Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Local division Munich

UPC_CFI_693/2025

Order

of the Court of First Instance of the Unified Patent Court

issued on 17 October 2025

GUIDELINES:

1. (Auxiliary) applications asserting applications for an injunction in interim relief proceedings under Art. 62 UPC Agreement on the basis of an (alternative) version of the claim deviating from the granted version of the patent in order to counter existing doubts as to the validity of the patent must generally be rejected.

2. If the patent proprietor (alternatively) considers it necessary to amend the claims of a patent, this means that the patent as granted is probably not valid. In this case, the court cannot normally be convinced of the validity of the patent as granted, which is the only decisive factor in proceedings under Art. 62 UPC Agreement.

APPLICANT

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

represented by: Matthias Helmut Traut, Peterreins Schley Patent- und Rechtsanwälte mbB

DEFENDANT

Niche Biomedical, Inc, (doing business as ANEUVO), 10940 Wilshire Blvd Suite 2030, Los Angeles, CA 90024, USA

represented by: Jan Zecher, Fish & Richardson P.C.

PATENT AT ISSUE

EP 3 421 081 B1

LANGUAGE OF THE PROCEEDINGS

German language

SUBJECT MATTER OF THE PROCEEDINGS

Application for interim measures

PANEL AND DECIDING JUDGE

This decision was issued by panel 1 of the Munich local division:

Dr Matthias Zigann, presiding judge
Tobias Pichlmaier, legally qualified judge and judge-rapporteur
Dr Tatyana Zhilova, legally qualified judge
Dr Christian Daniel, technically qualified judge

ORAL HEARING: 24 SEPTEMBER 2025

DECISION: 17 OCTOBER 2025

Facts of the case

The petitioner asserts a claim against the respondent for infringement of the European patent EP 3 421 081 B1 (patent in suit).

The applicant is the registered proprietor of the patent in suit.

The patent in suit was registered under the title

"System for neuromodulation"

on 30 June 2017. The patent grant notice was published on 15 April 2020. The patent-in-suit comprises 15 claims. Claim 1 of the patent in suit, asserted in the application for interim measures, reads as follows:

> System for neuromodulation (10), in particular for neurostimulation, for treating a patient, comprising
>
> - at least one stimulation controller (12),
> - at least one stimulation pattern storage means (14), which is connected to the stimulation controller (12) and 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 patient, wherein the electrical interface (18) can be connected to at least one bio-interface (20) of the patient's nervous system or to the nervous system itself, wherein the electrical interface (18) and the bio-interface (20) are set up in such a way that signals and/or data can be exchanged from the electrical interface (18) to the bio-interface (20), preferably also vice versa,
>
> wherein the stimulation data (SD) are pre-programmed patterns which contain at least
>
> - a spatial component (SC) relating to the stimulated part of the nervous system
> - a temporal component (TC) relating to the time at which each aforementioned spatial component 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) so that electrical stimulation can be provided to the bio-interface (20) via the electrical interface (18), wherein the electrical stimulation provided is characterised by stimulation parameters that vary over time in a pre-programmed manner.

The defendant is a medical technology company from Los Angeles. It offers stimulation systems in Germany and France under the name "ExaStim".

With the application for interim measures of 30 July 2025, the applicant claims that the contested embodiments infringe the patent in suit.

The applicant has **requested**,

I. order the defendant

1. to refrain from

offering, placing on the market, using or importing or possessing systems for neuromodulation, in particular for neurostimulation, for the treatment of a patient in the Federal Republic of Germany and/or in 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 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 set up such that signals and/or data are transmitted to the patient in such a way that the electrical interface and the bio-interface are connected in such a way that signals and/or data are transmitted to the patient.

interface are set up in such a way that signals and/or data can be exchanged from the electrical interface to the bio-interface, preferably also vice versa,

where the stimulation data are pre-programmed patterns,

comprising at least one spatial component relating to the stimulated portion of the nervous system,

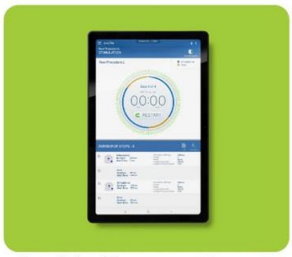
a temporal component relating to the time at which each aforementioned spatial component is applied,

and wherein the stimulation controller is capable of sending 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,

