is radially collapsible to a collapsed configuration and radially expandable to an expanded configuration: the prosthetic valve (10) comprising:

(1b) an annular frame (12);

(1c) a leaflet structure (14) positioned within the frame (12);

(1d) and an annular outer skirt (18) positioned around an outer surface of the frame (12), the outer skirt (18) comprising:

(1e) an inflow edge (160) secured to the frame (12) at a first location,

(1f) an outflow edge (162) secured to the frame (12) at a second location,

(1g) and an intermediate portion between the inflow edge (160) and the outflow edge (162);

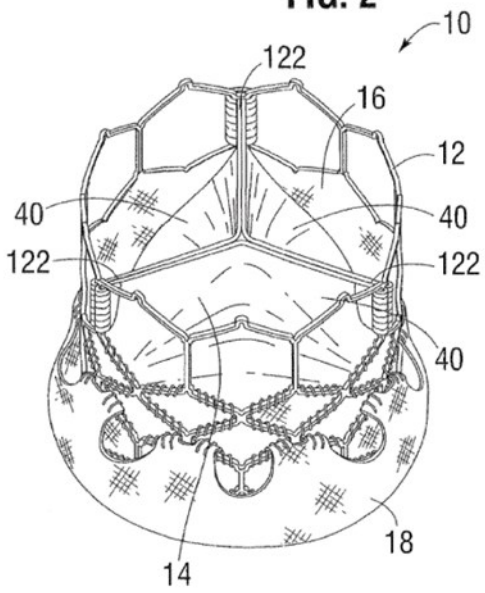
(1h) wherein when the valve is in the expanded configuration, the intermediate portion of the outer skirt (18) comprises slack in the axial direction between the inflow edge (160)

of the outer skirt (18) and the outflow edge (162) of the outer skirt (18),

(1i) and when the valve is collapsed to the collapsed configuration, the axial distance between the inflow edge (160) of the outer skirt (18) and the outflow edge (162) of the outer skirt (18) increases, reducing the slack in the outer skirt (18) in the axial direction.

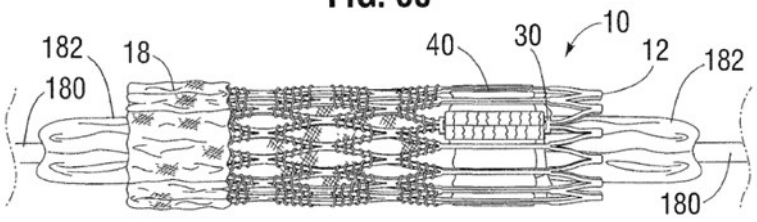
54. In summary, the patent discloses a specific type of prosthetic heart valves which comprise a substantially cylindrical support frame, or stent, upon which flexible leaflets substituting the biological valve flaps are connected (see Fig. 2, reproduced below, wherein the frame is denoted by 12 and individual leaflets by 40). As mentioned above, these prosthetic valves can be delivered *in situ* in the patient's body percutaneously (i.e. without open surgery) by means of a carrier catheter introduced in a peripheral blood vessel.

FIG. 2



55. Fig. 56 copied below shows the valve in the collapsed configuration for delivery to the implantation site.

FIG. 56



56. Once *in situ*, the valve can be brought again to its original, expanded configuration (so with increased diameter and decreased length). This change of configuration can be obtained by virtue of the intrinsic elasticity of the frame or by plastic deformation through and inflatable balloon (In Fig. 56 the delivery apparatus includes a shaft, denoted by 180, upon which the inflatable balloon, denoted by 182, is applied).

Person skilled in the art.

57. The claimants argue that the person skilled in the art is to be identified in a team made of an interventional cardiologist and a biomedical engineer with an interest and experience in the design and construction of prosthetic heart valves, including transcatheter delivery systems. They specify that interventional cardiologists use catheters to treat problems with the heart and associated vessels percutaneously (via needle puncture of the skin as opposed to open surgery), while the biomedical engineer is a medical device product designer.

58. In their reply, they also consider that additional competences may be needed in said team in specific cases, particularly because granted claim 1 is not limited to the field of heart valves.

59. The defendant substantially agrees with the initial identification, but not with the proposed enlargement of the team.

60. The Court agrees with the parties insofar as they consider that the person skilled in the art is to be identified in a team made of an interventional cardiologist and a biomedical engineer with an interest and experience in the design and construction of prosthetic heart valves, including transcatheter delivery systems.

61. The Court does not deem it correct to agree upon the enlargement of team to other competences, as proposed by the claimant, because this proposal was filed with regard to the fact that the claims are not limited to heart valves or to valves for percutaneous delivery. In fact, this assumption now proves moot, as the Court considers that the claims are to be limited to relate exclusively to heart valves, as it will be explained later.

Claim interpretation.

62. With regard to the interpretation of the claims, it must be born in mind that: 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, Court of Appeal, order of 26 February 2024, UPC_CoA_335/2023).

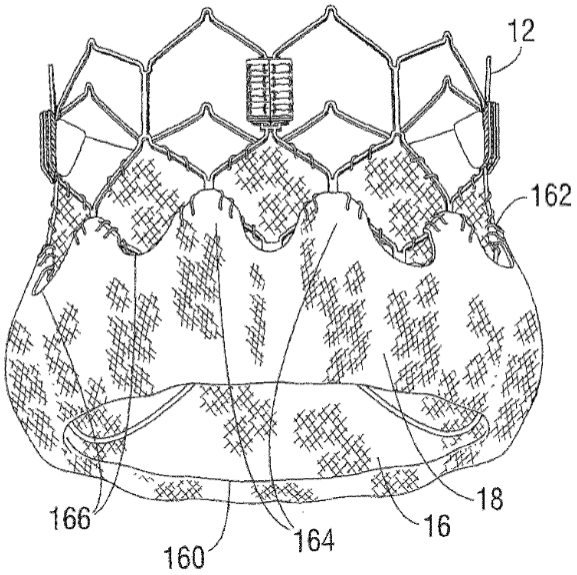
63. The relative assessment must be carried from the point of view of a person skilled in the art, as previously identified.

64. A few features need to be carefully examined as the parties debated about their interpretation and, in any case, relate to relevant aspect of the claimed invention.

65. Feature (1d) reads “an annular outer skirt (18) positioned around an outer surface of the frame (12)”. The claimants assert that the definition of the “outer skirt” requires that the claimed component has not, in any of the collapsed or deployed configuration, parts extending inside the inner space of the frame. Accordingly, feature (1d) would not be reproduced by a valve wherein the outer skirt is connected to the frame, at the valve inflow end, via the inner skirt by suturing respective skirt borders at a location that falls within the inner space defined by the frame. The defendant contends this position as in sharp contrast with the patent disclosure, in particular para. [0063] and Fig. 42.

66. This Court finds that the claimants' interpretation is inconsistent with the only detailed embodiment disclosed in the patent, wherein – see in particular Fig. 42 and para. [0063] – the suture line between the outer skirt (18) and the inner skirt (16) appears located (slightly) within the inner space defined by the frame.

FIG. 42



67. Therefore, feature (1d) must be interpreted as requiring that the outer skirt is generally located outside the frame, but without excluding that portions thereof, in particular end parts, may extend (slightly) inside it.

68. With regard to feature (1e), which reads "an inflow edge (160) secured to the frame (12) at a first location" the claimant assert that the this feature requires a direct connection between the outer skirt and the frame at the claimed first location; in other words, no other component (namely, in our case, the inner skirt) should mediate the connection. The defendant contends this position as in sharp contrast with the patent disclosure, which teaches, as explained previously, that the outer skirt is connected to the frame at its inflow end via the inner skirt.

69. The claimants further argue that features (1e) and (1f), read in combination with feature (1d), require that the full outer skirt, including its inflow and outflow edges, is positioned around the outer surface of the frame.

70. The Court considers that the same considerations illustrated with regard to feature (1d) apply. The claimants' interpretation is inconsistent with the only detailed embodiment disclosed in the patent. In addition, also the literal terms of claim 1 do not require a "direct" securement. Actually, the claimed language does not exclude that the securement locations of the outer skirt to the frame extend inside the frame, as it may be for the inflow edge according to the embodiment shown in Fig. 42 and discussed above.

71. Features (1e) and (1f) require identifying the meaning of the "inflow" and "outflow" edge of the outer skirt. The claimants assert that the "inflow" and "outflow" edges of the outer skirt are not defined in the patent disclosure and that it remains unclear whether they can be equated to the lower and upper edge, respectively, cited in the description. The defendant notes that the skilled

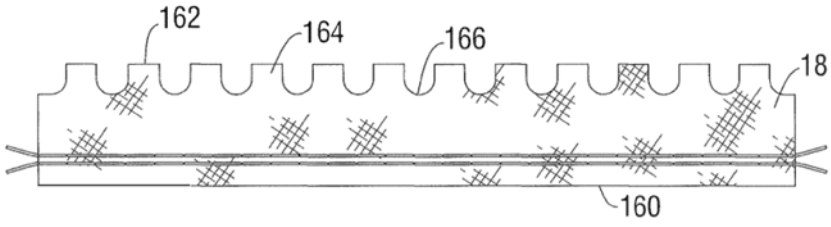
team would readily understand from the teaching of the patent that these terms refer to the outer skirt's lower edge and upper edge, respectively. The defendant explains that these terms are used synonymously throughout the entire description of the patent and that in most figures valves – or valve components – are shown such that the inflow side of the valve is the lower side, and the outflow side is the upper side.

72. The Court acknowledges that in the patent description reference to the "inflow" and "outflow" edges of the outer skirt is only made in para. [0020], which simply reproduces the wording of claim 1. However, the Court is of the opinion that the person skilled in the art would understand any "inflow" or "outflow" feature as related to the assembled valve during operation.

