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Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Düsseldorf local division
UPC_CFI_712/2025

Order

of the Court of First Instance of the Unified Patent Court
issued on 5 December 2025
concerning EP 1 962 668 B1

LEADING PRINCIPLES:

1. A method claim formulated as an independent auxiliary claim and the corresponding description can only be relevant for determining the scope of protection of an independent product claim to the extent that the patent specification provides indications that this also describes characteristics of the claimed product.

2. An injunction prohibiting the form of use involving manufacture may also be issued if the patent-infringing product has hitherto been manufactured by a third party outside the contracting member states.

KEYWORDS:

Product claim; process claim; manufacturing; injunction

HEADNOTES:

1. An independent process claim and the corresponding description can only be relevant when determining the scope of protection of an independent product claim if the patent specification indicates that it also describes characteristics of the claimed product.

2. An injunction covering the making of a product may also be issued if the infringing product has so far been manufactured by a third party outside the contracting member states.

KEYWORDS:

product claim; process claim; making; injunction

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APPLICANTS:

1. **F. Hoffmann-La Roche AG**, represented by its Board of Directors, represented by its Chairman Dr Severin Schwan, Grenzacherstr. 124, 4058 Basel, Switzerland

2. **Roche Diabetes Care GmbH**, represented by its Managing Director Marcel Hunn, Sandhofer Straße 116, 68305 Mannheim, Germany

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supported by:	Patent Attorney Dr Matthias Stößel, Patent Attorney Dr Eva Hennekemper, Theodor-Heuss-Anlage 2, 68165 Mannheim, Germany

OPPOSING PARTIES:

1. **A.Menarini Diagnostics S.r.l.**, represented by its legal representatives, Via Sette Santi 3, 50131 Florence, Italy

2. **BERLIN-CHEMIE AG**, trading as A.MENARINI DIAGNOSTICS DEUTSCHLAND, represented by its legal representatives, Glienicker Weg 125, 12489 Berlin, Germany

3. **A.Menarini Diagnostics France SASU**, represented by its legal representatives, 3-5, rue du Jura – BP 70531 – 94633 Rungis Cedex, France

represented by:	lawyers at Bird & Bird LLP, namely lawyer Dr Christopher Maierhöfer, Maximiliansplatz 22, 80333 Munich, Germany

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supported by:	Patent attorneys at Bird & Bird LLP, in particular patent attorney Dr. Jan van Dieck, Maximiliansplatz 22, 80333 Munich, Germany and patent attorney Leonard Lotz, Carl-Theodor-Straße 6, 40213 Düsseldorf, Germany

PATENT AT ISSUE:

EUROPEAN PATENT NO. EP 1 962 668 B1

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PANEL/CHAMBER:

Panel of the Local Division Düsseldorf PARTICIPATING JUDGES:

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

LANGUAGE OF THE PROCEEDINGS: German

SUBJECT: R. 206 RoP – Application for order of interim measures

ORAL HEARING: 7 November 2025

BRIEF DESCRIPTION OF THE FACTS:

1. The applicants (collectively also referred to as Roche) are suing the respondents (collectively also referred to as Menarini) for infringement of European patent EP 1 962 668 B1 (hereinafter referred to as the patent at issue).

2. The patent at issue was filed on 6 December 2006 in German, the language of the proceedings. It claims priority from application EP 05027755 of 19 December 2005 (hereinafter: P1) and application DE 102006041343 of 1 September 2006. The publication of the patent application occurred on 3 September 2008. The notice of grant of the patent at issue was published on 17 June 2009. The patent at issue is currently in force in Germany, France, Italy and the United Kingdom. No preliminary objection to the grant of the patent at issue was filed with the European Patent Office (EPO).

3. The second applicant is the sole proprietor of the German part of the patent at issue. The entry in the German patent register was made on 11 April 2016 and was published on 19 June 2016 (register extract submitted as Annex KAP 8).

4. The first applicant is the sole proprietor of the French (register extract submitted as Annex KAP 9) and Italian (register extract submitted as Annex KAP 10) parts of the patent at issue.

5. The patent at issue protects a "sandwich sensor for determining an analyte concentration". Its patent claim 1 is worded as follows:

> "Implantable sensor (110) for determining a concentration of at least one analyte in a medium, in particular a body tissue and/or a body fluid, wherein the implantable sensor (110) has a layered structure with at least one insulating carrier substrate (112; 210, 216; 710, 712, 714; 810, 812) and at least two layers arranged in at least two different layer planes of the implantable sensor (110), which are separated by the at least one insulating carrier substrate (112; 210, 216; 710, 712, 714; 810, 812) electrically separated from one another by the at least one insulating carrier substrate (112; 210, 216; 710, 712, 714; 238, 240, 242; 738, 740, 742; 830, 832, 836) with electrode surfaces, wherein the electrode surfaces face the medium when the sensor (110) is implanted and are in direct contact with the medium or via an analyte-permeable membrane layer.
> (146) are in contact with the medium over a large area and in a substantially uniform manner, wherein the implantable sensor (110) further comprises at least two electrodes (134, 136; 238, 240,

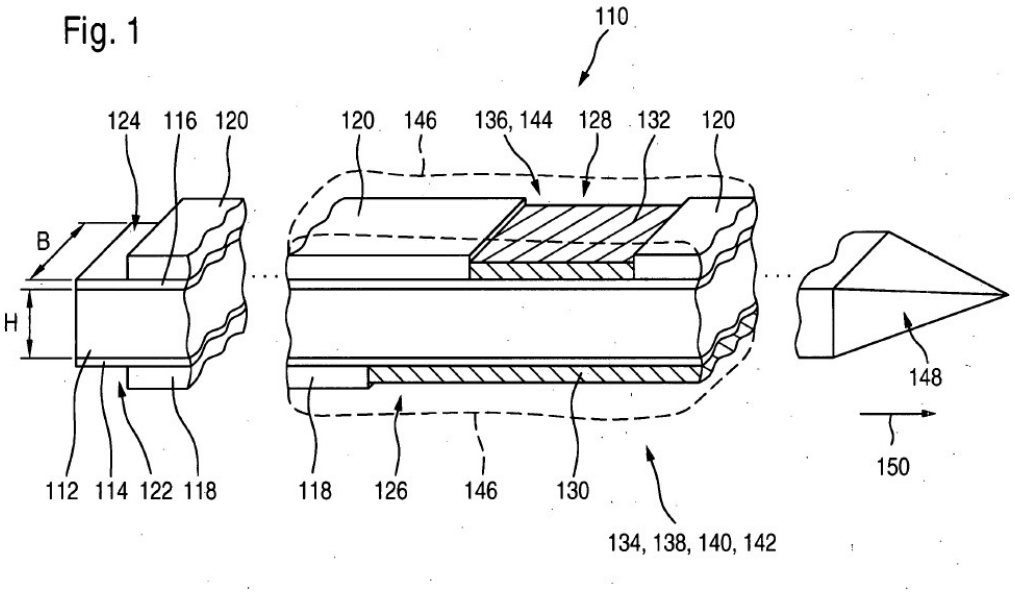
242; 738, 740, 742; 830, 832, 836) with electrode contact layers (114, 116; 212, 214; 222; 610, 612; 716, 718, 720; 814, 816, 822) that **electrically contact the at least two electrodes (134, 136; 238, 240,**
that the at least one insulating carrier substrate (112; 210, 216; 710, 712, 714; 810, 812) has a width, wherein the at least two electrodes (134, 136; 238, 240, 242; 738, 740, 742; 830, 832, 836) and/or the at least two electrode contact layers (114, 116; 212, 214; 222; 610, 612; 716, 718, 720; 814, 816, 822) extend over the entire width of the at least an insulating carrier substrate (112; 210, 216; 710, 712, 714; 810, 812).

6. Claim 16 reads as follows:

> Device (310) for determining the concentration of at least one analyte in a medium, in particular body tissue and/or body fluid, comprising at least one implantable sensor (110) according to one of the preceding claims and further comprising at least one voltage measuring device (312) for measuring a voltage between at least one working electrode (144; 740; 836) and at least one reference electrode (142; 738; 832) of the implantable sensor (110)."

7. Figure 1 below is a perspective schematic representation of a first embodiment of an implantable sensor according to the invention:

Fig. 1



8. With their application, the applicants are challenging the CGM (= Continuous Glucose Monitoring) system "GlucoMen iCan o3" (hereinafter: "challenged embodiment" or "iCan"). A product brochure for the contested embodiment is available as Annex KAP 12, a quick start guide as Annex KAP 13 and a German version of the user manual (April 2025) as Annex KAP 14.

9. The contested embodiment is a CGM system for people with diabetes. It uses minimally invasive sensor technology to continuously measure glucose concentration in tissue. Patients use the iCan together with the iCan app, which visually displays the measurement results on a connected smartphone.

10. For illustrative purposes, one of the figures taken from the quick start guide (Exhibit KAP 13, p. 1) and one from the product brochure (Exhibit KAP 12, title page) are shown below:

11. The image marked "1a" (top left) shows the "sensor pack", which comprises the applicator with the sensor unit. The image marked "1b" (top right) shows the "transmitter pack", which comprises a transmitter with integrated memory and Bluetooth interface that handles data transmission. Users connect the sensor unit and transmitter to form a functional unit, as can be seen in the foreground of the lower illustration. In the background on the right of the lower illustration, a smartphone with the associated application is shown.

12. The manufacturer of the contested embodiment is Changsha Sinocare Inc., based in China (hereinafter: Sinocare). Sinocare has concluded an exclusive distribution agreement with the first applicant for the market launch and marketing of the contested embodiment in over 20 European countries, including Italy, Germany and France.

13. The respondents are part of the Menarini Group, headquartered in Florence. The Menarini Group is the largest Italian pharmaceutical company and is represented in more than 140 countries worldwide. Respondent 1 is the distribution centre for Europe. It acts as the exclusive distribution partner for products from various manufacturers. Specifically:

14. The first respondent is the EU importer of the contested embodiment and distributes it as a distribution company in Italy. As such, the first respondent is also named in the instructions for use of the contested embodiment and on the packaging.

the contested embodiment delivered to Italy (see below). The first respondent advertises the contested embodiment on its English-language website at https://www.menarinidiagnostics.com/en-us/ (see Annex KAP 17). If the user selects the banner with the contested embodiment, they are redirected to another website of the first respondent at https://glucomen-i-can.com/ (see Annex KAP 18). On this website, the instructions for use of the contested embodiment can be downloaded in twelve different European languages. By clicking on the "Discover More (HCPs Only)" button, the user is also taken to another website of the first respondent, which contains information on the contested embodiment and from which the product brochure (Exhibit KAP 12) can also be downloaded.

15. The second respondent is the distributor for Germany for the contested embodiment and, as such, is named in the operating instructions (see Annex KAP 14, p. 80, p. 92) and in the quick start guide (Annex KAP 13) and on the packaging of the embodiments delivered to Italy. The second respondent advertises the contested embodiment on two German-language websites operated by it at https://www.menarinidiagnostics.de/de-de/ (see Annex KAP 21) and https://glu-comenday.com/newplatform/de/#ican. If you select the banner with the contested embodiment, you are redirected to the website of the first respondent at https://glucomen-ican.com/. On this website, the second respondent is named as a local service centre when you click on the "Support" button to open another subpage. Respondent 2 also operates another website at https://glucomenday.com/newplat-form-/de/#ican, on which it advertises the contested embodiment. The second respondent also advertises the exclusive distribution agreement between the first respondent and Sinocare on its website (https://www.menarinidiagnostics.de/de-de).

16. The third respondent is the distributor for France for the contested embodiment and, as such, is named in the operating instructions (see Annex KAP 14, p. 93) and in the quick start guide (Annex KAP 13) and on the packaging of the copies of the contested embodiment delivered to Italy. It advertises the exclusive distribution agreement between the first respondent and Sinocare on its website (https://www.menarinidiagnostics.fr/fr-fr/). Clicking on the "Patients Diabétiques" button takes you to a subpage offering various solutions. Selecting the "CGM" tab takes you to the website of the first respondent (https://glu-comen-ican.com/). The third respondent is also named as a local service centre on the website of the first respondent.

17. The contested embodiment is already available for sale in Italy. In June and July 2025, several copies of the contested embodiment were delivered to Italy following orders placed by an employee of the Roche Group.

18. The contested embodiment is not yet available in Germany and France.

19. The second respondent is already presenting the contested embodiment in Germany at events, such as the "50 Years of DBW" event organised by Diabetiker Baden-Württemberg e.V. on 20 July 2025. The sales manager of the second respondent responsible for the diabetes sector has also already used LinkedIn to search for a pharmaceutical representative for the distribution of the contested embodiment, with the specified start date being "immediately".

20. The packaging of the contested embodiment available in Italy complies with the labelling requirements for German and French, among other languages, and can also be used for distribution in Germany and France. The existing CE marking is valid for the entire European market.

21. The second applicant itself offers various products for the treatment of diabetes under the "Accu-Chek" brand. These include the Accu-Chek SmartGuide system. This comprises a CGM sensor, an electronic transmitter, an applicator and a software application. The second applicant has been marketing the system on the German market since October 2024 and now in twelve other European countries. The system is not yet available on the market in Italy and France.

APPLICATIONS OF THE PARTIES:

22. The applicants request:

I. The respondents are ordered to refrain from

1. manufacturing, offering, placing on the market or using implantable sensors for determining the concentration of at least one analyte in a medium, in particular body tissue and/or body fluid

in the Federal Republic of Germany, the French Republic and/or the Italian Reply, or to import or possess them for these purposes,

in which

the implantable sensor has a layer structure with at least one insulating carrier substrate and at least two electrodes with electrode surfaces arranged in at least two different layer planes of the implantable sensor and electrically separated from each other by the at least one insulating carrier substrate, wherein the electrode surfaces face the medium when the sensor is implanted and are in contact with the medium over a large area and essentially uniformly via a permeable membrane layer, wherein the implantable sensor further has at least two electrodes electrically contacting electrode contact layers, wherein the electrode contact layers are arranged on the electrode surfaces and are in contact with the medium over a large area and essentially uniformly via a permeable membrane layer, wherein the implantable sensor further has at least two electrodes electrically contacting electrode contact layers, wherein the electrode contact layers are arranged on the electrode surfaces and are in contact with the medium over a large area and essentially uniformly via a permeable membrane layer, wherein the implantable sensor further has at least two electrodes electrically contacting electrode contact layers, wherein the electrode contact layers are arranged on the electrode surfaces and are in contact with the medium over a large area and essentially uniformly via a permeable membrane layer, wherein the implantable sensor further has at least two electrodes electrically contacting electrode contact layers, wherein the electrode contact layers are arranged on the electrode surfaces and are in contact with the medium over a large area and essentially uniformly via a permeable membrane layer, wherein the implantable sensor further has at least two electrodes electrpermeable membrane layer, whereby the implantable sensor further comprises electrode contact layers that electrically contact the at least two electrodes, characterised in that the at least one insulating carrier substrate has a width, wherein the at least two electrodes and/or the at least two electrode contact layers extend over the entire width of the at least one insulating carrier substrate;

(direct infringement of claim 1)

2. Devices for determining the concentration of at least one analyte in a medium, in particular a body tissue and/or a body fluid

in the Federal Republic of Germany, the French Republic and/or the Italian Republic,

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which comprise

at least one implantable sensor according to item I. and furthermore at least one voltage measuring device for measuring a voltage between at least one working electrode and at least one reference electrode of the implantable sensor.

(direct infringement of claim 16)

II. For each individual infringement of the above order under point I, the respondents shall pay the court a (repeated, if necessary) penalty of up to EUR 10,000.00 per product and/or, in the case of continuous infringements such as offers on the Internet, up to EUR 30,000.00 per day.

III. The respondents are further ordered to surrender the implantable sensors and devices referred to in Section I to a bailiff for safekeeping until a final decision has been made between the parties on the existence of a claim for destructionor a mutually agreed settlement has been reached, or the applicant informs the court that safekeeping is no longer necessary.

IV. The respondents are further ordered to provide the applicants, within three weeks of delivery of this order, with a written and electronic report that can be evaluated using a computer, in a list structured for each month of a calendar year and according to patent-infringing products. (3) weeks after service of this order, in writing and in electronic form that can be evaluated using a computer, in a list structured for each month of a calendar year and by patent-infringing products, starting on 11 April 2016, providing information on the products referred to in section I.

a) the origin and distribution channels of the products referred to in Section I, specifying

- the names and addresses of the manufacturers, suppliers and other holders
- the names and addresses of the commercial customers and the points of sale for which the products were intended;
- of the individual offers, broken down by offer quantities, times,
  -prices, type designation, and names and addresses of commercial recipients of the offer;
- e of the individual deliveries, broken down by delivery quantities, times and prices, as well as type designations and names and addresses of the recipients;

b) the identity of all third parties involved in the manufacture and distribution of the products referred to in No. I.

V. The respondents are ordered to

1. to bear the costs and expenses of the proceedings and the measures ordered;

2. to reimburse the applicants provisionally for costs amounting to EUR 32,051.20.

VI. The orders are

1. immediately effective and

enforceable; alternatively to 1.

2. immediately effective and enforceable if the applicants have provided security in favour of the respondents by way of a guarantee or deposit.

23. The respondents request that the court

I. rejects the application for the order of interim measures;

II. alternatively (in the event that the court does not grant application I),

allows the alleged infringement to continue on condition that the respondents provide security, the amount of which is to be determined by the court;

III. in the event that the court orders interim measures, obliges the applicants to provide security for the enforcement of an interim injunction and/or other provisional measures, the amount of which is to be determined by the court, whereby the security should amount to at least EUR 1,500,000;

IV. in the event that the application for an order for interim measures is dismissed or withdrawn, the applicants shall be obliged to bear the costs of the proceedings;

V. to provisionally impose costs of EUR 23,302.40 on the applicants.

FACTUAL AND LEGAL ISSUES IN DISPUTE:

Legal standing

24. In the opinion of the respondents, claims relating to the German part of the patent at issue can only be asserted by the second applicant, and claims relating to the other national parts can only be asserted by the first applicant. The applicants, on the other hand, argue that no division according to the respective ownership of the national parts of the patent at issue is necessary.

Scope of protection

25. The applicants are of the opinion that, according to the understanding of the patent at issue, which is its own lexicon, the electrode contact layers together with the electrode systems form the electrode claimed. The wording of the claim itself specifies that the electrodes have electrode surfaces. The reactive electrode surfaces, which the patent at issue also optionally refers to as electrode systems,

are always part of the electrode. Any other interpretation would exclude the sensors shown in the embodiments from the scope of protection.

26. According to the claim, two of the electrodes are ordered in different layer planes, whereby the claim does not specify the positioning of any further electrodes. Functionally, too, the only thing that matters is the use of the third dimension, i.e. the advantages of the layer structure, which enables the construction of a sensor that is significantly more stable due to the ratio of width to thickness. In addition, the patent at issue itself describes it as particularly advantageous to form the counter electrode and reference electrode as a common electrode. The fact that the patent at issue also concerns cost-effective manufacturing does not mean that any structuring process must be dispensed with without exception.

27. Insofar as the patent at issue requires that electrode contact layers and electrodes make electrical contact, this does not, according to the clear wording, presuppose separate components. The patent at issue assumes, including in all figures, that electrical contact already exists through the electrode contact layer extending over the entire substrate.

28. With the requirement that the electrodes and/or electrode contact layers extend across the entire width of the carrier substrate, the patent at issue means that the relevant layers extend from one edge to the other edge of the carrier substrate. The width of the carrier substrate refers to the extent of the area of the carrier substrate that lies between the edges of the carrier substrate and is ultimately to be coated with electrode contact layers and electrode systems. It thus denotes the usable width of the carrier substrate. The claim does not relate to any extension over the length of the carrier substrate. The grant document cited by the respondents is not relevant to the interpretation. Furthermore, the deletion of the addition "essentially" in the grant procedure does not alter the understanding.

