Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

EPG Court of Appeal

UPC_CoA_898/2025

Order

of the Court of Appeal of the Unified Patent Court issued on 27 March 2026

in proceedings for the adoption of provisional measures

HEADNOTES:

1. The assertion of a patent in a version of the claims that has not been registered is not automatically precluded, even in proceedings for the granting of interim measures. Rather, admissibility depends on the specific circumstances of the individual case, taking into account the summary nature of the proceedings.

2. The admissibility of new (alternative) claims in appeal proceedings is determined in accordance with Rule 222 of the Rules of Procedure. When exercising its discretion under Rule 222.2 of the Rules of Procedure, the Court also takes into account the summary nature of the proceedings in proceedings for the granting of interim measures.

3. The intended use pursuant to Art. 26 EPGÜ may be determined and assumed on the basis of objective circumstances if such circumstances exist which allow the sufficiently certain conclusion that the product offered or supplied is intended to be used by the recipient of the offer or the party to whom it is supplied for the purpose of utilising the invention.

KEYWORDS:

Application for interim measures; assertion of an unregistered claim; admissibility of alternative claims; indirect patent use; intended use.

APPELLANT AND APPLICANT IN THE PROCEEDINGS BEFORE THE COURT OF FIRST INSTANCE

ONWARD Medical N.V., Schimmelt 2-16, 5611 ZX Eindhoven, Netherlands, hereinafter

"the applicant",

represented by: Dr Matthias Traut, Solicitor, of the law firm Peterreins Schley Patent- und Rechtsanwälte PartG mbB.

RESPONDENT ON APPEAL AND DEFENDANT IN THE PROCEEDINGS BEFORE THE COURT OF FIRST INSTANCE

Niche Biomedical, Inc., 10940 Wilshire Blvd. Suite 2030, Los Angeles, CA 90024, USA,

hereinafter 'Respondent',

represented by: Dr Jan Zecher, Solicitor, of the law firm Fish & Richardson P.C.

PATENT IN DISPUTE EP 3 421 081

LANGUAGE OF THE PROCEEDINGS

German

CHAMBER AND DECIDING JUDGES

Panel 3:
Ulrike Voß, Chair and Rapporteur Bart van den Broek, legally qualified judge Nathalie Sabotier, legally qualified judge Claus Elmeros, technically qualified judge Selma Schenkl, technically qualified judge

CONTESTED ORDER OF THE COURT OF FIRST INSTANCE

Order of the Munich Local Chamber, 17 October 2025, UPC_CFI_693/2025

ORAL HEARING

5 March 2026

Facts of the case

Parties and patent in dispute

1. The applicant and appellant (hereinafter: the applicant) is seeking interim relief against the respondent and respondent on appeal (hereinafter: the respondent) on the grounds of direct and indirect infringement of European patent 3 421 081 B1 (hereinafter: the patent in dispute) in Germany and France.

2. The patent in dispute, of which the applicant is the registered proprietor, relates to a system for neuromodulation. The language of the proceedings for the patent in dispute is English. The notice of grant of the patent in dispute, filed on 3 June 2017, was published on 15 April 2020. The patent in dispute is in force in Germany and France, amongst other countries.

3. Claims 1 and 9 of the patent in dispute read as follows in the language of the proceedings:

Claim 1

"A system for neuromodulation (10), especially for neurostimulation, for the treatment of a subject, comprising

- at least a stimulation controller (12),
- at least one stimulation pattern storage means (14), which is connected to the stimulation controller (12) and which comprises stimulation data (SD),
- at least one electrical stimulation device (16),
- at least one electrical interface (18) between the electrical stimulation device (16) and the subject, the electrical interface (18) being connectable to at least one bio-interface (20) of or relating to the subject's nervous system, wherein the electrical interface (18) and the bio-interface (20) are arranged such that signals and/or data can be exchanged from the electrical interface (18) to the bio-interface (20), preferably also in the opposite direction,

wherein the stimulation data (SD) are pre-programmed patterns, which comprise at least

- a spatial component (SC), which relates to the part of the nervous system being stimulated
- a temporal component (TC), which relates to the time at which each of the aforementioned spatial components is applied.

and wherein the stimulation controller (12) is capable of sending configuration signals based on the stimulation data (SD) to the electrical stimulation device (16) such that, via the electrical interface (18), electrical stimulation can be provided to the bio-interface (20), wherein the electrical stimulation provided is characterised by stimulation parameters that vary over time in a pre-programmed manner."

Claim 9

"The system (10) according to one of the preceding claims, characterised in that the system (10) comprises and/or is connected and/or connectable to a closed-loop system for neuromodulation, in particular for neurostimulation."

4. Claim 7 of the contested patent reads as follows in the English version and in the German translation of the contested patent:

Claim 7

"The system (10) according to claim 6, characterised in that the sequences comprise a plurality of ordered stages which are arranged such that, in their order, they replicate the physiological activation signals of relevant muscle groups at the appropriate time for a specific task or movement of the subject, the specific task or movement being at least one of walking, standing, standing up, sitting down, climbing stairs, cycling, lifting a foot, placing and/or moving a limb and/or trunk and/or the head of the subject and the like, especially wherein, for walking, the sequences comprise at least a first sequence related to left flexion and right extension, a second sequence related to right extension only, a third sequence related to left extension and right flexion, and a fourth sequence related to left extension only."

"System (10) according to claim 6, characterised in that the sequences comprise a plurality of ordered stages arranged such that, in their sequence, they replicate the physiological activation signals of relevant muscle groups at the appropriate time for a specific task or movement of the patient, wherein the specific task or movement is at least one of the following:

> walking, standing, standing up, sitting down, climbing stairs, cycling, lifting a foot, positioning and/or moving a limb and/or the patient's trunk and/or head, and the like, in particular, for walking, the sequences comprise at least a first sequence relating to left flexion and right extension, a second sequence relating only to right extension, a third sequence relating to left extension and right flexion, and a fourth sequence relating only to left extension."

5. The parties are competitors. They each market systems for transcutaneous spinal cord stimulation in the European Union. The stimulation systems are medical devices; they are available only on prescription. The applicant has recently begun marketing the system known as ARCEX®, for which it received CE certification in September 2025. The selling price for this system is approximately €35,000.00.

Contested embodiment

6. The defendant offers and distributes, inter alia in Germany, a stimulation system called ExaStim® (hereinafter: the contested embodiment). This is a portable, non-invasive multi-channel neurostimulation system for the delivery of transcutaneous spinal cord stimulation. The contested embodiment is intended for the stimulation of the spinal cord in order to improve or restore the motor functions of the upper limbs in adult patients with paralysis resulting from spinal cord injuries.

7. The contested embodiment comprises, inter alia, the components illustrated below:

8. The ExaStim® stimulator, which delivers electrical current, is connected via a ReCure® stimulation cable to the ReCure® electrode pad, a multi-electrode array comprising 16 individually activatable electrodes. The ReCure® electrode pad is attached to the patient's back or neck and is used to deliver electrical impulses to the patient's nervous system. Using the ExaStim® programmer, which can connect to the ExaStim® stimulator via Bluetooth, stimulation programmes can be created or existing programmes selected for use, and the respective treatment can be started and stopped. For further details regarding the design of the contested embodiment, reference is made to the user manuals submitted to the file, Annexes PS12 and PS13.

9. The contested embodiment is sold to hospitals or therapy centres. The selling price of the contested embodiment is approximately €15,000.00.

10. The ReCure® electrode pad can be purchased separately as a consumable item. This incurs a monthly cost of €500.00.

11. The contested embodiment has been registered in the EUDAMED database since June 2025 and has been available in Germany, amongst other places, since 17 June 2025 (Exhibits PS17, PS18).

12. On 16 June 2025, the respondent published the German-language user manual (Exhibit PS12) on its website. The applicant became aware of this on 20 June 2025.

Proceedings at first instance

13. By written submission dated 30 July 2025, the applicant applied to the Munich Local Chamber (hereinafter: Local Chamber) for the issuance of interim measures on the grounds of (alleged) direct and indirect infringement of claim 1 of the patent in dispute. After the respondent's written defence had been served on the applicant on 31 July 2025, the applicant, by a written submission dated 29 August 2025, filed eight alternative claims in the event that the court should not consider claim 1 of the patent in dispute to be valid. For the wording of these, reference is made to p. 2 et seq. of the first-instance written submission of
29 August 2025.

14. By order of 17 October 2025, the Local Chamber dismissed the application for interim measures of 30 July 2025 and the alternative claims submitted in this regard by written submission of 29 August 2025. The respondent's application for provisional reimbursement of costs was likewise dismissed.

15. With regard to the asserted claim 1 of the contested patent, the Regional Board stated that, in view of the prior art cited by the respondent, there were substantial doubts as to the novelty of the claim in its granted form. Citation US 2016/0263376 A 1 (Annex FR 13, 'Yoo') disclosed all the features of claim 1 of the contested patent.

16. The Local Chamber rejected the auxiliary requests filed by the applicant in its written submission of 29 August 2025 on the grounds that interim measures under Article 62 EPC could not be granted if the asserted patent required an amended version of the claims to be valid. Corresponding (subsidiary) applications must therefore be rejected. This applies both where such (subsidiary) applications are already filed with the application for interim measures and where they are filed only in the course of the proceedings, for example in response to the opposing party's submission regarding the lack of legal validity. (Subsidiary) applications in which, in proceedings for interim relief under Article 62

EPGÜ, are made to address existing doubts as to the legal basis, should generally be rejected, in the opinion of the Local Chamber. If a patent proprietor considers (in the alternative) that an amendment to the wording of a patent's claims is necessary, this implies that the patent in its granted version is likely to be invalid. In such a case, the court would generally not be satisfied as to the validity of the patent in its granted form, which is the sole determining factor for proceedings under Article 62 EPC. Nor is the purpose of the summary proceedings for the issuance of interim orders to order measures even though the asserted patent is recognisably defective in its granted claims. The assessment of the legal validity of a patent required under Article 62(4) EPC and Rule 211.2 of the Rules of Procedure relates solely to the version existing at the time the application was filed. Rule 211.2 of the Rules of Procedure refers expressly to 'the patent in question' and not to a patent whose claims have been amended.

17. By a written submission dated 22 December 2025, the applicant brought an action (the main proceedings) before the Local Chamber (Munich) for (alleged) infringement of the patent in dispute, UPC_CFI_2082/2025.

Claims of the parties

Applicant

18. In the notice of appeal and statement of grounds of appeal dated 30 October 2025, the appellant requested that the order of the Local Chamber of 17 October 2025 be set aside (claim I). She has also made claims for an injunction, disclosure, and destruction or safekeeping, basing her principal claim on the respective claims of claim 1 of the contested patent (Claims II.1–3, III. – IV) and, in the alternative, on a combination of claim 1 with claim 9 and with features of sub-claim 7 (claims II.a.1–3, III.–IV). For the wording of the claims, reference is made to pages 4 et seq. of the notice of appeal and statement of grounds of appeal dated 30 October 2025. Main claim II and auxiliary claim IIa were each subdivided into three claims for an injunction on the grounds of direct and/or indirect patent infringement. For the sake of simplicity, only the singular form is used below.

19. At the hearing, following the court's opening remarks, the applicant stated that it was withdrawing the main claim II and that the auxiliary claim IIa was now being made unconditionally.

20. The applicant therefore now requests that

I. that the order of the Local Chamber of 17 October 2025, UPC_CFI_693/2025, ACT_339922/2025, be set aside;

II. that the respondent be ordered

1. to **refrain** from

transcutaneous spinal cord stimulation ~~systems; systems for neuromodulation, in particular for neurostimulation,~~ intended for the treatment of patients, which are offered, placed on the market, used, imported or possessed for the aforementioned purposes in the Federal Republic of Germany and/or the French Republic, comprising

at least one stimulation controller, at least one stimulation pattern storage means connected to the stimulation controller and comprising stimulation data, at least one electrical stimulation device, at least one electrical interface between the electrical stimulation device and the patient, wherein the electrical interface can be connected to at least one bio-interface of the patient's nervous system or to the nervous system itself, wherein the electrical interface and the bio-interface are configured such that signals ~~and/or data~~ can be exchanged from the electrical interface to the bio-interface, ~~preferably also vice versa,~~ wherein the stimulation data comprises pre-programmed patterns comprising at least one spatial component relating to the stimulated part of the nervous system and a temporal component relating to the time at which each of the aforementioned spatial components is applied, and wherein the stimulation controller is capable of send configuration signals to the electrical stimulation device based on the stimulation data, so that electrical stimulation can be provided to the bio-interface via the electrical interface, wherein the electrical stimulation provided is characterised by stimulation parameters that vary over time in a pre-programmed manner,

wherein the electrical stimulation is provided in sequences comprising a plurality of ordered stages arranged such that their sequence replicates the physiological activation signals of relevant muscle groups at the appropriate time for a specific movement of the patient, wherein the specific movement is the positioning and/or moving of a limb, wherein the system (10) is an open-loop system.