73. From the disclosure of such assembled configuration the person skilled in the art would understand that the skirt longitudinal edges – as identified with reference numbers 160 and 162 in Fig. 41 (copied below) in the non-operative configuration in which the skirt is laid flat – might not exactly coincide with the lowermost and uppermost skirt parts located at the inflow and outflow section of the valve, respectively. In particular, in the only detailed embodiment disclosed – Fig. 41 in conjunction with para. [0063] – the outer skirt (18) is shown in said flat, disassembled view wherein said upper edge (162) and lower edge (160) are identified. When the outer skirt is secured to the frame (Figs. 42-43), the projections (164) of the upper edge (162) are folded inwardly, at their corners, over respective struts of the frame. Consequently, the above-defined upper edge does not fully correspond to the skirt part closer to the outflow edge of the valve (i.e. the uppermost part of the frame).

74. Similarly, in the assembled configuration the lower edge (160) of the outer skirt is sutured to the lower edge of the inner skirt (16). Therefore, the lower edge (160) may extend around the lower (inflow) border of the frame and slightly inside it and thus also the above-defined lower edge of the outer skirt does not fully correspond to the part closer to the inflow edge of the valve (i.e. the lowermost part of the frame).

FIG. 41



75. Moving now to consider the terms of claim 1 as a whole, the "inflow" and "outflow" edges of the outer skirt are introduced as the parts at which the skirt is secured to the frame. However, even if such parts may not exactly correspond to the lowermost (inflow) or uppermost (outflow) skirt portion, the person skilled in the art would understand that the skirt is secured at the frame at its longitudinal edges (identified as upper and the lower in said flat configuration), which edges are each close(r) to a respective outflow or inflow end of the valve/frame.

76. Features (1i) and (1h) require a definition of the term "slack". Para. [0064] clarifies that this term has to be understood ad meaning "excess material".

77. The defendant argues that the “slack” feature implies a bulging outward of the intermediate portion of the outer skirt in the valve expanded configuration and refers to para. [0064] according to which “[…] the outer skirt is configured with excess material which causes the outer skirt to bulge outwardly as the frame foreshortens (i.e., shortens in length) during radial expansion”. Therefore, according to the defendant the “slack” feature is to be associated with a circumference of the outer skirt being substantially larger than that of the frame and a skirt that is only higher than the frame in the axial (i.e. flow) direction and which has wrinkles allowing it to behave like an accordion (or a sock) is not to be considered as having “slack” in the meaning of claim 1. The defendant further argues that since the slack of the intermediate portion of the outer skirt occurs in three dimensions, there must not be tautness in any direction since otherwise there is no slack: instead, the slack as claimed requires that the outer skirt is configured such that both its diameter and height are substantially greater than the corresponding dimensions of the frame and this is only possible in the absence of circumferential tautness. Thus, according to the defendant, if the outer skirt does not comprise excess material in the circumferential direction, its intermediate portion cannot exhibit a larger diameter than the frame.

78. The claimants contend that these additional properties are implied by the “slack” feature, as they are not supported by the patent disclosure.

79. The Court considers that the definition of “slack” as implying excess material is disclosed in the patent and consistent with the general meaning of the term.

80. The Court further notes that the definition of “slack” proposed by the defendant as also implying a larger length of the outer skirt in its planar development as compared to the circumference of the frame, in addition to a greater height and no portions being tight or taut on the frame, thus excluding a merely accordion or wrinkles configuration, has no implicit or explicit basis in the patent, nor it appears intrinsic in the common meaning of the term “slack” for the person skilled in the art. This conclusion is also supported by the fact that claim 1 [see features (1h) and (1i)] mentions a “slack” only in the axial direction.

81. The claimants assert that the attachment of the outer skirt at two locations of a frame that changes its length from a collapsed to a deployed configuration inherently requires that the skirt has excess material, i.e. “slack”. The defendant objects that the adaptation of the skirt to said change of length of the frame can also be obtained by the elasticity of the material making the skirt, the specific re-arrangement properties of its fibre texture or the sliding of the sutures connecting the skirt to the frame.

82. On this point the Court notes that the mere capability of a skirt to follow changes in the frame length does not necessarily imply that the skirt has excess material or “slack”. Incidentally, the same patent teaches an elongation linked to the fibre orientation for the inner skirt (see para. [0045]).

Added subject-matter: claim 4.

83. Claim 4 recites as follows: “The valve of any one of the preceding claims, wherein the outer skirt (18) is configured to fill in gaps between the frame (12) and a surrounding native annulus when the valve is deployed within the body”.

84. The claimants note that the subject matter of claim 4 is drawn from para. [0084] of the originally filed disclosure (WO ‘035), corresponding to para. [0064] of the patent. This paragraph refers to a specific example of heart valve, as understood also by the use of the term “annulus”, which does not apply for venous valves. The latter is further confirmed in para. [0050] of the original application, corresponding to para. [0030] of the patent.

85. In addition, the claimants state that while para. [007] of WO '035 and original claim 13 refer to prosthetic valves in general, the claims as filed do not form a support for claims 4 to 13 of the patent: therefore, the fact that original claim 13 relates to prosthetic valves in general is not relevant.

86. As claim 4 is not limited to a heart valve, the claimants assert that it infringes Article 76 (1) ‘EPC’.

87. The defendant objects that: para [007] of the originally filed application, corresponding to para. [0012] of the patent, discloses that “The present disclosure is directed toward methods and apparatuses relating to prosthetic valves, such as heart valves, delivery apparatuses, and assemblies of heart valves mounted on delivery apparatuses”; claim 13 of the originally filed application, upon which claim 1 of the patent is based, read in combination with original para. [084] (para. [0064] in the patent) already gives the skilled person the information that the “slack” feature could be provided in other types of valves than heart valves; the omission of the “heart” feature would be a matter of lack an essential feature, thus relating to clarity under Article 84 ‘EPC’ and not to added matter; in any case, the “native annulus” is necessarily referred to the heart, so that the heart limitation is already included in claim 4.

88. The defendant further adds that the limitation to “heart” valves is not in original claim 13, thus it is clear for the person skilled in the art that the valves disclosed in WO ‘035 can be generally referred to as implantable prosthetic valves.

89. The Court agrees with the claimants.

90. There is no hint for the skilled person that the specific features of paras. [050] and [084] of WO ‘035 may be applied outside the field of prosthetic heart valves. Similarly, the term “annulus” is consistently used in the original application to refer to the heart only (see in particular: para. [004] in combination with para. [002]; paras. [050], [063] and [084], wherein all the detailed embodiments are explicitly referred to a heart valve). This meaning is also implicitly acknowledged by the defendant under the last line of defence mentioned under point 87 above.

91. Incidentally, in their preliminary opinion the ‘EPO’ Opposition Division does not share the above affirming that it “does not understand the qualification of the valve being a heart valve to imply any additional technical features”, that original para. [007] (para. [0012] of the patent at issue) constitutes a basis for generic “prosthetic valves” and that “there do not appear to be any additional technical features implied by the term ‘heart valve’ which are not already present in claims 4-13”.

92. These arguments do not appear convincing to this Court. Indeed, the distinction between generic “prosthetic valves” and “heart valves” is provided in original para. [007], if the “such as” expression used therein to introduce heart valves is to be given its normal, non-limiting meaning according to standard (patent) language.

93. The qualification of a valve as a “heart” one implies the suitability of the valve to be implanted in the heart. This is considered a positive technical feature implying limitation (e.g. in the valve dimensions and material choice).

94. The only basis for claim 4 is in original para. [084], which is clearly referred to heart valves only. The mere fact that the disclosure of the patent at issue, in the general statement of original para. [007], mentions “prosthetic valves” does not imply that specific features disclosed in conjunction with heart valves only are directly and straightforwardly understood by the person skilled in the art as applicable to other valve types.

95. Therefore, the invalidity ground based upon Art. 76 (1) ‘EPC’ is considered well founded and the intermediate generalization concerning the omission of the claimed valve being a “heart” one unallowable. Accordingly, the patent cannot be maintained in the form as granted.

Added subject-matter: claim 7.

96. Even if not strictly necessary in view of the above conclusion, the Court deems it appropriate to also examine the ground of invalidity for added-subject matter raised with reference to other claims.

97. Claim 7 recites as follows: “The valve of any one of the preceding claims, further 15 comprising an inner skirt (16)”.

98. The claimants bring the same objections as for claim 4, wherein the main basis for the subject-matter of claim 7 is the aforementioned para. [050] of the application as originally filed.

99. In their Reply, the claimants presented additional arguments which relate to an alleged intermediate generalization associated with the following omitted features: “the suturing of the lower edge of the outer skirt to the lower edge of the inner skirt” and “the suturing of the upper edge of the outer skirt to the frame”. According to them, these features are inextricably linked to the disclosure of the inner skirt in combination with the outer skirt according to paras. [083] and [084] of the originally filed application.

100. The defendant brings the same defence as for claim 4. Moreover, with respect to the argument presented in said Reply, the defendant requests their non-admittance as late filed and, subsidiarity, relies upon para. [083] of the originally filed application which presents the omitted features as optional: “[…] the lower edge 160 of the skirt 18 can be sutured to the lower edge of the inner skirt 16 at the inflow end of the valve […]” and “[…] each projection 164 can be sutured […]”.

101. As far as the first issue is concerned– that is, the omission of the limitation to “heart” valves – the same conclusions as for claim 4 do apply. As per the additional facts and arguments, as explained above they are considered late filed and are not admitted in the procedure.

102. In any case, the additional line of argumentation appears, *prima facie*, unconvincing, as the omitted features are presented as optional. Incidentally, this assessment is consistent with that of the Opposition Division (point 15).

Added subject-matter: claim 8.

103. Claim 8 recites as follows: “The valve of claim 7, wherein the inflow edge (160) of the outer skirt (18) is sutured to an inflow edge of the inner skirt (16) at the inflow end of the valve”.

