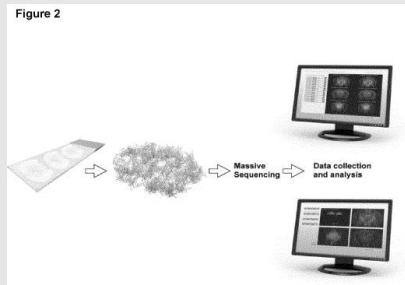


UPC CFI, Local Division Düsseldorf, 30 April 2024,
10x Genomics v Curio Bioscience



PATENT LAW – PROCEDURAL LAW

PROVISIONAL MEASURES

Provisional cease and desist order for the territories of the Federal Republic of Germany, the French Republic, and/or the Kingdom of Sweden, subject to Applicant providing € 2 million security ([Article 62 UPCA](#), [Rule 211 RoP](#))

- The local division in Düsseldorf is convinced with the requisite certainty for ordering provisional measures that the Defendant is unlawfully using provisional measures that the Defendant is unlawfully using the technical teaching protected by patent claim 14 of the patent at issue through the offer and distribution of the contested embodiments within the scope of the patent at issue. Likewise, the validity of the patent at issue is certain to the extent required for the ordering of provisional measures. Since the ordering of provisional measures is also both temporally and materially necessary, and furthermore the weighing-up of interests favours the Applicant, the following legal consequences ensue

Non-compliance with the substantive requirements for an application for provisional measures ([Rule 206.2\(d\) RoP](#))

- may be to the detriment of the Applicant. A possible infringement of R. 206.2(d) RoP does not therefore lead to the Application being inadmissible (UPC CoA 335/2023, Order of 26 February 2024).

Rebuttable presumption that a person registered as the patent proprietor in the respective national register is entitled to be registered ([Rule 8.5\(c\) RoP](#), [Rule 211.2 RoP](#), [Article 47 UPCA](#).)

- Since the Applicant is now registered as the patent proprietor in the registers relevant to the present dispute, in Germany, France and Sweden, it would therefore be up to the Defendant to set out and, if necessary, prove that the Applicant is nevertheless not entitled to be registered within the meaning of R. 8.5(a) RoP. The Defendant's submission is not sufficient in this regard.

Sufficient degree of certainty for provisional measures ([Rule 211.2 \(RoP\)](#))

- direct infringement of patent claim 14 by the offer and distribution of the contested embodiments ([Article 25\(a\) UPCA](#)). On summary examination, the contested embodiments make direct and literal use of the technical teaching of the patent at issue protected by patent claim 14. [...] The Defendant does not deny that it offers and supplies the contested embodiments in Germany, France and Sweden, among others. It is also not disputed that the contested embodiments were delivered to the University Medical Centre Mannheim of Heidelberg University in the 37th calendar week of 2023 (see annexes BP 17 and BP 18).

- indirect infringement of patent claim 1 cannot be established ([Art. 26 UPCA](#)). [...] the Local Division is unable to establish the suitability of the contested embodiments for carrying out the method protected by patent claim 1. Based on the understanding of the protective scope elaborated above in detail, the Applicant has not succeeded in demonstrating conclusively that feature group 1.6. of patent claim 1 has been realised.

Claim interpretation ([article 69 EPC](#))

- Statements made by the applicant in the granting procedure are not admissible material for interpretation. They are therefore generally not to be taken into account in the context of patent interpretation.

- Whether [...] at least publicly accessible documents, such as the laid-open application, can be used to interpret the patent claim of the applicable version of the claim (apparently so: [UPC CFI 292/2023 \(LD Munich\)](#), [Order of 20 December 2023](#), [...]), is not relevant for the present case and therefore requires no decision.

Insofar as the Defendant also refers, in the context of interpreting the patent, to statements made by the Applicant in the granting procedure, such statements are not admissible material for interpretation. They are therefore generally not to be taken into account in the context of patent interpretation ([UPC CFI 452/2023 \(LD Düsseldorf\)](#), [Order of 9 April 2023, headnote 1](#), GRUR-RS 2024, 7207). [Art. 24\(1\)\(c\) UPCA](#) in conjunction with [Art. 69 EPC](#) conclusively determine which documents are to be used for interpreting the patent claims determining the protective scope, namely the patent description and the patent drawings. Since the grant file is not mentioned in [Art. 69 EPC](#), it does not by law constitute admissible material for interpretation (see also Kühnen, Handbuch der Patentverletzung, 16th ed., Section A, para. 114; Benkard/Scharen, EPÜ Art. 69, para. 32 with further references). If the applicant has commented on the meaning of a feature or term during the examination procedure, this may at best be indicative of how a person skilled in the art would understand the relevant feature. Whether, on the other hand, at least publicly accessible documents, such as the laid-open application, can be used to interpret the patent claim of the applicable version of the claim (apparently so: [UPC CFI 292/2023 \(LD Munich\)](#), [Order of 20 December 2023](#), GRUR-RR 2024, 93 - Elektronisches

Etikett; in contrast: Kühnen loc. cit., para. 118), is not relevant for the present case and therefore requires no decision.

- Insofar as the German version of the patent claim, in contrast to the English version, speaks of a “different” (“unterschiedlichen”) position on the array, the English version – the language in which at issue was granted – prevails (Art. 70(1) EPC)

- The person skilled in the art must not stop at purely functional considerations, must bear in mind that patent claim 1 protects a method which is characterised by a specific sequence of method steps.

- The understanding of the term “array” on which the patent at issue is based:

an array within the meaning of the patent at issue can only be said to exist if oligonucleotides or oligonucleotide probes (plural) are applied to a surface in an ordered manner. There is no longer an array if the connection between the oligonucleotides or oligonucleotide probes and the surface and thus also the corresponding arrangement is dissolved.

- Patent claim 14 protects an array. What is protected is therefore a product per se, irrespective of the use to which it is actually put. Reference to a possible use is merely a stated purpose. Such statements of purpose usually serve to improve understanding of the invention and as a rule have the indirect effect of defining the subject matter protected by the patent in such a way that it must not only fulfil the spatial-physical features, but must also be designed to be usable for the purpose stated in the patent claim.

Insofar as, according to the wording of the patent claim, it is to be an "array for use in the localised detection of nucleic acid in a tissue sample comprising cells" (German: "Array zur Verwendung beim lokalisierten Nachweis von Nukleinsäure in einer Zellen umfassenden Gewebeprobe"), the reference to such a possible use is merely a stated purpose, which cannot on its own define the absolute protection granted by a product claim. Such statements of purpose usually serve to improve understanding of the invention and as a rule have the indirect effect of defining the subject matter protected by the patent in such a way that it must not only fulfil the spatial-physical features, but must also be designed to be usable for the purpose stated in the patent claim.

Sufficient certainty of the validity of the patent for the ordering of provisional measures (Article 62 (4) UPCA, Rule 211.2 RoP)

- Such "sufficient certainty" is lacking if the court considers it to be more likely than not that the patent at issue is not valid (UPC CoA 335/2023, Order of 26 February 2023, [...]; UPC CFI 452/2023 (LD Düsseldorf), Order of 9 April 2024, p. 19, [...]).

- The fact that the patent at issue has not yet survived any adversarial validity proceedings does not prevent the validity of the patent from being sufficiently certain

- Filing of auxiliary requests in light of Defendant’s submissions does not in itself give rise to any doubts as to validity. Rather an expression of legal caution, which is necessary because it is an open question whether auxiliary questions admissible in appeal.

[...] the Court of Appeal addressed the possibility of the inadmissibility of auxiliary requests in the second instance in its Order of 26 February 2024, but ultimately left the question open (UPC CoA 335/2023, Order of 26 February 2023, [...]).

Temporal urgency required for the ordering of provisional measures is only lacking

- if the infringed party has behaved in such a negligent and hesitant manner in the pursuit of its claims that, from an objective perspective, it must be concluded that the infringed party is not interested in promptly enforcing its rights, which is why it does not appear appropriate to allow it to claim provisional legal protection (Rule 209(2)(b) RoP)

(cf. also UPC CFI 2/2023 (LD Munich), Order of 19 September 2023, 1513, 1524 - Nachweisverfahren; UPC CFI 452/2024 (LD Düsseldorf), Order of 9 April 2024, [...]).

- In the absence of positive knowledge of the infringement of intellectual property rights or at least where such knowledge cannot be established, as is the case here, grossly negligent ignorance or wilful blindness to the infringement is considered equivalent.

However, since there is no general obligation to observe the market, it is not sufficient for the Applicant to have been able to become aware of the infringement of a right through observing the competition. However, it is expected of an intellectual property right holder who is already aware of specific circumstances suggesting an infringement of its intellectual property rights to take all measures readily available to it and further investigate the situation. However, the Defendant has not been able to specifically demonstrate specific knowledge triggering such an obligation for further investigation by the Applicant.

No award of damages possible in proceedings for provisional measures (article 62 UPCA, Rule 211(1) RoP)

- The content of provisional measures is exhaustively regulated in Art. 62 UPCA in conjunction with R. 211(1) RoP. The awarding of damages is not mentioned there. Its assertion is therefore reserved for the main proceedings.

No security for legal costs of Defendant in urgent proceedings (Article 69(4) UPCA, Rule 158 RoP, Rule 211.1(d) RoP)

- While Art. 69(4) [UPCA] only provides for the provision of security for costs by the claimant, R. 158 RoP extends the group of addressees of such an Order to include "the Parties" and thus also the Defendant in the main action.

- In urgent proceedings, there is neither scope nor (with regard to R. 211.1(d) RoP) a need for the (analogous) application of the provision, given the urgent nature of such proceedings.

No reason for a decision on costs in proceedings for the ordering of provisional measures if, as in this case, a main proceedings follows the urgent proceedings

- Unintended regulatory gap: interim award of costs in favour of Defendant not provided for in urgent proceedings (Rule 118.5 RoP, Rule 211.1 RoP)

This also applies to the extent that the Defendant seeks an interim award of costs. It is true that R. 211 RoP concerns "Orders on the application for provisional measures" (emphasis added). This suggests that the provision directly only addresses the content of a corresponding order against the Defendant and thus only an interim award of costs to the Applicant (R. 211.1 (d) RoP) (contra: UPC CFI 182/2023 (LD Vienna), Order of 13 September 2023, GRUR-RS 2023, 35213, para. 51 - Milchaufschäumer). However, if main proceedings follow urgent proceedings, the provision applies accordingly to the Defendant. As the Rules of Procedure do not provide for an interim award of costs in favour of the Defendant, there is a regulatory gap in this regard. This is also unintended. Since such a scenario is not covered by either R. 118.5 RoP or R. 211.1 (d) RoP, the Defendant would have to wait until the conclusion of the main proceedings at first instance and therefore bear the risk of insolvency until that time before being able to assert its claim for reimbursement of costs. It would therefore be in a significantly worse position than the Applicant, who even has an effective instrument available through the interim award of costs to obtain a title for its costs and thus enforce its claim to the award of costs. This imbalance highlights the existence of an unintended regulatory gap. The same interest arises from both sides in achieving the earliest possible awarding of the costs incurred by them in the urgent proceedings.

Source: Unified Patent Court

**UPC Court of First Instance,
Local Division Düsseldorf, 30 April 2024**

(Thomas, Thom, Kupecz and Schmidt)

Lokalkammer Düsseldorf

UPC_CFI_463/2023

Order

of the Court of First Instance of the Unified Patent Court
Local Division in Düsseldorf

issued on 30 April 2024

concerning EP 2 697 391 B1

HEADNOTES:

1. If in the case of a European patent a person is registered as the patent proprietor in the respective national register, there is a rebuttable presumption that the person recorded in the respective national register is entitled to be registered (R. 8.5(c) RoP). The result of such a legal presumption is to reverse the burden of

explanation and proof with regard to the presumed fact. If the Applicant can refer to his listing in the registers relevant to the respective dispute, it is up to the Defendant's side to set out and, if necessary, prove that the Applicant is not entitled to be registered.

2. If a patent claim contains stated purposes, these usually serve to improve understanding of the invention. As a rule, they have the indirect effect of defining the subject matter protected by the patent in such a way that it must not only fulfil the spatial-physical features, but must also be designed to be usable for the purpose stated in the patent claim.

3. If the Applicant lacks positive knowledge of an infringement of property rights, grossly negligent ignorance or wilful blindness to an infringement of intellectual property rights is considered equivalent to such knowledge. The patent proprietor is not under a general obligation to observe the market. However, as soon as the holder of a property right becomes aware of specific circumstances that suggest an infringement of his property right, he is expected to take all measures readily available to him and to further clarify the circumstances. It is up to the Defendant to explain such circumstances triggering a duty to provide information.

4. While Art. 69(4) [UPCA] only provides for the provision of security for costs by the claimant, R. 158 RoP extends the group of addressees of such an Order to include "the Parties" and thus also the Defendant in the main action. In urgent proceedings, there is neither scope nor (with regard to R. 211.1(d) RoP) a need for the (analogous) application of the provision, given the urgent nature of such proceedings.

KEYWORDS:

Right to bring an action; register; presumption; stated purpose; urgency; knowledge of infringement; negligent ignorance; weighing-up of interests; security for costs

APPLICANT:

10x Genomics, Inc., 6230 Stoneridge Mall Road, 94588-3260 Pleasanton, CA, USA, legally represented by the Board of Directors, which is represented by CEO Serge Saxonov, *ibid*,

represented by: Attorneys-at-law Prof. Dr Tilman Müller-Stoy and Dr Martin Drews, and patent attorney Dr Axel Berger, Prinzregentenplatz 7, 81675 Munich, Germany,

electronic address for service: [...]

DEFENDANT:

Curio Bioscience Inc., 4030 Fabian Way, Palo Alto, CA 94303, USA, represented by its CEO Stephen Fodor, *ibid*,

represented by: Attorney-at-law Agathe Michel-de Cazotte, and European Patent Attorney Cameron Marshall, 1 Southampton Row WC1B 5HA London, United Kingdom,

electronic address for service: [...]

PATENT AT ISSUE:

EUROPEAN PATENT NO. EP 2 697 391 B1

PANEL/DIVISION:

Panel of the Local Division in Düsseldorf

DECIDING JUDGES:

This Order was issued by presiding judge Thomas as judge-rapporteur, legally qualified judge Dr Thom, legally qualified judge Kupecz and technically qualified judge Dr Schmidt.

LANGUAGE OF PROCEEDINGS: German

RELATING TO: [Rule 206.1](#) of the Rules of Procedure (“RoP”) in conjunction with [R. 211.1 RoP](#) – Application for an Order on provisional measures

ORAL PROCEEDINGS: 26 March 2024

SUMMARY OF FACTS:

The Applicant has brought a claim against the Defendant for infringement of the European bundle patent EP 2 697 391 B1 (hereinafter the “patent at issue”). The patent at issue was applied for in English on 13 April 2012, claiming the priority of GB 201106254 of 13 April 2011. The patent application was published on 19 February 2014 and the mention of the grant of the patent at issue in Germany, France and Sweden, among others, was published on 30 October 2019. The patent at issue is in force in the aforementioned states. No opposition to the grant of the patent at issue was filed.

