



ORD_576853/2023 UPC_CFI_15/2023
Order of the Court of First Instance of
the Unified Patent Court
from 29/09/2023

GUIDELINES:

1. According to Rule 4.1, sentence 2, of the Rules of Procedure, the parties are required to use the official forms available online. These forms also include the separate workflows within the CMS.
2. A prerequisite for a successful application for security under Rule 158.1 of the Rules of Procedure is the demonstration that the financial circumstances of the other party give rise to fears that a possible claim for reimbursement of costs cannot be served or that, despite sufficient financial means, enforcement of a costs decision appears to be impossible or fraught with particular difficulties.

KEYWORDS: official forms, separate workflows, admissibility, security

REFERENCE CODE ECLI: ...

Parties

- | | | |
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| 1) | Edwards Lifesciences Corporation
(Claimant)
- 1 Edwards Way - 92614 - Irvine - US | Represented by
Elsa Tzschope |
| | | |
| 2) | Meril Gmbh
(Respondent to 1)
- Bornheimer Straße 135-137 - 53119 - Bonn - DE | Service of process on

07/07/2023 Represented by
Dr Andreas von Falck |

3)	Meril Life Sciences Pvt Ltd. (Respondent to 2) - M1-M2, Meril Park, Survey No 135/2/B & 174/2 Muktanand Marg, Chala, Vapi - 396 191 Gujarat - Vapi - IN	Service of process on 01/08/2023 Represented by Dr Andreas von Falck
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Patent in suit

Patent no.

Owner

EP3646825

Edwards Lifesciences Corporation

RAPPORTEUR

Presiding Judge

Matthias Zigann

LANGUAGE OF THE CASE: German

FACTS

The plaintiff filed an infringement action against the two defendants on 1 June 2023 with the following claims:

I. ordered the defendants to cease and desist,

A system comprising: a prosthetic flap comprising: a collapsible and expandable annular frame configured to be collapsed into a radially collapsed state for attachment to a feeder and expanded into a radially expanded state within t h e body; the frame including a plurality of rows of angled struts, the angled struts being interconnected to form a plurality of rows of hexagonal cells, the frame is composed entirely of hexagonal cells and wherein each of the hexagonally shaped cells is defined by six struts comprising: two opposing side struts extending parallel to a flow axis of the flap, a pair of lower angled struts extending downwardly from respective lower ends of the side struts and converging toward each other, and a pair of upper angled struts extending upwardly from respective upper ends of the side struts and converging toward each other; and a delivery catheter containing an inflatable balloon;

*wherein the prosthetic valve is crimped in its radially compressed state onto the balloon of the delivery device, and wherein the balloon is configured to be inflated to expand to radially expand the prosthetic valve at the desired deployment site, preferably within an endogenous aortic valve
(independent claim 1 of the patent in suit),*

to offer, put on the market, use, or import or possess for the said purposes in the territory covered by the Agreement on the Unified Patent Court at the time of the oral proceedings, except in Malta, or alternatively in Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Portugal, Slovenia and Sweden,

especially when

the frame is made of a plastically expandable material preferably selected from a group comprising stainless steel, a nickel-based alloy, a nickel-cobalt-chromium alloy, polymers or a combination thereof; (dependent claim 5 of the patent in suit),

and/or

*the system further includes a sail structure containing multiple sails and a sealing skirt;
(dependent claim 6 of the patent in suit), and/or*

*a system according to dependent claim 6, wherein each sail has a flap portion adjacent an upper free edge of the sail;
(dependent claim 11 of the patent in suit), and/or*

*a system according to dependent claim 11, further comprising at least one reinforcing strip covering the flap portion of a corresponding sail;
(dependent claim 12 of the patent in suit), and/or*

*a system according to any one of dependent claims 6 and/or 11 and/or 12, wherein the skirt comprises a fabric, the fabric preferably comprising PET or UHMWPE;
(dependent claim 13 of the patent in suit), in*

