Local Chamber Munich

Decision and orders
of the Court of First Instance of the Unified Patent Court in the proceedings for interim measures concerning EP 4 108 782
Procedure number UPC CFI 2/2023
Issued on: ***09f2023***

Date of receipt of the application: 01/06/2023

NanoString Technologies Inc. (Application Generator) - 530 Fairview Ave N - 98109 - Seattle (WA) - US	Written procedure served on 15/06/2023
NanoString Technologies Germany (defendant) - Birketweg 31 - 80639 - Munich - EN	GmbHProtocol served on 20/06/2023
NanoString Technologies Netherlands B.V. (defendant) - Paasheuvelweg 25 - 1105BP - Amsterdam - NL	Written procedure served on 20/06/2023

APPLICANT

1)	10x Genomics, Inc. (Applicant) - 6230 StoneridgeMall Mueller- Road- 94588-3260 - Pleasanton - US	Represented by: Tilman Stoy

2)	President and Fellows of Harvard College (Applicant) - Suit 727E, 1350 Massachussetts Avenue - 02138 - Massachusetts - US	Represented by: Tilman Müller-Stoy

APPLICANT

1)	**NanoString Technologies Inc.** (Respondent) - 530 Fairview Ave N - 98109 - Seattle (WA) - US	Represented by: Oliver Jan Jüngst
2)	**NanoString Technologies Germany GmbH** (Respondent) - Birketweg 31 - 80639 - Munich - DE	Represented by: Oliver Jan Jüngst
3)	NanoString Technologies Netherlands B.V. (Defendant) - Paasheuvelweg 25 - 1105BP - Amsterdam - NL	Represented by: Oliver Jan Jüngst

PATENT AT ISSUE

Patent no.	*Owner*
EP4108782	President and Fellows of Harvard College

DECISIVE J U D G E S

COMPOSITION OF THE PANEL - FULL COMPOSITION

Presiding Judge Rapporteur	Matthias Zigann
Legally qualified judge	Tobias Pichlmaier
Technically qualified judge	Andràs Kupecz
	Eric Enderlin

PROCESS LANGUAGE: DeutsCh

ORAL NEGOTIATION OF" 05/09/2023 and 06/09/2023 DATED ON"

19/09/2023

Facts and submissions of the parties

On 1 June 2023, the applicants applied to the Unified Patent Court (Munich Local Chamber) for interim measures, claiming that the unitary patent EP 4 108 782 (patent in suit) was directly and indirectly infringed by the respondents.

The patent in suit was filed under the title

"Compositions and methods for analyte detection"

on 27 April 2022. On 21 April 2023, the second applicant filed a request with the EPO for deferment of the decision on grant of the patent in suit in view of the forthcoming introduction of the unitary patent. The unitary effect of the patent-in-suit was requested at the European Patent Office on 9 May 2023. The patent in suit was granted on 11 May 2023. The publication of the mention of grant is dated 7 June 2023. Claim 1 of the patent in suit reads:

> A method for detecting a plurality of analytes in a cell or tissue sample, comprising:
>
> (a) mounting the cell or tissue sample on a solid support;
>
> (b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, the plurality of detection reagents comprising a plurality of sub-populations of detection reagents;
>
> (c) incubating the cell or tissue sample together with the plurality of detection reagents for a sufficient amount of time to allow binding of the plurality of detection reagents to the analytes; wherein each subpopulation of the plurality of detection reagents targets a different analyte, wherein each of the plurality of detection reagents comprises: a probe reagent targeting an analyte of the plurality of analytes and one or a plurality of pre-determined subsequences, wherein the probe reagent and the one or the plurality of pre-determined subsequences are conjugated to ether;
>
> (d) detecting in a temporally-sequential manner the one or the plurality of pre-de- termined subsequences, wherein the detecting comprises:

(i) hybridizing a set of decoder probes with a subsequence of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes and wherein each subpopulation of the decoder probes comprises a detectable label, each detectable label producing a signal signature;

(ii) detecting the signal signature produced by the hybridization of the set of de-coder probes;

(iii) removing the signal signature; and

(iv) repeating (i) and (iii) using a different set of decoder probes to detect other subsequences of the detection reagents, thereby producing a temporal order of the signal signatures unique for each subpopulation of the plurality of detection reagents; and

(e) using the temporal order of the signal signatures corresponding to the one or the plurality of the pre-determined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of analytes in the cell or tissue sample.

The patent in suit is a divisional application for EP 18173059.9, which is itself a divisional application for EP 12860433.7. The parent application is an international application dated 21 December 2012 (PCT/US2012/071398) claiming priority from 22 December 2011 (US 201161579265 P). With regard to the German part of the parent patent, an invalidity action with reference 3 Ni 20/22 (EP) is pending before the German Federal Patent Court (BPatG). In its qualified opinion of 7 February 2023, the 3rd Senate of the BPatG sets out its provisional opinion according to which the parent patent is patentable to the extent of auxiliary request 1.

The research on which the patent family is based was also financed with public funds from the US *National Institute of Health* (NIH). This funding gives rise to contractual obligations of the second applicant vis-à-vis the NIH, the concrete scope of which is subject to differing opinions between the parties to the present application proceedings.

The applicants have sued the 1st and 2nd defendants for exclusion from the German part of the parent patent before the Munich I District Court under the reference numbers

7 O 2693/22 and 7 O 5812/22 for injunctive relief. The judgments are dated 17 May 2023.

The 1st respondent filed an opposition against the grant of the patent in suit with the EPO on 18 July 2023.

The second applicant is registered as proprietor of the patent in suit. It has granted the first applicant an exclusive licence to the patent for disposal for the territory of the Federal Republic of Germany with effect from 14 February 2023 and an exclusive licence to the patent for disposal for the territory of the other UPC member states with effect from 30 May 2023. The parties to this application procedure have different views on whether these licences are legally valid.

The first defendant is an American company. It is the parent company of a group of companies operating under the name "NanoString". Respondent 2) is the German sales and marketing company in this group of companies. The third defendant is the European headquarters of the group.

In addition to the analysis systems "nCounter& Analysis System", "GeoMxo Digital Spatial Profiler" (DSP) and "Spatial Molecular Imager" (SMI), the defendants offer the disputed product "CosMx Spatial Molecular Imager", abbreviated to "CosMx SMI" (hereinafter referred to as **"**disputed **embodiment 1"**).

The challenged embodiment 1 enables highly sensitive, subcellular imaging of a variety of RNAs or proteins directly from individual cells in mor- phologically intact tissue samples. The challenged embodiment 1 allows samples, in particular biological samples such as fixed cells and tissue sections, to be automatically analysed for the presence of certain analytes, namely RNA and proteins. According to the applicants, the product has been offered on the market since December 2022. It is also used in the so-called CX-Lab of the defendants in Amsterdam. This is evident from the presentation of the CX-Lab on the website https://nanostring.com/about-us/cx-labs/cxlab-amsterdam/; in the section 'Platforms Designed to Accelerate Sample to

Discovery" is the name given to the products present in the laboratory in Amsterdam, including the challenged embodiment 1.

The **challenged embodiment** 2 is a detection reagent. It can only be used for the detection of RNA. The challenged embodiment 2 is sold in a kit as a so-called "CosMx RNA Panel" in a standard variant ("off-the-shelf RNA Add-On") as well as according to customer specifications ("Custom RNA Add-On Probes").

The **challenged embodiment** 3 is a probe that binds as a secondary probe to the primary probe that has already bound to its analyte (RNA or protein); the challenged embodiment 3 is used in so-called
"CosMx RNA Imaging Trays". These products are available for the detection of 100 RNAs (100-plex) or 1000 RNAs (1000-plex), each for 2 or 4 slides. The challenged embodiment 3 can be used for the detection of RNA as well as for the detection of proteins.

The challenged embodiments are also offered in combination. They have been supplied to the Max Delbrück Center in Berlin, for example, which offers available services and technologies under the name Nanostring-CosMx.

The defendants have carried out a promotional tour of the contested embodiments in Europe in the second half of April 2023 (European Summit, Exhibit BP 18, including events in Hanover and Würzburg). The defendants are holding numerous other events at research institutions to demonstrate the challenged embodiments and are also planning such events for the coming weeks and months (event announcements as Annexes BP 19 to BP 19c).

The defendant repeatedly requested the second applicant to submit a licence offer on reasonable terms with regard to the patent in suit.

The applicants filed an infringement action with the EPC (Munich Local Chamber) on the grounds of infringement of the patent in suit on 31 August 2023.

The applicants claim that the "CosMx Spatial Molecular Imager" (and similar models) offered and used by the respondents and also used by their customers and the associated detection reagents and decoder probes are devices for carrying out the method protected by the patent in suit.

The applicants describe the core of the invention according to the patent in suit in that it takes a fundamentally different approach compared to the prior art. Whereas the prior art methods for in situ analysis combined fluorophores in order to increase the number of detectable analytes, in the invention according to the patent in suit a probe was not directly labelled with a fluorophore; rather, a nucleic acid sequence (so-called predetermined partial sequence) was attached to the probe.

The second applicant was entitled to file an application as the registered proprietor of the patent in suit. The entry in the register was also decisive. Irrespective of this, the second applicant had fulfilled all legal requirements in connection with the invention in dispute here. This applied in particular to the requirements arising from the Bayh-Dole Act. The second applicant had disclosed the invention to the NIH in due time, had claimed the right to the invention in accordance with the requirements of the Bayh-Dole Act and had filed a patent application for the invention. The NIH had not raised any objections to date. This was proven by the affidavit of Ms Karen Sinclair, Director of Intellectual Property at the second applicant.

In view of the fact that the contested embodiment 2 (detection reagents) can only be used in the context of the detection of RNA, whereas the contested embodiments 1 and 3 can be used both in the context of the detection of RNA and in the context of the detection of proteins, the applicants request an unlimited prohibition only with regard to offering and carrying out the patent-infringing process (request no. A. I.) and offering and supplying the contested embodiment 2 (request no. A. III.).I.) and the offering and supplying of the contested embodiment 2 (application point A.III.).

With regard to the offering and supply of the contested embodiments 1 and 3, however, the applicants only request the affixing of a warning notice concerning the patent in suit and the obligation of the respondents to conclude a cease-and-desist agreement with their customers, subject to a contractual penalty, with regard to the use of the contested embodiments 1 and 3 for the detection of RNA (application numbers A.II. and A.IV.).

The applicants have chosen a version for the request for an order of 1 June 2023 which corresponds literally to claim 1 of the patent in suit and which is spatially referred to the "participating member states". On the basis of the submission in the opposition of 21 July 2023, the applicants adapted their request so that the contracting states of the UPCA are mentioned by name in the request and the passage
"one or" has been deleted before "a plurality of predetermined subsequences".

At the oral proceedings on 5 September 2023, the Local Board pointed out that the question of the validity of the patent in suit (validity in law) was open after the preliminary deliberations and therefore had to be discussed with the parties; in this context, the Local Board also pointed out that in the parallel proceedings concerning the parent patent (UPC_CFI_17/2023), the applications for an order were filed in a version restricting the claim of the parent patent. Taking up this indication, the applicants supplemented their main request with an auxiliary request. At the oral proceedings, the local board further pointed out that the indication "in font size 12" in the requests for injunctions II and IV could be indeterminate, as it remained open which typeface was concerned; the applicants consequently deleted this passage in each case. The local chamber also pointed out at the oral hearing that the competence of the Munich local chamber of the EPG to determine the appropriateness of the contractual penalties referred to in applications for orders II and IV could be questionable; the applicants then replaced the phrase "Munich local chamber" with "competent court". With regard to the naming of the second applicant in the applications for orders II and IV (there (1) and (2) respectively), the applicants stated that this had been agreed between the applicants.

Accordingly, the **applicants'** most recent **applications** are:

A. Orders the defendants to cease and desist, in the territories of the Republic of Austria, the Kingdom of Belgium, the Republic of Bulgaria, the Kingdom of Denmark, the Republic of Estonia, the Republic of Finland, the French Republic, the Federal Republic of Germany, the Italian Republic, the Republic of Latvia, the Republic of Lithuania, the Grand Duchy of Luxembourg, the Republic of Malta, the Kingdom of the Netherlands, the Portuguese Republic, the Republic of Slovenia and/or the Kingdom of Sweden from

i. A method for detecting a plurality of analytes in a cell or tissue sample comprising

(a) Mounting the cell or tissue sample on a solid support;

(b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, wherein the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents;

(c) incubating the cell or tissue sample together with the plurality of detection reagents for a period of time sufficient to allow binding of the plurality of detection reagents to the analytes; wherein

each subpopulation of the plurality of detection reagents targets a different analyte, wherein

each of the plurality of detection reagents comprises: a probe reagent targeting an analyte of the plurality of analytes; and

a plurality of predetermined subsequences, wherein the probe reagence and the plurality of predetermined subsequences are conjugated to each other;

(d) detecting said plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

(i) Hybridizing a set of decoder probes with a subset of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes, and wherein each subpopulation of the decoder probes comprises a detectable label, wherein each detectable label produces a signal signature;

(ii) Detect the signal signature produced by hybridising the set of deco- der probes;

(iii) Removing the signal signature; and

(iv) repeating (i) and (iii) using a different set of decoder probes to detect different sub-sequences of the detection reagents, thereby producing a temporal sequence of signal signatures unique to each sub-population of the plurality of detection reagents; and

(e) using the temporal order of the signal signatures corresponding to the plurality of predetermined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of analytes in the cell or tissue sample,

in the territory of one or more of the states mentioned under A. or to offer them for use in the territory of one or more of the states mentioned under A.;

(direct infringement of claim 1 of EP 4 108 782)

II. Devices suitable for performing a method for detecting a plurality of RNAs in a cell or tissue sample, comprising

(a) Mounting the cell or tissue sample on a solid support;

(b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, wherein the

multiplicity of detection reagents comprises a multiplicity of subpopulations of the detection reagents;

(c) incubating the cell or tissue sample together with the plurality of detection reagents for a period of time sufficient to allow binding of the plurality of detection reagents to the RNAs; wherein

each subpopulation of the plurality of detection reagents targets a different RNA, whereby

each of the plurality of detection reagents comprises: a probe reagent targeting an RNA of the plurality of RNAs, and

a plurality of predetermined subsequences, wherein the probe reagence and the plurality of predetermined subsequences are conjugated to each other;

(d) detecting said plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

(i) Hybridising a set of decoder probes with a subsequence of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes, and wherein each subpopulation of decoder probes comprises a detectable label, wherein each detectable label produces a signal signature;

(ii) Detection of the signal signature produced by hybridisation of the set of decoder probes;

(iii) Removing the signal signature; and

(in) r e p e a t i n g (i) and (iii) using a different set of decoder probes to detect different sub-sequences of the detection reagents, thereby producing a temporal sequence of signal signatures unique to each sub-population of the plurality of detection reagents; and

(e) using the temporal order of the signal signatures corresponding to the plurality of predetermined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of RNAs in the cell or tissue sample,

to offer and/or supply in the territory of one of the States mentioned under A. for use in the territory of one of the States mentioned under A. or in the territories of several of these States for use in the territory of one or more of the States mentioned under A.

without

(1) to state explicitly, conspicuously and prominently on each offer, on the first page of the operating instructions, in the delivery documents and on the packaging that the devices may not be used for the detection of RNA in a procedure pursuant to section A.I. without the consent of the second applicant) as owner of EP 4 108 782 and that they may not be used for the detection of RNA without the consent of the second applicant),

(2) impose on the purchasers a written obligation not to use the devices for the detection of RNA without the prior consent of the second applicant, subject to the imposition of a reasonable contractual penalty to be paid to the second applicant, to be determined by the second applicant and, if necessary, to be reviewed by the competent court, for each case of infringement;

(indirect infringement of claim 1 of EP 4 108 782)

iii. Detection reagents suitable for carrying out a method for detecting a plurality of analytes in a cell or tissue sample, comprising

(a) Mounting the cell or tissue sample on a solid support;

(b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, wherein the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents;

(c) incubating the cell or tissue sample together with the plurality of detection reagents for a period of time sufficient to allow binding of the plurality of detection reagents to the analytes; wherein

each subpopulation of the plurality of detection reagents targets a different analyte, wherein

each of the plurality of detection reagents comprises: a probe reagent targeting an analyte of the plurality of analytes; and

a plurality of predetermined subsequences, wherein the probe reagence and the plurality of predetermined subsequences are conjugated to each other;

