Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Hamburg - Local Division

UPC_CFI_553/2025
Final Order of the Court of
First Instance of the Unified Patent Court
delivered on 21/10/2025

HEADNOTES:

1. Since a CE marking is required for placing a medical device in any of the EU member states, obtaining such a CE-mark approval gives an indication of an expected market entry of the device in any of the EU member states including in Germany in the foreseeable future (Art. 5.1 regulation (EU) 2017/745 on medical devices, Art. 33 (1) lit. a UPCA).
2. By obtaining (and publicly announcing) CE-mark approval for the attacked (implantable) medical devices, providing "ordering information" and announcing to show-case their products on a trade fair, the Defendants have set the stage to market these products, R. 206.2 lit. c) RoP.
3. As CE-mark approval is a prerequisite for being able to legally market a medical device in the European Union, any knowledge of the Applicant regarding the attacked embodiments prior to this date is not relevant.

KEYWORDS:

Preliminary injunction; Art. 62(2) UPCA; Imminent infringement, R. 206.2 lit. c) RoP; Competence, Art. 33 (1) lit. a UPCA; Medical devices, regulation (EU) 2017/745 on medical devices; CE-mark approval.

APPLICANT

Occlutech GmbH
(Respondent) - Winzerlaer Str. 2 - 08845 - Jena - DE

Represented by Dr. Peter Koch

DEFENDANTS

1)	**Lepu Medcial Technology (Bejing) Co., Ltd.** (Applicant) - 37 Chaoqian Road - 102200 - Changping District, Beijing - CN	Represented by Dr. Ralph Nack
2)	**Lepu Medical (Europe) Cooperatief U.A.** (Applicant) - Abe Lenstra Boulevard 36 - 8448 JB - Heerenveen - NL	Represented by Dr. Ralph Nack

PATENT AT ISSUE

Patent no.	*Proprietor/s*
EP2387951	**Occlutech GmbH**

SUBJECT-MATTER OF THE PROCEEDINGS

Application for provisional measures

LANGUAGE OF THE PROCEEDINGS

English

PANEL

Panel of the Local Division in Hamburg

DECIDING JUDGES

This order has been issued by the presiding judge Sabine Klepsch, the legally qualified judge and judge-rapporteur Dr. Stefan Schilling and the legally qualified judge Samuel Granata.

ORAL HEARING

26.09.2025, 10:00 Uhr

SHORT SUMMARY OF FACTS

1 The Applicant asserts claims against the Defendants for direct infringement of independent claim 1 of the European patent EP 2 387 951 B1 (hereinafter “the patent”) protecting a braided occlusion device.

2 The Parties are competitors on the market for occlusion devices.

3 The Defendant 1), a company based in the Peoples Republic of China, was established in 1999 and is specialized in developing, manufacturing and marketing high-tech medical

devices and equipment. One of its subsidiaries is Defendant 2), which is domiciled in the Netherlands.

4 The Applicant is the registered proprietor of the patent. Its underlying patent application was filed by Occlutech Holding AG, Schaffhausen, Switzerland, on 23 May 2010 (application number 10163680.1) and published on 23 November 2011. The date of publication and mentioning of grant of the patent was 26 December 2012.

5 The patent had been opted out initially but the opt-out has been withdrawn in May 2025 (Exhibit Occ 2). The patent is fully in force within the territory of the Contracting Member States of the UPC where the patent has been validated (see extract from German Patent Register, Exhibit Occ 3).

6 The patent pertains in general to the field of braided implantable medical devices, as well as methods for manufacturing such devices. More particularly the invention relates to braided occlusion devices (cf. para [0001]).

7 With its application for provisional measures dated 18 June (signed 19 June) 2025, the Applicant claims that the Defendants are directly infringing claim 1 of the patent with their devices "MemoCarna ASD" and "MemoCarna VSD" (hereinafter "attacked embodiments"), or at least that infringement is imminent.

8 It is undisputed that the Defendants have recently obtained CE-mark approval for the attacked embodiments. It is also undisputed that they have participated at trade shows/conferences in Europe (EuroPCR Paris, 20 – 23 May 2025), and Asia (DCIC Dubai, 23 – 24 May 2025), and that they were announced as sponsors of the CSI Frankfurt (CSI, 18 – 21 June 2025), taking part in a "Focus Workshop PFO Closure" presenting their products (comp. Application, p. 29/30). At this conference the present application for provisional measures was served on the Defendants.

9 Claim 1 of the patent reads as follows:

A Medical implantable occlusion device (100, 200, 300, 400, 500, 600) having a collapsed state and an expanded state and comprising:

a braiding (101) of at least one thread,

a distal end (102) comprised of said braiding, wherein:

said distal end comprises loops (103, 104, 204, 304) formed by loop strands (105, 106, 206, 306) of said at least one thread, wherein, at least in said expanded state,

each loop strand having a curved shape and extending away from a centre point (105) of said distal end, whereby an apex point (107, 108, 208, 308) of each of said loop strands corresponds to the turning point of said curved shape and to the point of each of said loop strands being arranged closest to said centre point, and wherein at least one of said loop strands is displaced from said centre point by a centre distance (109, 110, 210, 310) such that the location of said apex point is different from said centre point, and wherein said apex point lie at a distance from a periphery (113) of said distal end,

characterized in that,

said distal end is closed by a plurality of centre strands (115) of said braiding crossing each other at said centre point.

STATEMENT OF THE FORMS OF ORDER SOUGHT BY THE PARTIES:

10 The Applicant requests with its application for provisional measures dated 18 June 2025:

A. The Defendants are ordered to cease and desist from

Offering, placing on the market or using, or importing or storing for those purposes within the territory of Germany, France, Italy, Netherlands and Ireland

A medical implantable occlusion device, having a collapsed state and an expanded state and comprising

a braiding of at least one thread,

a distal end comprised of said braiding,

wherein said distal end comprises loops formed by loop strands of said at least one thread, wherein, at least in said expanded state, each loop strand having a curved shape and extending away from a centre point of said distal end, whereby an apex point of each of said loop strands corresponds to the turning point of said curved shape and to the point of each of said loop strands being arranged closest to said centre point, and wherein at least one of said loop strands is displaced from said centre point by a centre distance such that the location of said apex point is different from said centre point, and wherein said apex points lie at a distance from a periphery of said distal end,

characterised in that said distal end is closed by a plurality of centre strands of said braiding crossing each other at said centre point.

B. If Defendants fail to comply with the order according to request A., the Defendants are ordered to pay to the Court a penalty payment of up to EUR 250.000 per each day of violation (R. 354.3 RoP), if need be repeatedly.

C. The Defendants are ordered to pay the costs of the proceedings.

D. These orders are immediately effective and enforceable.

E. (as an auxiliary request to D.): These orders are only enforceable against provision of a security by the Applicant to the benefit of the Defendants in the form of a cash deposit or bank guarantee.

11 The Defendants request with their objection to the application dated 15 July 2025:

I. The Application for provisional measures is dismissed.

II. Applicant bears the Defendants' reasonable and proportionate legal costs and other expenses in connection with the present proceedings. This order is directly enforceable.

III. In the alternative, the provisional measures requested by Applicant are only enforceable against provision of a security in the amount of at least EUR [redacted].

IV. [Request for confidentiality regarding the estimated amount of damage, granted by Court's order 16 July 2025]

POINTS AT DISPUTE

12 The parties disagree on the legal consequences for the recent obtained CE-mark-approval for territorial jurisdiction and assessment of imminent infringement. On this basis, competence of the Local Division Hamburg is challenged by the Defendants. Furthermore, the question of infringement and its likelihood of occurrence is disputed. The Defendants question the validity of the patent.

The Applicant's position

13 The Applicant claims to have only recently become aware of the Defendants CE-mark approval, which is a prerequisite for legally marketing a medical device in Europe. With its Reply to the Objection the Applicant further detailed how it became aware of the CE-mark approval and thus a marketable product in Europe in April / Mid-May (Evidence: Suppl. Witness Statement of [redacted] Exhibit Occ 8).

14 The Applicant asserts that the Defendants are offering the infringing products on their website, through product catalogues and during trade shows/conferences and on social media. Through its LinkedIn-profile https://www.linkedin.com/company/lepu-medical-technology-beijing-co-ltd-/ the Defendant 1) and its subsidiary, the Defendant 2), market their products.

15 Subsequently, the Defendants have attended various conferences, inter alia recently the Euro PCR 2025 in Paris (20 – 23 May 2025), the "world-leading course in interventional cardiovascular medicine" to introduce their new products. The product "MemoCarna ASD" has been prominently displayed at this trade fair, but only as schematic drawings; no actual products were shown (Application, mn. 52).

16 With its Reply to the Objection the Applicant stated that at the CSI Frankfurt, Mr [redacted] (VP Marketing & Business Development) was able to take pictures of the booth of the Defendants, show-casing their products both through display stands and the actual products, showing the "MemoCarna (ASD)"- and the "MemoCarna (VSD)"-Occluder with the CE-Mark.

17 Additionally, the Applicant claims to have become aware that the Defendants are offering the "MemoCarna (ASD)" in Italy at a price that is approximately 20-30 % below the

average price of the Applicant; other occluder devices are offered at even 60% of the price of the Applicant (cf. Exhibit Occ 8).

18 Regarding necessity, the Applicant is of the opinion that it is obvious that competing with infringing products cannot be accepted as fair. There is an increase in marketing activities, as the Defendants have been attending several conferences / trade shows in a short period of time and will attend Media 2025 in November as well. Once the demand for a new (and presumably cheaper) product is stimulated, it is difficult to reverse the newly established relationships and dissolve the market confusion caused by the Defendants. It is also possible that the infringing product is offered at a significantly lower price than the product of the Applicant based on the information regarding the market in Italy.

19 Regarding claim construction the Applicant argues that "*the distal end of the device is closed by a plurality of centre strands of said braiding, crossing each other at said centre point*" does not require the strands to cross through a centre point, but cross at a centre point or a region close to the centre point. This is supported by para [0034]. The person skilled in the art will understand against the background of the object of the patented invention, i.e. to provide greater flexibility, that the claim is not to be understood that all strands cross each other "through" a centre point, which would not only be harmful to the requirement of flexibility but would also create a protrusion, which the patent seeks to avoid.