particular when the system is

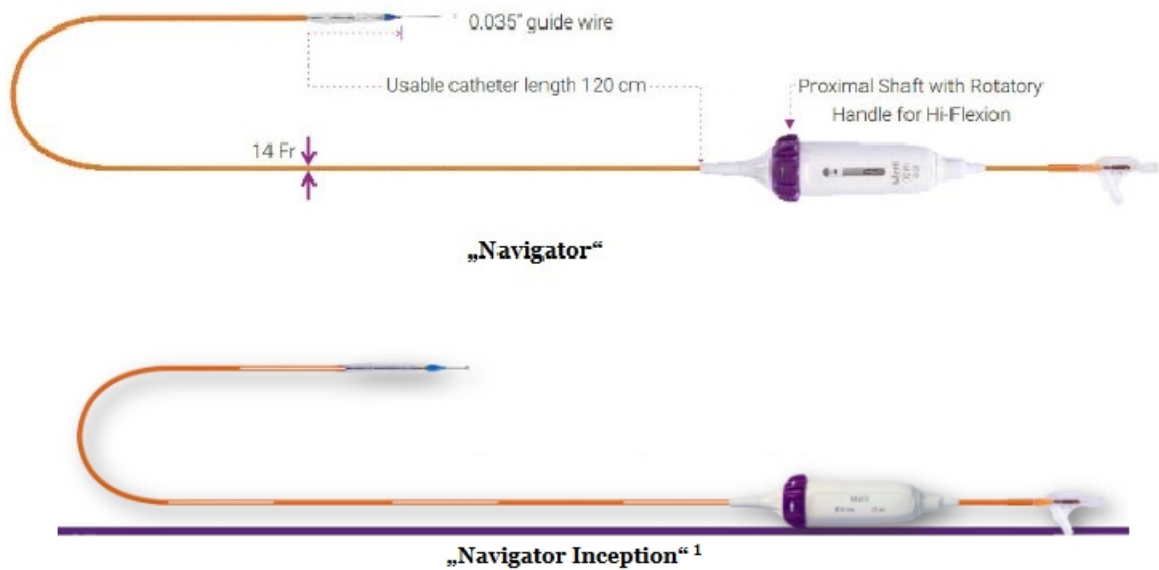
a) a transcatheter heart valve prosthesis called >Myval Octacor< such as

shown below



and/or

b) a feeder of the type >Navigator< and/or >Navigator Inception< as shown below



contains;

II. order the defendants to pay to the court periodic penalty payments for each case of infringement of the order under I. above, to be determined by the court in reasonable proportion to the importance of the order to be enforced, with a suggested amount of EUR 20,000 for each case of infringement and per item;

III. Finds that the patent-in-suit has been infringed by the defendants with regard to the products referred to in point I above;

IV. Order the defendants, under penalty of a penalty payment of EUR 1,000 to be paid repeatedly for each day of delay, to provide information within a period of three weeks after service of the decision on the applicant as to the extent to which the defendants have committed the acts referred to in point I. above since 17 March 2021, stating:

- 1) the origin and distribution channels of the infringing products,*
- 2) the quantities produced, manufactured, delivered, received or ordered and the prices paid for the infringing products, and*
- 3) the identity of all third parties involved in the production or distribution of infringing products;*

V. Order the defendants, under penalty of a repeated penalty payment of EUR 1,000 for each day of delay, to recall, within a period of one week after service of the decision, the products referred to in point I. above which have been placed on the market since 17 March 2021. The court orders the defendant to recall the products put on the market since 17 March 2021 from the commercial customers with reference to the patent-infringing condition of the products determined by the court and with the binding promise to pay any fees and necessary packaging and transport costs as well as customs and storage costs associated with the return and to take back the products, with the proviso that they are then finally removed from the distribution channels;

VI. Order the defendants, under penalty of a repeated penalty payment of EUR 1,000 for each day of delay, to return, within a period of one week from the date of notification of the decision, the property in their direct and/or indirect possession and/or ownership referred to in point I. above.

destroy the Designated Products and/or the relevant materials (including any products and/or materials coming into its direct and/or indirect possession and/or ownership pursuant to Clause IV or otherwise) or, at its option, surrender them to a bailiff to be appointed or engaged by the Claimant for the purpose of destruction;

VII. allow the applicant to publish the decision of the court in whole or in part, including the notice of the decision, in five public media and professional journals of its choice;

VIII. ordered the defendants to publish the operative part of the court's decision on their websites;

IX. declare that the defendants are obliged to compensate the plaintiff for the damage (including interest) which the plaintiff has suffered and will suffer as a result of the acts referred to under I. above committed since 17 March 2021;

X. Ordered the defendants to pay the plaintiff provisional damages, the amount being left to the discretion of the court, at least the

the anticipated costs of the damages and compensation proceedings on the part of the plaintiff must be covered and an amount of at least EUR 663,000.00 is suggested;

XI. order the defendants to pay the costs of the proceedings, including those relating to the measures requested in points I. to VIII. above;

XII. attaches an order for immediate enforcement to the decision, in the

alternative,

in the event that security is ordered, allows the applicant to provide it by way of a bank or savings bank guarantee and determines the amount of the security separately for each claim awarded and for the basic costs decision,

in the alternative,

the applicant be restrained from enforcing the judgment in respect of the costs against security;

XIII. make an order by default in the event that the respondents fail to perform an act within the time limit provided for in these Rules or fixed by the Court or fail to appear at a hearing after having been duly summoned.

