Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Düsseldorf local division
UPC_CFI_630/2025

Order
of the Court of First Instance of the Unified Patent Court
pronounced on 31 October 2025
concerning EP 1 998 686 B2

GUIDING PRINCIPLES:

1. The scope of protection of a device claim regularly extends to embodiments in which the claimed structural features are present, even if they do not fully and unrestrictedly realise the function or technical advantage intended for them by the patent specification (deteriorated embodiment). It is not compatible with adequate protection of the patent proprietor to limit the scope of protection of the claim to the fulfilment of a technical function or a corresponding technical advantage which is not claimed but is recognisable to a person skilled in the art.

2. If the defendant has specifically contested the applicant's submission, it is the applicant's responsibility in defence to this contestation by presenting facts which, with the certainty required for the order of provisional measures, allow the court to make a corresponding finding. Unlike in main proceedings, there is normally no room for further clarification of the facts in summary proceedings, for example in the form of obtaining an expert opinion.

3. In summary proceedings, the burden of proof and presentation of facts concerning the lack of legal validity of the patent lies with the respondent. If both parties submit translations of a citation and the accuracy of these translations is disputed between the parties, it is therefore the defendant's responsibility to provide detailed reasons why the (machine) translation submitted by them is correct. If the defendant fails to do so, the court will base its decision on the translation submitted by the applicant.

KEYWORDS:

Infringement; interpretation; burden of proof and presentation; application for order of interim measures; translation of citations

HEADNOTES:

1. The scope of protection of a device claim regularly extends to embodiments in which the claimed structural features are present, even if they do not fully and unrestrictedly realise the function or technical advantage intended for them in the patent specification (inferior embodiment). Limiting the scope of protection of the claim to the fulfilment of a technical function or a corresponding technical advantage that is apparent to a person skilled in the art but not claimed would not adequately protect the patent proprietor.

2. If the defendant has specifically contested the applicant's submissions, it is the defendant's responsibility to respond to this contestation by presenting facts which, with the certainty required for the ordering of provisional measures, allow the Court to make a corresponding finding. Unlike in main proceedings, there is normally no room for further clarification of the facts in summary proceedings, for example in the form of obtaining an expert opinion.

3. In PI proceedings, the burden of presentation and proof of facts concerning the validity of the patent lies with the defendant. If both parties submit translations of a prior art document and their accuracy is disputed, the defendant is obliged to provide detailed reasons why its translation is correct. If the defendant fails to do so, the Court will base its order on the applicant's translation.

KEYWORDS:

Infringement; claim construction; burden of presentation and proof; application for provisional measures; translation of prior art documents

APPLICANT:

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RESPONDENTS:

1. **Lepu Medical (Europe) Cooperatief U.A.,** Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, Netherlands

2. **Lepu Medcial Technology (Beijing) Co., Ltd**., 37 Chaoqian Road, Changping District, Beijing, China 102200

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PATENT IN QUESTION:

European Patent EP 1 998 686 B2 PANEL/CHAMBER:

Panel of the local division Düsseldorf. PARTICIPATING

JUDGES:

This order was issued by Presiding Judge Thomas, legally qualified
Judge Kupecz as judge-rapporteur, legally qualified Judge Dr Schumacher and technically qualified Judge Dr Schmidt.

LANGUAGE OF THE PROCEEDINGS:

German. SUBJECT:

R. 206 RoP – Application for order of interim measures

ORAL HEARING: 2 October 2025

BRIEF DESCRIPTION OF THE FACTS:

1. The applicant is suing the respondents for infringement of European patent (without unitary effect) EP 1 998 686 B2 (hereinafter: the patent in suit).

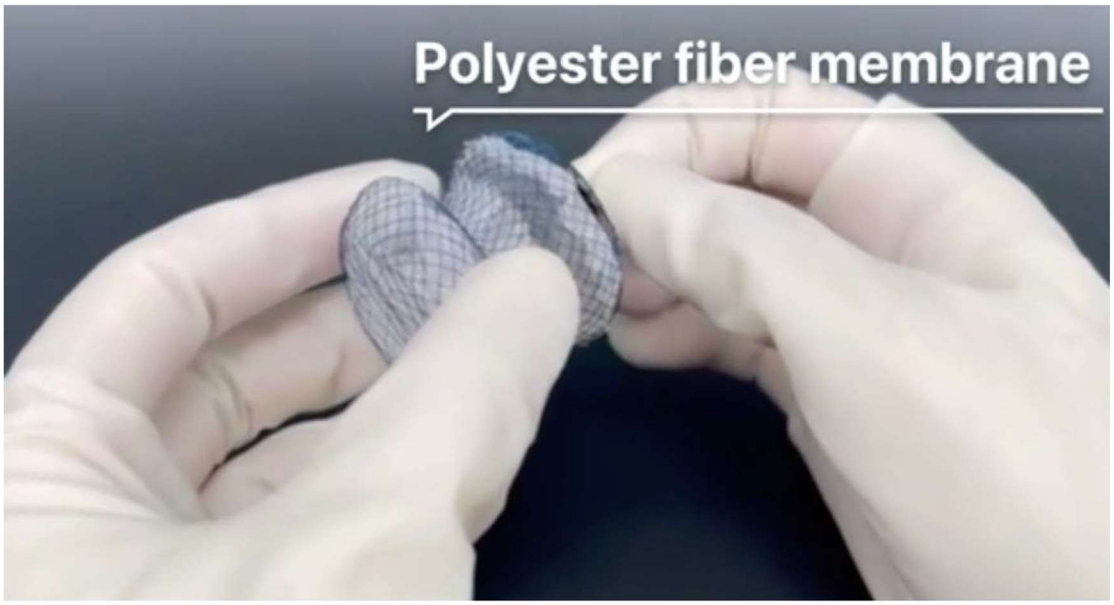
2. The patent in suit was filed on 22 March 2007 in the language of the proceedings, claiming priority from DE 102006013770 of 24 March 2006. The patent application was published on 10 December 2008. The notice of grant of the provisional patent was published on 9 September 2009. The provisional patent was upheld in amended form in opposition proceedings (decision of 1 June 2012, Annex Occ 12) and also survived appeal proceedings (Annex Occ 10). The publication date and the date of notification of the decision on a preliminary objection is 21 February 2018. The provisional patent is in force in the Federal Republic of Germany, France, Italy and the Netherlands.

3. The applicant submitted an opt-out for the provisional patent on 27 May 2023. On 26 May 2025, it declared its withdrawal from the claim, which was entered in the register on 1 June 2025.

4. The provisional patent is entitled "OCCLUSION INSTRUMENT AND METHOD FOR ITS MANUFACTURE". Its patent claim 1 is worded as follows:

> Occlusion instrument consisting of a frame (5) and a mesh (2) of thin wires or threads (4), which is given a suitable shape by means of a forming and heat treatment process, with a proximal retention area (6), a distal retention area (8), wherein the ends of the wires or threads (4) converge in the frame (16) in the distal retention area (8), and with a cylindrical web (10) between the proximal and distal retention areas (6, 8), wherein the two retention areas (6, 8) can be applied on both sides of a shunt to be closed in a septum by means of a mostly intravascular surgical procedure, while the web (10) passes through the shunt,
>
> **characterised in that**
>
> the proximal retention area (6) of the mesh (2) at the proximal end (12) of the occlusion instrument has a completely closed proximal wall (112), which is a continuous surface forming the proximal end (12) of the occlusion instrument.

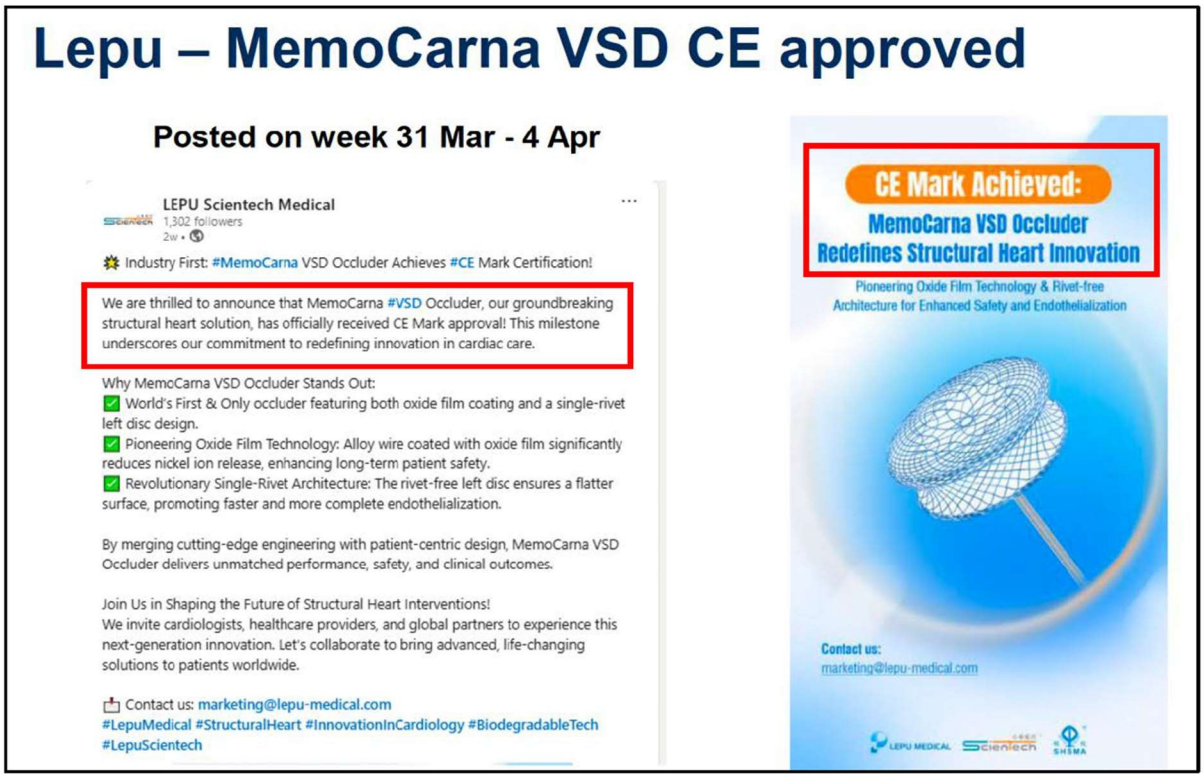
5. With its application for order of interim measures, the applicant is challenging the offer and distribution of the respondents' products, in particular the occluder "MemoCarna (ASD)":