20 According to the Applicant, the term "*centre point*" is to be understood in a broad sense, including the meaning of a "*centre region*". When taking into consideration the purpose and objective of the teaching of the patent, it becomes obvious that crossing of strands in a single point will lead to a bulge/bead/protrusions which the patent considers to be a risk for creating emboli (cf. para [0004]). Furthermore, the patent teaches that less strands crossing allows for a smaller cross-section, and thus reduced size not only for delivery and placement (cf. para [0030]), but also for reducing the amount of force required to compress the device (cf. para [0034]). All of this clearly teaches the skilled person to understand the term "centre point" not as a single point, but rather a region.

21 The Applicant considers both attacked embodiments are infringing claim 1 of the patent. In both cases, loop strands in a curved shape are extending away from the centre point. It is noteworthy that a centre point in the middle (i.e. in the centre) of the flat distal end exists, irrespective whether a fiber runs through it or not.

22 Regarding enforcement security the Applicant argues that the Defendants' request for a security for enforcement has no justification. It is not substantiated why serious difficulties would be expected in connection with the recovery of any possible damages from the Applicant, which is a German based company with sufficient funds.

The Defendants' position

23 The Defendants are of the opinion that the Court has no jurisdiction. They claim that the Applicant's allegations that this place of special connection is Germany by claiming that the attacked embodiments are offered in and delivered to Germany, are simply not true.

There is not a single reference to Germany in the Application that would support this allegation. The Applicant's assertion that the products are already on the market in various sizes is not substantiated and also contains no reference to Germany. Neither the English-language LinkedIn profile nor the English language website of the Defendants show a marketable version of the attacked embodiments and are not aimed at European customers, let alone German customers.

24 Further, the Defendants claim that the Applicant's reference to a CE-marking is not sufficient to establish competence under Art. 33 (1) lit. a UPCA. The CE marking provides no indication that a market entry into Germany is even planned in the foreseeable future. Since the (EU) regulation 2017/745 on medical devices (hereinafter "MDR") is directly applicable in all EU member states without further implementation, the CE marking is required for placing a medical device in any of the EU member states, not only in Germany. Therefore, the CE marking provides no evidence of intended sales in Germany in particular.

25 The Defendants assert that the Applicant's statements regarding alleged offers in Italy are irrelevant as these do not concern the attacked embodiments, but rather other occluder products of the Defendants that are entirely unrelated to the patent.

26 The Defendants are of the opinion that the application must also be dismissed for lack of urgency. They claim that the Applicant has waited several months after gaining knowledge of the general facts upon which the Application is founded before filing the Application. The Applicant attacks two products, one of which it was able to take pictures of in Dubai at the Third Dubai Congenital Intervention Course, the MemoCarna (ASD). However, the Applicant seems to have never physically interacted with the other product, the MemoCarna (VSD), as the Applicant relies only on a product catalogue. It has to be noted that the Applicant admits to having access to the catalogue since 2023, and again on or before 4 April 2025. As the Applicant claims that the contents of the catalogue are sufficient to find evidence of infringement at least with respect to MemoCarna (VSD), urgency would have required the Applicant to file their request for preliminary measures within the year 2023, following their first review of the catalogue.

27 No other conclusion can be drawn with respect to MemoCarna (ASD) which the Applicant was only able to review physically on 23 - 24 May 2025 but was able to review via the Defendants' catalogues for several years, as well.

28 Regarding claim construction, the Defendants point out that the term "centre point" is found in several features and always understood literally, excluding a line, circle, region or any other shape or spatial form. This understanding of a point at which all centre strands meet is also shown in Figure 1 of the patent specification, which is illustrated by the Applicant in mn. 38 and 39 of the Application and highlighted in colour by the Applicant.

29 The Defendants argue that patent clearly distinguishes the "centre point" from a centre region. The centre region referred to by the Applicant is expressly mentioned in para. [0034]. It was therefore known to the Applicant, but intentionally not used when drafting

the claims of the patent. There are a variety of reasons for such an approach. For example, substantive prior art may have precluded the Applicant from choosing a broader wording than centre point in the claim language. Extending the claim to a centre region would not have been patentable. Para. [0034] describes an alternative ("each thread crossing the centre point 105 or a region close to the centre point 105"). Only the first alternative (centre point, not region close to it) is included in Claim 1.

30 The Defendants claim that at least the feature

> *and wherein said apex point lie at a distance from a periphery (113) of said distal end,*

had been extracted from the original disclosure in isolation and was not included in the original application (Art. 138 (1) (c) EPC).

31 The Defendants further argue that based on the Applicant's broad interpretation of the feature "centre point" claim 1 is not novel over WO 2008/040555 A2 (document DN1), which was examined in the granting procedure and which discloses all features of the preamble of claim 1 (comp. para [0005] of the patent). They claim that not all embodiments in DN1 had been discussed by the EPO. They claim that feature

> *said distal end is closed by a plurality of centre strands (115) of said braiding crossing each other at said centre point.*

in the broad interpretation of the Applicant is anticipated by DN1. The Applicant bases its infringement allegation on an interpretation of the centre point as a "centre region" in which not all of the centre strands, but only some, cross in more than one different centre points. The Defendants claim that a respective configuration was already known from the embodiment of Fig. 24B of DN 1. Fig. 24B shows an embodiment of the device of DN 1 that has not been discussed during examination proceedings. Additionally, they are of the opinion that claim 1 of the patent is not novel over WO 1996/01591 A1 (document DN2), which was not examined in the granting procedure.

32 The Defendants' object the alleged patent infringement. They argue that the attacked embodiments do not even have a centre point and thus do not make use of claim 1. They are of the opinion that no strands cross through the centre point of the respective devices.

33 The Defendants assert that there is no necessity for provisional measures. The Applicant merely refers to serious concerns about substantial losses in purchase orders, sales and market shares. However, these unspecified allegations do not establish a hardship that justifies the grant of provisional measures under the UPCA and RoP. The acts of infringement alleged by the Applicant are not apparent in any way, especially not in the UPC territory. In the event of enforcement, the Defendants would suffer lasting damage, which would seriously harm their business. Even if this damage is mostly reputational and indirect in nature (reduction of sales of non-infringing products as Defendants' reputation would be tainted due by the patent infringement decision in the eyes of the market

participants), securities for these amounts must be rendered to secure the Defendants' claims and allow the Defendant to securely retrieve from Applicant the damages caused.

34 Regarding any additional arguments brought forward by the parties' reference is made to the submissions of the parties and to the audio recording of the oral hearing.

GROUNDS FOR THE ORDER

35 The Application for provisional measures is admissible and well-founded. R. 211.2 Rules of Procedure (hereinafter RoP) in conjunction with Art. 62 (4) Agreement on the Unified Patent Court (hereinafter UPCA) provide that the Court may invite the applicant for provisional measures to provide reasonable evidence to satisfy the Court to a sufficient degree of certainty that the applicant is entitled to institute proceedings under Art. 47 UPCA, that the patent is valid and that it is infringed, or that such an infringement is imminent (, see also Art. 9 (3) Directive 2004/48/EC). These criteria are met in the present case.

A. APPLICANT'S ENTITLEMENT TO BRING ACTIONS

36 As the Applicant is the registered proprietor of the patent at issue and as there have not been raised any concerns to the contrary, the Applicant is entitled to bring actions to the Court, Art. 47 (2) UPCA and R. 8.5 and 211.2 RoP.

B. COMPETENCE

I. INTERNATIONAL JURISDICTION

37 The Defendants have not objected that the UPC has international jurisdiction over the dispute, which indeed follows from Art. 31 UPCA in conjunction with Art. 7 (2) and Art. 71b (2) Brussels I recast regulation.

II. COMPETENCE

38 The Local Division Hamburg is competent to hear the case according to Art. 33 (1) lit. a UPCA. According to this provision actions referred to in Art. 32 (1) (a), (c), (f) and (g) UPCA shall be brought before (a) the local division hosted by the Contracting Member State where the actual or threatened infringement has occurred or may occur, or the regional division in which that Contracting Member State participates.

1. GENERAL

39 Pursuant to Art. 62 (1) and (4) UPCA, insofar as relevant, the Court may, by way of order, grant injunctions against an alleged infringer, intended to prevent any imminent infringement. The Court may require the applicant to provide any reasonable evidence in order to satisfy itself with a sufficient degree of certainty that the applicant's right is being infringed, or that such infringement is imminent. While the issue whether the patent has been infringed falls within the scope of the examination of the substance of the action by the court having jurisdiction (CoA, Order of 03 September 2024 – CoA_188/2024), to establish jurisdiction requires at least the plausible allegation of infringing acts by that

party in the country in question (LD Hamburg, Order of 14 August 2025 – UPC_CFI_387/2025 – Dyson/Dreame, mn. 48). That is here the territory of Germany. Provisional measures can also be ordered to prevent a threatened infringement (R. 206.2 lit. c) RoP). A situation of imminent infringement may be characterised by certain circumstances which suggest that the infringement has not yet occurred, but that the potential infringer has already set the stage for it to occur. The infringement is only a matter of starting the action. The preparations for it have been fully completed. These circumstances must be assessed on a case-by-case basis (CoA, Order of 13. August 2025, UPC_CoA_446/2025 APL_24205/2025 – Boehringer/Zentiva).

2. MEDICAL SECTOR

40 The Court of Appeal has decided that in the context of marketing of generic pharmaceuticals, the mere application for a marketing authorisation by a generics company does not amount to an imminent infringement, nor does the grant of such an authorisation create one. However, completion of the national procedures for health technology assessment, pricing and reimbursement for a generic medicine can amount to an imminent infringement. The assessment must be made with due regard to the national regulatory and legislative context and considering the circumstances of the case (CoA, Order of 13 August 2025, UPC_CoA_446/2025, APL_24205/2025 – Boehringer/Zentiva).

41 Implantable medical devices, like in the case at hand, are subject to the (EU) regulation 2017/745 on medical devices (hereinafter "MDR"). According to Art. 5.1 MDR a device may be placed on the market or put into service only if it complies with this regulation, which according to Art. 5.3 MDR requires a clinical evaluation in accordance with Art. 61 MDR. Despite the fact, that their marketing is, unlike generics drugs, not reliant on a grant of a national authority, obtaining the EU certification of conformity (CE-mark) is a prerequisite for being able to legally market a medical device in (all of) the European Union, and this requires clinical evaluation.