29. The patent at issue does not specify the shape of the carrier substrate and is therefore not limited to carrier substrates with a rectangular cross-section. In view of the rough coating techniques and starting materials, as described in paragraph [0075], for example, the skilled person would expect considerable error tolerances in the edge area of the coatings, even if the material is cut after coating. In addition, as the skilled person knows, single- or multi-stage laser cutting processes produce effects that result in the cutting edge not being absolutely straight ("tapering"). Functionally, 100% coverage is also not necessary. The decisive factor is that the electrodes and/or electrode contact surfaces can be applied over a large area and cut precisely, and that no complex structuring is required.

30. The respondents argue that the patent at issue differentiates between the terms "electrode" and "enzyme or auxiliary layer". The enzyme layer is applied "to" the electrode; these are different components. This also corresponds to the general understanding of the skilled person. The term "electrode" must also be distinguished from the term "electrode system". These are different components that should not be equated. An electrical contact, as mentioned in the claim, always requires two separate components.

31. With the wording "at least two electrodes arranged in at least two different layer planes", the patent at issue presupposes that the number of

layer planes corresponds to the number of electrodes present. The number of electrodes must therefore not exceed the number of layer planes. If several electrodes are placed in order in one layer plane, they cannot be separated from each other by the carrier substrate, and thus the advantages sought by the "sandwich structure" according to the invention, in particular the use of the "third dimension", cannot be realised. Furthermore, the separation of the electrodes in a layer plane would require the use of structuring methods, which would contradict the inventive concept of the patent at issue.

32. Claim 1 is characterised by the requirement that the carrier substrate has a width, with the at least two electrode contact layers extending across the entire width of the insulating carrier substrate. The deletion of the word "essentially" in the grant procedure, which was necessary to establish the novelty and inventive step of claim 1, meant that coverage across the entire width could only be understood as 100% coverage. This understanding is also compelling in light of the prior art acknowledged in the patent at issue, in particular US 2004/0111017 A1 (hereinafter: US '017). The applicants also referred to this acknowledged prior art in the grant proceedings, which is why the restriction made must be applied all the more. The understanding described is also prompted by the desire for simple and cost-effective production, which makes lithographic structuring processes or laser structuring processes in particular unnecessary. The wording in process claim 18 ("is cut into sensor strips in such a way that the ... carrier substrate has a width") makes it clear that the width of the carrier substrate should extend from one extreme cut edge to the other extreme cut edge. The fact that the width of the carrier substrate ultimately refers to its maximum horizontal physical extension is also apparent to the skilled person from claim 9 and the corresponding description in paragraph [0042].

33. The aforementioned requirement should also be understood to mean that the electrode and/or electrode contact layer should not only extend selectively across the entire width of the carrier substrate, but also across the entire length of the sensor in the longitudinal direction, i.e. from its "tip to its base". The term "edge" ("from one edge to the other") refers to the "edges" of the sensor along which the electrode or electrode contact layers must extend in the longitudinal direction. Sufficient signal strokes could only be achieved – in contrast to the recognised state of the art according to US '017 – if a large electrode area was available for this purpose.

34. On the other hand, based on the applicants' understanding, the feature no longer has any significance. If the feature-related width of the carrier substrate always refers to the part of its surface that is coated with the electrode, then logically the electrode always extends across the entire width of the carrier substrate. In addition, a large number of carrier substrates would then have at least two different widths, and it would be unclear to the skilled person which width to use for determining the width-to-height ratio according to claim 9.

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Infringement

35. In the opinion of the applicants, the contested embodiment literally fulfils all the features of claims 1 and 16.

36. It is undisputed that in the contested embodiment, the working electrode and the reference electrode are ordered in different layer planes, namely on opposite sides of the carrier substrate, and are electrically separated from each other by the carrier substrate. The positioning of the counter electrode is irrelevant for the realisation of the feature.

37. There are also two electrode contact layers. Regardless of the definition of the electrode, the structure of the sensor corresponds exactly to the embodiment in Figure 1. According to the respondents' own submission, the carbon layer is applied to the carrier substrate, with the enzyme layer on one side and the Ag/AgCl coating on the other.

38. Furthermore, if correctly understood, the electrode coating extends across the entire width of the carrier substrate, even if one assumes that
100% of the width of the carrier substrate must be coated. The figures provided by the respondents showed that the carrier substrate of the contested embodiment was coated from edge to edge with the electrodes and electrode contact layers. In fact, as shown, a person skilled in the art would not understand "entire width" to mean 100% coverage. Therefore, the feature is also fulfilled if, as the respondents argue, the respective outer edge of the carrier substrate is regarded as the edge.

39. As far as the description of the manufacturing process of the contested embodiment is concerned, it is disputed [...].

40. The respondents, on the other hand, argue that the contested embodiment does not make use of claim 1 and thus also of claim 16 of the patent at issue.

41. Because the contested embodiment has three electrodes in only two layer planes, the requirements of the claim are not met. The counter electrode and the working or reference electrode are also not separated from each other by the insulating carrier material, but by the insulating groove and thus the membrane layer.

42. Furthermore, the contested embodiment does not have at least two electrode contact layers. According to the correct interpretation, the carbon layer beneath the enzyme layer should be classified as an electrode, not the enzyme layer together with the carbon layer beneath it. The carbon layer applied directly to the insulating substrate does not therefore contact an electrode contact layer, as required by the claim. Even if one were to assume that the electrode contact layer together with the enzyme layer or the Ag/AgCl layer forms the
"electrode" within the meaning of the patent at issue, the necessary electrical contact between two separate components is lacking in any case.

43. In the contested embodiment, neither the electrode nor the electrode contact layer on the "enzyme side" of the sensor extends across the entire width of the carrier substrate. Rather, in the manufacturing process of the sensors [...].

44. If the carbon layer under the enzyme layer is correctly classified as an electrode, it does not extend longitudinally across the entire width of the insulating carrier substrate. Rather, the insulating groove in the carbon layer forms two electrodes – the counter electrode and the working electrode – each of which extends only over part of the insulating carrier substrate.

Legal status

45. The respondents are of the opinion that the legal status of the patent at issue is not sufficiently secure. Claim 1 lacks novelty in relation to WO 2006/0818447 (hereinafter: WO '447) and US 2006/0091006 (hereinafter: US '006).

46. The patent at issue does not effectively claim the priority of P1, so that WO '447 is not only prior art according to Art. 54(3) EPC, but full prior art according to Art. 54 para. 2 EPC . In view of the invalid priority , US '006 is also full prior art.

47. In their rejoinder, the respondents also argue that, if the applicants' interpretation is accepted, according to which the term "across the entire width" does not reflect complete coverage of the width, i.e. 100%, claim 1 also lacks novelty in relation to US 2005/0215871 (US '871) and US 2003/0042137 A1 (US '137), as these also disclose the corresponding feature.

48. Furthermore, based on US '871 and WO 2005/078424 (WO '424, D3 in the examination procedure), which originate from the same patent family, there is a lack of inventive step. Both documents also referred to a design of the electrodes extending across the entire width of the substrate. This was an obvious modification that a person skilled in the art could have implemented without difficulty. Based on US '447 and US '006, there was also no inventive step.

49. The applicants, on the other hand, consider the legal position to be sufficiently secure. The patent at issue, which has been accepted on the market for over 16 years, effectively claims the priority of P1. For this reason, US '006 is not prior art within the meaning of Art. 54 EPC, but regardless of this, it does not – like WO '447 – anticipate all the features of claim 1 in a manner that would destroy novelty. Based on the respondents' submissions, there is also no lack of inventive step.

Necessity of provisional measures

50. The applicants are of the opinion that the order of interim measures is necessary.

51. The application was filed within the urgency period. It was only when they discovered the offer on Amazon's Italian website that they became aware of a possible infringement in a relevant Member State, initially assuming that the infringement was caused by the red and white packaged Sinocare iCan i3 CGM with a round electronic unit. It was only upon delivery that they realised that it was in fact a product of the respondents. They then did everything in their power to obtain the contested embodiment as quickly as possible. It was not until 12 July 2025, with the

receipt of the first results of the microscopic examination of the contested embodiment that they obtained reliable knowledge of the infringement by the respondents.

52. […]

53. They had no knowledge of further marketing activities by Sinocare or the respondents and, in the absence of a market monitoring obligation, were not required to have such knowledge. Furthermore, it was not apparent from the offers how the sensor was precisely designed. This would require microscopic examination. Distribution in a patent-free UPC Agreement member state could not trigger the urgency period, as they could assume that the respondents were acting lawfully.

54. Without the order, they would face significant and irreparable damage. Continued distribution of the contested embodiment would significantly impair their chances of successfully entering the market in Italy and France and establishing themselves in the German market. Because they were still positioning and establishing themselves on the market with their product, there was a particular need for the order of interim measures. The acquisition of market share in a market with various competitors would be made considerably more difficult by each additional competing product. Patients tended to use their CGM system for several years, so that the loss of market share would be long-lasting.

55. In addition, the limited remaining term of the patent at issue meant that a referral to the main proceedings would lead to a de facto reduction in patent protection and deprive them of the opportunity to effectively enforce their exclusive rights.

56. In contrast, the respondents do not face any significant, or at least any unreasonable, damage.

57. In the respondents' view, there is no need for interim measures.

58. There is no urgency in terms of time. It is not clear why the applicants cannot wait for a decision on the main issue. The applicants' application, asserting that they were not convinced of the infringement until the end of July 2025, when they considered it appropriate to review the legal situation, is highly implausible and is disputed. [...] Therefore, the applicants could not have failed to notice the numerous trade fair appearances by Sinocare and later by the respondents since October 2023, at which the contested embodiment was intensively advertised and presented. The same applies to the announcement of the cooperation between Sinocare and the respondents. Furthermore, the 'information gathering process' described by the applicants themselves was neither well coordinated nor targeted.

59. Due to the special features of the CGM market, no short-term change in market shares is to be expected. The contested embodiment would therefore not be able to cause any disruptive changes in the relevant market, certainly not in the relevant period until a decision in the main proceedings, which the

Applicants who filed a lawsuit in the summer/autumn of 2026 could have expected this. Damages could not result from potential market share losses because the applicants were not actually represented on the market in Germany with their own product. The applicants' market share in Germany was less than 1%. Furthermore, no relevant sales activities had been observed in recent months.

60. In view of the short remaining term of the patent at issue, the respondent's interest in not being impeded in its preparations for market entry by an injunction issued shortly before the expiry of the patent protection prevails.

61. They would also face considerable disadvantages if the court were to order interim measures and these were found to be unlawful. They estimated that this would result in a significant loss of profit, which they estimated at [...]. In Italy, there was also a risk of losing guarantee amounts of up to 10% of the total volume of the supply contracts concluded in relation to the contested embodiment. Furthermore, there was a risk of exclusion from future tendering procedures in Germany and Italy, even if these procedures concerned other products. There was also a risk of irreparable damage to their reputation.

62. It must also be taken into account that it would have been possible for the applicants to file the application for order of interim measures much earlier. The applicants could quantify any claims for damages particularly quickly and easily in the extremely transparent market for the contested embodiment. Conversely, it would be almost impossible for the respondents to quantify their claims for unjustified enforcement of a possible injunction.

63. There are less severe measures available that could prevent potential damage to the applicants just as effectively as an injunction, but which would place significantly less of a burden on the respondents. It would be sufficient, for example, to prohibit the respondents from concluding contracts with health insurance companies and other healthcare providers for the supply of the contested embodiment at prices below those of the applicants. Because the applicants' interests were exclusively focused on avoiding economic disadvantages, it was also sufficient to make the continuation of the alleged infringement dependent on the provision of security.

Legal consequences

64. The respondents consider the asserted right to information to be too far-reaching insofar as it also requires information about individual offers and deliveries. In any case, measures to safeguard competition are necessary in this respect. The information should only be disclosed to an auditor or, at the respondents' discretion, to a limited number of the applicants' employees who have no influence on the applicants' pricing. In any case, a preliminary injunction should only be ordered against appropriate security, which must be at least EUR 1,000,000.

65. The applicants, on the other hand, are of the opinion that the right to information could also include a breakdown by individual offers and deliveries, insofar as this is necessary to determine the exact extent of the patent infringement.

KEY PROCEDURAL STEPS:

66. In a document dated 7 August 2025, the applicants filed an application with the local division in Düsseldorf for an order for interim measures without hearing the respondents.

67. In a procedural order dated 8 August 2025, the applicants were informed that, based on the arguments put forward in the application, it was intended to notify the respondents of the application in accordance with Rule 209.1(a) of the RoP and to request them to lodge a preliminary objection to the application for interim measures within a period to be determined. The applicants then declared to the court that they agreed to the respondents being informed.

68. The respondents were then informed of the application by procedural order of 11 August 2025 and requested to lodge a preliminary objection within one month of service of the order.

69. After the receipt of the preliminary objection on 23 September 2025, the rapporteur set a date for the oral hearing on 7 November 2025 by order of 24 September 2025 and set a deadline for the applicants to file a defence to the preliminary objection by
8 October 2025 and set the respondents a deadline of 22 October 2025 for their Reply to this.

70. On 30 September 2025, the respondents filed an application for review of the procedural order of 24 September 2025 pursuant to R. 333 RoP with the aim of limiting the content of the further statement granted to the applicants – as requested by the respondents in their statement of opposition – to arguments concerning the attacks on the legal status.

71. In its procedural order of 2 October 2025, the panel upheld the rapporteur's order and rejected a restriction on the content of the further documents.

72. The applicants submitted their defence to the preliminary objection on 8 October 2025, and the respondents submitted their rejoinder on 22 October 2025.

73. By procedural orders dated 1 October 2025 and 31 October 2025, confidentiality orders pursuant to R. 262A RoP were issued in favour of the respondents and, on 13 October 2025, in favour of the applicants.

REASONS FOR THE ORDER

74. The application for order of interim measures is admissible and has been largely successful on the merits.

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I. Admissibility

75. The application for order of interim measures is admissible.

76. The UPC Agreement has international jurisdiction.

77. The UPC is a common court within the meaning of Article 71a(1) of the Brussels Ia Regulation (Article 71a(2)(a) of the Brussels Ia Regulation). The UPC therefore has jurisdiction if the courts of a contracting member state would have jurisdiction under the Brussels Ia Regulation for an action within the meaning of Article 32(1) of the UPC Agreement (Article 71b(1) of the Brussels Ia Regulation). This is the case here.

78. As far as the second respondent is concerned, this follows from Article 4(1) of the Brussels Ia Regulation. With regard to the first and third respondents, jurisdiction is established under Article 8(1) of the Brussels Ia Regulation. Since the second and third respondents act as distribution partners of the first respondent for one contracting Member State each and all companies belong to the same group of companies, there is such a close relationship between the actions that it appears appropriate to hear and decide them together in order to avoid the possibility of conflicting decisions being made in separate proceedings.

79. The local division in Düsseldorf has jurisdiction "within the UPC Agreement" in any case pursuant to Article 33(1)(b) UPC Agreement because the second respondent has its principal place of business in Germany and, for the reasons just mentioned, there is a business relationship between the companies.

80. As the owners of the different national parts of the patent at issue, the applicants were able to assert these jointly in one action, cf. R. 302.1 RoP.

II. Legal ownership

81. The applicants are, to the court's sufficiently certain conviction, the legal owners of the patent at issue, Art. 62 (4) UPC Agreement.

82. Applicant 2 is the registered owner of the German part, and applicant 1 is the registered owner of the French and Italian parts of the patent at issue. As registered owners of the national parts of the patent at issue, the applicants are entitled to bring proceedings before the court pursuant to Art. 47 (1) UPC Agreement in conjunction with R. 8.5 (a) and (c) RoP.

83. With regard to the consequences for the individual claims, reference is made to the comments on the legal consequences (see VI.).

III. Infringement of the patent at issue

84. The court is also sufficiently convinced that the applicants' rights are infringed by the offer of the contested embodiment within the contracting member states of Germany, France and Italy and by the distribution in Italy, and that such infringement is also imminent with regard to the forthcoming distribution in Germany and France, Art. 62 (4) UPC Agreement R. 211.2 RoP.

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1. Relevant expert

85. The relevant expert is a team consisting of a medical technician and biochemist with several years of experience in the development of biosensors, and a physician who advises on in vivo application and in vivo compatibility. In this respect, the Chamber concurs with the respondents' opinion.

2. Determination of the scope of protection

86. With regard to the scope of protection of the patent at issue, the following applies:

a) Subject matter of the patent at issue

87. The patent at issue relates to an implantable sensor for determining at least one analyte in a medium, in particular body tissue and/or body fluid, a device using the implantable sensor, and a method for manufacturing the implantable sensor. According to the patent at issue, such sensors and/or devices are used in particular in the field of medical technology to electrochemically determine the concentration of blood glucose, triglycerides, lactate or other analytes (para. [0001]).

88. In its introductory remarks, the patent at issue describes how determining blood glucose concentration and the corresponding medication for diabetics is an essential part of the daily routine. Blood glucose concentration must be measured several times a day, typically two to seven times. Various mobile devices are available for this purpose, which can be used to evaluate the samples using, for example, an electrochemical measurement method or optical measurement methods. The methods are mainly based on the patient first taking a sample of the body fluid to be examined (e.g. blood or urine) and examining it using a test device (in vitro test strip). However, this method has disadvantages. It requires several handling steps, is difficult for older people or children, can only be performed discreetly in a few cases and can lead to incorrect measurements if operated incorrectly (see paragraphs [0002] to [0004]).

89. The prior art therefore already includes systems that can be implanted in body tissue and, for example, provide continuous measurements. These include, for example, an encapsulated glucose sensor system known from US 6,892,085 B2 (hereinafter: US '085) and an implantable microneedle system known from US 5,591,139 (hereinafter: US '139) (paras. [0005] to [0006]).

90. However, the known implant sensors have a number of disadvantages. For example,
For example, the sensors described in US '139 and US '085 require complex microstructuring processes such as lithographic processes for their manufacture, which are too expensive for the production of disposable items (see paragraphs [0007] to [0008]).

91. Another problem is that the sensors known from the prior art often do not allow sufficient free access of the analyte to the electrode. This applies
, for example, to the sensors described in US '139 and US '085, which use hollow needles or capillaries (paragraph [0009]).

92. The patent at issue also describes an in vivo sensor shown in US '017, which is based on an electrochemical principle and has two electrodes on a carrier substrate. A working electrode coated with a detector layer for the analyte to be detected is applied directly to the carrier substrate and covered by a top layer. On the side of the cover layer opposite the working electrode, a common reference and counter electrode is applied, which overlaps the working electrode but is separated from it by the cover layer. The analyte reaches the working electrode via diffusion mechanisms from the edge of the sensor. Alternatively, the cover layer itself can also be designed to be permeable to the analyte (para. [0010]).

93. However, a disadvantage of this sensor arrangement is that the cover layer must perform two different functions, which are difficult to reconcile in terms of materials technology. The sensor design with diffusion channels in the layer structure proposed in US '017 to solve this problem is so technically complex that the manufacturing advantages made possible by a layer structure are almost completely lost (para. [0011]).

94. Finally, the patent at issue states that US '017 and US '137 disclose implantable sensors in accordance with the general term of the independent claims (para. [0012]).

95. Against the background described above, the patent at issue states that its task is to provide a sensor for determining the concentration of at least one analyte in a medium, which can be manufactured simply and inexpensively using a reliable manufacturing process and which avoids the disadvantages of the sensors and methods known from the prior art as far as possible. In particular, the sensor should be implantable and ensure sufficient signal strokes (para. [0013]).

96. To solve this problem, the patent at issue protects a sandwich sensor with the following features:

Claim 1

1. Implantable sensor (110) for determining the concentration of at least one analyte in a medium, in particular body tissue and/or body fluid,

1.1. wherein the implantable sensor (110) has a layered structure with at least one insulating carrier substrate (112; 210, 216; 710, 712, 714; 810, 812) and

1.2 at least two electrodes (134,
136; 238, 240, 242; 738, 740, 742; 830, 832, 836) with electrode surfaces,

1.2.1 wherein the electrode surfaces face the medium when the sensor (110) is implanted

1.2.2 and are in contact with the medium over a large area and essentially uniformly, either directly or via an analyte-permeable membrane layer (146).