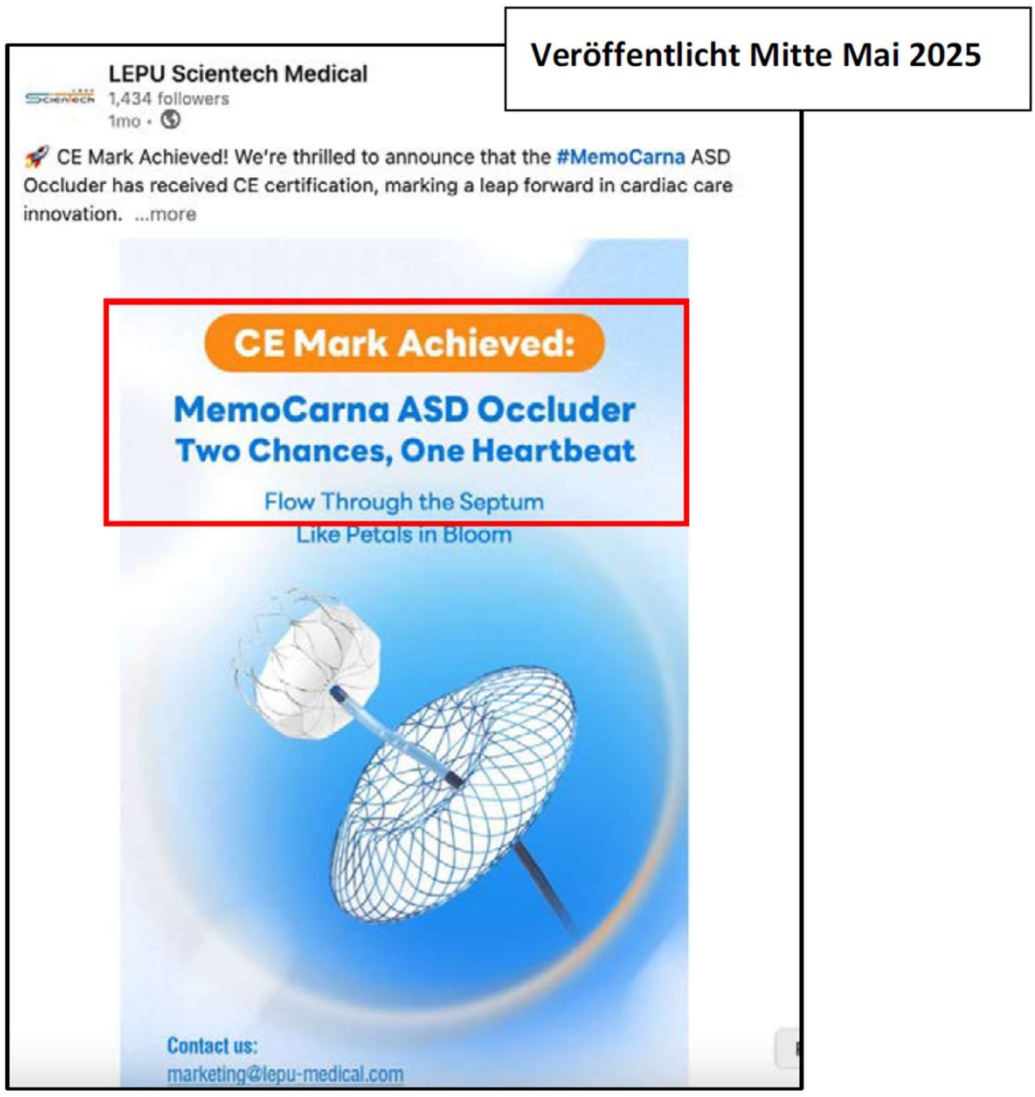


as well as the occluder "MemoCarna (VSD)":

6. The applicant has brought proceedings before the Hamburg local division for an order for interim measures against the respondents in relation to the same products, but based on a different patent (EP 2 387 951) (UPC_CFI_553/2025, hereinafter: "Hamburg parallel proceedings"). By order of 21 October 2025, the Hamburg local division granted the requested measures (UPC_CFI_553/2025, Hamburg local division, order of 21 October 2025, *Occlutech/Lepu)*.

7. The respondents have announced the approval of the CE marking for both products:





8. The respondents participated in various conferences, most recently at Euro PCR 2025 in Paris (20–23 May 2025). After Euro PCR, the respondents also attended the "DCIC – Third Dubai Congenital Intervention Course 23–24 May 2025". The MemoCarna ASD Occluder continues to be advertised on the website of the second respondent (https://en.lepumedical.com/products/memocarnaatrial-septal-defect-asd-occluder/). In addition to information about the product itself, the respondents provided "ordering information". The respondents then sponsored "CSI Frankfurt" (18–21 June 2025) and took part in a focus workshop.

APPLICATIONS BY THE PARTIES:

9. The applicant requests:

A. The respondents are ordered to refrain from

- Germany
- France
- Italy

- the Netherlands

occlusion instruments consisting of

a frame (5) and a mesh (2) of thin wires or threads (4), which is given a suitable shape by means of a forming and heat treatment process, with a proximal retention area (6) a distal retention area (8) wherein the ends of the wires or threads (4) converge in the frame (16) in the distal retention area (8), and a cylindrical bridge (10) between the proximal and distal retention areas (6, 8), wherein the two retention areas (6, 8) can be applied on both sides of a shunt to be closed in a septum by means of a mostly intravascular surgical procedure, while the web (10) passes through the shunt,

characterised in that

that the proximal retention area (6) of the mesh (2) at the proximal end (12) of the occlusion instrument has a completely closed proximal wall (112) which is a continuous surface forming the proximal end (12) of the occlusion device,

- EP 1 998 686 Claim 1, direct infringement -

manufacture, offer, place on the market, use or import or possess for the aforementioned purposes.

B. For each individual infringement of the order under point A, the defendant shall pay the court a (repeated, if necessary) penalty payment of up to EUR 250,000 per day (R. 354.3 UPC RoP).

C. The defendants shall bear the costs of the proceedings.

D. These orders are effective and enforceable immediately.

E. (as an alternative request to D.):

These orders shall only be enforceable if the applicant provides security in favour of the defendant in the form of a deposit or a bank guarantee.

10. The respondents have opposed the applicant's applications. They request:

1. The application for interim measures is dismissed.

2.a) The applicant shall bear the reasonable and proportionate legal costs and other expenses incurred by the respondents in connection with the present proceedings.

This order is immediately enforceable.

b) Alternatively, the interim measures sought by the applicant are only enforceable against security in the amount of at least [...].

FACTUAL AND LEGAL ISSUES IN DISPUTE:

11. The applicant considers the advertising of the contested embodiments (both online and at trade fairs) to be a direct infringement of the patent in suit.

12. In the applicant's view, the respondents' occluders "MemoCarna (ASD)" and "MemoCarna (VSD)" fulfil all the features of claim 1 of the patent in suit to the letter, so that there is a case of identical, direct patent infringement.

13. Furthermore, the legal validity of the injunction patent is also sufficiently secured. There is a presumption in favour of the legal validity of granted European patents. In addition, the injunction patent was challenged by a preliminary objection and subsequently also survived an appeal procedure. The injunction patent had been confirmed in its current form, so that the legal validity of the injunction patent could be assumed.

14. The order for interim measures is also urgent. The applicant would suffer considerable damage if it could only enforce its claim for injunctive relief in the main proceedings. The application was filed at the earliest possible date and without undue delay. It was only a few weeks ago that the applicant first obtained reliable knowledge of the current facts of the infringement and after it had carried out an infringement analysis at the end of May/beginning of June 2025.

15. Furthermore, the order of provisional measures is also objectively necessary. The infringing acts of the respondents are likely to cause the applicant considerable, and in particular long-term, damage by directly reducing the applicant's market share. The applicant operates on the market covered by the patent in question with its own products. The products have great economic value, based on sales. Due to the defendants' increased marketing efforts, there are serious concerns about significant losses in orders, sales and market share as a result of the defendants' distribution of infringing products. This reduction in sales and market opportunities cannot be compensated for in purely monetary terms. The losses caused by the infringement of the patent in suit are accumulating every day, without any possibility of enforcement. The protection of the applicant's own sales opportunities can only be guaranteed by the rapid and effective enforcement of its exclusive right. This temporal value of the patent in suit is irreversible.

16. The necessary weighing of interests also favours the applicant. The applicant is losing market share every day, and its exclusive right loses one day of its term for every day that it cannot be enforced. There is a serious fear that the applicant will suffer significant losses in orders, sales and its overall market share as a result of the

marketing of the infringing products by the respondents. There is also a likelihood of a decline in prices. No undue hardship on the part of the respondents is apparent.

17. The respondents defend themselves against the application for an order for interim measures.

18. According to the respondents, the application is already inadmissible because the Düsseldorf local division does not have jurisdiction to decide on the application. In particular, jurisdiction does not arise under Article 33(1)(a) UPC Agreement, as there is neither an infringement of rights in Germany nor a threat of infringement of rights in the contracting member state of Germany.

19. The respondents are of the opinion that the application should also be rejected due to lack of urgency. The applicant waited several months after becoming aware of the circumstances on which it bases its application before filing the application. Furthermore, the applicant had already challenged the two identical embodiments in question on 18 June 2025 before the Hamburg local division with an application for interim measures based on another patent. There was no apparent reason why the applicant had waited another two weeks to file its application before the Düsseldorf local division.

20. The application defendants further argue that the application should be dismissed as unnecessary. The applicant has neither demonstrated nor substantiated that interim measures are necessary. The applicant cannot point to any specific disadvantages or hardships that would arise if its request were only decided in the main proceedings.

21. There is already no risk of repetition, as the respondents have not committed any acts of infringement, particularly not within the jurisdiction of the UPC Agreement. The respondents' website, on which the applicant bases its allegation of infringement, among other things, is not specifically aimed at European customers. No prices are listed on the website, in particular no prices in the currencies of the UPC Agreement member states for which an infringement is alleged. Nor has any advertising for the European market or sales of the contested embodiments to Europe taken place. There is also no risk of first infringement in the UPC Agreement territory for which the applicant is asserting claims. The applicant had not presented any actual evidence from which a risk of first infringement in the UPC Agreement territory could be inferred.

22. Furthermore, the contested embodiments did not fall within the scope of protection of patent claim 1.

23. In particular, none of the contested embodiments had a completely closed proximal wall in the form of a continuous surface. The proximal surfaces of the contested embodiments were formed by a coarse-meshed mesh with a central opening which, like the generic occlusion device that the patent in suit was intended to further develop, did not guarantee complete endothelialisation but had to be provided with an insert for this purpose. When placed

state, therefore, precisely those irregularities formed on the surface that the patent in suit expressly sought to overcome. In addition, the contested embodiments had threads whose ends were not joined together in a socket but remained loose. Finally, insofar as the applicant drew a comparison between the contested embodiments and its own products, this was fundamentally unproductive. An allegation of infringement required the realisation of the features of the patent in suit, not merely a similarity to third-party products.

24. Furthermore, patent claim 1 was not new in relation to the disclosure of document DN 1, which was published before the priority date of the patent in suit. DN 1 disclosed all the features of claim 1 of the patent in suit and thus anticipated its subject matter in a manner prejudicial to novelty.

25. Claim 1 was also not new in relation to the disclosure of DN 2, which was also published before the priority date of the patent in suit. Document DN 2 had already been cited in the preliminary objection and appeal proceedings relating to the patent in suit (in each case as D4). In these proceedings, the applicant had used feature interpretations that contradicted those in the present application to argue that there was a distinction from DN 2.

26. The applicant has contested this. ESSENTIAL

STEPS IN THE PROCEEDINGS:

27. In a document dated 8 July 2025, the applicant filed an application for order of interim measures with the Düsseldorf local division. The application was served within the CMS on 10 July 2025.

28. Within the one-month preliminary objection period set by the judge-rapporteur, the respondents lodged a preliminary objection to the application for order of interim measures on 11 August 2025.

29. On 12 August 2025, the Düsseldorf local division set the date for the oral hearing for 2 October 2025 and summoned the parties accordingly.

30. In a procedural order dated 20 August 2025, the Düsseldorf local division decided to call in a technically qualified judge, who was then allocated to the proceedings by the President of the Court of First Instance.

31. In a document dated 26 August 2025, the applicant made use of the opportunity offered in the summons to respond to the preliminary objection. In a document dated 9 September 2025, the respondents made use of the opportunity offered in the summons to reply to this.