(d) detecting said plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

(i) Hybridising a set of decoder probes with a subsequence of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes, and wherein each subpopulation of decoder probes comprises a detectable label, wherein each detectable label produces a signal signature;

(ii) Detect the signal signature produced by hybridising the set of deco- der probes;

(iii) Removing the signal signature; and

(iv) Repeating (i) and (iii) using a different set of decoder probes to detect different partial se- quences of the detection reagents, resulting in a

temporal order of signal signatures is produced that is unique for each subpopulation from the multiplicity of detection reagents; and

(e) using the temporal order of the signal signatures corresponding to the plurality of predetermined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of analytes in the cell or tissue sample,

in the territory of one of the States mentioned under A. for the use of the process in the territory of one of the States mentioned under A. or in the territories of several of these States for use in the territory of one or more of the States mentioned under A. to offer and/or supply;

(indirect infringement of claim 1 of EP 4 108 782)

iv. Decoder probes suitable for performing a method for detecting a plurality of RNAs in a cell or tissue sample, comprising

(a) Mounting the cell or tissue sample on a solid support;

(b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, wherein the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents;

(c) incubating the cell or tissue sample together with the plurality of detection reagents for a time sufficient to allow binding of the plurality of detection reagents to the RNAs; wherein

each subpopulation of the plurality of detection reagents targets a different RNA, whereby

each of the plurality of detection reagents comprises: a probe reagent targeting an RNA of the plurality of RNAs, and

a plurality of predetermined subsequences, wherein the probe reagence and the plurality of predetermined subsequences are conjugated to each other;

(d) detecting said plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

(i) Hybridising a set of decoder probes with a subsequence of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes, and wherein each subpopulation of decoder probes comprises a detectable label, wherein each detectable label produces a signal signature;

(ii) Detection of the signal signature produced by hybridisation of the set of decoder probes;

(iii) Removing the signal signature; and

(iv) repeating (i) and (iii) using a different set of decoder probes to detect different sub-sequences of the detection reagents, thereby producing a temporal sequence of signal signatures unique to each sub-population of the plurality of detection reagents; and

(e) using the temporal order of the signal signatures corresponding to the plurality of predetermined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of RNAs in the cell or tissue sample,

in the territory of one of the States mentioned under A. for the use of the process in the territory of one of the States mentioned under A. or in the territories of several of these States in the territory of one or more of the States mentioned under A. to offer and/or supply the process,

without

(1) to point out explicitly, conspicuously and prominently on each offer, on the first page of the operating instructions, in the delivery documents and on the packaging that the decoder probes may not be used for the detection of RNA in a procedure pursuant to section A.I. without the consent of the second applicant) as owner of EP 4 108 782 and that they may not be used for the detection of RNA without the consent of the second applicant),

(2) impose on the purchasers a written obligation not to use the decoder probes for the detection of RNA without the prior consent of the second applicant, subject to the imposition of a reasonable contractual penalty to be paid to the second applicant, to be determined by the second applicant and, if necessary, to be reviewed by the competent court, for each case of infringement;

(indirect infringement of claim 1 of EP 4 108 782)

Alternatively to A.I to A IV

Aa. The defendants are ordered to cease and desist, in the territories of the Republic of Austria, the Kingdom of Belgium, the Republic of Bulgaria, the Kingdom of Denmark, the Republic of Estonia, the Republic of Finland, the French Republic, the Federal Republic of Germany, the Italian Republic, the Republic of Latvia, the Republic of Lithuania, the Grand Duchy of Luxembourg, the Republic of Malta, the Kingdom of the Netherlands, the Portuguese Republic, the Republic of Slovenia and/or the Kingdom of Sweden, from

Ia. A method for detecting a plurality of analytes in a cell or tissue sample using (i) immunohistochemistry and/or fluorescence
In situ hybridisation is used comprising

(a) Mounting the cell or tissue sample on a solid support;

(b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, wherein the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents;

(c) incubating the cell or tissue sample together with the plurality of detection reagents for a time sufficient to allow binding of the plurality of detection reagents to the analytes; wherein

each subpopulation of the plurality of detection reagents targets a different analyte, wherein

each of the plurality of detection reagents comprises: a probe reagent targeting an analyte of the plurality of analytes; and

a plurality of predetermined subsequences, wherein the probe reagence and the plurality of predetermined subsequences are conjugated to each other;

(d) detecting said plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

(i) Hybridizing a set of decoder probes with a subset of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes, and wherein each subpopulation of the decoder probes comprises a detectable label, wherein each detectable label produces a signal signature;

(ii) Detect the signal signature produced by hybridising the set of deco- der probes;

(iii) Removing the signal signature; and

(iv) Repeating (i) and (iii) using a different set of decoder probes to detect different partial sequences of the detection reagents, thereby producing a temporal sequence of signal signatures which is

is unique for each subpopulation from the variety of detection reagents; and

(e) using the temporal order of the signal signatures corresponding to the plurality of predetermined sub-sequences of the detection reagent to identify a sub-population of the detection reagents, thereby detecting the plurality of analytes in the cell or tissue sample, wherein

the analytes are selected from the group consisting of proteins, peptides and nucleic acids, wherein the nucleic acids are selected from the group consisting of cellular RNA, messenger RNA, microRNA, ribosomal RNA, and any combination thereof

in the territory of +one or more of the States mentioned under Aa. or to offer them for use in the territory of one or more of the States mentioned under Aa;

(direct infringement of claim 1 of EP 4 108 782)

IIa. Devices suitable for performing a method for detecting a plurality of RNAs in a cell or tissue sample used in (i) immunohistochemistry and/or FIuorescence in situ hybridisation, comprising

(a) Mounting of the cell or tissue sample on a solid support.
Porters;

(b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, wherein the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents;

(c) incubating the cell or tissue sample together with the plurality of detection reagents for a time sufficient to allow binding of the plurality of detection reagents to the RNAs; wherein

each subpopulation of the plurality of detection reagents targets a different RNA, whereby

each of the plurality of detection reagents comprises: a probe reagent targeting an RNA of the plurality of RNAs, and

a plurality of predetermined subsequences, wherein the probe reagence and the plurality of predetermined subsequences are conjugated to each other;

(d) detecting said plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

(i) Hybridizing a set of decoder probes with a subset of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes, and wherein each subpopulation of the decoder probes comprises a detectable label, wherein each detectable label produces a signal signature;

(ii) Detect the signal signature produced by hybridising the set of deco- der probes;

(iii) Removing the signal signature; and

(iv) repeating (i) and (iii) using a different set of decoder probes to detect different sub-sequences of the detection reagents, thereby producing a temporal sequence of signal signatures unique to each sub-population of the plurality of detection reagents; and

(e) using the temporal order of the signal signatures corresponding to the plurality of predetermined sub-sequences of the detection reagent to identify a sub-population of the detection reagents, thereby detecting the plurality of RNAs in the cell or tissue sample, wherein

the analytes are selected from the group consisting of proteins, peptides and nucleic acids, wherein the nucleic acids are

are selected from the group consisting of cellular RNA, measuring RNA, microRNA, ribosomal RNA and any combinations thereof

in the territory of one of the States mentioned under Aa. for the use of the process in the territory of one of the States mentioned under Aa. The applicant shall be entitled to offer and/or supply the process in the territory of one of the States referred to in Aa. or in the territories of several of these States for use in the territory of one or more of the States referred to in Aa,

without

(1) on each offer, on the first page of the operating instructions, in the delivery documents as well as on the packaging, it must be expressly stated in a conspicuous and eye-catching manner that the devices may not be used for the detection of RNA in a procedure pursuant to section A.la. without the consent of the second applicant as owner of EP 4 108 782 and that they must not be used for the detection of RNA without the consent of the second applicant,

(2) impose on the purchasers a written obligation not to use the devices for the detection of RNA without the prior consent of the second applicant, subject to the imposition of a reasonable contractual penalty to be paid to the second applicant, to be determined by the second applicant and, if necessary, to be reviewed by the competent court, for each case of infringement;

(indirect infringement of claim 1 of EP 4 108 782)

pur ple. Detection reagents suitable for performing a method for detecting a plurality of analytes in a cell or tissue sample used in (i) immunohistochemistry and/or fluorescence in situ hybridisation, comprising

(a) Mounting the cell or tissue sample on a solid support;

(b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, wherein the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents;

(c) incubating the cell or tissue sample together with the plurality of detection reagents for a time sufficient to allow binding of the plurality of detection reagents to the analytes; wherein

each subpopulation of the plurality of detection reagents targets a different analyte, wherein

each of the plurality of detection reagents comprises: a probe reagent targeting an analyte of the plurality of analytes; and

a plurality of predetermined subsequences, wherein the probe reagence and the plurality of predetermined subsequences are conjugated to each other;

(d) detecting said plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

(@ Hybridizing a set of decoder probes with a subset of said detection reagents, said set of decoder probes comprising a plurality of subpopulations of decoder probes.
and wherein each subpopulation of the decoder probes comprises a detectable tag, each detectable tag producing a signal signature;

(ii) Detect the signal signature produced by hybridising the set of deco- der probes;

(iii) Removing the signal signature; and

(iv) Repeating (i) and (iii) using a different set of decoder probes to detect different partial sequences of the detection reagents, thereby producing a temporal sequence of signal signatures which is

is unique for each subpopulation from the variety of detection reagents; and

(f) Using the temporal order of the signal signatures corresponding to the plurality of predetermined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of analytes in the cell or tissue sample, wherein the analytes are selected from the group consisting of proteins, peptides and nucleic acids, wherein the nucleic acids are selected from the group consisting of cellular RNA, messenger RNA, microRNA, ribosomal RNA and any combinations thereof

in the territory of one of the States mentioned under Aa. for the use of the process in the territory of one of the States mentioned under Aa. The applicant shall be entitled to offer and/or supply the process in the territory of one of the States referred to in Aa. or in the territories of several of these States for use in the territory of one or more of the States referred to in Aa;

(indirect infringement of claim 1 of EP 4 108 782)

IVa. Decoder probes suitable for performing a method for detecting a plurality of RNAs in a cell or tissue sample used in (i) immunohistochemistry and/or Fluorescence in situ hybridisation, comprising

(a) Mounting the cell or tissue sample on a solid support;

(b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, wherein the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents;

(c) incubating the cell or tissue sample together with the plurality of detection reagents for a time sufficient to allow binding of the plurality of detection reagents to the RNAs; wherein

each subpopulation of the plurality of detection reagents targets a different RNA, whereby

each of the plurality of detection reagents comprises: a probe reagent targeting an RNA of the plurality of RNAs, and

a plurality of predetermined subsequences, wherein the probe reagence and the plurality of predetermined subsequences are conjugated to each other;

(d) detecting said plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

(i) Hybridizing a set of decoder probes with a subset of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes, and wherein each subpopulation of the decoder probes comprises a detectable label, wherein each detectable label produces a signal signature;

(ii) Detect the signal signature produced by hybridising the set of deco- der probes;

(iii) Removing the signal signature; and

(iv) repeating (i) and (iii) using a different set of decoder probes to detect different sub-sequences of the detection reagents, thereby producing a temporal sequence of signal signatures unique to each sub-population of the plurality of detection reagents; and

(e) using the temporal order of the signal signatures corresponding to the plurality of predetermined sub-sequences of the detection reagent to identify a sub-population of the detection reagents, thereby detecting the plurality of RNAs in the cell or tissue sample, wherein

the analytes are selected from the group consisting of proteins, peptides and nucleic acids, wherein the nucleic acids are

are selected from the group consisting of cellular RNA, measuring RNA, microRNA, ribosomal RNA and any combinations thereof

in the territory of one of the States mentioned under Aa. for the use of the process in the territory of one of the States mentioned under Aa. The applicant shall be entitled to offer and/or supply the process in the territory of one of the States referred to in Aa. or in the territories of several of these States for use in the territory of one or more of the States referred to in Aa,

without

(1) to point out explicitly, conspicuously and prominently on each offer, on the first page of the operating instructions, in the delivery documents and on the packaging that the decoder probes may not be used for the detection of RNA in a procedure pursuant to section A.la. without the consent of the second applicant as owner of EP 4 108 782 and that they must not be used for the detection of RNA without the consent of the second applicant,

(2) impose on the purchasers a written obligation not to use the decoder probes for the detection of RNA without the prior consent of the second applicant, subject to the imposition of a reasonable contractual penalty to be paid to the second applicant, to be determined by the second applicant and, if necessary, to be reviewed by the competent court, for each case of infringement;

(indirect infringement of claim 1 of EP 4 108 782)

B. In the event of any infringement of the orders under clause A.I. to A.IV., the respective defendant shall pay to the court a penalty payment (repeated if necessary) of up to EUR 250,000 per infringement (R. 354.3 RoP).

c. Order the defendants to pay the costs for the time being.

D. This order is immediately enforceable.

The respondents have applied for,

1. Dismiss the application for interim measures dated 1 June 2023, as amended on 5 September 2023, and the auxiliary application dated 5 September 2023 as inadmissible and/or in any event unfounded;

- alternatively -

1.1. Allow the defendants to continue the alleged infringement actions against the provision of a security, the amount of which is left to the discretion of the court, but should not exceed € 1,000,000;

- most alternatively -

1.2. make the granting of interim measures dependent on the provision of a security by the applicants, the amount of which is to be determined by the court, but should not be less than € 20,000,000.

2. Order the applicants to pay the costs of the proceedings.

3. This order is immediately enforceable.

The respondents filed a protective statement dated 2 June 2023. Furthermore, they replied to the application with an objection dated 21 July 2023 and to the applicant's reply dated 11 August 2023 with a written statement dated 24 August 2023.

The defendants claim that **the Munich Local Chamber does not have jurisdiction.**
of the EPG.

Since two first-instance judgments of the Munich I Regional Court (Case No. 7 O 5812/22 and Case No. 7 O 2693/22) were issued and enforced in Germany prior to the filing of the present application, at least the attack against the second defendant was clearly unfounded, since relevant acts of infringement in Germany as a result of compliance with the prohibition pronounced by the Munich I Regional Court were not conclusively shown. The challenged proceedings were not carried out in Germany by the defendants. Therefore, there is no relevant reference to Germany.

Since the request was obviously unfounded with regard to Germany and the second applicant, the board seised also lacked jurisdiction; an obviously unfounded request against a party - who was clearly not carrying out an infringing act - only in order to be able to pursue local jurisdiction via Article 33(b) EPC in the case of several defendants/respondents by way of "forum shopping", as it were, was not worthy of protection and not within the meaning of the law.

- The respondents consider the **application** for interim measures to be inadmissible.

The request did not comply with the mandatory procedural requirements of the Rules of Procedure of the Unified Patent Court, as it did not contain the information required under Rule 206(2)(a), (c), (d) and (e) of the Rules of Procedure. In particular, the applicant had not provided evidence that it was entitled to institute the proceedings. Contrary to Rule 206 no. 2 d) of the Rules of Procedure, the applicant's side had submitted its submissions on the state of the law for the first time in its reply.

For the fulfilment of the mandatory application requirement under Rule 206 No. 2 (e) Furthermore, it was insufficient that a possible main action was ultimately only announced in a non-binding manner in the reply of 11 August 2023. The mere announcement of a main action was also not a "brief description" of the main action, which was, however, required by the Rules of Procedure.

The respondents object to the **petitioners' lack of active legitimacy (entitlement to file an application).**

Since the patent in suit was part of a patent family whose underlying research had been financed to a very considerable extent with public US funds from the US National Institute of Health (NIH), certain legal requirements had to be complied with.

The second applicant had failed to comply with certain requirements of the so-called Bayh-Dole Act, namely Art. 35 USC 2002 (c); therefore, the rights to the invention had passed to the US Government.

The US funding had been conditional on the granting of non-exclusive licences to third parties for the resulting technologies and innovations - also in relation to the EPC states. Consequently, the granting of an exclusive licence to the first applicant was excluded anyway. However, the first applicant had also not been granted a simple licence with legal effect, since the agreements submitted with Annex PB 1 were not legally valid under the relevant German law (Article 7(3) of Regulation (EU) 1257/2012 in conjunction with Article 6(1) EPC). Article 6(1) EPC) were null and void. The invalidity resulted from the conclusion of an exclusive licence agreement between the two applicants in collusion between the contracting parties and in breach of the NIH's conditions of grant; this view was also confirmed by the judgment of the Munich I Regional Court (Case No. 7 O 2693/22).