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1.3 wherein the implantable sensor (110) further comprises at least two electrodes (134, 136; 238, 240, 242; 738, 740, 742; 830, 832, 836) electrically contacting electrode contact layers (114, 116; 212, 214; 222; 610, 612; 716, 718, 720; 814, 816, 822) characterised in that the at least one insulating carrier substrate (112; 210, 216

1.4 characterised in that the at least one insulating carrier substrate (112; 210, 216; 710, 712, 714; 810, 812) has a width, wherein the at least two electrodes electrodes (134, 136; 238, 240, 242; 738, 740, 742; 830, 832, 836) and/or the at least two electrode contact layers (114, 116; 212, 214; 222; 610, 612; 716, 718, 720; 814, 816, 822) extend over the entire width of the at least one insulating carrier substrate (112; 210, 216; 710, 712, 714; 810, 812).

Claim 16:

16.1. Device (310) for determining a concentration of at least one analyte in a medium, in particular a body tissue and/or a body fluid, comprising

16.2 at least one implantable sensor (110) according to one of the preceding claims, and further

16.3 at least one voltage measuring device (312) for measuring a voltage between at least one working electrode (144; 740; 836) and at least one reference electrode (142; 738; 832) of the implantable sensor (110).

b) Design

97. Some features require explanation.

aa) Principles of design

98. According to Art. 69 EPC in conjunction with the Protocol on its interpretation, the patent claim is not only the starting point but also the decisive basis for determining the scope of protection of a European patent. The interpretation of a patent claim does not depend solely on its exact wording in the linguistic sense. Rather, the description and drawings must always be consulted as aids to the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim. However, this does not mean that the patent claim serves merely as a guideline and that its subject matter also extends to what, after examination of the description and drawings, appears to be the protection sought by the patent proprietor. In applying these principles, adequate protection for the patent proprietor should be combined with sufficient legal certainty for third parties. The patent claim must be interpreted from the perspective of a person skilled in the art. These principles for interpreting a patent claim apply equally to the assessment of infringement and the legal validity of a European patent (UPC_CoA_335/2023, order of 26 February 2024, headnote 2 and p. 26).
f. – 10x Genomics v. Nanostring; UPC_CoA_1/2024, order of 13 May 2024, para. 26 – VusionGroup v. Hanshow; UPC_CoA_182/2024, order of 25 September 2024, para. 82 – Mammut v. Ortovox).

bb) Interpretation in individual cases

(1) Electrode surfaces, electrode contact layers, electrodes

99. In view of the dispute between the parties, the terms used in the claim relating to electrodes (features 1.2, 1.3, 1.4), electrode surfaces (features 1.2, 1.2.1) and electrode contact layers (features 1.3, 1.4) as well as the term electrode system, which is only used in the description, require clarification with regard to the dispute between the parties.

Electrode

100. An implantable sensor according to the claim has at least two *electrodes*. These may be at least one working electrode and at least one further electrode, in particular at least one counter electrode and/or at least one reference electrode (paras. [0020], [0030]). A counter electrode and a reference electrode can also be designed as a common electrode (para. [0030]).

101. The function of the electrodes is to measure the analyte concentration. This can be done by amperometric measurement between the at least two electrodes (working electrode and counter electrode), in particular by means of a direct voltage. A reference electrode for currentless measurement of the working electrode potential can also be used (para. [0020]).

102. The electrodes can be coated with enzymes or other chemical additives that are specific to the analyte to be detected. For example, glucose oxidase (GOD) can be used for the detection of glucose (para. [0030], see also [para. [0028]).

103. Typical electrode layer thicknesses are in the range of 10 micrometres, but can be in the range of several hundred micrometres. Thinner electrode layers are also conceivable (para. [0036]).

Electrode surfaces

104. According to feature 1.2, the *electrode surfaces* ("electrodes ... with electrode surfaces") are part of the electrodes. The patent at issue defines electrode surfaces as active surfaces of the electrodes on which electrochemical reactions (redox reactions) can take place (para. [0017]).

105. According to the teaching of the patent at issue, the electrode surfaces face the medium in implanted sensors and are in contact with the medium over a large area and essentially uniformly, either directly or via an analyte-permeable membrane layer (features 1.2.1, 1.2.2). This design ensures that the analyte acts on the electrode surface perpendicularly and unhindered over essentially its entire extent (cf. para. [0017]). According to the invention, this ensures a maximum signal amplitude and thus reliable detection of the concentration of the analyte.

Electrode systems

106. In its description and in the embodiments – but not in patent claim

1 – the patent at issue uses the term "*electrode system*" to describe the electrochemically active layer as a whole.

107. The electrode system may be, for example, an Ag/AgCl coating in the case of one electrode system and a MnO2/C (brownstone) layer mixed with the enzyme glucose oxidase (GOD) (paras. [0064], [0075] et seq., [0105], [0108]).

Electrode contact layers

108. In addition, the implantable sensor according to the claim has *electrode contact layers* which electrically contact the at least two electrodes (feature 1.3). These may be electrically conductive layers, e.g. metallic layers containing carbon, graphite, gold, silver, platinum and/or aluminium (para. [0024], see also para. [0036]: pure metals). Organic conductor materials may also be considered (para. [0024]). The electrode contact layers may be partially covered by the electrodes (cf. para. [0026]).

109. The electrodes are applied to the electrode contact layers, whereby different methods can be used depending on the electrode material used (cf. para. [0036]).

Relationship between the terms

110. According to the understanding of the patent at issue, the *electrodes* consist of a combination of the electrode system and the electrode contact layer.

111. Paragraph [0064] states the following with regard to the first embodiment of a sensor according to the invention:

> *"... Other designs of the openings 126, 128 are also conceivable. In the area of these openings 126, 128, a first electrode system 130 is inserted into opening 126 and a second electrode system 132 is inserted into opening 128 in such a way that these electrode systems 130, 132 rest on the electrode contact layers 114, 116.* ***The electrode systems 130, 132 thus form a first electrode 134 and a second electrode 136 in these areas together with the electrode contact layers 114, 116.*** *In the embodiment shown here, the first electrode system 130 consists of an Ag/AgCl coating, whereas the second electrode system 132 is an MnO2/C (brownstone) layer mixed with the enzyme glucose oxidase (GOD)."*
>
> (Emphasis added)

112. It is clear from other passages that the patent at issue is not based on this understanding only in relation to the first embodiment. For example, in paragraph [0033], which is part of the general description, the patent at issue assumes that the electrode system is a component of the electrode. It states:

> *"... Thus, the at least one reference electrode should have an electron system (sic) with an electrochemical potential ...".*

113. Paragraph [0034], which also belongs to the general description, also indicates that the electrode system must be a component of the electrode:

> *"In principle, a variety of materials and/or material combinations can be used for the reference electrode (sic). A silver/silver chloride (Ag/AgCl) electrode system has proven to be particularly advantageous (sic). Other electrode systems can also be used in principle, but are less common, such as $_{HgCl2}$ electrode systems."*

114. Furthermore, paragraph [0035] of the general description should be mentioned, which uses the term "electrode system" as a component or even as a type of subform of the electrode. With regard to the design of the counter electrode, it states:

> *"... In principle, pure metals such as platinum can be used as counter electrodes. However, this has the disadvantage that gas formation typically occurs at such metal electrodes, for example the formation of hydrogen or oxygen. Such gas formation is undesirable in implanted sensors in body tissue. In this respect, it is again advantageous to use an electrode system, in particular a redox electrode system, in which gas formation is avoided. In particular, an Ag/AgCl electrode system can also be used here. ..."*

115. Finally, paragraph [0081] describes for the second embodiment of a sensor according to the invention in a configuration with three electrodes that the first, second and third electrode systems together with the associated electrode contact layers form a first, second and third electrode.

116. Several conclusions can be drawn from this understanding:

117. Insofar as the respondents wish the electrodes and the electrode contact layers that electrically contact them to be understood as separate components, this cannot be accepted in light of the understanding of the patent at issue as described above. In the finished state of a sensor according to the invention, the electrode contact layers form part of the electrode. With the specification contained in feature 1.3, according to which the electrode contact layers *electrically contact* the electrodes, the patent claim thus describes the function of the electrode contact layer within the context of the multi-layer electrode. The design as separate components is neither necessary nor, based on the understanding of the patent at issue, even possible. All embodiments of the patent at issue also show a design in which the electrodes are applied to the electrode contact layers and form the electrode together with the electrode system. Whether an electrical contact requires the presence of separate components according to the general understanding of the skilled person is not decisive. The only decisive factor is the understanding of the patent at issue, which forms its own lexicon.

118. Against this background, the Board also rejects the respondents' further argument that the electrode and any enzyme layer applied to it are separate components. According to the understanding of the patent at issue, an enzyme layer, such as a MnO2/C (brownstone) layer mixed with the enzyme glucose oxidase (GOD), is part of the electrode system and thus also a component of the electrode.

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(2) Electrodes arranged in two different layer planes (feature 1.2)

119. The at least two electrodes of an implantable sensor according to the claim are arranged in at least two different layer planes of the implantable sensor and are electrically separated from each other by the at least one insulating carrier substrate, feature 1.2.

120. The patent at issue explains what is meant by an order of the electrodes in at least two different layer planes in paragraph [0021]. It states:

> *"The term 'in different layer planes' is to be understood in particular to mean that at least one insulating carrier substrate is arranged between the at least two electrodes, so that at least two of the at least two electrodes are separated by the insulating carrier substrate. Thus, in contrast to the prior art described above, the 'third dimension' is also utilised in this structure of an implantable sensor."*

121. The order in different layer levels may, for example, be the order on a front and a rear side and/or in different step levels (cf. para. [0017]; [0044]).

122. The order described in feature 1.2 allows the electrodes to be designed very wide and still be reliably separated from each other (see para. [0084]). This ensures the use of the "third dimension" mentioned in the definition in para. [0021], which enables the compact design of the sensor sought by the invention.

123. The respondents take the view that it can be inferred from the wording "at least two electrodes arranged in at least two different layer planes" implies that the number of layer planes must correspond to the number of electrodes present. In particular, if there are three electrodes, three layer planes are also required.

124. The Chamber does not share this view. From a purely linguistic point of view, such an understanding has no basis in the claim. Nor can the skilled person find any indication of this in the patent specification.

125. The desired use of the third dimension is already ensured by the use of two electrodes in two layers separated from each other by the carrier substrate. The claim leaves open the question of how the proper functioning of additional electrodes is ensured.

126. The patent at issue also expressly mentions the possibility, in the presence of a working electrode, a counter electrode and a reference electrode, of forming the counter electrode and the reference electrode as a common electrode (para. [0030]), with the result that these are located in a single layer. In addition to the embodiment shown in Figure 8, the patent at issue also mentions the possibility of not forming the counter electrode and reference electrode as a common electrode, but rather providing them separately in one plane of the layer structure (para. [0109]).

127. The patent at issue also mentions the case of providing three electrodes in three different layer planes, in particular, in a stepped layer structure, one electrode

in the plane of the step (para. [0044], [0084]). However, this does not limit the broader wording of the claim. In addition to the possibility of a stepped structure, the patent at issue also mentions the so-called "back-to-back" structure as advantageous, in which at least two electrodes are arranged on opposite sides of the at least one carrier substrate and have oppositely directed electrode surfaces facing the medium (para. [0045], [0048]).

(3) Extension of the electrodes/electrode contact layers over the entire width of the carrier substrate (feature 1.4)

128. According to feature 1.4, the at least one insulating carrier substrate has a width, with the at least two electrodes and/or the at least two electrode contact layers extending over the entire width of the insulating carrier material.

"Entire" width

129. The patent at issue understands an extension over the entire width of the insulating carrier substrate to mean an extension from one edge of the insulating carrier substrate to the other. The skilled person derives this understanding from paragraph [0025], whereby the wording "in one edge ... to the other" is an obvious clerical error that the skilled person would readily correct.

130. Insofar as paragraph [0025] states that the electrode contact layers and/or the electrodes extend "essentially" from one edge of the insulating carrier substrate, whereby this is understood to mean that the electrode contact layer covers at least 80%, preferably 95% and particularly preferably 100%, this wording has not been received in the patent claim. It is irrelevant at this point whether the grant file must be taken into account when interpreting patent claims (left open: UPC_CoA_182/2024, order of 25 September 2024, para. 98 – Mammut v. Ortovox; rejected: UPC_CFI_452/2023 (LD Düsseldorf), order of 9 April 2024, p. 15 – Ortovox v. Mammut) UPC_CFI_292/2023 (LD Munich), p. 20 – SES v. Hanshow). In any case, it can be stated that the patent claim refers to the "entire width" of the at least one insulating carrier substrate and thus, in the opinion of the Chamber, also refers to a spread over 100% of the width. Whether and to what extent manufacturing tolerances are to be taken into account in this context does not need to be examined in detail in the present case.

Width in the area of the electrode systems or bulk width

131. However, this does not answer the question of what the patent at issue means by the term "width". The respondents are of the opinion that the total width refers to the width of the carrier substrate in terms of its total spatial and physical extent (hereinafter: bulk width) of the carrier substrate. In contrast, the applicants consider the area coated with the electrode to be relevant for determining the width.

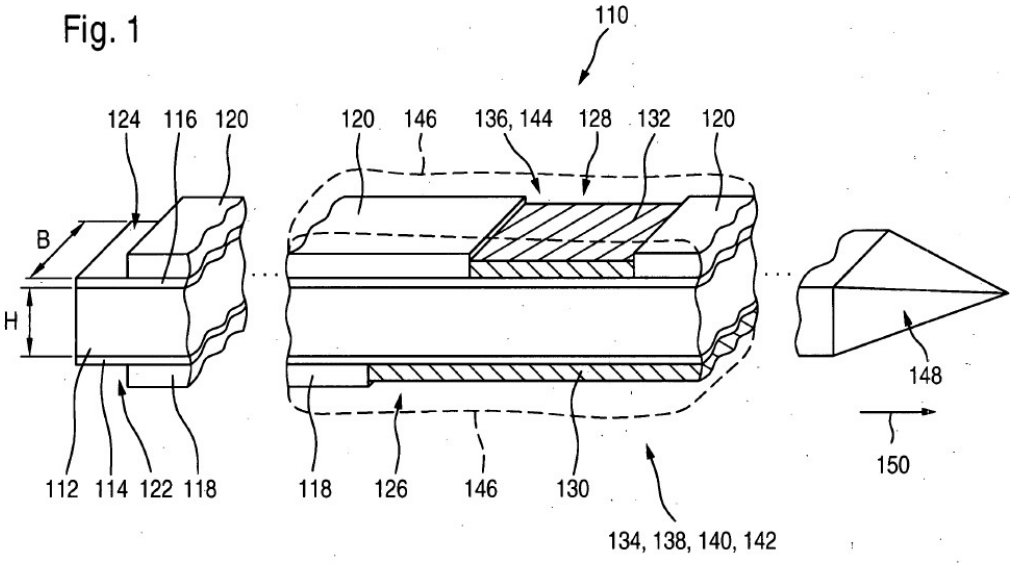
132. In the opinion of the Chamber, it is necessary to distinguish between the width of the carrier substrate in the area of the electrode systems (electrode layers) on the one hand and the total or bulk width of the carrier substrate on the other. Even if the two widths

coincide in all embodiments of the patent at issue, they may also differ from each other in a design according to the invention. In such a case, the width of the carrier substrate in the area of the electrode systems (electrode layers) is decisive for the realisation of feature 1.4. In detail:

133. The wording of the claim leaves open whether the width refers to the entire bulk width of the carrier substrate or whether the decisive factor is the area of the carrier substrate in which the electrodes are located. If the latter width is considered decisive, this means that the carrier substrate, if its cross-section is not strictly rectangular, may have more than one width, of which only one – namely that below the electrode layer – is relevant for the realisation of feature 1.4.

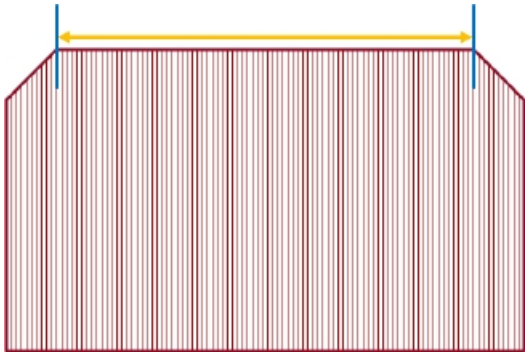
134. Feature 1.4 states that the at least one insulating carrier substrate has "a width" and that the at least two electrodes and/or at least two electrode contact layers extend over "the entire width" of the at least one carrier substrate. The definite article ("the ... width") is thus only used by the claim when it refers back to the term "width" previously defined with the indefinite article ("a width"). From a purely linguistic point of view, the wording does not therefore exclude the possibility that the carrier substrate may have more than a single width.

135. However, the expert does not stop at such a purely linguistic consideration. Rather, the expert will take into account that the patent at issue does not specify a particular design of the carrier substrate. It is true that all embodiments show a carrier substrate in the form of a rectangular cross-section, i.e. in the three-dimensional design of a cuboid shape, as can be seen in Figure 1, for example:



136. In such a design, the carrier substrate has only a single width in its entire three-dimensional configuration. However, the broader claim is not limited to such a design. Even though the second embodiment of the patent at issue describes an approximately square cross-section (across several insulating carrier substrates) as desirable (see para. [0086]), this is only a preferred design.

137. As those skilled in the art will know, a different geometric design of the carrier substrate can result in the carrier substrate having several widths. For example, cuts and/or separation processes at the end of the manufacturing process can result in cross-sections such as those shown in the following sketch, which has been discussed in detail by the parties:



138. In this illustration, the carrier substrate has a smaller width in the area of the working electrode (in the upper figure) than in the area of the reference electrode (in the lower figure).

139. If the carrier substrate has more than one width, the skilled person will not assume that the requirement in feature 1.4 refers to the entire bulk width. It should be noted that the requirement refers to the extent of the electrodes and electrode contact layers and thus to layer planes. Layer planes are two-dimensional and, according to the understanding of the skilled person, do not generally include areas that extend away from the electrode surface and do not lie in this layer plane. A requirement that refers to a specific extension of such layers will therefore not generally be understood by the skilled person to mean that the bulk width of the carrier substrate extending below such layers is relevant.

140. The two-dimensional electrodes/electrode contact layers also fulfil their function within a sensor according to the invention, namely measuring the analyte concentration in the area of their exposed surfaces (electrode surfaces) where the redox reactions take place and where the medium approaches perpendicularly. Those skilled in the art know that maximising the surface area of the electrodes – and thus their electrode surfaces – is advantageous for achieving maximum signal amplitude and is therefore sought by the patent at issue, as expressed in feature 1.2.2. In this context, too, the area of the carrier substrate in which the electrode layers are located is important, while its bulk width is irrelevant.