3. PRESENT CASE

42 It is undisputed that the Defendants had recently received CE-mark approval for both attacked embodiments, a fact, which they also announced in two posts on social media, for the VSD in the week of 31 March to 4 April and for the ASD mid-May 2025 (Application, mn 49). Subsequently the Defendants have attended various conferences, inter alia the Euro PCR 2025 in Paris (20 – 23 May 2025), the "world-leading course in interventional cardiovascular medicine" to introduce their new products (Application, mn. 51 ff.). As the Applicant demonstrated by an enlarged image, the infringing product "MemoCarna ASD" has been prominently displayed at this trade fair (Application, mn. 52). In addition, on Defendant's 1) website (https://en.lepumedical.com/products/memocarna-atrial-septal-defect-asd-occluder/), the MemoCarna ASD Occluder is advertised, including "ordering information" (Application, mn. 54 - 55).

43 In light of these facts, the announcement that the Defendants are sponsoring the "CSI Frankfurt" (18 – 21 June 2025) and will take part in a "Focus Workshop PFO closure", presenting their products ("device parade", Application, mn. 56), is sufficient to proof the threat of imminent infringement in the territory of Germany according to R. 206.2 lit. c) RoP. This is because, by obtaining (and publicly announcing) CE-mark approval for the attacked embodiments after the necessary clinical evaluation, providing "ordering information" and announcing to show-case their products on a trade fair ("device parade") the Defendants have set the stage to market these products. The Defendants' assertion that the CSI Frankfurt is a purely academic event, which is disputed by the Applicant, is neither convincing nor relevant. The clinical evaluation in accordance with Article 61 MDR for implantable medical devices is highly regulated and expensive and goes far beyond the self-certification that is sufficient for non-implantable medical devices. Thus, it makes sense that a product presentation on an international conference together with other competitors is an additional step in the direction of entering into market, be it a purely academical conference or a trade fair. Furthermore, also this presentation proves the Applicant's assertion that the Defendants were increasing their market activity by their active and constant presence at key medical conferences for example in Europe, including the EuroPCR in Paris and the CSI in Frankfurt and thus creating demand for their – now newly approved – products.

44 Contrary to the Defendants' position the CE-mark approval does also give an indication that a market entry into Germany is to be expected in the foreseeable future, since the CE marking is required for placing a medical device in any of the EU member states, not just, but including in Germany. Also, an expected (and in fact occurred) presentation of the attacked embodiments on a trade fair in Germany is a sufficient indication that marketing the products is prepared for the German market in particular.

45 It has to be acknowledged that the Applicant was able to demonstrate with its Reply to the Objection that both Defendants were show-casing their products both through display stands and were showing the "MemoCarna (ASD)"- and the "MemoCarna (VSD)"-Occluder with the CE-Mark at the CSI Frankfurt – which took place during the filing of the Application for provisional measures. Contrary to the Defendants' argument, the Applicant's submission of additional (new) facts in its Reply is not belated as these facts materialized first on the conference in Frankfurt, which took place between 18 and 21 June 2025, and thus on the date of the final draft of the Application, which was signed in the morning of 19 June 2025. The Defendants did not challenge the assertation that occlusion devices are not sold online but through direct sales channels or tender offers with hospitals or purchasing companies of the hospitals, making it difficult to obtain information on the specific products regardless of the (national) market.

46 However, as an imminent infringement was already sufficiently proven by the application for provisional measures dated 18 June 2025, the Court can refrain from answering the question whether the actual presentation of the attacked embodiments on the CSI Frankfurt turned an imminent infringement into an actual one in the form of an offering within the meaning of Art. 25 UPCA.

C. URGENCY

47 The Applicant has treated the matter sufficiently urgent, Rule 209.2 lit. b) RoP.

I. GENERAL

48 Art. 62 (2) UPCA and R. 211.3 RoP do not explicitly require that the preliminary injunction must be urgent. But according to R. 209.2 lit. b) RoP, the Court shall consider the urgency of the action whilst exercising its discretions under R. 209. 1 RoP. Moreover, according to R. 211.4 RoP, the Court shall have regard to unreasonable delay in seeking provisional measures.

1. TEMPORAL URGENCY

49 The temporal urgency required for the ordering of provisional measures is only lacking if the infringed party has behaved in such a negligent and hesitant manner in the pursuit of its claims that, from an objective perspective, it must be concluded that the infringed party is not interested in promptly enforcing its rights, which is why it does not appear appropriate to allow it to claim provisional legal protection (LD Hamburg, Order of 3 June 2024 – UPC_CFI_151/2024 – Ballinno/UEFA; LD Düsseldorf, Order of 30 April 2024 – UPC_CFI_463/2023 - 10x Genomics/Curio Bioscience; LD Munich, Order of 19 September 2023 – UPC_CFI 2/2023, GRUR 2023, 1513, 1524 - Nachweisverfahren; LD Düsseldorf, Order of 9 April 2024 – UPC_CFI_452/2024, p. 27, GRUR-RS 2024, 7207, mn. 126).

2. OBLIGATIONS OF AN APPLICANT

50 Pursuant to Rule 213.2 RoP, the court may, as part of its decision-making process, require the Applicant to submit all reasonably available evidence to ensure that it can be sufficiently certain that the Applicant is entitled to initiate proceedings under Art. 47 UPCA, that the patent in question is valid and that its right is being infringed or threatened with infringement. In urgent proceedings, the Applicant must typically respond to such an order within a short period of time, which requires appropriate preparation of the proceedings. The Applicant therefore only needs to apply to the court if they have reliable knowledge of all the facts that make legal action in the proceedings for provisional measures promising and if they can substantiate these facts. The Applicant may prepare for any possible procedural situation that may arise, based on the circumstances, in such a way that it can present the requested information and documents to the court upon such an order and successfully rebut the arguments of the Defendant's side. In principle, the Applicant cannot be instructed to carry out any necessary subsequent investigations only during ongoing proceedings and if necessary to obtain the required documents after the fact. On the other hand, the Applicant must not delay proceedings unnecessarily. As soon as it has knowledge of the alleged infringement, it must investigate it, take the necessary measures to clarify it and obtain the documents required to support its claims. In doing so, it must diligently initiate and complete the required steps at each stage. As soon as the Applicant has all the knowledge and documents that reliably enable a promising legal action, it must file the application for

the ordering of provisional measures within one month (LD Hamburg, Order of 3 June 2024 – UPC_CFI_151/2024 – Ballinno/UEFA, with additional references).

II. MEDICAL DEVICES

51 Based on these principles, the Applicant has treated the matter with the necessary urgency. It is not relevant at which point the Applicant gained *general* knowledge of the attacked embodiments and their appearance as long as their marketing in the European Union could not have been considered imminent due to lacking the EU certification of conformity (CE-mark). As this CE-mark approval is, as stated above, a prerequisite for legally marketing a medical device in the European Union, any knowledge of the Applicant regarding the attacked embodiments prior to this date is not relevant. Thus, it is not relevant that the Applicant was able to assess product features based on a product catalogue since 2023. The same applies to product presentations outside of Europe, like at the Third Dubai Congenital Intervention Course, as this did not create a tangible imminence of infringement within the EU, which would enable a patent owner to initiate legal proceedings at the UPC.

52 It is undisputed that the Defendants had announced CE-mark approval for both attacked embodiments in April and May (for the VSD in the week of 31 March to 4 April and for the ASD mid-May 2025) and that the Applicant gained knowledge of this later on. The Defendants did not contest the Applicant's assertion based on the written testimony by Mr [redacted] (VP Marketing & Business Development, Exhibit Occ 8) to not be able to "*recall the correct date we spotted the first post, announcing MemoCarna VSD CE mark, while we noticed the one announcing CE mark approval for MemoCarna ASD during week 20 (starting May 12th)*". Gaining knowledge of the CE-mark approval marks the starting point for the Applicant to investigate the situation, take the necessary measures to clarify it and obtain the documents required to support its claims, because from that moment on an infringement might be imminent. It is also undisputed that the Defendants subsequently showed only schematic drawings of the "MemoCarna (ASD)" device at the Euro PCR 2025 in Paris (20 – 23 May 2025), but no actual products (Application, mn. 52), and only at the CSI Frankfurt, starting on the 18th of June 2025, actual products were presented.

53 As until the filing date no actual products were presented within the EU, the Applicant, first with the CE-mark approval and the announcement that the Defendants are sponsoring the "CSI Frankfurt" (18 – 21 June 2025) and will take part in a "Focus Workshop PFO closure" *presenting* their products ("device parade", Application, mn. 56), was able to proof the threat of imminent infringement in the territory of Germany. This is the situation which forces an applicant to investigate the situation and to prepare for – if desired – legal action for provisional measures. Hence, the assessment of urgency does somewhat mirror the establishment of competence.

54 The Applicant has sufficiently shown to have taken the necessary steps to initiate the present application for the ordering of provisional measures already in advance, thus without undue delay. It demonstrated to have investigated actual sales and marketing

activities by the Defendants in Europe/Germany prior to the CSI Frankfurt, even though it is difficult to obtain information on the specific products as they are sold by direct sales channels or tender offers with hospitals or purchasing companies of the hospitals (cf. Suppl. Witness Statement, Exhibit Occ 8). The Application was then finalized on 18 June 2025.

D. THE PATENT

I. BACKGROUND

55 The patent relates to the field of braided implantable medical devices, as well as methods for manufacturing such devices. More particularly the invention relates to braided occlusion devices (para. [0001]).

56 Various braided medical devices are used for treating various conditions in a patient. In certain circumstances, it may be necessary to use such devices for occlusion of a patient's lumen, vessel, chamber, channel, hole, or cavity. When delivering or implanting such devices into the patient's body it is critical that the braided device is sufficiently flexible for safe delivery by a delivery device such as a catheter to a target site in the patient.

57 Issues with some prior art solutions are that the braided devices are not sufficiently flexible, and/or that a large force is required to manipulate the device, for example due to too high stiffness of the braided mesh of the device. This may lead to a difficult delivery of the braided device through for example a catheter. For braided devices having an expanded and a collapsed shape configuration the large force needed to collapse the device from the relaxed expanded state may lead to difficulties to pull the device into for example the delivery sheath of the catheter. Also, due to this force, making these braided devices less flexible, the friction between the device and the catheter will be too high in order to easily move and manipulate the device in the catheter, for both movements to pull and to push the device in the catheter. Thus, there is a need for a braided device which allows a secure deployment in the patient (para. [0003]).