-The defendants are of the opinion that the **patent in suit** is **not legally valid.** dig.

The validity of the patent in suit could not be presumed on the basis of its grant. This follows from the fact that the patent was granted without any comprehensible examination, as is evident from the EPO file: less than one year had passed between the filing of the divisional application on 27 April 2022 and the issue of the intention to grant on 6 April 2023.2023 - the examination of the patent had thus obviously not been carried out intensively; particularly relevant prior art (D6, D8, D12, D13, D27) had not been seen; novelty and inventive step were dealt with in just two sentences in the EPO's opinion. Furthermore, the applicants claimed a limited - and thus in every respect unexamined - version of the patent. There could not necessarily be a "presumption" of this.

The subject-matter of claim 1 of the patent in suit was not directly and unambiguously disclosed in the original application documents of the previous applications (to the parent patent and to EP "063) and was thus inadmissibly extended. There was also a lack of novelty of inventive step. The patent in suit also did not disclose the invention so clearly and completely that it could be carried out by a person skilled in the art.

O On the one hand, the **inadmissible extension** concerned the repetition of step (ii), which was not specifically required in the claim wording. On the other hand, the original application documents had included a Vrepeat of step (ii). Thus, the Vrepeat of only the hybridisation and signal removal steps (i) and (iii) without the claiming step (ii) was not directly and unambiguously disclosed in the previous applications. Claim 1 therefore went beyond the content of the original application in violation of Art. 76(1) EPC.

In the parent patent application, the temporal sequence *actively* identifies the detection reagents, whereas in claim 1 of the patent in suit, the sequence is used *passively* ("using the temporal sequence folae of the sianalsianatura I...1 to identify a partial pos- sion of the sianalsianatura I...1 to identify a partial pos- sion of the sianalsianatura I...1").

detection reagents"). The latter wording is broader, as it potentially includes the possibility that while the timing of signal signatures is used in some way in the identification process, other components or steps may also be included (and necessary) in the identification.

O The defendants also invoke a **lack of novelty of** the claimed procedure.

- The article by *Göransson et al.* (D6), which was not considered in the examination procedure, disclosed the claimed subject-matter by the detection method for amplified single molecules (ASM) used for this purpose. In *Göransson,* specific sections of genomic DNA (via ASM), i.e. a multitude of analytes, would be detected in one sample. According to the description of the patent in suit, the term "cell or tissue sample" encompassed both non-intact and pre-processed or prepared samples; this pre-processing could therefore also include the isolation of genomic DNA. It is obvious to a person skilled in the art that the generic decoding scheme of Gör- ansson et al. (D6) works completely independently of what analyte one wants to detect. For the details of the submission, reference is made to the statements of the defendants in the opposition (paragraphs 304 to 377) and the reply (paragraphs 139 to 158).
- However, the claimed method was also not new in view of US 2010/0151472 (D12) published on 17 June 2010. With regard to the details of the submission, reference is made to the statements of the defendants in the opposition (paragraphs 378 to 448) and the reply (paragraphs 182 to 189).

O With regard to the claimed method, the respondents also claim that it is not based on **inventive step. The** defendants named the following publications as relevant prior art:

- *Duose et a/. 2010* (D8); for the details of the submission, including the asserted combination (D8/D6), reference is made to the submissions of the respondents in the opposition (paragraphs 456 to 569) and in the rejoinder (paragraphs 159 to 175).
- *Duose et* a/. *2011* (D27); for the details of the submission, including the asserted combination (D27 in combination with D6 and/or D8), reference is made to the statements of the respondents in the application (paragraphs 570 to 607) and the reply (paragraphs 176 to 181).
- *WO 03/003810* (D23) (D6); for the details of the submission, including the claimed combination (D23 in combination with D6 and/or D8), reference is made to the respondents' submissions in the application (paragraphs 608 to 633).
- *Göransson et* a/. (D6); for the details of the submission, including the combination relied on (D6 in combination with D19, D13, D10, D11, D13 and D24), reference is made to the respondents' submissions in the opposition (paragraphs 634 to 669) and the rejoinder (paragraphs 144 to 158).
- *US 2010/0151472* (D12); for the details of the submission, including the asserted combination (D12 in combination with D6), reference is made to the statements of the defendants in the opposition (paragraphs 670 to 672) and the reply (paragraphs 182 to 189).

o According to the opponents, the subject-matter of the claims of the patent in suit is also not disclosed so completely that a person skilled in the art could carry out the invention **(insufficient disclosure).**

- The patent does not teach how unbound detection reagents can be removed prior to the detection step and how meaningful results can be obtained without such removal; it is not known to the skilled person in the art how the method can be carried out without a step for removing unbound detection reagent.

- The patent does not teach how a chronological order of the signal signatures is to be achieved if the detection step is not repeated together with the hybridisation and signal removal steps; but since this step is precisely not to be repeated according to the claim wording, the patent in suit is undoubtedly not executable.

- The claimed invention could not be carried out if extremely short decoder probes were used for hybridisation. The patent in suit states in paragraph [0059] that the decoder probe can be of any length. However, if a decoder probe is only a single nucleotide long, it cannot hybridise with the nucleic acid label or a predetermined partial sequence of the detection reagent; it would therefore not be possible to carry out the claimed method with decoder probes of only one nucleotide. The patent does not provide the skilled person with instructions on how a decoder probe with only a single nucleotide can nevertheless be used for detection by hybridisation.

- The patent in suit also does not contain a single example of an in situ "high-plex" detection, although the applicant's side asserts with regard to the parent patent that the claimed method enables an (allegedly better) high-plex analysis compared to the prior art.

o The BPatG's provisional and, from the respondents' point of view, correct reference to the parent patent also did not support the legal validity of the patent in question. It was undisputed that the BPatG did not consider the parent patent as granted to be legally valid and thus refuted a supposed presumption. The expected revocation of the patent in suit was impressively confirmed by an expert opinion of the "PRV-Swedish Intellectual Property Office" of 3 July 2023.

- The respondents claim that the **patent in suit** is **not infringed** by the contested products.

  The challenged embodiments were designed in such a way that essential steps of the process (creation of a temporal sequence of signal signatures, identification of the analyte) were not carried out on the device itself, but on a computer-aided system (cloud computing platform AtoMx Spatial Informatics) abroad and thus outside the scope of application of the UPCA. The request for an injunction was therefore already unfounded because the central step of the contested method and thus the advantage sought under the patent was carried out abroad.

  The process claimed by the patent is also not realised in technical terms. The following claim features were not realised by the process, which could be carried out with the contested products:

  O each subpopulation of the multitude of detection reagents targets a different analyte;

  O \/repeat (i) and (iii) using a different set of decoder probes to detect other partial sequences of the detection reagents, thereby producing a temporal sequence of signal signa- ture;

  O using the temporal order of the signal signatures corresponding to the one or the plurality of predetermined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of analytes in the cell or tissue sample.

  According to the patent, a "subpopulation" of the detection reagents, each of which binds to the same analyte, must be identical at the molecular level; this is also apparent from the description, for example [0138]. This was not the case, however, as different probe reagents bound to the same analytes.

However, the respective probe reagents would also have to be identical in order to be assigned to the same subpopulation.

According to a correct understanding of the asserted claim of the intervening patent, repetitions for the same sub-sequences were excluded in thought; by the term "thereby producing" there was a direct causality between the repetitions of steps (i) and (iii) for different predetermined sub-sequences and the generation of the temporal sequence of the signal signatures. The generation of the temporal order is therefore based on nothing other than the exclusive repetition of steps (i) and (iii) for other subsequences. Since this temporal sequence is not determined in the opponents' method, it is also not compared with the signal signatures for a subpopulation of the detection reagents. However, the patent claim presupposes that the analytes are detected by the temporal sequence of the signal signatures.

The respondents are of the opinion that the applications for an order **make** a **modification of the claim which** is **not provided for in the Rules of Procedure.**

The requests for an order modified claim 1 of the patent in suit by deleting the phrase *"one or"* before *"a plurality of predetermined subsequences*" and thus limited it. The version of the claim thus asserted was neither granted nor pending in substantive proceedings. On the other hand, Rule 211(2) Verfo clearly stipulates that the patent must be valid. A possibility to (alternatively) assert a version of the patent claim deviating from the granted version with the request for an injunction was not mentioned in the Implementing Regulations. The version of the claim asserted by the applicant in the order requests was non-existent. The amendment of the claim wording in question also had consequences for the legal status of the patent (novelty and inventive step; see duplicate paragraphs 210 to 222).

From the point of view of the respondents, there is in any case **no need to order interim measures.**

The requested measures were also neither urgent nor necessary in terms of time, as the applicants in the relevant jurisdictions had not proceeded from the parent patent against the challenged products since March 2022, as had happened in Germany; the internet presence https://www.nano- string.com had been known since March 2022.

The request filed with the EPO on 21 April 2023 for a postponement of the decision on the grant of the patent for invalidity in view of the above-mentioned introduction of the unitary patent also had to be taken into account in the assessment of urgency and led to a negative decision.

It also had to be taken into account that the applicants were not threatened with extraordinary damage, the compensation for which they could not pursue by way of an action on the merits. Rather, the defendants would be threatened with massive, currently unquantifiable and, above all, irreparable economic damage as well as considerable damage to their reputation if they were forced to take the challenged products off the market by way of a provisional measure. In view of the long product cycle and the considerable remaining patent term (until 31 December 2032), a main action alone was appropriate for this dispute.

Another argument against ordering provisional measures was that the defendants had an enforceable claim to a (non-exclusive) licence to the patent in suit; this was supported by the expert opinion of Professor Contreras, one of the most renowned professors in the field of US licensing law, submitted under Rule 181(1) of the Rules of Procedure. The respondents were willing to grant a licence and had therefore repeatedly requested the second applicant to submit a fair and reasonable licence offer, which the second applicant had ignored. The claim for a licence arises from

- On the one hand, from the fact that, according to the NIH funding conditions, a contract had been established between the NIH and the defendant 2, with which a corresponding obligation to (simple) licensing

was associated,

on which the defendants could also rely a s third party beneficiaries; the US court in Delaware had wrongly denied such a licence claim, this decision was not legally valid;

- The applicant further submits that the second applicant breached his contractual obligations towards the NIH by

  - did not grant a licence to the defendants,
  - granted an exclusive licence to the first applicant in collusive breach of the conditions of NIH funding; and

  had thus infringed US antitrust law and the US Unfair Competition Act; the legal consequence of these infringements was a claim by the opponents to a worldwide licence to the patent in suit. The Contreras opinion (German translation) states:

  > "If Harvard or 10x Genomics is shown to have engaged in acts that violate U.S. antitrust or unfair competition laws or otherwise constitute evidence of unclean hands with respect to the patents sponsored by NOH, NanoString shall be entitled to a license with respect to such patents."

- Flat in accordance with European antitrust law; the applicants used the patent in suit to monopolise the market in breach of contractual agreements of promotion with the NIH; therefore, a preliminary injunction was in any case also excluded in accordance with European antitrust law.

The applicant had withheld from the respondent the information that the second applicant had agreed to grant open, non-exclusive licences to third parties in return for the provision of NIH funding. If, on the other hand, the applicants had provided these documents in good time, or had simply complied with the terms of the grant, and thus

If the court had acted in accordance with the law, there would have been no reason for the present legal dispute.

The disregard of mandatory procedural requirements (Rule 206 No. 2 Verfo) and the lack of submissions in the petition on all known and foreseeable issues according to the German parallel proceedings on the parent patent, from the active legitimation to the non-infringement to the legal status, also prove the lack of urgency. (inter alia, failure to submit evidence).

- **Order provisional** measures only against provision **of security**

  If at all, security should be provided by the defendants to enable the alleged infringement to continue (see also Rule 206 No. 2 (c) Verfo), because the applicants' interest is purely financial.

- **Unsuitability of the subject-matter of the proceedings for the order of interim measures**

  ger measures

  The subject-matter of the proceedings was clearly unsuitable for interim measures - in particular an injunction - as the patent in suit and the subject-matter attacked not only concerned a highly complex technology, but the questions raised concerned admissibility, jurisdiction, active legitimacy, US law and general questions of contributory patent infringement and the existence of rights.

- **No need for legal protection**

  Since the applicants had the opportunity, on the basis of the titles of the Munich Regional Court I concerning the parent patent, to initiate simpler and less expensive proceedings to enforce their alleged rights - at least in Germany - with the application for an injunction than by pursuing an alleged substantive claim for injunctive relief in the context of the present proceedings, there was no need for legal protection.

Proportionality

The respondents are of the opinion that the order for interim measures - in particular an injunction - is disproportionate, as the weighing of interests under Art. 62(2) EPCÜ is clearly in favour of the respondents. Even if it were assumed that the patent was infringed and legally valid and that there was no enforceable licence claim, residual doubts in the exercise of discretion would have to lead to the rejection of the application. In this context, the irreparable damage threatening the defendants in the event of a prohibition was particularly serious; the defendants ran the risk of being excluded from the European market for good or at least for a very long time. The applicants, on the other hand, could await the outcome of the main proceedings without any financial or other business losses.

Even if one were to affirm the jurisdiction of the local chamber, the right to act, a risk of commission in Germany, an infringement, a sufficiently secure body of law, a "necessity" and an urgency, an injunction would remain disproportionate, as

- in any case, it is a completely subordinate part of a larger, complex product (the contested embodiment 1 consists of 2394 individual parts and is covered by a large number of patents and patent applications of the respondents, for example for chemical processes, but also contains specially developed fluidic and optical systems and data analysis methods; its technology goes far beyond the method of the patent in suit), for which development costs of over $93,000,000 were incurred,

  the second applicant, as a Non-Practicing Entity ("NPE"), had no interest in enforcing an injunction worthy of protection and

- The disproportionate nature of an injunction would also result from the fact that the challenged embodiments are of irreplaceable importance for research into a large number of serious, life-threatening diseases.

diseases and the development of therapies against them in the EPC Contracting States, as they cannot be replaced by an alternative analytical method available on the market.

It should also not be disregarded that the applicants would build up an unlawful patent thicket: With the parent patent, as well as EP 3 425 063 and the patent in suit, there are two family members, all of which are based on the regional phase of the international application WO 2013/096851; the applicants are thus trying to enforce their formal positions obtained by grant with three invalid patents.

The objection of disproportionality could only be sufficiently taken into account by refusing an injunction.

With regard to further details of the parties' submissions, reference is made to their written submissions and to their submissions at the oral hearing.

Reasons for the decision and orders

The Munich Local Chamber of the Unified Patent Court (hereinafter referred to as "EPC") has jurisdiction to decide on the request for interim measures at issue here. The main request is admissible and largely well-founded.

A.

i. The **Munich Local Chamber of** the EPG shall be **competent** to decide on the application for interim measures.

The jurisdiction of the Munich Local Chamber of the UPC is based on Article 33(1)(a) UPC. Pursuant to Article 32(1)(a) UPCA, the applicants have filed a request for provisional measures on account of the infringement of the patent in suit by the respondents in, inter alia, Germany.

The applicants have argued that patent-infringing products are offered via the internet presence under the URL https://nanostring.com. This offer of immediate dispatch ("Shipping now") refers, inter alia, to all Member States of the European Union, i.e. also the EPC contracting states and thus also Germany. In the "Legal" section of the website, the terms and conditions of sale refer in particular to shipping to the Member States of the European Union. There it says ("Sa- les Terms", available at https://nanostring.com/about-us/legal/termsofs-ale/#sales-of-products):

> "Unless otherwise set forth in writing by NanoString or otherwise agreed by the parties, all shipments are made EXW (Incoterms 2010) NanoString's manufacturing facility, except for shipments to member countries of the Eu- rooean Union, the United Kingdom, and Canada, which are made DDP (In- coterms 2010) excluding VAT." (underlining by the court)

Contrary to the defendants' submission, this is not merely "general information", but patent-relevant offers to supply.

According to the applicants, the contested designs were also supplied to Germany, for example to the Max Delbrück Center in Berlin. Furthermore, in the second half of April 2023, the defendants carried out a promotional tour for the contested products in Europe; events were also held in Germany (Hanover and Würzburg). The respondents are holding numerous other events at research institutions to demonstrate the challenged embodiments and are also planning such events for the coming weeks and months (event announcements as Annexes BP 19 to BP 19c).