On 1 September 2023 - within the extended opposition period - the defendant filed an opposition in the workflow of the infringement proceedings ACT_459987/2023 UPC_CFI_15/2023 as a "statement of defence" pursuant to Rule 19.1 of the Rules of Procedure as well as further requests.

The claimant replied to this as a "replica" in a written statement dated 26 September 2023 in the workflow of the infringement proceedings ACT_459987/2023 UPC_CFI_15/2023.

The respondent submits that the Court lacks jurisdiction insofar as the applicant seeks a decision with effect "in the area of application of the Agreement on the Unified Patent Court at the time of the oral proceedings - with the exception of Malta", because these states were not yet contracting states at the time the action was filed. The court also lacked jurisdiction insofar as the requests, in particular the requests under IV., V., VI., IX. and X., related to periods before 1 June 2023. The court was not authorised to decide on claims prior to the entry into force of the Convention. The opposition was also to be allowed and the action dismissed insofar as the asserted claims were based on an alleged infringement of the patent-in-suit by a system comprising the transcatheter heart valve "Myval Octacor" and the delivery system "Navigator". The local chamber in Munich was not competent to decide on this subject-matter of the dispute. It was obvious from the plaintiff's own submission that the plaintiff could not show any acts of infringement by a system containing the "Myval Octacor" and the "Navigator" by the first defendant in the area of jurisdiction of the local chamber. On the contrary, the plaintiff's own submission proved that there was neither a risk of first offence nor a risk of repetition. The "Myval Octacor" was sold in Germany exclusively with the associated "Navigator Inception". The first defendant did not market an allegedly patent-infringing system containing the "Myval Octacor" and the "Navigator" in the territory of the

Federal Republic of Germany, nor does it offer such a product there, place it on the market or use it or import or possess it for these purposes. Rather, the defendant had to

1) no longer distributed the "Navigator" in Germany since the defendants had issued a large number of declarations to cease and desist and to undertake to comply with penalties at the beginning of 2021. The jurisdiction of the local chamber in Munich was also not justified on the basis of the defendants' registered office.

1) in Bonn under Article 33(1)(1)(b)(1) EPC (seat chamber), insofar as the claims relate to an alleged infringement of the patent-in-suit by a system comprising the "Myval Octacor" and the "Navigator". The relevant German law (§§ 12 et seq. ZPO) did not establish the jurisdiction of the local chamber in Munich in particular. Rather, the local chamber in Düsseldorf had jurisdiction at most. This applied accordingly to the second defendant. It was undisputed that it did not have its seat in Germany. Contrary to the plaintiff's view, jurisdiction could also not be derived from the second sentence of Article 33(1)(b) UPCA, according to which a joint action against several defendants is possible if there is a business relationship between them and the action concerns the same allegation of infringement. Since the anchor court (local chamber Munich as the seat chamber concerning the first defendant) did not exist, a jurisdiction based on it could not be established with regard to the second defendant to the extent of the opposition. The action also did not concern "the same allegation of infringement" with regard to other national parts of the patent in suit. Since the applicant did not allege any actual or threatened infringement at all for the first defendant as anchor defendant for any other contracting member state in which the patent in suit has effect, there was no connectable allegation of infringement. At best, the central chamber was competent.

The further main proceedings would have to be stayed by the local division at its discretion pursuant to Rule 295(l) IR in conjunction with Art. 30(1), (3) of Regulation (EU) No 1215/2012. Article 30(1), (3) of Regulation (EU) No. 1215/2012, the local division will have to stay the further main proceedings as a court subsequently seised, because court proceedings concerning the European patent EP 3 583 920 B1 ("EP 920"), which is practically identical in scope, are pending in various member states and are connected with the proceedings at issue here. In addition, the stay was necessary for the proper administration of justice (Rule 295(m) of the Rules of Procedure). Meril Italy S.r.l. had filed a central invalidity action against the patent in suit EP 825. pending before the Central Chamber of Paris (ACT_551308/2023). The closely related European patents EP 920 and EP 3 583 922 B1 ("EP 922") were the subject of opposition appeal proceedings. EP 922 has already been revoked. The decision on the opposition, in respect of which an interlocutory decision outside the main proceedings had been requested, remained unaffected by the request for a stay.