58 The patent refers to WO99/12478 as an example of prior art where clamps are keeping together a bundle of strands (para. [0004]). The patent states that insufficient flexibility of some braided devices known in the art may also make the positioning of the device in the patient's body more difficult, for example, by the inability for the device to adapt to the unique anatomy of the target site. Further an inflexible device may cause embolies, which could be transported to organs such as the brain and cause blood clots. This appears in particular to be the case with some devices having ends clamped together. In particular it may be an issue to have a distal end having a structure protruding into an arterial (high blood pressure) blood stream leading to vital organs, such as the brain. One issue is protruding threaded clamps keeping together a bundle of strands, such as described in WO99/12478 (para. [0004]).

59 Next the patent refers to WO2008/040555 (later discussed as document DN 1) as an example of prior art [0005]. The patent acknowledges that WO2008/040555 discloses all the features of the preamble of claim 1. It describes a braided occlusion device having

folded sections in two or more layers for positioning in an opening to be occluded. Sections at the distal portion of the device are back-bent towards the proximal portion to contact the tissue of the wall having the opening to be occluded. The folded sections cause the device to exhibit a substantial amount of wires to be deformed when compressing the device, hence increasing the force necessary to compress the device and the cross-section of the compressed device.

60 Furthermore, the patent refers to US 2005/283962, which discloses a method of manufacturing a device of a tubular braiding [0006]. The wires of the braiding are looped at the peripheral edge of the distal and proximal portions of the tubular braiding. An issue with tubular braiding as disclosed in US2005/0283962 is insufficient stability that may lead to dislocation of the device from the implanted site.

61 The patent aims at an improved implant and a method for manufacturing such medical implant that would be advantageous by in particular allowing for increased flexibility, cost-effectiveness, and/or patient safety [0010].

62 In order to solve this problem, the patent discloses medical implantable occlusion device in claim 1, which can be broken down into the following features:

1. Medical implantable occlusion device (100, 200, 300, 400, 500, 600) having a collapsed state and an expanded state and comprising:

1.1. A braiding (101) of at least one thread,

1.2. A distal end (102) comprised of said braiding, wherein:

1.2.1. said distal end comprises loops (103, 104, 204, 304) formed by loop strands (105, 106, 206, 306) of said at least one thread,

wherein, at least in said expanded state,

1.2.1.1. each loop strand having a curved shape and extending away from a centre point (105) of said distal end,

1.2.1.2. whereby an apex point (107, 108, 208, 308) of each of said loop strands corresponds to the turning point of said curved shape and to the point of each of said loop strands being arranged closest to said centre point, and wherein

1.2.1.3. at least one of said loop strands is displaced from said centre point by a centre distance (109, 110, 210, 310) such that the location of said apex point is different from said centre point,

1.2.1.4. and wherein said apex point lie at a distance from a periphery (113) of said distal end,

characterized in that,

1.2.1.5. said distal end is closed by a plurality of centre strands (115) of said braiding crossing each other at said centre point.

II. Claim construction of claim 1

1. Principles of claim construction

63 According to Art. 69 EPC in conjunction with Art. 1 of the Protocol on its interpretation, the patent claim is not only the starting point, but the definitive basis for determining the protective scope 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 the drawings must always be taken into account as explanatory aids for the interpretation of the patent claim and not only be used to clarify any ambiguities in the patent claim. However, this does not mean that the patent claim serves only as a guideline and that its scope may extend to what, from a consideration of the description and drawings, the patent proprietor has contemplated. The patent claim is always to be interpreted from the point of view of a person skilled in the art (CoA, UPC_CoA_1/2024, Order of 13 May 2024, App_8/2024 – VusionGroup SA v Hanshow Technology Co. Ltd et al.; UPC_CoA_335/2023, Order of 26 February 2024, App_576355/2023 - 10X Genomics and Harvard/Nanostring case; Order of 11 March 2024, GRUR-RS 2024, 2829, headnote 2. and para. 73 - 77 - Nachweisverfahren; LD Düsseldorf, UPC_CFI_452/2023, Order of 9 April 2024, p. 13, GRUR-RS 2024, 7207, para. 49). Additionally, the skilled person is taking the purpose of every patent claim into account, to provide the average person skilled in the art with a technical teaching which, when reworked, leads to the intended success of the invention.

2. Person skilled in the art

64 The person skilled in the art is an engineer in the field of biomedical engineering, in particular catheter based implantable devices and procedures, potentially in team with a cardiac surgeon or interventional radiologist.

3. Feature 1

Medical implantable occlusion device (100, 200, 300, 400, 500, 600) having a collapsed state and an expanded state and comprising

65 According to feature 1 of claim 1 of the patent, the invention refers to a medical implantable occlusion device having a collapsed state and an expanded state. A medical implantable occlusion device according to claim 1 is a device that is well suited for the selective occlusion of a vessel, lumen, channel, hole, cavity, or the like. The occlusion devices are designed to close channels or holes through which blood flows from one vessel to another vessel, such as for example an Atrial Septal Defect (“ASD”) or a Ventricular Septal Defect (“VSD”). Other applications can be an Arterial Venous Fistula (“AVF”), Arterial Venous Malformation (“AVM”), a Patent Foramen Ovale (“PFO”), Para-Valvular Leak (“PVL”), or Patent Ductus Arteriosus (cf. para. [0012]).

4. Feature 1.1

a braiding (101) of at least one thread,

66 According to feature 1.1, the medical implantable occlusion device comprises a braiding of at least one thread, meaning that the braiding 101 may be formed from one thread or several threads (see para [0024]). Suitable materials for embodiments of the braiding are various and include shape memory materials, metal, superelastic alloys (such as NiTinol), or polymers, such as degradable polymers (cf. para. [0025]).

5. FEATURE 1.2 AND FEATURE 1.2.1:

[1.2] a distal end (102) comprised of said braiding, wherein

[1.2.1] said distal end comprises loops (103, 104, 204, 304) formed by loop strands (105, 106, 206, 306) of said at least one thread,

67 The distal end is comprised of the braiding (cf. para. [0024]) and comprises loops formed by loop strands of the at least one thread (cf. para. [0026]). This is also shown in figure 1 (colouring added by Applicant):

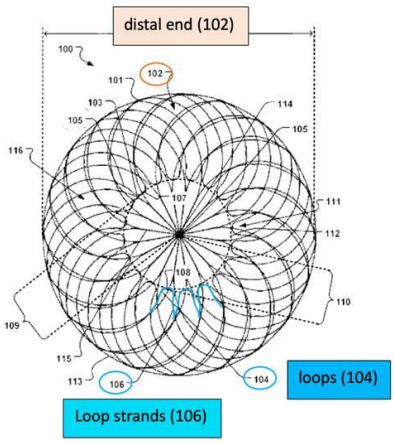


Fig. 1

68 The patent does not define the term “distal end”. The description shows that the designation of an embodiments end being distal or proximal is functionally irrelevant as the patent explains that also a proximal end of the device 100, or any other part of the device 100, may have the same features as the distal end 102 (cf. para. [0024]). Hence any part of the braiding 101 forming the device may have the features described with the associated advantages (cf. para. [0024]).

6. FEATURE 1.2.1.1:

[wherein, at least in said expanded state,] each loop strand having a curved shape and extending away from a centre point (105) of said distal end,

69 According to Feature 1.2.1.1, in at least the expanded state each loop strand has a curved shape and extends away from the centre point of the distal end (cf. para. [0026]). The patent teaches that by having a plurality of loop strands displaced from the centre point, a larger portion of the distal end may exhibit a smaller cross-section in the collapsed state of the device. This enables the device to be transported to a target site in a patient through a delivery device with a reduced cross-section, which may lead to an easier

delivery procedure or manipulation of the delivery device in the patient (cf. para. [0033]). The cross-section may be reduced in the expanded state as well (cf. para. [0033]).

70 The centre point refers to the tip of the device (cf. para [0030]), which is typically also the geometric middle of the distal end of the braided device (see further below regarding feature 1.2.1.5). It marks a specific point, like the other "points" mentioned in claim 1, such as apex point or turning point.

7. FEATURE 1.2.1.2

whereby an apex point (107, 108, 208, 308) of each of said loop strands corresponds to the turning point of said curved shape and to the point of each of said loop strands being arranged closest to said centre point, and wherein

71 According to Feature 1.2.1.2, an apex point of each of said loop strands corresponds to the turning point of said loop strand having a curved shape. At the same time, the apex point corresponds to the point of each of said loop strands being arranged closest to the centre point (cf. para. [0026]). The loops can be U-shaped but may have other shapes of the open curvature, e.g. elliptical, half circular, W-shaped (cf. para. [0027]). As shown in Fig. 1, the group of loop strands that are displaced from the centre point lie on an imaginary circle which marks the distance closest to the centre point (cf. para [0035]).

8. FEATURE 1.2.1.3: CENTRE DISTANCE

at least one of said loop strands is displaced from said centre point by a centre distance (109, 110, 210, 310) such that the location of said apex point is different from said centre point,

72 According to Feature 1.2.1.3, at least one of said loop strands is displaced from said centre point by a centre distance such that the location of said apex point is different from said centre point (cf. para. [0028]). The centre distance between the apex point and the centre point may vary and is preferably less than half the diameter (A) of the device, or less than half the cross-section at the location of the apex point, in case the device is non-circular (cf. para. [0029]). By having a displacement of at least one of the loop strands from the centre point 105 the device 100 may exhibit a smaller cross-section or diameter in the collapsed state of the device 100, as less strands are present at the tip or centre point 105 of the device (cf. para [0030]).