2. alternatively, should the Court of Appeal not consider that there is a direct infringement of the subject-matter in the form of the alternative claim, to **refrain** from

third parties in the Federal Republic of Germany and/or the French Republic from using transcutaneous spinal cord stimulation systems~~, systems for neuromodulation, in particular for neurostimulation,~~ for the treatment of a patient, comprising

at least one stimulation controller, at least one stimulation pattern storage means connected to the stimulation controller and comprising stimulation data, at least one electrical stimulation device, at least one electrical interface between the electrical stimulation device and the patient, wherein the electrical interface is connectable to at least one bio-interface of the patient's nervous system or to the nervous system itself, wherein the electrical interface and the bio-interface are configured such that signals ~~and/or data~~ can be exchanged from the electrical interface to the bio-interface, ~~preferably also vice versa,~~ and wherein the stimulation controller is capable of sending configuration signals to the electrical stimulation device on the basis of the stimulation data, so that electrical stimulation can be provided to the bio-interface via the electrical interface, wherein the

provided electrical stimulation is characterised by stimulation parameters that vary over time in a pre-programmed manner,

wherein the system (10) is an open-loop system.
such as, for example, the 'ExaStim stimulation system' shown in section I.1

wherein the transcutaneous spinal cord stimulation systems are adapted and designed such that the stimulation pattern storage means comprise stimulation data consisting of pre-programmed patterns that include at least one spatial component relating to the stimulated part of the nervous system, and a temporal component relating to the time at which each of the aforementioned spatial components is applied, wherein the electrical stimulation is provided in sequences comprising a plurality of arranged stages, which are arranged such that their arrangement forms a replication of the physiological activation signals of relevant muscle groups at the time appropriate for a specific movement of the patient, wherein the specific movement is the positioning and/or moving of a limb, to be offered and/or delivered for use in one or both states;

(indirect infringement of the subject-matter of EP 3 421 081 B1)

3. to **refrain** from

third parties in the Federal Republic of Germany and/or the French Republic,
electrical interfaces which can be connected to at least one bio-interface of the patient's nervous system or to the nervous system itself, wherein the electrical interface is configured such that signals ~~and/or data~~ can be exchanged from the electrical interface to the bio-interface, ~~preferably also vice versa,~~

such as, for example, the electrical interface described below and designated 'ReCure electrode pad':

which are suitable and intended for use in neuromodulation systems, in particular for neurostimulation, and in transcutaneous spinal cord stimulation systems for the treatment of a patient, comprising at least one stimulation controller, at least one stimulation pattern storage means connected to the stimulation controller and containing stimulation data, at least one electrical stimulation device, at least one electrical interface between the electrical stimulation device and the patient, wherein the electrical interface can be connected to at least one bio-interface of the patient's nervous system or to the nervous system itself, wherein the electrical interface and the bio-interface are configured such that signals ~~and/or data~~ can be exchanged from the electrical interface to the bio-interface, ~~preferably also vice versa~~, wherein the stimulation data comprises pre-programmed patterns comprising at least one spatial component relating to the stimulated part of the nervous system and a temporal component relating to the time at which each of the aforementioned spatial components is applied, and wherein the stimulation controller is capable of send configuration signals to the electrical stimulation device based on the stimulation data, so that the bio-interface is provided via the electrical

electrical stimulation can be delivered via an interface, wherein the delivered electrical stimulation is characterised by stimulation parameters that vary over time in a pre-programmed manner,
wherein the electrical stimulation is provided in sequences comprising a plurality of arranged stages configured such that their arrangement replicates the physiological activation signals of relevant muscle groups at the time appropriate for a specific movement of the patient, wherein the specific movement is the positioning and/or moving of a limb, wherein the system (10) is an open-loop system;

to offer and/or supply for use in the Federal Republic of Germany and/or the French Republic,

(indirect infringement of the subject-matter of EP 3 421 081 B1)

III. to submit to the applicant's legal representative, within four (4) weeks of service of the order in this matter, a written statement containing appropriate information and documentation regarding

a) the origin and distribution channels of the products referred to in Section II.1 – alternatively those referred to in Section II.2 – and those referred to in Section II.3 in the Federal Republic of Germany and the French Republic (including the full names and addresses of the legal entities involved);

b) the quantities of the products referred to in point II.1 – alternatively, those referred to in point II.2 – and those referred to in point II.3 that have been supplied, received or ordered in the Federal Republic of Germany and the French Republic; and

c) the identity of all parties involved in the distribution of the products referred to in section II.1 – or, in the alternative, those referred to in section II.2 – and the products referred to in Section II.3 in the Federal Republic of Germany and the French Republic (including the full names and addresses of the legal entities involved);

IV. The respondent is ordered to provide, within one (1) week of service of this order to surrender the products referred to in Section II.1 – alternatively those referred to in Section II.2 – and those referred to in Section II.3, which are in its direct or indirect possession or ownership, to a bailiff to be appointed by the claimant, at its (the respondent's) expense, for the purpose of safekeeping, which shall continue until a final decision has been made between the parties regarding the existence of a claim for destruction or a mutually agreed settlement has been reached, and to submit proof of full and timely compliance with the order under Section II to the applicant's legal representatives within ten (10) days of handing over the products to the bailiff;

V. For each individual breach of the orders under Section I or II, the respondent shall pay to the Unified Patent Court a (where applicable, repeated) penalty payment of up to EUR 250,000 per product and/or such other amount as the Court may determine for each breach of the orders under Sections II or III. or failure to comply therewith, as well as up to EUR 100,000 for each day or part of a day, which counts as a whole day, on which the breach or failure to comply continues, or such other amount as the Court may determine;

VI. The above orders are provisionally enforceable; in the alternative: the above orders shall only be enforceable against the applicant once it has provided security in favour of the respondent in the form of a deposit in the amount of EUR 250,000;

VII. The respondent is ordered to pay the applicant provisional costs of EUR 112,000.00 within three (3) weeks of service of this order;

VIII. The respondent shall bear the reasonable and proportionate costs of the proceedings and any other costs incurred by the applicant in the proceedings at first instance and on appeal, up to the applicable maximum amount or the amount determined by the court.

Respondent

21. The respondent requests:

I. The appeal of 31 October 2025 be dismissed.

In the alternative:

II. The continuation of the alleged infringement shall be made conditional upon the provision of security by the respondent, the amount of which shall be left to the court's discretion.

In the further alternative:

III. The enforcement of the interim injunction be made conditional upon the appellant providing security, the amount of which shall be left to the court's discretion.

In the event of the appeal being dismissed, the appeal being withdrawn or the application for a preliminary injunction being withdrawn:

IV. The appellant shall bear the costs of the appeal proceedings.

V. The appellant is ordered to pay the respondent provisional costs in the amount of EUR 100,000.00.

Summary of the parties' submissions relevant to the decision

Applicant

22. The applicant considers that the contested order should be set aside, as it contains legal errors in procedural matters, in its interpretation, and in its assessment of the legal situation, which were decisive for the outcome of the proceedings at first instance.

23. For reasons of procedural efficiency, she withdraws the (main) claim based on claim 1 and confines herself to seeking an injunction in the form of the original (alternative

claim). This does not alter or restrict the subject matter of the dispute; the scope of the injunction claim is not restricted.

24. In the applicant's view, the (alternative) claim now asserted unconditionally corresponds to alternative claim 8 as filed at first instance. The claim is based on a combination of limited claim 1 of the contested patent with dependent claims 7 and 9. This combination results in a narrower scope of protection for the contested patent, as further features of the asserted claim must be satisfied.

25. The applicant explains the differences in the wording of the asserted claim compared to auxiliary claim 8 of the first instance as a necessary adjustment to the German translation, in her view. During the oral proceedings before the Local Chamber, she had to conclude that the Local Chamber had proceeded on the basis of a misunderstanding regarding the pre-programmed patterns required by the claim. The Local Board had overlooked the fact that there must be a plurality of patterns. This error was reflected in the Local Board's decision, both in the interpretation of claim 1 and in the examination of the legal basis. In order to clear up this misunderstanding and make it clearer that there must be a plurality of patterns, she had formulated the German translation of the claim—originally asserted as a subsidiary claim, now as a main claim—more precisely and used terminology that would correspond to the correct interpretation. However, the linguistic adaptation of the application for an injunction drafted in German did not entail any changes to the content. The wording of claim 7 in the English language of the proceedings is decisive. Claim 7 of the contested patent is not amended in any way.

26. In the applicant's view, the assertion of a patent claim in an unregistered version is also admissible in proceedings for the granting of interim measures. Insofar as the Local Chamber rejected the alternative claims made at first instance, it misapplied Rule 211(2) of the Rules of Procedure. Contrary to the Local Chamber's view, the 'patent in question' is not limited to the patent in its granted version, as demonstrated by a detailed analysis of the inconsistent wording of the legislation on the one hand, and the legislative framework and the purpose of European patent law on the other.

27. In the applicant's view, the contested embodiment makes direct, or at any rate indirect, use of all the features of the contested patent claim in the version now asserted. The separate offering and supply of the electrode pad of the contested embodiment constitutes an indirect infringement of this limited claim. The realisation of the claim in the asserted version can be inferred from the German-language user manual (Annex PS12) as well as the English- and Spanish-language user manuals of the contested embodiment.

28. The patent claim in the asserted version is also found to be legally valid.

Respondent

29. The respondent objects to any partial withdrawal of the application. It argues that, in view of the pending main action, in which an injunction based on claim 1 is sought as the principal claim, it has an interest in a decision (dismissing) the principal claim originally filed in the appeal proceedings.

30. The respondent ultimately defends the contested order as correct.

31. The respondent takes the view that asserting a patent on the basis of an unexamined version of the claims is inadmissible from the outset in summary proceedings. Only the assertion of a claim that has been examined and granted in that form is admissible. However, the version of the claim asserted by the applicant is an unexamined version, as it is not merely a combination of the registered claim 1 of the patent in dispute with claims 7 and 9. In particular, the cross-reference to claim 6 contained in claim 7 is ignored. The applicant is therefore not merely asserting "less", but "something different".

32. Apart from that, the version of the patent claim now asserted does not correspond to auxiliary claim 8 as filed at first instance. The new claim has a different wording and must be interpreted differently. The claim originally filed as an auxiliary claim in the appeal proceedings and now as the main claim was consequently filed retrospectively and is therefore late, just like the auxiliary claims filed at first instance.

33. The contested embodiment does not implement the claim in the asserted version. Direct patent infringement fails simply because the contested embodiment does not contain any pre-programmed patterns upon delivery. Programming is only carried out by doctors or specialist medical staff. Since no programming in accordance with the claims can be inferred from the German-language user manual, it cannot be assumed that the claimed patent claim is certain to be realised. For the same reason, indirect patent infringement also fails. In any event, the required intended use is lacking. Furthermore, the alleged indirect patent infringement in no way justifies an absolute prohibition. The contested embodiment can also be used without infringing the patent. All of this applies all the more so with regard to the electrode pad.

34. The respondent further objects to the late filing in so far as the applicant bases the allegation of infringement on the Spanish-language user manual. This user manual is, moreover, irrelevant, as the case concerns alleged acts of infringement in Germany and France. But even if it were to be taken into account, it would not disclose the necessary specific programming.

35. In the respondent's view, the legal basis of the claim as asserted is not sufficiently established. The claim contains an impermissible extension as well as an impermissible extension of the scope of protection. According to the respondent, the claim is in any event not inventive in view of a combination of the prior art Yoo with the prior art US 2004/0 082 797 A1 (Annex FR 14, hereinafter 'Tong').