32. To avoid repetition, reference is made to the entire contents of the file. REASONS FOR THE ORDER:

33. The application for order of interim measures is admissible but unsuccessful on the merits.

I. (International) jurisdiction of the Düsseldorf local division

34. The Düsseldorf local division has international and "UPC Agreement-internal" jurisdiction.

35. The UPC Agreement has international jurisdiction over infringement actions if the European patent asserted by the plaintiff is effective in at least one contracting member state and the alleged damage can occur in that contracting member state (Art. 31 UPC Agreement, Art. 7(2) in conjunction with Art. 71b(1) Brussels Ia Regulation, cf. Court of Appeal UPC Order of 3 September 2024 – UPC CoA 188/2024 *AYLO/DISH,* GRUR-RS 2024, 29446). If it is alleged that the damage was caused via the internet, the likelihood of such damage may arise from the possibility of purchasing products and/or using services from a website that is accessible in the territory of the Contracting Member State in which the European patent takes effect (UPC Court of Appeal, *AYLO/DISH,* cited above).

36. Applying these principles to the present case, the local division of Düsseldorf (international) has jurisdiction.

37. It is undisputed that the patent in suit is in force in the Federal Republic of Germany, France, Italy and the Netherlands. It is also undisputed that the respondents, or at least the second respondent, are present at the CSI in Frankfurt.
a.M. (18 to 21 June 2025). In view of the applicant's substantiated submission, with reference to illustrations in which the respondents' contested products are prominently displayed – and bear a CE marking – on the back wall of the exhibition stand (Exhibit Occ 8), as well as the written witness statements of Mr Scienza, VP Marketing & Business Development at the applicant, who was personally present at the CSI (Annexes Occ 7, Occ 14), the respondents' objection that the contested embodiments were only made recognisable there, let alone offered for sale, is insufficient to raise significant doubts as to whether at least (clearly recognisable) images of the (allegedly) patent-infringing products were prominently displayed to the relevant specialist audience at the CSI. In addition, the applicant has argued, without contradiction, that the respondents will participate in Medica 2025 in November (application, para. 122).

38. The fact that the CSI, as asserted by the respondents and substantiated by documents and not disputed by the applicant in this respect, is not a sales fair but (primarily) a trade fair and that their presence there was "primarily academic" (only raised in the rejoinder of 9 September 2025) does not preclude this. In any case, the respondents admit that they were (also) present in order to give interested professional circles an impression of the subject matter and nature of their activities (reply, para. 22). Accordingly, the respondents participated in a "device parade" at the CSI (application, para. 71), although they dispute that this participation was related to the contested embodiments. Irrespective of this, the existence of an infringing act in the form of an offer at the CSI or, at least, the threat of an infringement has been presented in a manner that is at least sufficiently plausible, taking into account all the facts and circumstances. This is sufficient for the determination of jurisdiction.

39. With regard to the product "MemoCarna ASD Occluder", it remains clear that this is advertised on the website of the second respondent (https://en.lepumedical.com/products/ memocarnaatrial-septal-defect-asd-occluder/). The fact that the website, based on the respondents' argument that there is "no marketable version" of the contested embodiments, shows that this does not change anything. Nor is it relevant to the assumption of jurisdiction that the respondents' argument that there is "no marketable version" of the contested embodiments shows that this does not change anything.

shows a "non-marketable version" of the contested embodiments based on the respondents' submissions does not change this. Nor is it relevant to the assumption of jurisdiction that the website is not aimed at European, let alone German, customers, as argued by the respondents. It is undisputed that the website is accessible to European and German customers. Nothing more is required for jurisdiction (see Court of Appeal UPC, *AYLO/DISH,* reference above).

40. It follows from the above that the alleged patent infringement may cause damage in the contracting states of the UPC Agreement, and in particular in Germany. This means that the UPC Agreement has jurisdiction. For the sake of completeness, the court points out that it is not necessary for jurisdiction to be assumed that an infringing act or at least the threat of such an act be conclusively presented. This assessment is subject to the substantive examination of the application; see also below (cf. Court of Appeal UPC Agreement, *AYLO/DISH,* there: (Alleged) indirect infringement, local division Lisbon, Order of 15 October 2024 UPC_317_2024, *Ericsson/Asustek c*.s.).

41. This conclusion applies both to the first respondent, which is based in an EU Member State (the Netherlands), and to the second respondent, which is based in China. This is because, according to Article 71b(2) of the Brussels Ia Regulation, in cases where the defendant is not domiciled in a Member State and this Regulation does not otherwise establish jurisdiction over him, Chapter II (special jurisdiction, including Article 7), insofar as it is relevant, applies regardless of the defendant's domicile.

42. The fact that this is an application for interim measures does not lead to a different conclusion, see Articles 35 and 71b(2), second sentence, of the Brussels Ia Regulation.

43. Since the place where "the actual or threatened infringement has occurred or may occur" within the meaning of Article 33(1)(a) of the UPC Agreement is to be interpreted in the same way as the place "where the harmful event has occurred or may occur" in Article 7(2) of the Brussels Ia Regulation (see Court of Appeal UPC, *AYLO/DISH,* reference above), the "UPC-internal" jurisdiction of the local division of Düsseldorf is also established on the basis of the already affirmed international jurisdiction on the grounds that damage may occur in Europe, in particular also in Germany.

II. Right to sue

44. There are no objections to the right to bring proceedings. As the registered owner of the patent in suit pursuant to Article 47(1) of the UPC Agreement in conjunction with Rule 8(5)(a) and (c) of the RoP, the applicant is entitled to bring proceedings before the court.

III. Infringement of the patent

45. It cannot be established with sufficient certainty (Rule 211(2) of the RoP) that the applicant's rights are infringed by the offer of the contested embodiments, at least within the contracting member state of Germany (Article 25(a) of the UPC Agreement).

1. Realisation of features

46. On summary examination, it cannot be established with sufficient certainty (R. 211(2) RoP) that the contested embodiments directly and literally make use of the technical teaching of the patent in suit protected by claim 1.

a) Relevant skilled person

47. The relevant skilled person is, largely in accordance with the definition proposed by the parties, an engineer in the field of biomedical engineering, in particular catheter-based implantable devices and methods, possibly working in a team with a cardiologist or interventional radiologist.

b) Determination of the scope of protection

48. The invention underlying the patent in suit generally relates to the field of braided medical devices and methods for manufacturing such devices. In particular, the invention relates to occlusion devices (see paragraph [0001] of the patent in suit, hereinafter referred to only by the corresponding paragraph numbers).

49. In medical technology, septal defects, such as defects of the atrial septum, are known to be closed non-surgically, i.e. without surgery in the true sense of the word, by means of transvenous, interventional access, i.e. by catheter intervention. Various occlusion systems with different advantages and disadvantages have been proposed, but no particular closure system has been able to establish itself. The provisional patent refers to the various systems as "occluders" or "occlusion instruments" (para. [0002]).

50. In all interventional occlusion systems, a self-expanding umbrella system is inserted transvenously via a defect in the septum that is to be closed. Such a system could, for example, consist of two small umbrellas, each positioned on the distal (i.e. further away from the centre of the body or the heart) or proximal (i.e. closer to the centre of the body) side of the septum (para. [0003]), whereby the small umbrellas are then screwed together. When assembled, this results in a double umbrella system that is fixed by a short connecting bridge (cf. para. [0003]). However, according to the patent in suit, such occlusion instruments known from the prior art have the disadvantage that the implantation procedure is relatively complicated, difficult and time-consuming, and there is a risk of material fatigue with branch fracture. Furthermore, thromboembolic complications are often to be expected (paragraph [0004]).

51. Another type of occlusion device, known as the lock clamshell umbrella system, consists of two steel umbrellas covered with Dacron, each stabilised by four arms. This type of occluder is implanted via venous access in the patient. However, the Lock-Clamshell occluder has proven problematic because the insertion device required for implantation must be relatively large. Another disadvantage is that many different occluder sizes are needed to match the proportions of the septal defect to be closed. It has been found that the umbrellas do not flatten completely when inserted if the length or diameter of the bridge inserted into the defect is not optimally matched. This leads to incomplete endothelialisation. Furthermore, it has been shown that many of the systems implanted in the patient's body via over a longer period of time due to the considerable

mechanical stress, material fatigue and fractures in the metallic structures. This is particularly the case when there is permanent tension between the implant and the septum (para. [0005]).

52. To overcome these disadvantages, self-centring occlusion devices have been developed which are inserted into the patient's body using minimally invasive procedures, for example via a catheter and guide wires, and placed in the septal defect to be closed. The design is based on the principle that the occlusion device can be tapered to the size of the introducer sheath or catheter used for the intravascular surgical procedure. A tapered occlusion device is then inserted via the catheter into the septal defect or shunt to be closed. The occluder then exits the catheter, whereupon the self-expanding umbrellas or retention discs unfold and attach themselves to both sides of the septum. The umbrellas, in turn, contain tissue inserts made of Dacron, for example, or are covered by such inserts, thereby closing the defect or shunt. The implants remaining in the body are more or less completely enclosed by the body's own tissue after a few weeks to months (para. [0006]).

53. According to the description of the patent in suit, WO 2005/020822 A1 also discloses an occlusion instrument consisting essentially of a mesh of thin wires or threads made of a material with shape memory function. In its expanded state, the known occlusion instrument has a proximal and a distal retention area and a cylindrical web arranged between them. The fact that, in this prior art, the proximal retention area of the mesh has a shape that is open towards the proximal end means that, when the occlusion instrument is in use, the edge of the proximal retention area lies flat against the septal wall and the retention area does not protrude beyond the septal wall. By using a specific braiding technique, it is possible to produce a braid in which the proximal retention area has an open shape towards the proximal end (paras. [0011] - [0014]).

54. With regard to these occlusion instruments known from WO 2005/020822 A1, the patent in suit considers it disadvantageous that the mesh has an opening at the proximal end which must be covered with, for example, a Dacron insert or a cloth so that the finished occlusion instrument is no longer open at the proximal end. This is time-consuming and therefore costly. Another disadvantage is that different materials, namely the materials of the mesh and the materials of the Dacron insert or cloth, must be connected to each other by force, which leads to weak points and material fatigue. Furthermore, thromboembolic complications are to be expected. The proximal end of the known occlusion instrument has a proximal wall in which an opening is provided axially to the bar for manufacturing purposes. Even if this opening is closed, as described above, by means of, for example, the Dacron insert, the known system cannot prevent the finished occlusion device from having at least one hollow-shaped recess in the proximal retention area of the occluder, namely where the opening closed by the Dacron insert is ordered to be located, or, under certain circumstances, components protrude, which can lead to embolism-related problems, in particular consecutive embolisation (paras. [0016] - [0018]).

55. The invention is therefore based on the task of further developing such an occlusion instrument known from medical technology and described in WO 2005/020822 A1

in such a way that the aforementioned disadvantages can be overcome. In particular, an occlusion instrument is to be specified which ensures the closure of a septal defect, whereby the aforementioned complications are avoided.

56. To solve this problem, the patent in suit protects an occlusion instrument with the following features:

1. Occlusion instrument

1.1 The occlusion instrument consists of a frame (5) and a mesh (2) of thin wires or threads (4).

1.1.1 The mesh (2) of thin wires or threads (4) is given a suitable shape by means of a forming and heat treatment process.

1.2 The occlusion instrument has a proximal retention area (6) and a distal retention area (8).

1.2.1 In the distal retention area (8), the ends of the wires or threads (4) converge in the socket (16).

1.3 A cylindrical bar (10) is located between the proximal and distal retention areas.

1.4 The two retention areas (6, 8) can be applied on both sides of a shunt to be closed in a septum, usually by means of an intravascular surgical procedure.