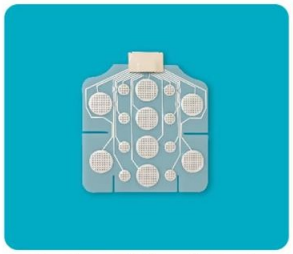
(direct infringement of claim 1 of EP 3 421 081 B1)

such as the "ExaStim stimulation system" shown below, comprising the "ExaStim stimulator", the "ExaStim programmer", the "ReCure electrode pad", and the "ReCure stimulation cable":

ExaStim Stimulator



ExaStim Programmiergerät



ReCure Elektrodenpad

ExaStim Stimulationssystem

2. In the alternative, unless the local division is of the opinion that there is direct infringement of claim 1 of European patent EP 3 421 081 B1, to refrain from,

   third parties in the Federal Republic of Germany and/or in the French Republic, systems for neuromodulation, in particular for neurostimulation, for the treatment of a patient, comprising

   at least one stimulation control,

   at least one stimulation pattern storage means connected to the stimulation controller and adapted to comprise 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 connected to at least one bio-interface of the patient's nervous system

of the patient or to the nervous system itself, wherein the electrical interface and the bio-interface are set up in such a way that signals and/or data can be exchanged from the electrical interface to the bio-interface, preferably also vice versa,

wherein the stimulation controller is capable of sending 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,

such as the "ExaStim stimulation system" described in section I.1

wherein the neuromodulation systems are suitable and intended for this purpose,

that the stimulation pattern storage means comprise stimulation data which are pre-programmed patterns comprising at least

a spatial component relating to the stimulated part of the nervous system, and

a temporal component relating to the time at which each aforementioned spatial component is applied,

to offer and/or supply for use in one or both states;

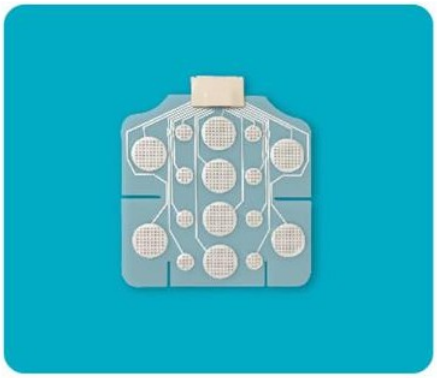
(indirect infringement of claim 1 of EP 3 421 081 B1)

3. to refrain from providing third parties in the Federal Republic of Germany and/or the French Republic with

   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 set up in such a way 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 shown below with the designation "ReCure electrode pad":



   which are suitable and intended for use for neuromodulation systems, 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,

   wherein the electrical interface can be ordered between the electrical stimulation device and the patient, and where-

wherein the bio-interface is arranged such that signals and/or data can be exchanged from the electrical interface to the bio-interface, preferably also vice versa,

whereby the stimulation data are pre-programmed patterns,

which comprises at least one spatial component relating to the stimulated part of the nervous system,

a temporal component relating to the time at which each aforementioned spatial component is applied,

and wherein the stimulation controller is capable of sending 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,

to be offered and/or supplied for use in the Federal Republic of Germany and/or the French Republic,

(contributory infringement of claim 1 of EP 3 421 081 B1)

4. within four (4) weeks of service of the Order in this matter, submit to the Applicant's authorised representatives a written declaration containing appropriate information and documents on

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

b. the quantities delivered, received or ordered for the products listed under item

I.1 - alternatively the products referred to in I.2 and I.3 in the Federal Republic of Germany and the French Republic; and

c. the identity of all parties involved in the distribution in the Federal Republic of Germany and the French Republic of the products mentioned under I.1 - alternatively under I.2 - and under I.3 (including the full names and addresses of the legal entities involved).

II. Order the Respondent to remove, within one (1) week of service of this Order, the products referred to in Clause I.1 - or in the alternative in Clause I.2 - and in Clause I.3 which are in its direct or indirect possession or ownership.