36. The respondent also seeks provisional reimbursement of costs. The value in dispute in the appeal proceedings is higher than that in the proceedings at first instance. Furthermore, the appeal proceedings have given rise to considerable additional legal costs, which are already higher than the amount claimed.

Reasons for the order

37. The admissible appeal is unfounded.

A. Admissibility of the new claims

I. Limitation of the claim / Amendment of the claim / Partial withdrawal of the claim

38. It is not necessary to determine whether the initially conditional auxiliary claim, now converted into an unconditional (principal) claim, constitutes an unconditional limitation within the meaning of Rule 263.3 of the Rules of Procedure, an amendment to the claim within the meaning of Rule 263.1 RoP, or a partial withdrawal of the application for interim measures within the meaning of Rule 265 of the Rules of Procedure. The unconditional filing of the original auxiliary claim as the main claim is admissible in any event. Insofar as Rule 265 of the Rules of Procedure is deemed applicable, it should be noted that the respondent, in particular, has no legitimate interest pursuant to Rule 265.1 of the Rules of Procedure in a decision by the Court of Appeal on the original main claim II. Such an interest does not arise solely from the fact that, in the main action pending at first instance, claim 1 of the contested patent serves as the basis for the main claim there. The decision of the Court of Appeal in these interim proceedings does not have any legally binding effect on the main proceedings. In particular, the Local Chamber is not bound by the interpretation of the Court of Appeal. Furthermore, the validity of a patent is not decided in proceedings for the granting of interim measures. In this respect, merely a prognosis as to probability is given.

II. Assertion of a non-granted version of a claim

39. The admissibility of the application asserted is not precluded by the fact that the subject-matter of the (injunction) application is not the registered version of claim 1 of the contested patent, but rather that the applicant is asserting a combination of claim 1 with features of claim 7 and claim 9.

40. The assertion of a non-registered version of a claim is not excluded from the outset, even in proceedings for the granting of interim measures.

Rule 211.2 of the Rules of Procedure

41. Rule 211.2 of the Rules of Procedure does not stipulate that, in proceedings for the granting of interim measures, the assertion of a patent claim in a non-granted (or unexamined) version is excluded from the outset. The provision does not state that there must be sufficient certainty regarding the legal validity of the patent ‘in its granted version’. Rather, it states that the court must be satisfied with sufficient certainty that the ‘patent in question’ (English version: ‘patent in question’, French version: ‘brevet en question’) is valid. ‘Patent in question’ is not synonymous with ‘granted’ patent. The term ‘in question’ is merely a reference to the specific contested patent.

42. The fact that the term “patent in question” in R. 211.2 of the Rules of Procedure is to be understood in the aforementioned sense is clarified by Art. 49(6), Art. 68(3), Art. 83(3) EPC, R. 5.6, 5.8, 13.1(e), 25.2, 16.1, 63(e), 77
and Rule 260(1) of the Rules of Procedure. These provisions also use the term ‘relevant’ patent. It is clear from the context of the respective provision that the term chosen establishes a reference to the patent at issue. By contrast, there is no indication of a connection with the
“granted version” of the patent is not apparent. There is no indication that the term “relevant” in Rule 211.2 of the Rules of Procedure is to be understood differently from the other provisions mentioned.

43. The term ‘in the granted version’ is used in the Rules of Procedure only in relation to the language of proceedings, e.g. in Rule 30.1(a), 39.1 or 321–323 of the Rules of Procedure. This indicates that the legislator is certainly familiar with this term. Nevertheless, it has not been used in Rule 211.2 of the Rules of Procedure.

Summary nature of summary proceedings

44. Nor does the summary nature of proceedings for the granting of interim measures require that the assertion of a non-granted version of the contested patent be excluded per se.

45. It is true that shorter time limits apply in summary proceedings and that the scope for presenting evidence is also restricted. There is also the possibility of an ex parte order, which may, where appropriate, be issued by a single judge. However, this applies regardless of the version in which a patent claim is asserted. It is not apparent that every assertion of a claim in an ungranted version automatically leads to a (further) restriction of a defendant’s means of defence in summary proceedings. In particular, it is not apparent that the possibility of asserting a claim in an unregistered version automatically leads to potential respondents having to examine an unmanageable number of possible combinations in advance to determine their legal validity. Rather, the only relevant factor is always the claim asserted in the specific proceedings.

46. Whether the specific version of the claim asserted is admissible is a matter to be decided on a case-by-case basis. If, in a particular case, a defendant’s legal protection were to be unreasonably curtailed as a result of the assertion of a non-granted version of a claim, this can and will be taken into account. In such a case, the asserted version of the patent is not suitable for assertion or enforcement by way of summary proceedings, which will lead to the rejection of the application for interim measures at the latest on the basis of the balancing of interests pursuant to Rule 211(3) of the Rules of Procedure and/or the lack of necessity for an interim order.

47. Nor does the notion that the summary proceedings are not intended to order measures, even though the patent asserted is manifestly defective in the form of its granted claims, imply a general prohibition on asserting a non-granted version. It cannot be concluded, merely from the fact that an applicant asserts a non-granted version of a patent claim, that the granted claim is manifestly defective. There may be a variety of reasons for asserting a non-granted version of a claim. An applicant may, for example, decide to assert a limited version of the granted claim because they assume that the contested embodiment also makes use of this limited version. Furthermore, if the applicant is of the view that no objections can be raised against the legal validity of the limited version, they are acting with due care from their perspective and choosing what they consider to be the safest route to successfully enforcing the patent in summary proceedings. No statement is thus made regarding the legal validity of the granted claim, and certainly not to the effect that it is recognisably defective. And even if the assertion of a (limited) non-granted version of a claim were to be attributable to the applicant himself harbouring doubts as to the legal validity of the claim in its granted version, the foregoing still applies. Even then, the applicant is choosing what they consider to be a safe route to assert their claims under the patent in a promising manner. There are

. Especially since the following also applies here: if, in a specific case, the asserted ungranted version of the patent proves unsuitable for summary proceedings, this can be taken into account on a case-by-case basis.

48. If an applicant asserts a patent claim in a version that has not been granted, it is, moreover, irrelevant whether there are doubts as to the validity of the granted version of the patent claim. The granted version is not the subject of the dispute.

49. Contrary to the respondent's view, an applicant cannot be required to first conduct a limitation procedure before the EPO before being able to rely on a patent claim in an unregistered version as the basis for summary proceedings. This is not possible, if only because such a limitation procedure takes several months. This stands in contrast to the urgency required for proceedings to order interim measures.

50. The case law of the ECJ, according to which there is a presumption of validity for European patents from the date of publication of their grant (ECJ, judgment of 28 April 2022, C-44/21, Phoenix Contact v Hartung), does not support a different view. This case law concerns the question of whether Article 9(1) of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights precludes national case law under which the granting of interim measures for patent infringement is, in principle, refused if the patent in question has not at least survived opposition or invalidity proceedings at first instance. The ECJ has affirmed this. However, it does not follow that (due to the presumption of validity) only the granted claims of a patent may be asserted in summary proceedings. Apart from that, it should be noted that Rule 211(2) of the Rules of Procedure expressly provides that the court must itself be sufficiently satisfied as to the validity of the patent, including with regard to the granted version of the patent.

51. In so far as the parties refer to differing legal practices in various Member States, this is not relevant in the present context. Rule 211 of the Rules of Procedure must be interpreted autonomously.

Rule 30 of the Rules of Procedure

52. Rule 30 of the Rules of Procedure does not apply in proceedings for the granting of interim measures. This provision concerns an application for amendment of a contested patent in the context of nullity proceedings. Proceedings for the granting of interim measures, by contrast, are infringement proceedings in which (primarily) a claim for an injunction is the subject matter of the dispute. No decision is made on the legal validity of the contested patent in proceedings for the granting of interim measures. The contested patent remains unchanged.

III. Alternative claim in proceedings for the granting of interim measures

53. Nor is the admissibility of the application in itself open to question on the grounds that the application, which is based on a combination of claim 1 of the contested patent with features of claim 7 and claim 9, was initially filed as a conditional auxiliary claim in the appeal proceedings and then as a principal claim at the oral hearing.

Admissibility in principle

54. Under Article 76(1) of the EPGÜ, the court must rule in accordance with the claims submitted by the parties. The parties are therefore 'masters of the proceedings'; the principle of party disposition applies. With regard to a claimant or applicant, this means that she determines the subject-matter of the proceedings, which is why she is (also) entitled to a possible joinder of claims in infringement proceedings. She may therefore, in principle, also submit an alternative claim.

55. If the statement of claim contains only one (main) claim and a subsidiary claim is made in the further course of the proceedings, Rule 263.1 of the Rules of Procedure becomes relevant. This rule provides that any party may, at any stage of the proceedings, apply to the court for leave to amend or extend the claim. Rule 263 of the Rules of Procedure applies to applications for interim measures (EPG-BerG, UPC_CoA_182/2024, Order of 25 September 2024, Mamut v Ortovox).

56. Consequently, if an application for extension and amendment may be made at any stage of proceedings for the granting of interim measures, this may – in accordance with Article 76(1) EPGÜ – also be done by way of a subsequent alternative application, subject to the procedural condition that the main application is unsuccessful. If the procedural condition applies, the admissibility of the subsidiary application is consequently determined in accordance with the requirements under Rule 263.2 of the Rules of Procedure.

Summary nature of summary proceedings

57. When assessing whether the requirements of Rule 263.2 of the VerfO are met in a particular case, the summary nature of the proceedings for the ordering of interim measures is of particular importance. In particular, the speed of the proceedings, the shorter time limits and the limited scope for taking evidence, as well as the nature of the proceedings as a provisional arrangement, are decisive in determining whether subsequent subsidiary claims are admissible in light of the circumstances of the individual case.

58. Where several subsequent auxiliary claims are filed which are based on versions of the contested patent that have not been granted, it must be assessed, in light of the specific circumstances of the individual case, whether the number of auxiliary claims is appropriate for summary proceedings. As a rule, only one or a small number of auxiliary claims can be regarded as appropriate. The proceedings for the ordering of interim measures on the grounds of (alleged) infringement of the patent in dispute do not, however, serve to examine the legal validity of a patent in dispute as comprehensively as possible on the basis of Rule 211(2) of the Rules of Procedure. The purpose of proceedings for the granting of interim measures is the provisional securing or enforcement of (injunctive) claims arising from patent infringement where the matter is urgent and the applicant cannot be referred to proceedings on the merits. No decision is made on the validity of the patent in dispute.

New (alternative) application in appeal proceedings

59. Under Article 73(3) of the EPGÜ, an appeal may be based on points of law and fact, although under Article 73(4) of the EPGÜ new facts and new evidence may only be submitted if this is in accordance with the Rules of Procedure and it cannot reasonably be assumed that the party concerned was unaware of these facts and

could have submitted evidence in the proceedings before the Court of First Instance.

60. In accordance with Rule 222.1 of the Rules of Procedure, the applications, facts, evidence and legal arguments put forward by the parties pursuant to Rules 221, 225, 226, 236 and 238 of the Rules of Procedure constitute the subject matter of the proceedings before the Court of Appeal, subject to Rule 222.2 of the Rules of Procedure. Rule
222.2 of the Rules of Procedure grants the Court of Appeal discretion to admit submissions, facts and evidence not raised by a party during the proceedings before the court of first instance. In exercising its discretion, the court shall take into account, in particular, (a) whether a party wishing to introduce new submissions can demonstrate that these new submissions could not reasonably have been introduced during the proceedings before the court of first instance, (b) the relevance of the new submissions to the appeal decision, and (c) the other party's position regarding the introduction of the new submissions.

61. Applications within the meaning of Rule 222.2 of the Rules of Procedure are both principal and subsidiary applications. In view of this, the admission of a new (subsidiary) application in appeal proceedings concerning proceedings for the ordering of interim measures pursuant to Rule 222 of the Rules of Procedure is at the discretion of the court. Even when exercising this discretion, the summary nature of the urgent proceedings must be borne in mind, and it must also be taken into account that the respondent may be deprived of a level of jurisdiction in relation to a new (subsidiary) application filed only at the appeal stage. Both factors mean that, as a rule, restraint is required when admitting such a (subsidiary) application.