At the request of the defendants, the applicant should be ordered to provide security for costs of proceedings pursuant to Article 69(4) UPCA, Rule 158.1 IR. The defendants feared that a possible enforcement of their claim for reimbursement of costs would be made considerably more difficult without the protection of a security for costs of proceedings because the applicant had its seat outside the European Union (specifically: USA). In the USA, unlike in the contracting member states, a decision of the court was not enforceable under Article 82.1 sentence 1 UPCA, but first required recognition. Since no precedent existed with regard to decisions and orders of the court by US courts, there was great legal uncertainty in this regard. In this context, it is irrelevant whether a plaintiff is wealthy.

The defendant makes the following submissions:

1. Grant the opposition to the extent requested and declare the action in part inadmissible

to be rejected because of

- the lack of jurisdiction of the Court (Rule 19.1(a) of the Rules of Procedure) with regard to all requests insofar as the applicant seeks a decision with effect "in the area of application of the Agreement on the Unified Patent Court at the time of the oral proceedings - except in Malta";
 - the lack of jurisdiction of the Court (Rule 19.1(a) of the Rules of Procedure) insofar as the applications, in particular the applications under points IV., V., VI., IX. and X., relate to periods prior to 1 June 2023;
 - lack of jurisdiction of the Munich Local Chamber (R. 19.1(b) of the Rules of Procedure) with regard to all requests insofar as they relate to an alleged infringement of the patent in suit EP 3 646 825 B1 by a system comprising the transcatheter heart valve "Myval OctacorTM" and the delivery system "NavigatorTM";
2. decide on the appeal in an interlocutory decision in accordance with Rule 20.1 of the Rules of Procedure;
 3. suspend the further main proceedings;
 4. that the Munich Local Chamber request the President of the Court of First Instance to assign to it, pursuant to Art. 18 para. 3 UPCA, an additional technically qualified judge from the pool of judges who has qualifications and experience in the field of medical technology, preferably expertise in the field of transcatheter heart valve replacement (Art. 8 para. 5, sentence 1 UPCA).
 5. Order the applicant to pay, within a period to be fixed by the Local Chamber, the costs of the proceedings and other expenses incurred and still to be incurred by the defendants. provide adequate security for any costs which the applicant may have to bear (Article 69(4) UPCA; Rule 158.1 IR);
 6. in the event that the applicant fails to provide adequate security within the specified time limit, to issue a default judgment against the applicant pursuant to R. 355 of the Rules of Procedure (R. 158.5 of the Rules of Procedure);
 7. in the event that the applicant fails to perform any act within the time limit provided for in the Rules of Procedure or fixed by the Local Chamber or fails to appear at an oral hearing after having been duly summoned, to make a default judgment against the applicant.
 8. stay the proceedings pending a preliminary ruling by the Court of Justice of the European Union pursuant to Article 267(2) TFEU in accordance with Rules 295(i), 266.5, first sentence, of the Rules of Procedure.

The plaintiff makes the following submissions:

1. Reject the opposition,
2. alternatively, to decide on the opposition in the main proceedings,
3. in the further alternative, to hear the parties at an oral hearing.
4. Dismiss the application for a stay of proceedings.
5. Reject the application for security for legal costs,
6. in the alternative, order the applicant to provide the security by way of a guarantee.

The plaintiff claims the following:

There was no doubt whatsoever as to the temporal jurisdiction of the court and the international and local jurisdiction of the local chamber in Munich. The plaintiff had a right of choice within the competent German local chambers. Referrals to the European Court of Justice and a stay of proceedings were not necessary. In particular, there were no foreign parallel proceedings concerning the patent in suit. The action for annulment against the patent in suit (ACT_551308/2023

UPC_CFI_255/2023) did not require a suspension. This was inadmissible due to the interposition of a straw man, Meril Italy S.R.L., to circumvent the concentration maxim of Art. 33.4 sentence 2 EPC. The only recourse open to the defendants would be an action for annulment before the Munich Local Chamber. The financial capacity of the plaintiff was undoubtedly given. The United States of America would regularly recognise foreign judgments. Since judgments of the court were to be treated like judgments of a court of one of the member states, there were no reservations.