By agreement dated 30 November/1 December 2023 (Annex BP 11), 10x Genomics AB transferred the patent at issue to the Applicant and assigned all associated rights and claims to the Applicant. In the intervening period, the Applicant has been registered in the national registers in Germany, France and Sweden as the sole proprietor of the patent at issue (Annexes BP 7a, BP 8a and BP 9a).

The patent at issue protects a “method and product for localised or spatial detection of nucleic acid in a tissue sample” (German: „Verfahren und Produkt zur lokalisierten oder räumlichen Erkennung von Nucleinsäuren in einer Gewebeprobe“). Claim 1 of the patent at issue reads as follows:

“A method for localised detection of nucleic acid in a tissue sample comprising cells, wherein said method comprises:

(a) providing an array comprising a substrate on which multiple species of capture probes are directly or indirectly immobilized such that each species occupies a distinct position on the array and is oriented to have a free 3’ end to enable said probe to function as a primer for a primer extension or ligation reaction, wherein each species of said capture probe comprises a nucleic acid molecule with 5’ to 3’:

- (i) a positional domain that corresponds to the position of the capture probe on the array, and
- (ii) a capture domain;

(b) contacting said array with a tissue sample and allowing nucleic acid of the tissue sample to hybridise to the capture domain in said capture probes;

(c) generating DNA molecules from the captured nucleic acid molecules using said capture probes as extension or ligation primers, wherein said extended or ligated DNA molecules are tagged by the positional domain or a complement thereof;

(d) optionally generating a complementary strand of said tagged DNA and/or optionally amplifying said tagged DNA;

(e) releasing at least part of the tagged DNA molecules and/or their complements or amplicons from the surface of the array, wherein said part includes the positional domain and all of the sequence that is 3’ to the positional domain or a complement thereof;

(f) directly or indirectly analysing the sequence of the released DNA molecules; and

(g) correlating the sequence analysis information to a position in the tissue sample.”

In the registered German translation, patent claim 1 reads as follows:

„Verfahren zum lokalisierten Nachweis von Nucleinsäure in einer Zellen umfassenden Gewebeprobe, wobei das Verfahren Folgendes umfasst:

(a) Bereitstellen eines Array, das ein Substrat umfasst, auf dem mehrere Arten von Einfangsonden direkt oder indirekt immobilisiert sind, so dass jede Art eine unterschiedliche Position auf dem Array einnimmt und so orientiert ist, dass sie ein freies 3’-Ende aufweist, so dass die Sonde als Primer für eine Primer-Verlängerungs- oder Ligationsreaktion fungieren kann, wobei die Arten der Einfangsonde jeweils ein Nucleinsäuremolekül mit von 5’ nach 3’:

- (i) eine(r) Positionsdomäne, die der Position der Einfangsonde auf dem Array entspricht, und
- (ii) eine(r) Einfangdomäne umfassen;

(b) Inkontaktbringen des Array mit einer Gewebeprobe und Ermöglichen einer Hybridisierung von Nucleinsäure der Gewebeprobe an die Einfangdomäne in den Einfangsonden;

(c) Erzeugen von DNA-Molekülen aus den eingefangenen Nucleinsäuremolekülen unter Verwendung der Einfangsonden als Verlängerungs- oder Ligationsprimer, wobei die verlängerten bzw. ligierten DNA-Moleküle über die Positionsdomäne oder ein Komplement davon mit einem Tag versehen sind;

(d) gegebenenfalls Erzeugen eines Komplementärstrangs der mit einem Tag versehenen DNA und/oder gegebenenfalls Amplifizieren der mit dem Tag versehenen DNA;

(e) Freisetzen wenigstens eines Teils der mit einem Tag versehenen DNA-Moleküle und/oder ihrer Komplemente oder Amplifikate von der Oberfläche des Array, wobei der Teil die Positionsdomäne und die gesamte Sequenz, die 3’ zur Positionsdomäne liegt, oder ein Komplement davon enthält;

(f) direktes oder indirektes Analysieren der Sequenz der freigesetzten DNA-Moleküle; und

(g) Korrelieren der Informationen aus der Sequenzanalyse mit einer Position in der Gewebeprobe.“

In addition, claim 14 of the patent at issue protects an array which is configured as follows:

“An array for use in the localised detection of nucleic acid in a tissue sample comprising cells, comprising a substrate on which multiple species of capture probes are directly or indirectly immobilized such that each species occupies a distinct position on the array and is oriented to have a free 3' end to enable said probe to function as an extension or ligation primer, wherein each species of said capture probe comprises a nucleic acid molecule with 5' to 3':

(i) a positional domain that corresponds to the position of the capture probe on the array, and
(ii) a capture domain to capture nucleic acid of a tissue sample that is contacted with said array comprising:

- (a) a poly-T DNA oligonucleotide comprising at least 10 deoxythymidine residues and/or a random or degenerate oligonucleotide sequence; or
(b) sequences specific for a group of genes.”

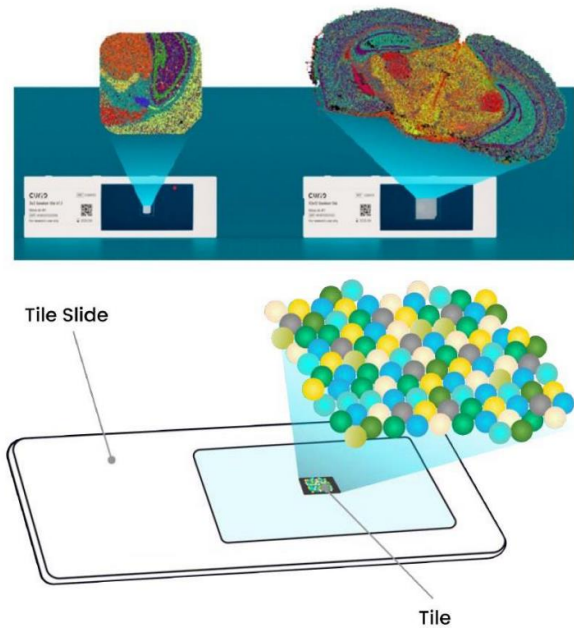
In the registered German translation, patent claim 14 is worded as follows:

„Array zur Verwendung beim lokalisierten Nachweis von Nukleinsäure in einer Zellen umfassenden Gewebeprobe, umfassend ein Substrat, auf dem mehrere Arten von Einfangsonden direkt oder indirekt immobilisiert sind, so dass jede Art eine unterschiedliche Position auf dem Array einnimmt und so orientiert ist, dass sie ein freies 3'-Ende aufweist, so dass die Sonde als Verlängerungs- oder Ligationsprimer fungieren kann, wobei die Arten der Einfangsonde jeweils ein Nukleinsäuremolekül mit von 5' nach 3':

(i) einer Positionsdomäne, die der Position der Einfangsonde auf dem Array entspricht, und
(ii) einer Einfangdomäne zum Einfangen von Nukleinsäure einer Gewebeprobe, die mit dem Array in Kontakt gebracht wird, umfassend

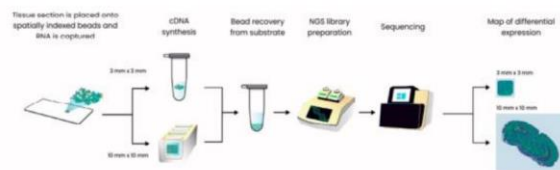
- (a) ein Poly-T-DNA-Oligonukleotid, das wenigstens 10 Desoxythymidinreste umfasst, und/oder eine zufällige oder degenerierte Oligonukleotidsequenz; oder
(b) Sequenzen, die für eine Gruppe von Genen spezifisch sind, umfassen.“

With its application for an Order on provisional measures, the Applicant opposes the offer and distribution of the product "Curio Seeker Spatial Mapping KIT", which is available in two different versions (hereinafter: contested embodiments). As the figures below illustrate, both contested embodiments consist of a slide on which there is a tile consisting of spatially indexed beads, the size of the tile being either 3 x 3 mm or 10 x 10 mm:



Each bead is coated with several oligonucleotides that can hybridise to mRNA via a Poly(dT) region and contain a bead barcode sequence. The barcodes are the same for all oligonucleotides on a bead, but differ from bead to bead.

A tissue sample can be analysed using the contested embodiments. This is applied to the tile on the slide, where molecules (RNA) from the tissue sample bind to molecules (capture structures) on the spatially indexed beads. The RNA then undergoes biomolecular processing (is transcribed into cDNA and amplified) and is sequenced using a sequencing device. Sequencing makes it possible to determine which specific RNA molecules were contained in the sample. Finally, each of the RNA molecules is assigned its position in the original tissue sample based on the indices of the spatially indexed beads. This process is illustrated in the following schematic illustration:



On 10 November 2023, a person appointed by the Applicant held a video conference with Mr Danilo Tait, the Defendant's Senior Business Director for EMEA. In this conference, Mr Tait, when asked whether delivery to Germany, France and Sweden was possible, stated that the contested embodiments would be shipped to customers in all EMEA states, with delivery being made by the Defendant. With regard to the further content of this conversation, reference is made to annexes BP 15 and BP 15a. Following this conversation, the Applicant received by email a PDF document with further information on the contested embodiments in presentation form (Annex BP 16).

In addition, the Defendant supplied the contested embodiments in the 37th calendar of week 2023 (11 September 2023 - 17 September 2023) to the University Medical Centre Mannheim of Heidelberg University (annexes BP 17 and BP 17a). In addition, and to avoid repetition, reference is made to the entire contents of the file.

STATEMENT OF THE FORMS OF ORDER SOUGHT BY THE PARTIES:

The Applicant requests that the Court:

A. order the Defendant to refrain from the following in the territories of the Federal Republic of Germany, the French Republic and/or the Kingdom of Sweden:

I. offering and/or delivering, to third parties in the territory of one or more of the states mentioned in A., means, namely arrays, in particular "Curio Seeker Spatial Mapping KITs", which are suitable and intended for carrying out a method for localised detection of nucleic acids in a tissue sample comprising cells (alternatively: where the tissue sample is a tissue section), wherein said method comprises

(a) providing an array comprising a substrate on which multiple species of capture probes are directly or indirectly immobilized such that each species occupies a distinct position on the array and is oriented to have a free 3' end to enable said probe to function as a primer for a primer extension or ligation reaction, wherein each species of said capture probe comprises a nucleic acid molecule with 5' to 3':

(i) a positional domain that corresponds to the position of the capture probe on the array, and

(ii) a capture domain;

(b) contacting said array with a tissue sample and allowing nucleic acid of the tissue sample to hybridise to the capture domain in said capture probe

(c) generating DNA molecules from the captured nucleic acid molecules using said capture probes as extension primers, wherein said extended DNA molecules are tagged by the positional domain or a complement thereof;

(d) optionally generating a complementary strand of said tagged DNA and/or optionally amplifying said tagged DNA;

(e) releasing at least part of the tagged DNA molecules and/or their complements or amplicons from the surface of the array, wherein said part includes the positional domain and all of the sequence that is 3' to the positional domain or a complement thereof;

(f) directly or indirectly analysing the sequence of the released DNA molecules; and (g) correlating the sequence analysis information to a position in the tissue sample for the purpose of carrying out the aforementioned method in the territory of the countries listed in A.;

II. offering, placing on the market, using or either importing or possessing for the aforementioned purposes, in the territory of one or more of the states mentioned in A., an array for use in the localised detection of nucleic acid in a tissue sample comprising cells, (alternatively: wherein the tissue sample is a tissue section) comprising a substrate on which multiple

species of capture probes are directly or indirectly immobilized such that each species occupies a distinct position on the array and is oriented to have a free 3' end to enable said probe to function as an extension primer, wherein each species of said capture probe comprises a nucleic acid molecule with 5' to 3':

(i) a positional domain that corresponds to the position of the capture probe on the array, and

(ii) a capture domain to capture nucleic acid of a tissue sample that is contacted with said array comprising a poly-T DNA oligonucleotide comprising at least 10 deoxythymidine residues.

B. order the Defendant to pay to the Court, in the event of any contravention of the Order in A. above, a (possibly repeated) penalty payment of up to EUR 100,000 for each day of contravention;

C. order the Defendant to reimburse the Applicant for the costs of the proceedings as well as provisional costs in the amount of EUR 200,000;

D. order that the Orders are immediately effective and enforceable;

E. reject the Defendant's request d) for compensation for "reputational and other damage incurred";

F. reject the Defendant's request e) for the provision of an enforcement security pursuant to Art. 82(2) UPCA and R. 211.5 RoP;

G. order, pursuant to R. 9.1 and 158 RoP (by analogy), the Defendant to provide, within a time limit to be set by the Court, security for all of the Applicant's anticipated costs of proceedings, including potential Court costs, in an amount to be determined by the Court;

H. issue a decision by default against the Defendant in the event that the Defendant does not comply with the order for security within the time limit set (R. 355 RoP).

The Defendant requests in this matter that the Court

a) reject the Application for provisional measures;

b) order that the Applicant must compensate the Defendant for the reputational and other damage suffered by the Defendant as a result of this method in accordance with Art. 68 (3) UPCA;

c) order, for the enforcement of provisional measures pursuant to Art. 82(2) UPCA and R. 211.5 RoP, the provision of a security at least equal to the value of the action;

d) order the Applicant to bear all litigation damages and other expenses incurred by the Defendant in these proceedings pursuant to Art. 69 UPCA and to refund provisional costs in the amount of EUR 200,000.

POINTS AT ISSUE:

The Applicant considers the offering and sale of the contested embodiments in Germany, France and Sweden to be a direct or indirect infringement of the patent at issue. The method used by means of the contested embodiments for the detection and localisation of nucleic acids realises literally all the features of patent claim 1. It is based on the "Slide-seq" method, which is described in the "Science" and "nb" articles submitted as annexes BP 3 and BP 4. The Applicant offers the contested embodiments, inter alia, in the aforementioned states for use in those states.

The validity of the patent at issue is sufficiently certain. Patents already granted are presumed to be valid. The burden of proof for invalidity lies with the Defendant. In addition, the competent Examining Division of the European Patent Office had not found any of the documents of the state of the art identified during the procedure of granting the patent at issue and mentioned on the cover sheet of the patent in suit to be prejudicial to the way of the novelty or inventive step of the subject matter of the asserted claims 1 and 14.

The ordering of provisional measures is necessary. The Applicant would suffer considerable damage if its only option for enforcing its cease-and-desist request were by way of proceedings on the merits. The Applicant and the Defendant are direct competitors. It must be assumed that research institutions and research teams will not readily switch to a product from another manufacturer, as this would make it significantly more difficult to compare their research work in research projects that have been running for multiple years. The Application for ordering of provisional measures is also urgent. It was made at the earliest possible time and without undue delay. In October 2023, the Applicant gained initial knowledge of the Defendant's possible marketing activities without knowing that it was also active in Germany, France and Sweden. In the course of this, the Applicant immediately carried out further searches and first determined the ex-post transparency notification about the acquisition of the contested embodiment by the University Medical Centre Mannheim.

The Applicant then expanded the investigations and learned from the sales conversation on 10 November 2023 that such activities were taking place in all the protection states for the patent at issue. The Applicant then immediately requested, by means of the present Application, the ordering of provisional measures.