IV. The present case

62. In so far as the applicant argues that the (alternative) claim in the appeal proceedings is alternative claim 8 as filed at first instance, this cannot, however, be accepted. The wording of the claim based on a combination of claim 1 of the contested patent with features of claim 7 and claim 9 does not correspond to auxiliary claim 8 filed at first instance, as the following comparison shows [differences underlined]:

Appeal proceedings	Auxiliary claim 8 of the first instance proceedings
"… whereby the electrical stimulation is delivered in sequences comprising a series of ordered stages, arranged in such a way that their sequence replicates the physiological activation signals of relevant muscle groups at the time appropriate for a specific movement of the patient, wherein the specific movement is the positioning and/or moving of a limb…"	"… wherein the electrical stimulation is provided in sequences comprising a plurality of ordered stages, which are arranged such that, in their sequence, they form a replication of the physiological activation signals of relevant muscle groups at the time appropriate for a specific movement of the patient, wherein the specific movement is the positioning and/or moving of a limb…"

63. Consequently, the admission of the (alternative) claim raised for the first time at the appeal stage is, pursuant to
Rule 222.2 of the Rules of Procedure, is at the discretion of the Court of Appeal. The Court of Appeal exercises its discretion for the following reasons to the effect that the application is admitted.

64. The applicant has explained why she has worded the application in the appeal proceedings differently from the alternative application 8 in the first instance. She has formulated the (German-language) application for an injunction in such a way that it contains a German translation of the feature arising from claim 7, which – in the applicant's view – expresses the interpretation of the feature more clearly. The applicant has also argued that it was only prompted to do so by the contested order, or rather by the interpretation of the feature "pre-programmed patterns".

65. However, the amendment to the German translation in the context of the asserted (injunction) does not, however, alter claim 7 of the contested patent, as an amendment to the patent claim is precluded in infringement proceedings, nor does the amended translation have any decisive significance for the interpretation of claim 7 of the contested patent. The basis for interpretation is the wording of claim 7 in the language of the proceedings, Art. 70 EPC (for interpretation, see below, para. 101 et seq.). Whether all terms in the English wording of the claim have been 'correctly' translated into German is not decisive for the understanding of the person skilled in the art.

66. Even if the applicant's submissions regarding the understanding of the feature arising from claim 7 are more extensive and precise in the appeal proceedings than the relevant submissions regarding auxiliary request 8 at first instance, the applicant did not, in accordance with the foregoing, put forward any interpretation at first instance that deviates from the interpretation in the appeal proceedings. In substance, she is asserting the same interpretation. The (auxiliary) claim in the appeal proceedings is intended to express the same limitation of claim 1 of the contested patent as in auxiliary claim 8 at first instance.

67. The fact that the applicant initially asserted the combination of claim 1 with features of claims 7 and 9 in the appeal proceedings in the form of a (conditional) auxiliary claim is irrelevant. Immediately after the presentation of the facts and the state of the proceedings at the start of the oral hearing before the Court of Appeal, the applicant stated that it was now submitting the conditional request as its main request. This was an immediate, understandable reaction to the Court of Appeal's preliminary view that the legal validity of claim 1 of the contested patent could probably not be regarded as sufficiently established.

68. There is no indication that the respondent's defence would be significantly impaired by the admission of the application. The respondent has, admittedly, criticised what it considers to be the applicant's complicated interpretation of the combined claim asserted in the (alternative) application. However, it has responded to this without any apparent difficulty and has thoroughly contested the claimant's interpretation. At the same time, the respondent has argued that the interpretation in accordance with the new wording of the claim would change neither the (lack of) patentability nor the (lack of) infringement. With regard to what it considers to be the insufficiently established legal basis of the asserted claim version, the respondent further relies on the same grounds for invalidity and the same citations that it had already put forward at first instance against auxiliary claim 8 there. The respondent itself does not argue that the application filed at the appeal stage significantly impairs its ability to defend itself, for example because a search of further prior art would have been necessary, which would not have been properly possible within the time available.

69. Since the applicant had immediately filed the asserted claim version as an auxiliary claim in the

appeal and grounds of appeal dated 31 October 2025, the respondent had the full time of the appeal response period at its disposal to respond to this as well. The respondent also made extensive use of this. The fact that the applicant made the conditional alternative claim the main claim during the oral hearing therefore does not result in any disadvantage for the respondent. Nor is there any indication in the present case that the respondent has incurred (additional) costs as a result of this submission. The costs of the proceedings are to be borne by the applicant in the present case.

70. Whether the number of eight alternative claims filed at first instance constituted an appropriate number of alternative claims for the present case is open to doubt, but need not be decided. Alternative claims 1 to 8 of the first-instance proceedings are no longer the subject of the dispute.

B. Merits

71. The ordering of interim measures pursuant to Art. 62(1) EPGÜ in conjunction with Rule 211.2 VerfO requires that the court be satisfied with sufficient certainty that the applicant is entitled to bring proceedings, that their right is being infringed or is at risk of being infringed, and that the patent in question is valid. Sufficient certainty means a preponderance of probability (EPG-BerG, UPC_CoA_335/2023, order of 26 February 2024, NanoString v. 10x Genomics; EPG-BerG, UPC_CoA_182/2024, order of 25 September 2024, Mammut Sports v. Ortovox; EPG-BerG, UPC_CoA_297/2024, order of 3 December 2024, SharkNinja v. Dyson; EPG-BerG, UPC_CoA_768/2024, Order of 30 April 2025, Insolet v. EOFlow; EPG-BerG, UPC_CoA_446/2025, Order of 13 August 2025, Böhringer v. Zentiva).

72. The Court of Appeal is not convinced with sufficient certainty that the alleged combination of claim 1 of the contested patent with features of claim 7 and with claim 9 is infringed by the contested embodiment.

I. Technical background of the patent

73. The contested patent relates to a system for neuromodulation, in particular for neurostimulation. The system serves to improve the recovery of a patient with neurological functional disorders, such as following a spinal cord injury (paragraph [0001]).

74. According to the contested patent, neurostimulation systems are known in the prior art. It begins by describing EP 2 868 343 A1, WO 2022/034331 A2, US 2002/0052539 A1 and EP 3 184 145 A1.

75. EP 2 868 343 A1 discloses a system for providing adaptive electrical spinal cord stimulation to facilitate and restore locomotion following a neuromotor impairment (paragraph [0002]). EP 3 184 145 A1 relates to a system for selective spatio-temporal stimulation of the spinal cord (paragraph [0005]). Both systems are so-called ‘closed-loop systems’. In such systems, sensors are used to capture information about the patient’s current condition, which is fed back to the stimulation system in real time, so that the delivery of electrical impulses to influence the nervous system can be continuously adjusted.

76. WO 2002/034331 A2 discloses an implantable medical device system without a closed-loop control system (paragraph [0003]). US 2002/0052539 A1 describes a partially closed-loop, non-continuous and non-real-time communication system for medical emergency information and corresponding methods (paragraph [0004]). These publications disclose so-called 'open-loop systems'. In these systems, the stimulation data is not influenced in real time based on feedback regarding the patient's current condition. The stimulation pulses are delivered according to a predefined programme.

77. According to the further explanations of the contested patent in the general part of the description, known stimulation systems use either stimulation of the central nervous system, in particular epidural electrical stimulation (hereinafter: EES), or stimulation of the peripheral nervous system, in particular functional electrical stimulation (hereinafter: FES) (paragraph [0006]).

78. According to the patent in dispute, EES systems are known for restoring motor control in animal and human models, particularly following a spinal cord injury. This is achieved by artificially activating the neural networks responsible for locomotion below the site of the spinal cord lesion. It is not the motor neurons, i.e. the efferent nerve cells, that are stimulated directly, but rather the afferent sensory neurons before they enter the spinal cord. In this way, the spinal networks responsible for locomotion are indirectly recruited via these afferents, thereby globally restoring locomotion through the activation of the necessary muscle synergies (paragraph [0007]). The contested patent considers EES systems to be disadvantageous because there is no selective control of individual muscles. Consequently, the controllability and precision of the movements are limited, and inaccuracies may occur that hinder the fluidity and full functionality of the possible movement (paragraph [0007]).

79. According to the contested patent, in FES systems, electrical stimulation of the target muscles is achieved using surface electrodes, either directly by stimulating their motor nerve fibres (neuromuscular stimulation) or through a limited series of reflexes (practically limited to the withdrawal reflex) or through transcutaneous stimulation of the peripheral nerves (paragraph [0008]). The patent in dispute also criticises these systems. It argues that the muscle fatigue resulting from this stimulation renders FES systems unsuitable for use in everyday life. Furthermore, according to the contested patent, success remains limited due to cumbersome adjustments in surface muscle stimulation, unmet requirements regarding selectivity (in transcutaneous nerve stimulation) and a lack of stability (it is impossible to reproduce the exact electrode placement in muscle stimulation on a daily basis, as the electrodes shift due to clothing and sweat) (paragraph [0008]).

80. On this basis, the contested patent formulates the task as improving a neuromodulation system by enabling neuromodulation and/or neurostimulation to be provided in virtually any environment and in everyday life (paragraph [0009]).

81. This problem is solved by a system according to the claimed version of the claims, the features of which can be summarised as follows:

    1. Transcutaneous spinal cord stimulation system for treat of a patient, comprising
    2. at least one stimulation controller (12),
    3. at least one stimulation pattern storage means (14) connected to the stimulation controller (12) and comprising stimulation data (SD),
    4. at least one electrical stimulation device (16),

5. at least one electrical interface (18) between the electrical stimulation device (16) and the patient.

    5.1 The electrical interface (18) is connectable to at least one bio-interface (20) of the patient's nervous system or to the nervous system itself.

    5.2 The electrical interface (18) and the bio-interface (20) are configured such that signals can be exchanged from the electrical interface (18) to the bio-interface (20).

6. The stimulation data (SD) are pre-programmed patterns comprising at least

    6.1 a spatial component (SC) relating to the stimulated part of the nervous system,

    6.2 a temporal component (TC) relating to the time at which each of the aforementioned spatial components is applied.

7. The stimulation controller (12) is capable of sending configuration signals to the electrical stimulation device (16) based on the stimulation data (SD), so that electrical stimulation can be provided to the bio-interface (20) via the electrical interface (18).

    7.1 The electrical stimulation provided is characterised by stimulation parameters that vary over time in a pre-programmed manner.

8. The electrical stimulation is delivered in sequences comprising a plurality of ordered stages, arranged such that their sequence replicates the physiological activation signals of relevant muscle groups at the appropriate time for a specific movement of the patient, wherein the specific movement is the positioning and/or moving of a limb.

9. The system (10) is an open-loop system.

82. A schematic representation of an embodiment of such a system can be found in Figure 1 of the contested patent reproduced below.

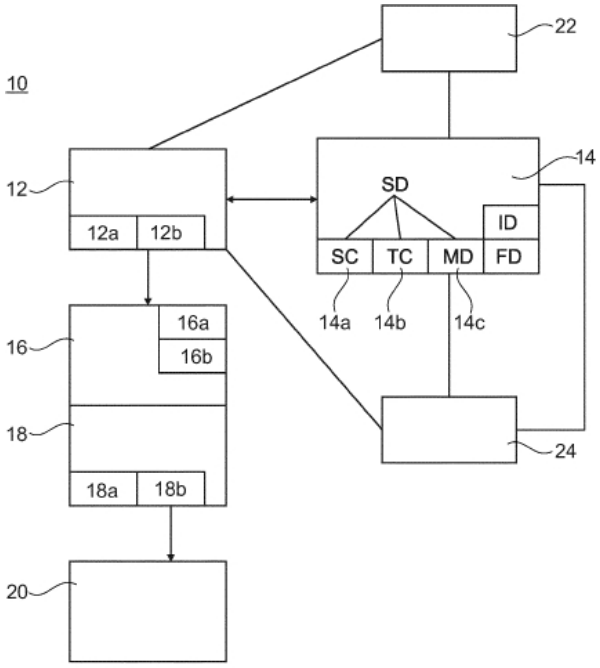

Fig. 1

II. Interpretation of the patent claim

Principles

83. Pursuant to Article 69 EPC, read in conjunction with the Protocol on its interpretation, the patent claim is not merely the starting point but the decisive basis for determining the scope of protection of a European patent. The interpretation of a patent claim does not depend solely on its exact wording in the linguistic sense. Rather, the description and the drawings must always be taken into account as aids to the interpretation of the patent claim and should not be used merely to resolve any ambiguities in the patent claim. However, this does not mean that the patent claim serves merely as a guideline and that its subject-matter also extends to what, following an examination of the description and the drawings, appears to be the patent proprietor's claim for protection. In applying these principles, appropriate protection for the patent proprietor should be combined with sufficient legal certainty for third parties (EPG-BerG, UPC_CoA_335/2023, Order of 26 February 2024, Nanostring v. 10x Genomics; EPG-BerG, UPC_CoA_1/2024, Order of 13 May 2024, VusionGroup v Hanshow; EPG-BerG, UPC_CoA_182/2024, Order of 25 September 2024, Mammut v Ortovox; EPG-BerG, UPC_CoA_297/2024, Order of 3 December 2024, SharkNinja v. Dyson; EPG-BerG, UPC_CoA_523/2024, Order of 3 March 2025, Sumi v. Syngenta).