Reference is made to the cited pleadings to supplement the parties' submissions.

REASONS

A.

The objection as well as the other applications will now be dealt with within the newly opened workflow ORD_576853/2023 UPC_CFI_15/2023.

In this respect, due to the special challenges which the new system poses for all parties to the proceedings, it is still refrained from treating the opposition as well as the further requests as inadmissible only because they have been filed as a "statement of defence" in the workflow of the infringement proceedings (Art. 42.2 UPCA). Correct would be would have been to submit the objection in a separate workflow as a "preliminary objection".

It should be noted, however, that such a handling would actually have been prompted by Rule 4.1 sentence 2 of the Rules of Procedure. According to this, the parties are required to use the official forms available online. These forms also include the separate workflows within the CMS.

In the present case, the submission as a "statement of defence" had the effect that the party bringing the action had reply has been filed as a "reply" and the CMS will assume that the written procedure on the merits has been concluded after the next pleading has been filed as a "duplicate". Whether and how this mess can be repaired by the system administrators is currently open.

B.

The objection thus filed in due form and time shall be dealt with in the main proceedings (Rule 20.2 of the Rules of Procedure). In detail:

1.

- the lack of jurisdiction of the Court (Rule 19.1(a) of the Rules of Procedure) with regard to all requests insofar as the applicant seeks a decision with effect "in the area of application of the Agreement on the Unified Patent Court at the time of the oral proceedings - except in Malta";

a. The defendant's request is to be understood as meaning that, in the event that further member states in which the patent-in-suit is validated ratify the UPCA between the filing of the application on 1 June 2023 and the date of the oral proceedings, an "automatic" extension of the action will occur which it, the defendant, deems inadmissible.

b. At present, this is a purely hypothetical question. Concrete ratification steps of further Contracting States are not known at present. This question can therefore be clarified in the main proceedings (Rule 20.2 of the Rules of Procedure), should it arise.

2.

- the lack of jurisdiction of the Court (Rule 19.1(a) of the Rules of Procedure) insofar as the applications, in particular the applications under points IV., V., VI., IX. and X., relate to periods prior to 1 June 2023;

a. The respondent's request is to be understood as assuming that the Unified Patent Court has no jurisdiction to decide on acts of infringement committed before the entry into force of the Agreement on a Unified Patent Court on 1 June 2023.

b. In the view of the rapporteur, this view is wrong in law. The Unified Patent Court has jurisdiction over infringement acts committed before the entry into force of the Agreement on a Unified Patent Court on 1 June 2023. This follows from Art. 3 c) and 32.1. a) UPCA and the absence of conflicting intertemporal orders.

c. In any case, however, the objection only concerns a part of the allegation. Even if it is successful, the main proceedings would have to be continued. Therefore, it is appropriate to deal with the objection in the main proceedings (Rule 20.2 of the Rules of Procedure).

3.

- lack of jurisdiction of the Munich Local Chamber (R. 19.1(b) of the Rules of Procedure) with regard to all requests insofar as they relate to an alleged infringement of the patent in suit EP 3 646 825 B1 by a system comprising the transcatheter heart valve "Myval OctacorTM" and the delivery system "NavigatorTM";

a. The defendant's request is to be understood to the effect that it is of the opinion that the question of jurisdiction is to be answered in a differentiated manner according to individual challenged embodiments or combinations of such challenged embodiments.

b. In the view of the rapporteur, this view is legally erroneous. In the context of Art. 33.1 b) EPC, the question is whether the same allegation of infringement is involved. For this purpose, the claim must be interpreted. In the present case, the relief sought is that the court should generally prohibit the defendants from further use of the technical teaching of the patent in suit. This is shown by the repetition of the wording of the granted claims in the request. The "in particular" reference to specific products or sets considered to be infringing in the application as well as the explanations in the statement of grounds merely serve as illustrations. Consequently, all specifically named products or sets concern the same allegation of infringement within the meaning of Article 33.1(b) EPC.