The offers are also attributable to all defendants. Although the written submissions of the respondents sometimes state that *respondent 1)* offers the disputed products (e.g. in paragraph 52 of the opposition), at other times it is stated that the products or a process are those of "the respondents" (e.g. in paragraphs 48, 159, 178, 198, 206 or 207 of the opposition). The Local Board therefore assumes with the applicants that the challenged embodiments and their offer in Europe are attributable to all respondents.

This establishes the jurisdiction of the Munich Local Chamber of the EPC. In this respect, it is not relevant for the question of jurisdiction whether, according to the legal assessment by the court, a patent infringement also follows from the conclusively presented allegation. The legal assessment of the assertion of an act performed in Germany as a patent infringement is not the subject of the examination of jurisdiction; in this respect, conclusive submission is sufficient.

II. The **application** for interim measures is **admissible.**

It is true that the respondents correctly point out that an application for interim measures may also be dismissed as inadmissible by default if the application does not comply with certain formal requirements; this follows from Rules 206(2), 208(1), 16(2), (3), (4) and (5) of the Rules of Procedure and applies to the formal requirements referred to therein. However, the registry responsible for examining these formal requirements (Rule 208 no. 1, first sentence of the Verfo) has pointed out corresponding deficiencies of the

application was not ascertained. As a result, there was also no request for rectification of defects under Rule 16 no. 3 of the Rules of Procedure and no referral to the judge under Rule 16 no. 5 of the Rules of Procedure. The application for a default judgment required under Rule 355 of the Rules of Procedure was also not filed.

Irrespective of this, the deficiencies complained of by the respondents do not exist.

For the examination of the formal requirements of the application by the Registry, the only decisive factor is whether the information required under the Rules of Procedure is available in *form.* Whether the information is also correct in terms of content is reserved for judicial review; in this respect Rule 211 no. 2 of the Rules of Procedure applies. Having said this, the following is to be said about the individual formal objections:

1. The second applicant submitted in the request that she is the proprietor of the patent in suit and that she has granted the first applicant an exclusive licence to the patent in suit. Thus, the formal requirements according to Rules 206 No. 2 (a), 13 No. 1 (f) of the Rules of Procedure are fulfilled. The validity of the patent or licence ownership is not to be assessed by the registry within the framework of the formal examination, but is the subject of the court's decision on the merits. A dismissal of the application under Rule 206 No. 2 (a), 13 No. 1 (f}, 16 IR as inadmissible is therefore not made even if the court denies the status as patent proprietor or (exclusive) licensee on the merits.

2. Even if, in the opinion of the opposing parties, the applicant's side only made a cursory statement in the application regarding the necessity of interim measures, the formal requirements under Rule 206 no. 2 are not met.
(c) of the Rules of Procedure. Rule 206 No. 2 (c) IR is not subject to the formal examination by the Registry. Rules 208(1) and 16 of the Rules of Procedure apply to the Registry's examination programme; Rule 206(2)(c) of the Rules of Procedure (corresponding to the grounds to be stated in the application in the main proceedings under Rule 13(1)(n) of the Rules of Procedure) is not mentioned there.

Rule 206(2)(c) of the Rules of Procedure requires only that reasons be given

for the necessity of the measures requested; whether these reasons are of substance to the court or not.

The question of whether the application is convincing is not the subject of the examination of the formal requirements of the application, but of the decision of the court on the merits. Dismissal of the application as inadmissible because the information in question is cursory or
are "not comprehensible" are therefore out of the question.

3. The objection with regard to Rule 206 no. 2 (d) of the Constitutional Rules is also unfounded.

The submission of facts and evidence - as in the case of a statement of *claim in* the main proceedings (Rule 13(m) of the Rules of Procedure) - are not subject to the formal examination by the Registry under Rules 208(1) and 16 of the Rules of Procedure.

a. The applicants based their application on certain evidence (BP 1 annexes etc.) and announced their submission for the time of the possibility of electronic service on the defendants; the ordering of provisional measures without hearing the opponents (Rule 209 no. 4 of the Rules of Procedure) was not applied for. Irrespective of the fact that the evidence was finally submitted, a dismissal of the application as inadmissible due to the fact that the evidence was not submitted at the time of the filing of the application is out of the question, if only because Rule 211 no. 2 of the Rules of Procedure expressly provides that the court may order the applicant to submit the available evidence if this has not already been done with the filing of the application.

To the extent that the respondents complain that the annexes were only submitted in response to the written procedural order of the Judge-Rapporteur of 27 June 2023, this also does not lead to the inadmissibility of the application for an injunction. At least in the initial phase of the EPC's activities relevant here, the applicants' representative and the Local Chamber assumed that the opening of a *workflow* by the court was required for the uploading of documents in the EPC's case management system; therefore, the aforementioned procedural order of the reporter was issued in order to enable the applicants' side to upload the annexes.

b. The statements on the body of law objected to by the applicants with regard to Rule 206 no. 2 (d) Verfo as being missing in the application do not lead to the

inadmissibility of the application either.

It is true that Rule 206(2)(d) of the Implementing Regulation also refers to the validity of the patent in suit; this already follows from the express reference to Rule 211(2) of the Implementing Regulation.

In their request for an order, the applicants stated that an action for revocation with the trade mark 3 Ni 20/22 (EP) was pending before the German Federal Patent Court (BPatG) in respect of the German part of the parent patent and that the BPatG had set out its preliminary view in its qualified reference of 7 February 2023, according to which the parent patent was patentable to the extent of auxiliary request 1. Corresponding statements on the patent in suit could not be expected due to the lack of ongoing legal proceedings at the time of filing the request; the opposition against the grant of the patent in suit is dated 18 July 2023.

In view of the principles on the burden of proof and presentation applicable to the presentation of the body of law - at least in proceedings conducted on two sides, as in the present case - on the basis of Article 54 UPCA (see in detail A. IV. 3. below), the requirements for the presentation of the validity of the patent in suit set out in Rule 206 No. 2 (d) Verfo must not be overstretched. By presenting the facts relating to the parent patent that are also indirectly relevant to the patent in suit (action for revocation; qualified reference of the BPatG), the applicants have satisfied the formal requirements of Rule 206 No. 2(d) of the Rules of Procedure with regard to the presentation of the legal status of the patent in suit.

4. The objection with regard to Rule 206 no. 2 (e) Verfo (requirement of a brief description of the action to be filed in the main action already in the application for an order) is also not valid.

The corresponding information is again not subject to the formal examination pursuant to Rules 208 No. 1, 16 of the Rules of Procedure; a complaint by the Registry and a submission by the judge pursuant to Rule 16 No. 5 of the Rules of Procedure were therefore not made.

Notwithstanding this, Rule 206(2)(e) of the RP cannot apply to requests for provisional measures under Article 62(1) of the UPCA, since in this case the

objective of the request (injunction) is no different from the final order on the merits (Article 63(1), first sentence, UPCA);

it would be mere formality to require the applicant to state that he will base the main action on the same facts and evidence as the request for an order under Article 62(1) UPCA. By its terms, Rule 206(2)(e) IR obviously concerns requests under Articles 60 and 61 UPCA which may precede the commencement of main proceedings; in such cases it is indeed useful to briefly describe the subsequent main action in accordance with Rule 206(2)(e) IR. Rule 206 No. 2(e) IR is to be reduced teleologically to the effect that requests under Art. 62(1) UPCA are not affected by this requirement.

5. Contrary to the view of the respondents (opposition, paragraph 89 et seq.), the application cannot be dismissed as inadmissible because it is manifestly unfounded. Whether the applicants' submission is convincing in terms of content is not the subject of the formal examination, but of the decision-making in the case. Consequently, it is not a question of the admissibility of the application.

6. Insofar as the respondents justify the inadmissibility of the application with reference to a decision of the Federal Court of Justice (BGH NJW-RR 2015, 541) on the basis of a lack of need for legal protection from the respondents' point of view, this argument also fails.

   It can be left open whether the enforcement of a judgment already given in one of the contracting states of the UPCA in respect of another IP right (here the parent patent) makes it easier to enforce the right than obtaining a decision of the UPC. While the enforcement of a judgment of the court of a contracting state of the UPCA only concerns infringements of the judgment in that contracting state, decisions of the UPCA in the case of a European patent have uniform effect in all contracting states of the UPCA. Thus, in view of the territorial scope of decisions of the UPC in relation to decisions of the courts in the contracting states, there is generally a need for recourse to the UPC. In addition, the applicants asserted the parent patent before the Munich Regional Court I, so that the subject matter of the dispute is different.

III. Both **applicants** are **eligible to apply.**

In view of their legal position, both applicants are also entitled to appeal to the EPC for the asserted patent infringement.

1. According to the patent in suit, the second applicant is its proprietor. Her entitlement to file a petition thus follows from Article 47(1) UPCA.

In their statement of opposition, the respondents contested the legal validity of the second applicant's ownership with regard to possible infringements of US law, namely the *Bayh-Dole Act.* The related submission of the second applicant in her reply that she had complied with the corresponding requirements resulting from the *Bayh-Dole Act*, in particular that she had disclosed the invention to the NIH in due time, The respondents did not dispute that they had claimed the right to the invention in accordance with the requirements of the *Bayh-Dole Act* and had filed a patent application for the invention, especially since the second applicant had submitted an affidavit by Ms Karen Sinclair, Director of Intellectual Property at the second applicant. The Local Board therefore considers the 2nd applicant's submission on compliance with the requirements of the *Bayh-Dole Act to* be undisputed. In view of this, the question as to whether the infringements initially alleged by the opposing parties under the relevant US law actually result in the second applicant losing its position as patent proprietor can remain open. Furthermore, the question of whether the formal legal position according to the entry in the register is sufficient for entitlement under Article 47(1) EPC or whether the substantive entitlement is ultimately decisive can also remain open.

2. The first applicant is at least entitled to file an application under Article 47(3) EPC as the holder of a non-exclusive licence.

a. The local division can leave open whether an exclusive licence in favour of the first applicant was legally agreed between the applicants - as claimed by them. According to Art. 62(4) EPCÜ, the court would have to be sufficiently convinced that the

Applicant No. 1) is the holder of an effective exclusive licence under Article 47(2) EPC and in this respect is in the same position as the applicant No. 2).
2) may bring an action before the court for infringement of the patent in suit. However, on the basis of the judgement of *the US District Court for the District of Delaware* (hereinafter "District Court of Delaware"), submitted as Annex B 15, there are doubts as to whether the second applicant could validly grant an exclusive licence to the first applicant, since, in the opinion of the *District Court of Delaware,* the second applicant had committed itself to the NIH,

"...to offer non-exclusive patent licenses..."

In the event that the second applicant has committed itself to granting non-exclusive patent licences to the NIH with respect to the patent in suit, the local division cannot be convinced with sufficient certainty in the summary proceedings that it was possible to grant an exclusive licence contrary to this commitment; this question is therefore reserved for a detailed examination of the relevant US law in the main proceedings in the event that it is relevant for a decision. The court is also not convinced by the applicants' argument that the grant of an exclusive licence under the *Bayh-Dole Act* was not precluded in view of the decision of the *District Court of Delaware.*

According to Art. 47(3) and (4) EPC, the simple licensee is also entitled to claim an injunction in his own name under Art. 62 EPC; according to Art. 47(3) EPC, the only decisive factor in this respect is that the licence agreement with the patent proprietor permits this. This is obviously the case here.

b. However, to the court's certainty, the first applicant is entitled to file a petition under Article 47(3) EPCÜ.

According to Article 47(3) EPC, the proprietor of a non-exclusive licence is also entitled to file a petition if the patent proprietor has been informed by the patent proprietor that the court will be seised and the licence agreement expressly allows the court to be seised. The court is convinced that both are the case here: the second applicant was informed of the referral to the court by the patent proprietor.

Applicant No. 1); the request was filed together with Applicant No. 1). According to the submission in the written statement of 11 August 2023, both applicants also agree that there is at least a non-exclusive licensing agreement between them concerning the patent in suit, which allows the first applicant to appeal to the court in the sense of the asserted request. It is also neither apparent nor submitted by the respondent that any infringements of NIH funding conditions resulting from the grant of an exclusive licence prevent a later agreement on a simple licence.

IV. The **local chamber** is **convinced of the legal validity of the patent in suit.**

The local board is also convinced with the "sufficient certainty" required under Article 62(4) EPC and Rule 211(2) IR, namely with even a clear preponderance of probability (from the local board's point of view, a "preponderance of probability" is sufficient; for the required degree of probability, see in detail under A. IV. 4.) that the patent in suit is legally valid.

Although the validity of the patent is not expressly mentioned as a subject-matter of the conviction in Art. 62(4) UPCA, in contrast to Rule 211(2) Verfo, only a person who relies on a patent which is valid to the satisfaction of the court can be considered to be the right-holder within the meaning of Art. 62(4) UPCA.

1. Subject-matter of the patent in suit

The subject-matter of the patent in suit is, as stated in the introduction to the claim, a method for detecting a large number of analytes in a cell or tissue sample.

a. The patent in suit first explains that in biology there is a need for multiplexing methods for the examination of biological samples because biological samples are valuable, it is often unclear what exactly is being searched for or the information in question has to be extracted from the sample (paragraph [0002]). Finally, paragraph [0002] (underlining on this side) states:

"Hence, it is desirable for clinicians and researchers to subject each samole to a laroe set of probes."

The patent in suit reports in its description that the prior art does not satisfactorily fulfil this wish. Since only a limited number of colours are available for optically reading a sample, one possibility is to repeat the examination of the sample several times (paragraph [0006]). This is described by way of example as follows:

"For example, the assay can involve probing the sample with 4 different antibodies at a time and imaging after every assay. If the test requires probing the sample with a total of 64 antibodies, the 4-probe procedure would have to be repeated 16 times using the sample."

For this purpose, however, the examination must sometimes be prioritised with regard to the various target analytes of a sample, since certain analytes can decompose during successive sampling. In the sense of a patent-compliant task, it is then stated (underlining on this side):

"Accordingly, there is still a stronn need for accurate and sensitive methods with a hioh throuohput for detection. identification. and/or quantification of tareet molecules in a sample, e.g., complex mixtures." (paragraph [0006]).

In the following paragraph [0007] of the description, the patent solution is finally described (underlining on this side):

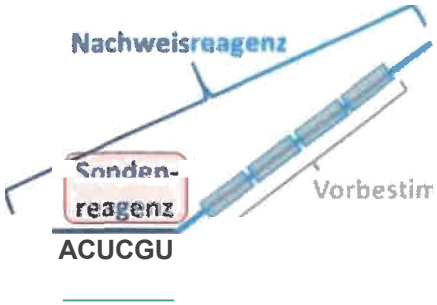
"The present invention is defined in the appended claims. Embodiments pro- vided herein are based on, at least in part, the development of a multiolexed bioloaical assa'y and readout, in which a multitude of detection reaaents com- prising one or more erobes and/or probe tvoes are applied to a sample. allowino the detection reagents to bind taroet molecules or analvtes. which can then be identified in a temporallV-seouential manner Accordingly, pro- vided herein are methods, for detecting multiple analytes in a sample."

b. On the basis of the above, the claimed invention can be described as follows on the basis of claim 1 of the patent in suit:

After the cell or tissue sample to be examined is placed on a solid support, the intended detection is carried out in a procedure that can be roughly divided into two sections:

In a first step of the procedure **("binding of the analyte"),** the cell or tissue sample is brought into contact ("contacted") with a composition containing a large number of detection reagents. In order to be able to actually detect the multitude of analytes that are presumably present in the sample and are to be detected, a multitude of detection reagents is also required, which are to bind to the multitude of analytes contained in the sample in this first process step.

According to the claim, a detection reagent consists of a probe reagent as well as one or more predetermined partial sequences. Both are connected to each other ("conjugated"). This can be illustrated as follows (figure from the application of 1 June 2023, page 43):



The probe reagent is important for the first stage of the procedure, while the partial sequences of the individual detection reagents only become relevant in a **second stage of the procedure ("detection of the analyte").** A probe reagent has the task of targeting one of the many analytes (this is also shown in the figure above). The plurality of detection reagents whose probe reagents target binding with different analytes are divided into groups, called subpopulations. According to the claim, each

subpopulation from the total group of detection reagents is aimed at a specific analyte, just as each probe reagent is aimed at a specific analyte. Consequently, the probe reagents determine the membership of a subpopulation.