84. The patent claim must be interpreted from the perspective of a person skilled in the art. The person skilled in the art always interprets a feature in the light of the claim as a whole (EPG-BerG, UPC_CoA_335/2023, Order of 26 February 2024, Nanostring v 10x Genomics; EPG-BerG, UPC_CoA_297/2024, Order of 3 December

2024, SharkNinja v. Dyson; EPG-BerG, UPC_CoA_768/2024, Order of 30 April 2025, Insulet v. EOFlow).

85. A statement of purpose contained in a claim typically defines the protected subject-matter in such a way that it must be objectively suitable for use in performing the function and serving the purpose specified in the patent claim (EPG-BerG, UPC_CoA_382/2024, Order of 14 February 2025).

86. Examples of implementation do not, in principle, limit a broader claim (EPG-BerG, UPC_CoA_335/2023, Order of 26 February 2024, Nanostring v 10x Genomics; EPG-BerG, UPC_CoA_297/2024, Order of 3 December 2024, SharkNinja v. Dyson; EPG-BerG, UPC_CoA_523/2024, Order of 3 March 2025, Sumi v. Syngenta). Sub-claims, which generally merely indicate the possibility of a particularly advantageous interpretation of the main claim, may in principle contribute to determining the scope of protection of the main claim.

87. These principles for the interpretation of a patent claim apply equally to the assessment of infringement and the validity of a European patent (EPG-BerG, UPC_CoA_335/2023, Order of 26 February 2024, Nanostring v. 10x Genomics; EPG-BerG, UPC_CoA_1/2024, Order of 13 May 2024, VusionGroup v Hanshow; EPG-BerG, UPC_CoA_182/2024, Order of 25 September 2024, Mammut v Ortovox; EPG-BerG, UPC_CoA_297/2024, Order of 3 December 2024, SharkNinja v. Dyson).

Expert

88. The Local Chamber was correct in assuming, in agreement with the parties, that in the present case a team comprising a medical technician and an engineer with a university degree in medical technology, biomedical engineering or electrical engineering and several years' practical experience in the field of the development of active medical implants and their control is to be regarded as a specialist.

Claim as asserted

89. In view of the dispute between the parties, the following features require closer examination.

Transcutaneous spinal cord stimulation system (feature 1)

90. According to feature 1, transcutaneous spinal cord stimulation systems for the treatment of a patient are protected.

91. A person skilled in the art understands a transcutaneous spinal cord stimulation system to be a system in which nerves connected to the spinal cord are stimulated from the outside via the skin of a patient to be treated by means of electronic pulses or electrical signals. The system therefore relates to the stimulation of the central nervous system.

Electrical interface (feature group 5, feature 7)

92. The system comprises at least one stimulation controller (12) (feature 2), which is connected to the

at least one stimulation pattern storage means (14) (feature 3) and the at least one electrical stimulation device (16) (feature 4). The at least one stimulation controller (12) is capable of sending configuration signals based on stimulation data (SD) to the at least one electrical stimulation device (16), so that electrical stimulation can be provided to the at least one bio-interface (20) (features 5.1, 5.2) via the at least one electrical interface (18) (feature 5), electrical stimulation can be provided (feature 7).

93. In accordance with feature 5, the at least one electrical interface (18) is located between the at least one electrical stimulation device (16) and the patient. Feature 5.1 requires that the at least one electrical interface (18) be connectable to at least one bio-interface (20) of the patient's nervous system or to the nervous system itself. Feature 5.2 further stipulates that the at least one electrical interface (18) and the at least one electrical bio-interface (20) are configured such that signals can be exchanged from the at least one electrical interface (18) to the at least one bio-interface (20).

94. By 'connectable' within the meaning of feature 5.1, a person skilled in the art understands the possibility of an electrical connection, i.e. that electrical signals can be transmitted from the at least one electrical interface (18) – more specifically, the electrode of the electrical interface (18) – to the nervous system of the spinal cord. The exchange of signals described in feature 5.2 is to be enabled. Since it is irrelevant for the transmission of electrical signals or the exchange of signals whether tissue is present between the electrode and the nerve, and since a transcutaneous spinal cord stimulation system is required according to the claims,
'connectable' does not require a direct physical connection between the electrode and the bio-interface (20).

95. In the applicant's view, the claim requires that the at least one electrical interface comprises a plurality of electrodes. The respondent, by contrast, takes the view that a single electrode is sufficient. The Court of Appeal concurs with the respondent's view for the following reasons. Claim 1 is not limited to (at least) one electrical interface with a plurality of electrodes.

96. The claim merely refers to an 'electrical interface (18)' and requires that this must be present at least once in the system. The claim contains no further characterisation of the electrical interface (18). There is no indication of the required number of electrodes of the (at least one) electrical interface (18).

97. Consequently, paragraph [0069] of the specification of the contested patent, to which the applicant still referred in the first instance, states that the electrical interface (18) may comprise 'one or more electrodes 18a, 18b'. The specification of the contested patent therefore (also) describes an electrical interface with only one electrode as falling within the scope of the claim.

98. This corresponds to the technical purpose of the (at least one) electrical interface (18). As can be inferred in particular from feature 7 of the claim, this purpose is to be able to provide electrical stimulation at the at least one bio-interface (20). The electrical interface (18) therefore serves the purpose of establishing electrical contact between the stimulation device and the patient (see also paragraph [0084] et seq.). In principle, the presence of an electrode is sufficient for this purpose.

99. Paragraph [0014] and sub-claim 4, which the applicant cites as evidence for its view, do not preclude this. Both state that the electrical stimulation device
(16) may comprise a plurality of electrodes and that the spatial component (SD) may comprise data relating to the activation and deactivation of defined subgroups

of electrodes. Apart from the fact that this, too, is merely a preferred embodiment, paragraph [0014] and sub-claim 4 refer to the (at least one) electrical stimulation device (16), not to the (at least one) electrical interface (18). The embodiment is consistent with the assumption that an electrical interface (18) as claimed may also comprise only one electrode. This is because, according to feature 5, there is at least one electrical interface (18) between the (at least one) electrical stimulation device (16) and the patient. Consequently, a stimulation device as claimed may also comprise several electrical interfaces. If this is the case and each of the electrical interfaces (18) has (at least) one electrode, then the electrical stimulation device (16) comprises a plurality of electrodes. The number of electrodes in the electrical stimulation device (16) may therefore be greater than in an electrical interface (18).

100. Even if it may therefore be sufficient for an (1) electrical interface to have only one electrode, the following must be borne in mind. Feature 8 requires stimulation capable of acting at at least two different stimulation sites (see below, para. 130 et seq.). However, this is only possible if the system comprises at least two electrodes capable of transmitting electrical signals to the nervous system. If a single (1) electrical interface
(18) has only one (1) electrode, this consequently means that it can only be a transcutaneous back stimulation system as claimed if the system comprises a further electrical interface (18) with at least one electrode.

Pre-programmed patterns (feature 6)

101. According to feature 6, the stimulation data (SD) (feature 3), which form the basis of the configuration signals sent by the (at least one) stimulation controller (12) to the (at least one) electrical stimulation device (16), are pre-programmed patterns. These comprise at least one spatial component (SC) relating to the stimulated part of the nervous system (feature 6.1) and a temporal component (TC) relating to the time at which each of the aforementioned spatial components is applied (feature 6.2).

102. The applicant takes the view that claim 6 requires a plurality of patterns, whereby a (first) pattern differs from a (second) pattern only if the respective spatial components of the patterns – that is, the stimulated parts of the nervous system – differ from one another. The same stimulated part of the nervous system, i.e. the same electrode configuration, merely results in the same pattern. Correctly, therefore, one stimulation site is required per (individual) pattern. Multiple patterns do not exist if the duration of application remains the same and the stimulated part of the nervous system does not change. Contrary to the view of the Local Chamber, the stimulated parts of the nervous system do not result solely from where the electrical interface is attached to the bio-interface. Furthermore, the patterns must be pre-programmed as claimed. This means that the stimulation data must consist of predefined sequences which are created in advance, stored and then retrieved.

103. In the respondent's view, feature 6 does not necessarily require that the patterns differ in their spatial components. It is sufficient if there are different temporal components.

Plurality of patterns

104. According to the claims, the stimulation data (SD) consists of a plurality of patterns.

105. The skilled person derives this understanding from the wording of the claims. As the use of the plural form indicates, this requires a plurality of patterns. This is clearly evident in the language of the proceedings of the contested patent pursuant to Art. 70 EPC ("… pre-programmed patterns, which comprise at least …"). In accordance with this, the embodiments described in more detail in the description of the contested patent also feature several patterns.

106. In accordance with features 6.1 and 6.2, a pattern is characterised by (at least) one spatial (SC) and (at least) one temporal component (TC).

Spatial component

107. The (at least one) spatial component (SC) refers, as feature 6.2 expressly states, to the stimulated part of the nervous system. The spatial component of a pattern thus determines which area of the nervous system is to be stimulated when the transcutaneous spinal cord stimulation system is used. The (at least one) spatial component therefore defines the intended site of stimulation (site of action). The electrodes to be activated for the stimulation are selected.

108. In the specification of the contested patent, this is described, for example, in paragraph [0014]. This paragraph explains (within the context of an embodiment) that the spatial component may comprise data relating to the activation and deactivation of defined subsets of electrodes, thereby making it possible to control and/or direct which part of the nervous system is to be stimulated.

109. This is illustrated, for example, in Figures 3 and 4a-d of the contested patent shown below.

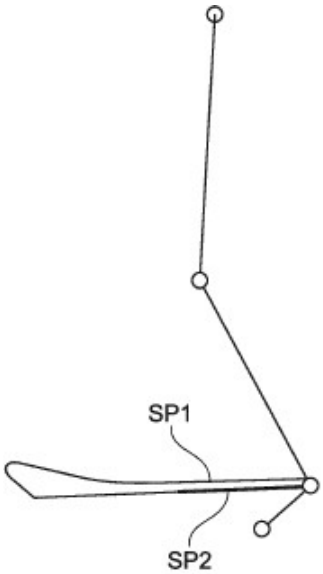

Fig. 3

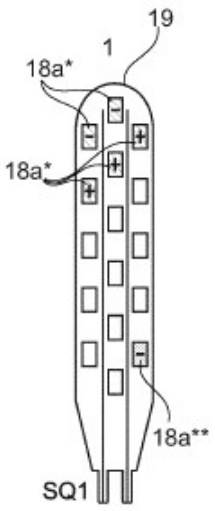

Fig. 4a

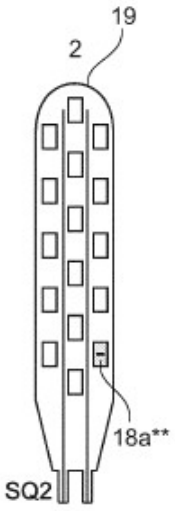

Fig. 4b

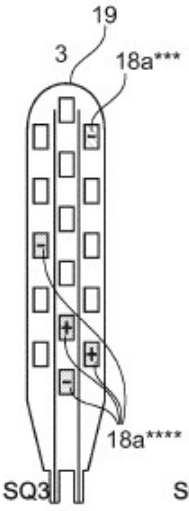

Fig. 4c

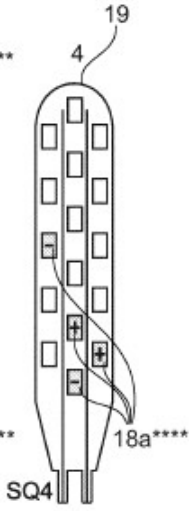

Fig. 4d

110. Figure 3 shows a schematic diagram of the trajectory of a leg and foot during locomotion, enabled by the phasic stimulation described above in

in conjunction with the walking sequences, whereby two stimulation patterns are applied sequentially, one during the swing phase SP1 and one during the stance phase SP2 of the gait (paragraph [0115]). Figures 4a–4d show the corresponding activation of electrode (18a) of the electrode paddle (19) (paragraph [0116]). In Fig. 4a, the activated electrodes (18a*) relate to the stimulation of the left leg for left flexion. In Figs. 4a and 4b, the activated electrodes (18a**) relate to the stimulation of the right leg for right extension. In Fig. 4c, the activated electrodes (18a***) relate to the stimulation of the right leg for right flexion. In Figs. 4c and 4d, the activated electrodes (18a****) relate to the stimulation of the left leg for left extension (paragraphs [0119]–[0122]). According to paragraph [0123], the stimulation patterns resulting from Figures 4a–d, which are the result of selecting the specific electrodes (18a) on the electrode paddle (19) shown in Figs. 4a–d, promote flexion and extension of the left or right leg, respectively.