104. With regard to this claim the claimants file two lines of attacks: the first one is similar to that relating to claims 4 and 7 above, wherein the main basis for the subject-matter of claim 8 is para. [083] of the application as originally filed; the second attack relates to the combination of the subject-matter of claim 8 with feature (1e) of claim 1. In particular, according to the claimants from the combined reading of para. [015] of the originally filed application (corresponding to para. [0020] of the patent), substantially containing the wording of claim 1, with the disclosure at para. [083], the person skilled in the art would not understand the “inflow edge” of the outer skirt as being the same as the “lower edge”, nor would equate the “first location” of claim 1 with the “inflow end of the valve” of claim 8. Accordingly, the claimants assert that the person skilled in the art would read the combination of claims 1 and 8 as requiring a double connection of the outer skirt to the frame and to the inner skirt that has no basis in the originally filed application.

105. In addition, the claimants note that the expression “inflow edge” of the outer skirt is more general than “lower edge” and encompasses additional embodiments not originally disclosed, as exemplified in the figure proposed in their reply (at para. [72]) and copied below.

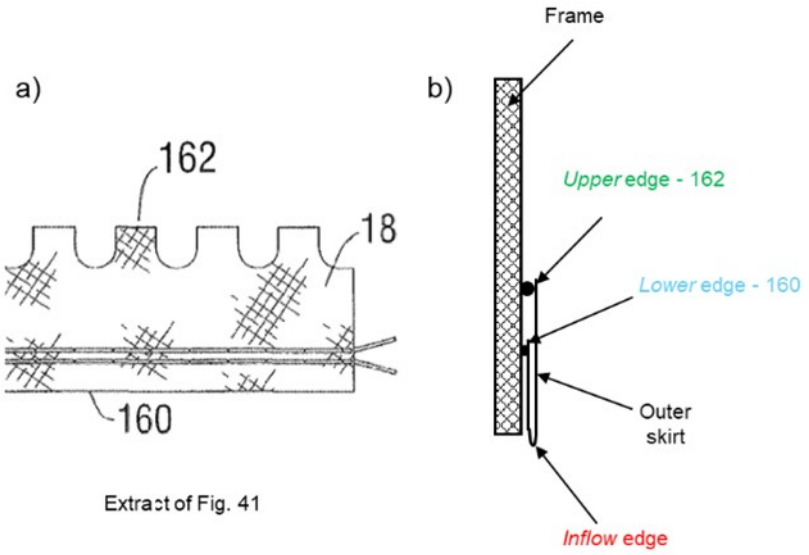


Fig 4 – Lower edge vs. Inflow edge

106. According to the defendant, claim 8 refers to “the inflow edge” of the outer skirt, i.e., the same inflow edge of the outer skirt as recited in claim 1. Therefore, the person skilled in the art would understand claim 8 as specifying how the securement of the inflow edge of the outer skirt to the frame is established, which is by suturing it to the inner skirt.

107. In conjunction with the potential difference between the “inflow edge” and the “lower edge” of the outer skirt, the defendant affirms that these terms are synonyms, and so are the terms “upper edge” and “outflow edge”. According to the defendant, the terms “upper” and “lower” are a simple consequence of describing the valve in an upright orientation in which the direction of blood flow is from bottom to top, as consistently shown throughout the figures of WO ‘035 and EP ‘181. Therefore, there are no reasons for the person skilled in the art to assume that they have different meanings.

108. The Court points out that with regard to the first line of attack concerning the "heart" issue, the same conclusions as per claims 4 and 7 do apply.

109. As per the second line of attack, paras. [015] and [083] of the originally filed application already support the combination of feature (1e) of claim 1 with the subject-matter of claim 8. Indeed, in the context of the patent disclosure and as previously explained, the "lower edge" and "inflow edge" identify the same end, border part of the outer skirt at which the latter is secured to the frame. With this understanding, also the hypothetical embodiment shown in the above drawings does not hold, because the fold indicated as "inflow edge" is not, indeed, an "edge" within the meaning of the original disclosure (para. [083]). Therefore, the Court considers this second line of attack not convincing.

Added subject-matter: claim 12.

110. Claim 12 recites as follows: "The valve of any one of claims 10 or 11 wherein plastically-expandable material that is used to form 35 the frame (12) includes stainless steel, a nickel based alloy, a cobalt-chromium alloy, a nickel-cobalt-chromium alloy, polymers, or combinations thereof; preferably wherein the frame (12) is made of a nickel-cobalt-chromium-molybdenum alloy".

111. The claimants argue that para. [53] of the originally filed application, forming the basis for claim 12, discloses "Suitable plastically-expandable materials that can be used to form the frame 12 include, without limitation, stainless steel, a nickel based alloy (e.g., a cobalt-chromium or a nickel-cobalt-chromium alloy), polymers, or combinations thereof. […]" and point out an inconsistency in the above definition, in that a "cobalt-chromium" alloy is presented as an example of a "nickel-based alloy" and as an alternative to a "nickel-cobalt-chromium alloy". Claim 12 contains a list of all the materials indicated above, removing the inconsistency (in that the cobalt-chromium alloy is listed without reference to it being a "nickel based alloy"), thus, according to the claimants, the person skilled in the art is presented with new information by the mention of the "cobalt-chromium alloy" without including nickel.

112. The defendant considers that the person skilled in the art understands the relevant passage of para. [053] to mean that the "cobalt-chromium alloy" refers to any cobalt-chromium alloy, including but not limited to a nickel-cobalt-chromium alloy.

113. According to this Court, the claimants' argument is not well-grounded. It is evident that para. [053] contains an inconsistency and the person skilled in the art would easily understand that listing the "cobalt-chromium" alloy among the "nickel based" alloys is a refuse, even much so as the "nickel-cobalt-chromium" is also explicitly mentioned.

Auxiliary Requests: admissibility.

114. Having established the invalidity of the patent as granted, the defendant's contingent request to consider maintaining the patent according to one of the proposed amendments must be examined. In particular, the defendant has submitted a set of amendments consisting of 17 Auxiliary Requests (Auxiliary Requests 1 to 9 and 1' to 8').

115. The claimants object to the admissibility of the application to amend the patent because: the number of Auxiliary Requests and their combination is not reasonable; the subject matter

of Edwards' requests is undefined; the defendant does not explain why the more than 1,800 additional auxiliary requests comply with Articles 84, 123 (2) and 123 (3) 'EPC' nor why they are valid; the conditions to which each request is subject are not defined.

116. The Court considers that the filing of 17 Auxiliary Requests does not appear to be 'unreasonable', for the purpose of addressing the criteria set by Rule 30 (a) 'RoP', considering the complexity of the case (in particular, the number of lines of attacks to the patent). In this regard, it must be noted that, as stated by this Central Division in a previous decision between the same parties, the lack of a consistent interpretation of the expression 'reasonable in number' also suggests a less strict interpretation of this relevant provision (see CD Paris, decision of 19 July 2024, UPC_CFI_255/2023 and UPC_CFI_15/2023).

117. In any case, the sanction in case the requirement of "reasonable number" is not met is not made explicit by the Rules of Procedure and the prevailing interpretation is that it would be unreasonable and too far-reaching to reject the application to amend altogether and, instead, appropriate to deal with the auxiliary requests in the order they have been submitted until a reasonable number has been reached (see LD Munich, order of 18 April 2025, UPC_CFI_526/2024; CD Paris, decision of 5 November 2024, UPC_CFI_309 /2023).

Auxiliary Request 1: added subject matter in claim 8.

118. According to Auxiliary Request 1, claim 1 is amended by specifying that the implantable prosthetic valve is an implantable prosthetic "heart" valve and claim 12 is amended by deleting the option of a "cobalt-chromium alloy". The other claims remain unchanged.

119. The claimant argue that is amendment does not address the added matter attack of claim 8 of the patent as granted.

120. The argument is not convincing for the reason illustrated above with regard to the patent as granted.

Auxiliary Request 1: lack of novelty of claim 1 in view of 'Sadra Medical Lotus valve'.

121. The claimants argue that claim 1 and dependent claims 2, 4, 5, 10, 11 and 12 lack novelty in view of 'Sadra Medical Lotus valve', as evidenced by 'Feldman 2007' (Gide 28 and 29), 'Buellesfeld 2008' (Gide 30), 'Tamburino 2010' (Gide 31 and 32) and the 'Sadra Medical' webpage (Gide 33), and over 'Feldman 2007' and 'Buellesfeld 2008' independently

122. The 'Sadra Medical Lotus valve is a self-expandable prosthetic heart valve.

123. 'Feldman 2007' is a journal article discussing contemporaneous developments in the field of percutaneous valve therapies around the year 2007. Figure 2 on page 2871 of 'Feldman 2007' discloses two images of the 'Lotus Valve', reproduced below.

124. ‘Buellesfeld 2008’ is a journal article concerning a medical report of the “first-in-man” experience of the ‘Lotus Valve’. This documents states, at page 581: “the lower part of the prosthesis is surrounded by a flexible sealing membrane (Adaptive Seal TM) made of polyurethane, which fills potential gaps between the prosthesis and the native valve in the final compressed state of the device to minimise or even eliminate paravalvular leakage”.

125. The claimants equate said “flexible sealing membrane” to the claimed outer skirt and argue that said membrane shows wrinkles in the expanded configuration which can be consider as “slack”. They rely on pictures at page 16 of GIDE 86, copied below.

126. The defendant contends specifically only the presence of features (1h) and (1i), based on an interpretation of the term “slack” being more than simple wrinkles.

127. This Court is of the opinion that from the pictures from ‘Feldman 2007’ and the other related documents on file evidence of the presence of the contended features of claim 1 is given. In this regard, it may be noted that the defendant specifically objects to the sole presence of features (1h) and (1i), arguing that it is not apparent that the alleged intermediate portion of the sealing membrane comprises slack, while acknowledging the presence of wrinkles.

128. As for the contested presence of “slack” the Court notes that the fact that the membrane “fills potential gaps between the prosthesis and the native valve” (as stated in ‘Feldman 2007’) is not per se evidence of “slack”, as the mere presence of the flexible membrane can provide this effect. However, the pictures from GIDE 86 show a change in the wrinkles from the expanded to the collapsed configuration as a consequence of a change in distance between the inflow and outflow edge of the outer skirt. This constitutes a “slack”, according to the preferred interpretation of this term (see above).