The weighing-up of interests that is to be carried out should be understood in such a way that it serves to mitigate undue hardship in individual cases. As a rule, therefore, provisional measures should be ordered if the other requirements are met. Such hardship was not evident in the present case. Since the contested embodiments are consumable products that are distributed internationally without regional specifics, there is in particular no need for the Defendant to be able to distribute any stocks to the three protection states of Germany, France and Sweden. Nor could any market launch costs incurred by the Defendant in other regions be offset. By contrast, the Applicant loses market share every day and its exclusive right loses one day of its term for each day on which it cannot be enforced.

In the opinion of the Defendant, the contested embodiments do not make use of the technical teaching of the patent at issue. The patent at issue relates to ordered arrays of oligonucleotide sequences which are printed onto the substrate in a defined, predetermined configuration so that unique sequences correspond to specific positions on the array. To facilitate analysis of the array after hybridisation of the sample, the method protected by the patent at issue comprises a step in which the oligonucleotide sequences are separated from the

array surface to enable subsequent processing in the solution phase (e.g. sequencing). In contrast, the tiles of the contested embodiments use barcoded beads, which are distributed at random on a substrate and which are not so unique "that each species occupies a distinct position on the array" due to "bead duplicates" present in the tile. Therefore, each tile is unique. In addition, the barcode sequences would not correspond to specific positions. Thanks to the random bead-based technology, the oligonucleotide sequences do not have to be separated from the surface of the array either. The array is destroyed in order to permit the subsequent processing in a single pool.

Insofar as the Applicant refers to scientific articles (Annexes BP 3 and BP 4) in the context of the reasons for the allegation of infringement, these do not describe the contested forms of implementation, which is why the Applicant has so far failed to provide evidence of infringement.

Validity is not certain to the extent required for the ordering of provisional measures. The protected teaching was not novel over US 2010/00357763 ("Chen"), US 2003/0162210 ("Chetverin"), WO 2012/048341 ("Harvard") and Kuhn et al. (2004) Genome Res 14(11):2347-56 ("Kuhn"). In any case, there was no inventive step when proceeding from Chen or Chetverin. Moreover, claim 1 of the patent at issue, among others, went beyond the original disclosure.

The Applicant also unreasonably delayed its Application. The Applicant had been aware of the features of the kit and the Defendant's allegedly infringing activities since November 2022 at the latest. The Applicant had known that the kit had been marketed worldwide from the end of 2022 and had been sold worldwide since February 2023. At the end of January 2023, the Defendant operated a stand at the "Festival of Genomics" in London, where it advertised its only product line. The Applicant must have noticed this stand. On 8 February 2023, the Defendant announced the worldwide launch of the kit. In the same month, the sales manager for Europe was hired. He had been based in Heidelberg from the very first day and had already made contact with potential customers in the EU and also in Germany within a few days of taking up his position. The Applicant was therefore aware that the Defendant had been offering the kit for sale in Europe since at least January 2023 and that it had been available for sale worldwide since February 2023. With regard to the list of other events at which the kit was advertised, in particular for participants in Europe, reference is made to Annex CR-1.

The patent at issue was already available as a bundle patent in Germany, France and Sweden prior to 1 June 2023. With regard to the Unified Patent Court, the applicant could also have been ready to bring an action as of 1 June 2023. Nevertheless, not only did it not bring an action before the national courts before 1 June 2023, but it also did not make use of the possibility – that already existed at the start of the Unified Patent Court – of filing an Application for provisional measures.

The ordering of provisional measures is not necessary. The Unified Patent Court is set up to issue a permanent prohibitory injunction within one year if necessary. The ordering of provisional measures is therefore necessary and admissible only in particular circumstances. Damage that can be compensated for by an award for damages cannot per se justify the ordering of provisional measures. Rather, such damage must be so great that it cannot be remedied by an award for damages at the end of the proceedings. The Applicant has not demonstrated the risk of such damage. The Applicant's products and the contested embodiments are not interchangeable, and therefore the Applicant is not at risk of losing market share. Even if there were a loss of market share, this would cease in the event of a prohibitory injunction after the trial. The mere allegation or even the mere finding of a possible loss of market share does not per se necessitate the ordering of provisional measures or guarantee the risk of significant or irreparable damage. Moreover, the damage arising from the issuance of a prohibitory injunction at a later time is low. In the context of the weighing-up of interests, which is always necessary, it must be taken into account that a prohibitory injunction would constitute undue hardship for the Defendant. If such an injunction were to be issued by the Court ordering provisional measures, the Defendant would suffer irrecoverable damage. The Defendant is a small company with a single product line. The Defendant's small size and young age make said company particularly vulnerable to fluctuations in financing. In addition, the Defendant had only a very limited amount of time to examine the validity and ownership of the patent. In contrast, the damage to the Applicant if it waited for the proceedings on the merits would be small and predictable. The Applicant does not manufacture a product that is interchangeable with the contested embodiment. Any damage it may suffer would generally be of a financial nature and can be remedied by an award for damages.

The Applicant has contested the Defendant's submissions.

In addition, and to avoid repetition, reference is made to the parties' exchanged written submissions and annexes.

GROUND FOR THE ORDER:

The admissible Application for an Order on provisional measures is partially justified.

I.

Insofar as the Defendant objects to the Application for provisional measures with regard to [R. 206.2\(d\) RoP](#), the requirements set out in this provision relate to the content of the Application. They therefore concern its merits. In the context of the Orders to be made by the judge in the proper exercise of discretion in accordance with [R. 209](#), [211](#) and [212 RoP](#), non-compliance with the requirements set out in [R. 206.2\(d\) RoP](#) may be to the detriment of the Applicant. A possible infringement of [R. 206.2\(d\) RoP](#) does not therefore lead to the Application being inadmissible ([UPC CoA 335/2023, Order of 26 February 2024, GRUR-RS 2024, 2829, para. 61](#)).

II.

As the registered proprietor of the patent at issue, the Applicant is entitled to file a request pursuant to [Art. 47\(1\) UPCA](#) in conjunction with [R. 8.5\(a\) and \(c\) RoP](#).

Pursuant to [R. 211.2 RoP](#), the Court may require the applicant to provide reasonable evidence to satisfy the Court with a sufficient degree of certainty that the applicant is entitled to commence proceedings pursuant to [Art. 47 UPCA](#). In principle, it is therefore up to the Applicant to prove its entitlement to apply.

2.

The Applicant has thus fulfilled its burden of proof by submitting, as annexes BP 7a, BP 8a and BP 9a, extracts from the national patent registers for all Contracting Member States relevant to the present dispute, each of which identifies it as the patent proprietor. If in the case of a European patent a person is registered as the patent proprietor in the respective national register, there is a rebuttable presumption that the person recorded in the respective national register is entitled to be registered, [R. 8.5\(c\) RoP](#) (see Tilmann/Plassmann, Einheitspatent, Einheitliches Patentgericht, [Art. 47 UPCA, para. 4](#)). The result of such a rebuttable legal presumption is to reverse the burden of explanation and proof with regard to the presumed fact.

Since the Applicant is now registered as the patent proprietor in the registers relevant to the present dispute, in Germany, France and Sweden, it would therefore be up to the Defendant to set out and, if necessary, prove that the Applicant is nevertheless not entitled to be registered within the meaning of [R. 8.5\(a\) RoP](#). The Defendant's submission is not sufficient in this regard.

It is not disputed that the three inventors named in the patent at issue (Jonas Friesen, Patrik Ståhl and Joakim Lundberg) were the applicants for the GB priority application and the PCT application on which the patent at issue is based. The rights to the invention, including the PCT application, were then assigned by the three applicants to Spatial Transcriptomics AB under Swedish law (see Annex BP 23). By means of a further assignment, the Applicant became the registered proprietor of the patent at issue.

To the extent that the Defendant attempts to cast doubt on Patrik Ståhl's right to the GB application and the PCT application by referring to his employment as a post-doctoral researcher at Karolinska Institutet, its submission in this regard is not sufficient to rebut the presumption of the Applicant's entitlement to apply. The Applicant has not only disputed that Patrik Ståhl's invention contribution is related to his work for the Karolinska Institutet, as asserted by the Defendant, but has also set out in detail that the invention work was carried out at the SciLifeLab in Stockholm according to a report by the renowned Swedish university KTH Royal Institute of Technology (KTH) (Annexes BP 24 and BP 25). In addition, according to the Defendant's submission, the work contract in question had already begun on 11 February 2011. The UK patent application, comprising 85 pages of description alone, was filed with the UK Intellectual Property Office on 14 April 2011 and thus only 9 weeks after the start of work. Even if the

British patent application coincides with the activity (started only a short time before) as a post-doctoral researcher, the scope of the patent application alone does not necessarily indicate that the invention is related to Patrik Ståhl's work at Karolinska Institutet. This would require further explanations, which are lacking. Apart from this, the Defendant has also not specifically shown that the Karolinska Institutet could have had rights to the relevant invention under Swedish law, nor has it sufficiently commented on possible legal consequences under Swedish law.

III.

The Local Division in Düsseldorf is convinced with a sufficient degree of certainty (**R. 211.2 RoP**) that the Applicant's right is infringed by the offer and distribution of the contested embodiments within the Contracting Member States of Germany, France and Sweden (**Art. 25(a) UPCA**). On summary examination, the contested embodiments make direct and literal use of the technical teaching of the patent at issue protected by patent claim 14. In contrast, an indirect infringement of patent claim 1 (**Art. 26 UPCA**) cannot be established.

1.

The invention relates to the localised or spatial detection of nucleic acid in a tissue sample.

In terms of state of the art, the document of the patent at issue first describes possibilities for nucleic acid analysis (para. [0005] to [0009]), which are subdivided into in vitro techniques on the one hand and in situ techniques on the other (para. [0009] f.).

In vitro techniques that require the extraction of nucleic acids from the tissue and thus lead to the loss of spatial context information include the VP Elisa (enzyme-linked immunosorbent assay), qPCR (quantitative polymerase chain reaction), (micro) assays and RNA sequencing, including NGS ("next-generation sequencing") technologies (para. [0010] f., [0016] - [0019]). These examination methods usually also result in average values being determined for a large number of cells from a tissue. At the time of priority, methods for sampling smaller tissue areas or individual cells for analysis were generally labour-intensive, costly and had low precision (para. [0011] f.). Array technology was developed to analyse genes in parallel. The "next-generation DNA sequencing analyses" developed around 2009 make it possible to carry out genomic studies much more cheaply and quickly (Abs. [0016] - [0019]). An approach described by Tang et al. (Nat Protoc 2010, 5: 516-35) and Wang & Bodovitz (Trends Biotechnol 2010, 28: 281-90) for global gene expression analysis enables very precise analysis of cell-cell variations, but not high-resolution, highthroughput studies in intact tissues [0012]).

The patent at issue mentions in situ hybridisation (para. [0008]) as a possibility for the in situ study of gene expression in which the contextual information of the tissue is retained. However, such in situ methods have the disadvantage that they can only be used to analyse one or a few nucleic acids (e.g. for a tissue section) (para. [0013]). The patent at issue is therefore based on the task of providing transcriptomic information with a spatial

resolution in order to enable global gene expression analysis in tissue samples (cf. para. [0013]).

In order to solve this problem, the patent at issue protects, in patent claim 1, a method for the localised detection of nucleic acid in a tissue sample comprising cells, having the following features:

1.1. A method for localised detection of nucleic acid in a tissue sample comprising cells, wherein said method comprises:

1.2. (a) **providing an array** comprising a substrate,
1.2.1. on which multiple species of capture probes are directly or indirectly immobilized such that each species occupies a distinct position on the array and

1.2.2. is oriented to have a free 3' end to enable said probe to function as a primer for a primer extension or ligation reaction,

1.2.3. wherein each species of said capture probe comprises a nucleic acid molecule with 5' to 3':

1.2.3.1. (i) a positional domain that corresponds to the position of the capture probe on the array, and

1.2.3.2. (ii) a capture domain;

1.3. (b) **contacting said array with a tissue sample**

1.3.1. and allowing nucleic acid of the tissue sample to hybridise to the capture domain in said capture probes;

1.4. (c) **generating DNA molecules from the captured nucleic acid molecules** using said capture probes as extension or ligation primers,

1.4.1. wherein said extended or ligated DNA molecules are tagged by the positional domain or a complement thereof;

1.5. (d) optionally generating a complementary strand of said tagged DNA

1.5.1. and/or optionally amplifying said tagged DNA;

1.6. (e) **releasing at least part of the tagged DNA molecules**

1.6.1. and/or their complements or amplicons from the surface of the array,

1.6.1.1. wherein said part includes the positional domain and all of the sequence that is 3' to the positional domain or a complement thereof;

1.7. (f) **directly or indirectly analysing the sequence** of the released DNA molecules; and

1.8. (g) **correlating the sequence analysis information** to a position in the tissue sample.

The array protected by patent claim 14 has the following features:

14.1. An array for use in the localised detection of nucleic acid in a tissue sample comprising cells,

14.2. comprising a substrate

14.2.1 on which multiple species of capture probes are directly or indirectly immobilized such that each species occupies a distinct position on the array and

14.2.2. is oriented to have a free 3' end to enable said probe to function as an extension or ligation primer,

14.3. wherein each species of said capture probe comprises a nucleic acid molecule with 5' to 3':

14.3.1 (i) a positional domain that corresponds to the position of the capture probe on the array, and

14.3.2. (ii) a capture domain to capture nucleic acid of a tissue sample that is contacted with said array comprising

14.3.2.1. (a) a poly-T DNA oligonucleotide comprising at least 10 deoxythymidine residues and/or 14.3.2.1.1. a random or degenerate oligonucleotide sequence; or 14.3.2.2. (b) sequences specific for a group of genes.

2.