111. When the system is used, which part of the nervous system is stimulated depends not only on the spatial component of a pattern, but also on the location at which the (at least one) electrical interface (18) according to feature 5 is attached. As already explained, the function of the (at least one) electrical interface (18) is to provide electrical stimulation at the (at least one) bio-interface (20) (feature 5.1). This in turn requires that the (at least one) electrical interface (18) and the (at least one) bio-interface (20) are able to communicate with one another and that an electrical connection or signal exchange can take place (see paragraph [0085]). For the system to be used properly (and effectively), this requires that the (at least one) electrical interface (18) be positioned or attached in such a way that the stimulation, by means of the signals provided—which are sent by the stimulation controller (12) and configured on the basis of the stimulation data (SD) – which also includes the spatial component of a pattern – also reach the intended site of action. Stimulation is not an end in itself. It is not intended to stimulate any random area of the central nervous system. Rather, the aim is to facilitate, enable or trigger (specific) muscle movements in the patient. Depending on the intended muscle movement, specific spatial components are therefore specified in the stimulation data. If the (at least one) electrical interface (18) is attached to any location on the patient's body, electrical signals are indeed provided at that point. However, there is no guarantee that electrical stimulation can be carried out in accordance with the spatial component of the stimulation data (SD). Coordination is therefore required to this end. For proper use, the (at least one) electrical interface (18) must be positioned or attached in such a way that the intended part of the spinal cord nervous system can actually be stimulated.

Temporal component

112. According to feature 6.2, the temporal component (TC) of a pattern refers to the time at which each spatial component is applied. The temporal component determines at what point in time a specific spatial component is applied. For example, it determines the time at which the electrode(s) selected by the spatial component are active or inactive for the stimulation of a specific part of the nervous system, or the duration of individual stimulation phases and their sequence.

113. The temporal component is illustrated by way of example for the embodiment shown in Figures 4a–d. The electrode configuration shown there corresponds to four temporal

consecutive sequences (paragraph [0118]). Paragraph [0117] states the following regarding these sequences: The first sequence, SQ1, relating to flexion on the left and extension on the right, lasts 400 ms. The second sequence, SQ2, relating to extension on the right, lasts 600 ms. The third sequence SQ3, relating to left flexion and right extension, lasts 400 ms. The fourth sequence SQ4, relating to left extension, lasts 600 ms. In addition to the durations, the temporal components also determine the sequence of the stimulation sequences, as illustrated in Figure 8.

Both components

114. In order to be able to assume a pattern as claimed, both (at least one) spatial component and (at least one) temporal component must be present. It is true that the components are not linked by the word 'and' in the wording of the claim. However, the mention of both components, the use of the word 'comprise' and the clause in feature 6.2 relating to the temporal component, which refers to the previously described (at least one) spatial component, make it clear that both components are essential for characterising a pattern.

115. This is also addressed in the description of the contested patent, for example where paragraph [0011] explains that the use of pre-programmed temporal stimulation data patterns in conjunction with the use of pre-programmed spatial stimulation data patterns enables stimulation at the right place at the right time to facilitate, enable or trigger the patient's intended action (see also paragraphs [0027], [0028]).

116. In view of this, a (stimulation data) pattern according to claim 1 is characterised by (at least) a specific spatial (SC) and (at least) a specific temporal (TC) component in the sense described.

Different patterns

117. According to the claim, several patterns of this kind must be present, i.e. different patterns must be included as stimulation data (SD) by the system, or more precisely by the stimulation pattern storage means (14).

118. Feature 6 does not specify any order of priority for the necessary components of each pattern mentioned in features 6.1 and 6.2, nor does it stipulate that the (at least one) spatial component must always be different in order to assume the existence of several different patterns.

119. Claim 6.2 states that the temporal component relates to the time at which "each of the aforementioned spatial components is applied". The word 'each' is due to the fact that, according to the claims, a pattern must contain at least one spatial component. Consequently, there may also be several spatial components. If this is the case, a temporal component must also be present for each of these several spatial components (of a pattern).

120. Insofar as the contested patent specification describes an embodiment in which reference is made to several patterns, whereby the spatial components (selection of the electrodes to be activated) and the temporal components of the individual sequences SQ1 and SQ4 differ from one another (Figures 4a-d, paragraph [0123]; see also Figures 8a–8b, 9a–9b), the person skilled in the art will know that an embodiment does not, in principle, entail any limitation of a broad

claim.

121. In view of this, when considering feature 6 in isolation, the person skilled in the art understands that different patterns exist (already at that stage) if the patterns differ in at least one of the two components.

122. It should be noted, however, that the issue at hand is not the interpretation of claim 1 in the registered version, but the claim in the version asserted by the applicant. Feature 6 must therefore be interpreted in the light of the claim as a whole, which is why the person skilled in the art must also take into account the requirements that feature 8 (which is not included in claim 1 in the registered version) sets out for the system claimed. As already mentioned, this feature provides for electrical stimulation that can act at at least two different stimulation sites. It requires a replication of the physiological activation signals of relevant muscle groups at the time appropriate for a specific movement of the patient (see below, para. 130 et seq.). This is only possible if both the spatial (selection of electrodes) and temporal components (duration and sequence of electrode application) differ from at least two of the patterns.

123. Consequently, the skilled person concludes that different patterns are to be assumed in the claimed version of the claim if at least one electrode in the set of activated electrodes differs.

Pre-programmed

124. The stimulation data (SD) must consist of pre-programmed patterns. The patterns are pre-programmed if they are defined prior to the use of the transcutaneous spinal cord stimulation system and are stored by the stimulation pattern storage means (14). The stimulation data (SD) therefore consists of predefined sequences that are created in advance, stored and then retrieved to generate the configuration signals.

125. This understanding arises for the person skilled in the art from the term ‘pre-programmed’, which inherently embodies the understanding described. The contested patent also uses the term in precisely this sense. This follows, on the one hand, from the fact that the stimulation data (SD) must, in accordance with feature 3, be comprised by the stimulation storage means (14), which presupposes that they are stored, which in turn presupposes that they are (pre-)defined. Secondly, this follows from feature 7, according to which the patterns, as stimulation data (SD), form the basis of the configuration signals. This, too, presupposes that they have been previously defined or established and stored, so that they can subsequently be used to generate technical control commands or instructions.

126. In accordance with this, paragraphs [0011]–[0020], [0027] and [0028], for example, describe the storage of predefined patterns, which can then be retrieved (repeatably) for use by the system.

Stimulation parameters varying over time in a pre-programmed manner (feature 7.1)

127. The electrical stimulation to be provided in accordance with feature 7 must, in accordance with feature 7.1, be characterised by stimulation parameters that vary over time in a pre-programmed manner.

128. The stimulation parameters must therefore be defined and stored before the start of stimulation, i.e. they must be pre-programmed and vary, which means that the stimulation parameters must change over time. This is described, for example, in paragraphs [0011], [0020], [0044], [0096] and [0099] and illustrated in Figures 8b and 9b of the contested patent. Since the claim contains no limiting information regarding the nature of the stimulation parameters, all stimulation parameters are covered, in particular frequency, current intensity, pulse width and electrode configuration (paragraphs [0020], [0102], claim 3).

Electrical stimulation in sequences (Feature 8)

129. Feature 8 provides that the electrical stimulation is delivered in sequences comprising a plurality of arranged stages, which are configured such that their arrangement replicates the physiological activation signals of relevant muscle groups at the time appropriate for a specific movement of the patient, wherein the specific movement is the positioning and/or moving of a limb.

130. Feature 8 is based on claim 7 of the contested patent, although not all of the tasks and movements mentioned in that claim have been included in the version of the claim asserted here, and furthermore the cross-reference to claim 6 of the contested patent contained in claim 7 has been omitted. However, this is not relevant to the interpretation of the claim.

131. The applicant is of the view that the German translation of the term 'order' contained in claim 7 in the language of the proceedings, as chosen by it in the application for an injunction, corresponds to "arrangement" is accurate and that this German term more clearly conveys that feature 8 does not require a temporal sequence. The applicant further considers that the subordinate clause "which are configured such that their arrangement replicates the physiological activation signals of relevant muscle groups …" refers to the stages previously mentioned in the feature. The respondent, by contrast, relies on the German translation of claim 7 in the specification of the contested patent. In this, the term "order" is translated as
"Reihenfolge". It therefore assumes that feature 8 provides for a temporal sequence. The respondent further takes the view that the said subordinate clause refers to the sequences mentioned at the beginning.

132. The Court of Appeal concurs with the appellant's view on the basis of the following considerations.

133. Claim 7 reads as follows in the passage under discussion here in the English language of the proceedings:

> "… that the sequences comprise a plurality of ordered stages which are arranged such that they form, in their order, a replication of the physiological activation signals of relevant muscle groups at the appropriate time for a specific task or movement of the subject …".

134. It is immaterial whether "in their order" is to be translated into German as "Anordnung" or "Reihenfolge". Both are possible. As already explained, it is not decisive for the interpretation of the feature whether the wording of a claim has been 'correctly' translated into another language. Rather, what is decisive for the understanding of the person skilled in the art is the language of the proceedings, Art. 70 EPC, and the (technical) literal meaning of the claim or of the feature in question.

135. On this basis, sequences are required which comprise a plurality of ordered stages, with the subordinate clause of feature 8 relating to the stages. This is already apparent from a linguistic or grammatical analysis of the feature or of claim 7. The

adjective ‘ordered’ is echoed by the noun ‘order’, which suggests a direct connection between the terms used. Furthermore, subordinate clauses usually refer to the immediately preceding nouns. In this case, these are the stages (‘stages’).

136. The expert further deduces that the arrangement of the steps is relevant from the requirement that this arrangement should replicate the physiological activation signals of the relevant muscle groups at the appropriate time for a specific movement by the patient. The aim is to replicate the movement of a limb. To achieve this, the nerves of the respective desired muscle group must be stimulated, which requires the selection of electrodes to be activated. According to the contested patent, the selection of electrodes leads to steps.

137. This is described in particular in paragraph [0018], according to which a stage is used in the context that a phasic ‘open-loop’ stimulation is a predefined sequence of stages capable of activating several sets of active electrodes, which in turn influence several muscle groups.