141. The advantages further mentioned in the patent at issue do not give rise to any other understanding either. The layer structure according to the invention, in conjunction with the large-area application of the electrodes/electrode contact layers made possible by it, enables simplified manufacture of such sensors and, in particular, the elimination of the complex structuring processes known in the prior art. Paragraph [0025] describes this as follows:

> *Since the at least two electrodes are ordered in at least two layer planes of the layer structure of the sensor, it is now possible for the at least two electrodes and/or the at least two electrode contact layers to extend essentially over the entire width of the at least one insulating carrier substrate ... Structuring of the electrodes and/or electrode contact layers is therefore no longer necessary due to the separation by the structure in different layers, so that complex lithographic structuring processes or laser structuring processes (e.g. laser ablation) can be dispensed with. ..."*

142. The fact that the electrode contact layers can be applied over a large area and do not need to be structured also allows for a structure with a high aspect ratio. The patent at issue describes this in paragraphs [0042] and [0043] as follows:

> *"[0042] However, the problem with previous sensors is that they are usually very thin and wide. This causes the layer structure to bend during penetration, so that the force required to penetrate the sensor cannot be transmitted via the sensor because it bends beforehand. The sensor according to the invention, in which the electrode contact layers are preferably applied over a large area and do not need to be structured, however, enables a structure with a high aspect ratio. The aspect ratio is understood to be the ratio between the height and width of the insulating carrier substrate and/or the entire layer structure. For example, insulating carrier substrates and/or layer structures can be used in which this aspect ratio, referred to below as k, is at least 0.3, preferably 0.5 and particularly preferably at least 0.9.*
>
> *[0043] If one wanted to achieve such aspect ratios with conventional sensors in which the electrode contact layers are structured, very thick sensors would also have to be used, since structured electrodes require a high width of the insulating carrier substrate. This in turn means a high cross-section of the sensor's penetration channel. The design according to the invention, in which a high aspect ratio is achieved while minimising the puncture area, avoids this disadvantage.*

143. In order to achieve the advantages described, it is irrelevant whether the electrodes/electrode contact layers extend across the entire width of the carrier substrate or, in the case of a carrier substrate that is not strictly rectangular in cross-section, only in the area of the electrode layers. It is true that the bulk width is important for the mechanical stability of the sensor , as the respondents emphasise. Whether the electrode /electrode contact layers extend across the entire width of the carrier substrate does not, however, affect the mechanical stability.

144. The fact that the patent at issue cites the simplification of the manufacturing process as an advantage does not mean that manufacturing must be carried out according to this process. This applies in particular with regard to the manufacturing process according to process claim 18 and the passages describing a possible manufacturing process from the general description (para. [0051] ff.) and the embodiments (para. [0072] ff.; para. [0089] ff.).

145. Claim 1 is a product claim. The manner in which the protected product is manufactured is therefore irrelevant. The

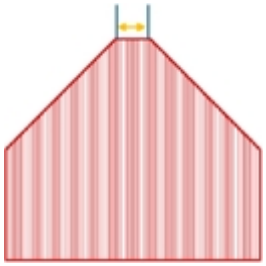
advantage sought by the invention, namely simplification of the manufacturing process, is already achieved by the mere fact that it is possible to manufacture the claimed product in this way.

146. Something else could only apply if the patent specification provides evidence that the manufacturing process is reflected in certain properties of the product or that the claimed properties can only be achieved by a very specific process. However, the layer structure described in the patent claim and the reliable electrical separation of the electrodes achieved as a result already make it possible to dispense with complex structuring processes such as those used in the prior art. Whether or not this advantage is exploited is left to the discretion of the skilled person.

147. The fact that the patent at issue does not exclude any further processing steps is also made clear in paragraph [0106], which describes the manufacture of the embodiment of an implantable sensor shown in Figure 8 as follows:

> *"... However, in contrast to Figure 6, not a single electrode contact layer but two electrode contact layers 814 and 816 are applied to the first insulating carrier substrate 810, each of which occupies approximately half the width B of the first insulating carrier substrate 810 and extends along the length of this first insulating carrier substrate 810. In terms of manufacturing technology, this can be achieved, for example,* ***by first applying a large-area electrode contact layer to the first insulating carrier substrate 810 and then using, for example, a cutting process or a laser ablation process to electrically or mechanically separate this large-area electrode contact layer into the two individual electrode contact layers 814 and 816.*** *Alternatively, both electrode contact layers 814, 816 can be applied directly, i.e. already electrically insulated from each other, to the first insulating carrier substrate 810. ..."*
>
> (Emphasis added)

148. Insofar as the respondents attempt to refute the understanding described above with the following example, the Chamber's view is that this does not change anything:



149. As already discussed, the large-area extension of the electrode layers enables maximum signal amplitude and thus reliable measurement of the analyte. For this reason alone, a person skilled in the art would reject the example given by the respondents as technically nonsensical.

Width across the longitudinal extension

150. Finally, the respondents argue that the electrodes or electrode contact areas must extend across the entire width of the carrier substrate over their entire longitudinal extension. However, there is no evidence in the patent specification to support this understanding. The considerations already outlined apply accordingly in this respect.

3. Feature realisation

151. Based on the understanding described above, it can be determined with the degree of certainty required for the order of provisional measures that the contested embodiment literally makes use of the technical teaching of patent claims 1 and 16.

a) Patent claim 1

152. It is undisputed between the parties that features 1, 1.1, 1.2.1 and 1.2.2 are literally realised in the contested embodiment. Further comments on this are unnecessary.

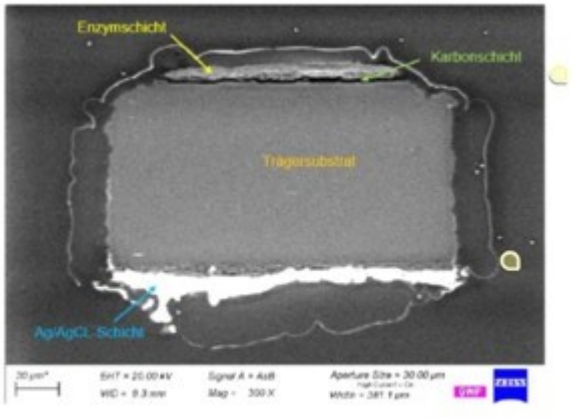
153. The contested embodiment also makes use of features 1.2, 1.3 and 1.4, which are disputed between the parties.

aa) Electrodes arranged in two different layer planes (feature 1.2)

154. The contested embodiment implements feature 1.2. The sensor of the contested embodiment comprises an insulating carrier substrate coated on both sides. On one side of the carrier substrate is the reference electrode, which comprises an Ag/AgCl electrode system. On the other side of the carrier substrate is a working electrode comprising an electrode system with an enzyme layer (MnO2/C/GOD). The reference and working electrodes are electrically separated from each other by the insulating carrier layer.

155. The electrodes of the contested embodiment have electrode surfaces, namely in the form of the outward-facing, exposed surfaces of the electrodes on which the electrochemical redox reactions take place.

156. This design of the contested embodiment, which is also not disputed between the parties, can be seen in the figure below:



157. Thus, electrodes with electrode surfaces are present, arranged with the working and reference electrodes in at least two (here: exactly two) different layer planes of the implantable sensor and electrically separated from each other by at least one (here: exactly one) carrier substrate. These are located in the layers arranged on one side and the other side of the carrier substrate and are electrically separated from each other by the carrier substrate due to its insulating properties.

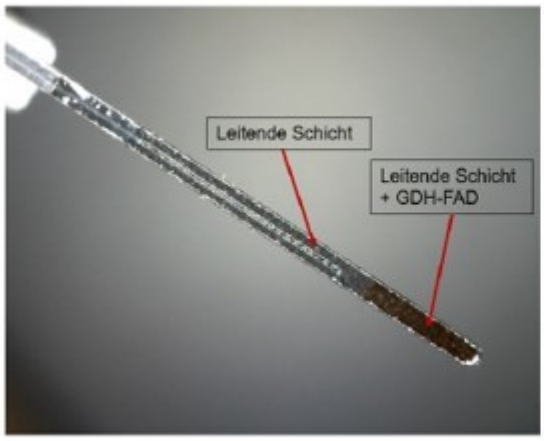
158. The fact that there is a third electrode, the counter electrode, which is arranged in the same layer as the working electrode, does not, according to the interpretation described above, constitute an infringement.

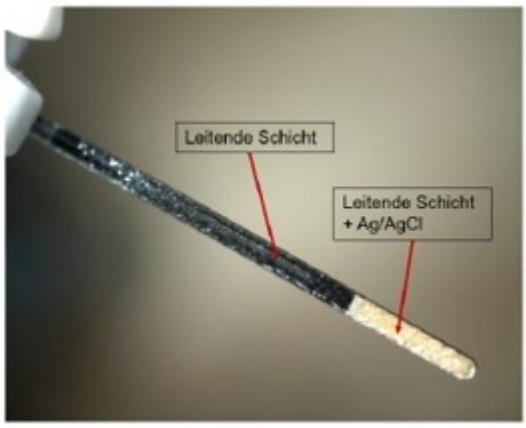
bb) The electrode contact layers electrically contacting the electrodes (feature 1.3)

159. The contested embodiment also has at least two electrode contact layers that electrically contact the electrodes.

160. As explained in the interpretation, according to the understanding of the patent at issue, the electrodes are composed of a combination of the electrode system and the electrode contact layer.

161. In the contested embodiment, part of the electrode is therefore initially a conductive carbon layer, which can be seen as black material in the following figures:





162. In addition, the Ag/AgCl layer or enzyme layer above it is also part of the electrode.

163. The conductive carbon layer is an electrode contact layer as claimed, which electrically contacts the electrodes – specifically the layers arranged above it.

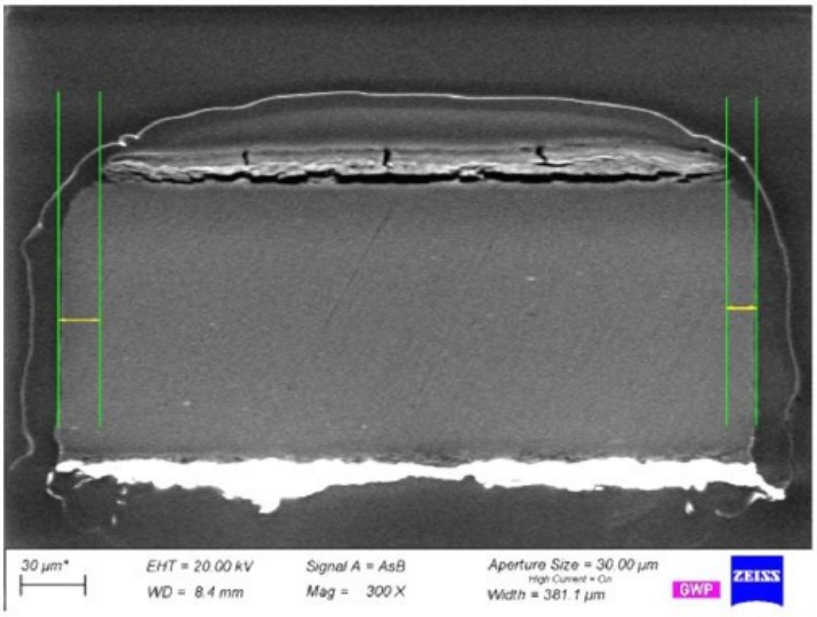
164. The fact that the carbon layer also forms the electrode contact layer, which, according to the understanding underlying the patent at issue, is to be regarded as part of the electrode, does not, according to the interpretation set out above, constitute an infringement. It is not necessary – nor is it possible according to the understanding of the patent at issue – for the electrode and the electrode contact layer to form different components.

cc) Extension of the electrodes/electrode contact layers over the entire width of the carrier substrate (feature 1.4)

165. The contested embodiment also fulfils feature 1.4 of patent claim 1. Based on the interpretation described above, the two electrodes and electrode contact layers extend across the entire width of the insulating carrier substrate.

(1) Design of the finished contested embodiment

166. The design of the contested embodiment in its finished state can be seen in the cross-sectional SEM image shown below:



167. The added green and yellow lines illustrate the respondents' view that the working electrode (top) does not extend across the entire width of the insulating carrier substrate. They mark the difference between the width of the electrode layer and the bulk width of the substrate.

168. As explained in the interpretation, the width of the insulating carrier substrate relevant to feature 1.4 in the case of a cross-section that is not strictly rectangular is the width in the area of the electrode layers. A bulk width of the carrier substrate that deviates from this is, by contrast, irrelevant.

169. Against this background, the realisation of feature 1.4 is readily apparent from the illustration shown: in the area of the electrode layers, the electrode extends across the entire width of the insulating carrier substrate, namely from one edge to the other. The relevant edges are formed by the cut edges created during the manufacture of the contested embodiment (more on this in a moment). They are illustrated in the upper figure by the inner green lines.

(2) Manufacturing process of the contested embodiment

170. Nor does anything else follow from the method used to manufacture the contested embodiment.

171–186. […]

187. As discussed in the interpretation, since this is a product claim, the process used to manufacture it is essentially irrelevant.

188. […]

b) Patent claim 16

189. The contested embodiment, which comprises not only the implantable sensor but also the other (non-implantable) parts of the sensor unit and the transmitter, is also a device for determining an analyte in a medium within the meaning of feature 16.1. In view of the realisation of claim 1, this has an implantable sensor according to one of the preceding claims (feature 16.2). The device also has at least one voltage measuring device for measuring a voltage between at least one working electrode and at least one reference electrode of the implantable sensor (feature 16.3). The realisation of the additional features of claim 16 is undisputed between the parties.

4. Infringing acts

190. It can also be established with sufficient certainty that the offer and distribution of the contested embodiment by the respondents constitutes a direct infringement of the patent at issue pursuant to Art. 25(a) UPC Agreement.

191. The respondents offer the contested embodiment in Germany, France and Italy within the meaning of Art. 25 a) UPC Agreement.

192. The term "offering" is to be understood in the economic sense. It is not to be based on the legal understanding in the sense of a binding contractual offer. An offer therefore does not need to contain all the details that would be necessary for the immediate conclusion of a contract by mere acceptance of the offer (UPC_CoA_534/2024 et al., decision of 3 October 2025, para. 205 – Belkin v. Philips).

193. On this basis, it can be established that all of the respondents have made offers. Each of the companies advertises the contested embodiment on the internet. The second applicant has also already offered the contested embodiment at a trade fair in Germany. The respondents have rightly not contested the existence of offers.

194. In Italy, the respondents also market the contested embodiment. In France and Germany, there is a threat of marketing and thus of infringement within the meaning of Article 62(4) of the UPC Agreement.

IV. Sufficiently established legal status

195. According to the case law of the Court of Appeal, there is insufficient conviction as to the validity of the patent within the meaning of Rule 211(2) of the RoP to issue an order for provisional measures if the Court considers it highly probable that the patent is invalid. The burden of proof and presentation of facts concerning the invalidity of the patent lies with the respondent (UPC_CoA_335/2023, order of 26 February 2024, p. 30 – 10x Genomics v. Nanostring).

196. Applying these principles, the court is unable to determine with a high degree of probability that the patent is invalid.

197. It should first be noted that the patent at issue was granted in 2009 without

A preliminary objection has been filed against its grant or the legal validity of the patent at issue has been challenged by way of national nullity proceedings. A US patent with even broader claims has also been granted.

198. But even independently of this, the respondents' arguments do not make it appear highly probable that the patent at issue will not prove to be legally valid.

1. Effective claim to the priority of P1 (EP05/027,755)

a) Standard of priority examination

199. Pursuant to Art. 87 EPC, any person who has duly filed an application for a patent, a utility model or a utility model certificate, or their successor in title, shall enjoy a right of priority for the application of the same invention for a European patent during a period of twelve months from the filing date of the first application. This right may be claimed pursuant to Art. 88 EPC. The effect of the right of priority is that the priority date is deemed to be the filing date of the European patent application for the purposes of determining the state of the art (Article 89 in conjunction with Article 54(2) and (3) EPC).

200. The term "the same invention" in Art. 87 EPC is to be interpreted as meaning that a claimed invention is to be regarded as the same invention as the invention in an earlier application if the skilled person can derive the subject-matter of the claim directly and unambiguously from the earlier application as a whole using general technical knowledge (see UPC_CFI_1/2023 (ZK Munich), decision of 16 July 2024 – Sanofi v. Amgen). The decisive factor is what the skilled person, using their general technical knowledge and viewed objectively, can directly and unambiguously derive from the entire application filed at the time of filing, whereby an implicitly disclosed subject matter, i.e. a subject matter that can be clearly and unambiguously derived from what is expressly stated, must also be considered part of the content (UPC_CFI_115/2024, decision of 15 October 2025, para. 110 – Hartmann Packaging v. Omni-Pac; UPC_CFI_461/2024 (LD Hamburg), decision of 5 November 2025, headnote 1 – Dolle v. Fakro).

b) Examination in individual cases

201. On this basis, it is probable, to the extent necessary for the order of provisional measures, that the patent at issue effectively claims the priority of P1 of 19 December 2005.

aa) Electrically separated electrodes with electrode surfaces (feature 1.2)

202. P1 directly and clearly discloses electrodes with electrode surfaces that are electrically separated from one another.

203. This disclosure can be found on page 7, last paragraph, to page 8, first paragraph, of P1. It states:

> *"The design of the at least two electrodes can be varied in different ways. In particular, the at least two electrodes can comprise, as described above, at least one*

> *working electrode and at least one further electrode, which has at least one counter electrode and at least one reference electrode. In particular, the at least one counter electrode should have a redox behaviour that is opposite to that of the at least one working electrode. A counter electrode and a reference electrode may also be designed as a common electrode,* ***preferably as a common electrode whose area is larger than the area of the at least one working electrode.*** *Examples of the use of electrode materials for electrochemical measurement methods are known from the prior art.* ***For example, electrodes can be coated with enzymes or other chemical additives that are specific to the analyte to be detected. For example, glucose oxidase (GOD), which converts glucose into gluconolactone, can be used to detect glucose. The charge carriers released in this process are detected.*** *To enable this detection, overvoltage-reducing materials are used, which serve as "charge mediators" between the medium and the electrodes.*
>
> (Emphasis added)

204. It can be seen from these explanations that the surface area of the working electrodes is formed, for example, by enzyme-containing coatings on which electrochemical reactions
, e.g. for glucose detection. This disclosure refers preferably to a common electrode formed by a counter electrode and a reference electrode, but is not limited thereto.

205. The fact that the electrodes are electrically separated from each other can be directly and unambiguously inferred from the disclosure on page 5, second paragraph of P1, which reads:

> *The working electrode and the at least one further electrode are ordered in different layers of the layer structure . In particular, is understood*
> *"different layer levels" is to be understood as meaning that at least one insulating carrier substrate is arranged between the at least two electrodes, so that at least two of the at least two electrodes are separated by the insulating carrier substrate. Thus, in contrast to the prior art described above, the "third dimension" is also utilised in this structure of an implantable sensor.*

206. Furthermore, the electrical separation of the electrodes in connection with the manufacture of the "sandwich layer structure" of the sensor is directly and unambiguously disclosed in Figure 1 on page 14, last paragraph, to page 15, second paragraph:

> *"In one step of the process, a layer structure is created, in particular a 'sandwich' structure.*
> *"Layer structure" or a similar multi-layer structure as described above,* ***wherein two electrode contact layers, in particular two metal layers, are applied over a large area in at least two different layer planes to at least one carrier film comprising at least one non-electrically conductive material.*** *The materials described above can be used, for example, for the metal layers and the at least one carrier film. Furthermore, at least two electrodes are applied to the at least two electrode contact layers, whereby the materials described above can again be used. The layer structure is then cut into sensor strips using a precision cutting process.*
>
> *In contrast to the prior art, the method according to the invention involves applying electrode contact layers over a large area and in at least two different layer planes. An additional structuring of the at least two*

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> *electrode contact layers is preferably not carried out. This avoids the need for complex lithographic structuring processes.* ***Nevertheless, the electrode contact layers and thus also the electrodes are electrically separated from each other, as they are arranged in different layer planes****.*
>
> (Emphasis added)

bb) Electrode surfaces facing the medium (feature 1.2.1)

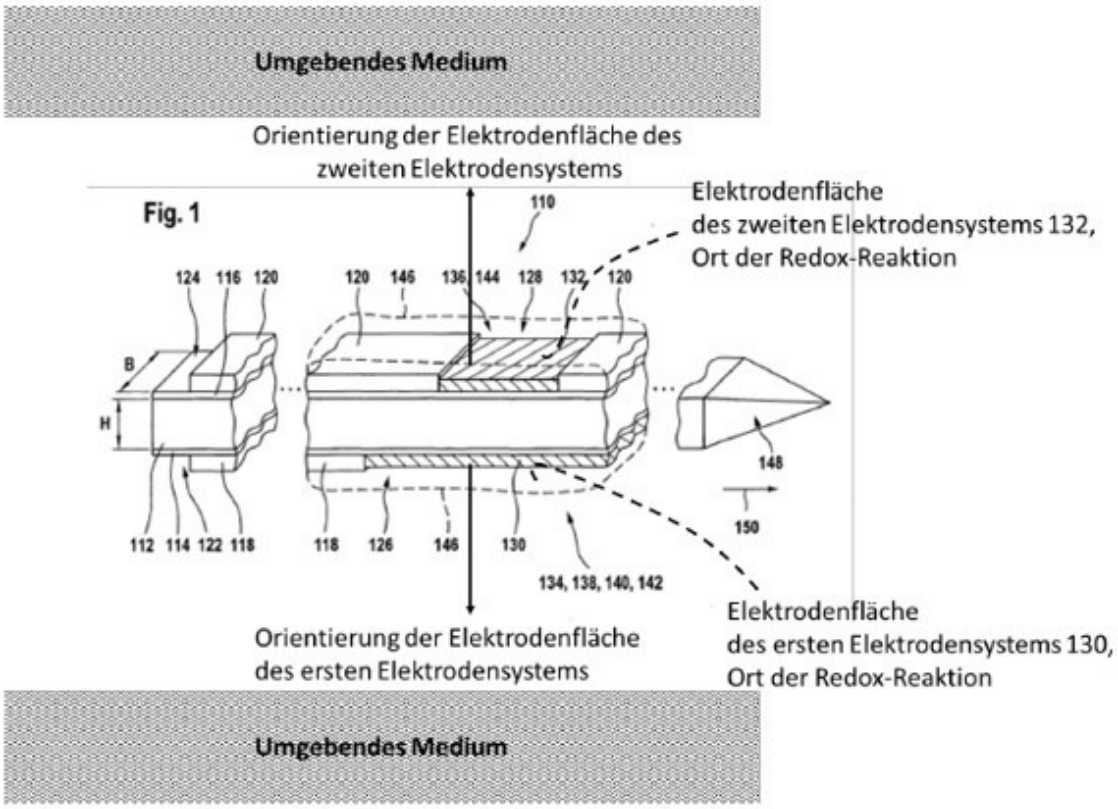
207. The requirement that the electrode surfaces face the medium when the sensor is implanted is also disclosed directly and unambiguously in P1.