1.4.1 while the bar (10) runs through the shunt.

1.5 The proximal retention area (6) of the mesh (2) at the proximal end (12) of the occlusion instrument has a completely closed proximal wall (112).

1.5.1 The completely closed proximal wall (112) is a continuous surface.

1.5.2 The completely closed proximal wall (112) forms the proximal end (12) of the occlusion instrument.

57. Some features of this claim require explanation.

58. According to Art. 69 EPC in conjunction with the Protocol on its interpretation, the patent claim is not only the starting point but also the decisive basis for determining the scope of protection of a European patent. The interpretation of a patent claim does not depend solely on its exact wording in the linguistic sense. Rather, the description and drawings must always be consulted as aids to the interpretation of the patent claim and not only to resolve any ambiguities.

in the patent claim. However, this does not mean that the patent claim serves merely as a guideline and that its subject matter also extends to what, after examination of the description and drawings, represents the patent holder's claim for protection. When applying these principles, appropriate protection for the patent holder should be combined with sufficient legal certainty for third parties. The patent claim must be interpreted from the perspective of a person skilled in the art. These principles for interpreting a patent claim apply equally to the assessment of the infringement and validity of a European patent (UPC_CoA_335/2023, order of 26 February 2024, headnote 2 and p. 26 f. – *10x Genomics/Nanostring;* UPC_CoA_1/2024, order of 13 May 2024, para. 26 – *VusionGroup/Hanshow;* UPC_CoA_182/2024, order of 25 September 2024, para. 82 – *Mammut/Ortovox)*.

59. That said, claim 1 refers to an occlusion device according to feature 1. Such a device is defined in the description as a transvenous, catheter-based closure system for septal defects, such as atrial septal defects (para. [0002]). It is clear to the skilled person and is not disputed between the parties that this is an implant which is inserted in a collapsed form in a minimally invasive manner via a catheter system and released at the target location, where it unfolds independently and mechanically closes an intracardiac defect, such as an atrial septal defect (i.e. a defect in the heart wall). Fig. 2 of the patent in suit shows a detailed perspective view of an occlusion device in its expanded state (edited by the applicant, undisputed in this respect):

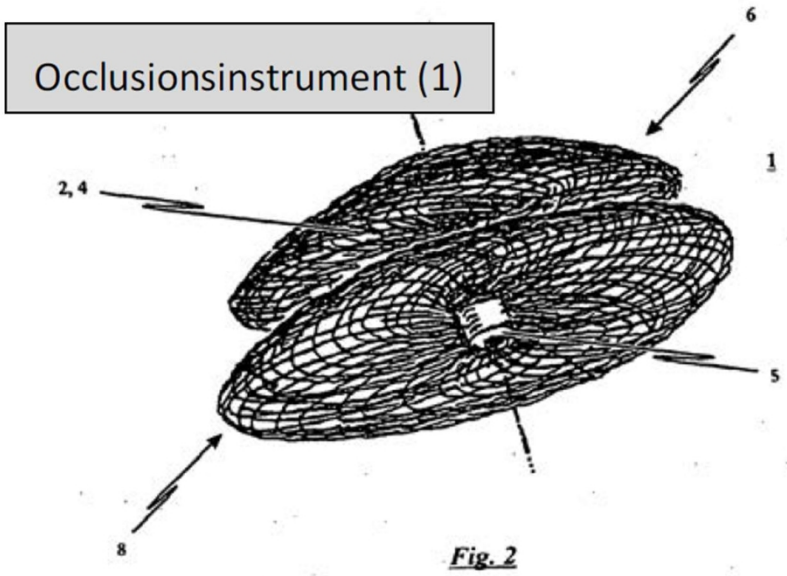


Fig. 2

60. Feature group 1.1 requires that the occlusion device consist of a frame (5) and a mesh (2) of thin wires or threads (4).

61. The term "braid" is not defined in more detail in the claim, except that it must be a braid of thin wires or threads. However, based on the wording of the claim, but also in view of the description and drawings, it is clear to the skilled person that a braid is a structure that can be produced by braiding wires or threads. Braiding methods that can be used for this purpose are described in the patent specification as "known per se" (para. [0028]). However, claim 1 is not limited to a specific braiding method, either in terms of wording

nor functionally limited to a specific braiding method. The description refers in general terms to the "processing into a braid" of the wires or threads (para. [0028]). Furthermore, the skilled person understands that the function of the braid is to act as a basic framework for the occlusion instrument (para. [0053]).

62. Feature 1.1.1 adds that the braid of thin wires or threads is given a suitable shape by means of a forming and heat treatment process. The claim does not specify what a suitable shape is. The shaping of the mesh is thus left to the skilled person. However, it is clear to the skilled person that a suitable shape is one that can be used as an occlusion instrument and, in particular, a shape that can fulfil the other (spatial-physical) features of the claimed occlusion instrument (in particular features 1.2-1.5, see below). For example, the mesh can be "sack-shaped", "spherical", "pear-shaped" or
"drop-shaped" (para. [0028]). Furthermore, a fully formed occluder can, for example, be tapered to the size of a catheter. After exiting the catheter, the occlusion device then unfolds independently and resumes the shape that was imparted to it during the forming and/or heat treatment step in the manufacturing process (para. [0043]).

63. The mesh (or thin wires or threads) is not limited to a specific material or thickness, as long as the material, as required by feature 1.1.1, is suitable for obtaining a suitable shape within the meaning of the claim by means of a forming and heat treatment process and is suitable for functioning as the basic framework for the occlusion instrument. The description prefers that the mesh be made of nitinol or another material with shape memory or
"memory effect". However, according to the description, metallic wires as well as organic threads can also be processed into the mesh (paras. [0042] - [0043]).

64. The skilled person cannot deduce from the claim or the description how many threads or wires the mesh is made of (in this respect, the court concurs with the applicant, reply, para. 22). The specific number of threads or wires is left open in the claim. However, this does not mean that the skilled person understands patent claim 1 to mean that the braid may also consist of a single thread or wire. According to the wording, the braid consists of wires or threads (i.e. plural). These are processed into a braid. The ends of the wires or threads (4) converge in the socket (16) (see below for feature 1.2.1). Thus, the other features of the claim, which the skilled person always considers as a whole (UPC_CoA_768/2024, order of 30 April 2025, para. 37 – *Insulet/EOFlow)*, also require multiple wires or threads. Furthermore, the description teaches the skilled person that the use of a braid made up of several thin wires or threads as the starting material for the occlusion instrument according to the invention results in a certain advantage, since the braid has better mechanical stability and greater rigidity (para. [0025], as stated by the applicant, application, para. 44, and the respondents during the oral proceedings). Furthermore, both parties assumed during the oral proceedings that it is common knowledge that it is advantageous to use several wires or threads instead of just one when manufacturing the mesh.

65. The court also notes that, in the context of the discussion of the legal situation, both in the present proceedings (Reply, paras. 76, 88) and in the opposition proceedings before the EPO, where it successfully argued with regard to citation DN2 (D4 in

opposition proceedings, see Annex Occ 12, 12.6), that the occlusion device disclosed in the prior art consisted of only one wire, whereas the claimed device was an occluder consisting of several wires or threads. This assertion, and in particular its confirmation by the Opposition Division of the EPO, is a further indication that the skilled person interprets feature 1.2 as meaning that a mesh made of a wire or thread does not fall within the scope of the claim (see UPC_CoA_405/2024, Order of 20 December 2024, Headnote 2 and para. 43 – *Alexion/Amgen)*. Irrespective of this, the court must in any case ensure that a uniform interpretation of the claims is applied both in the infringement assessment and in the assessment of legal validity.

66. It follows from the above considerations that the claim leaves it to the discretion of the skilled person to decide how many wires or threads the braid consists of. However, there must be several, i.e. more than one wire or thread.

67. By a holder as claimed in feature 1.1, the skilled person understands a component with which the ends of the threads/wires of the braid are bundled or held together (paras. [0001] and [0007] regarding the prior art; para. [0013] also regarding a frame from the prior art; para. [0027] "a frame for bundling or gathering the mesh" [can be dispensed with at the proximal end], and para. [0054], see also below regarding feature 1.2.1). Fig. 3 of the patent in suit shows an occlusion instrument, whereby the frame (5) is shown (edited by the Claimant, undisputed in this respect).

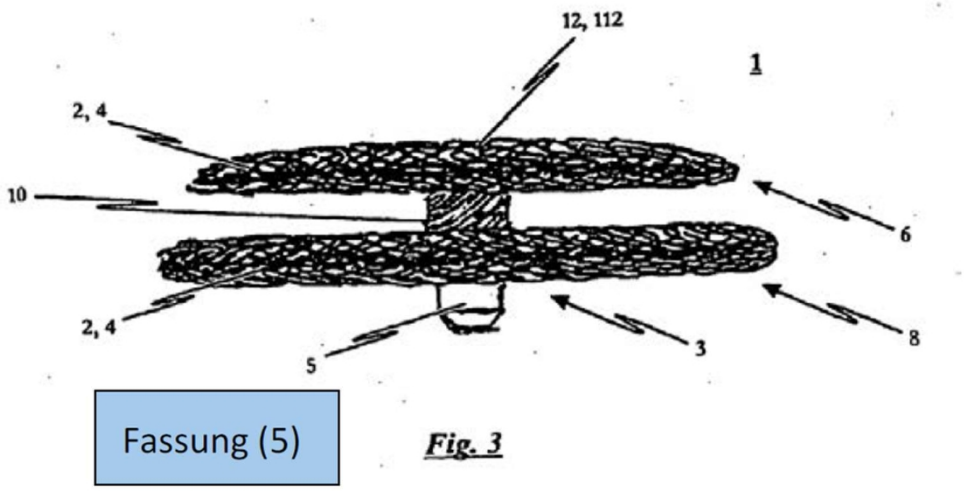


Fig. 3

68. According to <u>feature 1.2,</u> the occlusion instrument has a proximal retention area (6) and a distal retention area (8). As explained above, an occlusion device serves to close septal defects. To this end, the occlusion device is intended to "retain" the blood beyond the defect (Latin *retentere,* see 72 preliminary objection). For this purpose, claim 1 provides for two "retention areas", namely a proximal and a distal retention area. "Distal" is defined in the description as further away from the centre of the body or the heart, and "proximal" as closer to the centre of the body. The skilled person will therefore understand the terms accordingly. This has been illustrated by the claimant with the help of the edited Figure 3 of the patent in suit (see below), and both parties have rightly assumed this interpretation.

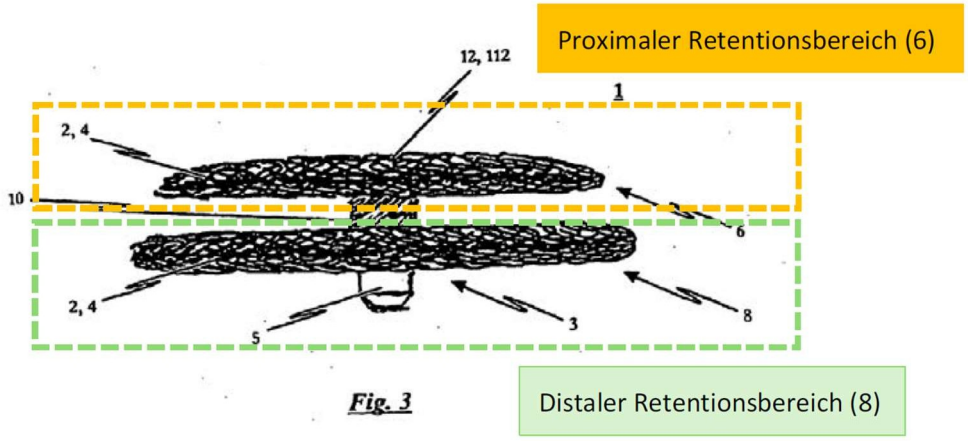


Fig. 3

69. Feature 1.2.1 of claim 1 requires that the ends of the wires or threads (4) converge in the distal retention area (8) in the holder (16). The holder must therefore be suitable for bundling the ends of the wires or threads together. According to the description, the advantage of bundling the ends of the wires or threads together in the distal holder is that this eliminates the need for a holder to bundle or gather the mesh together in the proximal retention area. This means that no component of the occlusion instrument protrudes beyond the septal wall, thus preventing constant blood contact with components of the implant. This has the advantage that there is no risk of immune reactions or thromboembolic complications (para. [0027]).