138. This is also evident from Figures 8a-b shown below.

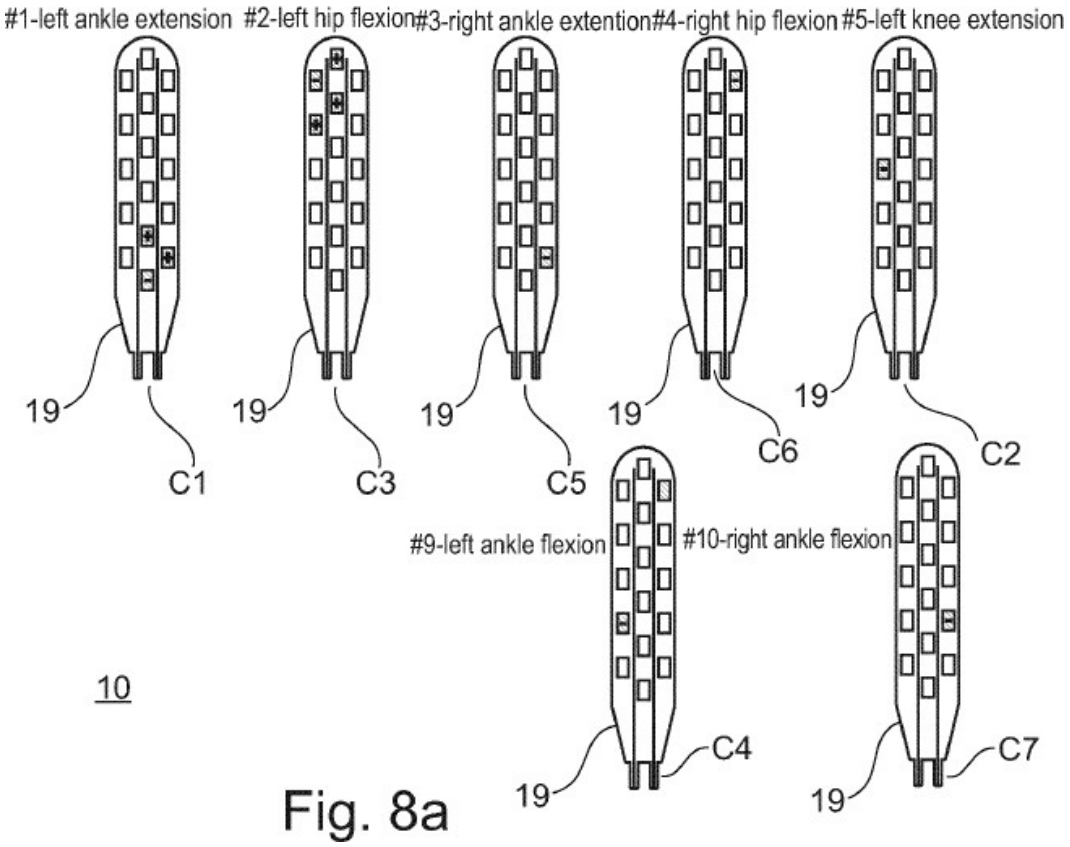

Fig. 8a

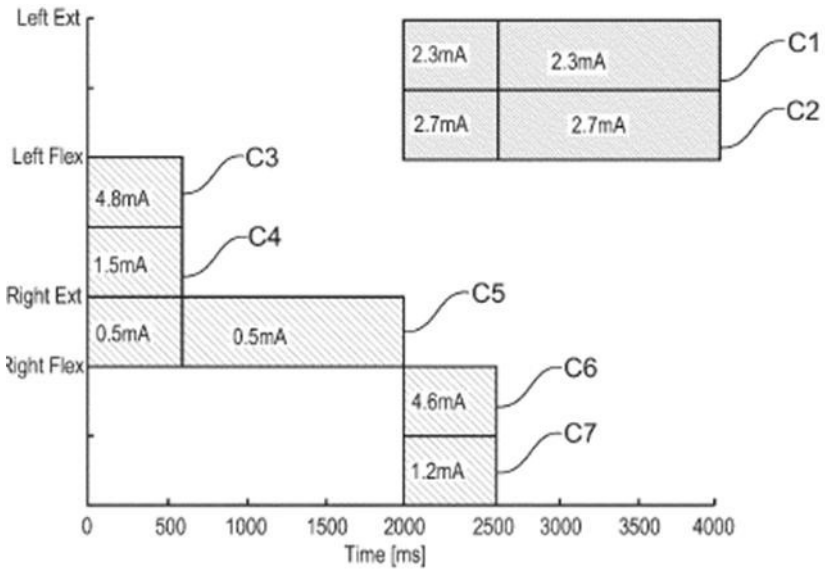

Fig. 8b

139. Figure 8a is a schematic view of an electrode pad with specifically activated electrodes for stimulating a human walking movement. Figure 8b shows the respective sequences, the specific current and the duration for the stimulation of right flexion, right extension, left flexion and left extension (paragraphs [0141] et seq.).

140. In Figures 8a-b, stages (C1-C7) are labelled. Each stage represents the stimulation of a specific part of the nervous system. For example, stage C1 indicates stimulation for extension of the left ankle and stage C2 indicates extension of the left knee (paragraph [0142]).

141. Figure 8b shows a stimulation protocol for human walking comprising four consecutive sequences (SQ1–SQ4). These consist first of left flexion and right extension (SQ1), followed by pure right extension (SQ2), then left extension and right flexion (SQ3), and finally left extension (SQ4) (paragraph [0114]). The chronological sequence of SQ1 to SQ4 is to be read from left to right along the time axis ('Time [ms]'). Each sequence comprises at least one step ('C1'…'C7') (paragraph [0117]). Sequence SQ1 is formed by stages C3, C4 and C5. Sequence SQ2 is formed by stage C5. Sequence SQ3 is formed by stages C1, C2, C6 and C7. Sequence SQ4 is formed by stages C1 and C2.

142. The configuration of the stimulation for the intended movement is therefore achieved by the sequences of the movement sequence (for example, SQ1–SQ4) being 'composed' of a plurality of stages (for example, C1–C7). Consequently, the arrangement of a plurality of stages leads to the intended replication of the physiological activation signals of relevant muscle groups at the appropriate time for a specific movement or the positioning of a limb.

143. Given the need to replicate the physiological activation signals of relevant muscle groups and the requirement for a multitude of stages, it is necessary to stimulate at least two different muscles that contribute to the same (desired) movement. This means that there must be at least two different stimulation sites or points of action. Different sets of electrodes must be activated to address different muscle groups

of the limb required for the specific movement or positioning. The spatial components of at least two patterns contributing to the replication of the physiological activation signals of relevant muscle groups must differ from one another.

144. The replication of physiological activation signals also requires a directly sequential, temporally defined and coordinated stimulation of different muscles that contribute to the desired movement or positioning of the limb. At least two stages must follow one another in which electrodes are activated, as this is the only way to (meaningfully) replicate a movement sequence. A complete pause in stimulation between individual stimulation phases, by contrast, cannot lead to the desired result of replicating a movement. Consequently, the various pre-programmed stimulation patterns must also take effect at different times and thus exhibit different temporal components.

145. Even though it is necessary for the multitude of stages to be defined in terms of time and coordinated with one another, the person skilled in the art does not interpret this to mean that a strict chronological sequence of all stages is required. The replication of the physiological activation signals is also possible when stages occur simultaneously or overlap. This is evident from Figure 8b and paragraph [0142]. For example, the sequences SQ1, SQ3 and SQ4 are formed by stages applied simultaneously over time. This embodiment further shows that a single sequence may comprise one or even several stages.

Open-loop system (feature 9)

146. In the claimed version of the claims, the claimed transcutaneous spinal cord stimulation system must be a system with an open control loop, i.e. a so-called 'open-loop' system. By this, the person skilled in the art understands a system in which the stimulation data is not influenced in real time by the patient's current condition. Any feedback regarding the patient's current condition is not taken into account in determining the stimulation data. Rather, stimulation is carried out by means of a predefined programme with pre-programmed stimulation patterns (paragraphs [0027], [0029]).

III. <u>(Non-)Infringement</u>

147. It cannot be established with sufficient certainty that the applicant's rights, as set out in the claims asserted, are infringed by the offering and sale of the contested embodiment within the contracting member states of Germany and France.

Direct patent infringement (Art. 25a EPC)

148. The applicant claims that the ready-to-use contested embodiment embodies all the features of the claim. Its offer and distribution therefore constitute a direct literal infringement. The applicant considers it a blanket assertion of protection when the respondent argues that the contested embodiment is only offered and distributed without pre-programmed simulation procedures. In the applicant's view, this is not strictly necessary for a direct infringement. Rather, it is sufficient if the simulation patterns claimed in the patent are only implemented shortly before the

The applicant takes the view that the respondent is adopting, in the sense of an extended workbench, the actions of its customers, who are instructed in the user manuals on how to programme patterns prior to use. On the basis of the user manuals, a specifically defined completion of the patented device is to be expected with certainty. In the claimant's view, it is therefore unreasonable to hold the defendant liable solely on the grounds of indirect patent infringement.

149. The respondent contests the allegation of infringement. In its delivery state, the contested embodiment is not programmed. Nor are its customers in any way instructed to carry out the programming claimed in accordance with features 7.1 and 8.

150. The Court of Appeal does not consider a direct infringement of the contested patent in the limited version asserted pursuant to Article 25(a) of the EPGÜ to be sufficiently certain or predominantly probable for the following reasons.

State upon delivery

151. Direct use of a device claim within the meaning of Article 25(a) EPGÜ generally requires that the contested embodiment exhibits all the features of the claim at the time of the act of use of the claimed subject-matter, i.e. at the time of the offer, placing on the market, etc. This cannot be assumed with sufficient certainty in the present case.

152. The applicant has not demonstrated any specific instance in which the contested embodiment, at the time of the offer and/or the placing on the market by the respondent, embodied all the features of the asserted claim and, in particular, possessed pre-programmed patterns as defined in the claim within the meaning of features 6, 6.1, 6.2, 7.1 and 8.

153. Nor do the submitted annexes demonstrate this. On the contrary, the user manual (Annex PS12, page 3) states that the contested embodiment is intended for use in hospitals and in inpatient and outpatient rehabilitation clinics by qualified medical staff. Before patients are discharged to their home environment with the contested embodiment, the medical professionals must be able to "use the system in its entirety, programme it and instruct the patient in its use. … The system may only be used with the settings determined and prescribed by the medical staff' (see also p. 23). The contested embodiment also includes an ExaStim® programming device, which is used to programme the stimulation device. On pages
Pages 17–22 of the user manual, Appendix PS12, also explain how to create, rename and save a procedure, as well as various stimulation steps and modes. Furthermore, it is undisputed that the selection of stimulation modes and settings depends on the condition and severity of the spinal cord injury of the respective patient, whereby several patients can be treated in a clinic using one and the same unit of the contested embodiment.

154. The affidavit submitted by the applicant, Annex PS14, regarding the functionality of the contested embodiment states, among other things, that medical professionals use the ExaStim® programmer with the associated app for doctors. This app is used to create and save stimulation protocols.

155. Against this background, it is not apparent why the applicant considers the respondent's submission

regarding the state of delivery of the contested embodiment is merely a blanket assertion of protection. Rather, it is apparent from the documents submitted that the contested embodiment is programmed (for the first time) by the respondent's customers.

'Extended workbench'

156. It need not be determined whether the applicant's legal view on the 'extended workbench' and the purported extension of liability arising therefrom is correct. Even if that were the case, such an extension of liability would (in any event) require that it be certain that the respondent's customers would, prior to use, program the contested embodiment in accordance with the features of the limited claim and, in particular, in accordance with feature 8. This programming would have to occur automatically or inevitably. However, no such certainty is apparent.

157. However, the PS12 user manual does not contain any instructions or guidance for doctors or medical staff that would, with the requisite certainty, lead to the programming of the contested embodiment in accordance with the claims and that could justify the attribution of liability (see also para. 170 et seq. below).

Indirect patent infringement (Art. 26 EPGÜ)

158. In the applicant's view, the contested embodiment infringes the claim in the asserted version at least indirectly. Through the German, English and/or Spanish-language user manuals, the respondent instructs medical professionals in detail on how the programming in accordance with the claim is to be carried out. There is also no meaningful non-infringing use for the contested embodiment. Individual parts of the contested embodiment are not compatible with any other system or programme. Consequently, the respondent is aware that offering and supplying the contested embodiment to third parties will inevitably result in patent infringement.

159. The claimant also considers the separate provision of the ReCure® electrode pad to constitute an indirect infringement of the claim as asserted. The ReCure® electrode pad is the electrical interface within the meaning of the contested patent. It constitutes an essential component of the patented invention and is suitable as a means for using the invention. The ReCure® electrode pad is an electrode pad specifically developed and approved for the ExaStim® stimulation device. There is no alternative device to which the ReCure® electrode pad can be connected, let alone one to which it may be connected due to the regulatory requirements for medical devices.