Some features require interpretation.

a)

According to [Art. 69 EPC](#) in conjunction with the [Protocol on its interpretation](#), the patent claim is not only the starting point, but the definitive basis for determining the protective scope of a European patent. The interpretation of a patent claim does not depend solely on its exact wording in the linguistic sense. Rather, the description and the drawings must always be taken into account as explanatory aids for the interpretation of the patent claim and not only be used to clarify any ambiguities in the patent claim. However, this does not mean that the patent claim serves only as a guideline and that its scope may extend to what, from a consideration of the description and drawings, the patent proprietor has contemplated ([UPC CoA 335/2023, Order of 26 February 2023 in conjunction with Order of 11 March 2023](#)), [Order of 11 March 2024, GRUR-RS 2024, 2829, headnote 2](#), and para. 73 - 77 - Nachweisverfahren; [UPC CFI 452/2023 \(LD Düsseldorf\), Order of 9 April 2024](#), p. 13, GRUR-RS 2024, 7207, para. 49).

b)

Having said this, [patent claim 1](#) protects a method for the localised detection of nucleic acid in a tissue sample comprising cells. If such localised detection is to be used to localise the RNA or DNA to its native position or location (para. [0032]), it is clear that the morphological structure of the tissue sample must be intact (cf. also para. [0012] "However, high throughput methods to study transcriptional activity with high resolution in intact tissues have not, until now, been available.", emphasis added). Only then, as envisaged by the invention, can the expression profiles or the location/distribution pattern of the expressed genes or the genome sequences be determined (cf. para. [0002]). In other words, it is precisely where a nucleic acid is located in a sample relative to other nucleic acids or to other native structures in the sample that is important. That this is the case is confirmed to a person skilled in the art by paragraphs [0013] f. of the description of the patent in suit: The method according to the invention is intended to enable global gene expression analysis in tissue samples which provides transcriptomic information with a spatial resolution. The aim is to obtain transcriptional information in a sample while retaining the positional information for each transcript. Nothing to the contrary follows from the paragraphs [0097] f. of the description of the patent at issue, referred to by the Defendant to justify its differing opinion. There is no dispute that the tissue sample to be analysed may be a collection of individual blood cells or other cell suspensions. Nevertheless, the relevant passage expressly states, "cells that do not interact directly, or are not present in a tissue context." (emphasis added). It therefore appears questionable whether single cells are

actually a "tissue sample" within the meaning of the patent claim. Even if this were the case, such an examination of single cells according to the invention in any case serves to localise the RNA or DNA at their original position in these cells (cf. para. [0032] and [0097], last sentence), which presupposes that their structure is still intact at the time of the examination. Only then are such cells suitable tissue samples within the meaning of the patent at issue.

Insofar as the Defendant also refers, in the context of interpreting the patent, to statements made by the Applicant in the granting procedure, such statements are not admissible material for interpretation. They are therefore generally not to be taken into account in the context of patent interpretation ([UPC CFI 452/2023 \(LD Düsseldorf\), Order of 9 April 2023, headnote 1, GRUR-RS 2024, 7207](#)). [Art. 24\(1\)\(c\) UPCA](#) in conjunction with [Art. 69 EPC](#) conclusively determine which documents are to be used for interpreting the patent claims determining the protective scope, namely the patent description and the patent drawings. Since the grant file is not mentioned in [Art. 69 EPC](#), it does not by law constitute admissible material for interpretation (see also Kühnen, Handbuch der Patentverletzung, 16th ed., Section A, para. 114; Benkard/Scharen, EPÜ Art. 69, para. 32 with further references). If the applicant has commented on the meaning of a feature or term during the examination procedure, this may at best be indicative of how a person skilled in the art would understand the relevant feature. Whether, on the other hand, at least publicly accessible documents, such as the laid-open application, can be used to interpret the patent claim of the applicable version of the claim (apparently so: [UPC CFI 292/2023 \(LD Munich\), Order of 20 December 2023](#), GRUR-RR 2024, 93 - Elektronisches Etikett; in contrast: Kühnen loc. cit., para. 118), is not relevant for the present case and therefore requires no decision.

Moreover, the Applicant's submission in the granting procedure only proves that the localised detection of nucleic acids in a tissue sample comprising cells in accordance with the claim depends on the preservation of the information on the native sample context.

c)

As a person skilled in the art will be able to see from patent claim 1, the method for which protection is sought includes as a first step "providing" an array comprising a substrate. Feature group 1.2. does not contain further method steps that go beyond such provision; rather, feature group 1.2. is limited to the description of the more detailed technical design of the substrate. As long as the array provided complies with the spatial-physical requirements mentioned in feature group 1.2., the feature is realised, irrespective of how and above all using which process this spatial-physical design was created. Based on this, the substrate of the array is characterised by the fact that it has on it multiple species of capture probes which are directly or indirectly immobilized on the substrate, where each species occupies a distinct position on the array (feature 1.2.1.). Insofar as the German version of the patent claim, in contrast to the

English version, speaks of a “different” (“*unterschiedlichen*”) position on the array, the English version prevails. The patent at issue was granted in the English language of proceedings. Therefore, the English version of the patent claim is the binding version in each Contracting Member State ([Art. 70\(1\) EPC](#); see also [Benkard/Osterrieth, Europäisches Patentübereinkommen, 4th ed. 2023, Art. 70 para. 7](#)).

In order for the capture probes to act as primers for a primer extension or ligation reaction, they are orientated so that they have a free 3' end (feature 1.2.2.), whereby they have a position domain and a capture domain (feature group 1.2.3.) when viewed from 5' to 3'. The positional domain corresponds to the position of the capture probe on the array (feature 1.2.3.1.). It therefore enables the assignment of a capture probe to a specific position or feature on the array. The capture domain can selectively bind to a nucleic acid strand and is selected or designed accordingly (see also paragraphs [0063] - [0067] of the document of the patent at issue).

Patent claim 1 does not deal with the question of achieving such an arrangement. The only decisive factor is therefore that, at the time of providing the array, the capture probes are arranged as described in feature group 1.2. and are thus in particular directly or indirectly immobilised in such a way that each species occupies a unique position on the array, to which the positional domain corresponds. Put simply, each species must therefore be in a unique position at the time the array is provided. As long as this is ensured, patent claim 1 leaves it to the person skilled in the art to decide whether to ensure such positioning of the capture probe by firstly, as in the case of the printing methods described in paragraphs [0217], [0268], [0348] and [0351], determining the desired position on the array and then placing the capture probes there or whether, alternatively, by initially distributing the capture probes at random on the array and only subsequently determining their position. If such linking of position and capture domain takes place before the provision of the array, each species occupies a unique position at the time of providing the array, as required by features 1.2. and 1.2.1.

Why unique positioning of this kind is required will become clear to a person skilled in the art when considering the last steps of the method protected by patent claim 1: in order to permit the localised detection of nucleic acids, which is the purpose of the invention (cf. para. [0001]), it is crucial that the position domain which is read out can be assigned to its original position on the array during the analysis at the end of the method. To ensure this, each species should occupy a predefined position on the array at the time of provision of the array and be (directly or indirectly) immobilised in this position. The time at which this determination is made prior to the provision of the array is irrelevant for the subsequent position evaluation.

d)

Feature group 1.6. requires the release of at least part of the tagged DNA molecules from the surface of the array, wherein the (released) part includes the positional

domain and the entire sequence that is 3' to the positional domain, or a complement thereof.

If at least part of the tagged DNA molecules are to be separated from the surface of the array, it is clear that both parts of DNA molecules and a surface of the array, which are separated from each other, must be present at the time of separation. However, nothing is said about the question of the constitution of such a surface or surface structure. In particular, patent claim 1 does not require the surface of the array to remain unchanged throughout the method, nor does it require the surface to be intact at the time of release.

A person skilled in the art attempting to deduce therefrom the scope of feature group 1.6. will therefore turn to the description of the patent at issue. There, para [0143] discloses that in the release step DNA is removed from the array, wherein this DNA includes the positional domain (or its complement). If this condition is met, it will be possible to obtain sequence analysis data which can be correlated with the various regions in the tissue sample. Thus, in order to obtain the information sought by the method according to the invention about the distribution, location or expression of genomic sequences in a tissue sample while maintaining the spatial pattern of expression, distribution or location (see para. [0002]), it is crucial that the linkage of DNA and positional domain is maintained. From a functional point of view alone, it is therefore crucial that the array remains intact as long as and only to the extent that a DNA molecule has been synthesised which comprises the position domain and the sequence of the analyte. In addition, paragraph [0144] of the description of the patent at issue clarifies that the release step may comprise a separation of a DNA molecule from the array. However, nucleic acid cleavage is not required, as DNA can also be released by denaturation of a double-stranded molecule. Accordingly, a DNA molecule can be released by nucleic acid cleavage and/or by denaturation (para [0144]).

However, the person skilled in the art must not stop at such purely functional considerations.

Art. 69 EPC should not be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. Rather, the patent claims define the protective scope of the patent under Art. 69 EPC and thus the rights of the patent proprietor in the designated Contracting States under Art. 64 EPC, taking into account the requirements for patentability under Art. 52 to 57 EPC (see [EPO EBA, 11 December 1989, G 2/88, OJ 1990, 93](#) para. 2.5). In the context of its interpretation, adequate protection for the patent proprietor must be combined with sufficient legal certainty for third parties (cf. Art. 1 Prot. on the interpretation of Article 69 EPC; [UPC CoA 335/2023, Order of 26 February 2023, GRUR-RS 2024, 2829, para. 78 f. - Nachweisverfahren](#)).

On this basis, the person skilled in the art must bear in mind that patent claim 1 protects a method which is characterised by a specific sequence of method steps.

The fact that this is the case and that all obligatory method steps are to be carried out one after the other is already made clear in patent claim 1 by the designation of the individual steps ((a), (b), (c) etc.) provided there. Apart from this, the steps mentioned in the patent claim also build on each other in terms of content: The provided array is brought into contact with a tissue sample, enabling hybridisation of nucleic acid of the tissue sample at the capture domain in the capture probes. DNA molecules are generated from the captured nucleic acid molecules, whereby the extended or ligated DNA molecules are provided with a tag via the positional domain or a complement thereof. Some of the (tagged) DNA molecules are released from the surface of the array. The sequence of the released DNA molecules is analysed before the information from the sequence analysis is correlated with a position on the tissue sample (emphasis added). Nothing else emerges from the English version of the patent claim, which is authoritative in the present proceedings and states, inter alia, that

"A method for localised detection of nucleic acid in a tissue sample comprising cells, wherein said method comprises:

- (a) providing an array [...]
- (b) contacting said array with a tissue sample and allowing nucleic acid of the tissue sample to hybridise to the capture domain in said capture probes;
- (c) generating DNA molecules from the captured nucleic acid molecules using said capture probes as extension or ligation primers, [...]
- (e) releasing at least part of the tagged DNA molecules and/or their complements or amplicons from the surface of the array, wherein said part includes the positional domain and all of the sequence that is 3' to the positional domain or a complement thereof;
- (f) directly or indirectly analysing the sequence of the released DNA molecules; and
- (g) correlating the sequence analysis information to a position in the tissue sample." (emphasis added)

If some of the generated and tagged DNA molecules are to be removed from the surface of the array ("releasing ... from the surface of the array"), a surface structure of the array, from which the release takes place, must be present at the time these molecules are released. In contrast, both the method used for the release and the more detailed design of this surface structure are left to the discretion of the person skilled in the art. In particular, patent claim 1 does not require that the surface structure is complete, nor that it is unchanged or intact compared to the start of the process. However, it must still exist and thus be identifiable.

What the patent at issue understands by an "array" will be clear to a person skilled in the art from paragraph [0016] of the description of the patent at issue, where it states:

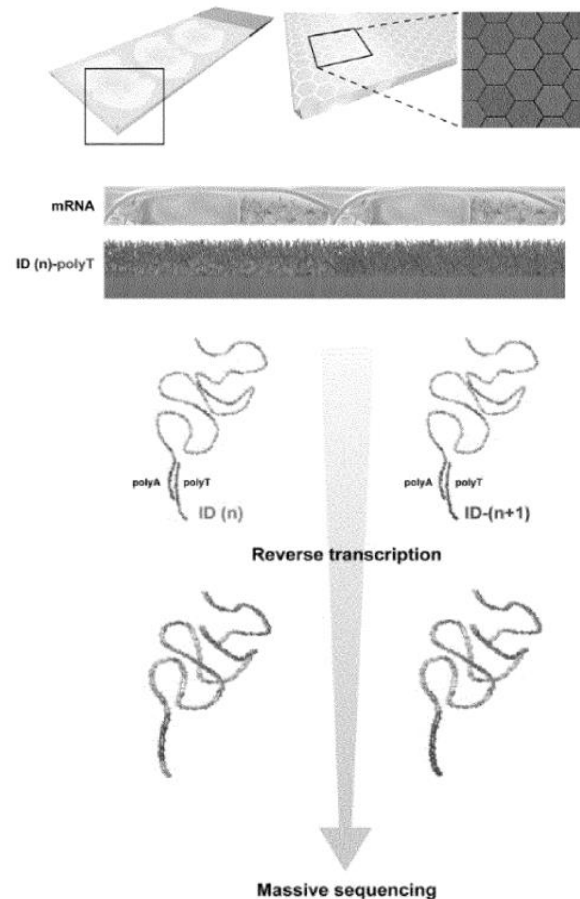
"Array technology, particularly microarrays, arose from research at Stanford University where small amounts of DNA oligonucleotides were successfully attached to a glass surface in an ordered arrangement, a so-called array [...]". (emphasis added)

In addition, paragraph [0021] states:

"[...] The invention requires reverse transcription (RT) primers, which also comprise unique positional tags (domains), to be arrayed on an object substrate, e.g. a glass slide, to generate an 'array'". (emphasis added)

In addition, Figure 1, shown in reduced form below, illustrates how oligonucleotide probes can be bound to an array substrate at either the 5' or 3' end to obtain an array with capture probes (see para [0216]).

Figure 1



Even if Figure 1 merely represents an exemplary embodiment to which the protective scope of the patent at issue may not be reduced, it illustrates the insight already gained from the passages of the description of the patent at issue quoted above regarding the understanding of the term "array" on which the patent at issue is based: an array within the meaning of the patent at issue can only be said to exist if oligonucleotides or oligonucleotide probes (plural) are applied to a surface

in an ordered manner. There is no longer an array if the connection between the oligonucleotides or oligonucleotide probes and the surface and thus also the corresponding arrangement is dissolved.

3.

Patent claim 14 protects an array. What is protected is therefore a product per se, irrespective of the use to which it is actually put.

Insofar as, according to the wording of the patent claim, it is to be an "array for use in the localised detection of nucleic acid in a tissue sample comprising cells" (German: "Array zur Verwendung beim lokalisierten Nachweis von Nukleinsäure in einer Zellen umfassenden Gewebeprobe"), the reference to such a possible use is merely a stated purpose, which cannot on its own define the absolute protection granted by a product claim. Such statements of purpose usually serve to improve understanding of the invention and as a rule have the indirect effect of defining the subject matter protected by the patent in such a way that it must not only fulfil the spatial-physical features, but must also be designed to be usable for the purpose stated in the patent claim (see Benkard/Scharen, Europäisches Patentübereinkommen - EPÜ, 4th ed., Art. 69 para. 51). The claimed array comprises a substrate which, in its spatial-physical design, initially corresponds to feature groups 1.2.1. to 1.2.3. of patent claim 1. To avoid repetition, reference can therefore be made to the relevant explanations. Since patent claim 14 protects a product, a design already falls within the protective scope if it has the spatial-physical features included in the claim.

In contrast, the method used to manufacture the product is irrelevant. The question discussed by the parties of possibly restricting the scope of protection to the print methods mentioned in the description of the patent at issue therefore has no significance from the outset with regard to patent claim 14. In contrast to patent claim 1, patent claim 14 further defines the capture domain for capturing nucleic acid from a tissue sample (feature group 14.3.2.). According to feature 14.3.2.1., the capture domain comprises a Poly-T DNA oligonucleotide which comprises at least 10 deoxythymidine residues, i.e. a series of at least 10 consecutive deoxythymidine residues which are linked by phosphodiester bonds. According to feature 14.3.2.1.1. the capture domain may contain a random or degenerate oligonucleotide sequence in addition to or instead of the Poly-T DNA oligonucleotides. In addition, the capture domain may also include sequences specific for a group of genes (feature 14.3.2.2.). In this case, the capture domain does not comprise a Poly-T DNA oligonucleotide as in feature 14.3.2.1. but specific nucleotide sequences matched to the nucleic acid to be detected.