For the targeting of a large number of subpopulations from the total amount of detection reagents to a large number of analytes in the sample, as described in the patent in suit for the purpose of binding, the time factor also plays a role: The process of binding requires sufficient time, which is made possible by incubating the sample with the detection reagents.

After the first stage of the procedure, a large number of detection reagents are found in the sample, which are bound to a large number of analytes. In the following (second) stage of the procedure, the detection reagents are detected via their partial sequences. This is done by using decoder probes that hybridise specifically with corresponding partial sequences of detection reagents. These decoder probes are also subdivided into subpopulations according to the patent. Each decoder probe subpopulation hybridises with a specific partial sequence of a detection reagent. For this purpose, each decoder probe subpopulation produces a signal signature by means of a detectable label.

After detection and removal of the signal signature, the process of hybri- dising is repeated with a new set of decoder probes "in a temporally sequential manner" so that other partial sequences can be detected. This produces a temporal sequence of signal signatures. This is unique for each subpopulation of the multitude of detection reagents; it follows that the detection reagents of a specific subpopulation (e.g. subpopulation A) must be identical with regard to their subsequences.

The temporal sequence of signal signatures produced in this way is finally used to identify the detection reagents and thus to detect the respective analytes.

2. Claim 1 can be read in the German translation of the patent in suit as follows (colouring/underlining on this side):

A method for detecting a plurality of analytes in a cell or tissue sample, comprising

(a) Mounting the cell or tissue sample on a solid support;

2.1. (b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents,

2.1.1 wherein the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents;

2.2 (c) incubating the cell or tissue sample together with the plurality of detection reagents for a sufficient period of time to allow binding of the plurality of detection reagents to the analytes; wherein

2.2.1 each subpopulation of the plurality of detection reagents targets a different analyte, wherein

2.2.2 each of the plurality of detection reagents comprises: a probe reagent targeting an analyte of the plurality of analytes; and

2.2.3 one or a plurality of predetermined partial sequences, wherein the sonic reagent and the one or the plurality of predetermined partial sequences are conjugated to each other;

3.1 (d) detecting said one or plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

3.1.1 (i) Hybridise a set of decoder probes with a partial sequence of the detection reagents,

3.1.1.1 wherein the set of decoder probes comprises a plurality of sub-populations of decoder probes, and wherein

3.1.1.2 each subpopulation of the decoder probes comprises a detectable marker, wherein

3.1.1.3 each detectable mark produces a signal signature;

3.1.2 (ii) Detecting the signal signature produced by hybridisation of the set of decoder probes;

3.1.3 (iii) removing the signal signature; and

3.1.4 (iv) repeating (i) and (iii) using a different set of decoder probes to detect different subsequences of the detection reagents, thereby producing a temporal sequence of signal signatures unique to each subpopulation of the plurality of detection reagents; and

4. (e) using the temporal order of the signal signatures corresponding to the one or the plurality of predetermined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of analytes in the cell or tissue sample.

3. The meaning of individual terms and features of the patent claim is disputed between the parties, so that they require **interpretation.**

a. Assuming that the subject-matter of the patent in suit is a method for detecting a plurality of analytes in a cell or tissue sample, it is first necessary to clarify what the patent in suit means by a cell or tissue sample. For a person skilled in the art who reads the patent claim in the light of the description and taking into account his general knowledge of the art, it is thus clear that the "cell or tissue sample" as claimed is a sample that is still recognisable as a cell or tissue.

The defendant correctly points out that the patent claim does not speak of an *intact* cell or tissue sample, so there does not seem to be a corresponding limitation according to the wording; furthermore, cell or tissue samples according to the claim can be untreated or pre-treated, because based on the wording of the patent claim there is no limitation in this respect either. However, this does not justify the conclusion that every component belonging to a cell is also a cell or tissue sample within the meaning of claim 1. The claim also requires the mounting of the cell or tissue sample on a solid support. This means that in any case the sample must not be pre-treated to such an extent that it is in fact no longer a cell or tissue sample.

The following is explained in the description for pre-treatment:

> "{0048] In some embodiments, the method described herein can further comprise processing the sample before contacting with the composition comprising a plurality of detection reagents described herein. Depending on the types and/or natures of the samples and/or analytes, different sample processing techniques can be used with the methods described herein. Exemplary sample processing tech- niques include, but are not limited to, mechanical processing of a sample (e.g., with- out limitations, homogenizing, centrifuging, vortexing, sectioning and shearing), ad- dition of at least one reagent to a sample (e.g.., without limitations, lysis buffers, RNA or DNA extraction reagents, RNA or DNA digestion reagents, enzyme inhibitors, fix- ing agents, organic solvents, antibodies, permeabilizing agents and immunohisto- chemistry agents), separation of a sample (e.g., without limitations, filtering, centri- fuging, electrophoresis, western blot, and Northern blot), mounting a sample on a **solid support (e.g., a microscopic slide),** and any combinations thereof.
>
> [By way of example only, if a sample is a tissue from a subject (e.g., a biopsy for immunostaining), sample processing can include, but are not limited to, tissue sectioning, mounting on a solid support, fixing the tissue, permeabilizing the tissue (if intracellular proteins are to be detected), blocking non-specific reactions with the detection reagents".

The question to what extent a cell or tissue must still be present as such in the sample can be left open from the point of view of the local chamber; what is decisive for the consideration here is that according to the wording of the application it is excluded to qualify a part of the genomic DNA isolated and amplified from a cell as a cell or tissue sample meeting the requirements, because for the person skilled in the art this is not a cell or tissue *sample.* This understanding is confirmed in the expert reports submitted by the respondents. The PRV expert report (B10) acknowledges that a cell or tissue sample is not the same as a *"genomic DNA sample".* Dr Fur- neaux explains on p. 12 of his expert report:

> *"It is clearly understood that DNA fixed on a slide differs in some obvi- ous respects to DNA present in a fixed tissue sample on a slide".*

In other words, what is claimed is not the examination of genomic DNA isolated from a cell or tissue sample, but the examination of cell or tissue samples

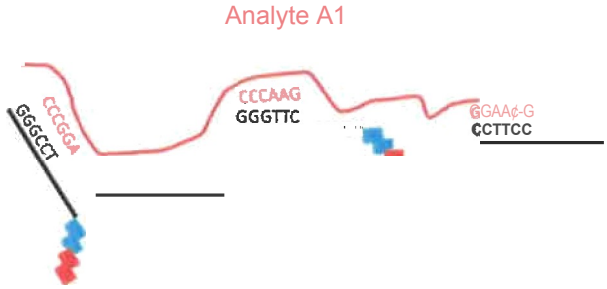
containing such analytes. The view of the

The defendant's claim that the pre-treatment of a sample can also include the isolation of genomic DNA according to the patent cannot therefore be accepted. Although such a pre-treatment of a sample is not excluded according to the description, the skilled person no longer speaks of a cell or tissue sample after such a treatment.

b. Also in need of clarification is the proper assignment of a detection recipe to a certain **subpopulation.**

Contrary to what one might assume from a cursory reading of the claim wording ("multitude of ana- lytes", "multitude of detection reagents"), there are not necessarily as many detection reagents as analytes in the sophisticated composition. Rather, there is a correlation between the number of analytes to be detected in the cell or tissue sample and the number of subpopulations of the plurality of detection reagents. This results from the fact that the multitude of detection reagents is considered as a whole (total quantity), which in turn has a multitude of so-called "subpopulations" (subsets). Each of these subpopulations targets a different analyte, which establishes the correspondence between the multiplicity of analytes and the multiplicity of subpopulations of detection reagents. Consequently, the defendant's side must be agreed that a subpopulation according to the claim is a subset of a total set (namely the plurality of detection reagents); it is also true that a subpopulation is characterised by the fact that certain properties of the elements of a subpopulation are identical. However, the defendant's view that both the probe reagent and the predetermined partial sequences of the detection reagents belonging to a subpopulation must be identical in order to be assigned to one and the same subpopulation cannot be accepted. Claim 1 of the patent in suit itself defines the assignment of a detection reagent to a subpopulation to **the** effect that **the reagent targets the same analyte as the other reagents of this subpopulation.** This does not require the probe reagents to be identical, because the probe reagent can - like the probe reagents - be used in the same way.

The following illustration shows how the defendant's side itself presents the case - by binding to various sections of an analyte.



Thus, the identity of the probe reagents is not necessary for the detection reagents to belong to a certain subpopulation of detection reagents, since different probe reagents can also bind to the same analyte. According to the requirements, it is not decisive to *which section of an analyte* is bound, but only to *which analyte* is bound. Each subpopulation of detection reagents fastidiously targets a particular analyte; subpopulation A targets analyte A, subpopulation B targets analyte B, and so on.

According to this understanding of the patent in suit, it is correct to speak of X subpopulations of the totality of detection reagents aiming at binding to X analytes. According to claim 1, all detection reagents that target the same analyte are elements of a subpopulation of detection reagents. Crucial for this binding process is the so-called probe reagent, which is a component of each detection reagent and has the function of targeting a specific analyte. However, with regard to targeting a specific analyte, the patent in suit does not require the probe reagents to be assigned to a subpopulation to be identical; according to the wording of the patent claim, it is sufficient that they target the same analyte - from the point of view of a person skilled in the art, they do not have to be identical for this purpose.

C. It also needs to be clarified what is the subject of a **re-inspection** according to 3.1.4. fetching.

According to the wording of the patent claim, only the hybridisation of the decoder probes with the partial sequences (i) and the removal of the signal signature (iii) seem to have to be repeated in the following detection sequences, but not the detection of the signal signature produced in each case **(**ii); the claim literally states: **"Repeating (i) and (iii)".** The conclusion drawn from this by the defendants that the patent discloses in this respect that only in the first of the several sequential verification rounds the verification of the signal signature must take place, while this should no longer take place in the further rounds, is technically obviously absurd. The technical endeavour is to extract a meaningful content from a patent.

If the detection of the signal signature is only carried out in the first round as required, the "use of the temporal sequence of the signal signatures" required by the claim would no longer be possible. The claim feature describing this repetition process therefore also states: "Repeat... in order to detect other partial sequences of the detection reagents, thereby producing a temporal sequence of the signal signatures...". However, this is only possible if the signal signatures are also detected with each \repeat.

d. Finally, the meaning of feature 4, the **use of the temporal order of the signal signatures** to identify the detection reagents and thus to detect the analytes, needs to be clarified.

The wording of the patent claim ("...using the temporal sequence . ... to identify...") is clearly to be understood as meaning that the temporal sequence of the signal signatures is the means for identifying the partial po- pulation of detection reagents according to the patent. No other means are mentioned. The claim also does not give any reason to assume that further means of identification might be involved or even necessary, since it attributes the quality of being unique to the temporal sequence of the signal signatures.

4. Standard of "sufficient certainty" with regard to the validity of the dispute package

Neither the UPCA nor the Rules of Procedure specify which degree of conviction is required if this is to be "sufficiently certain" with regard to the validity of the patent in suit. In principle, any **degree of probability** can be considered ("certain probability", "overwhelming probability", "substantial probability" (Art. 55(2) EPC), "high probability", "probability bordering on certainty", to name just a few examples of degrees of probability). The correct understanding of the term "sufficient certainty" must be based on the specific purpose of the conviction. In the case of Art. 62(4) UPCA and Rule 211(2) IR, it must be taken into account in particular that it is a matter of ordering temporary interim *measures* in *summary proceedings* (Rule 205 IR) in accordance with Rule 213 IR, not final orders within the meaning of Art. 63 UPCA. In view of the interlocutory nature of the measures and the limited possibilities of discovery in summary proceedings in comparison with proceedings on the merits, it follows that the standard of probability must be lowered. Therefore, a probability bordering on certainty cannot be demanded. Ultimately, for a sufficiently certain conviction of the validity of the patent in suit, a **preponderance of probability** is necessary, but also sufficient. It must therefore be more probable for a sufficiently certain conviction of the court that the patent is valid than that it is not valid.

Insofar as the respondents rely on the fact that, according to German case law on the prediction of the validity of a patent in proceedings for interim relief, the destruction of the patent must not be predominantly probable but merely possible on the basis of the respondent's invalidity claim, this case law on national procedural rules is not relevant in the scope of application of the UPCA and the Regulation.

As far as the respondents point out in connection with the standard for the examination of the stock of rights that the stock of rights of the

If the court is to assess the validity of the patent in suit independently, this reference is entirely in line with the EPC and the Verfo; in particular Rule 211 No. 2 of the Implementing Regulation expressly states that the court must be able to satisfy itself that the patent in question is valid. Rule 209 No. 2 (a) of the Implementing Regulation also indicates that
- albeit in a different context (exercise of discretion according to Rule 209 No. 1 of the Implementing Regulation) - that the legal status of the specific patent in dispute is decisive. According to Rule 209(2)(a) Verfo, it is therefore of importance in the context of forming a conviction with regard to the validity of the patent in suit whether "the patent" was maintained in opposition proceedings before the European Patent Office or was the subject of proceedings before another court; with regard to the patent in suit, however, none of this is the case, so that this circumstance cannot contribute to the conviction of the court. In Germany, the parent patent was the subject of legal disputes between the parties, whereby the impact on the proceedings here is assessed differently by the parties.

Insofar as the respondents make detailed submissions on the "high destruction rates of granted patents" (opposition, paragraph 267) and deduce from this that these high destruction rates must also be taken into account in the present proceedings, the Local Board does not follow this. First of all, it must be noted that the figures submitted by the respondents show at most a high destruction rate of the patents challenged with an opposition or an action for revocation; however, this is at most a small part of the patents *granted.* According to Rule 211 No. 2 Verfo, the court has to make a case-by-case decision with respect to the concretely asserted patent in view of the body of law. It follows from the necessity of a case-by-case assessment that general statistical findings on the frequency of destruction are not to be taken into account.

3. Burden of presentation and proof on the body of law

a. The **burden of proof** for facts relating to the lack of legal validity of the patent in suit lies with the defendant according to the principle laid down in Art. 54, first sentence, EPC, because the defendant claims that the patent in suit will

have to be declared invalid. This also corresponds to the

Distribution of the burden of proof in invalidity proceedings and in the case of an invalidity action. Insofar as Art. 62(4) UPCA or Rule 211(2) IR provide that the court may *order* the applicant to submit evidence of the validity of the patent, this does not mean a departure from this principle in the sense of a different burden of proof rule for the injunction proceedings. Article 62(4) EPC and Rule 211(2) Verfo are "may" provisions, so that the court has a discretion. The court will exercise this discretion in particular and order the applicant to provide evidence of the validity of the patent in suit if it considers the validity of the patent in suit to be endangered by the arguments of the opposing party, who is in principle obliged to provide evidence of the lack of validity. This is also in line with the case law of the European Court of Justice (decision C-44/21, paragraph 41 with reference to decision C-307/18, paragraph 48; for the binding effect of decisions of the European Court of Justice on the UPC, see Art. 21 UPC). The presumption of validity of granted European patents according to this case law may be shaken by the opponent's submissions, so that orders to produce evidence against the applicant may then be justified.

It follows from the system of allocation of the burden of proof described above that the applicant side - contrary to the view of the respondents - does not bear the burden of proof for the validity of the patent in suit, at least initially.

b. Irrespective of the above-mentioned principles on the distribution of the burden of proof, the applicants were obliged under Rule 206 no. 2 (d) in conjunction with Rule 211 no. 2 of the Rules of Procedure to submit evidence on the state of the law (see A. II. 3. b. above). Rule 211 No. 2 of the Rules of Procedure, the applicants were obliged to *submit information* on the state of the law with the request (see A. II. 3. b. above). The obligation to make such submissions is not limited to the patent in suit, but also extends - as in this case - to other patents from the patent family of the patent in suit that are relevant for the examination of the validity of the patent in suit, provided that they are the subject of an attack on the validity of the patent in suit. The obligation to make a corresponding submission also applies, of course, if these attacks have not yet led to destruction. This obligation for applications for provisional measures, which deviates from the proceedings on the merits, is already justified because

interim measures may also be granted without hearing the defendant.

4. Specialist

In the view of the local chamber, the expert to be consulted for the assessment of the legal situation here is a chemist or biologist with a university degree in the field of biochemistry who has experience in the field of detection strategies for biomolecules. This corresponds to the statements of the respondents on the relevant expert. The local division is staffed with a relevant technically qualified judge. One of the legally qualified judges also has a university degree (MSc) in molecular biology.