70. According to the description, bundling the mesh in the socket at the distal end of the distal retention area has the additional advantage that an internal thread can be created in the socket, which serves to engage with a guide wire of an insertion device not shown, while the occlusion instrument 1 is brought to the corresponding position where the defect in the septum is located, for example by means of an intravascular surgical procedure. Notwithstanding any contrary statements by the applicant, such a design is not (implicitly) part of the claimed device for a person skilled in the art (see applicant's reply, para. 23, paras. [0054], [0060], see "can be produced").

71. The court further finds, in agreement with the respondents (cf. preliminary objection, para. 74), that based on the wording of the claim, read in light of the description, in particular the technical function of the holder – the gathering or bundling of the thin wires or threads at the distal retention area, whereby a holder at the proximal retention area can be dispensed with – as described above, understands that all wires or threads must come together in the holder, but (for clarification) only insofar as all wires or threads of the braid are concerned (cf. para. [0054], "At the distal end 3 of the distal retention area 8, the braid 2 is combined in a frame 5", and para. [0027] "...a frame for bundling or combining the braid [at the proximal retention area] can be dispensed with"). Incidentally, the claim does not exclude the possibility of additional wires or threads that do not belong to the braid being present in the device. From a specialist's point of view, it is also not apparent why this should be excluded.

However, such other wires or threads, insofar as they do not belong to the braid, do not necessarily have to be brought together in the socket. In this respect, there may be "loose ends" that are not brought together in the socket (contrary to the respondents, rejoinder, para. 34).

72. Features 1.3, 1.4 and 1.4.1, which are not disputed by the parties, are considered together by the skilled person. They require that the occlusion instrument has a cylindrical bridge between the proximal and distal retention areas. The bridge is shown in Figure 3 with the number (10) (see above). If the two retention areas (6, 8) are applied on both sides of a shunt to be closed in a septum (i.e. the opening in a septum to be closed) by means of a mostly intravascular surgical procedure (feature 1.4), the bar runs through the shunt (feature 1.4.1) (cf. paras. [0048] - [0050]). Such bridges were known in the prior art, namely bridges that centre themselves in the shunt to be closed during the tensioning of the umbrellas (para. [0009]).

73. Another point of debate is how the specialist understands feature group 1.5. This requires that the proximal retention area (6) of the mesh (2) at the proximal end
(12) of the occlusion instrument. The term "proximal wall" is defined in the description as that section or area of the proximal retention area of the mesh at the proximal end of the occlusion device which forms the proximal closure for the defect to be closed (para. [0023], see the term "proximal" above). The skilled person considers this feature in conjunction with feature 1.5.1, which claims that the completely closed proximal wall (112) is a continuous surface, while feature 1.5.2 requires that the completely closed proximal wall (112) forms the proximal end (12) of the occlusion device.

74. If the skilled person were to rely solely on the wording of the patent claim, the use of the terms "completely closed", "proximal wall" and "continuous surface" in feature group 1.5 could give the impression that the outer wall of the occlusion device (to be closed) must have a completely closed, uninterrupted surface. However, the parties rightly assume that the skilled person would not leave it at that. The skilled person takes into account the description and drawings and always interprets a feature of a patent claim in the light of the entire claim (see, inter alia, *Insulet/EOFlow* Appeal Court*,* above). From the function of the individual feature in the context of the entire patent claim, the skilled person will deduce the technical function of the feature individually and in its entirety. With regard to the terminology used in a patent specification, this may lead the skilled person to assign a meaning to a term that differs from its general usage. The patent specification can define terms independently and thus constitutes its own lexicon (UPC_CFI_248/2024 (local division Munich), decision of 22 August 2025, *Brita SE/Aquaschield;* UPC_CFI_1/2023 (Central Chamber Munich), decision of 16 July 2024, *Sanofi/Amgen;* UPC_CFI_309/2023 (Central Chamber Paris), decision of 5 November 2024, *NJOY/Juul Labs)*.

75. Based on this, the specialist recognises that feature group 1.5 places further demands on the spatial and physical properties of the claimed occlusion instrument. This concerns the proximal retention area of the instrument, which consists of a mesh. As required by the claim and as explained above

, the mesh consists of thin wires or threads. The choice of material, the type and number of wires or threads are left to the discretion of the skilled person. However, the skilled person is aware that it is inherent in a mesh of thin wires or threads that it may contain "holes". These are located in the spaces created by the crossing of the various wires or threads of the mesh (cf. para. [0062] of the description: "spaces remaining in the mesh 2"). The presence of such (usual) openings therefore does not preclude the skilled person from considering the mesh as a "wall" or "completely closed" or as a "continuous surface" within the meaning of the claim. The skilled person finds further confirmation of this in the drawings, for example in Fig. 3 shown above, which shows a mesh with openings.

76. According to feature 1.5.1, the completely closed proximal wall (112) located at the proximal end (12) of the occlusion instrument (feature 1.5) is a "continuous surface". Although a concrete definition of the term "continuous surface" is missing from the description, it is clear from the description that the term "continuity" is to be understood in the mathematical (topological) sense (para. [0030]). Similarly, the description teaches the skilled person that a completely closed proximal wall does not have any indentations or other (in the mathematical sense) "discontinuities", such as sharp edges, kinks, etc. The reason for this is to avoid the usual complications associated with this, in particular with regard to embolism-related problems (para. [0024]). This has the advantage that no parts of the occlusion instrument protrude beyond the plane in which the septal wall with the defect lies on the proximal side of the defect. In the solution according to the invention, this plane, i.e. the plane in which the septal wall with the defect lies, is formed by the completely closed proximal wall of the occlusion instrument (para. [0024]). Furthermore, according to the description, it is possible to achieve, in particular, that the occlusion device used is completely enclosed by the body's own tissue much more quickly than with the closure systems known from the prior art (para. [0025], para. [0050]: "complete endothelialisation occurs relatively quickly").

77. For the understanding of the skilled person, the distinction from the prior art as described in the description is also relevant (UPC_CFI_373/2023 (LD Düsseldorf), decision of 31 October 2024, p. 16 et seq., *SodaStream/Aarke*). The description mentions as a disadvantage of the occlusion instruments known from WO 2005/020822 A1 that the mesh of WO 2005/020822 A1 has an opening at the proximal end. This must be covered, for example, with a Dacron insert or a cloth so that the finished occlusion device is no longer open at the proximal end (para. [0016], see also Fig. 16a, a representation of a mesh according to WO 2005/020822). According to the description, at least one trough-shaped recess remains at the point where the opening closed by the Dacron insert is located, and components may protrude. According to the description, this leads to embolism-related problems, in particular to consecutive embolisation. The invention aims to solve these problems with the aid of an occlusion instrument which, when inserted, closes as flat as possible with the septum on the proximal side of the septal defect (paras. [0017] - [0020]).

78. The skilled person will deduce from this information that the technical function of feature group 1.5 is to provide as flat a seal as possible at the proximal end of the defect in order to promote complete endothelialisation and avoid embolism problems. The skilled person will feature group 1.5, in particular

Feature 1.5.1, understand accordingly (see also para. [0021]). Contrary to the respondents' view, however, this does not mean that a retention area constitutes (only) a completely closed proximal wall and continuous surface (within the meaning of the claim) if complete endothelialisation is permitted or embolism-related problems can no longer occur (preliminary objection, para. 82). It is not compatible with the appropriate protection of the patent proprietor to be taken into account under the Protocol to interpret the patent claim in a strictly functional manner in such a way that the scope of protection of this claim is limited to the complete fulfilment of the unclaimed but technically recognisable function or advantages of the feature in question (in this case, that complete endothelialisation occurs relatively quickly, see above). The scope of protection of a device claim regularly also extends to embodiments in which the claimed structural features are present which, although suitable for performing the technical function and performing this function, do not do so in a manner which fully and unrestrictedly realises the advantages mentioned in the patent specification.

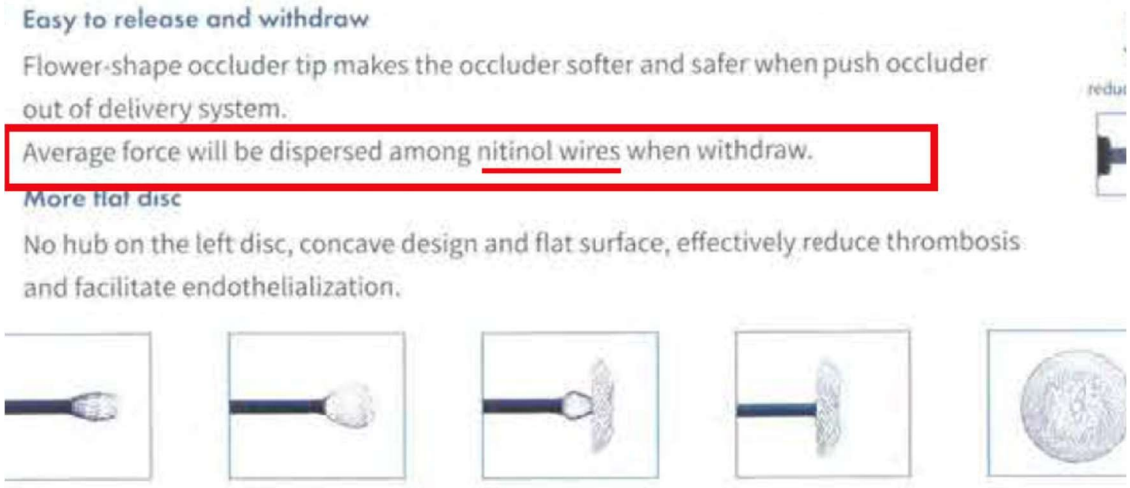
79. In view of the above, the respondents are also correct in assuming that the claim does not exclude the possibility that an occlusion device according to the patent in suit may be provided with a tissue insert (preliminary objection, para. 61 with reference to paragraph [0052]), according to which the occlusion instrument according to the invention "naturally" can also have tissue inserts, which are not explicitly shown in the drawings and which are known from the prior art. However, there is no question that, in order to fall (literally) under claim 1, the remaining (structural) features of (occlusion device) claim 1 must still be fulfilled even when a tissue insert is used.