129. This is also consistent with [redacted] opinion which, at paras. [redacted] states that the ‘Lotus valve’ has these debated features (1i) and (1h).

130. It follows that Auxiliary Request 1 is not able to overcome the novelty attack on independent claim 1, as amended, based on the ‘Sadra Medical Lotus valve’ and the related cited prior art documents. Therefore, the patent cannot be maintained as amended by Auxiliary Request 1.

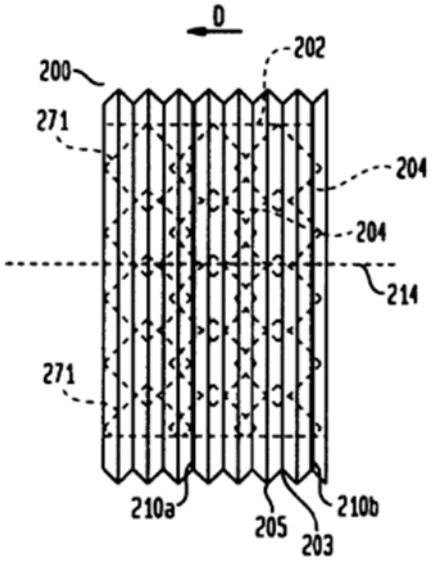
Auxiliary Request 1: lack of novelty of claim 1 in view of ‘Braido’.

131. Although the ground for the patent’s nullity, as amended by Auxiliary Request 1, due to a lack of novelty compared to the ‘Lotus valve’ is well-founded and the patent cannot be maintained even as amended, this Court deems it appropriate, for the sake of greater completeness of the decision, to also examine the ground for nullity advanced against Auxiliary Request 1 due to a lack of novelty in view of WO2010/008548 A9 ('Braido').

132. ‘Braido’ discloses a prosthetic heart valve including a stent body and an external cuff (denoted by 200) with a pleated configuration. The pleats have valley regions (203) and ridge regions (205). The cuff may be attached to the stent body at the valley regions. The pleats deform in the axial direction when the valve changes its configuration from a radially expanded to a radially collapsed one. In the radially expanded configuration, the pleats help to form a seal with the native tissue. Pleats may or may not be present in the radially collapsed configuration (see para. [0065]). The cuff 200 can be formed of “woven polyester” (see para. [0058]).

133. In addition, the valve of ‘Braido’ may also include bands (210) of hygroscopic, sponge-like material that swells in the expanded configuration and urge the regions of the cuff outwardly (para. [0066]). Para. [0009] of ‘Braido’ discloses that “[B]y biasing the cuff outwardly from the stent body, the biasing elements tend to promote intimate engagement between the cuff and the surrounding tissues, even where the[n] surrounding tissues are irregular”. The stent body may be brought from the collapsed to the expanded condition by one or more inflatable balloons or mechanical elements (para. [0064]).

FIG. 7



134. The defendant argues that 'Braido' discloses a structured, rigid pleated element which, as such, cannot have slack and the pleats cannot abandon their fixed shape to adapt to fill the gaps in the native anatomy (which would be confirmed by the need for the sealing bands).

135. On the contrary, according to the claimants "[t]he arguments raised by Edwards should be rejected, first because the cuff of Braido is not to "rigid" but instead, the description states that it can be made of soft materials such as woven polyester, and second because the "biasing element" of Braido is optional and does not preclude the presence of a slack".

136. The Court is of the opinion that pleats imply, by their own definition, excess material and, thus, (axial) slack. Therefore, by following claim interpretation as previously explained, claim 1 of Auxiliary Request 1 is anticipated by 'Braido'.

137. The Court takes note that the Preliminary Opinion of the 'EPO' Opposition Division, at point 21, acknowledges novelty of claim 1 in view of 'Braido' because "[…] the opposition Division does not understand the pleats of D12, which appear to be a preformed structure of the cuff as being the same as a slack portion as they are structured to form pleats in a preformed manner".

138. The Court considers that this reasoning does not hold if it is accepted that "slack" means only excess material. The cuff of 'Braido' is disclosed as serving to reduce perivalvular leakage, while not exerting an excessive force over the annulus (see para. [0004]) and does not appear to include any implicit feature or property contradicting the terms of claim 1. Moreover, the cuff is indicated as possibly made of woven polyester (paras. [0058] and [0065]), the same as in the patent (see claim 6).

Auxiliary request 2: added subject matter in claim 1.

139. Claim 1 of Auxiliary Request 2 is based upon claim 1 of Auxiliary Request 1 and additionally requires that the valve comprises an inner skirt (16). Moreover, granted dependent claim 7 is deleted.

140. With specific regard to this Auxiliary Request 2 the claimants argue that the addition of "an inner skirt" in claim 1 constitutes an impermissible intermediate generalization with regard to the omission of the suturing of the lower edge of the outer skirt to the lower edge of the inner skirt and of the upper edge of the outer skirt to the frame.

141. However, as previously noted, this line of attack is late filed as, and such, must be disregarded.

Auxiliary request 2: lack of novelty of claim 1 in view of 'Letac'.

142. The claimants argue that claim 1, as amended by Auxiliary Request 2, is not novel in view of WO 98/29057 ('Letac'). This document relates to valve prosthesis for implantation in body channels, in particular a prosthetic heart valve, and describes a prosthesis comprising a collapsible valvular structure and an expandable frame on which said valvular structure is mounted and valves having inner and outer covers attached the valve frames are described.

143. In particular, the claimants point out that in the configuration of a balloon expandable heart valve shown in Fig. 6d of 'Letac', copied below, an internal cover (19) is extended at its lower end (19') to form an external cover (19''). The covers are fixed to the bars (11) of the stent (10) (page 15, lines 10-18; page 22, lines 23-26: "[…] The internal and external cover are moulded, glued or soldered to the bars of the stent 10"; page 23, lines 15-18; page 24, lines 15-16; page 24, lines 14-27). The cover is disclosed as possibly made in a continuous body with the valvular structure (14) (page 21, lines 16-26; page 22, lines 11-14).

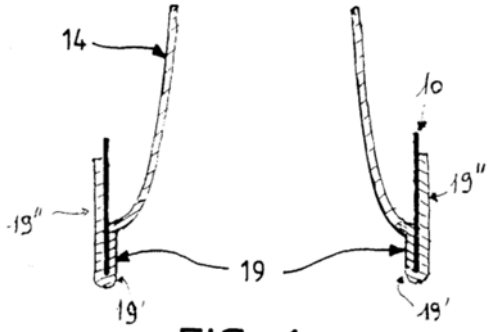


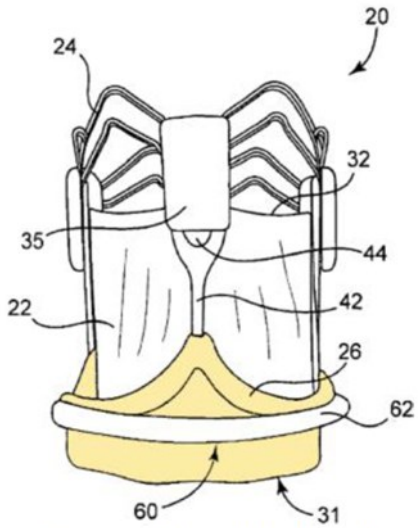
FIG_6d

144. The fastening of the valvular structure to the frame can be made by sewing the internal and/or the external cover to the bars (page 23, lines 15-18). 'Letac' mentions PET as a material for the cover (page 8, lines 16-19, in combination with page 22, lines 11-14), which is read by the claimants as an inextensible material necessarily implying slack for allowing the valve collapsed configuration.

145. The Court disagrees with the claimants on this latter argument because no specific disclosure is provided in 'Letac' about the relative arrangement of the valvular structure and covers in the valve collapsed configuration and the presence of "slack" cannot be regarded as intrinsic in the disclosed features. Therefore, there does not appear to be an unambiguous disclosure of the presence of "slack", as required in features (1h) and (1i).

Auxiliary request 2: lack of novelty of claim 1 in view of 'Toomes'.

146. The claimants argue that claim 1, as amended by Auxiliary Request 2, is not novel also in view of 'Toomes' (Gide 35). 'Toomes' is a document entitled "Methods and systems for reducing paravalvular leakage in heart valves" and discloses an aortic heart valve having a replacement valvular structure (22), a support structure (24) and an external cuff (26) attached to inflow end of the valvular structure and including a skirt (60) and a flange (62). The support structure can be self-expandable or not (para. [44]; Fig. 6). The cuff provides valve seal by conforming to irregularities in the valve annulus (para. [58-61]).



Toomes: Figure 7 (coloured)

147. However, as in 'Letac' in this document there is no unambiguous disclosure of the presence of "slack"; therefore features (1h) and (1i) are not anticipated.

148. It follows that Auxiliary Request 2 withstands the novelty attacks advanced by the claimants.

Auxiliary request 2: inventive step.

149. The claimants argue, and substantiate, that Auxiliary Request 2 lacks inventive step mainly over: a) WO 2009/149462 A2 ('Hariton') in combination with common general knowledge and/or any of 'Sadra Medical Lotus Valve' or 'Braido'; b) 'Sadra Medical Lotus Valve' in combination with 'Hariton'; c) 'Braido' alone, optionally in combination with 'Hariton'; d) 'Letac' in combination with 'Sadra Medical Lotus Valve' and/or 'Braido'; e) 'Seguin' alone, or taken in combination with 'Hariton' or 'Sadra Medical Lotus Valve' or 'Braido' or 'Letac' or 'Furuta' (Gide Exhibit 52 and 52*bis*).

150. 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".

151. The jurisprudence of the Court of Appeal (see, in particular, orders of 26 February 2024, UPC_CoA_335/2023; of 14 February 2025, UPC_CoA_382/2024; of 20 April 2025, UPC_CoA_768/2024) shows that this assessment requires, first, the identification of the objective problem underlying the claimed invention, which must be carried out in light of the patent's specification. It may be added that the problem should be identified in an abstract and neutral way as to avoid the risk of hindsight.