208. This is evident from the following description on page 7, first paragraph, of P1:

> *"... However, it is particularly preferable if the implantable sensor can be inserted directly, i.e. without a surrounding cannula or capillary,* ***into the medium****,* ***in particular the body tissue (sic)****.* ***This ensures that the electrodes arranged in at least two planes can be freely surrounded by body fluid.*** *For this purpose, the implantable sensor may have at least one membrane layer that completely or partially encloses the layer structure. Advantageously, this at least one membrane layer is at least partially permeable to the at least one analyte to be detected*
>
> (Emphasis added)

209. This description implies that the electrodes face the medium. The specialist knows that the electrodes could not be surrounded by the medium if they
covered with top layers, for example.

210. Figure 1 of P1, annotated by the applicants, illustrates this:



211. From Figure 1 of P1, which is identical to Figure 1 of the patent at issue, the electrode surfaces facing the medium are immediately and unambiguously apparent to the skilled person. The skilled person knows where the medium is located in the illustration of the sensor and can easily read the corresponding orientation. The same applies to Figure 2 of P1, which is identical to Figure 2 of the patent at issue.

212. Furthermore, the description already cited above on page 7, last paragraph, to page 8, first paragraph, of P1 describes the mode of action of overvoltage-reducing materials using the example of the enzyme GOD. According to this description, the overvoltage-reducing materials serve "... quasi as 'charge mediators' between the medium and the electrodes" (page 8, lines 4 ff. of P1). Experts know that such a mode of action is only possible if the surfaces of the electrodes that "exhibit a ... redox behaviour" (page 7, lines 31 ff. of P1) face the medium.

cc) Electrode surfaces that are in direct contact with the medium over a large area and in a substantially uniform manner, either directly or via an analyte-permeable membrane layer (feature 1.2.2)

213. The requirement that the electrode surfaces are in direct contact with the medium over a large area and in a substantially uniform manner, either directly or via an analyte-permeable membrane layer, can also be derived directly and unambiguously from P1.

214. The passage already cited on page 7, first paragraph, of P1 shows that the electrode surfaces can be assigned to the medium directly or via a membrane:

> *"... However, it is particularly preferable if the implantable sensor can be* ***inserted directly****, i.e. without a surrounding cannula or capillary****, into the medium, in particular the body tissue (sic)****. This ensures that the electrodes arranged in at least two planes can be freely surrounded by body fluid. For this purpose, the implantable sensor may have at least one* ***membrane layer*** *that completely or partially encloses the layer structure.* ***Advantageously****,* ***this at least one membrane layer is at least partially permeable to the at least one analyte to be detected****.*
>
> (Emphasis added)

215. The fact that this is a "large-area" contact is evident from page 11, line 16 of P1, according to which the "electrode contact layers are preferably applied over a large area". According to the disclosure of P1, the electrode contact layers and/or the electrodes extend "essentially from one edge of the insulating carrier substrate to the other" (page 6, lines 6 f. of P1). From this, it is immediately and unambiguously clear to the skilled person that the electrode surfaces contact the medium over a large area.

216. The skilled person can also immediately and unambiguously conclude from P1 that the contact between the electrode surfaces and the medium is "essentially uniform" within the meaning of feature 1.2.2. The passage already cited on page 7, first paragraph, shows that the electrodes can be surrounded by body fluid (page 7, lines 5 ff. of P1). The skilled person knows that the body fluid (= analyte) therefore uniformly impinges on the electrode surfaces, since the body fluid – unlike in the prior art (see page 3, lines 31–36 of P1) – has unhindered access to the electrode surface and there are no local concentration distortions.

217. The term "essentially" uniform will be understood by the skilled person to mean within the tolerance range, as is apparent from general technical knowledge and does not require any specific disclosure. The skilled person knows that certain differences in the concentration of the analyte can arise, e.g. due to the type of measurement (intermittently every 5 minutes or continuously, see page 14, lines 10-13). Against this background, there is no inadmissible intermediate generalisation.

218. In all other respects, the explanations relating to feature 1.2.1, to which reference is made, apply.

2. Novelty

219. The subject matter of claims 1 and 16 is novel in relation to the prior art cited by the application opponents, with the degree of probability required for the order of provisional measures, Art. 54 EPC.

a) Standard of novelty examination

220. An invention is considered new if it does not belong to the state of the art. Assessing novelty within the meaning of Article 54(1) EPC requires determining the overall content of the prior publication. The decisive factor is whether the subject-matter of the patent at issue, with all its features, is directly and unambiguously disclosed in the citation (UPC_CoA_182/2024, order of 25 September 2024, para. 123 – Mammut v. Orto-vox). As already explained, the court must apply the same interpretation of the

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scope of protection, regardless of whether an infringement of the patent at issue or its legal validity is being examined (UPC_CoA_335/2023, order of 26 February 2024, headnote 2 and p. 26 f. – 10x Genomics v. Nanostring).

b) Application in the case in dispute

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

aa) Novelty in relation to WO '447

222. WO '447 is a subsequently published prior art within the meaning of Art. 54(3) EPC. It must therefore be taken into account in the novelty examination.

223. WO '447 does not directly and unambiguously disclose that the at least two electrodes and/or the at least two electrode contact layers extend "across the entire width" of the at least one insulating carrier substrate (feature 1.4 of the contested patent).

(1) Disclosure of WO '447

224. WO '447 discloses implantable sensors with a layered structure or "sandwich structure", which is shown, for example, in Figure 1b in a longitudinal cross-section along the dotted line in a top view of the sensor according to Figure 1a:

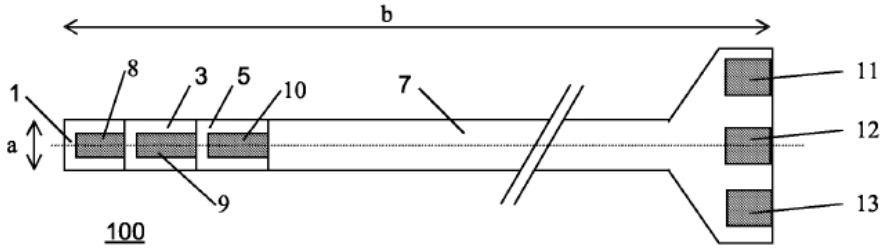


Figure 1a

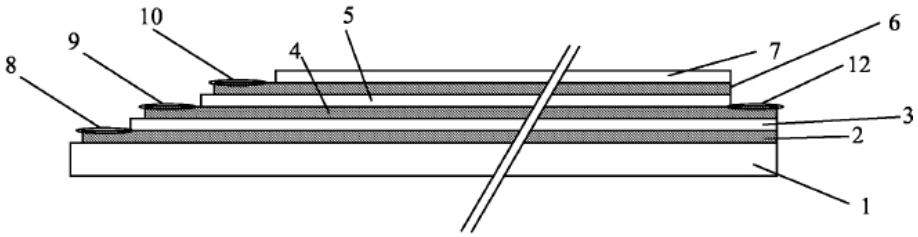


Figure 1b

225. The cross-section in Figure 1b shows that the sensor has electrodes 8, 9, 10, which are connected via the conductive layers 2, 4, 6 (layers marked in grey) to the contact surfaces 11, 12, 13 for contacting a measuring device.

226. The top view according to Figure 1a shows three contact surfaces 11, 12, 13. The cross-section according to Figure 1b, on the other hand, shows only the contact surface 12 belonging to electrode 9, which is connected via the conductive layer 4. The electrodes and the conductive layers are electrically separated from each other by the dielectric substrate 1 and the dielectric layers 3, 5 and 7.

The steps for manufacturing the sensor according to Figures 1a and 1b are shown in Figure 2:

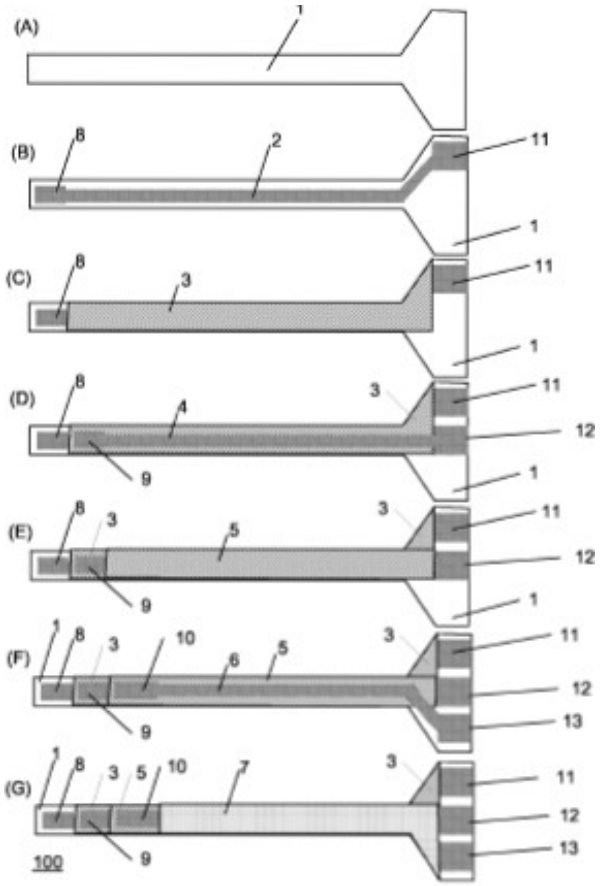


Figure 2

(2) Lack of disclosure of feature 1.4

227. In WO '447, the widths of the electrodes and electrode contact layer in all figures are smaller than the width of the dielectric substrate and the dielectric layers. This applies not only to the sensors shown, but also to the sensors with two or three layers shown in Figures 5 to 8. This is clearly evident from Figures 6 to 8, which show cross-sections along line c-c in Figure 5.

228. Contrary to the respondents' opinion, a disclosure of feature 1.4 cannot be inferred from Figure 3 in conjunction with various passages of the description.

229. Figure 3 is a top view of a sensor with three electrodes 8, 9, 10:

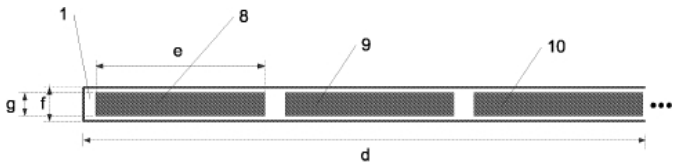


Figure 3

230. The respondents derive the disclosure of feature 1.4 from the fact that a range of 0.1–0.3 mm is specified for the electrode width g, whereby the two end points, including the upper end point of 0.3 mm, are individualised. Thus, the combination of an electrode width of g = 0.3 mm and a dielectric layer width of f = 0.3 mm is individualised and therefore disclosed.

231. In this context, they refer in particular to page 21, paragraphs 3, 4 and 5 of WO '447 and page 23, paragraph 2 of WO '447. These read as follows:

> Page 21, paragraphs 3, 4 and 5:
>
> *Figure 3 schematically illustrates an electrode assembly for a three-electrode system according to an embodiment of the present invention. Shown is a part of a three-electrode assembly that is used for insertion into the skin of a user. The shown part of the assembly comprises a dielectric substrate (1) comprising a first, a second and a third electrode surface (ES) (8, 9, 10), respectively, corresponding to those explained above and below. The part shown has an indicated length 'd', which may vary according to design issues/decisions. An exemplary length 'd' is, for example, 5 mm. The part shown has an indicated width f, which may also vary. An exemplary width 'f' is 0.3 mm.*
>
> *Each ES has a length 'e', which may depend on various design issues/decisions. An exemplary length 'e' is e.g. 1.5 mm, but this may vary. Each ES has a width 'g', which may also depend on various design issues/decisions. An exemplary width 'g' is e.g. 0.2 mm.*
>
> *As mentioned, the various sizes may vary and the above values merely serve as examples for illustrative purposes. Typically, the length 'd' is, for example, in the interval 3-8 mm, but may vary.*
>
> Page 23, 2nd paragraph:
>
> *To achieve a good signal-to-noise ratio with a cost-effective potentiostat, an in-vivo amperometric glucose sensor working electrode should not be significantly smaller than 0.25 mm². To decrease tissue damage and pain, the sensor width 'f' should be about 0.3 mm and the length 'd' of the active area (housing all electrodes) should be a maximum of 5 mm. Using the 3D sandwich structure of the present invention for a three-electrode system with the same size on all sensors, the maximum electrode area that can be housed on the sensor is 0.3 mm^2(0.05 mm left along the side, 0.1 mm on the tip and 0.2 mm between the electrodes) as illustrated in Figure 3 giving the above values. When usual 2D electrode geometry is used, it is not possible to make a three-electrode sensor when the line-and-space definition is 50 um (this width is common for many technologies). With a line-and-space definition of 40 um, the electrode area can be 0.117 mm^2; correspondingly, 30 um gives 0.183 mm^2as illustrated in Figure 4 using the above values. To be close to^0.25 mm^2, a line-and-space definition of less than 20 µm is needed (20 µm gives 0.230 mm^2), which requires quite expensive techniques during production.*

232. This does not provide any immediate and clear indication of an extension of the at least two electrodes and/or the at least two electrode contact layers "across the entire width" of the at least one insulating carrier substrate.

Figure 3 shows a different design

233. Figure 3 does not show a design in which the electrodes are arranged in different layer planes within the meaning of the teaching of the patent at issue.

234. Figure 3 of WO '447 is a top view of a sensor in which only a dielectric substrate 1 and the three electrodes 8, 9 and 10 are visible. The third-last paragraph on page 21 of WO '447 is shown here:

> *Figure 3 schematically illustrates an electrode assembly for a three-electrode system according to an embodiment of the present invention. Shown is a part of a three-electrode assembly that is used for insertion into the skin of a user.* ***The shown part of the assembly comprises a dielectric substrate (1) comprising a first, a second and a third electrode surface (ES) (8, 9, 10),*** *respectively, corresponding to those explained above and below. The part shown has an indicated length 'd', which may vary according to design issues/decisions. An exemplary length 'd' is, for example, 5 mm. The part shown has an indicated width 'f', which may also vary. An exemplary width 'f' is 0.3 mm."*
>
> *(Emphasis added)*

235. This differs from the 3D order shown in Figure 1b, as can be seen, for example, by comparing Figures 1a and 3. Figure 1a shows the three substrates 1, 3 and 5 arranged one above the other, while Figure 3 shows only one substrate 1. The top view of Figure 3 is therefore compatible with a design in which all three electrodes are arranged on the same substrate in one plane.

236. Nothing else follows from page 22, third paragraph of WO '447, which states:

> *"... According to the present invention, as e.g. shown in Figure 3, the conductive tracks are located above/below each other in the 3D/sandwich type assembly of the present invention, thereby making it possible to use the entire space across the sensor/assembly for the ESs."*
>
> (Note: ES = electrode surface)

237. This paragraph merely discloses that the electrode contact layers (conductive tracks) are arranged one above the other, which can be achieved, for example, by partially insulating the electrode contact layers. An order in which the electrodes are arranged in different layer planes is not disclosed.

No arbitrary combination of values

238. Furthermore, no immediate and unambiguous disclosure results from any combination of the values specified in the passages cited.

239. Firstly, according to the disclosure content of WO '447, the second and third paragraphs on page 21 on the one hand, and the last paragraph on page 21 and the first paragraph on page 22 on the other, each form a unit whose disclosure cannot be easily combined.

240. The second and third paragraphs on page 21 refer to an exemplary embodiment for which a specific combination of values d, e, f and g is specified. The electrodes are spaced apart and do not extend across the entire width of the electrical layer.

241. In contrast, the two following paragraphs (page 21, last paragraph, and page 22, first paragraph) provide four ranges from which four specific individual values would have to be selected (taking into account obvious constraints, e.g. that the width of the electrodes and the electrode layers g must not be greater than the width of the dielectric substrate).

242. However, WO '447 does not contain any clues as to how these specific individual values should be combined. The selection of the identical value for the width of the electrode (g = 0.3 mm) and the width of the dielectric layer (f = 0.3 mm) appears to be purely arbitrary.

bb) Novelty compared to US '006

(1) No prior art within the meaning of Article 54(2) and (3) EPC

243. Patent application US '006 was filed on 17 November 2005 and published on 4 May 2006. Since the patent at issue effectively claims the first priority of 19 December 2005, US '006 is not prior art. Patent applications published after the filing date which are not European patent applications or patents are not prior art within the meaning of Art. 54(3) EPC.

(2) In any case, no novelty-destroying anticipation

244. However, even if one were to assume that US '006 is prior art within the meaning of Art. 54(2) EPC to be taken into account in the novelty examination, it would not anticipate the teaching of the patent at issue in a manner prejudicial to novelty.

(a) Implantable sensor (features 1, 1.1, 1.2, 1.3)

245. US '006 does not directly and clearly disclose an implantable sensor.

246. For illustrative purposes, Figures 1 and 2 of US '006 are shown below, which show a first embodiment of a sensor strip according to the teaching of US '006 in perspective view and as an exploded view:

FIG. 1

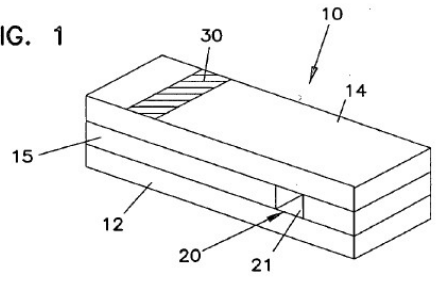
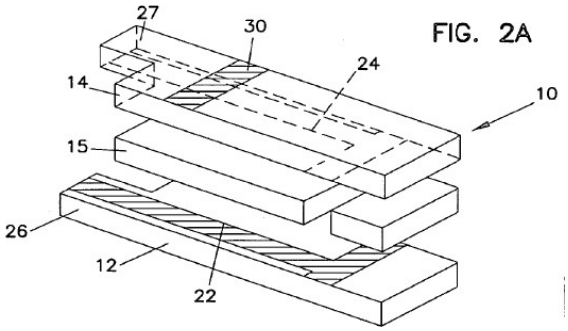


FIG. 2A



247. The sensor strip has a three-dimensional structure, with the working electrode 22 applied to the upper side of the first substrate 12. The working electrode has an L-shaped form, with the lower leg of the L extending across the entire width of the substrate 12. The counter electrode 24 is applied to the lower side of the second substrate 14 (shown as dashed lines in the exploded view of Figure 2A) and has an L-shape that is mirror-inverted relative to the working electrode, with the lower leg of the L of the counter electrode extending across the entire width of the second substrate. Element 30 is not an electrode, but an insertion monitor (para. [0088] ff.).