4.

On the basis of such an understanding, it is at least more likely than not that the contested embodiments make literal use of the teaching of patent claim 14. The Local Division is therefore satisfied with a sufficient degree of certainty that the contested embodiments infringe the

patent at issue (Art. 62(4) UPCA in conjunction with R. 211.2 RoP, see [UPC CoA 335/2023, Order of 26 February 2023](#), GRUR-RS 2024, 2829, headnote 3. and para. 90 - 94 - Nachweisverfahren; [UPC CFI 452/2023 \(LD Düsseldorf\), Order of 9 April 2024](#), GRUR-RS 2024, 7207).

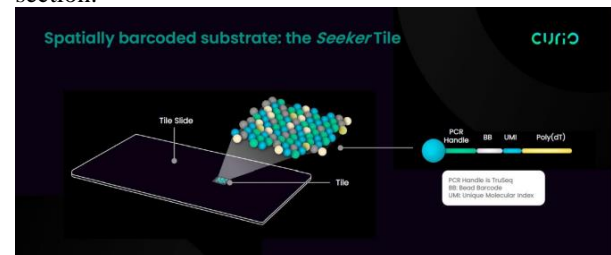
aa)

The realisation of features 14.1. and 14.2., 14.2.2. and 14.3.2. is correctly not in dispute between the parties, and for that reason no further explanation is required in this respect.

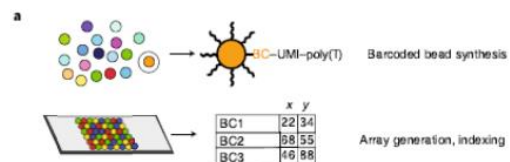
bb)

Furthermore, multiple capture probes are also directly or indirectly immobilised on the substrate such that each species occupies a distinct position on the array (feature 14.2.1.). Correspondingly, the species of capture probes each comprise a nucleic acid molecule with from 5' to 3' a positional domain that corresponds to the position of the capture probe on the array (feature 14.3.1.).

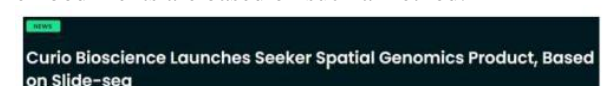
As the figure shown below, taken from annex BP 14, illustrates, the capture structure of the contested embodiments consists of a barcode, a positional domain (BB), a unique molecular identifier (UMI) and a poly-T section.



Each capture structure/capture probe therefore has a barcode (BB) that represents a specific position on the array. This can be seen in the figure below, in which the barcodes are labelled with the abbreviation "BC":



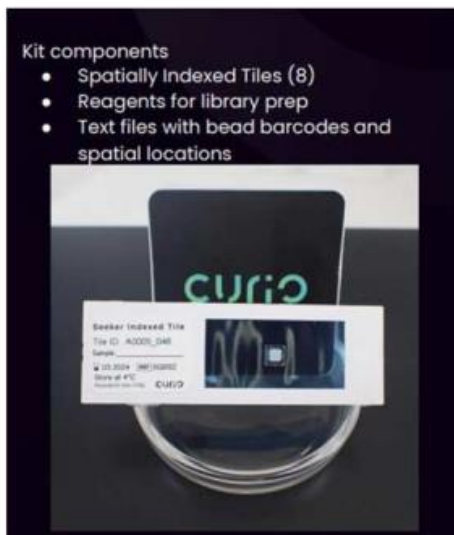
The fact that this figure is taken from Annex BP 4 does not diminish its significance for the present proceedings. Even if this annex is a scientific publication which describes a so-called "Slid-seq" method, but not directly the contested embodiments, the Defendant itself emphasises in the press release submitted to the file by the Applicant as Annex BP 20 that the contested embodiments are based on such a method:



If, as here, the Defendant refers to alleged deviations between the contested embodiments and the method described in the aforementioned article, it is up to the Defendant to work out in each case in relation to individual features of the patent claim how specifically the technical design of the contested embodiments deviates in each case from the description in the article.

The Defendant did not sufficiently fulfil this requirement. It merely refers to the fact that the contested embodiments have at least 50% more beads per tile for the 3x3 variant and more for the 10x10 tile. In addition, the section "First-Strand synthesis" referred to by the Applicant refers to a "template switch oligonucleotide", which is not contained in the contested kit. On the other hand, the Defendant did not (specifically) deny that the principle shown in the above figure, taken from Annex BP 4, is also found in the contested embodiments (R. 171.2 RoP).

The barcode of the capture probes located on a bead is identical and can therefore be assigned to the original position of the bead within the array. It is undisputed and confirmed by the figure shown below, taken from annex BP 14, that the shipment package of the contested embodiments includes files with the aid of which the barcodes or positional domains can be assigned to the associated positions on the array:



Since in the contested embodiments the barcoded beads are distributed randomly, it is imperative that the beads are localised following this random distribution. In any case, this is accounted for by means of the text file provided, which can be used to combine the positional domain information with the localisation information. Thus, in the contested embodiments, each capture structure/capture probe has a specific position, which can also be read out via the positional domain. A predetermination of the position of the beads on the array is not required in order to realise the protected technical teaching.

The fact that the use of bead technology may occasionally result in duplicate beads containing the same bead codes does not justify a different assessment, if only because the patent at issue expressly permits the use of such bead technology (see also subclaim 21, which is dependent on claim 14, and para. [0044]). It therefore knowingly accepts possible inaccuracies with such a method.

cc)

The Applicant's assertion that the contested embodiments contained at least 10 deoxythymidine

residues was not substantially contested by the Defendant (feature 14.3.2.1., R. 171.2 RoP).

On the basis of the article submitted as annex BP 4, with regard to the relevance of which reference is made to the above explanations, the Applicant submitted detailed information on the configuration of the capture domain of the capture probe of the contested embodiments and, as evidence, specifically explained the length of the poly-T sequence (cf. written application, p. 57 f.). The Applicant has referred to the "supplementary Information" to the disclosure according to annex BP 3, from which a length of the poly-T sequences of 30 deoxythymidine residues is derived (cf. annex BP 3, p. 2 "Materials and Methods"). Like Annex BP 4, this annex is also relevant for the present proceedings. Concrete evidence that this length would have been changed during the development of the Defendant's commercial product, and in particular reduced to be less than 10, is neither submitted nor apparent. The Defendant has therefore not significantly countered the submissions of the Applicant supported by annexes BP 3 and BP 4. It can therefore be assumed that feature 14.3.2.1. has been realised.

5.

The Defendant does not deny that it offers and supplies the contested embodiments in Germany, France and Sweden, among others. It is also not disputed that the contested embodiments were delivered to the University Medical Centre Mannheim of Heidelberg University in the 37th calendar week of 2023 (see annexes BP 17 and BP 18). Against this background, the content of the video conference of 10 November 2023 is not relevant in the present case. Therefore, the question raised by the Defendant regarding the usability of the findings obtained on the basis of this conference, and in particular Annex BP 16, is not relevant to the decision and therefore does not require a decision.

6.

As is already clear from the wording of the requests, the Applicant is only asserting an indirect patent infringement with regard to patent claim 1 and not, as the Defendant has at times suggested, a direct patent infringement. The Local Division is not able to establish such an indirect infringement of patent claim 1 through the offer and distribution of the contested embodiments in Germany, France and Sweden for use there.

a)

Under Art. 26(1) UPCA (right to prohibit indirect use of the invention), a patent confers on its proprietor the right to prevent any third party not having the proprietor's consent from supplying or offering to supply, within the territory of the Contracting Member States in which that patent has effect, any person other than a party entitled to exploit the patented invention, with means, relating to an essential element of that invention, for putting it into effect therein, when the third party knows, or should have known, that those means are suitable and intended for putting that invention into effect.

b)

On this basis, the Local Division is unable to establish the suitability of the contested embodiments for carrying

out the method protected by patent claim 1. Based on the understanding of the protective scope elaborated above in detail, the Applicant has not succeeded in demonstrating conclusively that feature group 1.6. of patent claim 1 has been realised. As the Local Division has already worked out in detail in the context of the interpretation, features 1.6. and 1.6.1. require "releasing at least part of the tagged DNA and/or their complements or amplicons from the surface of the array" (in German: "eine Freisetzung wenigstens eines Teils der mit einem Tag versehenen DNA-Moleküle und/oder ihrer Komplemente oder Amplifikate von der Oberfläche des Arrays", emphasis added). Even if patent claim 1 does not specify the more detailed technical design of the surface structure of the array at the time of release, the presence of an array in the aforementioned sense, from the surface of which the release takes place, remains necessary.

This is lacking in the contested embodiments. As the Applicant explained in detail at the oral proceedings, the amplification (feature group 1.5.) optionally preceding the release step (feature 1.6.) in patent claim 1 already takes place on individual beads. However, an individual bead is not an ordered structure in the aforementioned sense and thus not an array. If the array has already been destroyed in the step preceding the release and is therefore no longer present, no release from the surface of such an array within the meaning of feature 1.6. can take place in the subsequent step. Therefore, the contested embodiments are not suitable for the realisation of the aforementioned feature.

III.

The validity of the patent at issue is certain to the extent required for the ordering of provisional measures. Also taking into account the submissions of the Defendant, the local division in Düsseldorf is satisfied with the "sufficient certainty" required under [Art. 62 \(4\) UPCA](#) in conjunction with [R. 211.2 RoP](#) of the validity of the patent at issue. Such "sufficient certainty" is lacking if the court considers it to be more likely than not that the patent at issue is not valid ([UPC CoA 335/2023, Order of 26 February 2023](#), GRUR-RS 2024, 2829, headnote 3. and paras. 73 - 77 - Nachweisverfahren; [UPC CFI 452/2023 \(LD Düsseldorf\), Order of 9 April 2024, p. 19](#), GRURRS 2024, 7207, para. 78).

1.

In this light, the local division assumes that the subject matter of patent claim 14 will prove to be patentable with sufficient certainty, at least in the alternative underlying the allegation of infringement. The validity of patent claim 1 requires no further discussion, since the local division has already been unable to establish any (indirect) infringement of this patent claim.

2.

The fact that the patent at issue has not yet survived any adversarial validity proceedings does not prevent the validity of the patent from being sufficiently certain. If the patent on which an application for the ordering of provisional measures is based has already been upheld in opposition proceedings before the European Patent Office, this must be taken into account in the exercise of

discretion, as must the outcome of other proceedings relating to the patent at issue before other courts in accordance with [R. 209.2 \(a\) RoP](#). In other words, upholding the validity of the patent at issue in proceedings before the European Patent Office or upholding a national part of the patent at issue before a national court is a strong indication of sufficiently certain validity (cf. Tilmann/Plassmann/vs. Falck/Dorn, Einheitspatent, Einheitliches Patentgericht, Rule 209 para. 8 et seq.).

If such other proceedings are merely to be included in the exercise of discretion, it follows conversely that the validity can also be sufficiently certain without such prior proceedings. An important indication of this is if the patent in question was published several years ago, as in this case, but its validity was not challenged. In such a case, it is also the task of the panel to assess whether the validity of the patent at issue is sufficiently certain on the basis of the state of the art presented by the Defendant's side. This is the case regardless of the differentiation of certain degrees of probability in any event (cf. [UPC CFI 2/2023 \(LD Munich\), Order of 19 September 2023](#), GRUR 2023, 1513, 1520, 1521 - Nachweisverfahren) if the objections raised against the validity of the patent at issue are not likely to give rise to significant doubts as to the validity of the patent at issue ([UPC CFI 452/2023, Order of 9 April 2024](#), p. 19, GRUR-RS 2024, 7207, para. 80).

3.

Based on these principles, the validity of the patent at issue is sufficiently certain to the extent relevant in the present case. The patent at issue was granted in 2019 without any objection having been lodged against its grant. On summary examination, the Defendant's arguments do not have the potential to give rise to significant doubts as to the validity of patent claim 14 of the patent at issue.

a)

The fact that the Applicant has decided to file auxiliary requests in the light of the Defendant's submissions does not in itself give rise to any doubts as to validity. The formulation of such auxiliary requests is rather an expression of legal caution. This is already necessary because the Court of Appeal addressed the possibility of the inadmissibility of auxiliary requests in the second instance in its Order of 26 February 2024, but ultimately left the question open ([UPC CoA 335/2023, Order of 26 February 2023](#), GRUR-RS 2024, 2829, para. 116 - Nachweisverfahren).

b)

On summary examination, the subject matter of patent claim 14 proves to be novel compared to the state of the art cited by the Applicant, [Art. 54 EPC](#).

aa)

A technical teaching is new if it differs from what is known in the state of the art in at least one of its known features. It is anticipated if all its features are also found in the state of the art (cf. Benkard/Mellullis/Koch, Europäisches Patentübereinkommen - EPÜ, 4th ed., Art. 54 para. 22). Only that which is directly apparent to a person skilled in the relevant technical field from the

publication or prior use is anticipated in the state of the art. Knowledge gained by a person skilled in the art only on the basis of further considerations or the consultation of further publications or uses is not relevant for the assessment of novelty.

bb)

In light of the above, the following applies in the present case:

(1)

US 2010/0035763 A1 ("Chen", Annex CR 9) discloses a "method of screening single cells for the production of biologically active substances".

As the Defendant concedes (cf. objection document, para. 7.85), there is in any event no disclosure of feature 14.3.2.1. of patent claim 14 in this document of the state of the art, where the capture domain is specified to contain "a Poly-T DNA oligonucleotide comprising at least 10 deoxythymidine residues". For this reason alone, at least not all features of patent claim 14 are disclosed in the alternative on which the allegation of infringement is based.

Otherwise, patent claim 14 of the patent at issue protects an "array for use in *the localised detection of nucleic acid in a tissue sample comprising cells*" (emphasis added).

It is not apparent that the method disclosed in the document of the state of the art is suitable for such detection. Picotiter plates are used there (cf. para. [0117]), into which different cells are placed. These cells are then lysed (and thus destroyed). In addition, the proteins are removed from the sample solution containing mRNA (the target molecules) (paras. [0117] and [0123] - [0125]). The picotiter plate is then covered with a NimbleGen-HD-2 microarray chip (paras. [0103], [0130], [0206]). The sample is then dried and further processed at (para [0132] et seq.). When the sample solution is transferred between the two plates, the connection of the lysate of a single cell to the well of the picotiter plate is lost, because oligonucleotide pads are partially covered by walls of the picotiter plate, which results in lysates from several picotiter plate wells being transferred to a single oligonucleotide pad and the lysate from a picotiter plate well being transferred to several oligonucleotide pads (para. [0206]).