Based on the principles set out above concerning the burden of proof and the standard of probability to be applied in forming a conviction, the following applies with regard to the patent in suit from the point of view of the skilled person relevant here:

5. The Local Board is convinced that the patent in suit will not be destroyed due to **inadmissible extension.**

Any amendment to the parts of a European patent application or a European patent relating to the disclosure (the description, the claims and the drawings) is subject to the mandatory prohibition of additions laid down in Article 123(2) EPC and may therefore, irrespective of the context of the amendment made, only be made within the scope of what the person skilled in the art can directly and unambiguously infer from the entirety of these documents in their originally filed version, using general technical knowledge - objectively and in relation to the filing date.

Based on this standard of review, the following can be stated here from the perspective of an expert:

a. Insofar as the defendants see an inadmissible extension in the fact that the wording of the patent in suit (feature 3.1.4) does not explicitly mention th

e

The local chamber does not follow the statement that step (ii) ("Detection of the signal signature produced by the hybridisation of the set of decoder probes") is repeated.

According to the correct understanding of the claim, the proof described in feature 3.1.2 is required in each repetition, since otherwise no "temporal sequence of signal signatures could be produced" (feature 3.1.4). Any other understanding would obviously be incompatible with the technical sense of the method according to the claim, which is clearly expressed by its wording: The patent claim explicitly indicates several times (features 3.1.4 and 4) that the proof is provided by determining the temporal sequence of the signal signatures produced by multiple repeated hybridisations. In view of this, it is technically and functionally indispensable that proof is also provided for all signal signatures produced with a hybridisation (feature 3.1.2); the respondent's side also did not oppose this during the discussion of this question in the oral proceedings. An infringement of Article 76(1) EPC is therefore not discernible.

b. Insofar as the respondents see an impermissible extension in the fact that in the application for the parent patent the temporal sequence *actively* identifies the detection reagents, whereas in claim 1 of the patent in suit the sequence is used *passively* ("using the temporal sequence of the signal ionatures I...1 to identify a subpopulation of the detection reagents"), this is also not an impermissible extension.

Since the wording of the patent claim ("...using the temporal order to identify...") - as stated in the context of claim interpretation
- is clearly to be understood to mean that the temporal sequence of the signal sig- natures is the patent-compliant means for identifying the detection reagents and that the identification results without further analysis steps from this order produced in accordance with the requirements, no difference results from whether this feature is formulated linguistically in an active or (allegedly) passive manner.

6. A declaration of invalidity of the patent in suit for lack of **novelty** is not to be expected according to the certain conviction of the local chamber.

The local board is convinced that the patent in suit will not be destroyed for lack of novelty. On the contrary, the local board assumes with sufficient certainty that the patent in suit is valid with regard to the novelty required for the grant of the patent.

In order to be able to identify a lack of novelty, the subject-matter of the invention must clearly, unambiguously and directly result from the prior art. This applies to all claim features. The standard for the disclosure content of a publication is what can and may be expected from an average person skilled in the relevant art in terms of knowledge and understanding.

Based on this standard of review, the following must be stated here:

a. Insofar as the respondents deny the novelty of the patent in suit with reference to *Göransson* (D6), the court does not consider this objection to be prejudicial to novelty.

Contrary to the wording of the claims of the patent in suit, the object of the proof in D6 is not cell or tissue samples, but so-called single amplified molecules ("amplified single molecules" or ASMs), which are derived from "padlock or selector probes", with which isolated genomic DNA fragments of cells were detected. ASMs are therefore not ana- lytes of cell or tissue samples within the meaning of the patent in suit.

Insofar as the Federal Patent Court (BPatG) in its qualified reference of
7. The BPatG's finding that it is possible that the subject-matter of claim 1 of the parent patent is anticipated in a manner prejudicial to novelty by *Göransson* (in these proceedings "D6", at the BPatG "NK12") cannot be applied to the patent in suit, because in contrast to the wording of the relevant claims of the parent patent, which use the term "specimen" alone (for the term "specimen" see point 3.2 of the qualified reference of the BPatG), claim 1 of the patent in suit contains the term "sample".

obviously restricted term of *"cell or* tissue sample". So while
Although "amplified single molecules" (ASM), as they are the basis for the consideration in Göransson, can be qualified as "samples" within the meaning of the parent patent, they are not cell or tissue samples within the meaning of the patent in suit, according to the Local Board.

The court also assumes, as already indicated at the oral proceedings, that the patent in suit according to claim 1 also requires the mounting of the cell or tissue sample on a fixed support. In the case of *Göransson*, on the other hand, it is ASMs that are mounted on a fixed support; in this respect, too, *Göransson* cannot be novelty-damaging in the view of the court.

The Local Board further assumes, as already indicated at the oral proceedings, that the patent in suit, as shown by its claim 1, also requires the continuation of the binding between the analyte and the detection reagent, established by incubating the cell or tissue sample with the detection reagents, during the second stage of the process; the Court reads this in particular from feature 2.2 ("...sufficient time to allow binding of the cell or tissue sample with the detection reagent").
") and the fact that the dissolution of this bond is neither mentioned in claim 1 of the patent in suit nor does it appear to make technical sense. In contrast, in *Göransson* the bond between the analyte and the reagent is broken in each case ("after each imaging") ("dehybridization of ASMs"); in the view of the court, *Göransson* cannot be detrimental to novelty in this respect either.

b. Even insofar as the respondents deny the novelty of the patent in suit with reference to US 2010/0151472 (D12), the court does not follow the respondents' argumentation.

D12 is not novelty-damaging because it does not show (also in its example 2) that a temporal sequence of signal signatures relating to the same detection reagents is generated in a temporally sequential manner by repeated hybridisation (of a set of decoder probes with the partial sequences of the respective detection reagents) in order to identify them. In example 2 of D12, two rounds of hybridisation are also performed.

However, different detection reagents are used in the first round (specifically: HLA-DR antibodies and CD24 antibodies) than in the second hybridisation round (CD44 antibodies and CD66 antibodies).

7. The Local Board is also convinced that a declaration of invalidity of the patent in suit on the grounds of **lack of inventive step** is not to be expected.

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

The (closest) prior art to be used for determining lack of inventive step is usually a prior art document disclosing an object developed for the same purpose or with the same aim as the claimed invention and having the most important technical features in common with it, i.e. requiring the fewest structural changes. An important criterion in choosing the most promising starting point is the similarity of the technical task. In this respect, aspects such as the designation of the subject-matter of the invention, the formulation of the original task and the intended use as well as the effects to be achieved should generally be given more weight than a maximum number of identical technical features.

Based on this standard of examination, the Local Board is not convinced, in view of the documents submitted by the respondents, that the patent in suit will be declared invalid for lack of inventive step.

a. Insofar as the defendants want to use *Duose et* a/. *2010* (D8) as prior art to prove the lack of inventive step of the patent in suit, the Court cannot see that this document suggests the invention according to the patent.

The subject of D8 is the "in situ imaging of molecular markers" (D8; Introduction, first sentence). This deals with the problem that the number of markers is

(analytes) in a biological sample exceeds the number of detection agents (in the case of the D8 a combination of a so-called "targeting agent", a so-called "catalyst" and a substrate with fluorophore) that can be used simultaneously for detection. The approach of the D8 to solve this problem is to remove the substrate after a first run under particularly mild processing conditions in order to be able to use it again in a subsequent run to detect *a different marker* (".... re-move fluorescent probes ...such that new markers ...could be labelled and detec- ted using the same fluorescent reporting molecules."). Notwithstanding the fact that the D8 explicitly distances itself from the use of the in situ hybridisation probes (page 2327, Introduction, 2nd and 3rd paragraph), the skilled person is also not encouraged to use the demanding procedure with the D8 because the solution principles differ considerably: Whereas according to the solution principle of the D8, *one and the same colour marker is* to be used in a second run for the detection of a *different* analyte (marker) after intermediate detachment ("remove fluorescent probes"), according to the demanding solution principle, a *different set of decoder probes* (i.e. not the same one) is used in the further hybridisation rounds in order to produce a temporal sequence of signal signatures for the same analyte (i.e. not a *different* marker as in the case of D8), with which the multitude of analytes is then detected in the cell or tissue sample.

The principle of D8 can thus be described as using the same substrate in a first run for the detection of a marker (analyte) A, while in a second run it is to be used for the detection of a marker (analyte) B. This idea of multiple use of a colouring substrate for the detection of different analytes is far removed from the challenging principle of detecting an analyte to which a detection reagent has bound by producing a temporal sequence of signal signatures on that detection reagent - and therefore does not suggest the invention.

As far as the respondents argue that for a person skilled in the art the invention would have been obvious at least by a combination of D8 with *Göransson* (D6), the Local Board does not see a concrete technical reason for this; there is no technical reason for this.

it is also not possible to deduce from the respondents' submission why the skilled person should have been motivated to deviate from the solution taught in *Duose* (D8) for an in situ analysis for cell or tissue samples and instead use a fundamentally different method from a fundamentally different context in order to be able to detect more analytes, as taught in *Gör- ansson* (D6). D8 therefore teaches away from the claimed invention for the reasons given above.

b. The printed publication *Duose et al. 2011* (D27), which originates from the same group of researchers as D8, also does not suggest the invention according to the patent to the person skilled in the art. D27 is based on the same principle as D8, so that reference can be made to the above explanations. In the context of D27, the markers are also removed in order to use them in a second round of marking for "new complexes"; the targets of the first round are called TS1 and TS2, and TS3 and TS4 in the second round.

As far as the respondents argue that for a person skilled in the art the invention would have been obvious at least by a combination of D27 with D8 and/or D6, this does not lead to a different result; in this respect the explanations concerning D8 apply accordingly.

C. Insofar as the respondents wish to refer to WO 03/003810 (D23) as prior art in order to prove the lack of inventive step on the part of the intervening patent, the Local Board does not follow this either. D23 concerns a detection method with which different analytes are simultaneously detected by so-called multiplex staining and are thus to be distinguishable from each other. According to the respondent's submission, it remains open "how exactly this distinction is to be made". It is not discernible for the local chamber how the relevant skilled person, starting from D23, should have come to consider a temporal-sequential approach as taught by the patent in suit. The Court also cannot see any reason for the skilled person to read publications D6 and/or D8 on the basis of D23.

d. Also, insofar as the defendants want to refer to *Göransson* as prior art to prove the lack of inventive step of the patent in suit, the Court does not follow this.

The skilled person would not have used *Göransson* as a realistic starting point, let alone as the closest prior art, in view of the task definition according to the patent. Göransson is not aimed at detecting a large number of analytes in a cell or tissue sample (D6, abstract). Rather, the object of consideration in *Göransson* is ASMs on "a new random array format". *Göransson* does disclose a similar "encoding and decoding method" to that used in the patent in suit, but in a very different context, namely ASMs on an array. This method would not "transport" the person skilled in the art from an array of ASMs to a cell or tissue sample (mounted on a solid support) without a retrospective observation. To the conviction of the local chamber, however, nothing has been submitted regarding such an inducement. The mere reference to *"in situ"* in *Göransson in* relation to ASM used in earlier genotyping techniques is not sufficient for this. As the Federal Patent Court also opined, the application of the Göransson doctrine in an in situ context is not at issue here.

Finally, and for the sake of completeness, the Local Board notes that even if the skilled person had proceeded from *Göransson* to application to a cell and tissue sample, this would not have led to the claimed invention, since the claim requires that the detection reagents remain bound to the analytes and are not renewed at each step for detection in a sequential manner of the partial sequences of these reagents. *Göransson* gives no reason to adjust this measure. In contrast, in *Göransson's* method, the binding between analytes and reagents is released "after each imaging" (D6, page 3, paragraphs "Hybridisation of ASM" and "Dehybridisation of ASM").

A combination with *Gunderson et al. 2004* (D13) also does not lead the skilled person to the claimed invention. It cannot be seen why the skilled person would be drawn to the teachings of *Gunderson,* which also deal with microarray technology.

technology, should "go back in time" and thus arrive at the invention. In addition, the Fourneaux opinion also admits that there are "obvious differences" between "DNA fixed on a slide" (i.e. a microarray) and "a fixed tissue sample on a slide" (the patent claim).

Moreover, Fourneaux's thesis, which amounts to saying that the person skilled in the art would have no insurmountable objections to the application of the teaching from Görans- *son to* a cell or tissue sample (and would thus see a "very high expectation of success"), is based on a retrospective view *(ex post facto* analysis) with knowledge of the invention; even if one wanted to follow this, however, it does not follow without further ado that the person skilled in the art would actually have done so, which would, however, be required to establish a lack of inventive step.

e. As far as the respondents want to refer to US 2010/0151472 (D12) as prior art to prove the lack of inventive step of the patent in suit, the Local Board does not follow this either. The teaching contained therein is far removed from the patented solution for the reasons stated with regard to novelty.

A person skilled in the art would not have chosen D12 as the starting point for his considerations in view of the task underlying the patent in suit; thus the combinations put forward by the respondents for discussion in this context are not relevant either.

8. The **invention according to the patent** is **disclosed** so **completely** that a person skilled in the art can carry out the invention.

A successful defence of insufficient disclosure requires serious doubts, substantiated by verifiable facts, that a skilled reader of the patent would not be able to carry out the invention on the basis of his general knowledge of the subject matter.

Based on this standard of review, the following must be stated here:

a. Insofar as the defendants claim that the patent does not teach how unused detection reagents are removed before the detection step and how meaningful results can be obtained without such removal, this cannot be accepted in view of the clear references to this in the description of the patent in suit. Paragraph [0011] states unequivocally:

> "As described herein, the method can further comprise **removing any un-bound detection** reagents **before detection of the pre-determined sub-**sequences in a temporally-sequential manner."

Paragraph [0050] also provides sufficient guidance to remove unbound detection reagents where necessary.

b. As far as the respondents also argue with regard to the practicability (as already with regard to the inadmissible extension) that it is not taught in the patent how a chronological order of the signal signatures is to be achieved if the detection step is not repeated together with the hybridisation and signal removal steps, reference is made to the corresponding explanations on the subject of inadmissible extension (above 5.a).

c. To the extent that the respondents further argue that the invention cannot be carried out with extremely short decoder probes and that the patent does not provide the person skilled in the art with instructions on how a decoder probe with only a single nucleotide can nevertheless be used for detection, the Court does not find this to be insufficient disclosure.

The person skilled in the art knows from his general knowledge of the art and also from the patent description (paragraph [0059]) that there are decoder probes of different lengths; also on the basis of the claim and the description of the patent in suit the respondents have not shown any reason to doubt that a person skilled in the art is able to choose an appropriate sequence length for the implementation of the patented method.

d. As far as the respondents claim that the patent in suit does not contain a single example of an in situ "highplex" detection, although the applicant claims with *regard to the parent patent* that the claimed method enables an (allegedly better) highplex analysis compared to the prior art, it is only to be noted from the point of view of the local chamber that, based on the patent claim, an *in situ "highplex" detection as a* claim feature is not to be discussed.

V. The Local Board is convinced with sufficient certainty, namely with at least a high degree of probability, that the respondents infringe the **patent in suit** both **directly** and **indirectly.**

1. The respondents violate the applicants' right to prohibition on **direct use of** the patented process.

According to Art. 25 lit. b) EPC (right to prohibit direct use of the invention), a patent grants its proprietor the right to prohibit third parties from using, without his consent, a process which is the subject-matter of the patent or, if the third party knows or ought to have known that the use of the process is prohibited without the consent of the proprietor, to offer it for use in the territory of the contracting member states in which the patent has effect.

The respondents directly infringe the rights deriving from the patent in suit under Art. 25(b) EPC by using the process protected by the patent in suit themselves in their laboratory in Amsterdam and by offering to use it to third parties; corresponding acts in the territory covered by the EPC are the subject of the request for an order A. 1.

a. The defendants' method indisputably serves to detect a large number of analytes in a cell or tissue sample.

b. The defendants' procedure indisputably involves mounting the cell or tissue sample on a solid support.

c. The defendants' method indisputably involves contacting the cell or tissue sample with a composition comprising a plurality of detection reagents. The respondents also do not dispute that in their method the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents (feature 2.1.1); rather, the respondents dispute the realisation of feature 2.2.1 (feature 3.1.1 according to the respondents' outline; see e. below).