248. Between the two electrodes there is a non-conductive spacer 15, which is not continuous but leaves a sample chamber 20, which is bounded at the top and bottom by the two L-shaped legs of the working and counter electrodes 22, 24.

249. The sensor of US '006 is a test strip. For testing, a sample of the analyte is placed in the analysis chamber. Figure 1 shows that the working and counter electrodes 22, 24 are only in contact with the sample placed in the sample chamber.

250. In any case, it is not immediately and clearly disclosed that such an in vitro product (test strip) would be suitable as an in vivo product and thus "implantable" within the meaning of the teaching of the patent at issue.

(b) Electrodes electrically separated from each other by the insulating carrier substrate (feature 1.2)

251. Electrodes electrically separated from each other by an insulating carrier substrate are also not directly and unambiguously disclosed in US '006.

252. In the figures shown above, the spacer layer 15 is not continuous and is missing in the area of the sample chamber, so that the working electrodes 22, 24 are not electrically separated from each other by the spacer layer 15.

(c) Electrode surfaces facing the medium and in large-area and essentially uniform contact with it (features 1.2.1, 1.2.2)

253. US '006 also does not directly and unambiguously disclose the requirements of features 1.2.1 and 1.2.2, according to which the electrode surfaces of the implanted sensor face the medium and are in contact with the medium over a large area and in a substantially uniform manner, either directly or via an analyte-permeable membrane layer.

254. The electrode surfaces in the figures shown above do not face outwards and are in large-area and uniform contact with the analyte in the sample chamber 20, but not with the surrounding medium. Nor do they face the surrounding medium. The analyte is drawn into the sample chamber by capillary forces.

cc) Novelty compared to US '871 and US '137

255. For the first time in their rejoinder, the respondents argue that if the applicants' interpretation is accepted, according to which the term "across the entire width" does not reflect complete coverage of the width, i.e. 100%, claim 1 would also lack novelty in relation to US '871 and US '137, as these also disclosed the corresponding feature.

256. It can be left open whether this attack is still to be taken into account from the point of view of delay. In any case, it does not reveal any anticipation of the teaching of the patent at issue that would destroy novelty.

257. In any case, US '871 does not disclose feature 1.4. In this respect, reference can be made to the following comments on inventive step. This applies mutatis mutandis to US '137, which uses the same figures.

3. Inventive step

258. The subject matter of claims 1 and 16 is based on an inventive step, Art. 56 EPC, with the degree of probability required for the order of provisional measures, as opposed to the prior art cited by the respondents.

a) Standard for assessing inventive step

259. According to Art. 56 EPC, an invention is considered to involve an inventive step if it is not obvious to a person skilled in the art from the prior art.

260. According to the case law of the Board of Appeal, the following procedure should be followed when assessing inventive step (see UPC_CoA_464/2024, decision of 25 November 2025, headnotes 7 ff., para. 131 ff. – Meril v. Edwards; UPC_CoA_528/2024, decision of 25 November 2025, headnotes 10 ff., para. 126 ff. – Amgen v. Sanofi; see also UPC_CoA_335/2024, order of 26 February 2024, p. 34 et seq. – Nanostring v. 10x Genomics):

261. First, it must be determined what the subject matter of the invention is, i.e. the objective task (the objective technical problem) must be identified. This must be assessed from the perspective of a person skilled in the art with their general technical knowledge at the time of filing or the priority date of the patent (relevant date). To this end, it must be determined what contribution the invention makes to the state of the art, not by considering the individual features of the claim, but by comparing the claim as a whole in conjunction with the description and drawings, taking into account the inventive concept underlying the invention (the technical teaching), which must be based on the technical effect or effects that the skilled person understands to be achieved on the basis of the application with the claimed invention.

262. In order to avoid retrospective consideration, the objective problem should not contain any references to the claimed solution.

263. The claimed solution is obvious if, at the relevant time, the skilled person, starting from a realistic starting point in the prior art in the relevant technical field and with the aim of solving the objective problem, would have arrived at the claimed solution and not only could have arrived at it.

264. The relevant technical field is the specific field relevant to the objective task to be solved, as well as any field in which the same or a similar problem occurs and which must be expected to be known to the person skilled in the specific technical field.

265. A starting point is realistic if its teaching would have been of interest to a person skilled in the art who, at the relevant time, wished to solve the objective problem. This may be the case, for example, if the relevant prior art already discloses several features similar to those of the claimed invention and/or addresses the same or a similar underlying problem as that of the claimed invention. There may be more than one realistic starting point, and the claimed invention must be inventive based on each of these starting points.

266. The skilled person has no inventive skills or imagination and needs a clue or motivation that prompts them, starting from a realistic starting point, to take the next step towards the claimed invention. As a rule, a claimed solution is to be regarded as non-inventive/obvious if the skilled person would take the next step on the basis of the clue or routinely and arrive at the claimed invention.

267. For inventive step to be present, it is not necessary to demonstrate an improvement in the claimed technical teaching over the prior art. Inventive step may also be present if the patent claims disclose a non-obvious alternative to the solutions known in the prior art.

b) Application in the case in dispute

268. Measured against this, the respondents' submissions are not sufficient to cast doubt on the existence of inventive step with the required degree of probability.

aa) Determination of the objective task of the patent at issue

269. In the opinion of the Chamber, the task can also be objectively determined by specifically naming the disadvantages to be avoided from the prior art, namely to provide an implantable sensor and a measuring device contained therein and a corresponding manufacturing method for the sensor, which have the following characteristics:

- Simple, cost-effective and reliable manufacturing process;
- Avoids local concentration distortions, which occur particularly in capillary sensors;
- Sufficient signal amplitude at physiologically acceptable currents and voltages.

270. In the opinion of the Chamber, however, avoiding lithographic or microstructuring processes is only one aspect of the desired simplification and cost-effective design of the manufacturing process.

bb) Inventive step based on US '871

271. No inventive step can be derived from US '871.

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272. In this regard, it can be assumed in favour of the respondents that US '871 is a realistic starting point.

(1) Consideration of US '871 alone

273. The respondents argue that a lack of inventive step already results from US '871 alone.

274. US '871 discloses electrochemical sensors in Figures 2A to 2C, 4A and 4B, as well as in Figures 10A and 10B.

(a) Sensor according to Figures 2A to 2C

275. The embodiment according to Figures 2A to 2C was already the subject of examination in the grant procedure. This is because the sensor according to Figures 2A to 2C was taken from US '137, referred to there as D1, in the international examination procedure on the basis of which the patent at issue was granted (see paragraph [0097] of US '871).

276. The sensor according to Figures 2A to 2C, shown here initially in the side view according to Figure 2A, shows a three-dimensional layer structure:

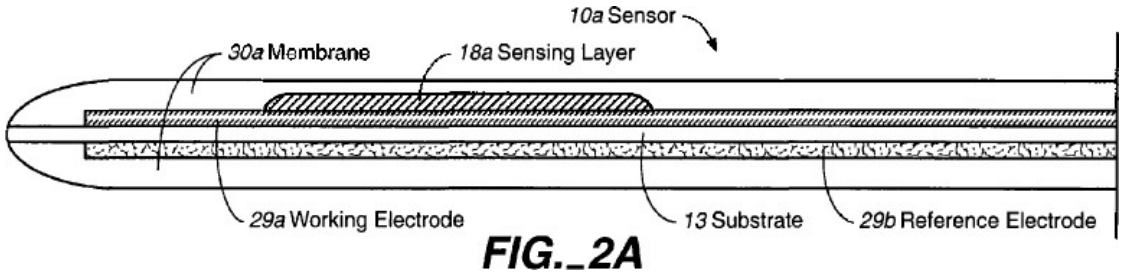

FIG._2A

277. Figure 2A is described in paragraph [0097] of US '871 as follows:

> *"... The amperometric glucose sensor 10a of FIG. 2 comprises a substrate 13 disposed between a working electrode 29a that is typically carbon-based, and an Ag/AgCl counter/reference electrode 29b. A sensor or sensing layer 18a is disposed on the working electrode. ..."*

278. The manufacture of the transcutaneous sensor shown in Figures 2A to 2C is described in paragraphs [0093] to [0097] of US '871. The sensing layer 18a, which contains glucose oxidase (GOD), corresponds to the electrode system layer of the patent at issue, while the working electrode is the associated electrode contact layer.

279. Figures 2B and 2C show top views from above and below (cf. para. [0019] of WO '871):

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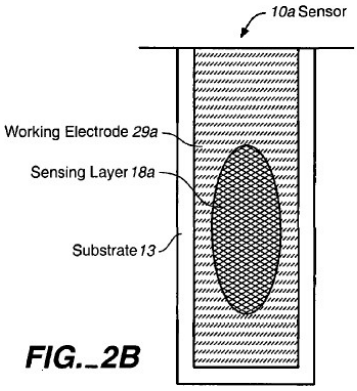

FIG._2B

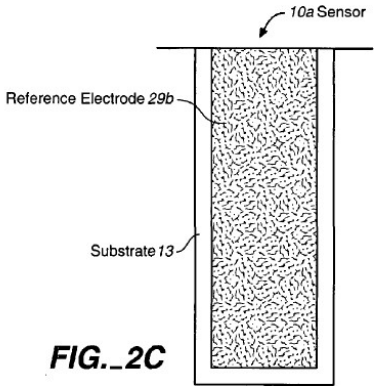

FIG._2C

280. The top views show that the working electrode 29a in Figure 2B and the reference electrode 29b in Figure 2C do not extend across the entire width of the substrate 13 and therefore do not disclose feature 1.4 of the patent at issue.

281. The respondents emphasise that the working electrode (electrode contact layer) consists of carbon ink and refer to paragraph [0096] of US '871. They state that carbon ink can be applied by a screen printing process and that such a printing process is compatible with a design of the electrode layers across the entire width of the substrate. This may be true. However, the compatibility resulting from retrospective consideration does not provide any motivation for the skilled person to modify the electrode geometry of US '871 in such a way that the electrode geometry according to the invention is obtained. Accordingly, there is no pointer in US '871 that would indicate the preferred method according to claim 18, which combines large-area application of the electrodes with subsequent separation of the sensors according to the invention by means of cutting.

282. Furthermore, US '871 discloses that the use of catalytic sensor layers results in measurement data of higher accuracy and lower noise compared to conventional electrodes (para. [0122] of US '871), so that there would have been no incentive for the skilled person to increase the signal amplitude by using a larger electrode area.

(b) Sensor according to Figures 4A and 4B

283. Figures 4A and 4B shown below illustrate a further embodiment of a sensor:

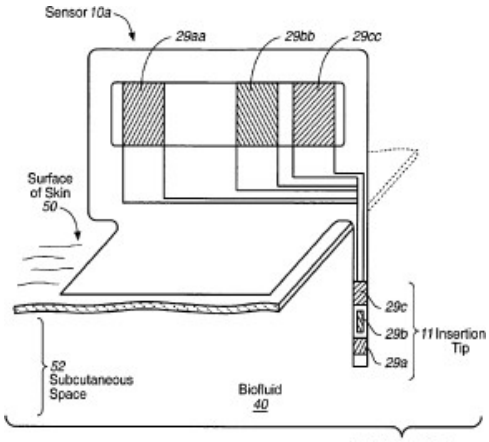

FIG._4A

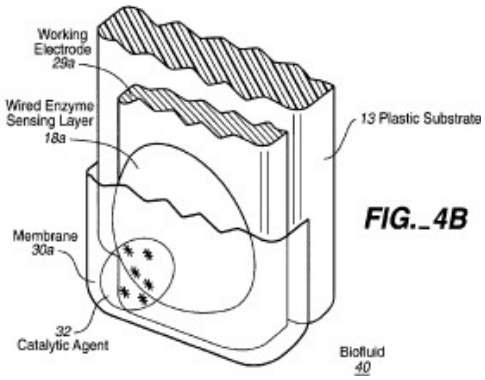

FIG._4B

284. The figures are described in paragraph [0105] of US '871 as follows:

> *FIGS. 4A and 4B, together, illustrate a fully fabricated sensor, with a catalytic agent incorporated into a protective membrane, as the sensor would be seen placed on the skin, with a portion of the sensor transcutaneously inserted into the subcutaneous space.* ***FIG. 4A provides a perspective view of a sensor 10a****, the major portion of which is above the surface of the skin 50,* ***with an insertion tip 11 penetrating through the skin and into the subcutaneous space 52, where it is bathed in biofluid 40****. Contact portions of a working electrode 29aa, a reference electrode 29bb, and a counter electrode 29cc can be seen on the portion of the sensor 10a situated above the skin surface.* ***Working electrode 29a, a reference electrode 29b, and a counter electrode 29c can be seen at the end of the insertion tip 11.*** *FIG. 4B provides an expanded and cutaway view of sensor insertion tip 11.* ***The working electrode 29a is shown resting on top of a plastic substrate 13, a wired enzyme sensing layer 18a rests on top of a portion of the working electrode 29a.*** *…"*
>
> (Emphasis added)

285. Figures 4A and 4B do not disclose features 1.1, feature group 1.2 or feature 1.4.

286. The embodiment according to Figures 4A and 4B does not have a layered structure within the meaning of feature 1.1 and feature group 1.2. Figure 4A is merely a top view that does not reveal any layered structure. It is a schematic representation showing the entire monitoring system, including the extracorporeal device for connecting a measuring device and the order of the subcutaneously inserted sensor in relation to the skin. The specialist cannot readily derive specific dimensional relationships from a schematic representation.

287. In the detailed perspective view shown in Figure 4B, a substrate 13 can be seen which has a working electrode 29a on only one side, the width of which is smaller than the width of the substrate. A catalytic agent is applied to part of the working electrode. This structure corresponds to the upper part of Figure 2A. Thus, Figures 4A and 4B do not disclose feature 1.4.

288. In contrast to the sensor in Figure 2A, however, the sensor in Figure 4B has no electrode and no electrical leads on the side of the substrate opposite the working electrode.

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289. Figures 4A and B therefore disclose a two-dimensional structure of the sensor, with the working electrode, reference electrode and counter electrode applied next to each other on one side of the substrate. Nothing else can be inferred from a combined view of Figures 4A and 4B.

(c) Combination of the sensor according to Figures 2A to 2C with the sensor according to Figures 4A and 4B of US '871

290. Since, in the opinion of the Board, neither the embodiment according to Figures 2A to 2C nor that according to Figures 4A and 4B disclose an extension of the working and counter electrodes over the entire width of the substrate, the combination of embodiments asserted by the respondents is irrelevant. In any case, there is also no motivation for such a combination. A person skilled in the art would not carry out such a combination.

291. The respondents argue that the design of the sensor according to Figures 2A to 2C, with working and counter electrodes extending across the entire width of the substrate as shown in Figure 4A, would simplify manufacture. The electrode edges would no longer need to be removed. Conversely, the skilled person would have had reason to transfer the three-dimensional layer structure of the sensor according to Figures 2A to 2C to the sensor according to Figures 4A and 4B in order to electrically separate the overlapping electrode contact layers from each other and to simplify the manufacturing process. Insofar as, according to paragraph [0122] of the contested patent specification, the use of a "catalyst" results in higher accuracy and less noise, this does not prevent the skilled person from making further optimisations. In particular, they would have considered extending the electrodes across the entire width of the substrate, as shown in Figure 4A, in order to maximise the signal amplitude. In the respondents' view, the skilled person would have had high expectations of success for extending the electrodes across the entire substrate width, as this would be easily possible with the carbon ink disclosed in paragraph [0096] of US '871. Furthermore, it is common knowledge in the art to use carbon ink for electrode production by means of screen printing.

292. The Board does not share this view. The sensor geometries of the embodiments disclosed in Figures 2A to 2C on the one hand and 4A and 4B on the other hand differ fundamentally from each other in terms of design. This applies in particular with regard to the two-dimensional design and the layered structure, which represent fundamentally different approaches. The Chamber cannot see any reason for a person skilled in the art to combine both designs. If the person skilled in the art had nevertheless made such a combination, it would not have led to the sensor design according to the invention, as mentioned at the receipt, because feature 1.4 is not disclosed in Figures 2A to 2C or in Figures 4A and 4B.

(2) US '871 in combination with US '999

293. Based on US '871, the skilled person had no reason to refer to US '999, nor would they have been able to arrive at the teaching of the patent at issue even if they had referred to US '999. The designs of US '999 and US '871 differ fundamentally from each other, so that there would have been no motivation for the skilled person to combine the references.

294. US '999 discloses, among other things, sensors with a layered structure in which the counter or reference electrode is spatially separated from the working electrode 11 and the reference/counter electrode 48 by a spacer 43. A corresponding manufacturing process is shown in Figure 5 and the finished sensor is shown in Figure 6:

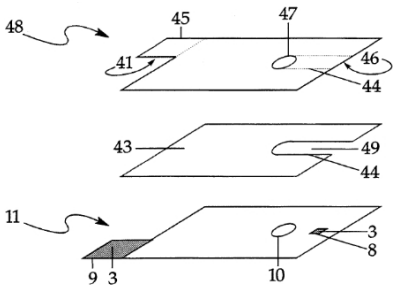

Fig. 5

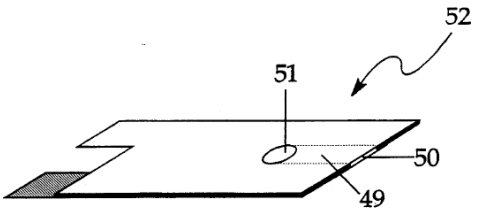

Fig. 6

295. In the finished sensor of Figure 6, the analyte is drawn through narrow openings 50, 51 into the capillary space 49 of the sensor by capillary forces. This mode of operation is diametrically opposed to a structure such as that of the patent at issue, according to which the electrodes are surrounded by the analyte (cf. feature 1.2.2).

296. The working electrode 11 has a thin metallised support material 3, which has a small opening 8 in the support material 3 in the area of the capillary space 49, through which the metallised surface is exposed. The working electrode and the counter or reference electrode are thus not separated by the substrate material in the area of the capillary space, so that no layer structure within the meaning of feature 1.2 is disclosed in the sensor area.

297. Finally, US '999 relates to an in vitro sensor strip and not to an implantable in vivo sensor (see column 2, lines 7-12 and claims 1 and 12 of US '999). The sensor strip of US '999 is not implantable because the electrode surfaces would not face the medium when implanted (feature 1.2.1). Sensor strips have different design criteria compared to implantable sensors, such as different size requirements. It is not apparent why the skilled person would nevertheless have considered a combination.

(3) US '871 in combination with WO '790

298. Based on US '871, the skilled person would have had neither an indication nor a motivation to refer to WO '790, nor would they have been able to arrive at the teaching of the patent at issue even if they had referred to US '790. The designs of US '871 and WO '790 differ fundamentally from each other.