73 This feature refers to a central aspect of the invention which is that due to the displacement of the loop strands from the centre point the amount of force required to compress the device from the expanded state is reduced as the loop strands do not cross the centre point. This is described in para [0034]:

> *[0034] Further thanks to the displacement of the loop strands 105, 106, 206, 306, from the centre point 105 the amount of force required to compress the device from the expanded state, as illustrated in Fig. 1-4, to the collapsed state, as illustrated in Fig. 8, is reduced. This is thanks to the fact that the loop strands 105, 106, 206, 306, do not cross the centre point 105. Thus, the amount of*

threads that must be bent at the centre point 105 when compressing the device 100 is reduced. Each thread crossing the centre point 105 or a region close to the centre point 105 that is subjected to substantial deformation when compressing the device 100 to the collapsed state has a certain amount of structural integrity and an associated force that must be exceeded in order to deform the thread. By having several loop strands 105, 106, 206, 306 displaced from the region subjected to the most of the deformation, e.g. the centre point 105 or tip 801, the force required for deformation is thus substantially reduced [..]

74 Hence, by having several loop strands displaced from the region subjected to most of the deformation, which is the centre point or tip, the force required for deformation is substantially reduced.

9. FEATURE 1.2.1.4: DISTANCE FROM PERIPHERY

and wherein said apex points lie at a distance from a periphery (113) of said distal end,

75 Feature 1.2.1.4. establishes that an apex point of the loop strands cannot lie at the periphery of the distal end but must exist at a distance therefrom.

10. FEATURE 1.2.1.5: CENTRE STRANDS

[characterised in that,] said distal end is closed by a plurality of centre strands (115) of said braiding crossing each other at said centre point.

76 According to feature 1.2.1.5, the distal end is closed by a plurality of centre strands of said braiding crossing each other at said centre point. This feature, which is the characterizing aspect of the invention, requires that not all strands are looped back but that there is a plurality of strands that cross each other at the centre point to close the distal end, the centre strands. However, based on the wording of the claim, the description of the feature and its functionality centre strands do not only cross each other in that sense when going through the very (microscopic) centre point but also when they cross each other in a crossing section close to the centre point, which can be understood as “at” the centre point.

a) Wording

77 The wording of the feature refers to the centre point 105 which is described by the patent as the tip of the device (cf. para [0030]), and which can be seen as the geometric middle of the distal end of the braided device. However, the wording that (a plurality of) centre strands are crossing each other “at the centre point”, does not necessarily limit the crossing section to the very microscopic centre point. Crossing “at” does not demand that the strands are precisely crossing the very centre point and cross each other right there (“in” the centre point). Para [0034] supports this broader interpretation as it mentions that it could also be a region close to the centre point ("*each thread crossing the centre point 105 or a region close to the centre point 105*"). This indicates that the implementer has a margin for designing the size of the crossing section, allowing for a crossing section

that extends around the (microscopic) centre point. In that respect, it has to be acknowledged that the teaching of the patent is not reliant on metrics or specific distances but discloses a general concept of how to design occlusion devices. This is explicitly stated in para [0055], which reads:

> *"[..] those skilled in the art will readily appreciate that all parameters, dimensions, materials, and configurations described herein are meant to be exemplary and that the actual parameters, dimensions, materials, and/or configurations will depend upon the specific application or applications for which the teachings of the present invention is/are used"*

78 Hence, the wording "at the centre point" gives the skilled person an indication that the crossing could still be at a larger defined area close to ("at") the centre point.

79 The drawings are, as always, no basis to limit the open wording of the feature. Even though they seem to indicate one single crossing point right at the centre point, it has to be born in mind that they are schematic views of unknown resolution, thus not giving a closer indication of the size of the crossing section at the centre point. However, they do show no protrusion created by the crossing section at a centre point, see e.g. fig. 5b.

80 b) Function

81 The function of the feature is to reduce the force required to compress the device by displacing a plurality of strands (the loop strands) from the centre point - a central aspect of the invention as stated above regarding feature 1.2.1.3. The aim is to reduce the number of threads that must be bent at the centre point when compressing the device. Para [0034] (cited above) makes clear that each thread crossing the centre point 105 or a region close to the centre point 105 is influencing the force that must be executed in order to deform the thread. Thus, from a functional perspective the person skilled in the art has no reason to limit the crossing section to the very microscopic centre point but understands it as a somewhat larger defined crossing section close to the centre point as this supports the desired effect of reducing the force necessary to compress the device.

82 Additionally, when taking into consideration that the patent recognized it being an issue to have a distal end with a structure protruding into an arterial (high blood pressure) blood stream leading to vital organs, such as the brain (para. [0004]), the skilled person understands that a crossing of strands at a single point will lead to a bulge or a protrusion, that the patent considers a risk for creating emboli. Furthermore, the patent teaches that less strands crossing allows for a smaller cross-section, and thus reducing the amount of force required to compress the device (cf. para [0034]). This gives the skilled person another indication that also functionally crossing "at the centre point" cannot not limit the crossing-section to the very microscopic centre point but allows for a crossing section that extends closely around the centre point.

c) Closed distal end

83 Feature 1.2.1.5 furthermore requires that the centre strands of said braiding are closing the distal end by crossing each other at said centre point. It is clear for the skilled person

that the term “closed” by centre strands allows for spaces between the braided mesh of wires as it is the nature of a braiding of this kind. This is even more clear as the teaching of the patent relates to reducing the strands at the distal end to enhance flexibility and reduce the force needed to compress the device, as described in para [0043]:

> *[0043] The amount of the centre strands 115 may be varied. The flexibility of the device 100-600 may be adjusted by varying the amount of centre strands 115, hence providing customization of the device 100-600 to various applications. Fewer centre strands 115 may decrease the force required for compressing the device 100-600 from the expanded state to the collapsed state, hence increasing the flexibility. The ratio between the amount of the centre strands 115 and the loop strands may be set to a defined value. In Fig. 1 and Fig. 2 50% 50 of the threads are looped back, i.e. are comprised of loop strands 105,106,206,306. In Fig. 2 75% of the threads are looped back, and in Fig. 4 100% of the threads are looped back. By varying the amount of loop strands the flow through the device may also be optimized. More or less dense loop strands or more strands crossing the centre may increase the maximum flow through put of the device.*

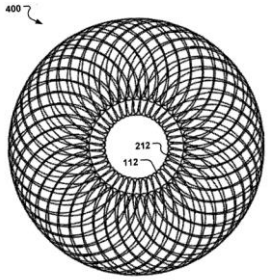
84 This shows the skilled person that a distal end is “closed” even when it is braided in a lighter way, with through holes remaining. Thus, the patent still considers a distal end being closed even if less centre strands allow for a greater flow through the device. Para [0043] teaches that the percentage of the threads looped back are decisive to achieve a closed (and thus patented) or an open (and thus not patented) distal end.

d) Prior Art

85 During the granting procedure the Applicant added this feature 1.2.1.5. in question. Contrary to the Defendant’s position this was not introduced by the Applicant, because of prior art rejections regarding the disclosure of centre strands. Indeed on the contrary, as the Defendants cited themselves, it aimed at distinguishing the patent from WO 2008/040555 A2 (document DN1), which disclosed a completely open distal end. Thus, the adding of feature 1.2.1.5. to the patent limited the invention to closed distal ends, excluding open distal ends, like in figure 4 of the patent (see above). And this closing of the distal end is to be achieved by the implementation of centre strands as the Applicant wrote to the EPO (exhibit D 2):

> *„The D1 device does not have a distal end braiding comprising loops strands as specified in claim 1 and at the same time the distal end being closed by centre strands.“*

86 In that respect, the Defendants convincingly argue that the specification discloses two different types of embodiments: (i) devices including both loop strands and centre strands, so that the distal end is closed as shown in fig. 1- 3 and (ii) devices including only loop strands and no centre strands, so that the distal end is open. An open distal end is e.g. shown in figure 4 of the patent, where 100% of the threads are looped back:



87 However, claim 1 covers only the first type of the embodiments, by expressly requiring both loop strands and a plurality of centre strands, which form a closed distal end.

III. VALIDITY SUFFICIENTLY SECURED

88 In the opinion of the Court the validity of the patent is reasonably certain.

1. PRINCIPLES OF EVALUATING THE VALIDITY OF A PATENT

89 As confirmed by the Court of Appeal a sufficient degree of certainty regarding the validity of the patent lacks if the Court considers it on the balance of probabilities to be more likely than not that the patent is invalid. The burden of presentation and proof for facts concerning the lack of validity of the patent lies with the defendant (CoA, UPC_CoA_335/2023, Order of 26 February 2024 - NanoString/10x Genomics, see p. 26-27; UPC_CoA_182/2024, Order of 25 September 2024 – Mammut Sports v. Ortovox Sportartikel). It should be noted that the assessment of these probabilities is based on an examination of how the Court would probably decide about the revocation of the patent in the event of a counterclaim on the merits. Decisions of other European Courts or decisions of the EPO concerning the same patent do not bind the Court but may provide helpful indications that the Court may consider (LD Hamburg, Order of 16 June 2025 - UPC_CFI_281/2025, p. 21).

90 Based on these principles, it is more likely than not that the patent-in-suit is valid. The Defendants have not submitted convincing attacks on the validity of the patent.

2. NO ADDED MATTER

91 The Defendants' assertion that the subject matter of the patent was illegally extended, because the original disclosure might not have contained any teaching, suggesting an arrangement of the apex points at a distance from a periphery of the distal end having a configuration other than an imaginary circle enclosing the centre point, is not convincing. To the contrary, the added feature 1.2.1.4 introduced only a limitation of the patented scope of the invention and does not cover embodiments that have not been disclosed.

92 Feature 1.2.1.4 had in fact been examined during prosecution and was not objected by the EPO. Several parts of the originally filed application contain disclosures of an arrangement of the apex points at a distance from a periphery of the distal end having a configuration other than an imaginary circle enclosing the centre point. This can be seen for instance on pages 9 lines 21 to page 10 line 8 (Exhibit D_03), which disclosed that the loop strands are displaced from the centre point 105 and do not cross the centre point

105, in particular the sentence bridging pages 9 and 10 explicitly states that loop strands "*displaced from the region subjected to the most of the deformation, e.g. the centre point 105 or tip 801, the force required for deformation is thus substantially reduced*."