160. The defendant denies that there has been an indirect infringement of the patent. It emphasises that the contested embodiment is in any case not intended to be programmed in accordance with features 7.1 and 8. The contested embodiment can also be operated effectively without such programming – and thus without infringing the patent – for example, with constant stimulation or by manually varying the stimulation parameters. The 'correct' stimulation always depends on the individual condition of the patient being treated, which is why a great deal of trial and error is currently required. This is a new technology. We are still a long way from a situation where paraplegic patients can walk again through stimulation. As a rule, the initial focus is on

applying simple stimulation, strengthening muscles through targeted stimulation, and then checking at a later stage whether movement is possible without stimulation.

161. The respondent objects to the delay insofar as the claimant bases the allegation of infringement on the Spanish-language user manual. Apart from that, it considers the Spanish-language user manual to be irrelevant to the present legal dispute; the same applies to the English-language user manual. However, even if these were taken into account, they would not show a replication of the signals of a movement sequence. No other user manual shows anything of the sort either.

162. According to the defendant, there is also no indirect infringement by the ReCure® electrode pad. The claimant has not even argued on what basis it is supposed to be suitable and intended specifically for use in accordance with the patent. The ReCure® electrode pad contains no control unit of its own; it consists solely of electrodes, conductive tracks, a carrier material and a connector. The ReCure® electrode pad cannot be programmed. However, the ability to pre-program stimulation parameters is essential to the contested patent. The range of possible, non-infringing uses is considerably wider for the ReCure® electrode pad than for the contested embodiment (which comprises all components). The ReCure® electrode pad need not necessarily be used in a patent-infringing device of the respondent. In principle, it could also be used in devices from other manufacturers. This applies in particular to devices in which stimulation parameters cannot be pre-programmed.

163. In the view of the Court of Appeal, there is insufficient certainty that the contested embodiment and/or the ReCure® electrode pad indirectly infringe the asserted claim within the meaning of Article 26 of the EPC.

164. Under Article 26(1) of the EPGÜ, a patent grants its proprietor the right to prevent third parties, without his consent, within the territory of the contracting member states in which the patent is in force, to offer or supply, to persons other than those authorised to use the patented invention, means relating to an essential element of the invention for the purpose of using the invention in that territory, if the third party knows or ought to have known that those means are suitable and intended for use in connection with the invention. Indirect patent infringement therefore requires the fulfilment of both objective and subjective elements.

Objective elements

165. The objective elements of Art. 26 EPGÜ are, however, present in the present case. With regard to the contested embodiment, this is undisputed. In so far as the defendant disputes the existence of the objective elements in relation to the ReCure® electrode pad, this is without success.

166. Firstly, it is not necessary for the ReCure® electrode pad itself to be programmable. What is required is the objective suitability of the ReCure® electrode pad to be used for the purpose of the invention as set out in the claimed version. This is to be affirmed. It is designed in such a way that it can be used with a transcutaneous spinal cord stimulation system which possesses the spatial and physical features claimed and is programmed in accordance with those features. Nor is it relevant at this stage whether the ReCure® electrode pad can be used only with the contested embodiment or also in conjunction with other systems.

167. The ReCure® electrode pad is, moreover, a means relating to an essential element of the invention claimed. Such a means is deemed to exist where it is capable of functioning in conjunction with one or more features of the patent claim in the realisation of the protected inventive concept. What constitutes the essential elements of the invention in this sense must be determined on the basis of the subject-matter of the invention. Since the patent claim is decisive in determining which subject-matter is protected by the patent, all features named in the patent claim are generally essential elements of the invention. The claim specifies the (at least one) electrical interface as a component of the protected device. No evidence has been presented, nor is there any other indication, that this interface is not a means relating to an essential element of the invention.

Subjective requirements

168. However, the subjective requirements are not met. It cannot be assumed with sufficient certainty that the contested embodiment and/or the ReCure® electrode pad are separately intended to be used for the purpose of the invention. Nor can the subjective requirements on the part of the defendant be assumed with sufficient certainty.

169. The intended use is determined by the recipients of the offer and/or the defendant's customers. Their subjective intention is decisive. They must therefore, in particular, have had or have the intention to programme the contested embodiment in accordance with feature 8 or to use the ReCure® electrode pad in a system that is also programmed in accordance with feature 8.

170. The intended use may be determined and presumed on the basis of objective circumstances where such circumstances exist that allow for the sufficiently certain conclusion that the product offered or supplied is intended to be used by the recipient of the offer or the party to whom it is supplied for the purpose of utilising the invention. An objective circumstance or an indication in this sense may, for example, be an actual subsequent use of the patent or a user manual in which use in accordance with the patent is described or to which reference is made (by way of recommendation). The intended use may also be assumed, for example, if the product is tailored to use in accordance with the patent or can (economically sensibly) be used exclusively in accordance with the patent. In the present case, however, no such circumstances can be identified.

171. The applicant has not presented any specific case in which the contested embodiment and/or the ReCure® electrode pad have been used within the meaning of the asserted claim. The applicant relies solely on user manuals for the contested embodiment to substantiate the intended use.

172. The Spanish-language user manual is not to be relied upon. Pursuant to R.
222.2 of the Rules of Procedure. According to the applicant's submission, this user manual was published on 11 September 2025. This was prior to the oral proceedings at first instance. The applicant does not explain why it did not submit this user manual at the first instance. Apart from that, it is not apparent that the Spanish-language user manual can be of any significance. The applicant alleges indirect patent infringement in Germany and France. Consequently, what is decisive is the intended use by recipients of the offer and/or purchasers who use the contested

The ReCure® electrode pad is offered and/or supplied in these Member States. It has not been argued, nor is it otherwise apparent, that these recipients of the offer and/or purchasers refer to a Spanish-language user manual when they are provided with a German- or French-language user manual for the medical device, in accordance with the legal requirements.

173. It cannot be established that the German-language user manual (Annexes PS12, PS13) describes and/or recommends programming in accordance with the claims, which includes feature 8, or that purchasers are even encouraged to carry out such programming.

174. On page 3 of the user manual (Annex PS12), under 'Indications', it is stated that the contested embodiment is 'intended for the stimulation of the spinal cord to improve or restore motor functions in the upper limbs of adult patients with paralysis resulting from spinal cord injuries'. The stimulation provided by the contested embodiment therefore serves to improve or restore physical conditions in the extremities that enable movements to be performed. Furthermore, pages 17–18 of the user manual (Annex PS12) describes, amongst other things, the creation of stimulation programmes and the addition of a stimulation step, whereby, amongst other things, the desired electrodes of the ReCure® electrode pad can be selected, various stimulation parameters determined and the timing sequences for the activation of electrodes set (see also page 28 of the user manual). Pages 21 ff. of the user manual (Appendix PS12) then explain how to start, pause and stop saved stimulation programmes.

175. However, the user manual (Annex PS12) does not describe any programming that provides sequences comprising a number of arranged stages, configured such that their arrangement replicates the physiological activation signals of relevant muscle groups at the appropriate time for a specific movement of the patient, where the specific movement is the positioning and/or moving of a limb.

176. Insofar as the applicant refers to page 27 of the user manual (Annex PS12) and emphasises that different recommended electrodes are listed there for various muscle groups and, amongst other things, it is recommended to "use two to four electrodes simultaneously for the left or right side of each muscle group with at least one central electrode … ' and it is also stated that all 16 electrodes can be used simultaneously and that, if several muscles are to be activated, different electrodes could be used simultaneously or sequentially for stimulation, this is not sufficient to substantiate programming in accordance with feature 8. Similarly, the reference to the example configuration shown on page 28 of the user manual (Annex PS12) is insufficient. It follows from this that different or multiple muscle groups (of different limbs or of the left and right thumbs) can be activated, simultaneously if necessary. However, there is no indication of sequences comprising multiple stages, which feature at least two patterns with different spatial and temporal components and which follow one another in such a way that their arrangement replicates the movement of a limb.

177. In view of this, it should also be noted that the contested embodiment can be used without infringing the patent, based on the claim as asserted. There is insufficient evidence to suggest that using the contested embodiment without programming in accordance with feature 8 would be economically or medically nonsensical. On the basis of the arguments put forward, it is not apparent that the contested

embodiment can only be usefully employed for transcutaneous spinal cord stimulation in which the stimulation is intended to lead to the movement or positioning of a limb. This is particularly not the case because the 'correct' stimulation always depends on the condition of the patient being treated, and stimulations which (initially) serve 'only' to strengthen muscle groups may also be applied.

178. Finally, the required intended use does not arise from any 'off-label use' of the contested embodiment. Whilst the parties agree in principle that doctors and medical professionals occasionally use medical devices in ways other than those described in instructions for use, etc., it cannot be inferred from this alone that use of the claim in the asserted version is intended.

179. It follows from all of the above that the respondent's required level of subjective knowledge is not sufficiently evident.

IV. Conclusion

180. Since neither direct nor indirect use of the contested patent in the asserted version is sufficiently certain, there is no need to clarify the further issues in dispute between the parties as to whether the legal validity of the claim in the asserted version is sufficiently certain and whether the further requirements for the ordering of interim measures are met.

181. The appeal against the contested order must therefore be dismissed. The interim measures sought are not to be ordered.

182. Since, pursuant to Article 69(1) of the EPGÜ, the applicant, as the unsuccessful party, must bear the costs of the proceedings, its seventh application for provisional reimbursement of costs must also be dismissed (EPG-BerG, UPC_CoA_182/2024, Order of 25 September 2024, Mammut v Ortovox).

C. Reimbursement of costs in favour of the respondent

183. The respondent's application 5, which relates solely to the costs of the appeal proceedings and thus does not constitute a cross-appeal within the meaning of Rule 237 of the Rules of Procedure or necessitate such a cross-appeal, is partially well-founded. The applicant is to reimburse the respondent for provisional costs in the amount of EUR 56,000.00.

184. Under Article 69(1) of the EPGÜ and Rule 150(2) of the Rules of Procedure, the court may award the successful party provisional reimbursement of legal representation costs. As a rule, this amounts to 50% of the ceiling for reimbursable costs set by the Administrative Committee in accordance with Rule 152.2 of the Rules of Procedure. A lower reimbursement is justified only if there are clear indications that the successful party actually incurred lower legal representation costs or that 50% of the applicable upper limit is more than is appropriate or proportionate in the particular circumstances of the case. A higher reimbursement of costs may likewise only be granted in the presence of special circumstances (EPG-BerG, UPC_CoA_464/2024 UPC_CoA_457/2024 UPC_CoA_458/2024 UPC_CoA_530/2024 UPC_CoA_532/2024 UPC_CoA_533/2024 UPC_CoA_21/2025 UPC_CoA_27/2025, decision of 25 November 2025, Meril v. Edwards).

185. The value of the claim in the appeal proceedings is to be set at EUR 1,000,000.00, in line with the value of the claim at first instance. The respondent's contention that the value of the claim used as a basis at first instance increased by EUR 112,000.00 as a result of the claimant's Claim VII is incorrect. In Claim VII, the claimant is seeking provisional reimbursement of costs. The fact that the claimant initially used the term 'provisional damages' incorrectly in Claim VII does not preclude this. Parties' claims are open to interpretation. Both the amount stated in the claim and paragraph 283 of the notice of appeal and grounds of appeal dated 31 October 2025 clearly indicate that this was an error and that provisional reimbursement of costs is in fact sought. The applicant also clarified this during the oral hearing. However, a claim for provisional reimbursement of costs as an ancillary claim does not increase the value in dispute of the appeal proceedings.

186. The upper limit for reimbursable legal representation costs is EUR 112,000.00 for a value in dispute of EUR 1,000,000.00. No clear evidence and/or special circumstances within the above-mentioned meaning have been substantiated. In particular, the respondent's mere reference to substantial legal costs incurred, which exceeded the amount claimed, is insufficient. Consequently, in the present case, reimbursement of costs is awarded (only) in the amount of 50% of the upper limit for reimbursable costs.

ORDER

1. The appeal is dismissed.

2. It is ordered that the applicant shall reimburse the respondent for provisional costs amounting to EUR 56,000.00.

3. The applicant shall bear the costs of the appeal proceedings.

Ulrike Voß Digitally signed by Ulrike Voß Date: 27 March 2026 10:46:55 +01'00'

Ulrike Voß, Presiding Judge and Rapporteur

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