c) Feature realisation

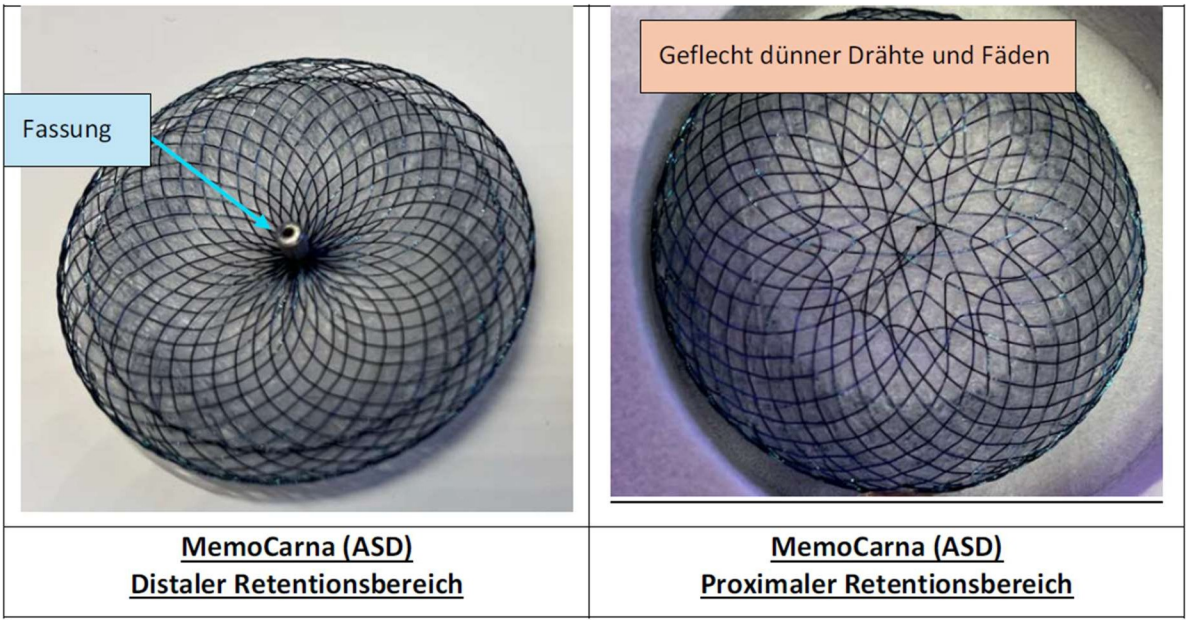
80. The court recalls that, in summary proceedings, it must be satisfied with sufficient certainty that the applicant's rights are being infringed or are at risk of being infringed. Such sufficient certainty requires that the court consider it at least highly probable that the patent is being infringed. The burden of proof and presentation of facts alleged to constitute infringement or threatened infringement of the patent, as well as all other circumstances supporting the applicant's application, lies with the applicant (Court of Appeal in *10x Genomics v Nanostring,* reference above, p. 30).

81. Based on these principles and taking into account the available facts and documents, in the context of the summary examination of the present urgent proceedings, after hearing the parties in the oral proceedings, it cannot be established with sufficient certainty that the two contested embodiments, based on the understanding explained in detail above, make use of the technical teaching of patent claim 1 in the literal sense.

82. For the two contested embodiments, the parties' debate has focused on the question of the realisation of feature 1.1, according to which the braid is a braid of thin wires or threads, and – in this context – on feature 1.2.1, according to which the ends of the wires or threads are to converge in the socket. The applicant argues that the braiding technique used in MemoCarna ASD and VSD is based on the use of Nitinol wires – i.e. a plurality of wires (application, para. 77 et seq. and 101 et seq.). In this regard, it refers to the product catalogue (Exhibit Occ 4):



and the images of the contested embodiments shown below:



83. The respondents dispute the literal realisation of feature 1.1 asserted by the applicant alone on the grounds that the wire skeleton of the contested embodiments is made of a single wire. It is therefore not a mesh of wires or threads, but a mesh made from a single thread (preliminary objection, para. 101 and 109).

84. As is already apparent to the naked eye and as was also confirmed by both parties in the oral proceedings, the illustrations of the MemoCarna ASD and VSD are unsuitable for deducing or proving on this basis whether the mesh of the devices in question consists of one, two or more wires or threads. The wires converge in the socket. It is therefore not visible whether there are only two (in the case of one wire) or four or more (in the case of several wires) ends. Theoretically, this could be determined by loosening the 'socket'. However, both parties agreed in the oral hearing that such a solution was neither feasible nor sensible in the context of the oral hearing. This means that neither the illustrations submitted by the applicant

nor the products shown at the hearing and inspected by the court are suitable for drawing conclusions about the number of wires that make up the mesh.

85. The applicant's further submissions are also not suitable for establishing the existence of multiple wires or threads with the sufficient certainty required for the order of interim measures.

86. The applicant argues that the use of only a single wire is much more complicated and expensive in the manufacturing process. Furthermore, if the single wire were to fatigue, there would be a risk of the entire mesh becoming defective, which would not be the case with multiple wires or threads (Reply, para. 53).

87. However, the respondents have countered that they (nevertheless) actually use only one wire to manufacture the mesh. To substantiate this argument, they have submitted braiding instructions as Annex AG 9/9a, which are intended to show the use of one wire in the manufacture of the contested embodiments.

88. The respondents' statement leaves many questions unanswered. For example, it is unclear who created the braiding instructions. Furthermore, no one has assumed legally binding responsibility for the accuracy of these instructions, for example in the form of an affidavit or a (written) witness statement. The fact that the respondents' representatives named a person from the legal department from whom they had received the instructions when asked by the court during the hearing only raises further questions without conclusively clarifying the issue of responsibility. In addition, on the basis of the respondents' submissions and the documents submitted, it is also not possible to conclusively clarify which product is shown in these braiding instructions and whether the product braided in this way ultimately corresponds to the contested embodiments.

89. However, it should not be forgotten that the respondents nevertheless specifically contested the applicant's submission, which was also only general in nature and not supported by a corresponding statement of facts, let alone corresponding evidence, that the contested embodiments had several threads or wires within the meaning of Rule 171(2) of the RoP. This is all the more true since both parties assume that braiding methods using a single wire were known in the prior art. The applicant also confirmed in the hearing that the use of only one wire or thread is not impossible in any case.

90. In light of the arguments put forward by the respondents, it would now have been incumbent upon the applicant to present facts which, with the certainty required for the order of provisional measures, would allow the court to find that the contested embodiments had at least two wires or threads and therefore directly made use of feature 1.1.

91. However, the applicant was unable to meet these requirements. Even at the oral hearing, it was unable to supplement its previous submissions and present further facts on the technical design of the contested embodiments

and the number of wires or threads present therein. Unlike in main proceedings, there is normally no room for further clarification of the facts in summary proceedings, for example in the form of obtaining an expert opinion. This would be contrary to the urgent nature of these proceedings.

92. Against this background, based on the submissions of the parties and the documents submitted, including the products inspected during the oral hearing, it cannot be established with the certainty required for the order of provisional measures that feature 1.1 has been realised. The fact that the product brochure (Exhibit Occ 4) refers to "Nitinol wires" does not change this. Without further (technical) context, this statement appears in a product brochure whose technical content and purpose are unclear and which in any case does not serve to explain whether one or more wires are used for braiding. The product brochure is therefore not sufficient to establish compliance with feature 1.1 in these proceedings.

93. Since the fulfilment of feature 1.1 cannot be conclusively clarified on the basis of the limited sources of information available in the summary proceedings alone, the court points out for the sake of completeness that, in the opinion of the Chamber, the contested embodiments fulfil the remaining features of the claim.

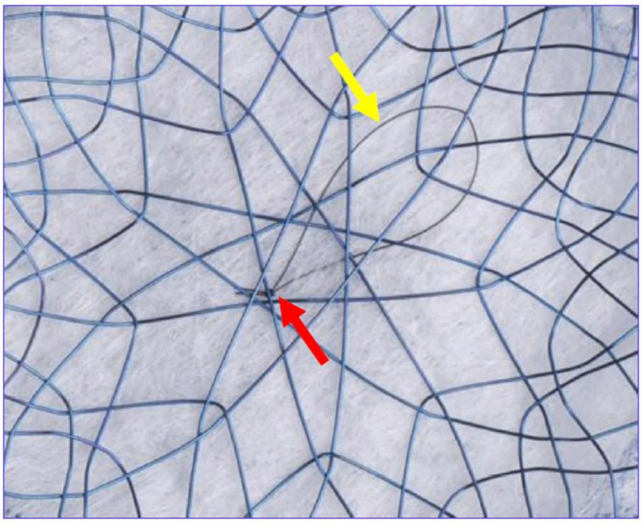
94. The parties rightly agree that features 1, 1.3 and 1.4 have been realised. With regard to features 1.5 and 1.5.1, the mesh at the proximal end of the contested occlusion device has a completely closed proximal wall within the meaning of the claim. The openings visible in the figure above represent (only) the usual openings that belong to a mesh. These openings are not of such a nature that the proximal wall can no longer be described as "completely closed", let alone that the contested embodiments have such an opening at their proximal ends that would have to be spanned so that the finished occlusion instrument is no longer open at the proximal end (as is the case in the prior art, from which the patent in suit is distinguished, see interpretation above). In particular, the wall forms (in a mathematical sense) a continuous surface within the meaning of feature 1.5.1. In the proximal retention area there are no recesses or other "Irregularities" such as sharp edges, kinks, etc.

95. Contrary to the respondents' opinion (preliminary objection, para. 96), the presence of a fabric insert does not mean that feature group 1.5 is not fulfilled. The fabric insert is located on the inside of the occlusion instrument below the mesh and therefore does not form part of the surface/(proximal) wall of the instrument. The use of such a tissue insert is not excluded by the claim. Since the insert is not part of the wall, the defendant's assertion that the wire strands of the surface would lie raised on the insert and form unevenness (preliminary objection, para. 96) cannot be accepted for this reason alone.

96. Insofar as the respondents base their defence on the assertion that the openings in the proximal surface are too large to allow complete endothelialisation and that an insert is therefore essential in their products (preliminary objection, para. 94, reply, para. 57), this is inaccurate because it is based on an incorrect interpretation of the claim. The claim does not require

not necessarily that complete endothelialisation is enabled (see above). The respondents have not argued that the proximal wall of the MemoCarna products does not at least (significantly) contribute to faster endothelialisation. Furthermore, this assertion would contradict the respondents' own product information, which refers to 'faster endothelialisation'. See also Annex Occ 5 under the heading "Better for endotheliazation": "the flattened surface promotes endothelial adhesion and lowers thrombosis risk".

97. The fact that the contested embodiments comprise inserts held in place by black threads intertwined with the wire strands of the surface (see the figure below from the rejoinder, para. 44) did not, in the Chamber's view, give rise to any concerns regarding infringement. The presence of an insert and one (or more) threads to hold the insert in place is not excluded by the claim. The claim does not require that its (loose) ends must (also) converge in the socket.