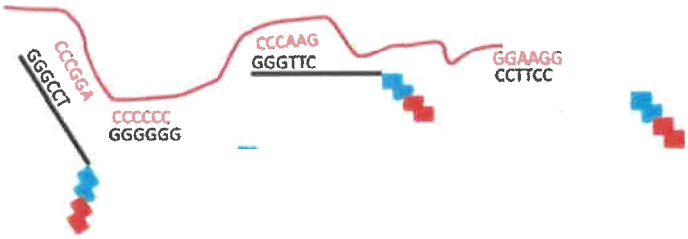
d. The defendants' method indisputably involves incubating the cell or tissue sample together with the plurality of detection reagents for a sufficient period of time to allow the plurality of detection reagents to bind to the analytes.

e. In so far as, from the point of view of the defendants in the contested proceedings, criterion 2.2.1, according to which

> ". .each sub-population of the multitude of detect ion reagents [targe ts] a different analyte...".

is not realised, this cannot be accepted on a correct interpretation of the patent claim (see A. IV. 3. b. above).

The defendants are of the opinion that both the probe reagent and the predetermined subsequences of the detection reagents belonging to a subpopulation must be identical in order to be assigned to one and the same subpopulation. However, this was not the case in the challenged method, since different subpopulations of ISH probes targeted the same analyte; they were therefore different subpopulations because the probes differed in their probe reagent. The opponents of the motion illustrated this with the following figure:



From the point of view of the defendants, it is thus decisive for an assignment to a partial po- pulation that the reagents are identical at the molecular level, which must also apply to the probe reagent.

However, according to the applicants' understanding, a subpopulation that meets the requirements is not necessarily characterised by an identity in the probe reagent, but only by the fact that each detection reagent belonging to the same subpopulation binds to the same target analyte. This does not require an identity of the probe reagent.

The applicants' interpretation is correct (see already A. IV. 3. b. above): According to the clear wording of the patent application, all detection reagents targeting the same analyte are elements of a subpopulation. Decisive for this binding process is indeed the so-called probe reagent, which is a component of each detection reagent and has the function of targeting a specific analyte. However, the patent in suit does not require the probe reagents to be identical with regard to targeting a specific analyte; according to the wording of the patent claim, it is sufficient that they target the same analyte - from a technical point of view, they do not have to be identical. This is also shown in the illustration above. Consequently, a sophisticated subpopulation may also include detection reagents with different probe reagents (and therefore binding to different sections of the analyte). This understanding of the term "subpopulation" corresponds to the claim feature in question, according to which the only decisive factor for belonging to a subpopulation is that the same analyte is targeted. Thus, if there are

for example in a tissue sample, the analytes A, B, C and D, the detection reagents contained in a composition according to the patent are assigned to a subpopulation (A) in that they target the analyte A, irrespective of the section of the analyte to which the binding occurs. Each detection reagent that targets analyte A consequently belongs to subpopulation A.

The ISH probes shown in the figure above therefore all belong to the same subpopulation, because they bind to the same analyte according to the requirements; the fact that the ISH probes bind to different sections of the same analyte is not relevant according to the patent claim and does not lead to the allocation of the ISH probes shown to different subpopulations.

In the defendants' method, therefore, each subpopulation of the multitude of detection reagents targets a different analyte.

e. Each of the plurality of detection reagents in the defendants' method indisputably comprises a probe reagent that targets one analyte of the plurality of analytes and a plurality of predetermined subsequences, wherein the probe reagent and the one or plurality of predetermined subsequences are conjugated together.

f. The defendants' procedure indisputably also involves proving the multiplicity of predetermined partial sequences in a temporally sequential manner.

g. In the proceedings of the respondents, the step of proof indisputably comprises first of all

- hybridising a set of decoder probes to a subsequence of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes, and wherein each subpopulation of the decoder probes comprises a detectable label, wherein each detectable label produces a signal signature (i),

- the detection of the signal signature produced by the hybridisation of the set of decoders (ii) and

- the removal of the signal signature (iii).

However, in the Defendants' method, contrary to the Defendants' assertion, detection also includes repeating (i) and (iii) using a different set of decoder probes to detect different sub-sequences of the detection reagents, thereby producing a temporal sequence of signal signatures that is unique to each sub-population of the plurality of detection reagents.

In this respect, the respondents have argued that in their procedure the evaluation is carried out in a different way; the order of the signal signatures is generated in a completely different way. This cannot be followed. The respondents' argument is based on an incorrect interpretation of claim 1 of the patent in suit (for interpretation see A. IV. 3. c. above).

aa. The respondents claim that in their method a detection step (ii) (taking an image of the slide after staining the decoder probes) is carried out *in each hybridisation round in* accordance with the requirements. According to the patent claim, on the other hand, only steps (i) and (ii) are repeated.
(iii) takes place.

It is to be conceded to the respondents that according to the wording of the feature 3.1.4 only mentions a repetition of steps (i) and (iii). However, the opponents of the application overlook the fact that feature 3.1.4 does not only state that

". .repeating (i) and (iii) using a different set of decoder probes,...",

but further:

. to detect other partial sequences of the detection reagents..."

It is thus clear that feature 3.1.2 ("(ii) Detection of the signal signature produced by the hybridisation of the set of decoder probes") also applies in any

hybridisation round must take place, because only then can the signal signature produced by the hybridisation of the set of decoder probes be verified. Without the verification specified in feature 3.1.2, a hybridisation round would make no sense at all. The requirement of (ii) in each round of hybridisation is therefore clearly stated in the sentence

to detect other partial sequences of the detection reagents..." was

expressed.

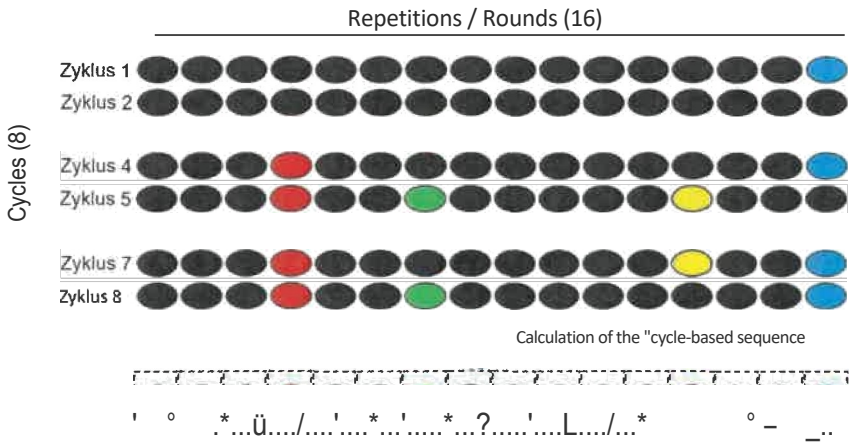
bb. To the extent that the Respondents claim that in their procedure the ana- lytes are not identified by the temporal sequence of signal signatures generated by repeating steps (i) and (iii), the Local Board does not follow this either.

The defendants submitted that in their procedure a hybridisation cycle (in the example in paragraph 213 of the opposition there are 16 hybridisation rounds in each cycle) is repeated identically several times (in the example eight times, i.e. eight cycles). This was the only way to achieve a reliable and correct result. The temporal sequence of possible signal signatures in the individual cycles (i.e. after rounds 1 to 16) is neither determined ("thereby generated") nor used to identify analytes. Such a temporal sequence (only rounds 1 to 16 of a cycle) would also not be unique for each subpopulation of the multitude of detection reagents. The temporal sequence of the signal signatures of the individual test rounds would not provide a sufficiently accurate identity of an analyte. Therefore, instead of the mere temporal order, a cycle-based order is calculated in the applicants' method and only this cycle-based order is used for the identification of analytes in order to obtain a reliable and correct result. **The "temporal order" of** the individual 16 test rounds per se, on the other hand, is not unique for an analyte and is not directly used for the identification of the analyte.

The defendants thus concede that in their process a temporal sequence of signal signatures is produced by carrying out several rounds of hybridisation in accordance with the patent; this is done repeatedly in

the proof of the signal signature in each round. As far as the respondents argue that the hybridisation rounds are repeated in eight cycles in order to obtain the most accurate result possible, which is determined at the end of the last cycle, this is not detrimental to the realisation of the patent claim. The respondents thus merely claim that the process as claimed is repeated several times in total in order to obtain a result that is as reliable as possible.

It is also harmless that in the procedure of the respondents the mere chronological order of the signal signatures from the individual cycles is not regarded as a sufficient *final result,* but a so-called cycle-based order (so to speak an average value of the signal references from all cycles) is calculated on the basis of all cycles. Thus, the method of the applicants goes one step further than required by claim 1 of the patent in suit, but not without having first implemented the method steps according to the claim. The method according to the claim also does not require that the chronological order of the signal signatures *is* always *correct*, i.e. that each individual hybridisation takes place without error and produces the correct signal signature; it only has to be *unambiguous.* The model of the defendants in paragraph 213 of the opposition (figure below)



suggests that the sequence of signal signatures is not correct in any cycle (none of the cycles show the correct sequence of red/green/yellow/blue signal signatures). However, the respondents have

does not claim that in practice (i.e. independently of a theoretical model as shown in paragraph 213 of the objection) its method never produces a temporal sequence of signal signa- tures with respect to the individual cycles which is unique for each subpopulation of the multitude of detection reagents so that it can be used to identify such a subpopulation and thus the corresponding analyte.

In particular, the method performed with the accused products also comprises using the temporal order of the signal signatures corresponding to the one or the plurality of predetermined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of analytes in the cell or tissue sample.

h. Insofar as the respondents are of the opinion that the implementation of certain procedural steps with a **cloud-based solution** is outside the scope of application of the EPC and thus an infringement is to be denied, the Local Chamber does not share this view.

aa. First of all, it should be noted that the **temporal sequence of signal signals,** the creation of which the defendants attribute to the cloud-based solution, is not produced by a data analysis, but rather - as required and also in the case of the challenged method - by the repetitions described in claim feature 3.1.4. This is nothing other than the consequence of the sequential procedure. According to the patent claim relevant for the examination of infringement, a data analysis is not required in this respect; a data analysis may only be necessary for the further, non-demanding process steps in the opponents' method. The production of the temporal sequence of signal signatures is thus the subject matter of the proceedings in the proceedings of the respondents conducted and offered in the territory of the EPC.

Insofar as data processing in the attacked process is necessary because the sequence of signal signatures produced in the individual cycles is deemed to be insufficient and is therefore not sufficient.

several cycles are carried out, which are finally concluded with the calculation of a cycle-based sequence, nothing else follows from this. A patent infringement cannot be denied because the infringer carries out further process steps in addition to the process steps according to the claim that require data processing, which are carried out outside the scope of the patent.

bb. Insofar as the respondents claim that the **identification of the analyte in** the challenged embodiments is not carried out on the device itself but on a computer-aided system (cloud computing platform AtoMxTM Spatial Informatics) abroad and thus outside the scope of application of the EPC, infringement cannot be denied on this ground either.

Claim feature 4 provides that the temporal sequence of signal signatures is used to identify a subpopulation of detection reagents and thus to detect the analytes. This claim feature can thus be understood as a mere reference to the purpose of the sequence of signal signatures produced by the method according to the claim (claim features 1 to 3.1.4), without expressing an independent process step in substance. Claim feature 4 thus does not represent a substantial process step, but rather merely a statement of purpose that is not immanent with any new technical information that goes beyond the preceding claim features. This is shown by the following feature analysis, in which it is shown which sub-features of claim feature 4 must already have been realised in the preceding claim features:

Procedure zum Nachweisen einer Vielzahl von Analyten in einer Zell- oder Gewebe-
, comprehensive

3.1.4 (iv) Repeat (i) and (iii) using a different set of decoder probes to detect other subsequences of the detection r e a g e n t s , Signalsignaturen produziert wird, die für jede Teilpopulation von der

(and thereby identifies them); and

4. (e) Use the , zahl der vorbestimmten Teilsequenzen des Nachweisreagenzes entspricht, zum Identifizieren einer Teilpo tion der Nachweisreagenzien, wodurch die Vielzahl von Analyten in der Zell- oder Gewebeprobe nachgewiesen wird.

This makes it clear that feature 4 has no independent technical content, since the essential elements of the feature are already contained at least implicitly in the other features, so that the realisation of that feature follows directly from the realisation of the other features. It is not apparent that this linguistically different formulation results in an additional technical meaning, in particular a further process step, which has not already been expressed in the other features. From the point of view of the expert reader, feature 4 therefore merely describes the result of the process, i.e. the effect intended by the application of the process.

2. The respondents also violate the applicants' right to prohibit **indirect use of** the patented process.

Under Article 26(1) EPC (right to prohibit indirect use of the invention), a patent confers on its proprietor the right to prohibit third parties from offering or supplying, without his consent, in the territory of the contracting member states in which the patent has effect, means relating to an essential element of the invention to persons other than those entitled to use the patented invention, for the use of the invention in that territory, if the third party knows or ought to have known that those means are suitable and intended for use in the use of the invention.

a. The respondents indirectly infringe the contested patent by offering and supplying the contested embodiment 2 (detection reagents) in the territory of the EPC for the use of the process according to the claim; corresponding acts are the subject matter of request for an order A. III. it is obvious to the respondents that the contested embodiment form 2 is suitable and intended for use by their customers for a process

The patent application is to be used in Germany and other EPC contracting states according to claim 1, because the contested embodiment 2 is an object with which a direct act of use - the application of the process according to claim 1 - can be realised, i.e. a means which is objectively suitable for direct patent use.

b. The respondents further infringe the contested patent by offering and supplying the contested embodiments 1 and 3 in the territory of the EPC for use of the process according to the claim; corresponding acts are the subject of the requests for orders A. II. (contested embodiment 1) and A. IV. (contested embodiment 3).

It is obvious to the respondents that the challenged embodiments 1 and 3 are in principle suitable and intended to be used by their customers for a process according to patent claim 1 in Germany and other EPC contracting states, because the challenged embodiments 1 and 3 are objects with which a direct act of use - the application of the process according to patent claim 1 - can be realised, i.e. means which are objectively suitable for direct patent use.

The defendants know that the infringing articles supplied by them are tailored to the application of the process according to the patent. They are described both in Annex BP 3, BP 4 and BP 11 and on the website https://nanostring.com/products/cosmxspatial-molecular-imager/single-cell-imaging-overview/ for use in accordance with the requirements. Accordingly, they are used by customers of the defendants for patent-infringing use - as envisaged by the defendants.
- determined.

However, since the challenged embodiments 1 and 3 can be used not only for the detection of RNA, but also for the detection of proteins, no unlimited ban was to be ordered with regard to these embodiments. The applicants

have therefore only applied for a limited ban with the addition of a warning notice.

The obligation of the respondents to offer and supply the contested designs 1 and 3 only if a cease-and-desist agreement with a contractual penalty is concluded with the customers is, in the view of the local chamber, a suitable and reasonable means for the respondents to prevent possible infringements of rights by the customers of the respondents or at least to secure them by means of financial compensation.

3. The applicants unsuccessfully applied not only for an injunction against the use of the patented process or its offer, but also for a "discontinuance". Insofar as this was intended to make a *consequence elimination* obliging the respondents to recall the patent the subject of the request, there is no legal basis for this under the UPCA. The local division therefore dismissed the request for an injunction in this respect; a decision on the auxiliary requests was not prompted by this partial dismissal, as the auxiliary requests were only filed in the event that the local division considered the patent in suit to be valid only in a limited claim version.

VI. The order sought is in accordance with the Rules of Procedure.

1. The wording of the applications for orders is not objectionable; in particular, it does not violate the Rules of Procedure.

According to Art. 62(1) UPCA, the court may issue an order temporarily prohibiting the continuation of an infringement. A comparison with the measure in Art. 62(3) UPCA, which relates to potentially infringing products and is thus much more concrete, shows that the Convention gives the court a wide scope in the wording of the order to prohibit the continuation of infringements when ordering measures under Art. 62(1) UPCA. A

It is not possible to infer from Art. 62(1) EPC that the order is limited to the specific designation or description of the contested products. It is therefore permissible to formulate the act to be prohibited under Art. 62(1) EPC with the aid of the patent claim. This is in particular also in accordance with Art. 25 EPC, according to which the subject-matter of the patent is decisive for the use to be prohibited; this is found in the respective patent claims concerned.