152. Next, it's necessary to identify the state of the art at the time of the claimed invention, which serves as one of the comparative elements. This state of the art can be represented by one or more realistic starting points (see, on this point, CD Munich, decision of 17 October 2024, UPC_CFI_252/2023; LD Dusseldorf, decision of 10 October 2024, UPC_CFI_363/2023). Its identification is left to the initiative of the parties. Indeed, judicial proceedings before the UPC are guided by the principle of party disposition, meaning that, unlike what generally happens before administrative patent-granting offices, the Court cannot independently acquire relevant prior art evidence on its own motion.

153. The cited order of the Court of Appeal of 26 February 2024 used as a realistic starting point a document 'of interest' for solving the objective problem. In this regard, it may be assumed that realistic starting points, in general, are the pieces of evidence which disclose the main relevant features as those disclosed in the challenged patent and for that reason have constituted the basis for the developing of the inventive idea and/or which address the same or a similar underlying problem (see CD Paris, decision of 21 January 2025, UPC_CFI_311/2023). Indeed, only this evidence may be considered 'of interest' for solving the underlying problem.

154. Once the objective underlying problem and one or more starting points have been identified it must be assessed whether it would have been obvious for the skilled person – whose identification has already been done for the purpose of carrying out the claim construction process – to arrive at the claimed solution (see, in addition to the cited rulings, CD Paris, decision of 29 November 2024, UPC_CFI_307/2023). In this regard, a "holistic approach" – that is, a broader way of assessing this non-obviousness by considering the invention as a whole, rather than just focusing on isolated distinguishing features – appears, in general, to be more appropriate.

155. Given this background, the Court understands that the underlying problem of the claimed invention is to design a prosthetic heart valve which is capable of reducing the risk of perivalvular leakage while not increasing the diameter of the folded or crimped profile. Furthermore, the problem of securing the valvular structure to the frame and to block the flow of blood through the open cells of the frame below the lower edge of the leaflets is also of relevance.

156. Auxiliary Request 2 addresses the above problems by inserting slack between the lower and upper edges of the outer skirt. As disclosed in para. [0064], this slack causes the outer skirt to bulge outwardly as the frame shortens in length during radial expansion and to fill in gaps between the frame and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus when the valve is deployed within the body. Moreover, the slack between the lower and upper edges of the outer skirt allows the frame to elongate axially during crimping without any resistance from the outer skirt and the outer skirt does not substantially affect the outer diameter of the prosthetic valve in the crimped condition.

157. The problem of avoiding perivalvular leakage after implantation of the valve is also addressed by designing an inner skirt which cooperated with the outer skirt for this purpose (see para. [0064]).

158. The inner skirt is also designed to assist in securing the valvular structure to the frame and to assist in forming a good seal between the valve and the native annulus by blocking the flow

of blood through the open cells of the frame (see para. [0043]), so addressing the problem in this regard.

159. The claimants' ground for invalidity of Auxiliary Request 2 for lack of inventive step is developed along two main lines: the first one starts from documents disclosing an inner skirt and lacking an outer one; the second one starts by disclosures of a valve having an outer skirt (possibly with slack) but missing the inner one.

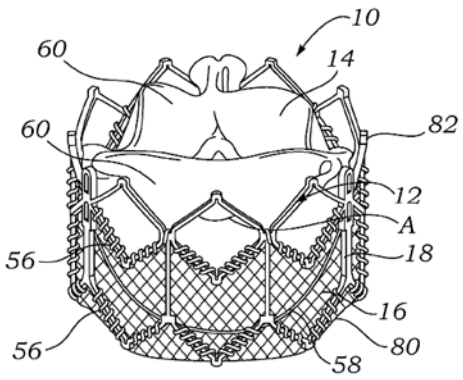
160. The claimants note that with a view to further mitigating valvular leakage, the skilled person would be aware of, and strongly motivated to implement, the prior art outer skirts, especially those of the 'Lotus Valve', 'Braido' and WO 2005/062980 A2 ('Salahieh'), given that these documents explicitly teach the benefit of these outer skirt designs in improved valvular sealing and conformity with the native annulus. With respect to the second category of attacks, the claimants point out that the skilled person would be motivated to add an inner skirt to valves already having an outer skirt to achieve the benefits known to be attributed to use of inner skirts.

161. The defendant objects that starting from a valve with an inner skirt, it may not have been impossible to add an outer skirt, but that alone does not establish a clear motivation to make the modification. Likewise, adding an inner skirt to a valve with an outer skirt may not have been impossible, but the person skilled in the art had no motivation to do so. Moreover, the defendant notes that adding an inner skirt would need modification of other components, notably the way the leaflets are attached to the frame, which typically entails extensive testing and the necessity to go through long approval procedures. In addition, the defendant observes that the mere fact that a certain feature was known to the person skilled in the art does not mean that there is an automatic motivation to add this feature to existing pieces of prior art.

Auxiliary request 2: lack of inventive step starting from 'Hariton' and other disclosures of an 'inner skirt'.

162. The Court considers that 'Hariton' is a realistic starting point. 'Hariton' discloses an implantable prosthetic heart valve having a frame (12) and a leaflet structure (14) supported by the frame. The valve includes an inner skirt (denoted by 16 in Fig. 1 copied herein) sutured to the frame (see, e.g., sutures denoted by 56), interposed between the frame and the valvular leaflets (14) and attached to the latter (paras. [008], [046] and [056]; Fig. 16). To further limit the crimped profile of the valve and avoid wrinkles after expansion, 'Hariton' also provides for the inner skirt be made of a stretchable and/or compressible material, such as silicon (paras. [076] and [077]). In order to protect the leaflets during the crimping process an external protective sleeve or cover, preferably made of elastic silicon, may be used (Fig. 25; paras. [078], [083] and [084]).

Fig. 1



163. The problem underlying 'Hariton' is, similarly to the one in the patent at issue, to design a prosthetic heart valve which has a reduced overall crimped profile, as well as being capable to prevent the risk of perivalvular leakage and to protect the leaflets against the damage caused by contact with the frame during crimping and during working cycles of the valve.

164. The significant similarity of the technical problems that the two documents seek to solve, as well as the coincidence of important technical features of the two solutions developed, allows appreciating the reasons why 'Hariton' is "of interest" (to use the expression mentioned in the cited order of the Court of Appeal of 26 February 2024) for the person skilled in the art who must assess the obviousness or otherwise of the claimed invention.

165. In this regard, the Court points out that while in the patent at issue the problem of avoiding or reducing the risk of perivalvular leakage and of minimizing the diameter of the crimped profile of the valve is mainly solved by providing the outer skirt with slack, in 'Hariton' this problem is solved, in addition to a specific configurations of cell rows and columns which are comprised in the frame and to a specific orientation of the relative struts, by the use of an elastic material for both the inner and the cover (see paras. [76-77]).

166. Therefore, providing slack in the outer skirt is an alternative solution in respect of the one in 'Hariton' to the same problem and is contrary to the teaching of this latter prior art document. It follows that, starting from 'Hariton', the person skilled in the art would not have any justification to look at prior art disclosing outer skirts provided with slack – as in the 'Sadra Medical Lotus Valve' and in 'Braido' – to minimize the crimped profile of the valve or to reduce the risk of perivalvular leakage and, consequently, would not consider implementing the outer skirt in 'Hariton' with slack.

167. Neither 'Letac' nor 'Seguin' can be considered realistic starting points, as while they disclose prosthetic heart valves equipped with an inner skirt, they do not share significant similarities with the patent at issue regarding the technical features and the problems addressed.

168. In any event, it should be noted that even in these documents, the problem of designing a reduced crimped profile for the valve and of minimizing the risk of perivalvular leakage is addressed in a different way to the claimed solution and by peculiar configurations. This is achieved, respectively, by acting on the size and the strength of the bars (11) that compose the frame (see page 14, lines 23-29), as an ancillary requirement to resisting the recoil force of the native structure and standing the forceful balloon inflation, and by means of an axial valve

support portion and its radial force (see para. [0016]). Consequently, starting from this prior art, the person skilled in the art would have no motivation to look at disclosures of valves provided with outer skirts comprising slack to solve the problem of minimizing the valve's crimped profile or of reducing the risk of perivalvular leakage as this problem is already addressed in this prior art in an alternative and antithetical way.

Auxiliary request 2: lack of inventive step starting from 'Sadra Medical Lotus Valve' or 'Braido'.

169. Also 'Sadra Medical Lotus Valve' and 'Braido' may be considered realistic starting point as they disclose significant technical features of the patent at issue – particularly the presence of "slack" in the outer skirt – and have in common with this latter one most of the underlying problems. The main difference between claim 1 of Auxiliary Request 2 and the disclosure of these prior arts consists of the provision of an inner skirt.

170. As previously noted, a valve with an inner skirt is disclosed in various prior art evidence, mainly in 'Hariton'; this document, in particular, teaches that the inner skirt allows to prevent perivalvular leakage and to secure the valvular structure to the frame. These objectives are also associated with the provision of the inner skirt in the claimed invention.

171. However, the designs of 'Sadra Medical Lotus Valve' and 'Hariton' are quite different: in the first one the leaflets are locked to the braided frame, while in the second one they are (also) attached to the inner skirt. Also, the frame constructions in these valves appear different, as based upon, respectively, a tight braided structure and chevron-shaped, large cells. This has reflections concerning the modes of leaflets and inner skirt attachment and protection within the frame: in particular, the attachment modes of the inner skirt to the frame of 'Hariton' (see, paras. [62-63]) do not appear immediately applicable to the braided frame of the 'Sadra Medical Lotus valve'. Moreover, 'Hariton' encourages using a tight, elastic silicon material for the inner and the outer skirt/cover in order to minimize the crimped profile and avoid wrinkles (par. [77], [78] and [84]) or even a dipping of the frame in a liquified material to obtain a silicon covering (paras. [79-80]). Therefore, the general configuration of 'Hariton', also in conjunction with the outer skirt, is rather different from that of 'Sadra Medical Lotus Valve'.