Angegriffene Ausführungsform MemoCarna ASD; proximale Oberfläche mit Drahtsträngen und Einlage darunter: Verflochtener schwarzer Faden gelb hervorgehoben; Knoten loser Enden des Fadens rot hervorgehoben

98. In the case of MemoCarna VSD, the loose thread ends are also not part of the mesh. As argued by the respondents (preliminary objection, para. 108), the proximal insert is secured by a large number of threads that are intertwined with the wire strands of the surface (see Figure 13, preliminary objection, below). Since the threads serve (only) to secure the insert, they are not part of the mesh. It is therefore irrelevant that they do not end in the socket or are not bundled. See Figure 13 below from the defence

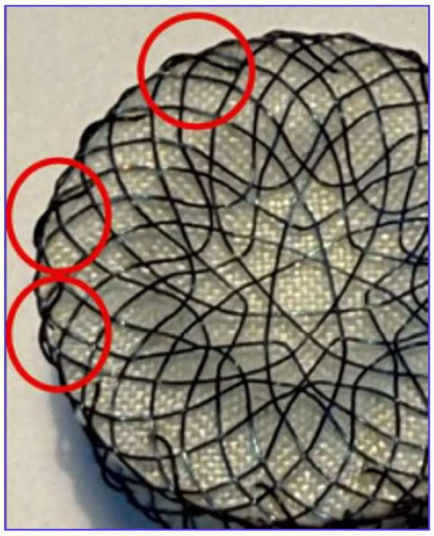
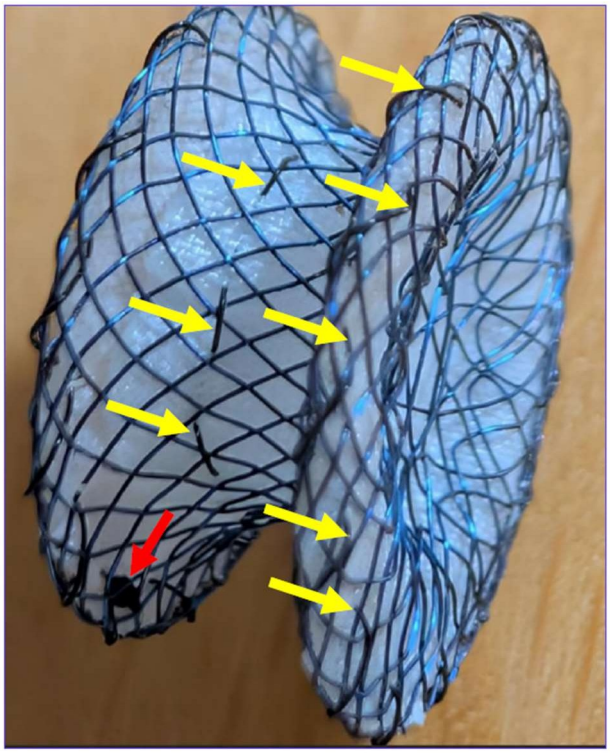


Abbildung 13: Angegriffene Ausführungsform MemoCarna VSD, proximales Ende zeigt nach oben; Fäden mit losen Enden farbig hervorgehoben

and the rejoinder, p. 14/33:



Angegriffene Ausführungsform MemoCarna VSD; proximales Ende zeigt nach rechts: Verflochtene schwarze Fäden gelb hervorgehoben; Knoten loser Enden eines Fadens auf distaler Seite rot hervorgehoben

99. In summary, the court is not sufficiently convinced that the contested embodiments make use of the technical teaching of patent claim 1. Infringement cannot therefore be established in these summary proceedings.

2. Infringing act

100. Incidentally, the court would have had no reservations in assuming that the offer of the contested embodiments by would constitute an (imminent) infringement of the respondents'

direct infringement of the patent in suit pursuant to Art. 25(a) UPC Agreement if it had been established that the contested embodiments fell within the scope of the patent claim (*quod non*, see above).

101. The respondents argued that they had not committed any acts of infringement, in particular not within the jurisdiction of the UPC Agreement. Therefore, there was no risk of repetition (preliminary objection, para. 44).

102. The respondents overlook the fact that their activities at the CSI in Frankfurt already constitute an offer within the meaning of Article 25(a) of the UPC Agreement. The court is sufficiently convinced that the products in question were in fact offered at the CSI in the sense relevant to patent law. The term "offer" in patent law is to be understood in economic terms. Offering is not only a preparatory act preceding manufacture, placing on the market, importation or possession, but also a separate type of use alongside these acts, which must be assessed independently. It is not to be based on the legal understanding in the sense of a binding contractual offer. The offer therefore does not need to contain all the details that would be necessary for the immediate conclusion of a contract by mere acceptance of the offer. The term "offering" encompasses – in the case of a product – the presentation of an item in such a way that viewers can make an offer to acquire it, e.g. by concluding a purchase, rental or lease agreement. It is not necessary to specify a price (see Court of Appeal, UPC_CoA_534/2024, decision of 3 October 2025, *Philips/Belkin,* and also: UPC_CFI_177/2023 (LD Düsseldorf), order of 18 October 2023, *myStromer/Revolt)*.

103. As the Chamber has already established above in the context of jurisdiction, it is undisputed that the respondents were present at the CSI in Frankfurt am Main (18 to 21 June 2025). At least (clearly recognisable) images of the (allegedly) patent-infringing products were shown at the CSI. Even if the court were to agree with the applicants that the products themselves were not exhibited or offered for sale at the CSI, this would not lead to a different assessment. This is because the undisputed display of images (from product brochures) of the products is sufficient in itself to promote demand for the products in question, and this in itself qualifies as an offer within the meaning of Article 25 of the UPC Agreement. This is not affected by the fact that, in the respondents' view, their presence at the CSI was "primarily academic". The decisive factor is the undisputed presentation of the products to the relevant professional circles, which, as already explained, created or at least could have created demand. This qualifies as an "offer" within the meaning of Art. 25 UPC Agreement. Furthermore, this at least gives rise to the risk of further offers at Medica 2025, in which the respondents will participate.

104. In addition, the respondents have obtained CE marking for the contested designs. According to the respondents' own statements (preliminary objection, para. 11), such marking is, as is generally known, required for the marketing of a medical device in all EU Member States. The CE certification was prominently announced by the respondents on the internet (at the end of April/mid-May via LinkedIn) and was also clearly displayed at the CSI trade fair in Frankfurt. Even if the affixing of the CE marking is to be classified solely as a preparatory act which, in itself, does not constitute any of the infringements specified in Article 25 UPC Agreement (UPC_CFI_213/2025 (LD Düsseldorf), order of 10 July 2025, para. 90, *Aesculap/Shanghai)*, this contributes to the promotional nature

of the respondents' activities at the trade fair and also makes it plausible that, even if one had to assume that there is no evidence of distribution specifically in Germany, the respondents are offering the products at least also for Germany, France, Italy and the Netherlands, or that there is at least a concrete risk of this (see also the Hamburg local division in the parallel proceedings in Hamburg, UPC_CFI_213/2025). Apart from that, the affixing of the CE marking may in any case give rise to liability as an intermediary within the meaning of Art. 63(1) sentence 2 UPC Agreement (see (LD Düsseldorf), order of 10 July 2025, para. 86, *Aesculap/Shanghai;* UPC_CFI_387/2025 (LD Hamburg), order of 14 August 2025, para. 181, *Dyson/Dreame)*).

IV. Legal status

105. For the sake of completeness, the court also points out that the legal status of the patent in question would have been secured to the extent necessary for the order of provisional measures. According to the case law of the Court of Appeal, there is a lack of sufficient conviction as to the validity of the patent required for the order of provisional measures if the court considers it highly probable that the patent is not valid. The burden of proof and presentation of facts concerning the invalidity of the patent lies with the respondent (Court of Appeal in *10x Genomics/Nanostring,* reference above).

106. The patent in suit was challenged by a preliminary objection and subsequently survived (in its current amended form) an appeal. The respondents' arguments do not make it highly probable that the patent in suit will not prove to be legally valid.

1. Novelty

107. The respondents question the validity of the patent in suit by referring to two prior art documents, DN1 (CN 2705130 Y, published on 22 June 2005, Annex 6/6a) and DN2 (CN 2524710 Y, published on 11 December 2002, Annex 7/7a), which they appeal against the novelty of the patent. The parties dispute the correct translation of documents DN1 and DN2. In view of the summary nature of these proceedings, the burden of proof regarding the facts justifying the invalidity of the patent, which lies with the respondents, and the additional circumstance that the accuracy of the translation was already disputed in the proceedings before the EPO, it would have been incumbent on the respondents to provide detailed reasons why the (machine) translation they submitted is correct. In the absence of such justification, the court will proceed on the basis of the applicant's translation (Annex Occ 13 (translation DN1) and Occ 11 (translation DN2)).

108. Upon summary examination, the subject-matter of claim 1 is found to be new in relation to the prior art cited by the applicant, Art. 54 EPC.

109. An invention is considered new if it does not belong to the state of the art. Assessing novelty within the meaning of Article 54(1) EPC requires determining the overall content of the prior publication. The decisive factor is whether the subject-matter of the patent in suit, with all its features, is directly and unambiguously disclosed in the citation (UPC_CoA_182/2024, order of 25 September 2024, para. 123, *Mammut/Ortovox)*. In this context, the court must apply the same interpretation of the scope of protection, regardless of

whether an infringement of the patent at issue or its legal validity is being examined (see principles above, Court of Appeal in *10x Genomics/Nanostring,* reference above).

110. That said, the following applies in the present case:

111. The subject matter of patent claim 1 is novel in relation to DN2. As the applicant has undisputedly argued – contrary to the reference to the inaccurate translation – DN2 discloses an occluder made of a single filament. Thus, claim 1 is novel over DN2, since at least features 1.1 and 1.2.1 (wires or filaments (plural) and their ends) are not disclosed in DN2. The EPO Opposition Division also came to the same conclusion (see Annex Occ12, section 13.2). In light of this conclusion, the other arguments against novelty did not need to be discussed.

112. Claim 1 is also novel in relation to DN1. DN1 was not taken into account in the grant, preliminary objection or appeal proceedings of the patent in suit. The occlusion instrument disclosed in DN1 is also made from a single wire (the term "wire" (singular) is used consistently); at least, it is not directly and unambiguously disclosed that this is not the case or intended. This means that there is no disclosure of features 1.1 and 1.2.1 and, on summary examination, DN1 does not destroy novelty. In light of this conclusion, the other arguments against novelty do not need to be discussed.

113. Based on the above principles, applied to the arguments put forward by the respondents in the context of the legal status, the Chamber considers the legal status of the patent in suit to be sufficiently secure.

V. Balancing of interests

114. Pursuant to Art. 62(2) of the UPC Agreement and R. 211(3) of the RoP, it is within the discretion of the court to weigh up the interests of the parties, taking into account in particular the potential damage that would be caused to one of the parties by the granting or refusal of provisional measures.

115. The court must also take the time factor into account. In particular, it must examine whether the proceedings in the main action should be awaited or whether provisional measures are necessary (UPC_CoA_540/2024, order of 24 February 2025 – Biolitec v Light Guide et al., para. 19; UPC_CoA 768/2024, order of 30 April 2025 – Insulet Corporation v. EOFlow).

116. Provisional measures are necessary, for example, if a delay would cause irreparable damage to the patent holder. However, such damage is not a necessary prerequisite for ordering provisional measures (UPC_Co_182/2024, order of 25 September 2024, APL_21143/2024, para. 237 – Mammut v Ortovox; UPC_CoA_540/2024, order of 24 February 2025, APL_52692/2024 – Biolitec v Light Guide et al., para. 21; UPC_CoA 768/2024, order of 30 April 2025, APL_64374/23024, para. 103 – Insulet Corporation v. EOFlow).

117. The need for provisional measures may also arise from the fact that there is direct competition between the contested embodiment and the patent holder's product (UPC_CoA_540/2024, order of 24 February 2025, APL_52692/2024 –

Biolitec v. Light Guide et al., para. 26). In such cases, provisional measures may be justified if they are necessary to maintain the status quo prior to the alleged infringement until a decision is made on the main issue (UPC_Co_182/2024, order of 25 September 2024, APL_21143/2024, para. 238 – Mammut v. Ortovox; UPC_CoA_540/2024, order of 24 February 2025, APL_52692/2024, para. 28 – Biolitec
v. Light Guide et al.). The need for interim measures may also arise from a change in the market situation from one in which only one product is available to one in which two competing products are available. Such a transition can lead not only to price pressure but also to permanent price erosion (see UPC_CoA_523/2024, APL_51115/2024, order of 3 March 2024, para. 93 – Sumi-Syngenta; UPC_CoA 768/2024, APL_64374/23024, Order of 30 April 2025, para. 104 – Insulet Corporation v. EOFlow)

118. Based on these principles, the Chamber would have had no concerns that the necessary balancing of interests would be in favour of the applicant in the present case.