93 Additionally, page 8 lines 20-23 state that each of the loop strands may be displaced from the centre point 105, and page 10 lines 13-14 explicitly discloses an arrangement of the apex points at a distance from a periphery according to feature 1.2.1.4:

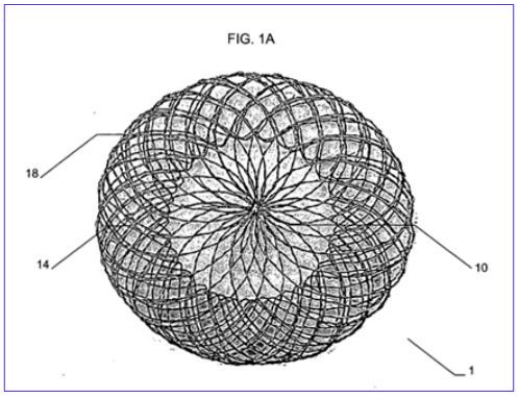
> *"The apex points 107, 108 also lies at a distance from a periphery 113 of the distal end 102."*

3. NOVELTY OVER DN 1 (WO 2008/040555 A2)

94 The patent is more likely than not novel over document DN 1 (WO 2008/040555 A2) as this document did not disclose centre strands within the meaning of feature 1.2.1.5. to close the distal end.

a) Prior art document

95 DN 1 discloses a medical device for closing or partially closing defect openings, cavities, organ passages , etc., or for creating a defined connecting opening between walls, organs, cavities, etc. (cf. p. 1, 1st para., DN 1). A respective device is also shown throughout the Figures of DN 1, e.g., in Fig. 1A:

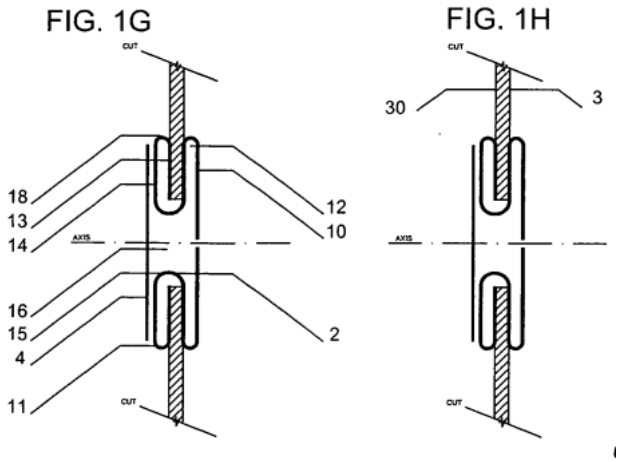


96 DN 1 was examined in the granting procedure. Based on DN 1 the Applicant introduced feature 1.2.1.5. as the characterizing feature to distinguish the claimed subject-matter from this prior art and cited this document in the patent description (see para. [0005]). Accordingly, the patent itself acknowledged that WO 2008/040555 discloses the features of the preamble of claim 1.

b) Feature 1.2.1.5

97 Contrary to the Defendants' position, DN 1 does not disclose loop strands and centre strands with the latter closing the opening on the distal side. The patent does not claim closed distal ends in general (that was known before), but it claims specific means to achieve a (relatively) closed distal end with a limited set of centre strands that cross each other at the centre point (see above section D. II. 10. c)). The patent obtains the closure of the distal end by implementing centre strands that are not looped back but cross each other at the centre point, which includes crossing each other close to the centre point.

98 DN1 takes a different approach. It is based on the concept that the distal section 11 is formed in a double layer configuration by two sub-sections 13, 14 folded one on top of the other as shown in figures 1 G and 1 H:



99 The opening 16 is closed by a membrane not by strands that are not looped back. This is described on page 29 of DN1:

> *"Figure 1 A shows a top view of an implantable device 1. As can be seen more clearly from the side views of the implantable device in Figures 1 G and 1 H, in which the implantable device 1 is arranged in an opening 2 of a wall 3, e.g., a heart of a human or animal, wherein Figures 1 G and 1 H differ only in that, for the sake of clarity, the reference numerals relating to the wall 3 are shown in Figure 1 H, the implantable device has a proximal section 10 and a distal section 11. The proximal section 10 is shaped to surround an interior space 12, whereas the distal section 11 is formed in a double layer by two sub-sections 13, 14 folded one on top of the other. One sub-section 13 is bent back toward the proximal section 10 and rests against the outer side 30 of the wall 3, whereas the other sub-section 14 is arranged distally on the outer side and connected to an intermediate section 15 which connects the proximal and distal sections 10, 11 and is arranged in the opening 2 in the wall 3. Furthermore, a membrane element 4 is applied to the outside of the distal section 14. This closes an opening 16 which is bounded on the inside by the section 14 and passes through the intermediate section. This also closes the distal section 11 distally, as well as the proximal section, which is already closed due to its essentially closed shape.*

100 Fig. 1G of DN 1 shows the proximal section by reference number 10 to the right in the figure, as well as the distal section by reference number 11 to the left. The distal section 11 includes double folded partial sections 13 and 14 and a through channel 16. The distal section 11 also has a perimeter 18. However, the distal section 11 has a central through going channel 16 that lacks anything like centre wires. Instead, the through channel 18 is closed by a membrane element 4.

101 Neither the sub-section 13 – which according to the Defendants should be loop strands – nor the sub-section 14 – which according to the Defendants should be centre strands – close the distal end as taught by the patent in suit. Also, the threads of the sub-section

14 do not cross each other at the centre point, even when "at" is considered allowing for a crossing-section somewhat around the centre point. Sub-section 14 – the alleged centre strands – is in fact taught to be connecting "the proximal and distal sections 10, 11" (via a connection to an intermediate section 15). Hence, DN1 does not unambiguously disclose centre strands that cross each other (at the centre point, if anywhere) in order to close the distal end within the meaning of feature 1.2.1.5.

c) Figure 24B

102 Nothing else follows from figure 24B of DN1, which shows a side section view which is similar to the side section view shown in figure 1G and which is to be seen in connection with figure 24A:

FIG. 24A

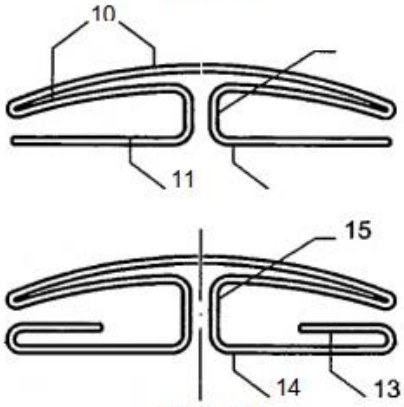


FIG. 24B

103 The Defendants' argument that not all embodiments in DN 1 had been discussed by the EPO, especially not figure 24B of DN 1, and that this figure would disclose feature 1.2.1.5 in the broad interpretation of the Applicant, is not convincing. Figure 24B is described in the DN1 on page 35:

> *Figure 24A shows a side view as a schematic sketch of an implantable device in which the distal section 11 is flat or planar, whereas the proximal section 10 is curved and closed. In Figure 24B the distal section 11 is formed with partial sections 13, 14 folded back on each other.*

104 This passage repeats the double-layer configuration without unambiguously disclosing centre strands which serve the purpose of closing the distal end. Fig. 24b does not teach centre strands, but shows a channel on the distal side, that remains empty and is designed to be closed by a membrane. As stated above, the sub-section 14 – the alleged centre strands – is taught to be connecting "the proximal and distal sections 10, 11" (via a connection to an intermediate section 15). That the sub-section 14 strands would cross each other at the centre point is not unambiguously disclosed. Furthermore, DN1 does not disclose centre strands that cross each other in order to close the distal end within the meaning of feature 1.2.1.5. Hence, the patent is more likely than not novel over document DN1.

4. NOVELTY OVER DN 2 (WO 1996/01591 A1)

105 Claim 1 of the patent is also more likely than not novel over document DN2.

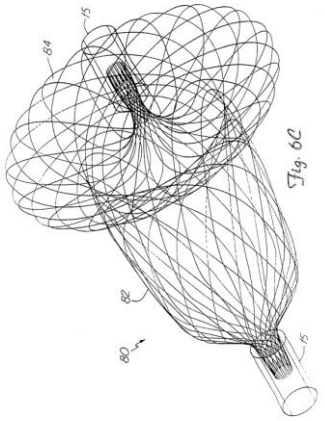
a) Prior art document

106 DN 2, which has not been cited during examination proceedings, relates to occlusion devices. It discloses an intravascular device for treating certain medical conditions, wherein the device comprises a collapsed state and an expanded state. It discloses a method for forming intravascular devices from a resilient metal fabric and medical devices which can be formed in accordance with this method. In the method of the invention, a metal fabric formed of a plurality of resilient strands is provided, with the wires being formed of a resilient material which can be heat treated to substantially set a desired shape (p. 3, lines 19 f.).

b) Features 1.2.1.1 to 1.2.1.5,

107 DN2 does neither disclose loop strands that are looped back at specific apex points nor centre strands that close the distal end. All wire strands in the tubular braiding uniformly are braided in a helical interlaced structure from one end of the tubular braid to the other end (p. 6, lines 12 f.). Thus, DN2 discloses no wire strands that are looped back as claimed.

108 Moreover, as described on page 21 line 16 stating “the forward end may be substantially flat (except for the clamp 15)”, the basic principle of the teaching of DN2 is that the ends of the wire strands at the distal portion of the device, are held in a bundle by the clamp to prevent unravelling of the tubular braid. This is for example shown in figure 6C:



109 Thus, DN2 belongs to the group of prior art which the patent desired to overcome, especially the necessity to clamp (or braze or glue) the strands together at the distal end. As stated above, the patent does not claim closed distal ends in general (that was known before), but it claims means to achieve a relatively closed distal end with centre strands that go through the centre area and thus need no cutting and clamping, which would otherwise lead to an undesirable protrusion, in combination with a controllable degree of flexibility for the folding/expanding the device.

110 Such a solution, however, is the subject of DN 2 as can be taken from its page 19 lines 7 to 10:

> *"As detailed above, in making a device of the invention it is desirable to attach the ends of the wire strands forming the metal fabric 10 to one another to prevent the fabric from unraveling. In the illustrations of Figures 6A-6C, a clamp 15 is used to tie 10 together the ends of the wire strands adjacent the front end 84 of the device".*

111 This means that the clamp protrudes, which is a construction the patent criticizes as it relates to the risk for creating emboli by protruding elements like the clamp 15 (cf. para [0004] of the patent).