I.2 - and under item I.3 to a bailiff to be named by the applicant at her (the respondent's) expense for the purpose of safekeeping, which shall continue until the existence of a claim for destruction has been finally decided between the parties or an amicable settlement has been reached, and to submit proof of complete and timely fulfilment of the Order under Section II. to the applicant's legal representatives within ten (10) days of handover to the bailiff;

III. order the defendant to pay a (possibly repeated) penalty payment to the Unified Patent Court of up to EUR 250,000 per product for each individual infringement of the orders under I. or II. and/or another amount determined by the court for each infringement of the orders under I. or II. or non-compliance with them, as well as up to EUR 100,000 for each day or part of a day during which the infringement or non-compliance counts as a whole day. or II. or failure to comply therewith, and up to EUR 100,000 for each day or part of a day that counts as a full day during which the infringement or failure to comply continues, or such other amount as the court may determine;

IV. declare the above Orders provisionally enforceable;

in the alternative: to declare the above orders enforceable for the applicant only after she has provided security in favour of the defendant in the form of a deposit in the amount of EUR 250,000;

In response to the protective letter submitted by the defendant, the applicant submitted a request in a document dated 29 August 2025 in the event that the court should consider the patent for injunction in its granted version to be predominantly not legally valid in the course of the summary examination**,**

to allow the amendment of the applications made in the application for interim measures of 30 July 2025 in accordance with the attached Annex PS24 and to order interim measures on the basis of the corresponding auxiliary applications (for the wording of auxiliary applications 1 - 8, see documents of 29 August 2025, pages 2 - 26).

The defendant has opposed the application for interim measures. In its defence to the application for interim measures, it asserts - as already in its protective letter of 25 July 2025 - that the subject matter of claim 1 of the patent in suit is not new in view of the following citations:

- US 2016/0263376 A1 ("Yoo"),
- US 2004/0082979 A1 ("Tong"),
- US 9,409,030 B2 ("Perryman").

The defendant therefore **requested that** the **court**

dismiss the application for a preliminary injunction of 30 July 2025 and reject the application for leave to amend the application for an injunction of 29 August 2025.

In the alternative,

to make the continuation of the alleged infringement dependent on the provision of security by the defendant, the amount of which is left to the dutiful discretion of the court.

In the further alternative,

to make the enforcement of the interim injunction dependent on the provision of security by the applicant, the amount of which is left to the dutiful discretion of the court.

In the event that the application for an interim injunction is rejected or withdrawn, the defendant has **requested** that

1. order the applicant to pay the costs of the summary proceedings, including the costs of filing the defendant's protective letter and

2. order the applicant to provisionally reimburse the defendant's costs in the amount of EUR 168,000.

For further details of the facts of the case and the dispute, reference is made to the documents exchanged between the parties, including annexes, and to their submissions at the hearing on 24 September 2025.

Reasons for the decision

The application for interim measures is unsuccessful.

A.

The court does not consider it to be overwhelmingly probable that the patent in suit is valid in its *granted* version. The validity of the patent-in-suit with *amended* versions of the claims did not have to be decided in the proceedings for a temporary injunction.

I. Person skilled in the art

The person skilled in the art for assessing the teaching according to the patent is a team consisting of a medical technician and an engineer with a university degree in medical technology, biomedical technology or electrical engineering and several years of practical experience in the development of active medical implants and their control.

II. Subject matter of the patent in suit

The patent at issue relates to a system for neuromodulation (in particular for neu-rostimulation). Such systems are used in the treatment of patients, for example in the case of neurological disorders such as spinal cord injuries (paragraph [0001]). Stimulation systems known in the prior art use either stimulation of the central nervous system (CNS), in particular epidural electrical stimulation (EES), or stimulation of the peripheral nervous system (PNS), in particular functional electrical stimulation (FES) (paragraph [0006]). In functional electrical stimulation (FES), the target muscles are electrically stimulated with surface electrodes either directly by stimulating their motor fibres (neuromuscular stimulation) or by a limited series of reflexes (practically limited to the retraction reflex) or by transcutaneous stimulation of the peripheral nerves.

The patent in suit describes various disadvantages existing in the prior art, such as muscle fatigue resulting from FES, lack of success due to cumbersome settings in surface muscle stimulation, unfulfilled requirements with regard to selectivity (in transcutaneous nerve stimulation) and lack of stability (in particular the impossibility of accurately reproducing electrode placement in muscle stimulation on a daily basis, as the electrodes shift due to clothing and sweat) (paragraph [0008]).

Based on this, the aim of the invention is to improve a neuromodulation system in that the neuromodulation and/or neurostimulation can be adapted to the needs of the patient in almost any environment and in everyday life (paragraph [0009]).

The stimulation controller should be able to send configuration signals to the electrical stimulation device on the basis of the stimulation data, so that electrical stimulation can be delivered to the bio-interface via the electrical interface, wherein the delivered electrical stimulation is characterised by stimulation parameters that vary in a pre-programmed manner over time (paragraph [0010]). The invention is then based on the basic idea that the electrical stimulation parameters defining the stimulation for the patient to be treated can vary cyclically over time in a pre-programmed manner, i.e. a cycle is repeated with predefined times for the different stimulation patterns (paragraph [0011]).