The Defendant has not been able to conclusively demonstrate why the array should nevertheless be capable of a localised detection of nucleic acid in a tissue sample in the aforementioned sense. Based on the disclosure content of the document of the state of the art, such circumstances are also not apparent in such a manner that, in the event of a challenge to the validity of the patent at issue, it is more likely than not that the patent will be revoked. The mere fact that NimbleGen chips are mentioned both in the document of the patent at issue and in the document of the state of the art (document of the patent at issue: para [0052]; document of the state of the art: para [0126]) does not justify such a capability, because the cells are lysed and thus destroyed according to the solution disclosed in the document of the state of the art. As a result of the disclosed procedure, the assignment to a specific

position on the array required by the claim is therefore lost. This in itself prevents localised detection of nucleic acid within the meaning of the patent at issue, irrespective of the chip used.

(2)

US 2003/0162210A1 ("Chetverin", annex CR 11) relates to "novel oligonucleotide arrays and their use for sorting, isolating, sequencing, and manipulating nucleic acids" (German: "Neuartige Oligonukleotid-Arrays und ihre Verwendung zum Sortieren, Sequenzieren und Manipulieren von Nukleinsäuren"). The array comprises predetermined regions, with each region containing multiple copies of a binary oligonucleotide of a predetermined sequence, which are covalently bonded to the surface. The binary oligonucleotide consists of a constant and a variable nucleotide sequence, wherein the constant nucleotide sequence is the same for all oligonucleotides on the array.

The solution disclosed in the document of the state of the art therefore concerns a gene analysis and not a cell analysis. Why the array disclosed therein should be suitable for use with a tissue or intact cells is neither sufficiently argued nor apparent. In any case, the array described in paras. [0242] and [0247] is brought into contact with digested DNA. Apart from this, the Defendant has in any case not been able to demonstrate that the array disclosed in the document of the state of the art has a positional domain within the meaning of feature 14.3.1. corresponding to the position of the capture probe on the array. Such positional domains are not required in the procedure described in the document of the state of the art. Insofar as the Defendant wishes to identify such a positional domain in the variable segments of the oligonucleotides, these segments can vary both in their sequence and in their length (cf. para. [0009] of the document of the state of the art) and are thus not uniform over the entire array. However, this alone does not allow for the conclusion that the variable sequences correspond to the position of the capture probe on the array and are therefore positional domains within the meaning of the patent at issue.

(3)

Also, WO 2012/048341 A1 (Harvard) (Annex CR 13), which is only relevant with regard to novelty under Art. 54(3) EPC, does not anticipate the technical teaching protected by the patent claims in question in a manner prejudicial to novelty.

The document of the state of the art relates to methods and compositions for obtaining and analysing nucleic acid sequences derived from many cells at once (para [0003]). As the person skilled in the art will appreciate from para [0007] of the document of the state of the art, the disclosed approach can be used to efficiently produce bar-coded beads coated with clonal copies of the bar-coded oligonucleotides having the correct sequence. This means that millions of uniquely bar-coded beads can be generated for single cell analysis (para. [0007]). In one configuration of the disclosed invention, many individual cells in a complex mixture of cells are bar-coded. Each cell is provided with a unique individual barcode for each cell. Here, the term "barcode" refers to

a unique oligonucleotide sequence that allows a corresponding nucleic acid base and/or nucleic acid sequence to be identified (para [0036]). This unique barcode therefore allows the nucleic acids of each cell to be linked to the original cell. The barcode is inserted into each individual cell in such a manner that each cell receives a unique barcode and is present in a sufficient quantity to enable subsequent genomic or transcriptomic targeting. Once the barcode is inserted, downstream manipulations are performed to capture and sequence all these unique barcodes and the genomic and transcriptome sequences of interest in one simultaneous reaction. When such an approach is combined with high-throughput sequencing technology, it enables the analysis of a large number of single cells in a single reaction assay (para. [0009]).

Thus, unlike in the technical teaching protected by the patent at issue, the barcode does not correspond to a specific position on an array. Instead, it marks a specific cell in order to be able to assign the nucleic acid sequence to a specific cell (cf. para. [0029] at the end, "Each independent cell in the reaction has a different barcode."). The barcode sequence makes it possible to correlate each target sequence to a cell from which the sequences originate. While each transcript originating from the cell will have the same barcode sequence, variation in genomic or transcriptomic information across the entire cell population by assaying many single cells at the same time. Because each single cell contains a unique barcode that differs from those of the other single cells, the identified cells can be assigned to the same cell of origin with the same barcode (para. [0030] at the end).

The Defendant has not been able to demonstrate that the barcode also marks the position of a capture probe on an array and therefore also functions as a positional domain within the meaning of the patent at issue (feature 14.3.1.). While the oligonucleotide sequences are immobilised on a solid support in certain exemplary embodiments (para. [0051]), the support may also consist of beads, for example (para. [0053]). However, in such a design, it is at least not directly and unequivocally disclosed in the document of the state of the art that each position on the array corresponds to a barcode. Such information cannot be derived, in particular, from example 6 referenced by the Defendant or from patent claim 17 mentioned during the oral proceedings. The latter does not disclose an array within the meaning of feature 14.1. but merely a bead. In example 6, on the other hand, several copies of the same barcode are generated for single cell analysis using "rolling circle amplification" (Rolony) (para. [0090]).

(4)

Finally, the article entitled "A novel, high-performance random array platform for quantitative gene expression profiling" by Kuhn et al. (Annex CR 12) referred to by the Defendant does not directly and unequivocally disclose all the features of patent claim 14.

The document of the state of the art describes a new microarray technology for quantitative gene expression profiling on the basis of randomly assembled arrays of

beads. Each bead carries a genespecific sequence, with multiple copies of each gene-specific bead in the array (cf. Introduction, p. 2347 above). Typically, each array has 1536 different bead types, with each type occurring about 30 times in the array (p. 2348, left column, "Results").

Despite the small number of different beads and the high repetition rate, it is not apparent that the disclosed design would be suitable for use in the localised detection of nucleic acid in a tissue sample comprising cells. This is all the more true since the document of the state of the art also lacks a more detailed description of the "bead identifier" and thus fails to provide a direct and unambiguous disclosure of a positional domain within the meaning of feature 14.3.1.

c)

According to [Art. 56 EPC](#), an invention is deemed to involve an inventive step if it is not obvious to a person skilled in the art having regard to the state of the art. Measured against this standard, the submissions of the Defendants are not sufficient to raise significant doubts as to the existence of an inventive step.

aa)

Based on US 2010/0035763 A1 ("Chen", Annex CR 9), the Defendant's arguments do not raise any significant doubts regarding the inventive step concerning the sole relevant patent claim 14. As stated, the document of the state of the art not only lacks disclosure of a Poly-T DNA oligonucleotide within the meaning of feature 14.3.2.1. It is also not apparent that the disclosed array is suitable for use in the localised detection of a nucleic acid in a tissue sample comprising cells (feature 14.1.). Even if the person skilled in the art were to nevertheless consider the cited document to be state of the art, which they would not, there is still no reason to further develop the array disclosed therein, which is described only in the context of examining lysed cells, in such a way that it allows for such localised detection in intact tissue or in intact cells.

bb)

Since US 2003/0162210 A1 ("Chetverin", annex CR 11) already lacks disclosure of positional domains within the meaning of the patent at issue, the Defendant's submissions are inherently incapable of casting doubt on inventive step. The Defendant solely addresses whether a poly-T domain at the 3' end of the immobilised oligonucleotides, as per feature 14.3.2.1. of the patent at issue, would be obvious to a person skilled in the art on the basis of the disclosure in "Chetverin" and a reference to "Sambrook". In contrast, the Defendant does not address the (lack of) disclosure of a positional domain.

d)

The Defendant's submissions on a possible intermediate generalisation ([Art. 123 \(2\) EPC](#)) relate solely to patent claim 1. The local division was already unable to establish any infringement of this claim. Further elaboration on this matter is therefore unnecessary.

IV.

The ordering of provisional measures is necessary to prevent the continuation of the infringement or at least

to prevent a threatened infringement (cf. [R. 206.2 \(c\) RoP](#)).

According to the Rules of Procedure, both temporal and substantive circumstances are relevant for the necessity of ordering provisional measures. In addition to [R. 209.2 \(b\) RoP](#) ("urgency"), the relevance of temporal circumstances derives in particular from [R. 211.4 RoP](#), which states that the court takes into account undue delays in the application for provisional measures. That substantive circumstances must also be taken into account in the decision to order provisional measures is evident, for example, from [R. 211.3 RoP](#), which states that in deciding on the application for provisional measures, particular consideration must also be given to the potential damage that may be incurred by the Applicant. In contrast, the potential damage incurred by the Defendant must be taken into account in the weighing-up of interests ([UPC CFI 2/2023 \(LD Munich\), Order of 19 September 2023](#), GRUR 2023, 1513, 1525 - Nachweisverfahren; [UPC CFI 452/2024 \(LD Düsseldorf\), Order of 9 April 2024](#), p. 27, GRUR-RS 2024, 7207, para. 124).

1.

Due to the circumstances of this case, the ordering of the requested provisional measures is urgent from a temporal perspective ([R. 209.2 \(b\) RoP](#)).

a)

The temporal urgency required for the ordering of provisional measures is only lacking if the infringed party has behaved in such a negligent and hesitant manner in the pursuit of its claims that, from an objective perspective, it must be concluded that the infringed party is not interested in promptly enforcing its rights, which is why it does not appear appropriate to allow it to claim provisional legal protection (cf. also [UPC CFI 2/2023 \(LD Munich\), Order of 19 September 2023](#), 1513, 1524 - Nachweisverfahren; [UPC CFI 452/2024 \(LD Düsseldorf\), Order of 9 April 2024](#), p. 27, GRUR-RS 2024, 7207, para. 126).

Pursuant to [R. 213.2 RoP](#), the court may, as part of its decision-making process, require the Applicant to submit all reasonably available evidence to ensure that it can be sufficiently certain that the Applicant is entitled to initiate proceedings under [Art. 47 UPCA](#), that the patent in question is valid and that its right is being infringed or threatened with infringement. In urgent proceedings, the Applicant must typically respond to such an order within a short period of time, which requires appropriate preparation of the proceedings. The Applicant therefore only needs to apply to the court if they have reliable knowledge of all the facts that make legal action in the proceedings for provisional measures promising and if they can substantiate these facts. The Applicant may prepare for any possible procedural situation that may arise, based on the circumstances, in such a way that it can present the requested information and documents to the court upon such an order and successfully rebut the arguments of the Defendant's side. In principle, the Applicant cannot be instructed to carry out any necessary subsequent investigations only during ongoing proceedings and if necessary to obtain the

required documents after the fact. On the other hand, the Applicant must not delay proceedings unnecessarily. As soon as it has knowledge of the alleged infringement, it must investigate it, take the necessary measures to clarify it and obtain the documents required to support its claims. In doing so, it must diligently initiate and complete the required steps at each stage. As soon as the Applicant has all the knowledge and documents that reliably enable a promising legal action, it must file the application for the ordering of provisional measures within one month ([UPC CFI 452/2023 \(LD Düsseldorf\), Order of 9 April 2024](#), GRUR-RS 2024, 7207, para. 128).

b)

Based on these principles, the Applicant has treated the matter with the necessary urgency.

aa)

According to the sworn affidavit of Randy Wu, Vice President for Intellectual Property of the Applicant, submitted as Annex BP 33, no employee of 10x Genomics at the levels from the Board of Directors to senior management, and thus no relevant decision-maker, had knowledge of the offer and the distribution of the contested embodiments by the Defendant in Germany, France and Sweden before October 2023. It is undisputed that a video conference took place on 10 November 2023 with the Senior Business Director of the Defendant for the EMEA countries. There, he not only confirmed the possibility of delivery of the contested embodiments to Germany, France and Sweden but also subsequently sent a PDF document containing further information about the Defendant and its products (Annex BP 16). Based on this, the Applicant has diligently pursued its rights and filed its application for the ordering of provisional measures on 4 December 2023 in a timely manner. The fact that the delivery referred to in support of the urgent application to the University Medical Centre Mannheim of the University of Heidelberg was already made in September 2023 does not change this finding, particularly because the Applicant undisputedly only obtained knowledge of this delivery through ex-post transparency (Annex BP 17).

bb)

The Defendant has not been able to demonstrate specific facts indicating that the Applicant had earlier (positive) knowledge of the offer and distribution of the contested embodiments in the relevant Contracting Member States of Germany, France and Sweden.

Insofar as it refers to a letter sent on 17 November 2022 (Annex BP 26), there is no mention therein of either the contested embodiments or the relevant Contracting Member States of the UPC. Instead, it is a letter sent by the Applicant to the Defendant, thus constituting an exchange of correspondence between two US companies. In it, the Applicant merely refers in general terms to its existing patent portfolio in the field of spatial transcriptomics, together with the request to respect it. Even according to the Defendant's submissions, the kit was only distributed to a selected group of customers at the end of 2022 and sold worldwide from February 2023 (cf. written submissions of 15 February 2024, p. 10). The

aforementioned letter could therefore naturally not (yet) have a specific product reference.

The Applicant's further letter of 14 June 2023, submitted as Annex BP 32 to the file, suggests that the Applicant was aware of the "Curio Seeker" and thus of the contested embodiments at that time. However, this alone is not sufficient basis for filing an application for the ordering of provisional measures. In order for such an application to succeed, there must be specific indications of infringement activities in at least individual Contracting Member States where the patent at issue is validated. There is no evidence of this in the above-mentioned letter, which deals exclusively with three US patent documents and makes no reference to the relevant Contracting Member States. This is especially true since the Applicant itself in this letter merely describes distribution in the USA as possible ("appears to be offering").

Insofar as the Defendant attempts to substantiate the Applicant's knowledge by referring to a workshop in Heidelberg, it can be assumed in its favour that such an event entitled "Introducing the Curio Seeker" did indeed take place in June 2023. However, the Defendant does not claim that representatives of the Applicant took part in this workshop. There is also no evidence of this in either the email correspondence submitted as Annex CR-25 to the file or in the sworn affidavit of Mr Yeung submitted as Annex CR-20.

cc)

In the absence of positive knowledge of the infringement of intellectual property rights or at least where such knowledge cannot be established, as is the case here, grossly negligent ignorance or wilful blindness to the infringement is considered equivalent. However, since there is no general obligation to observe the market, it is not sufficient for the Applicant to have been able to become aware of the infringement of a right through observing the competition. However, it is expected of an intellectual property right holder who is already aware of specific circumstances suggesting an infringement of its intellectual property rights to take all measures readily available to it and further investigate the situation. However, the Defendant has not been able to specifically demonstrate specific knowledge triggering such an obligation for further investigation by the Applicant.

(1)

[...] (cf. objection document, p. 21, point 4.13). According to the affidavit of Neil Kennedy submitted as Annex CR-3, the Defendant sold [...] of the contested embodiments [...], of which [...] were sold [...]. In absolute terms, [...] of the contested embodiments were thus distributed [...]. At the oral proceedings, the Defendant quantified revenue generated with the contested embodiments in [...] at [...]. Based on this, the market success of the Defendant [...] that it is neither far-fetched nor can it be ruled out that the contested embodiments, at least regarding a potential distribution in the Contracting States relevant here, initially did not attract any attention on the part of the Applicant. In other words, it cannot be ruled out that the Defendant "initially

flew under the radar" with the contested embodiments, at least with regard to the relevant Contracting States in this case. It was therefore incumbent on the Defendant to specify concrete circumstances that justify the conclusion that, despite [...] before October 2023, an infringement of the patent at issue in the relevant Contracting Member States would have been apparent to the Applicant. The Defendant's submissions do not meet these requirements, even taking into account the relatively small target audience of the contested embodiments.