299. WO '790 discloses in vitro test strips as disposable articles for determining the concentration of analytes and not implantable sensors (see paragraph [0002] of WO '790). An exemplary embodiment is shown in Figures 3 (cross-section) and Figures 6 (perspective view) as follows:

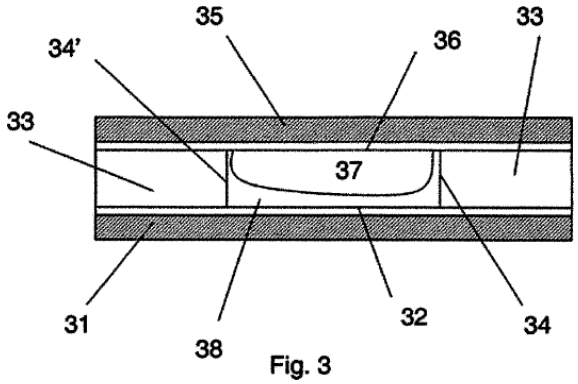

Fig. 3

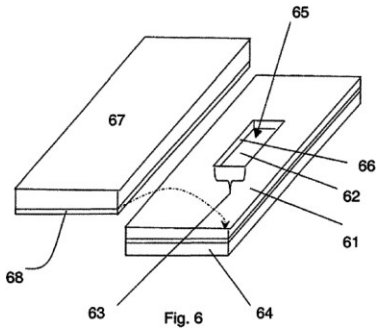

Fig. 6

300. The strip has two electrodes 31, 35, 65, 68 located on both sides of an insulating layer 38, 61. An opening 37, 63 for receiving the analytes is arranged in the insulating layer. Paragraph [0035] states:

> *"... A sample introduction opening to the sample receiving space can be created by trimming the intermediate structure thus formed transversely through the opening 63/73 and contacts are formed with the electrodes to allow connection to an external meter."*

301. The opening 37, 63 is filled by capillary forces.

302. The order shown in WO '790 thus differs fundamentally from the implantable order of US '871, so that the skilled person would have been deterred from combining them. Based on US '871, the skilled person would not have been able to arrive at the teaching of the patent at issue, nor would they have had any reason to do so. The comments on US '999 apply accordingly in this respect.

(4) US '871 in combination with WO '447

303. A combination of US '871 with WO '447 also does not call into question the inventive step.

304. As already mentioned in the novelty examination, WO '447 constitutes prior art within the meaning of Article 54(3) EPC. It is therefore not to be taken into account in the examination of inventive step under Article 56 EPC.

305. Apart from that, WO '447 also does not disclose feature 1.4 of the patent at issue. A combination of WO '871 with WO '447 would therefore not have led the skilled person to the teaching of the patent at issue.

(5) US '871 in combination with general technical knowledge

306. The combination of US '871 with general technical knowledge, which was only briefly presented by the respondents, is not sufficient to cast doubt on the inventive step. Insofar as the respondents refer to Figure 4A of US '871 in this context, reference can be made to the above statements.

cc) Inventive step based on WO '424

307. The absence of an inventive step cannot be established on the basis of WO '424 either. This belongs to the same patent family as US '871 and does not contain any relevant differences in the disclosure. The respondents have not asserted anything to the contrary.

dd) Inventive step based on WO '447 or US '006 in combination with US '871

308. Even based on WO '447 or US '006 in combination with US '871, the absence of inventive step cannot be justified.

309. These references have already been discussed in detail above, and the combination of WO '447 with US '871 has also already been discussed. US '006 discloses an in vitro test strip, so that the skilled person would not have considered a combination with US '871 for this reason alone. For the significant design differences between US '006 and US '871, which would have prevented the skilled person from combining these references, reference is made to the above discussion.

310. The respondents discuss these combinations with regard to the second alternative of feature 1.2.2, according to which the electrode surfaces are in contact with the medium over a large area and in a substantially uniform manner via an analyte-permeable membrane layer. However, due to the lack of disclosure of further features, this does not justify the absence of inventive step from the outset. Reference is made to the above statements.

V. Necessity of provisional measures and balancing of interests

311. Pursuant to Art. 62(2) UPC Agreement and R. 211.3 RoP, the court weighs up the interests of the parties at its discretion, taking into account in particular the possible damage that would be caused to one of the parties by the granting or refusal of provisional measures.

312. According to the Rules of Procedure, both temporal and factual circumstances are relevant to the necessity of ordering interim measures. The relevance of temporal circumstances arises from R. 209.2 (b) RoP ("urgency") and, in particular, from R.
211.4 RoP, according to which the court takes into account any unreasonable delay in applying for interim measures. The fact that factual circumstances must also be taken into account in the decision on the order of interim measures is evident, for example, from Rule 211.3 of the RoP, according to which the decision on the application for an order must also take into account, in particular, the possible damage that may be caused to the applicant. Potential damage to the defendant, on the other hand, must be taken into account when weighing up the interests (UPC_CFI_2/2023 (LD Munich), order of 19 September 2023, p. 84 – Nanostring v. 10x Genomics; UPC_CFI_452/2023 (LD Düsseldorf), order of 9 April 2024, p. 27 – Ortovox v. Mammut).

1. No unreasonable delay

313. It cannot be established that the applicants waited an unreasonable amount of time to file their application and thereby demonstrated that the enforcement of their rights was not

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urgent for them.

a) Principles

314. When weighing up the interests, the court takes into account any unreasonable delay in applying for provisional measures in accordance with R. 211.4 RoP in conjunction with
R. 209.1(b) RoP. This is based on the fact that the patent proprietor's conduct shows that the enforcement of his rights is no longer urgent for him. In such a situation, there is no need to order provisional measures.

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

316. Pursuant to R. 213.2 of the RoP, the Court may, in the course of its decision-making, request the applicant to submit all evidence at its disposal in order to satisfy itself that the applicant is entitled to initiate proceedings under Article 47 of the UPC Agreement, that the patent in question is valid and that its rights are being infringed or are at risk of being infringed. In urgent proceedings, the applicant must generally respond to such an order within a short period of time, which requires adequate preparation for the proceedings. The applicant must therefore only apply to the court if he has reliable knowledge of all the facts that make legal action in the proceedings for provisional measures appear promising and if he can substantiate these facts. They can prepare for all possible procedural situations that may arise due to the circumstances in such a way that they can provide the court with the requested information and documents in response to such an order and successfully refute the arguments of the opposing party. In principle, the applicant cannot be instructed to conduct the necessary investigations during the ongoing proceedings and, if necessary, to obtain the necessary documents retrospectively. On the other hand, the applicant must not unnecessarily delay the proceedings. As soon as they become aware of the alleged infringement, they must investigate it, take the necessary measures to clarify it and obtain the documents necessary to substantiate their claims. In doing so, they must carefully initiate and complete the necessary steps at each stage (UPC_CFI_452/2023 (LD Düsseldorf), order of 9 April 2024, para. 128 – Ortovox v. Mammut; UPC_CFI_151/2024 (LD Hamburg), order of 3 June 2024 – Ballinno v. UEFA; UPC_CFI_347/2024 (LD Düsseldorf), order of 31 October 2024, p. 42 – Magna v. Va-leo).

317. On this basis, the time limit within the meaning of Rule 211(4) of the RoP shall be calculated from the date on which the applicant knew or should have known of the infringement that would have enabled him to file a promising application for provisional measures pursuant to Rule 206(2) of the RoP. Whether a delay within the meaning of Rule 211(4) of the RoP is unreasonable depends on the circumstances of the individual case (UPC_CoA_182/2024,

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Order of 25 September 2024, paras. 228 and 232 – Mammut v. Ortovox; UPC_CFI_347/2024 (LD Düsseldorf), Order of 31 October 2024, p. 42 – Magna v. Va-leo). Ultimately, it must always be examined whether the applicant's conduct as a whole justifies the conclusion that the enforcement of their rights is not urgent.

b) Application in the case in dispute

318. Based on these principles, the applicants did not wait an unreasonably long time with their application for an order for interim measures and did not behave hesitantly in other respects either.

aa) Sinocare

319. The respondents justify what they consider to be the early start of the urgency period by referring to acts of use by the manufacturer of the contested embodiment, the Chinese company Sinocare. It is already doubtful whether knowledge of (imminent) patent-infringing acts by another party is at all suitable for triggering the urgency period with regard to another party, in this case the subsequent distribution partners. However, further discussion is unnecessary here because the respondents' submissions in connection with Sinocare do not in any case indicate that the applicants had sufficient knowledge.

(1) […]

320–326 […]

(2) Presentation and distribution of the Sinocare device

327. The respondents also refer to the presentation and distribution of the Sinocare device "Sinocare iCan i3" in Europe from October 2023 onwards. The device was offered at various trade fairs and also sold online. The respondents are of the opinion that these activities could not have escaped the applicants' attention.

328. The respondents' submission does not indicate that the applicants actually took note of these activities. If there is no positive knowledge of the infringement of property rights, or if such knowledge cannot be established, this is equivalent to grossly negligent ignorance or deliberately turning a blind eye to the infringement. However, since there is no general obligation to monitor the market, it is not sufficient that the applicant could have been aware of the infringement of property rights when observing the competition (see UPC_CFI_463/2023, order of 30 April 2024, p. 32 – 10x Genomics v. Curio Bioscience).

329. Apart from that, it cannot be established that the applicants could have obtained a Sinocare device for testing purposes. This applies both to the presentation at various trade fairs put forward by the respondents and to online sales.

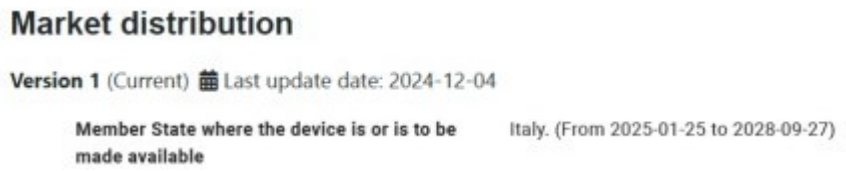
bb) Menarini

(1) Until 12 June 2025

330. For the period up to 12 June 2025, it cannot be established that the applicants had any evidence of acts of use by the respondents in a country where the patent at issue is in force.

331. On 3 December 2024, the respondents published a press release on their cooperation with Sinocare (Exhibit KAP 16). Sinocare published a corresponding announcement on 4 December 2024 (Exhibit BB 30).

332. The EUDAMED database has contained the following entry since 4 December 2024:



333. On 14 December 2024, the contested embodiment was presented at the "Les Recontres de Diabétologie" conference in Brussels.

334. Between January and March 2025, according to the respondents' submissions, the contested embodiment was also presented at the following additional trade fairs and conferences:

- 23 to 25 January 2025: DIATEC 2025 in Berlin
- 19 and 22 March 2025: ATTD Congress in Amsterdam
- 6 to 8 March: 21st Portuguese Diabetes Congress in Vilamoura
- 26 to 28 March 2025: Endodiabeletes 2025 in Linköping.

335. Furthermore, according to their own statement, the applicants had been aware "for several months" at the time of filing the application that the contested embodiment was on the market in Portugal.

336. The respondents merely assert that there was relevant use in a country in which the patent at issue is valid by presenting the contested embodiment at the trade fair in Berlin in January 2025. However, it cannot be established that the applicants were aware of this. In the absence of a market observation obligation, it cannot be argued that the applicants should have become aware of this. Insofar as the respondents point out that employees of the applicants were present at all these events, in some cases in the immediate vicinity of the respondents' stands (see Annex BB 31), this is also not sufficient to justify grossly negligent ignorance.

337. However, even if one assumes that the applicants must have been aware of the offer at the trade fair in Berlin, it cannot be established that they could have acquired and examined a copy of the contested embodiment exhibited there or distributed in one of the relevant countries at that time.

338. Nor were they required to purchase a product sold in a patent-free country (such as Portugal) and examine it "on suspicion". Rather, they were generally entitled to assume that their rights would be protected. Such an examination would also have offered no guarantee that products sold later in validated countries would be designed in the same way.

(2) From 12 June 2025

339. On 12 June 2025, following their presentation, the applicants received information about the distribution of the product manufactured by Sinocare in Italy, and on 3 July 2025, they also received information about the distribution of the contested embodiment. The sequence of events was as follows:

340. On 12 June 2025, an employee of the second applicant became aware that the "Sinocare ICan i3 CGM" was being sold in Italy via Amazon. At that time, they assumed, according to their statement, that it was the product in the red and white packaging from the manufacturer Sinocare, which is equipped with a round electronic unit.

341. After consulting with the legal representatives, the responsible employee at the applicants' company, Ms. Lead Patent Counsel Strategic IP Solutions at Roche Diagnostics GmbH, ordered three of the products offered on Amazon to the address of a private contact in Italy on 20 June 2025. The private contact in Italy was chosen because the applicants had not initially received a response from the Italian colleague contacted from the Roche group. The applicants explain that the eight days required were necessary not only for consultation with the legal representatives, but also because the delivery address in Italy required organisational arrangements that took several days to complete.

342. However, Ms However, she cancelled the order placed on 20 June 2025 with her private contact after she was finally able to get in touch with her Italian colleague at Roche. On 26 June 2025, she reordered three of the products on offer and had them delivered to her Italian colleague's address in Italy.

343. On 1 July 2025, the products arrived at the Italian colleague's premises and were forwarded by her on 3 July 2025 to Mannheim, where Ms is based. Together with Ms Head Strategic IP Solutions at Applicant 1, she is responsible for enforcing the applicants' IP rights in a position of responsibility.

344. On 4 July 2025, the ordered products arrived at Roche in Mannheim. On that day, Ms took a day off and worked from home on Monday, 7 July 2025.

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345. On 8 July 2025, she received the products and realised that they were not the "Sinocare iCan i3 CGM" (in the manufacturer's red and white packaging with an octagonal sensor) as depicted on Amazon, but rather the GlucoMen iCan o3 CGM, the contested embodiment, in the green and white packaging of the first respondent with an octagonal sensor.

346. On the same day, 8 July 2025, Fra one of the ordered designs to a colleague at the second applicant for examination and testing. Further tests on this CGM were also carried out by the project manager at the second applicant.

347. On 10 July 2025, Fra also handed over one of the embodiments to another colleague at applicant 2, who was also to examine and test it.

348. Ms on 12 July 2025. These were supplemented by further results in the following days.

349. On 3 July 2025, persons acting on behalf of the applicants discovered another offer in Italy, namely in the online shop of the Italian pharmacy Farmacia die Fiducia. In this case, the contested embodiment, the GlucoMen iCan o3, was offered in the green and white packaging of the first respondent with an octagonal sensor.

350. On 4 July 2025, Fragdrei ordered the products and had them sent to her colleague in Italy. They arrived there on 8 July 2025.

351. These products were then shipped from Italy to Mannheim on 15 July 2025. They arrived there on 16 July 2025 and were received by Ms on the same day.

352. On 29 July 2025, a colleague of Ms. one of the embodiments to Mr Senior Scientist at the second applicant for further investigation and examination.

353. At the same time, according to their submission, the applicants began internal and ultimately also external consultations to examine the legal status of the patent at issue.

354. Sufficiently reliable knowledge of a patent infringement, on the basis of which the application for an order for interim measures could be initiated, was available on 12 July 2025 with the first results of microscopic examinations, as the applicants themselves assume. The application was filed on 7 August 2025, i.e. less than a month later, which is sufficient in any case given the scope of the facts to be presented. This is all the more true since the further microscopic examinations by Mr. X, to which the applicants also appeal in their statement of grounds for the infringement allegation, were not available until 29 July 2025.

355. Insofar as the respondents assert that the relevant characteristics of the sensor in the contested embodiment can be clarified by examination with a simple light microscope, the scanning electron microscope images commissioned by the applicants are purely a precautionary measure in the course of this

Even if the applicants had been negligent, this does not result in a reduction of the reasonable period of time. The applicants did not have to take any risks in demonstrating the patent infringement and could have carried out the more detailed scanning electron microscope examination purely as a precautionary measure. Apart from that, a detailed examination was obviously indispensable in view of the requirements of the claim. The respondents themselves submitted scanning electron microscope examinations with their preliminary objection. In their preliminary objection, they also complained that the applicants' presentation of the design of the contested embodiment was insufficient and that the photographs taken were not detailed enough. It cannot therefore be concluded that a less detailed examination prior to the application would have been sufficient.

356. Although the internal coordination and ordering process within the group was not entirely free of delays once the first indications of distribution in Italy became apparent, an overall assessment shows that the applicants considered legal action to be urgent. This is true even if one takes into account the first indications of distribution of the Sinocare device in Italy, i.e. 12 June 2025.

357. Although, due to organisational arrangements and the fact that Ms. did not initially receive a response from her Italian colleague at the Roche Group and therefore an order was initially placed via a private contact, it took a total of two weeks for the order to be placed. However, even if the organisational difficulties within the Roche Group could be attributed entirely to the applicants, this cannot justify the conclusion that the applicants did not have an urgent need to pursue legal action. In particular, a certain period of consultation seems entirely reasonable after the Sinocare products were first discovered but could only be ordered from Italy, rather than from the relevant department within the group in Germany. The fact that Fra attempted to establish private contact in the meantime proves that the applicants were keen to act swiftly despite organisational difficulties. It is also entirely understandable that she cancelled this order after she finally managed to reach her Italian colleague.

2. Objective necessity

358. Furthermore, the order of interim measures is also necessary from a factual point of view.

a) Principles

359. The court must also examine whether the proceedings in the main action should be awaited or whether provisional measures are necessary (UPC_CoA_540/2024, order of 24 February 2025, para. 19 — Biolitec v Light Guide; UPC CoA 768/2024, order of 30 April 2025 — Insulet Corporation v. EOFlow).

360. Interim measures are necessary, for example, if a delay would cause irreparable damage to the patent holder. However, such damage is not a necessary prerequisite for ordering interim measures (UPC_CoA_182/2024, order of 25 September 2024, para. 237— Mammut v Ortovox; UPC CoA 540/2024, order of 24 February 2025 — Biolitec v. Light Guide, para. 21; UPC_CoA 768/2024, order of 30 April 2025, para. 103 — Insulet Corporation v. EOFlow).

361. The need for interim measures may also arise from the fact that there is direct competition between the contested embodiment and the patent holder's product (UPC_CoA_540/2024, order of 24 February 2025, para. 26 – Biolitec v. Light Guide). In such cases, provisional measures may be justified if they are necessary to maintain the status quo prior to the alleged infringement until a decision is made on the main issue (UPC_CoA_182/2024, order of 25 September 2024, para. 238 – Mammut v. Ortovox; UPC_CoA_540/2024, order of 24 February 2025, para. 28 – Biolitec v. Light Guide). The need for interim measures may also arise from the fact that the market situation is changing from one in which only one product is available to one in which there are two competing products. Such a transition can lead not only to price pressure but also to permanent price erosion (see UPC_CoA_523/2024, order of 3 March 2024, para. 93 – Sumi-Syngenta; UPC_CoA 768/2024, order of 30 April 2025, para. 104 – Insulet Corporation v. EOFlow).

b) Application in the event of a dispute

362. Based on these principles, the order of interim measures is necessary in substantive terms.

363. The applicants face the threat of losing market share and encountering difficulties in establishing themselves in markets they have not yet entered. This applies primarily to the German market, where the applicants are already represented and where the respondents are about to enter the market. This is because the entry of another market participant gives rise to concerns that patients who are either initially supplied with a CGM system or, in rare cases, decide to switch, will resort to the contested embodiment and not to the applicants' system. On the Italian market, the applicants' anticipated market entry in early 2026 is made more difficult by the fact that the respondents, another competitor, are already present on the market. As the applicants have explained in a comprehensible manner, every additional competitor makes market entry more difficult for new market participants. As far as the French market is concerned, it should be noted that, according to their own statements, the applicants do not expect to enter the market before the end of 2026. However, if the respondents have already succeeded in establishing themselves on the market at an earlier stage, even if only on the self-payer market, later market entry will be made more difficult by the additional competitor already present.

364. The inertia of the market for CGM systems increases the damage threatened to the applicants. It is undisputed between the parties that, due to the special features of the market for CGM systems, it is extremely difficult for new providers to win over patients who are already supplied with a CGM system as customers. The greatest potential for new providers to gain market share therefore lies in new patients who are being supplied with a CGM system for the first time. The respondents do not dispute that such patients exist. Once these patients have decided on a system during their initial treatment, the aforementioned inertia of the market comes into play again. Changing an existing system is unusual and costly, which is why it is understandable that once "new patients" have been lost, they can hardly be won back. This is particularly important in the market entry phase, which the applicants are currently in in Germany and which is imminent for them in Italy and France. In this

It first needs to establish itself on the market and thus carve out a position alongside the dominant providers Abbott and Dexcom. For this reason, the respondents' argument that the applicants can simply wait until a possible injunction has been issued in proceedings on the merits and patients won by the respondents are thus forced to switch is not valid.