III. Claim 1 of the patent in suit

Based on the problem described in the patent in suit and the solution outlined in paragraphs [0010] and [0011], claim 1 proposes a system whose claim features can be organised as follows:

1. System for neuromodulation (10), in particular for neurostimulation, for the treatment of a patient, comprising
2. at least one stimulation controller (12),
3. at least one stimulation pattern storage means (14), which is connected to the stimulation controller (12) and comprises 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. wherein 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. wherein the electrical interface (18) and the bio-interface (20) are set up in such a way that signals and/or data can be exchanged from the electrical interface (18) to the bio-interface (20), preferably also vice versa,
6. wherein the stimulation data (SD) are pre-programmed patterns which contain 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 aforementioned spatial component is applied,
7. and wherein 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. wherein the electrical stimulation provided is characterised by stimulation parameters that vary over time in a pre-programmed manner.

IV. Interpretation

For the interpretation of claims, the patent claim is not only the starting point, but also the decisive basis for determining the scope of protection of a European patent under Art. 69 EPC in conjunction with the Protocol on the Interpretation of Art. 69 EPC. The interpretation of a patent claim does not depend solely on its exact wording in the linguistic sense. Rather, the description and the drawings must always be taken into account as explanatory aids for the interpretation of the patent claim and not only be used to resolve any ambiguities in the patent claim (UPC_CoA_335/2023).

Claim 1 covers invasive, epidural and transcutaneous systems for neurostimulation; neither the claim itself nor the description imposes any limitations on the scope of application of neuromodulation systems according to the claim; this applies both to the type of application and to the area of application on or in the body. In sophisticated systems, pre-programmed stimulation patterns are stored in the form of stimulation data for the treatment of patients; the respective stimulation pattern is thus already defined and stored in the system memory before the respective stimulation is applied.

According to the claim, the stimulation patterns have at least a spatial and a temporal component. By "spatial" is meant the part of the patient's nervous system to be stimulated, whereby the patent claim refers somewhat imprecisely to the "stimulated part" (instead of "part to be stimulated"). Since *at least one* spatial component must be present, a single spatial component (site of action), i.e. *a* specific stimulation site, is already sufficient. The same applies to the temporal component, which refers to the time of application of the spatial component. According to the applicant's submission, this component determines when and for how long the respective stimulation takes place; according to the respondent's submission, the temporal component indicates the time at which electrodes are active for stimulation. The parties understand this feature to be consistent and accurate.

The electrical stimulation to be provided by the claimed system is based - as shown - on temporally and spatially determined (pre-programmed) patterns. In feature 7.1, the temporal aspect is further specified by stimulation parameters that "vary over time in a pre-programmed manner". According to the applicant's submission, the parameters mentioned can be frequency, current intensity, pulse width or electrode configuration; in this context, variance means that the stimulation changes systematically over time in accordance with the defined pattern (application, paragraph 58). Paragraph [0011] of the patent in suit states:

> The invention is based on the basic idea that in the context of neuromodula-tion, especially neurostimulation, the electrical stimulation parameters defin-ing the stimulation for the subject to be treated **can vary cyclically over time in a pre-programmed manner**, **i.e. one cycle with pre-defined timings for the various stimulation patterns is repeated over and over again**.

From the defendant's point of view, possible time parameters are, for example, the length of the successive steps or the total duration of the treatment, whereby these parameters enable varying temporal stimulation (defence, paragraph 178). The parties therefore also understand this feature to be consistent and correct.

The stimulation with the pre-programmed stimulation patterns is carried out according to requirements with an electrical stimulation device, with which the stimulation data is transmitted to the patient as electrical pulses via an electrical interface of the device in order to generate a targeted neuromodulatory stimulus in the patient. For this purpose, the electrical interface can be connected to a bio-interface of the patient's nervous system (or to the nervous system itself). The bio-interface has been aptly described by the applicant as the "site of action" on the human body to be treated. In the case of transcutaneous stimulation, the relevant bio-interface of the nervous system is the human skin.

a specific site is selected at which the stimulation is to take place. However, the patent claim leaves open how data is to be collected and transmitted in the opposite direction. Feature 5.2 reads:

> "...wherein the electrical interface (18) and the bio-interface (20) are set up in such a way that signals and/or data can be exchanged from the electrical interface (18) to the bio-interface (20), preferably also vice versa,..."