(2)

In this context, the fact that the Defendant provided selected customers with "early access" to its kit in the third and fourth quarters of 2022 (cf. Annexes CR-20 and CR-21) is irrelevant in this regard, at least as long as the Applicant was not among these customers or at least did not otherwise gain knowledge of this distribution. There is no evidence to support either assertion.

(3)

Likewise, the Defendant cannot successfully rely on the announcement of the market launch of the "Curio Seeker" on the Defendant's website of 8 February 2023. Apart from the fact that it cannot be established whether this announcement was even noticed by the Applicant, it is merely a general notification about the commencement of distribution activities related to the "Curio Seeker". There is no indication regarding the distribution area or channels. The further reference by the Defendant that it collaborates with various research institutes worldwide (cf. written submissions of 15 March 2024, p. 8 above) does not advance the argument at this point, as such information cannot be inferred from the excerpt from the website provided.

(4)

Regarding the Defendant's assertion that its sales manager for Europe has been continuously in contact with potential customers in the EU since 21 February 2023, there is no claim or indication that the Applicant belongs to this group. The fact that the sales manager's activities also included writing posts on LinkedIn could only justify a different assessment if at least one employee gained knowledge of this post, and it can be expected that he or she would internally pass on knowledge of any potential infringement, so that it could be pursued by the relevant department.

The Defendant has not been able to demonstrate any such circumstances. The post mentioned by the Defendant and displayed below, taken from Annex CR-22, p. 2, of its sales manager in March 2023, is not sufficient for this purpose:



Even if the post can be interpreted as an announcement of the market launch of the kit, it lacks in any event a specific reference to the relevant Contracting Member States. The "Senior Business Director" who made the post is responsible for all EMEA countries, which include a large number of further markets. Moreover, this post was only liked by an employee of the Applicant working as a "Senior Research Associate". The Defendant has not been able to demonstrate that this employee, despite not being part of the leadership, was obligated to forward the information contained in the post to the relevant decision-makers.

(5)

Based on the Defendant's submissions, the contested embodiments were showcased at several conferences besides the aforementioned workshop in Heidelberg. However, no conclusions can be drawn about the Applicant's level of knowledge from this. Except for one instance, the Defendant failed to provide further details of these events. In addition, most of the events mentioned took place in the USA. The Defendant doesn't specify what opportunities to gain knowledge these events might have given the Applicant regarding the potential distribution of the contested embodiments in the Contracting Member States relevant for the present proceedings.

This also applies in particular to the webinar of 14 April 2023 referred to in the oral proceedings. Regarding this event, it can be inferred from Annex CR-1, p. 14 that, in addition to representatives from both parties, participants from Europe were also among the participants. However, there is also a lack of detailed submissions by the Defendant regarding the specific content of the event in this regard.

The same applies to the "Festival of Genomics", which took place in London at the end of January 2023. Even if this is one of the most important events in the relevant field and both parties exhibited there, the Defendant has failed to demonstrate that the Applicant actually obtained knowledge of the Defendant's stand and the product exhibited there or at least must have obtained such knowledge. Merely making a general reference to the conference app available to all participants, in which all participating persons and companies are listed, is not sufficient for this purpose.

2.

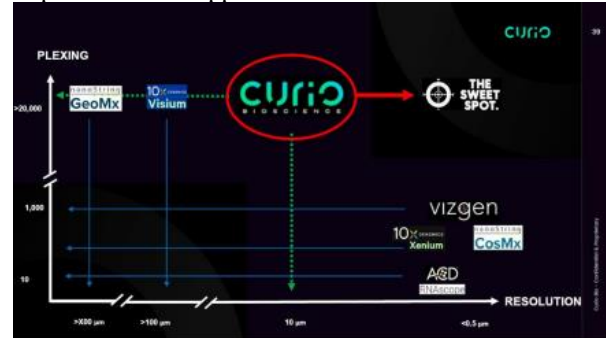
The ordering of provisional measures is also necessary from a substantive perspective due to the damage that the Applicant is threatened with by the infringing product offerings of the Defendant.

a)

Even through the parties' products differ both in their technical design and in their scope of application, they address the same target audience, namely researchers and research institutes dealing with the localised or spatial detection of nucleic acids in a tissue sample. The parties are therefore in competition with each other.

b)

This fact is confirmed by the Defendant itself on page 39 displayed below of the presentation submitted as annex BP 16 to the file, in which it refers to its products as the "sweet spot" and directly relates them to its competitors, in particular the Applicant:



The question raised by the Defendant regarding the usability of this annex sent following the conversation in November 2023 does not require a conclusive answer. Even if such usability is lacking, the Applicant has submitted a number of additional documents from which, independently of this annex, the existence of a corresponding competitive situation can also be inferred. Thus, the Applicant has submitted reports from market observers to the file as annexes BP 34 and BP 35, which identify competing products to the Applicant's "Vision" line in the contested embodiments. From these documents, independent of BP 16, a corresponding competitive situation can also be inferred.

Moreover, the contested embodiments are also compared to the product "Visium" of the Applicant in the article submitted as Annex BP 4 (starting from p. 1, right-hand column, last paragraph). Furthermore, the article "Genetic Engineering & Biotechnology News" submitted by the Defendant as Annex CR-1, para. 9, also describes the attacked embodiments as an alternative to the Applicant's product (cf. Annex BP 36, p. 2). Even though these articles highlight the differences between the products, they compare their features and therefore serve as a useful tool for interested professionals in planning experiments and making decisions in favour of a specific product. Since the articles submitted have appeared in trade journals, the local division has no reason to doubt the expertise of the authors. The Defendant has neither presented nor shown any concrete evidence indicating that the authors in question have a relationship with the Applicant.

c)

Because research institutions and research teams cannot readily exchange products due to the different characteristics of both product lines and the resulting lack of comparability of research results, customer

relationships which the Defendant currently establishes through the distribution of the contested embodiments are automatically long-term. If a research team decides to use the Defendant's product for a specific series of experiments, the relevant market is thus sealed off for the Applicant. The fact that the kit consists of single-use tiles for obtaining transcriptomic data and that the subsequent sequencing step is carried out on machines not provided by the Defendant does not change this. Precisely because the respective research teams cannot switch to alternative products during an ongoing research project due to the lack of comparability of research results, even if the kit is acquired through individual purchase contracts, as claimed by the Defendant, it can be assumed that the demand for kits will be covered in the long term, even for research projects lasting several years. This would be even more true if the local division in the present legal dispute were to affirm infringement of the patent at issue by the contested embodiments and merely reject the order on provisional measures on the grounds of their lack of necessity. In such a case, it can be assumed that research teams, to secure their project, will stock up on the necessary number of kits required until the completion of their project even before the conclusion of the main proceedings.

d)

Contrary to the Defendant's opinion, the necessity of the ordering of provisional measures cannot be questioned on the grounds that the damage incurred by waiting for the main case proceedings is limited, calculable and, [...] low [...]. It is undisputed that the relevant market environment is characterised by significant dynamism. It is neither foreseeable nor sufficiently predictable that the Applicant can easily regain at a later date the market share that it is currently losing. The Defendant has been unable to counter the Applicant's assertion, for example, that it is not predictable whether a current competitor with a current or new product, or a new competitor with a new product, will be in the market when future market shares are captured (cf. written submissions of 1 March 2024, p. 17 et seq.). The Applicant rightly points out that, even considering that there are only eight years remaining of the patent at issue's term, its reward and amortisation function would be irreversibly diminished if the Defendant currently continues to establish long-term customer relationships. The fact that this is not merely a theoretical scenario but a real threat is illustrated by the product "Visium HD" of the Applicant. To develop the "Visium" product platform into a marketable product on the basis of research efforts, the Applicant has invested several years of development work and thousands of working hours, with approximately 345 million euros invested (cf. sworn affidavit of Eric Whitaker, Annex BP 38). The Applicant could only economically justify this personnel, time and financial effort because the patent at issue legally guarantees the recovery of this expenditure without infringement from competing products. The refinancing of this expenditure would be jeopardised in the face of the dynamic market environment if the Defendant were

able to continue distributing the contested embodiments until the conclusion of the main proceedings and, on this basis, to divert research projects to itself, possibly also in the long term.

e)

To the extent that the Defendant refers to possible third-party damages caused by a prohibitory injunction (cf. written submissions of 15 February 2024, p. 17), these do not have an effect on the necessity of ordering provisional measures. At most, they may be relevant in the subsequent weighing-up of interests.

V.

The weighing-up of interests to be carried out also favours the Applicant.

1.

Pursuant to [Art. 62\(2\) UPCA \(R. 211.3 RoP\)](#), the court must exercise its discretion in weighing up the interests of the parties with regard to issuing the order or rejecting the application; in doing so, all relevant circumstances must be taken into account, in particular the potential damage that may be incurred by the parties as a result of the issuance of the order or the refusal of the application. For the purposes of exercising discretion, the degree of probability to which the court is convinced of the existence of each circumstance to be weighed up is also crucial. The more convinced the court is that the right holder is asserting the infringement of a valid patent, due to factual and temporal circumstances necessitating the issue of the order, and that possible damage to the opponent or other justified objections do not stand in the way, the more justified the issuance of an injunction becomes. However, if there are relevant uncertainties regarding individual circumstances relevant to the weighing-up of interests that undermine the court's conviction, the court may consider, as a milder measure, allowing the alleged infringement to continue subject to the provision of security or even the refusal of the Application ([UPC CFI 2/2023 \(LD Munich\), Order of 19/09/2023, 1513, 1525 et seq.](#) - Nachweisverfahren; [UPC: CFI 452/2023 \(LD Düsseldorf\), Order of 09/04/2024, p. 30](#)).

2.

Given the foregoing, the issuance of the requested order is also justified after weighing up the interests involved.

Since the Defendant has failed in the urgent proceedings to significantly dispute at least an infringement of patent claim 14 of the patent at issue, the local division is convinced on summary examination of an infringement of the patent at issue by the actions of the Defendant. Furthermore, the Defendant has failed to create significant doubts about the validity of the patent at issue. To the extent that the Defendant in this context points out that it had very little time to verify the validity of the patent at issue, the local division cannot agree with this, especially since almost 2 ½ months passed between the service of the application for the ordering of provisional measures and the oral proceedings. This is close to the period of time envisaged by the Rules of Procedure for the preparation of the Statement of Defence, including a possible Counterclaim for revocation, in the main proceedings ([R. 23](#) and [R. 25.1](#)

RoP). Finally, the local division is ultimately also of the clear conviction that the ordering of provisional measures is necessary in the present case due to the infringement of the patent at issue, both substantively and temporally.

In the light of the established infringement of the patent at issue, the Defendant has no legitimate interest in offering or distributing the contested embodiments that infringe the patent at issue in Germany, France or Sweden, either without or against security. To the extent that the Defendant argues that it is a small company with a single product line, [...] this must be taken into account in its favour in the weighing-up of interests, as well as the possibility associated with a prohibitory injunction that some of these investors may withdraw as a result of such an order. However, such a risk also exists if the local division refrains from issuing a prohibitory injunction for the time being, citing allegedly overriding interests of the Defendant, while simultaneously finding an infringement of the patent at issue with a sufficiently secured validity. [...] Moreover, based on the current state of the facts and legal dispute, it can be assumed that an action on the merits will also be more likely than not to succeed. If the local division refrains for the time being from ordering the provisional measures necessary to protect the Applicant as proprietor of the patent at issue, it gives the Defendant the opportunity to expand its market position at the expense of the Applicant until the mandatory main proceedings under R. 213.1 RoP is concluded. The result would potentially be the same with regard to investor withdrawal, albeit with a time delay.

The Applicant cannot accept such a delay, even taking into account the principle of proportionality (Art. 42 (2) UPCA), given the damage it may suffer if the provisional measures were not granted. This is all the more true since the Defendant has also failed to substantiate its claim of a high probability of bankruptcy in the event of a prohibitory injunction by merely referring abstractly to the potential withdrawal of financial investors. According to the affidavit submitted as Annex CR3, the Defendant [...] in 2023, of which [...] are attributable to the relevant Contracting States in this case. Therefore, an injunction would only affect [...]. The Defendant has not been able to plausibly demonstrate why the cessation of sales in Germany, France and Sweden, as claimed, [...]. According to paragraph 12 of Annex CR-3, [...] are also significant relevant markets that would not be affected by a prohibitory injunction issued by the local division.

Insofar as the Defendant refers to the effects of legal proceedings on its competitors NanoString and Vizgen, the Chapter 11 proceedings initiated by NanoString were triggered by a damages liability of USD 31 million imposed by a US judgement. Such circumstances are not at issue in the present case. On the other hand, the reasons for the dismissal of employees at Vizgen can only be speculated upon. The Defendant merely alludes to the fact that Vizgen dismissed many employees during the legal proceedings before the US courts and

the UPC, although it had previously been considered a stable player in the market (emphasis added).

The Defendant has not been able to demonstrate that the issuance of a prohibitory injunction forces researchers to abandon their research projects, thus causing them irreparable damage. If, on the other hand, researchers are forced to change the kits they use, this is the natural consequence of a prohibitory injunction. The effort associated with such a change is to be accepted in the interest of effective enforcement of the patent at issue.

VI.

The local division in Düsseldorf is convinced with the requisite certainty for ordering provisional measures that the Defendant is unlawfully using the technical teaching protected by patent claim 14 of the patent at issue through the offer and distribution of the contested embodiments within the scope of the patent at issue. Likewise, the validity of the patent at issue is certain to the extent required for the ordering of provisional measures. Since the ordering of provisional measures is also both temporally and materially necessary, and furthermore the weighing-up of interests favours the Applicant, the following legal consequences ensue:

1.

The Court, exercising its discretion (**R. 209.2 RoP**), deems the issuance of a prohibitory injunction to be appropriate and justified (**Art. 62(1), 25(a), 26(1) UPCA**). Only a prohibitory injunction serves the Applicant's interest in the effective enforcement of the patent at issue. The interest of the Defendant in continuing distribution, without or against security, must yield to this, for the reasons stated.

2.

The threat of penalty payments in the event of non-compliance is based on **R. 354.3 RoP**. The number of days is already fixed for the calculation of penalty payments. However, setting a maximum limit per day of contravention provides the local division with the necessary flexibility to also consider the conduct of the infringer in the event of non-compliance and, based on that, to be able to impose an appropriate penalty payment in accordance with **R. 354.4 RoP**.

3.

An infringement of the patent at issue cannot be determined from the perspective of an indirect infringement of patent claim 1, at least based on the current state of facts and legal proceedings. Therefore, the application for the ordering of provisional measures was to be rejected in this respect.

4.