365. The respondents' argument that the applicants (or the respondents) are not expected to achieve significant market shares in the period leading up to an expected judgment in the main proceedings, so that the applicants cannot suffer any damage as a result of the market presence of the contested embodiment, is not convincing. On the contrary, the already difficult task of establishing themselves on the market is made even more difficult by the presence of another competitor, and if they fail to establish themselves on the market, there is a risk of lasting damage.

366. The fact that the term of protection of the patent at issue will expire in December 2026 also suggests that significant damage will occur. By the time the main proceedings are concluded, at least a substantial part of the remaining term of protection would probably have expired.

367. The respondents are of the opinion that this circumstance does not speak in favour of, but rather against, the order of interim measures if the damage claimed is fully quantifiable and compensable. They argue that the potential damage only relates to a short remaining period of damage. Market conditions allow for a reliable determination of any damage, and there are no indications of an abrupt, irreversible loss of market share or a sustained price erosion, as is typical in generic drug situations. [...].

368. It may be true that the market situation is not comparable to that of the entry of a generic manufacturer and, in particular, that there is no reason to fear price erosion as a result of the contested embodiment. However, the disadvantages to be feared for the applicants result from the special circumstances on the market for CGM systems as explained above. The competitive situation created by the market entry is based not only on the mere fact that another participant is entering the market, but also on the fact that the Menarini Group can draw on established distribution structures and is well established, and less on the fear of price erosion.

3. Balancing of interests in the narrower sense

369. Also the final to be carried out weighing of interests is in favour the applicants.

a) Principles

370. Pursuant to Art. 62(2) of the UPC Agreement and R. 211.3 of the RoP, the court shall weigh the interests of the parties against each other at its discretion, taking into account in particular the possible damage that would be caused to one of the parties by the granting or refusal of provisional measures.

371. The degree of probability with which the court is convinced of the existence of the individual circumstances to be weighed is also decisive for the exercise of its discretion

. The more certain the court is that the right holder is asserting the infringement of a valid patent, that the circumstances of fact and time make it necessary to issue an injunction, and that this is not precluded by possible damage to the opponent or other justified objections, the more justified the issuance of a prohibition is. Conversely, the more uncertainties there are with regard to individual circumstances relevant to the weighing of interests, which are detrimental to the court's conviction, the more the court will have to consider, as a milder measure, allowing the alleged infringement to continue subject to the provision of security, or even dismissing the application (UPC_CFI_2/2023 (LD Munich), Order of 19 September 2023, p. 98 – Nanostring v. 10x Genomics; UPC_CFI_452/2023 (LD Düsseldorf), Order of 9 April 2024, p. 30 – Ortovox v. Mammut).

b) Application in the case in dispute

372. On this basis, after weighing up all the circumstances, including the high degree of conviction that the Chamber has reached with regard to the infringement and the legal validity of the patent at issue, the applicants' interest in enforcing the patent at issue takes precedence over the interests of the respondents.

373. Insofar as the respondents claim that the order would lead to irrevocable disadvantages, these are ultimately only the usual consequences of such an order. These include the specific consequences on the Italian market listed by the respondents, such as exclusion from future tendering rounds, contractual penalties, vaguely presented criminal consequences or the loss of guarantee amounts. The consequences threatening on the German market, such as warranty and damage claims by health insurance companies or non-consideration in future tendering procedures, are also to be regarded as the usual consequences of an injunction.

374. The respondents estimate their threatened loss of profit at […]. They appeal to a prevented or delayed admission to the LLPR in France, a significant delay in market entry in Italy due to non-participation in tendering procedures, and the inability to conclude contracts with health insurance companies and carry out planned sales in Germany. Furthermore, they argue that it is not possible to reliably quantify the damage retrospectively, as it remains unclear whether and on what terms they would have been considered in the prevented tenders. The damage is therefore not legally actionable and is in fact irreparable.

375. The economic consequences feared by the respondents are not irrevocable or particularly serious disadvantages. The economic damage is to be compensated in accordance with R. 213.2. RoP. Difficulties in quantifying such damages are always to be expected in view of the hypothetical scenarios to be considered and do not distinguish the dispute from other cases of this kind. The respondents have not claimed that the feared loss of profit threatens their existence. They have opposed the applicants' argument that the stated amount of lost profits is not substantially detrimental in relation to the size and turnover of the group. However, their submission does not show that the existence of even one of the companies in the Menarini group is threatened.

376. The respondents also argue that, in the market for medical aids, which is characterised by public tenders, the reputation of a supplier is of decisive importance in addition to the price and quality of the products it supplies. It is only obvious that suppliers who have been unreliable in the past would not have the same chances of success in future tenders as their more reliable competitors. Ultimately, however, the damage to reputation described is only a normal consequence of such an injunction.

377. In weighing up the interests involved, the respondents also argue that the applicants should have filed the application for order of interim measures earlier and that they, the respondents, could have been informed of the alleged infringement out of court at that time and could have filed an application for the production of evidence in accordance with Rule 190 of the RoP. As far as the possibility of an earlier application for order of interim measures is concerned, reference is made to the above comments on urgency. With regard to the possibility of evidence preservation proceedings or out-of-court letters, it remains unclear to what extent such measures would have specifically influenced the respondents' behaviour. In this regard, they assert in general terms that if they had been informed of the allegations now being made in spring 2025, they would have been able to examine them and take them into account in their considerations and adjust their business decisions accordingly, in particular the conclusion of contracts with health insurance companies and other healthcare providers. However, this does not mean that this examination would have led to a different result than the rejection of all claims.

378. The respondents' argument that the applicants are not at risk of suffering any damage cannot be accepted. In this regard, reference can be made to the comments on the factual necessity.

379. Insofar as the respondents see a discrepancy in the possibility of calculating damages and consider the damage they themselves could potentially incur to be extremely difficult to quantify, whereas the damage incurred by the applicants is very easy to quantify, the court does not share this view. Both damage calculations require hypothetical considerations and thus present difficulties, but this is also a common consequence of injunctions.

380. The decision of the High Court of England and Wales, which the respondents refer to in this context, is not comparable. That case only concerned the self-pay market, after Sinocare had voluntarily undertaken not to enter the NHS reimbursement market with its CGM device within the UK until the main proceedings had been decided and to document all sales on the self-pay market. No conclusions can be drawn from this for the balancing of interests to be carried out in the present case.

VI. Legal consequences

381. With regard to the legal consequences, the following applies:

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1. Injunction

382. In exercising discretion, the issuance of a preliminary injunction (R. 209.2 RoP) appears appropriate and justified (Art. 62 (1), 1st alternative, 25 a) UPC Agreement). Only an injunction takes into account the applicants' interest in the effective enforcement of the patent at issue.

383. On the other hand, it is not sufficient to link the continuation of the infringement to the provision of security to guarantee compensation for the right holder, Art. 62 (1), 2nd alternative UPC Agreement. In the opinion of the Court of Appeal, such security can only partially protect the interests of the patent holder if the damage suffered by the latter is difficult to quantify (see UPC_CoA_768/2024, order of 30 April 2025, para. 128 – Insulet v. EOFlow). This is also the case here.

384. It is also insufficient to prohibit the respondents from concluding contracts with health insurance funds and other healthcare providers for the supply of the contested embodiment at prices below those of the applicants. As explained in the context of factual necessity, potential price erosion is not the decisive factor in the present case with regard to the threatened damage. The order proposed by the respondents is therefore not suitable for preventing the damage threatened to the applicants.

385. The penalty payments sought by the applicants in the event of an infringement are based on Rule 354.3 of the RoP. The number of products or the number of days already provides a basis for calculating the penalty payments. However, setting a maximum limit per product or day gives the local division the necessary flexibility to also take into account the behaviour of the infringer in the event of an infringement and, on that basis, to be able to set an appropriate penalty payment in accordance with Rule 354.4 of the RoP. The distinction between the distribution of the contested embodiment and continuous acts, such as offers on the internet, takes sufficient account of the principle of proportionality (UPC_CFI_452/2023 (LD Düsseldorf), order of 11 December 2023, p. 9 – Ortovox v. Mammut).

386. The injunction also covers the form of use involving manufacture, regardless of the fact that the contested embodiment is currently being manufactured by Sinocare in China. Such an order is in the interest of the applicants in effectively enforcing their property rights. Since the respondents are also not entitled to manufacture the contested embodiment in the relevant Member States, such an order does not disadvantage them.

387. As far as the different ownership of the applicants in the national parts of the patent at issue is concerned, the injunction is issued with regard to Germany on the basis of the ownership of the second applicant in the German part of the patent at issue and with regard to France and Italy on the basis of the ownership of the first applicant in the French and Italian parts of the patent at issue. Since the injunction is ordered against everyone, this did not have to be reflected in the operative part of the order.

2. Seizure

388. The requested seizure order is based on R. 211.1 (b) RoP. Such an order appears appropriate and necessary, taking into account the interests of both parties. There is no apparent interest on the part of the respondents in retaining possession of copies of the contested embodiment, which infringes the patent at issue with sufficient probability, in the contracting member states affected by the order for provisional measures.

389. The above statements on injunctive relief apply mutatis mutandis to the applicants' ownership of the various national parts of the patent at issue. The surrender shall be made to a bailiff, so that no express order was necessary in this respect in the operative part of the order.

3. Information

390. Furthermore, an obligation to provide information may also be ordered in the context of interim measures, provided that there is an urgent interest and these measures are proportionate (UPC_CoA_382/2024, order of 14 February 2025, paras. 160–164 – Abbott v. Sibio; UPC_CoA_768/2024, order of 30 April 2025, paras. 129–132 – Insulet v. EOFlow). This is the case with the requested information on the origin and distribution channels of the contested embodiment, as specified in the application under IV. a), indent 1 and indent 2. This information enables the applicants to take appropriate measures to prevent further infringements within the scope of the UPC Agreement and the patent at issue.

391. However, it is excessive for the applicants to request information on individual offers and individual deliveries in their application under IV. a), indent 3 and indent 4. As the respondents rightly argue, this information is primarily relevant for the calculation of damages and therefore cannot be requested in the context of interim measures (see: UPC_CoA_768/2024, order of 30 April 2025, para. 132 – Insulet v. E-OFlow). In response to the respondents' objection, the applicants did not provide further reasons as to why this information could prevent further patent infringements. They merely pointed out that the right to information could also include a breakdown by individual offers and deliveries, insofar as this was necessary to determine the exact extent of the patent infringement. In fact, however, this is not merely a breakdown, even if the information is requested under the heading "Origin and distribution channels".

392. Since the applicants have not been granted access to this information, the respondents' objection that measures to safeguard competition, such as an auditor's reservation or disclosure only to a limited group of employees, are necessary in this respect has also been rendered moot.

393. The information requested in application IV. b) ("identity of all third parties involved in the manufacture and distribution of the products listed under No. I")

to the identification of further infringers and can therefore be requested. The respondents do not object to this either.

4. Provisional reimbursement of costs

394. Pursuant to Art. 69 UPC Agreement in conjunction with R. 211.1 (d) RoP, the applicants may request provisional reimbursement of costs. The applicants calculate the provisionally claimed costs in accordance with the Lawyers' Fees Act. There are no objections to this (UPC_CFI_452/2023 (LD Düsseldorf), order of 11 December 2023, p. 33 – Orto-vox v. Mammut).

5. Costs

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

396. Pursuant to Article 69(1) of the UPC Agreement, the reasonable and proportionate costs of the proceedings and other expenses incurred by the successful party shall, in principle, be borne by the unsuccessful party, unless equity requires otherwise. Under Article 69(2) of the UPC Agreement, where a party has been successful only in part or where there are exceptional circumstances, the court may issue an order requiring that the costs be shared fairly or that each party bear its own costs. Where a party has been unsuccessful only in part, the costs do not necessarily have to be shared proportionally. In particular, if the unsuccessful claim of one party was relatively minor and did not incur any further costs, the entire costs of the other party may be imposed on it.

397. This is the case here. The rejected part of the request for information would have been insignificant in relation to the successful claims and would not have incurred any further costs (comparable: UPC_CoA_768/2024, order of 30 April 2025, para. 135 et seq. – Insulet Corporation v. EOFlow, see also UPC_CFI_213/2025 (LD Düsseldorf), order of 10 July 2025, para. 127 – Aesculap v. Shanghai International). The division with regard to the applicants' ownership of the national parts of the patent at issue has no economic consequences.

6. (No) security for enforcement

398. Pursuant to Art. 82(2) of the UPC Agreement, the enforcement of a decision may, where appropriate, be made conditional upon the provision of security or an equivalent guarantee, in particular to secure any claim for damages in the case of an injunction.

399. For provisional measures, this is reflected in Rule 211(5) of the RoP, first sentence, according to which the Court may require the applicant to provide adequate security for any reasonable compensation that may be payable by the applicant to the defendant for damage that the defendant is likely to suffer in the event that the Court revokes the order for provisional measures. In addition, pursuant to R. 352.1 RoP, decisions and orders may be enforced by one party against the other.

other party with security (whether by deposit, bank guarantee or other means) for the costs of the proceedings and other expenses, as well as for compensation for damages incurred or likely to be incurred by the other party as a result of the enforcement and subsequent revocation of the decisions and orders.

400. If provisional measures are revoked or expire due to an act or omission on the part of the applicant, or if it is subsequently determined that there is no infringement or threatened infringement of the patent, the court may, at the request of the defendant, order the applicant to pay the defendant reasonable compensation for the damage caused by the measures (R. 213.2 RoP). Pursuant to R.
354.2 of the RoP, if, during the course of proceedings, an enforceable decision or order of the Court is subsequently modified or revoked, the Court may, upon application from the party against whom the decision or order was enforced, award the party that enforced the decision or order reasonable compensation for the damage caused by the enforcement.

401. The provision of security is not dependent on an application by one of the parties. If interim measures are ordered without the applicant having been heard, the court shall order the applicant to provide appropriate security, unless there are special circumstances that militate against this (R. 213.2 RoP, second sentence). While security is therefore normally ordered for unilateral measures, the court has discretion in the case of provisional measures where the defendant is heard (inter partes) (in R. 211.5 RoP, first sentence, mentioned above, "may") see UPC_CoA_523/2024, order of 3 March 2025, paras. 110–113 – Sumi Agro v. Syngenta).

402. If the court sees no reason to order the provision of security for the extension of the interim measures ex officioenforcement of the interim measures, the defendant may nevertheless put forward arguments and facts to show that the outcome of the main proceedings could be different and/or that the enforcement of an order to compensate for damage caused by the interim measures would constitute an unreasonable burden if those measures were to be lifted. The burden of proof then generally lies with the defendant. The unreasonable burden may, for example, be related to the financial situation of the applicant or to the foreign law applicable in the territory where the order for compensation is to be enforced, including the application of that foreign law (UPC_CoA_523/2024, order of 3 March 2025, para. 114 – Sumi Agro v. Syngenta; UPC_CoA_768/2024, order of 30 April 2025, para. 134 – Insulet v. EOFlow).

403. The respondents have argued that a preliminary order should only be granted against adequate security, which must be at least EUR 1,000,000. However, based on the principles outlined above, there is no apparent reason for this. The respondents do not claim that this would constitute an unreasonable burden. In particular, they did not contest the applicants' argument, already made in the application, that the Roche companies are in good financial health.

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ORDER:

I. The respondents are ordered to refrain from

1. manufacturing, offering, placing on the market or using implantable sensors for determining the concentration of at least one analyte in a medium, in particular body tissue and/or body fluid

in the Federal Republic of Germany, the French Republic and/or the Italian Reply, or to import or possess them for these purposes,

where

the implantable sensor has a layer structure with at least one insulating carrier substrate and at least two electrodes with electrode surfaces arranged in at least two different layer planes of the implantable sensor, which are electrically separated from each other by the at least one insulating carrier substrate, wherein the electrode surfaces face the medium in the implanted sensor and are in contact with the medium over a large area and essentially uniformly via an analytepermeable membrane layer, with the implantable sensor further comprising electrode contact layers that electrically contact the at least two electrodes, characterised in that the at least one insulating carrier substrate has a width, wherein the at least two electrodes and/or the at least two electrode contact layers extend over the entire width of the at least one insulating carrier substrate;

(direct infringement of claim 1)

2. Devices for determining the concentration of at least one analyte in a medium, in particular body tissue and/or body fluid

in the Federal Republic of Germany, the French Republic and/or the Italian Republic, to offer, market or use them, or to import or possess them for these purposes,

which comprise

at least one implantable sensor according to item I. and furthermore at least one voltage measuring device for measuring a voltage between at least one working electrode and at least one reference electrode of the implantable sensor.

(direct infringement of claim 16)

II. For each individual infringement of the above order under point I, the respondents shall pay the court a (repeated, if necessary) penalty of up to EUR 10,000.00 per product and/or, in the case of continuous infringements such as offers on the Internet, up to EUR 30,000.00 per day.

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III. The respondents are ordered to surrender the implantable sensors and devices referred to in Section I to a bailiff for safekeeping until a final decision has been made between the parties on the existence of a claim for destruction or an amicable settlement has been reached, or the applicantsinform the court that safekeeping is no longer necessary.

IV. The respondents are ordered to provide the first applicant with information on activities in the French Republic and the Italian Republic and the second applicant with information on activities in the Federal Republic of Germany within three (3) weeks of service of this order, in writing and in electronic form that can be evaluated using a computer, in a list structured for each month of a calendar year and according to patent-infringing products, from
11 April 2016, on the products referred to in section I,

a) the origin and distribution channels of the products referred to in No. I, specifying

- the names and addresses of the manufacturers, suppliers and other holders;

- the names and addresses of the commercial customers and the points of sale for which the products were intended;

b) the identity of all third parties involved in the manufacture and distribution of the products referred to in No. I.

V. The respondents are ordered to provisionally reimburse the applicants for costs in the amount of EUR 32,051.20.

VI. In all other respects, the application for the order of interim measures is dismissed.

VII. The respondents shall bear the costs of the proceedings.

VIII. This order is enforceable without security.

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

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Düsseldorf, 5 December 2025 NAMES AND SIGNATURES

Presiding Judge Thomas	Ronny Thomas signed Digitally by Ronny Thomas Date: 03/12/2025 19:34:32 +01'00'
Legally qualified judge Dr Schumacher	JuleKathrin Schumacher Digitally signed by Jule Kathrin Schumacher Date: 04/12/2025 13:03:45
Legally qualified judge Kupecz	András Ferenc Kupecz Digitally signed by András Ferenc Kupecz Date: 04/12/2025 09:10:33 +01'00'
Technically qualified judge Dr Wilhelm	Stefan Maria Wilhelm Digitally signed by Stefan Maria Wilhelm Date: 4 December 2025 10:05:14
For the Deputy Chancellor	LAURA CHANTAL DANIEL Digitally signed by LAURA CHANTAL DANIEL Date: 04/12/2025 13:15:04

INFORMATION ABOUT THE APPEAL

Both parties may appeal against this order within 15 days of its notification (Art. 73(2)(a), 62 UPC Agreement, R. 220.1(c), 224.2(b) RoP).

INFORMATION ON ENFORCEMENT (ART. 82 UPC Agreement, ART. 37(2) EPGS, R. 118.8, 158.2, 354, 355.4 R. 118.8, 158.2, 354, 355.4 R. 118.8, 15

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

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NOTE THAT THE MAIN PROCEEDINGS MUST BE INITIATED WITHIN A CERTAIN PERIOD OF TIME:

If the main proceedings are not initiated within a period of no more than 31 calendar days or 20 working days, whichever is longer, from the date of service on the respective respondent, the court may, at the application of the respective respondent concerned, order that the present order be revoked or otherwise cease to have effect (Art. 62 (5), 60 (8), R. 213.1 RoP).