It is understandable that signals are sent from the stimulation device via the interface to the human body in order to be transmitted there, for example via the skin, as impulses to the corresponding nerves. However, it is not clear how, conversely, data can be transmitted from the biointerface (skin) to the electrical interface; at least there is no explanation as to how the biointerface itself can generate corresponding data.

V. Validity of the patent in suit

In view of the prior art submitted by the defendant, there are considerable doubts that claim 1 of the patent in suit in its granted version can be assessed as new and thus patentable under Art. 54 EPC.

1. Principle

A sufficiently certain conviction under Rule 211.2 RoP in conjunction with Art. 62(4) UPC Agreement requires that the court considers it at least overwhelmingly probable that the applicant is entitled to institute proceedings and that the patent is infringed. A sufficiently certain conviction exists if the court considers it to be predominantly probable that the patent is valid (UPC_CoA_335/2023).

2. Citation "Yoo"

The defendant has argued that the subject-matter of claim 1 is not new compared to the prior art, since the combination of features protected by claim 1 has already been disclosed in the citation "Yoo".

had already been disclosed in the "Yoo" citation. The applicant, on the other hand, claimed that features 6.1, 6.2 and 7.1 were not disclosed in "Yoo"; the court does not agree with this.

Firstly, it should be noted that "Yoo" indisputably discloses a neuromodulation system for treating patients. This system has a stimulation controller and a means for storing stimulation patterns based on stimulation data. Furthermore, "Yoo" discloses an electrical stimulation device and an electrical interface between the electrical stimulation device and the patient, wherein the electrical interface is connectable to a bio-interface of the patient's nervous system.

According to the court, "Yoo" also discloses sophisticated pre-programmed stimulation patterns with spatial and temporal components that vary over time:

a. Feature 6.1 - spatial component of stimulation data

With regard to feature 6.1 (spatial component of the pre-programmed stimulation pattern), the applicant argues that in "Yoo" the activation of the electrodes is detached from a specific site of action in the nervous system, as required by feature 6.1; a targeted addressing of *different* sites of action in the nervous system does not take place according to "Yoo". In the case of "Yoo", information about which part of the nervous system is to be stimulated is derived solely from the positioning of the surface electrodes at the desired site of action, but not from the stimulation data.

Since, according to claim 1 of the patent in suit, a spatial component is already sufficient for a pre-programmed stimulation pattern, there is no need to specifically address *different* sites of action, contrary to the applicant's view. Whether "Yoo" also discloses different sites of action in accordance with the defendant's submission (defence, paragraph 151 et seq.) can therefore be left open.

Insofar as the applicant claims that the activation of the electrodes in "Yoo" occurs independently of a specific site of action in the nervous system, this contradicts the applicant's own submission.

contradicts the applicant's own submission, according to which the conductive component in the embodiment of "Yoo" described in paragraph [0127] is implanted around a nerve in order to focus the electric field generated by the electrode on the target nerve.

Insofar as the applicant further argues that the site of action of "Yoo" cannot be determined from the stimulation data, the respondent correctly counters that "Yoo" describes a stimulation protocol with which various lines of electrodes can be activated in order to focus the stimulation on the target nerve. Paragraph [0308] of "Yoo" explicitly states:

> "... In the embodiment of FIG.32, each of the stimulators can be connected to a **device** 50/400 **which is able to independently activate the stimulators in order to provide spatial or spatial temporal patterns of stimulation according to a therapy protocol stored in the device**, ..."

Insofar as the applicant believes that information as to which part of the nervous system is to be stimulated results in "Yoo" - contrary to the solution according to the patent - exclusively from the positioning of the surface electrodes at the desired site of action, it should be pointed out that, according to the applicant's submission on feature group 6 of the patent in suit, the location of the stimulation depends on where the electrical interface is applied to the human body (application text number 54).

This means that stimulation data with a spatial component are already disclosed pre-programmed with "Yoo".

b. Feature 6.2 - temporal component of the simulation data

"Yoo" also discloses a stimulation system with a temporal component within the meaning of claim 1 of the patent in suit.

The applicant concedes the disclosure of a time component in "Yoo" (see statement on the protective letter, paragraph 39 et seq. concerning paragraph [0202] of the citation "Yoo"). However, it does not consider this to be sufficient, as a reference of the temporal component to the spatial component is required according to the claim (combination of temporal and spatial components).