172. For these reasons introducing the inner skirt of 'Hariton' valve in the 'Sadra Medical Lotus valve' would imply structural modifications of this latter valve which, according to the Court, would be viewed with caution by the person skilled in the art, considering, in particular, that heart valves are devices wherein the performance is highly sensitive to any variation in structure. The person skilled in the art would not pick this feature from 'Hariton' without due consideration of the overall disclosed configuration of the starting point. Therefore, starting from 'Sadra Medical Lotus Valve', the person skilled in the art would not obviously conceive the claimed subject-matter.

173. As for 'Braido', the Court acknowledges that this document teaches that a single, continuous cuff body may be applied at the frame of the valve, inside and outside (see paras. [0057-0064]). However, this teaching is disclosed with regard to two different embodiments: the cuff shown in the first embodiment (depicted in Figs. 3-6) is an alternative to the pleated cuff (shown in Fig. 7).

174. The pleated configuration of the outer cuff shown in Fig. 7 is not suitable to be applied to the frame inside as an inner cuff, because the pleats would interfere with the leaflets and it would be not an obvious activity for the person skilled in the art to change the configuration of Fig. 7 of 'Braido' with the cuff shown in the embodiment depicted in Figs. 3-6.

175. The same negative conclusions apply with regard to whether the person skilled in the art would implement 'Braido' with the inner skirt disclosed in 'Hariton' or in the other submitted prior art describing heart valves provided with an inner skirt.

Infringement claim.

176. The defendant filed a counterclaim of infringement, contending that the claimants – Meril Life Sciences Private Limited as a manufacturer and distributor, Meril GmbH and Meril Italy S.r.l. each wholly owned subsidiaries of the first company, as suppliers – infringed claims 1, 2 and 4-13 of the patent at issue through the commercialization of the 'Octacor THV' and the 'Navigator Inception delivery system components' (the 'Octacor System').

177. On this basis the defendant (counterclaimant) requested that the Court orders with immediate enforceability that the claimants (defendants in the counterclaim) cease and desist from making, offering, placing on the market or using (or importing or storing for these purposes) in the territory of the Agreement on a Unified Patent Court the 'Octacor THV' and the 'Navigator Inception' and any products corresponding to the claims of the patent, to recall and/or definitively remove the infringing products from all channels of commerce and destroy all these products which are in their custody or control, to inform the counterclaimant of the origin and distribution channels of the infringing products, the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for these products and the identity of any third person involved in the production or distribution of the infringing products. The counterclaimant further requested that the Court issue the consequential orders regarding the publishing of the decision and penalties for non-compliance with the order and order the defendants in counterclaim to pay the counterclaimant an interim award of damages, as well as the costs of the proceedings.

178. The defendants in counterclaim requested the Court to dismiss the counterclaim as none of the claims of the patent at issue 181 is infringed. In particular, they contended the reproduction of features (1d), (1e), (1h) and (1i). In the alternative, they requested to reject the request for an injunction as it would be disproportionate and further in the alternative, refer the question on the interpretation of Article 3, para. 2, 'Enforcement Directive' to the Court of Justice. Further in the alternative, they requested the Court: to exclude any injunction in return for a reasonable compensation of payment under the circumstances of the case and the economic value of a hypothetical license; to exclude from such injunction the 'Octacor system', in sizes in which no the self-expandable valves are available; to grant a grace period in which the defendants in counterclaim and their distributors will be allowed to offer, place on the market, import and store for those purposes the 'Octacor systems'; to grant a stay of the injunction for at least 12 months to allow clinicians to find equivalent alternatives; to grant an exception to the injunction for particular patient groups for whom the 'Octacor system' is the only suitable device.

179. During the course of the proceedings the Court granted the counterclaimant leave to explicitly extend its counterclaim to the products: the 'Myval Octapro THV' ('Octapro THV') and

'Navigator Pro THV delivery system' ('Navigator Pro') (together, the 'Octapro System'). In their written submission the parties agreed that the specific features relevant to the patent at issue are identical between the 'Octacor THV' and the new 'Octapro THV'.

180. 'Octacor THV' is reproduced in the pictures below, taken from par. 102 of the Counterclaim and uncontested by the defendants in counterclaims. For further reference, additional images from the defendants' submissions are also copied below (as reproduced, e.g., at para. 43 of the Rejoinder to the Reply to the Defence to the Counterclaim). The samples analysed are consistent with the disclosure of the structural features of the product according to the documents on file.

181. The valve includes a frame, a valvular structure, an outer skirt and an inner skirt.

182. According to Meril "the frame of the "Octacor" valve consists of only two rows of cells in the form of overlapping octagons and – in the area of overlap of two adjacent octagonal cells – of the resulting rhombus-shaped cells" (para. 40 of the Defence to Counterclaim).

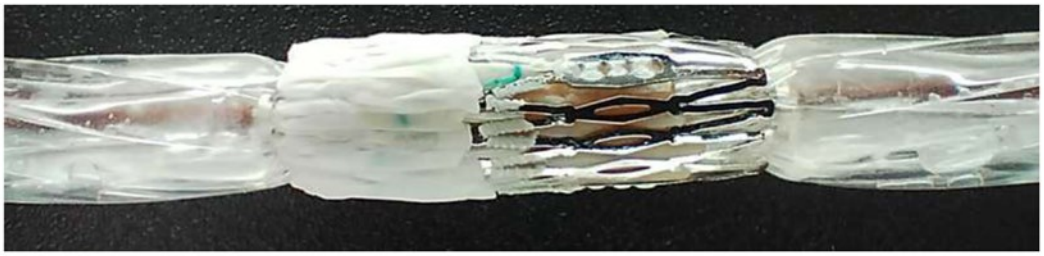
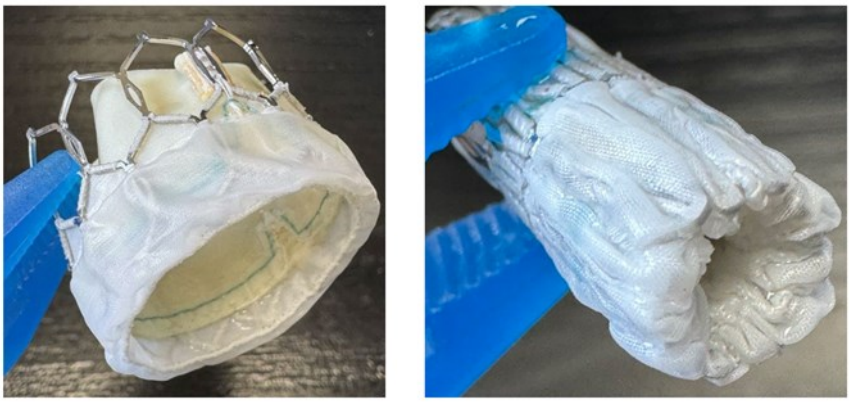


Figure 23: Photograph of Octacor THV in crimped condition[23].



Pictures of an Octacor valve of 26 mm in expanded configuration (left) and collapsed configuration as per the crimping diameter of a 26 mm valve on a balloon (right)
(Gide Exhibit CC_39)

183. The valvular structure is sutured to the inner skirt (green suturing line shown in the pictures) and the inner skirt is sutured to the angular struts of the frame. In particular, at the inflow end of the valve the inner skirt makes a U-fold, and the lower edge of the leaflets is sandwiched within this fold. The upper edge of the outer skirt is sutured to the frame, and its lower edge is sutured to a lower end of the U-shaped fold, i.e. at the curved part of the "U".

Infringement claim: features (1d) and (1e).

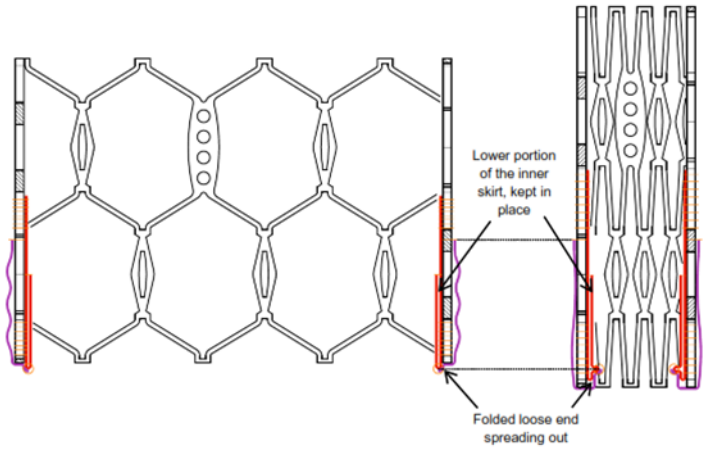
184. The defendants in counterclaim object to the presence of features (1d) and (1e) assuming that these features do not cover arrangements wherein the outer skirt is not directly connected to the frame at the external side thereof. From this they argue that as in the 'Octacor' THV the inflow edge of the outer skirt is secured to the inner skirt (and not directly to the frame) at a portion extending within the internal space of the frame, these debated features are not reproduced.

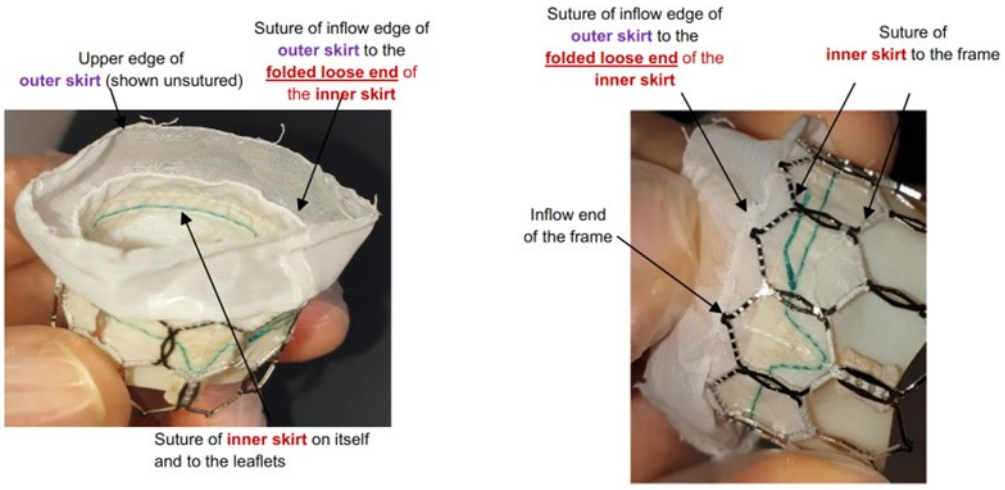
185. The Court considers this argument incorrect. As previously stated, features (1d) and (1e) must be interpreted as not requiring a direct securement between the outer skirt and the frame and they do not exclude that the securement locations of the outer skirt to the frame extend inside the frame.