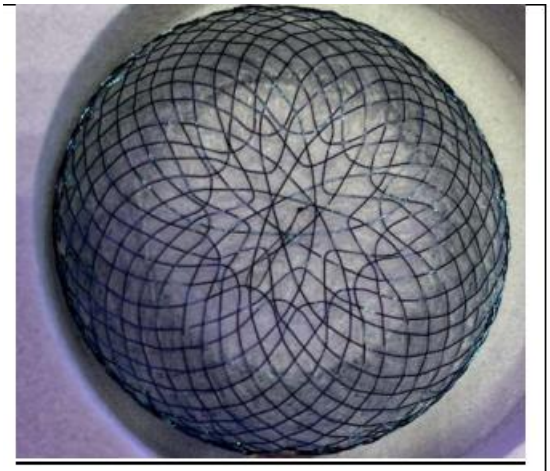
112 Apart from clamping, DN2 suggests as an alternative that one can solder, braze, weld or otherwise affix the ends of the desired length together (e.g. with a biocompatible cementitious organic material) before cutting the braid. Although soldering and brazing of NiTi alloys has proven to be fairly difficult, the ends can be welded together, such as by spot welding with a laser welder (p. 9, lines 6 f.). By cutting and clamping (or soldering or brazing) the one set of strands together they cannot be defined as centre strands in the meaning of feature 1.2.1.5 as they do not continue throughout the centre point and hence do not cross each other at the centre point.

E. INFRINGEMENT

113 Based on the understanding of the features of the patented claims stated above, the attacked embodiments make literal use of the technical teaching of claim 1 of the patent. The attacked embodiments in particular make use of feature 1.2.1.5.

I. MEMOCARNA ASD

114 Regarding the MemoCarna ASD the Applicant relies on pictures taken of actual product samples and that are not disputed by the Defendants.



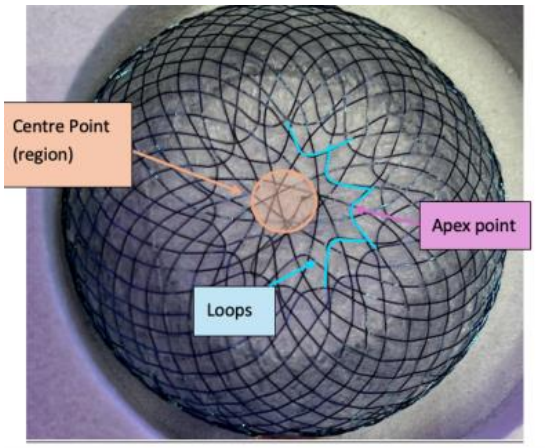
MemoCarna (ASD) distal end

1. FEATURES 1. TO 1.2.1.2

115 The realization of features 1. to 1.2.1. is undisputed. Also feature 1.2.1.1. and 1.2.1.2. are realized. According to feature 1.2.1.1. each loop strand has a curved shape and which is extending away from a centre point of said distal end. By having a plurality of loop strands displaced from the centre point by a plurality of centre distances, a larger portion of the distal end may exhibit a smaller cross-section in the collapsed state of the device.

116 The Defendants' argument, that their products do not even have a centre point according to claim 1 is not convincing. The attacked embodiments without question have a centre or tip in the middle of the flat distal end, irrespective whether a fiber runs through it or not.

117 As depicted by the Applicant the "MemoCarna (ASD)" has loop strands in a curved shape, extending away from the centre point, as can be seen in the following picture (with markings added by the Applicant):



MemoCarna (ASD) distal end

118 The Defendants' reference to a braiding tool, indicating that the strands are linear, not curved, is not of relevance as the curved shape of the loop strands in the actual product in the extended state is clearly visible in the picture above and also in the drawings the Defendants presented themselves.

119 According to feature 1.2.1.2., each loop strand has an apex point, which is the turning point of the curved shape loop and is the point of the loop that is closest to said centre point. This feature is also fulfilled as the apex (turning) points of the loop strands are the closest points of these loop strands to the centre of the distal end.

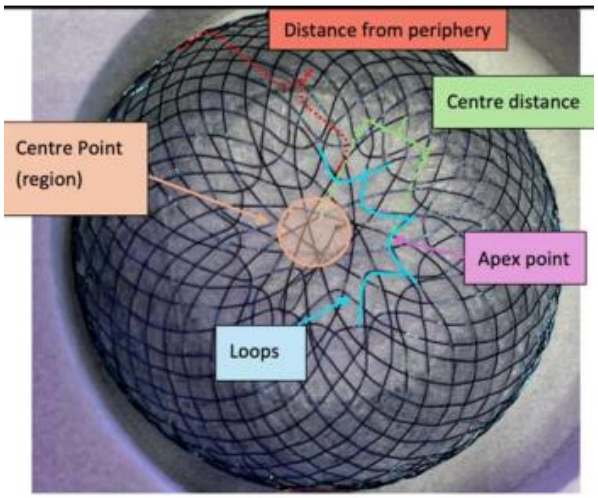
2. FEATURES 1.2.1.3 AND 1.2.1.4

120 According to Feature 1.2.1.3, at least one of said loop strands is displaced from said centre point by a centre distance such that the location of said apex point is different from said centre point. Feature 1.2.1.4. establishes that an apex point of the loop strands cannot lie at the periphery of the distal end but must exist at a distance therefrom.

121 These features are also present. Features 1.2.1.3. and 1.2.1.4. both describe, that the loop strands are not at the centre point, but "displaced from said centre point by a centre distance" and where at the same time "the apex point lie at a distance [away] from the

periphery of said distal end. The patent does neither teach nor require any specific distance, but only refers to regions of the device where the centre strands shall cross and the loop strands shall turn relative to other parts of the device, like the distal or proximal periphery. The centre distance between the apex and the centre point may vary and is preferably less than half the diameter (A) of the device, or less than half the cross-section at the location of the apex point in case the device is non-circular (cf. para. [0029]).

122 The realization of these features can be seen in the edited picture of the MemoCarna (ASD) presented by the Applicant (Application mn. 67). The "centre distance" (graphically represented in green) is the distance from the centre point to the apex point, whereas the "distance from the periphery" is the distance from the periphery of the distal end to the apex point (graphically represented in red):



MemoCarna (ASD) distal end

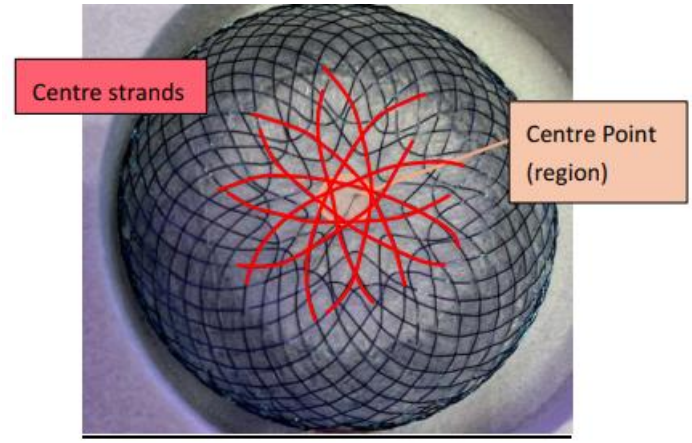
3. FEATURE 1.2.1.5

123 According to feature 1.2.1.5, the distal end is closed by a plurality of centre strands of said braiding crossing each other at said centre point. As laid out in the claim interpretation above, this feature requires that not all strands are looped back but that there is a plurality of strands that cross each other at the centre point to have the distal end closed, the centre strands. The Court sees also this feature being realized.

124 The MemoCarna ASD has centre strands that result in a closed distal end within the meaning of this feature. As stated above, it is not necessary that the crossing section of the centre strands is limited to the very microscopic centre point, but it is sufficient that there are strands that are not looped back and are crossing each other in the area at the centre point, which can be a crossing section close to the centre point as this supports the desired effect of reducing the force necessary to compress the device. Thus, it is not relevant, that there are no crossings in the very centre point, but only close to the centre point as this also qualifies as a crossing at the centre point.

125 The centre strands in the attacked embodiment close the distal end within in the meaning of claim 1. That is because, an open distal end is e.g. shown in figure 4 of the patent and

is defined as one where 100% of the threads are looped back (see para [0043]). The Applicant proved that not 100% of the strands are looped back in the attacked embodiment, but that there are several strands that are continued through the centre area/centre region and are thus closing the distal end in the meaning of claim 1, as depicted below (edited by Applicant):



MemoCarna (ASD) distal end

II. MEMOCARNA VSD

126 The same applies to the MemoCarna VSD, where the Applicant relies on drawings from the Defendants' presentations/catalogues, which are undisputed:

127 The MemoCarna VSD, as well, has centre strands that result in a closed distal end within the meaning of feature 1.2.1.5. It is not relevant, that there are no crossings of (non-looped-back) centre strands in the very centre point, but only close to the centre point, as this also qualifies as a crossing at the centre point.

III. LIABILITY OF THE DEFENDANTS

128 Both Defendants are liable for imminent patent infringement in the countries stated in the request. The Applicant has referred to the Defendants being jointly liable for the already enacted marketing and (imminent) sale of the attacked embodiments in Germany. The Defendants did not counter the liability question apart from denying any intention for sale in Germany/Europe, which can be disregarded for the reasons stated above in the establishment of competence.

129 As imminent infringing acts in Germany are sufficiently proven, an injunction according to Art. 34 UPCA also in other UPCA countries can be granted, whereas the Applicant specifically requested one only for Germany, France, Italy, Netherlands and Ireland.

IV. Weighing of interests

130 The interests of the Applicant outweigh those of the Defendants, what justifies to grant the requested preliminary injunction.

1. Principles

131 Pursuant to Art. 62(2) UPCA and Rule 211.3 RoP, the Court has to weigh the interests of the parties against each other at its discretion, taking into account in particular the possible damage that could arise for one of the parties from the issuance of the Provisional measures or the dismissal of the request (see also CoA, Order of 25 September 2024, UPC_CFI_182/2024 – Ortovox Sportartikel v Mammut Sports Group; LD Munich, Order of 27 August 2024, UPC_CFI_74/2024 = ACT_ 9216/2024 – Hand Held Products v. Scandit; LD Düsseldorf, Order of 31 October 2024, UPC_CFI_347/2024 = ACT_37931/2024 – Valeo Electrification v. Magna PT; LD Hamburg, Order of 16 June 2025, UPC_CFI_281/2025 = ACT 14764/2025). The mentioned circumstances are not limitative when weighing up interests (see 'in particular' in Art. 62 (2) UPCA and Rule 211.3 RoP). Rather, all relevant circumstances must be considered in the balancing of interests (LD Munich, Order of 27 August 2024, UPC_CFI_74/2024 = ACT_9216/2024 – Hand Held Products v. Scandit). Above all, the balance of interests must consider the probability of an erroneous decision and also the objective urgency in terms of the necessity of provisional measures with regard to equally possible proceedings on the merits. All aspects are to be weighed against each other in relation to each other.