"Yoo" also reveals such a relationship between the two components when it states in paragraph [0236], for example:

> "...One stimulation protocol can have a first step where a stimulation signal is provided by all the elements of rows 1 and 10, a second step where a stimulation signal is provided by rows 4 and 10, and a third where stimulation is provided by rows 8 and 10. **In each step, unique row activation is pro-vided for 1 minute, and within a 30 minute stimulation period**..."

This clearly shows that a stimulation protocol can be used to activate different rows of electrodes (spatial component) in a specific temporal sequence (temporal component). This results in a spatio-temporal stimulation pattern as described in feature group 6 of the patent in suit.

c. Feature 7.2 - temporally varying stimulation parameters

"Yoo" also discloses that in such a stimulation system, stimulation parameters can vary over time. According to the applicant's submission, the variance may relate, for example, to the parameters of frequency, current intensity, pulse width or electrode configuration. Paragraph [0412] of "Yoo" states:

> "...The options of modifying the stimulation frequency (between 2 Hz and 50 Hz), the stimulation amplitude, and even the site of stimulation, provides fur-ther tools for the clinician to program a "customized stimulation profile" for a stimulation protocol that will improve long-term compliance to, for example, SAFN therapy. **Changes in the stimulation waveform (e.g., sinusoidal) and pulse width may also contribute to achieving effective therapy**.

And further in paragraph [0413]:

> "Some side effects, such as potential issues associated with paresthesia ... may be circumvented by **using stimulation protocols with time-varying paradigms of stimulation** in the case of the SAFN and other targets dis-closed herein. **This may include, for example, periodic increases and de-creases in stimulation amplitude, pulse width, frequency, waveform, or**

> **any other relevant parameter**. For example, rather than turning the stimulation signal off, it may be reduced by 30-50% in terms of duration or amplitude over a selected interval. **These changes may occur over periods of milliseconds, seconds, minutes, or hours. Furthermore, one or more of these parameters may be varied simultaneously or at different pre-de-terminated times.** These changes can be controlled by the stimulation proto-col of a device 50.

Thus, the stimulation parameters that can be varied over time (pre-programmed) with feature 7.1 are clearly already disclosed in "Yoo".

B.

The auxiliary requests filed by the applicant in a document dated 29 August 2025, requesting the adoption of provisional measures on the basis of *amended* versions of application 1 of the patent in suit, were also to be rejected.

I. Admissibility of applications under Rule 263 RoP in proceedings under Art. 62 UPC Agreement

Applications for amendments under Rule 263 RoP are also generally admissible in interim relief proceedings. This was already established by the Court of Appeal in its decision UPC_CoA_182/2024, in which the subject of the extension was an application for provisional reimbursement of costs.

II. Amendment of the wording of the claim in the event of doubts about the legal validity of the patent

Provisional measures under Art. 62 UPC Agreement cannot be granted if the asserted patent requires an amended version of the claim in order to be valid. Corresponding (auxiliary) applications must therefore be rejected. This applies both if such (auxiliary) requests are already filed with the application for provisional measures and if - as here - they are only filed in the course of the proceedings, for example in response to submissions by the opposing party on the lack of legal validity, with reference to Rule 263 RoP.

(Auxiliary) applications asserting requests for an injunction in interim relief proceedings under Art. 62 UPC Agreement on the basis of an (alternative) version of the claims deviating from the granted version in order to counter existing doubts as to the validity of the patent must generally be rejected: If the patent proprietor (alternatively) considers it necessary to amend the claim version of a patent, this means that the patent as granted is probably not valid. In this case, the court cannot normally be convinced of the validity of the patent as *granted*, which is the only decisive factor in the proceedings under Art. 62 UPC Agreement.

The purpose of the summary procedure for issuing provisional Orders is also not to order measures although the asserted patent is recognisably defective in its *granted* version of the claim. The local division has therefore already made it clear in the decision of 10 October 2023 (UPC_CFI_17/2023) that the formation of a conviction required under Art. 62(4) UPC Agreement and Rule 211 No. 2 RoP with regard to the legal validity of a patent relates solely to the version existing at the time the application is filed: Rule 211 No. 2 RoP expressly refers to "the patent in question" and not to "the patent in question".
"the patent in question" and not to a patent whose claims *have been amended*.