Infringement claim: features (1h) and (1i).

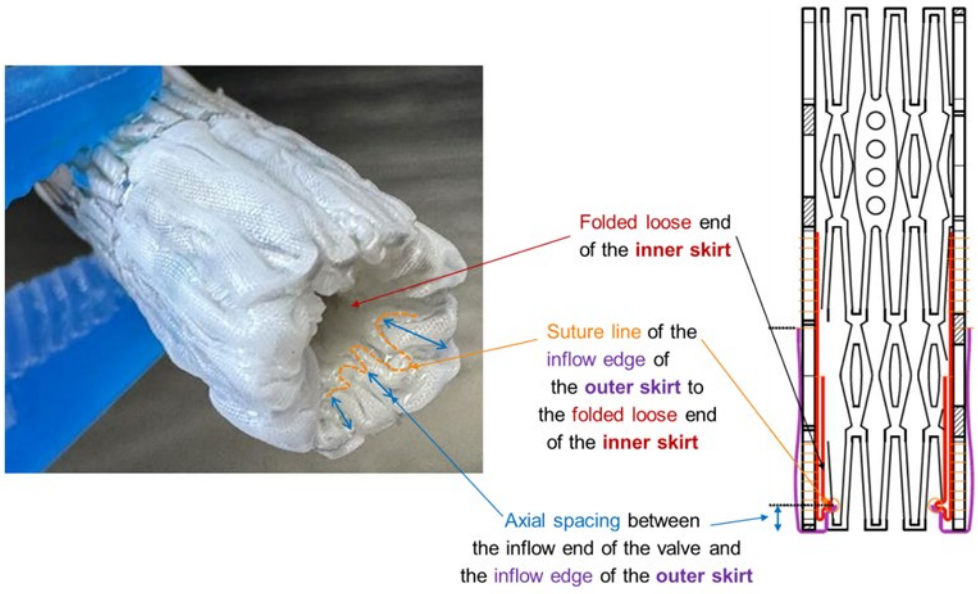
186. The defendants in counterclaim object to the alleged reproduction of features (1h) and (1i), arguing that there is no evidence of a reduction of the slack in the outer skirt in the collapsed configuration, that the outer skirt does not lie flat against the frame in the collapsed configuration and that there is no increase of an axial distance between the inflow and outflow edges of the outer skirt in the collapsed configuration.

187. In this regard, they contend that in the 'Octacor' this valve the lower edge of the outer skirt is sutured to a folded loose end of the inner skirt and that in consequence of such arrangement, the "axial distance between the inflow edge of the outer skirt and the outflow edge of the outer skirt" does not increase in the collapsed configuration of the valve, contrary to the wording of feature (1i). They support their explanation with the drawing and the pictures reproduced below (taken from paras. 67 and 47 of the Defence to the Counterclaim and from para. 44 of their Rejoinder, respectively).

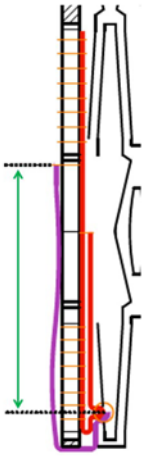




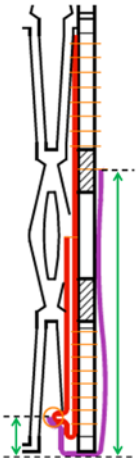
"Octacor" valve with the upper edge of the outer skirt unsutured from frame



188. The different interpretation of the parties is exemplified in the pictures taken from the Rejoinder (para. 49), reproduced below.



Genuine interpretation: the axial distance between the inflow and outflow edges of the outer skirt corresponds to **the green arrow only**



Edwards' interpretation: the axial distance between the inflow and outflow edges of the outer skirt would correspond to the **sum of the two green arrows**

189. The Court notes that the 'Octacor' valve's outer skirt has excess material ("slack") in the axial direction and such axial "slack" reduces in the collapsed configuration and that the material length between the terminal edges of the outer skirt increases in the collapsed configuration.

190. The defendants in counterclaim argue that said material length actually does not correspond to the "the axial distance between the inflow edge (160) of the outer skirt (18) and the outflow edge (162) of the outer skirt (18)" according to the terms of feature (1i).

191. However, this argument is incorrect, as this "axial distance" must be interpreted as equated to the distance between the skirt terminal ends. This is consistent with the interpretation of features (1e) and (1f) regarding the identification of "inflow" and "outflow" edge of the outer skirt and with the production of the same claimed effect of reducing the slack according to the terms of feature (1i). In addition, the arrangement of the product appears the same as that of Fig. 42 as far as the attachment of the inflow edges of the outer and inner skirt are concerned.

192. It follows that, the 'Octacor' valve reproduces also features (1h) and (1i).

193. Therefore, the 'Octacor System' and the 'Octapro System' infringe claim 1 of Auxiliary Request 2 literally. Since the additional features of dependent claims 4, 6, 7, 8, 9, 10, 11 and 12 are also reproduced (or present), the patent is also infringed under these dependent claims. As far as the remaining dependent claims enforced by the counterclaimant are concerned (namely, dependent claims 2 and 5), no conclusive facts and/or evidence about the reproduction of the corresponding specific features has been produced.

194. Furthermore, the liability of all defendant companies must be affirmed, given that their involvement in the infringement, in relation to the role they assumed in the production and marketing of the infringing products, as alleged by the counterclaimant, is undisputed.

Injunction relief and corrective measures.

195. The defendants assert that should the Court find 'EP 181' to be valid and infringed, it ought not to order the injunction or the corrective measures requested by the counterclaimant, as these would be disproportionate, having regard to the public health interest and its prevalence over the counterclaimant's interest in such an injunction or corrective measures. They point out

that granting an injunction against the attacked embodiments would unduly limit the diversity of available TAVI treatment options for treating patients with aortic valve stenosis, as well as the diversity of available balloon-expandable valves with different features and different sizes.

196. In this latter regard, they note that, unlike the claimant's offering, their product range is not limited to valves in conventional sizes of 20 mm, 23 mm, 26 mm and 29 mm and delivery systems in corresponding sizes, but is also available in intermediate sizes (covering intervals of only 1.5 mm instead of intervals of 3mm as in the counterclaimant's heart valves) and XL-sizes that can be used for an aortic annulus diameter up to 32.7 mm. They note that approximately 40% or more of the studied patients are treated regularly with intermediate sizes, and XL-sizes are required for a non-trivial number of studied patients ranging from 0,6% to 8%.

197. The defendants further argue that their heart valve is provided with specific unique features (mainly, the design of the rows of cells of the frame and of the crimping and the retractability up to expansion) which have beneficial effects for the patients.

198. They assert that granting an injunction against the 'Octacor' (and the 'Octapro') valve would cause an undue hardship to the public health interest as it would prevent the long-term monitoring of the performances, thus hindering the advancement of scientific knowledge.

199. Lastly, the defendants point out that an injunction would be disproportionate in view of the counterclaimant's interests, having regard to the fact that the alleged infringement is not "serious" in view of the very limited importance of the patented features and that the counterclaimant's sole interest in obtaining an injunction is to exclude competitors from the market.

200. The counterclaimant objects that Article 63 (1) 'UPCA' does not call for a proportionality test, rather a rule-exception relationship is to be assumed, according to which the grant of the Court prohibition is the general rule and only in exceptional cases may the prohibition order be denied. In any case, the counterclaimant denies that the sought injunction would be disproportionate, nor that it would be detrimental to the interests of third parties, in particular patients suffering from aortic valve stenosis.

201. The Court notes that according to the relevant provision of the Unified Patent Court Agreement where a decision is taken finding an infringement of a patent, the Court may grant an injunction against the infringer aimed at prohibiting the continuation of the infringement (Article 63) and may also order, at the request of the applicant, that appropriate measures be taken with regard to products found to be infringing a patent and, in appropriate cases, with regard to materials and implements principally used in the creation or manufacture of those products (Article 64). Article 64 (4) adds that "In considering a request for corrective measures pursuant to this Article, the Court shall take into account the need for proportionality between the seriousness of the infringement and the remedies to be ordered, the willingness of the infringer to convert the materials into a non-infringing state, as well as the interests of third parties".

202. This appears consistent with Article 3 'Enforcement Directive', which imposes a general obligation on Member States (and therefore also the Unified Patent Court, as a common court subject to European Union law), to provide for the measures, procedures and remedies

necessary to ensure the enforcement of the intellectual property rights covered by this Directive. Said Article 3 specifies that those measures, procedures and remedies shall be fair and equitable, shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays and shall also be effective, proportionate and dissuasive and shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

203. Also relevant is the Agreement on Trade-Related Aspect of Intellectual Property, whose Article 28 (1) provides that a patent shall confer on its owner the exclusive right to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling, or importing for these purposes that product, with the possibility for the Member States, set out at Article 30 of the said Agreement, to grant limited exceptions to this exclusive right, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

204. From the stated legislative framework, it follows that while a general injunction to restrain future infringements is the normal remedy for the patentee where its patent is infringed, the Court has a discretionary power on the request and must refuse to grant an injunction or to issue corrective measures where it would be disproportionate or would be unreasonably detrimental to the public interest, including the interests of third parties (see Munich LD, decision of 15 November 2024, UPC_CFI_15/2023).