132 The necessity of also taking these aspects into account in the context of the weighing of interests arises from the relationship between the proceedings on provisional measures under Rule 206 et seq. RoP and possible proceedings on the merits. In procedural terms, the proceedings on the merits are the rule, while the preliminary proceedings, with their summary examination and the possibility of a subsequent legal defence, are the exception (LD Düsseldorf, Order of 31 October 2024, UPC_CFI_347/2024 = ACT_37931/2024 – Valeo Electrification/Magna P; LD Brussels, Order of 21 March 2025, UPC_CFI_582/2024 – ACT_54438/2024 – Barco / Yealing (§50)). Therefore, an application for provisional measures should be the exception to this standard (default). Since the rights of the defence in such proceedings are not protected to the same extent as they are in proceedings on the merits, a request for provisional measures can only be granted in exceptional circumstances. These exceptional circumstances may relate to temporal and/or factual necessity, considering a balance between the rights of the applicant and the rights (of the defence) of the respondent (which are already limited by nature - due to the summary nature of a provisional measures procedure; LD Brussels, Order of 21 March 2025, UPC_CFI_582/2024 – ACT_54438/2024 – Barco / Yealing (§50)).

133 The necessity of provisional measures may, however, also follow from the fact that there is direct competition between the attacked embodiment and the product of the patent

holder (see CoA, order of 24 February 2025, UPC_CoA_540/2024, APL_52692/2024, Biolitec v Light Guide et al, para. 26).

2. ASSESSMENT

134 In the present case there are special circumstances that justify an injunction.

135 The parties are direct competitors in the field of occlusion devices. There is a proven increase in marketing activities by the Defendants as they have been attending several conferences / trade shows in a short period of time, several of them in Europe. They have recently achieved the necessary CE-mark for the attacked embodiments, which sets the stage to enter the European market with these products. Even though there are other competitors on the market, it is very likely that the introduction of the attacked embodiments will directly affect the Applicant's own sales opportunities. The introduction on the market and stimulation of the demand for such a new (and presumably cheaper) product, indeed changes the status quo on the market. Once the demand for a new (and presumably cheaper) product is stimulated, it is difficult to reverse the newly established relationships and dissolve the market confusion caused by the Defendants. It is not disputed between the parties that the distribution of products in question is based on long-term business relations.

136 As the Court of Appeal held in Sumi Agro v. Syngenta, the applicant does not have to demonstrate and quantify how sales have been affected by the infringing activity (Order of 3 March 2025, UPC_CoA_523/2024, mn. 95- 96). The necessity test is therefore assessed ex ante based on the reasonable potential for significant harm.

137 The Applicant could successfully argue that it is likely that the infringing product is offered at a significantly lower price compared to the product of the Applicant, leading to price erosion. This is because, the Applicant asserted that there is information from the Italian market that the products at question (or at least similar products) are offered at a substantially lower price than that of the Applicant. Despite the fact, that the Defendants have denied this allegation by claiming that it concerned different products, the Defendants have not disclosed which ones. Generally, the Applicant is under the obligation to provide the facts for the real risk of price erosion. However, as it is difficult to obtain reliable information on actual sales and their conditions in this very special field of implantable medical as these products are not sold online but through direct sales channels or tender offers with hospitals or purchasing companies of the hospitals (cf. Suppl. Witness Statement, Exhibit Occ 8), it would have been up to the Defendants to substantiate their counterargument with relevant facts.

138 These circumstances justify that the Applicant, who is the holder of the patent which dates back to 2010 and which is – so far unchallenged – in force since 2012, can successfully request a preliminary injunction, without awaiting the main proceedings.

V. SECURITY

139 The Defendants' request to condition the enforcement of the order on the placing of a security is unfounded.

1. PRINCIPLE

140 Where appropriate, the enforcement of a decision may be pursuant to Art. 82 (2) UPCA be subject to the provision of security or an equivalent assurance to ensure compensation for any damage suffered. This in particular applies in the case of injunctions which is reflected in R. 211.5 RoP, first sentence stating that the Court may order the applicant to provide adequate security for appropriate compensation for any injury likely to be caused to the defendant, which the applicant may be liable to bear in the event that the Court revokes the order for provisional measures. Further, according to R. 352.1 RoP, decisions and orders may be subject to the rendering of a security (whether by deposit or bank guarantee or otherwise) by a party to the other party for legal costs and other expenses and compensation for any damage incurred or likely to be incurred by the other party if the decisions and orders are enforced and subsequently revoked.

2. ASSESSMENT

141 The Defendants request a security in a specific amount based on (the calculation of) figures brought to the Courts' attention and subject to a confidentiality order. They argue that they would suffer lasting damage, which would seriously harm their business. Even if, as they argue, this damage is mostly reputational and indirect in nature (reduction of sales of non-infringing products as Defendants' reputation would be tainted due by the patent infringement decision in the eyes of the market participants), they claim that securities for these amounts have to be rendered to secure the Defendants' claims and allow the Defendants to securely retrieve from Applicant the damages caused. The damage by a cease and desist order targeting one of these products, is according to the Defendants enormous and might on a medium term threaten sales in an amount which they stated in the request. They state that this sum is based on last year's sales of occlusion devices in Europe, which Defendants expect to grow by a margin as (confidentially) specified in the submission.

142 The Defendants' request is unfounded. Regardless of the fact, that it is contradictory to deny an imminent entering into the market with the attacked embodiments and at the same time request an enforcement security, the information provided by the Defendants does not enable the Court to assess any possible damage, which the Applicant may be liable to bear in the event that the Court revokes the order for provisional measures. The calculation for damages has to be based on endangered profits of the attacked embodiments not based on the turnover of other products. Thus, a substantiation of a possible damage caused by the injunction requires an estimation of the expected profit per sold attacked product. As an alternative, a substantiation could encompass at least the typical royalty rate – which the Defendants in fact indicated in the oral hearing –

based on the sales price. However, in order to enable the Court to estimate any damage other factors need to be considered such as the sales price and the expected amount of products. The Defendants have not substantiated these factors. An alleged reputational damage as such is not sufficient to demand an enforcement security.

143 In addition, the Defendants have not substantiated why serious difficulties would be expected in connection with the recovery of any possible damages from Applicant, which is a EU based company with sufficient funds.

VI. VALUE

144 The value of the case is set to one million Euro as indicated in the oral hearing. Despite the fact, that the Applicant stated 500.000 Euro in its application, which the Defendants did not challenge, this amount is not apt with respect to the number of countries where the injunction is requested to have effect, which is Germany, France, Italy, Netherlands and Ireland.

VII. COSTS

145 According to the case law of the Court of Appeal (Order of 3 March 2025, UPC_CoA_523/2024 – Sumi Agro/Syngenta; Order of 6 August 2024, UPC_CoA_335/2024, 10x Genomics/NanoString), which the Local Division Hamburg follows, a decision on the obligation to bear legal costs is justified in inter partes proceedings for provisional measures, since it concludes the action (Order of 21 February 2025, ORD_68880/2024, UPC_CFI_701/2024; Order of 26 June 2024, ORD_38032/2024, UPC_CFI_124/2024). As the Applicant prevails in the present case the obligation to bear the costs of the proceedings is on the Defendants.

VIII. DATE ACCORDING TO R. 213 ROP

146 The Court shall ensure that provisional measures are revoked or otherwise cease to have effect, upon request of the defendant, without prejudice to the damages which may be claimed, if, within a time period not exceeding 31 calendar days or 20 working days, whichever is the longer, from the date specified in the Court's order, the applicant does not start proceedings on the merits of the case before the Court.

147 The Court sets the date on which the period according to R. 213 RoP on the day following the day of the upload of the order into the CMS.

ORDER

I. The Defendants are ordered to cease and desist from

Offering, placing on the market or using, or importing or storing for those purposes within the territory of Germany, France, Italy, Netherlands and Ireland

A medical implantable occlusion device, having a collapsed state and an expanded state and comprising

a braiding of at least one thread,

a distal end comprised of said braiding,

wherein said distal end comprises loops formed by loop strands of said at least one thread, wherein, at least in said expanded state, each loop strand having a curved shape and extending away from a centre point of said distal end, whereby an apex point of each of said loop strands corresponds to the turning point of said curved shape and to the point of each of said loop strands being arranged closest to said centre point, and wherein at least one of said loop strands is displaced from said centre point by a centre distance such that the location of said apex point is different from said centre point, and wherein said apex points lie at a distance from a periphery of said distal end,

characterised in that said distal end is closed by a plurality of centre strands of said braiding crossing each other at said centre point.

II. If Defendants fail to comply with the order according to item I., the Defendants are ordered to pay to the Court a penalty payment of up to EUR 250.000 for each individual case of non-compliance (R. 354.3 RoP), if need be repeatedly.

III. The Defendants are ordered to pay the costs of the proceedings.

IV. These orders are immediately effective and enforceable.

V. The date on which the period according to R. 213 RoP begins is the day following the day of the upload of the order into the CMS.

INFORMATION ON THE APPEAL

Parties may appeal against this order within 15 days of its notification, Art. 73 (2) lit. a),

Art. 62 UPCA, R. 220.1(c), 224.2(b) RoP.

INFORMATION ON THE ENFORCEMENT

A certified copy of the enforceable decision or order is issued by the Deputy Registrar at the request of the enforcing party, R. 69 RoP.

SIGNATURES

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Digital unterschrieben von Sabine Maria Klepsch
Datum: 2025.10.20 13:44:13 +02'00'

Presiding judge Sabine Klepsch

Stefan Schilling
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Judge rapporteur Dr. Stefan Schilling

Samuel Rocco M Granata

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Legally qualified judge Samuel Granata

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For the sub-registry