The question of whether a patent can be maintained in an amended version only arises if applications for amendment of the patent are made under Rule 30 RoP in the context of an action for revocation or a revocation counterclaim. Rule 30 is not applicable in proceedings for interim measures under Art. 62 UPC Agreement. Alternative versions of claims are not a subject of examination in injunction proceedings.

It is primarily the inventor's responsibility to apply for a patent for his invention in a version that is eligible for grant. Corresponding errors in the application can be corrected at a later date - for example in accordance with Rule 30 RoP. However, the issuance of provisional measures is not justified on the basis of a patent that has been incorrectly applied for and granted in the claim version. This does not constitute an unreasonable burden for the proprietor.

hardship or impairment of property: It is up to the inventor to obtain the grant of a legally valid version of the claim. However, the inventor may not legally expect to be able to claim comprehensive legal protection from an erroneously granted patent at any time, even in the event of significant deficiencies in the application.

C.

I. Decision on costs

The decision on costs follows from Art. 69 UPC Agreement. The application for interim measures is unsuccessful. The applicant must therefore bear the costs of the legal dispute.

II. Provisional reimbursement of costs

The defendant's application for provisional reimbursement of costs in the amount of € 168,000.00 was to be rejected.

Pursuant to Rule 211.1 (d) RoP, the court may also order provisional reimbursement of costs in proceedings concerning the adoption of interim measures. The costs are to be estimated in accordance with Rule 151 (e) RoP. Even if the requirements for the corresponding party submission must not be set too high, as it is only a provisional reimbursement of costs, a corresponding application requires at least a comprehensible explanation so that the court can examine the appropriateness and proportionality of the claim in accordance with Rule 152.1 RoP.

With the protective letter dated 25 July 2025, a provisional reimbursement of costs in the amount of **€ 135,000.00** was claimed without further justification. In contrast, in a protective letter dated 1 August 2025, which concerns the patent in suit but a different potential defendant, a provisional reimbursement of costs in the amount of **€ 80,000.00** was claimed by another law firm for an almost identical protective letter without further justification. In addition to the amount of **€ 168,000.00**, which was claimed for legal services in the proceedings

The defendant merely stated in general terms that legal fees of at least this amount had been incurred, which was assured by the lawyer.

This information on the costs incurred is not even remotely comprehensible and verifiable. In addition, the amounts stated differ greatly from one another and therefore appear to be arbitrary. No provisional reimbursement of costs can be made on this basis, not even with regard to a minimum amount incurred in any case. This is because there is no submission in this regard either. The lawyer's statement submitted is not sufficient in this respect because it is not supported by a substantiated submission.

For the above reasons, the presiding judge Dr Zigann, the legally qualified judge Dr Zhilova, the technically qualified judge Dr Da-niel and the judge-rapporteur Pichlmaier have issued the following decision

Decision

I. The application for interim measures of 30 July 2025 and the alternative applications submitted in the document of 29 August 2025 are dismissed.

II. The applicant shall bear the costs of the proceedings, including the costs of filing the protective letter.

III. The defendant's application for provisional reimbursement of costs is rejected.

Dr Zigann Presiding judge	Matthias ZIGANN Digitally signed by Matthias ZIGANN Date: 2025.10.16 13:00:10 +02'00'
Dr Zhilova Legally qualified judge	Tatyana Zhilova Signature numérique de Tatyana Zhilova Date : 2025.10.16 13:17:59 +02'00'
Pichlmaier judge-rapporteur	(Tobias) (Günther) Pichlmaier Digitally signed by Tobias Günther Pichlmaier Date: 2025.10.16 12:38:08 +02'00'
Dr Daniel Technically qualified judge	CHRISTIAN. DANIEL Digitally signed by CHRISTIAN DANIEL Date: 2025.10.17 07:09:29 +02'00'
For the Deputy-Registrar	(Anja) (Mittermeier) Digitally signed by Anja Mittermeier Date: 2025.10.17 08:55:20 +02'00'

INFORMATION ON THE FULL COVERAGE (Art. 82 UPC Agreement, Art. Art. 37(2) UPC Agreement, R. 118.8, 158.2, 354, 355.4 RoP)

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

INFORMATION ON THE APPEAL

An appeal against this decision may be lodged with the Court of Appeal within 15 calendar days of service of the decision by any party whose applications were unsuccessful in whole or in part (Art. 73(2)(a) UPC Agreement, R. 220.1(c), 224.1(b) RoP).