Insofar as the Applicant seeks an Order for the provision of security for the costs of the legal proceedings and the costs incurred and/or yet to be incurred by it, the conditions for such an order are not met.

a)

Pursuant to **R. 158.1 RoP**, the court may, at any stage of the proceedings, upon a reasoned request from one party, order the other party, within a specified period, to provide adequate security for the costs of the legal proceedings and any other costs incurred and/or yet to be incurred by the requesting party, which the other

party may be required to bear. Before such an order is issued, the parties must be given the opportunity to be heard (**R. 158.2 RoP**). If the party affected by the order fails to comply with such an order, a decision by default may be issued against them. Similarly, the court may demand security for the costs of the court (**R. 159 RoP**).

b) Unlike **Art. 69(4) UPCA**, the Rules of Procedure therefore provide that the request to provide security may be made not only by the Defendant in the main action, but also by "a party" and thus also by the Claimant. Even if the Rules of Procedure must be in accordance with the UPCA according to **Art. 41(1)(2) UPCA**, this is not a case of conflict requiring precedence of the Agreement. If the Agreement does not exclude a specific provision, the Rules of Procedure may make additional provisions (cf. also Kiefer in: BeckOK Patentrecht, 31st edition as of 15 July 2023, **Art. 69 UPCA** para. 59; contra: Tilman/Plassmann, Einheitspatent, Einheitliches Patentgericht, **Rule 158 para. 3**). Such a case arises under **Art. 69(4) UPCA** in conjunction with **Rule 158 et seq. RoP**. While the Agreement only envisages the Claimant providing security for the Defendant's legal costs, **R. 158 RoP** extends the scope of recipients of such an order to "the parties", thereby including the Defendant. Additionally, **R. 159 RoP** provides for the possibility of ordering security for costs of the court as a supplementary measure.

c)

However, it must be distinguished whether ordering the provision of security is also applicable in urgent proceedings. **R. 158 et seq. RoP** can be found in Part 1 ("Procedures before the Court of First Instance") in Chapter 6 "Security for costs", which immediately follows the provisions on the procedure for cost decision. In **R. 205 et seq. RoP** concerning urgent proceedings, such an order is not provided for. From the structure of the Rules of Procedure, it can be inferred that the ordering of security for costs of proceedings is only applicable in main proceedings and not in urgent proceedings. As will be further explained in connection with the discussion of the (lack of) necessity of a cost decision, there is a possibility to request an order obliging the Defendant to provide an interim award of costs (**R. 211.1(d) RoP**). If the Applicant avails itself of this option, the resulting cost order can be promptly enforced. This adequately addresses the security needs of the Applicant. Therefore, there is neither scope nor a need for the (analogous) application of **R. 158 et seq. RoP** in urgent proceedings, given the urgent nature of such proceedings.

5.

To the extent that the Defendant, referring to **Art. 68(3)(a) UPCA**, seeks compensation for reputational and other damage, such claims cannot be asserted in the proceedings for ordering provisional measures from the outset. The content of provisional measures is exhaustively regulated in **Art. 62 UPCA** in conjunction with **R. 211(1) RoP**. The awarding of damages is not

mentioned there. Its assertion is therefore reserved for the main proceedings.

R. 213.2 RoP, which the Defendant has alternatively referred to, is part of the provisions regarding "revocation of provisional measures". All the situations mentioned there have in common that a provisional order was initially issued, but then revoked or rendered void due to the conduct of the Applicant. If such a case arises, the court, upon the request of the Defendant, may order the Applicant to provide the Defendant with appropriate compensation for all damage incurred as a result of these measures (emphasis added). The mere rejection of a request for the imposition of such measures is therefore not covered by the provision from the outset.

Furthermore, there is no scope for awarding compensation for potential reputational damage if a prohibitory injunction is issued against the Defendant.

VII.

According to **R. 211.5(1) RoP**, the court may, in the event of the revocation of the provisional measures by the court, require the provision of appropriate security for any compensation that must be payable by the Applicant to the Defendant for the damage that the Defendant is likely to incur. Unless the specific case, as here, exceptionally requires otherwise, this option is generally to be utilised. The decision to order provisional measures is based on only a preliminary assessment of the facts and legal situation, which inherently involves uncertainty. Furthermore, the provisional measure constitutes a significant infringement on the rights of the patent infringer, who is severely restricted in the exercise of its economic activity. Only ordering the provision of security addresses this uncertainty and intensity of interference (Tilman/Plassmann, Einheitspatent, Einheitliches Patentgericht, **Rule 211**, para. 32).

Regarding the amount of the security provided, it should cover the legal costs of the proceedings, other costs related to enforcement as well as the potential compensation for damage incurred or likely to be incurred, **R. 352.1 RoP**. At the time of issuing this order however, it is difficult for the local division to estimate accurately the potential extent of enforcement damages. Against this background, the amount of the security deposit set is determined by the value of the dispute. Even if the value of the dispute does not necessarily correspond to the risk of damages, it nevertheless provides an indication of the economic significance that the Applicant attaches to the matter. It was within the power of the Defendant to present in detail the risks to be secured by the security benefit. As it did not make use of this opportunity, there are no grounds to deviate from the value of the dispute in determining the security deposit.

VIII.

There is no reason for a decision on costs in proceedings for the ordering of provisional measures if, as in this case, a main proceedings follows the urgent proceedings (**UPC CFI 452/2024 (LD Düsseldorf), Order of 9 April 2024, headnote 2**, GRUR-RS 2024, 7207).

1.

According to [Article 69\(1\) UPCA](#), the costs of the dispute and other costs of the successful party, up to a maximum limit determined in accordance with the Rules of Procedure, shall be borne by the unsuccessful party, unless equity considerations dictate otherwise. The norm therefore determines the content of the cost decision, namely by whom and to what extent the costs of the dispute and the other costs of the unsuccessful party are to be borne ([UPC CFI 452/2024 \(LD Düsseldorf\), Order of 9 April 2024](#), headnote 2 and p. 34 et seq., GRUR-RS 2024, 7207, para. 161; contra: [UPC CFI 2/2023 \(LD Munich\), Order of 19 September 2023](#), p. 103 = GRUR 2023, 1513, 1526, para. 315 - Nachweisverfahren). Rather, this is the subject of [R. 118.5 RoP](#) (cf. Dold/W. Tilmann in Tilmann/Plassmann, Einheitspatent, Einheitliches Patentgericht, Art. 69 para. 1 and 3). However, according to its systematic position, this provision already pertains to the main proceedings. There is no corresponding provision in [R. 205](#) et seq. concerning the ordering of provisional measures.

2.

Even though the Court of Appeal has not yet had to address in detail the question of the award of costs in urgent proceedings, it has already acknowledged that a decision on costs is not required in every case. In the opinion of the Court of Appeal, if a decision is not a "final order" or a "final decision", the court can only determine in a subsequent final decision whether and to what extent a party must bear the costs of the other party because it is unsuccessful within the meaning of [Art. 69 UPCA](#) ([UPC CoA 433/2023](#), [UPC CoA 435/2023](#); [UPC CoA 436/2023](#); [UPC CoA 437/2023](#); [UPC CoA 438/2023](#), [Order of 3 April 2023](#), headnote 2). Such an approach is at least also appropriate when, as in this case, urgent proceedings are followed by main proceedings. A basic prerequisite for an analogous application of [R. 118.5 RoP](#) would be the existence of an unintended regulatory gap, which is not the case ([UPC CFI 452/2024 \(LD Düsseldorf\), Order of 9 April 2024](#), headnote 2 and p. 34 et seq., GRUR-RS 2024, 7207, para. 161 - 163; also [UPC CFI 249/2023 \(LD Munich\), Order of 19 December 2023](#), headnote, GRUR-RS 2023, 40572).

According to [R. 211.1 \(d\) RoP](#), the court may order an interim award of costs. If the Applicant fails to initiate the main proceedings within the prescribed time limit following the ordering of provisional measures, the corresponding order must be repealed according to [R. 213.1 RoP](#) upon a corresponding request from the Defendant. In general, the ordering of provisional measures is followed by main proceedings. For the decision in the main proceedings, [R. 118.5 RoP](#) requires the issuance of a cost decision. If main proceedings are preceded by the ordering of provisional measures, the Rules of Procedure therefore provide for a two-stage process: To ensure that the Applicant does not have to advance the costs arising from the application for the ordering of provisional measures over a longer period of time and thus also bear the insolvency risk of the

opposing party, the Applicant has the option of including in the order on provisional measures a provision obliging the Defendant to reimburse interim costs. In the main proceedings, the court then makes a cost decision based on [R. 118.5 RoP](#), which forms the basis of any subsequent cost assessment procedure ([R. 150 et seq. RoP](#)). As long as the procedure for ordering provisional measures is followed by main proceedings, there is therefore no (unintended) regulatory gap. The conditions for an analogous application of [R. 118.5 RoP](#) are therefore not met, at least in such a scenario.

This also applies to the extent that the Defendant seeks an interim award of costs. It is true that [R. 211 RoP](#) concerns "Orders on the application for provisional measures" (emphasis added). This suggests that the provision directly only addresses the content of a corresponding order against the Defendant and thus only an interim award of costs to the Applicant ([R. 211.1 \(d\) RoP](#)) (contra: [UPC CFI 182/2023 \(LD Vienna\), Order of 13 September 2023](#), GRUR-RS 2023, 35213, para. 51 - Milchaufschäumer). However, if main proceedings follow urgent proceedings, the provision applies accordingly to the Defendant. As the Rules of Procedure do not provide for an interim award of costs in favour of the Defendant, there is a regulatory gap in this regard. This is also unintended. Since such a scenario is not covered by either [R. 118.5 RoP](#) or [R. 211.1 \(d\) RoP](#), the Defendant would have to wait until the conclusion of the main proceedings at first instance and therefore bear the risk of insolvency until that time before being able to assert its claim for reimbursement of costs. It would therefore be in a significantly worse position than the Applicant, who even has an effective instrument available through the interim award of costs to obtain a title for its costs and thus enforce its claim to the award of costs. This imbalance highlights the existence of an unintended regulatory gap. The same interest arises from both sides in achieving the earliest possible awarding of the costs incurred by them in the urgent proceedings.

3.

The request for an interim award of costs expressed for the first time by both parties during the oral proceedings constitutes a subsequent amendment to the application. Such an amendment to the application can be requested by the parties at any time ([R. 263.1\(1\) RoP](#)). According to [R. 263.2 RoP](#), however, such an application is to be rejected if the applying party cannot convince the court, taking into account all circumstances, that the proposed amendment could not have been made earlier with due diligence and that the amendment does not unduly hinder the other party in its conduct of the proceedings. The court is convinced of both conditions in the present case, so that the application was allowed.

It should be noted in favour of the parties that the issue of the handling of the award of costs in urgent proceedings before the Unified Patent Court has not yet been definitively settled by the highest court and has already been handled differently at first instance. The local division in Düsseldorf rejected the request for a cost decision in urgent proceedings for the first time ever

in an ex-parte order dated 11 December 2023 and thus after the submission of the application underlying this procedure. At the same time, the local division pointed out the lack of a request for an interim award of costs ([UPC CFI 452/2024, Order of 11 December 2023](#), p. 10 below = GRUR-RR 2024, 97, 101, para. 44 - Buried search device). The local division in Düsseldorf drew the parties' attention to this Order in a procedural order dated 21 March 2024. The parties responded to this notice by submitting their subsequent request for an interim award of costs. This cannot be denied to them under the principle of the right to be heard. There is no evidence that the parties did not conduct the proceedings with due care in light of the specific circumstances of the case. Since both parties are now seeking an interim award of costs in the event of their success, they will not be unduly disadvantaged by a subsequent granting of the requests for an interim award of costs. In the event of their success, they benefit from the award of costs, while in the event of their defeat, they must bear the respective costs of the opposing party.

4.

At the oral proceedings, the parties mutually acknowledged interim costs of EUR 200,000 each as reimbursable and requested an interim award of costs in this amount. Further elaborations on the amount of the reimbursable costs are therefore unnecessary. The same applies regarding a decision on the application submitted by the Defendant to raise the ceiling for the reimbursable costs. Given the agreement reached on the amount of the costs eligible for the interim award of costs, this application is not relevant to the present order and therefore does not require a decision.

The amount of the costs awarded is based on the proportion of success or failure. For both parties, half of their respective requests were unsuccessful. Therefore, they can only claim reimbursement of half of the mutually acknowledged costs through an interim award of costs ([Art. 69 UPCA](#) in conjunction with [R. 211.1 \(d\) RoP](#)).

ORDER:

I. The Defendant is ordered to refrain from offering, marketing, using, or possessing, for the purposes mentioned, in the territories of the Federal Republic of Germany, the French Republic, and/or the Kingdom of Sweden

an array for localised detection of nucleic acid in a tissue sample comprising cells, comprising a substrate on which multiple species of capture probes are directly or indirectly immobilized such that each species occupies a distinct position on the array and is oriented to have a free 3' end to enable said probe to function as an extension primer, wherein each species of said capture probe comprises a nucleic acid molecule with 5' to 3':

- (i) a positional domain that corresponds to the position of the capture probe on the array, and
- (ii) a capture domain for capturing nucleic acid of a tissue sample brought into contact with the array, comprising a Poly-T DNA oligonucleotide comprising at least 10 deoxythymidine residues.

II. For each contravention of the above Order, the Defendant shall pay to the Court a penalty payment (which may be repeated) of up to EUR 100,000.00 for each day of the contravention.

III. In all other respects, the application for the ordering of provisional measures is rejected.

IV. The Applicant's request to order the Defendant to provide security for all of the Applicant's anticipated litigation costs, including potential court costs, within a timeframe to be determined by the Court and in an amount to be determined by the Court, is rejected.

V. The Defendant's request to order the Applicant to compensate it for the reputational and other damages incurred as a result of this proceeding is rejected.

VI. Both parties are ordered, with the rejection of their further requests, to provisionally reimburse the other party's costs in the amount of EUR 100,000 each.

VII. This order is enforceable, but for the Applicant only once it has provided security in favour of the Defendant in the form of a deposit or bank guarantee in the amount of EUR 2,000,000.

ORDER DETAILS:

Main action number ACT_590953/2023

UPC number: UPC_CFI_463/2023

Type of proceedings: Application for an order on provisional measures

Issued in Düsseldorf on 30 April 2024

NAMES AND SIGNATURES

Presiding judge Thomas

Legally qualified judge Dr Thom

Legally qualified judge Kupecz

Technically qualified judge Dr Schmidt

for the Deputy Registrar Boudra-Seddiki

INFORMATION ABOUT APPEAL

An appeal against this present Order may be lodged by both parties within 15 days of service of this Order (Art. 73(2)(a), 62 UPCA, R. 220.1(c), 224.2(b) RoP).

INFORMATION ON ENFORCEMENT (ART. 82 UPCA, ART. 37(2) EPGs, R. 118.8, 158.2, 354, 355.4 ROP)

An authentic copy of the enforceable decision or enforceable order will be issued by the Deputy Registrar upon request of the enforcing party, R. 69 RegR.

This is a certified translation of the Order from German into English. The contents of the German and English versions are identical.

Certified in Luxembourg on 29 April 2024

For the UPC Translators

Sean Grogan UPC Translator