Therefore, the Munich local chamber is competent for the first defendant at least because it has its seat in Bonn and thus in the Federal Republic of Germany. The argumentation used by the defendant in this respect that for a selection within the competent German local chambers not the will of the party bringing the action but national law would apply due to a lack of norms of the EPC law is absurd. This is already shown by the consideration that this approach does not answer the question of jurisdiction for defendants domiciled in the Länder without a local chamber, especially in the east of Germany.

could.

On this basis, the Munich Local Board is also competent for the second defendant at least according to Art. 33.1 b) EPC. This is because the latter has a continuous business relationship with the first defendant concerning the infringing objects and the same infringement allegation is involved, namely the infringement of the patent in suit. The first defendant is a wholly-owned subsidiary of the second defendant.) The first defendant acts as the "European Headquater" of the group of companies and is supplied with the challenged embodiments by the second defendant.

c. In any case, however, it must be taken into account that the objection only concerns a part of the allegation and that even if it were to be accepted, the action would not have to be dismissed in its entirety, but - depending on the facts of the case - would have to be referred in part to the competent local or regional chamber to be determined (in the alternative) by the party to the action. It is therefore appropriate to deal with the objection in its entirety in the main proceedings (Rule 20.2 of the Rules of Procedure).

C.

A referral to the European Court of Justice and a stay of proceedings is not necessary at this point in time.

First of all, however, it must be stated that the other motions filed in their abundance cannot (actually) be made the subject of a preliminary objection. The possible subjects of a preliminary objection are listed exhaustively in Rule 19.1 a) of the Rules of Procedure. Questions of suspension due to pending parallel proceedings, for example, are not among them.

The above-mentioned objections as well as the further objections will be dealt with by the Board in the main proceedings. In the course of these proceedings, the question of referring certain questions to the Union Court and of staying the proceedings will be re-examined.

D.

The ordering of a security for the legal costs by the plaintiff is not occasioned.

First, however, it must be stated again that such a request cannot (actually) be made the subject of a preliminary objection. The possible subjects of a preliminary objection are exhaustively listed in Rule 19.1 a) of the Rules of Procedure. Motions according to Rule 158.1 of the Constitution are not included.

Such an order is within the discretion of the court (Art. 69(4) UPCA; Rule 158.1 IR). The judge-rapporteur exercises the discretion granted to him to decide on the application immediately within that order and not to order the provision of security.

The prerequisite for a successful application would be the demonstration that the financial circumstances of the other party give rise to fears that a possible claim for reimbursement of costs cannot be served or that despite sufficient financial means an enforcement of a decision on costs appears to be impossible or fraught with particular difficulties.

The respondent argues solely on the basis of the consideration that there is still no precedent with regard to decisions and orders of the court by US courts and that there is therefore great legal uncertainty. It is irrelevant in this context that the plaintiff claims to be wealthy.

This argument is not convincing. Since the court did not commence its activities until 1 June 2023, there is naturally no experience with the recognition and enforcement of decisions of the court abroad. In the United States of America, judgments of foreign courts as well as associated cost decisions can in principle be recognised and enforced. That this could be different with decisions and orders of this court or that this is seriously to be expected is neither submitted nor otherwise evident.

E.

A technical judge shall be called upon at the request of the respondent (Art. 8 para. 5 sentence 1 UPCA).

However, it should again be noted that such a request cannot (actually) be made the subject of a preliminary objection. The possible subjects of a preliminary objection are exhaustively listed in Rule 19.1(a) IR. Requests under Art. 8(5) sentence 1 UPCA are not among them.

ARRANGEMENTS

1. The objection shall be dealt with in the main proceedings.
2. The proceedings are not currently suspended.
3. Dismisses the defendant's application to order the plaintiff to provide security for the costs of the proceedings.
4. The parties can continue to present their arguments on the subject matter of the objection within the regular time limit regime. For this purpose, they will be given the option "to amend pleadings" - as far as this is possible in the CMS.
5. The President of the Court of First Instance is requested to assign from the pool of judges a technically qualified judge who has qualifications and experience in the field of medical technology, preferably expertise in the field of transcatheter heart valve replacement. The language of the proceedings shall be German.

NOTE ON LEGAL REMEDIES

Orders Nos. 2 to 4 may be reviewed by the panel upon a reasoned application by a party. The application for review must be filed within 15 days of service of this order.

DR ZIGANN
PRESIDING JUDGE AND RAPPORTEUR

Matthias ZIGANN  Digitally signed by Matthias
ZIGANN
Date: 2023.09.29 15:45:28 +02'00'