119. When weighing up the interests, the court takes into account any unreasonable delay in applying for provisional measures in accordance with Rule 211(4) of the RoP in conjunction with Rule 209(1)(b) of the RoP. This is based on the fact that the patent proprietor's conduct shows that the enforcement of his rights is no longer urgent for him. In such a situation, there is no need to order provisional measures. In the present case, however, there are no indications of such unreasonable delay on the part of the applicant.

120. The urgency required for the order of provisional measures is only lacking if the injured party has pursued their claims so negligently and hesitantly that it can be objectively assumed that they have no interest in the rapid enforcement of their rights and it therefore does not appear appropriate to order provisional measures (UPC_CFI_347/2024 (LD Düsseldorf), Order of 31 October 2024, p. 42 – Magna v. Valeo; see also UPC_CFI 2/2023 (LD Munich), Order of 19 September 2023 – 10x Genomics v. Nanostring; UPC_CFI_452/2024 (LD Düsseldorf, order of 9 April 2024, p. 27, para. 126 – Ortovox v. Mammut; UPC_CFI_151/2024 (LD Hamburg), order of 3 June 2024 – Ballinno v. UEFA).

121. Pursuant to R. 213(2) of the RoP, the court may, in the course of its decision-making, request the applicant to submit all evidence at its disposal in order to satisfy itself that the applicant is entitled to initiate proceedings under Article 47 of the UPC Agreement, that the patent in question is valid and that its rights are being infringed or are at risk of being infringed. In urgent proceedings, the applicant must generally respond to such an order within a short period of time, which requires adequate preparation for the proceedings. The applicant must therefore only apply to the court if he has reliable knowledge of all the facts that make legal action in the proceedings for provisional measures appear promising and if he can substantiate these facts. They can prepare for all possible procedural situations that may arise due to the circumstances in such a way that they can provide the court with the requested information and documents in response to such an order and successfully refute the arguments of the opposing party. In principle, the applicant cannot be instructed to conduct the necessary research during the ongoing proceedings and, if necessary, to obtain the necessary documents retrospectively. On the other hand, the applicant must not unnecessarily delay the proceedings. As soon as he becomes aware of the alleged

infringement, they must investigate it, take the necessary measures to clarify it and obtain the documents necessary to substantiate their claims. In doing so, they must carefully initiate and complete the necessary steps at each stage (UPC_CFI_452/2023 (LD Düsseldorf), order of 09.04.2024, para. 128 – *Ortovox/Mammut;* UPC_CFI_151/2024 (LD Hamburg), order of 3 June 2024 – *Ballinno/UEFA;* UPC_CFI_347/2024 (LD Düsseldorf), order of 31 October 2024,
p. 42 – *Magna/Valeo*).

122. On this basis, the time limit within the meaning of Rule 211(4) of the RoP is to be calculated from the date on which the applicant knew or should have known of the infringement that would have enabled it to file a promising application for provisional measures under Rule 206(2) of the RoP. Whether a delay within the meaning of Rule 211(4) of the RoP is unreasonable depends on the circumstances of the individual case (UPC_CoA_182/2024, order of 25 September 2024, paras. 228 and 232 – *Mammut/Ortovox;* UPC_CFI_347/2024 (LD Düsseldorf), order of 31 October 2024, p. 42 – *Magna/Valeo)*. Ultimately, it must always be examined whether the applicant's conduct as a whole justifies the conclusion that the enforcement of its rights is not urgent.

123. Based on these principles, the applicant did not wait an unreasonably long time to file its application for order of interim measures in the present case.

124. It is undisputed that the applicant first became aware of the CE marking and thus of marketable products in Europe in April/mid-May when it noticed the LinkedIn post (for both "MemoCarna VSD" and "MemoCarna ASD") (see AEM, para. 64, reply 100). However, unlike the respondents (reply 116), no reliable knowledge of all the facts could be derived from the LinkedIn posts that would make legal action in the proceedings for provisional measures appear sufficiently promising; at the very least, the applicant could reasonably be expected to conduct further investigations, which it did. At the Euro PCR 2025 conference in Paris (20–23 May 2025), the "world's leading course for interventional cardiovascular medicine" with around 12,000 participants, the respondents exhibited and schematic drawings of the device
"MemoCarna (ASD)" (see application, para. 67, reply 102, undisputed). During the *Third Dubai Congenital Intervention Course on 23-24 May 2025,* the applicant was able to photograph the MemoCarna ASD, cf. Annex Occ 6, and see the MemoCarna VSD (104 Reply, also undisputed).

125. The court therefore does not agree with the respondents that the applicant had already obtained such knowledge in 2023 that an application for order of interim measures should have been filed at that time. This applies even if, in favour of the respondents, it were assumed that the applicant had been aware of the contents of the respondents' product catalogue since 2023 (which is disputed by the applicant, 110 Reply). After all, at that time there were still no concrete indications of infringements in at least some of the contracting member states in which the patent is validated. Nor did the applicant have to have such knowledge. There is no general obligation to monitor the market. It is therefore not sufficient that the applicant could have been aware of the infringement of property rights when observing the competition (see UPC_CFI_463/2023 (LD Düsseldorf), order of 30 April 2024 – *10x Genomics/Curio)*.

126. For the sake of completeness, the court points out that it does not agree with the applicant that the relevant knowledge only became available after CSI Frankfurt (18 to 21 June

2025). It was incumbent upon the applicant to conduct an infringement analysis within a reasonable period of time after the trade fairs in Dubai and Paris and against the background of the LinkedIn posts on CE marking (i.e. at the end of May/beginning of June). The applicant did in fact comply with this (see reply, para. 110). In the court's view, however, the applicant cannot be criticised for initially waiting for the results of this analysis before submitting an application to the CSI in Frankfurt in order to obtain confirmation of the (imminent) infringement. Subsequently, an application was filed in Hamburg on 18 June 2025 and the present application was filed on 4 July 2025. Taking all relevant circumstances into account, the applicant acted sufficiently quickly and there can be no question of unnecessary delay.

127. The applicant cannot be blamed for waiting two weeks before initiating the present proceedings before the local division in Düsseldorf. The applicant and its representatives were entitled to take this time to prepare for these proceedings.

128. Furthermore, the Chamber would have considered the order of provisional measures to be necessary in this case for objective reasons.

129. The contested embodiments are (undisputedly) in direct competition with corresponding products of the applicant. It is therefore to be feared that the applicant will lose (potential) customers due to the offer and distribution of the contested embodiment.

130. As the applicant has argued without contradiction, the respondents' marketing activities are increasing, as the respondents have participated in several conferences/trade fairs within a short period of time and will also participate in Media 2025 in November. The applicant is right to appeal to the fact that, if the applicant were to be forced to rely on proceedings on the merits, the respondents would be able to present their products at this important trade fair and establish or further deepen customer relationships. In the context of the present summary proceedings, it appears credible that, as argued by the applicant and not specifically disputed by the respondents, it would be difficult to dissolve the newly established relationships and eliminate the market confusion caused by the defendant once demand for a new (and presumably cheaper, see below) product has been stimulated.

131. Furthermore, it is plausible that there is at least a concrete risk that the respondents will offer the products at a significantly lower price than the applicant. Even if the court were to agree with the respondents that the Italian tender procedure concerned occlusion devices other than the contested embodiments (namely the MemoPart series, see reply, para. 121), the fact remains undisputed that these products were offered at a price 60% lower than the applicant's products and that the respondents are known for setting their prices below those of other competitors (Exhibit 14a, also undisputed). The court is therefore sufficiently convinced that there is a well-founded fear of price pressure and, as a result, of permanent price erosion.

132. In addition, even if one had to assume that the respondents have not (yet) committed any infringing acts on the German or European market, there is at least a concrete risk of this happening. This would have tended to support the applicant's interest in the measures sought, as the

status quo on the market, namely that no competing product is yet available, would be maintained until the conclusion of the main proceedings. In this case, there can be no threat to the respondents' turnover either.

133. Furthermore, it is unclear to the court how the respondents can deny that infringing acts are being committed in Europe on the one hand, and, on the other hand, fear a threat to their turnover based on the respondents' turnover from occlusion devices in Europe last year, which the respondents assume would increase without the effects of the requested injunction, as well as on an additional estimated loss of potential customers. Insofar as this argument is based on an alleged (imminent) damage to reputation as a result of the imposition of an injunction, this is a circumstance that is regularly to the detriment of the infringer. It has neither been claimed nor proven that the damage to reputation in this specific case would be so disproportionate that the applicant's interest in enforcing the patent in suit would not outweigh the respondents' interest in avoiding such damage.

134. After weighing up all the relevant circumstances, the court would not have had any reservations that the order of interim measures was necessary.

VI. Legal consequences

135. Since the requirements for ordering a provisional measure are not met, the applicant's applications must be dismissed and she must be ordered to pay the costs as the unsuccessful party.

136. The value in dispute has been provisionally estimated by the applicant at EUR 1,000,000. The respondents have not commented. The Chamber therefore had no reason to set the value in dispute differently from the applicant's statement.

137. The decision on costs follows the guidelines of the Court of Appeal, according to which a decision on costs should be made in proceedings for interim measures conducted *inter partes* (UPC_CoA_523/2024, order of 3 March 2025, para. 117 – *Sumi Agro/Syngenta*).

138. Pursuant to Art. 69(1) of the UPC Agreement, the reasonable and proportionate costs of the legal dispute and other expenses incurred by the prevailing party shall, in principle, be borne by the unsuccessful party, unless equity dictates otherwise. In this case, the respondents are the prevailing party and the applicant must therefore bear the costs of the legal dispute. Equity does not dictate otherwise – no arguments to this effect have been put forward by the parties, nor is it apparent that this should be the case here.

ORDER:

1. The application for order of interim measures is dismissed.

2. The costs of the proceedings shall be borne by the applicant.

3. The value in dispute is set at EUR 1,000,000.00.

Düsseldorf, 31 October 2025 NAMES
AND SIGNATURES

Presiding Judge Thomas	Ronny Thomas signed by Ronny Thomas Date: 31 October 2025 07:05:33 +01'00'
Legally qualified judge Dr Schumacher	JuleKathrin Schumacher Digitally signed by Jule Kathrin Schumacher Date: 29 October 2025 13:18:08
Legally qualified judge Kupecz	András Ferenc Kupecz Digitally signed by András Ferenc Kupecz Date: 29 October 2025 10:49:36 +01'00'
Technically qualified judge Dr Schmidt	Martin SCHMIDT Signature numérique de Martin SCHMIDT Date: 29 October 2025 11:37:31 +01'00'
For the Deputy Chancellor	Rachida Boudra-Seddiki Digitally signed by Rachida Boudra-Seddiki Date: 29 October 2025 16:05:49 +01'00'

INFORMATION ABOUT THE APPEAL

The applicant may appeal against this order within 15 days of its notification (Art. 73(2)(a), 62 UPC Agreement, R. 220(1)(c), 224(2)(b) RoP).

INFORMATION ON ENFORCEMENT (ART. 82 UPC Agreement, ART. 37 PAR. EPGS, R. 118 PAR. 8, 158 PAR. 2, 354, 355 PAR. 4 UPC RoP)

A certified copy of the enforceable decision or enforceable order shall be issued by the Deputy-Registrar on the application of the enforcing party, R. 69 RegR.