205. *A fortiori*, the Court may tailor the requested injunction – by limiting its substantive scope or temporal effect – in order to eliminate its disproportionate aspects.

206. These conclusions render the issue underlying the defendants' request for a preliminary ruling to the Court of Justice of European Union irrelevant.

Injunction relief and corrective measures: public interest.

207. The defendants argue that an injunction would limit the diversity of available treatment options for aortic valve stenosis and of available balloon-expandable valves and they rely on the results from the LANDMARK clinical trial (EDW-CC-16) which has established the non-inferiority, including comparable safety and effectiveness, of their valves compared to a group of other approved valves, including notably counterclaimant's "Sapien 3" and "Sapien 3 Ultra" valves.

208. On this point, the Court observes that as stated in the mentioned decision issued by Munich LD on 15 November 2024 in order to justify a public interest in the availability of the infringing embodiment, it is essential to demonstrate that this is the sole available treatment method or that it represents an improvement upon a known treatment method, resulting in a notable enhancement in patient care. Therefore, excluding a certain product from the range of those available to doctors for the performance of certain procedures does not engage in itself a relevant public interest, because it does not necessarily carry with it the implication that, had the choice not been available, all the patients could not have been treated adequately with the remaining products.

209. In substance, the defendants did not prove that such opportunity of a variety of products in the present case is essential to public health in the specific field to an extent that overwhelms the very essence of patent rights to establish an exclusive on the market.

210. The same conclusions can be drawn with regard to the defendants' assertion that their valve presents unique features. Indeed, the defendants did not demonstrate that the aforementioned features result in a notable enhancement of patient care. On the contrary, evidence, in particular the findings of the LANDMARK clinical trial, show, at best, that their products are not inferior to other available heart valves. In any case, as previously stated, this is not sufficient for establishing the presence of a public interest for the purpose of excluding the sought injunction relief.

211. With regard to the defendants' assertion that the 'Octacor' (and 'Octapro') valve is offered in a unique range of sizes, including intermediate sizes that show promising clinical results and XL-sizes which are the only approved treatment for large aortic annuli, both parties agree that there is not "one size fits all" for the valves at stake. Moreover, it is substantially undisputed that the only approved treatment directly conceived for aortic annuli larger than 30 mm is the defendants' 'Octacor' (and 'Octapro') valve.

212. From these allegations, the Court considers that a public interest is to be recognized in the context of valves for annuli exceeding 30 mm in diameter. In fact, there appears to be a clear public need for the defendants' XL-size valve, as proper sizing is a critical factor in the success of the transcatheter aortic valve implantation procedure and currently this valve seems to be the sole available treatment method for patients having annuli of this size.

213. This is consistent with the assessment made by the Munich Local Division, in the decision of 15 November 2024, based, substantially, on the same circumstances and evidence.

214. The fact that the defendants may be considered as unwilling licensees does not exclude the existence of a public interest in the use of the XL-valves offered by said defendant, as the members of the public regularly do not have possibility to influence the defendant's behaviour and still might face serious consequences if access to the these valves is denied.

215. According to the decision of the Munich Local Division, the public interest is adequately addressed through the existing Medical Request Portal for the 'Myval' valve prosthesis, which is being made accessible for XL-size 'Octacor' products. In particular, this Portal would allow the attending physician to apply for the use of the defendants' XL-size valve and to a team of highly qualified doctors working on behalf of the counterclaimant to verify that a "Sapien 3" valve is out of the question in the case under review and to communicate the answer to the requesting physician without delay.

216. This panel is of the opinion that it is neither necessary nor appropriate to shape the injunction so as to subject the use of the defendants' XL-size valves to such a procedure. Indeed, once it is established that valves of such a size are the only approved treatment directly conceived for aortic annuli larger than 30 mm, the public health interest sought to be protected is satisfied by the free production and commercialization of those valves.

217. Subordinating the use of these valves by physicians to the described request and authorization procedure by the counterclaimant, on one hand, renders their utilization by

doctors more cumbersome by introducing a bureaucratic compliance requirement, and on the other hand, appears to confer upon the counterclaimant a power of scrutiny over the evaluations made by the attending physicians that seems inappropriate, having regard to both the need to respect the professionalism and ethical standards of those physicians – who will presumably choose to utilize the XL-size valves only when they truly correspond to the patients' anatomical characteristics – and the theoretically non-impartial position of the counterclaimant which, as a competitor in the prosthetic heart valve market, has an interest adverse to the dissemination of the valves produced and commercialized by the defendants.

218. Therefore, pursuant to Article 63 (1) 'UPCA' the defendants are obliged to refrain from any further infringing acts as set forth in Article 25 (a) 'UPCA' with any product according to claim 1, 4, 6, 7, 8, 9, 10, 11 and 12 of the patent at issue, as amended by Auxiliary Request 2, with the exception of those acts concerning prosthetic heart valves having a size exceeding 30 mm in diameter (XL-size valves) and related delivery apparatus.

219. This exclusion from the injunction relief must be understood as it will be acknowledged until another treatment valve directly conceived for aortic annuli larger than 30 mm. is approved.

Injunction and corrective measures: further orders.

220. Under Art. 63 (2) 'UPCA' and Rule 354 (3) 'RoP' non-compliance with the injunction shall be subject to a recurring penalty payment payable to the Court. In light of the five-digit market price of the product in question, it seems reasonable to impose a penalty of EUR 20,000.00 for each case of non-compliance and per infringing product.

221. The Court deems it appropriate, as requested by the counterclaimant, to declare the infringement and to order the recalling of the products specified in the injunction order from all channels of commerce and the destroy all products specified therein which are in the custody or control of the defendants. These orders have to be complied with by the defendants within three weeks after service of the order are enforced by a periodic fine of EUR 1,000.00 for each day of delay.

222. Pursuant to Article 67 (1) 'UPCA' and Rule 191 'RoP', the defendants are further ordered, within four weeks after service of this judgment, to inform the counterclaimant of: (i) the origin and distribution channels of the infringing products specified in the injunction order; (ii) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for these products; and (iii) the identity of any third person involved in the production or distribution of these products.

223. With regard to the counterclaimant's request concerning the publication of the decision, the Court consider appropriate to order the publication of the operative part of the decision in five public media of choice of the counterclaimant and at expenses of the defendants, jointly and severally.

224. The defendants are liable for all damages resulting from the assessed infringement, the amount of which is to be determined by the Court in eventual separate follow-up proceedings. The counterclaimant requested to be entitled to payment of preliminary damages in accordance with Rule 119 'RoP'. This request must be dismissed as it lacks detailed information which allows the Court to carry out the relative assessment in the proper, accurate way.

Costs.

225. 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, with regard to the relative costs the parties bear their own costs.

226. With regard to the counterclaim for infringement, the costs of the Court and of the defendant shall be borne by the defendants, jointly and severally, as the unsuccessful parties. The panel notes that during the interim conference, the value of the counterclaim for infringement for the purpose of applying the scale of ceilings for recoverable costs was set at 8,000,000 euros and confirms this evaluation.

DECISION

The Court,

a) rejects the revocation action filed by Meril Life Sciences Private Ltd., Meril GmbH and Meril Italy s.r.l. on 15 May 2024;

b) maintains European patent n° EP 4 151 181 B1 as amended by Auxiliary Request 2 submitted on 12 July 2024;

c) grants the counterclaim for infringement filed by Edwards Lifesciences Corporation and orders Meril Life Sciences Private Ltd., Meril GmbH and Meril Italy s.r.l., jointly and severally, to refrain from any infringing acts as set forth in Article 25 (a) 'UPCA' with any product according to claim 1, 4, 6, 7, 8, 9, 10, 11 and 12 of the European patent n° EP 4 151 181 B1, as amended by Auxiliary Request 2, in the Contracting Member States in which the patent is in force, with the exception of those acts concerning prosthetic heart valves having a size exceeding 30 mm in diameter (XL-size valves) and related delivery apparatus;

d) orders Meril Life Sciences Private Ltd., Meril GmbH and Meril Italy s.r.l., jointly and severally, to provide Edwards Lifesciences Corporation, within four weeks after service of this decision, with a written statement: the origin and distribution channels of the infringing products specified in the injunction order sub para. c); the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for these products; the identity of any third person involved in the production or distribution of these products;

e) orders Meril Life Sciences Private Ltd., Meril GmbH and Meril Italy s.r.l., jointly and severally, to deliver, at their own expense, the products specified in the injunction sub para. c) in stock and/or otherwise held, owned or in their direct or indirect possession in the Contracting Member States in which the patent is in force, within three weeks after the service of this decision;

f) orders Meril Life Sciences Private Ltd., Meril GmbH and Meril Italy s.r.l., individually and jointly, to comply with the order sub para. c) subject to a recurring penalty payment of up to EUR 20,000.00 for non-compliance and per product;

g) orders Meril Life Sciences Private Ltd., Meril GmbH and Meril Italy s.r.l., individually and jointly, to comply with the orders under d) and e) subject to a recurring penalty payment of up to EUR 1,000.00 for each day of delay;

h) declares that claim 1, 4, 6, 7, 8, 9, 10, 11 and 12 of the European patent n° EP 4 151 181 B1, as amended by Auxiliary Request 2, were infringed by Meril Life Sciences Private Ltd., Meril GmbH and Meril Italy s.r.l., in respect to the products named as 'Octacor System' and 'Octapro System';

i) orders that each party bears their own costs of the revocation action proceedings;

j) orders that Meril Life Sciences Private Ltd., Meril GmbH and Meril Italy s.r.l. to jointly and severally bear the costs of the counterclaim for infringement proceedings;

k) 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.

Issued on 20 October 2025.

The presiding judge and judge-rapporteur

Paolo Catallozzi

Paolo Catallozzi
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The legally qualified judge

Tatyana Zhilova

Tatyana Zhilova
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The technically qualified judge

Elisabetta Papa

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Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Signature numérique de MARGAUX MARIE-ANGE GRONDEIN