In view of this, it is not objectionable that the applications for an order refer to the wording of claim 1 of the patent in suit to describe the act to be prohibited. This makes it clear and definite which acts are to be prohibited.

To the extent that the respondents object to the fact that the deletion of the phrase "*or" in* the applications for an order would result in modifications of the patent claim and thus assert a limited version of the claim which was not granted in this way and thus does not exist, this does not constitute a violation of the EPC or of the Rules of Procedure. If a patent claim - as in this case - provides several alternatives for the design of a product or process according to the claim, it is permissible to select in the request for an order the one that is the subject matter of the contested embodiment or the contested process. A correspondingly restricted wording of the application for an injunction merely specifies the infringement to be prohibited, but does not mean that the subject matter of the dispute is asserted in a limited or non-grant version. A correspondingly restricted request for an order must be possible because the applicant could also describe the concrete form of infringement in the request instead of reproducing the patent claim; in this case, it would be obligatory to refrain from describing an alternative claim that does not have the form of infringement.

2. Insofar as the applicants did not file further written auxiliary requests at the oral proceedings and thus followed a suggestion of the local board in order to still be able to submit a written request after the discussion of the question of the validity of the patent in suit at the oral proceedings, if necessary.

The local division does not consider this to be a violation of the Rules of Procedure or of higher-ranking law. The indication given by the local division is in accordance with Art. 42 UPCA and Rule 210 No. 2 IR; countering a court indication, which also concerns the wording of the petition, by filing a corresponding auxiliary request cannot be assessed as a violation of the Rules of Procedure. Ultimately, however, this is not relevant, since no decision had to be taken on the auxiliary request.

VII. The **ordering of interim measures** is also necessary.

It follows from the requirement to state reasons for the provisional measure under Rule 206 No. 2(c) IR that there must be a necessity for ordering provisional measures. The mere finding of a (threatened) patent infringement, which is also a prerequisite for a final order under Art. 63 EPC, cannot therefore be sufficient for ordering provisional measures.

According to the Code, both temporal and factual circumstances are relevant for the necessity of ordering interim measures. The relevance of temporal circumstances results not only from Rule 209 no. 2 (b) of the Code ("urgency") but also from Rule 211 no. 4 of the Code, according to which the court takes into account an unreasonable delay in applying for provisional measures. The relevance of factual circumstances for the necessity of granting interim measures results, for example, from Rule 211 no. 3 Verfo, according to which, when deciding on the application for an injunction, the possible damage that the applicant may suffer must also be taken into account (while the possible damage to the defendant must be taken into account when weighing up the interests).

1. Due to the circumstances in this case, the issuance of the requested interim measures is necessary in terms of time.

The application to the local chamber for interim measures was filed at the earliest possible time. In the view of the local chamber

the applicants cannot be expected to wait for the decision on the merits. The respondents continue to offer the challenged embodiments in the contracting states of the UPCA; the judgments handed down by the Munich I Regional Court on 17 May 2023 have not changed this.

a. The applicants have filed the application for an order at the earliest possible time.

In order to establish a possibly unreasonable delay in filing the application, it must first be asked since when the applicants have been aware of the (threatened) patent infringement; on this basis, the point in time must be determined from which it was possible to apply for provisional measures due to the infringement of the asserted unitary patent before the EPC.

In their request for an order dated 1 June 2023, the applicants allege infringement of a European patent with unitary effect granted on 11 May 2023. The EPC, which has exclusive jurisdiction to order provisional measures for infringement of a European patent with unitary effect (Article 32(1)(c) EPC), commenced its activities on 1 June 2023. In view of the commencement of the EPC's activities, it was not possible to file a request with the EPC before 1 June 2023. Consequently, from this point of view (possibility of filing an application with the EPC), there can be no delay in filing the application (Rule 211 no. 4 IR).

b. Insofar as the respondents are of the opinion that the applicants had shown by their conduct prior to 1 June 2023 - in particular with regard to the, in the view of the respondents, negligent enforcement of the parent patent - that the ordering of provisional measures due to a possible infringement of the patent in suit is not urgent, the Local Board does not follow this line of argument.

There would have been no need to establish the EPC and a European patent with unitary effect (unitary patent) if adequate enforcement had already been possible on the basis of European (bundle) patents (o/use unitary effect). From the recitals of the UPCA it follows that

However, it is precisely the fact that the enforcement of European patents without unitary effect is difficult and associated with considerable disadvantages due to the fragmented patent market and the considerable differences between the national court systems. With the establishment of the UPC and the creation of the unitary patent, this situation, which is rightly described as disadvantageous, should be improved and legal certainty thereby strengthened. The enforcement of a European patent without unitary effect, which has to be carried out separately in all member states, is therefore not an equivalent means of enforcing rights in the case of infringement compared to the enforcement of a unitary patent before the UPC. According to the wording and the system, Rule 211 No. 4 of the Regulation accordingly refers only to the request for provisional measures under the UPCA and before the UPC. There are no indications that applications for provisional measures in the individual contracting states on the basis of a bundle patent or national patents could also be taken into account.

To the extent that the respondents nevertheless argue that the applicants were negligent in enforcing the parent patent (European patent without unitary effect) by either not taking any enforcement measures at all in the Contracting States concerned despite being aware of the alleged infringement or, in any event, not applying for provisional measures in the individual Contracting States, although this would have been possible well before 1 June 2023, this argument does not hold water. As shown, before 1 June 2023, the applicants did not have at their disposal any enforcement measures equivalent to the application for an injunction filed here and thus reasonable to achieve the same objective (uniform enforcement of patent protection in the entire territory concerned). The enforcement of a European bundle patent by way of interim relief, irrespective of the fact that it has to be carried out separately in each Contracting State concerned, is associated with additional obstacles, some of which are considerable; this applies in particular to enforcement in the Federal Republic of Germany, where the relevant infringement courts, at least until the ECJ decision in Case C-44/21 (Phoenix/Harting), made the issuance of interim measures conditional on

that the patent has successfully undergone adversary proceedings at least at first instance. In view of this, it is understandable that the applicants, based on the parent patent in the Federal Republic of Germany, "only" brought proceedings on the merits before the Munich Regional Court I; this cannot be considered negligent in view of the legal practice described. Therefore, and also in view of the increase in the marketing activities of the opponents in the period before 1 June 2023 (in particular the advertising tour through Europe in the second half of April 2023 "European Summit", Annex BP 18), the applicants cannot be successfully accused of having been negligent in enforcing the parent patent and also the patent in suit.

In view of the enforcement options available with a unitary patent compared to a bundle patent, the second applicant cannot be accused of delaying the enforcement of rights by filing a request with the European Patent Office on 21 April 2023 for postponement of the decision on the grant of the patent for invalidity in view of the imminent introduction of the unitary patent. In any case, this does not result in a delay in requesting provisional measures before the EPC, because provisional measures could be requested before the EPC on 1 June 2023 at the earliest, which the applicants did. Through the possibility of uniform enforcement of rights with the unitary patent applied for, the second applicant ultimately accelerated and did not delay the enforcement of rights.

C. The applicants cannot be expected to wait for the decision in the main action. Even according to the submissions of the respondents, it must be assumed that the rejection of the application for an injunction and the continued possibility of the respondents to launch patent-compliant products on the market as a result of this means that these very products will take the place of the first applicant's products and thus permanently block the market. Even if the applicants, despite the actions of the defendants and third parties alleged to be patent-infringing, currently make profits with their products in the amount of

market, this does not mean that the challenged actions of the respondents do *not* cause the described (long-term) damage to the applicants. Consequently, the marketing activities of the respondents are likely to cause the applicants (whether as licensors or licensees of the patent in suit) considerable, in particular long-term, damage. Pursuant to Art. 62 EPC, the necessity of ordering provisional measures against the applicants is also not dependent on whether and to what extent the applicants are also threatened with damage by the acts of third parties, especially since there is no concrete submission on these acts (subject matter of infringement, area of distribution, market significance, etc.) and it thus remains unclear whether and to what extent such unspecified acts of other market participants are of equal significance and are thus to be treated equally.

2. The ordering of provisional measures is also necessary from a factual point of view.

The necessity arises from the damage threatened to the applicants by the respondents' infringing product offering. The respondents also unsuccessfully object to the order for interim measures on the grounds of alleged disregard for mandatory procedural requirements. The order for interim measures is also subject to the licence claim asserted by the respondents against the applicant.
2) because the existence of such a licence claim has not been established to the conviction of the local chamber.

a. The applicants argued that they would be threatened with irreparable damage if they were referred to wait for the decision in the main action. The market for the patented products is very young and is in an initial phase in which it is decided to which suppliers customers of high-multiplex in-situ imaging systems will commit themselves for the next decade. This argument is confirmed by the advertising measures of the defendants.

The parties to the dispute agree that the products in dispute have a long product life cycle (application for an injunction, p. 99; opposition, para. 873). The applicants have argued that, due to the acquisition of the infringing product 1, customers would commit themselves to purchasing the detection reagents and decoder probes from the opposing parties for many years. This assessment corresponds - conversely - to the submission of the respondents according to which the market would be closed for years by an injunction to the detriment of the respondents because customers would commit themselves for years by making a purchase. In the expert opinion submitted by the respondents, Professor Stierle therefore correctly speaks of a mirror image risk resulting from long-term customer loyalty.

In this way, the parties agree to describe a situation in which either the respondents may suffer damage from the issuance of the order or - in a mirror image - the applicants may suffer corresponding damage from the refusal of the application:

- If the defendants are temporarily excluded from the market by a prohibition order, this has the consequence that missed business opportunities from the phase of exclusion are likely to be irretrievably lost even in the event of a later admission to the market (for example by a decision in favour of the defendants in the main proceedings) in view of the long life of the products;

- If, in the event that the application for an injunction is dismissed, the applicants have to tolerate the respondents being given the opportunity, at least for the time being, to occupy parts of the market with the long-term consequences described by both parties in agreement, this too can hardly be reversed in fact in view of the special features of the products concerned and the downstream sales market for the challenged embodiments 2 and 3. Insofar as the applicants believe that the applicants would have the possibility to recover market shares gained by the respondents by rescinding the relevant contracts of the respondents with their customers, this is not the case.

If the applicants were to reacquire the licence, this would be unreasonable for them, as they would have to take action against their own and potential customers; irrespective of the effort involved, this would also damage the applicants' reputation in relation to their customers. Incidentally, all this also applies to the licence applicant (2) with regard to the proceeds from the licence.

Consequently, the described risk of damage does not affect the respondents unilaterally. On this basis, in the view of the local chamber, the interest of the right holder in not having his rights infringed outweighs the interest of the potential infringer in securing market share now through the continuation of the infringement, which he can no longer obtain later through a possible licence agreement. The damage potentially caused to the applicants by a continuation of the infringing acts by the defendants is also difficult to compensate financially, as the acquisition transactions have a long-term effect; their reversal is much more difficult for the applicants than for the defendants who are contractually involved in these transactions.

b. The applicants also did not disregard any procedural rules when filing the application; in this respect, reference can be made to the statements under A. II. The local division can therefore leave open whether - as the respondents argue - the disregard of procedural rules proves the lack of necessity for ordering interim measures.

c. The respondents were also unable to convince the court that they were entitled to a licence claim against the second applicant, which could be held against the injunction sought.

aa. A licence claim existing under *US law* has not been set out to the satisfaction of the court.

(1.) Insofar as the respondents argue that the **licence claim** arises directly **from the contract between the NIH and respondent 2),** this is opposed by the fact that the respondents do not refer to a possible obligation of the applicant 2) to grant simple licences as an obligation of the **NIH.**

third party beneficiaries. The *District Court of Delaware*, in its decision dated 10 July 2023, referred to as the *Memorandum opinion and order, reached the* following conclusion:

> ". NanoString has not plausibly alleged that it is a third-party beneficiary of the NIH grant agreement."

The local chamber, which itself has no in-depth expertise in US law, follows the comprehensibly reasoned explanations of the US court.

The arguments of the respondents against this, submitted with two expert opinions by Professor Contreras, are not convincing. It is to be assumed with the respondents that appeals are possible against the final decision of the US court (the *memorandum* appears to be a preliminary decision on the admission of various applications). In the view of the local chamber, however, the US court was correct in denying the licence claim.

It can be left open whether legal opinions submitted to prove a legal assertion (here: existence of a licence claim under US law) constitute expert evidence at all within the meaning of Rule 181 Verfo (according to Art. 54 EPCÜ, the subject matter of the evidence is facts).

Ultimately, it can also be left open whether the expert opinion of Professor Contreras is an independent and objective expert opinion pursuant to Rule 181 no. 2 of the Constitutional Rules; at least due to the somewhat disconcerting and uninitiated discussion of the expert with the internet presence of the applicant's representatives (expert opinion of 23 August 2023, there no. 3.) and the overall tendency towards one-sided legal statements in favour of the applicants, considerable doubts are indicated in this respect.

However, it is decisive that the expert opinions of Professor Contreras do not show, beyond the mere legal assertion, why the defendants are to be third party beneficiaries in the specific case; in this respect, the expert opinions are essentially exhausted in general statements, but do not show the concrete application of the relevant US regulations (mostly mentioned at most in footnotes) to the facts to be assessed here.

(Opinion of 17 July 2023, paragraph 65 et seq.). The expert opinions state that other US courts have recognised a third party beneficiary in comparable cases (expert opinion of 17 July 2023, paragraph 64 ff.). Next, comments are made on FRAND constellations without explaining that the case to be assessed here also involves a corresponding FRAND constellation and that the respective decisions are relevant at all in this respect (Opinion of 17 July 2023, paragraph 68 et seq. and again at paragraph 81). The comments on *federal funding agencies* (Opinion of 17 July 2023, paragraph 73 et seq.) are also not helpful in this context, as the respondents obviously do not represent such an institution.

(2.) The Local Board is convinced that a **licence claim** which includes the territory of the contracting member states of the UPCA also does not arise as a consequence of any infringements of the applicants' contractual obligations towards the NIH **under US competition or US intellectual property law.**

A decision of a US court in favour of the defendants which deals with the alleged licence claim under US competition or antitrust law and is recognisable and enforceable in the territory of the contracting member states of the UPCA has not been submitted.

The respondents merely assert that they have a claim for relief if the applicants' conduct violates US antitrust law or US competition law ("unfair competition") or is otherwise relevant with regard to the "unclean hands" jurisprudence. The expert states (German translation):

> "If Harvard or 10x Genomics is shown to have engaged in acts in violation of U.S. cardll law or the Unfair Competition Law, or otherwise to be evidence of "unclean hands" with respect to the patents promoted by NOH, Nano-String shall be entitled to a license with respect to such patents."

This is followed by general statements on US law and the *possibilities of* US courts (expert opinion of 17 July 2023, paragraphs 100 ff., 108 ff.); however, there is no mention of specific provisions of US tort law.

or the Unfair Competition Act and their concrete application to the underlying facts. There is also no explanation as to what effects a *possible* decision by a US court would have on the territory of the contracting member states of the UPCA and according to which provisions of US law such a decision should be able to extend to this territory at all.

bb. The objection that the defendants have a licence claim against the second applicant under European law is also invalid. The respondents cannot rely on an obligation of the second applicant under European law to grant a licence to the patent in suit. The respondents unsuccessfully oppose the applicants' abuse of a dominant position in this respect. According to the submissions of the respondents, a dominant position of the applicants cannot be assumed; even if a dominant position of the applicants were to be assumed, its abuse is not evident.

(1.) It cannot be assumed - insofar as this can be reasonably assessed in summary proceedings and on the basis of the brief written submissions of the parties - that the applicants have a dominant position.

A prohibited abuse of market power in European law (Art. 102 TFEU) requires the existence of a dominant position. The ECJ understands this to mean

> "the position of economic strength enjoyed by an undertaking ... which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of consumers" (see, for example, the ECJ's decision in Case C-549/10 P).

In order to establish a dominant position, the relevant market must first be defined in product and geographic terms before it can be determined whether a dominant position exists on this market.

exists. This also applies in principle to situations involving intangible property rights. In accordance with the prevailing demand market concept, the question is whether the products or services are demand-substitutable, i.e. whether the products are interchangeable from the buyer's point of view. Another question is whether each service protected under intellectual property law forms its own product market. This can only be assumed if a protected service is not interchangeable with other services from the demand perspective. As a result, even the existence of a significant IP right does not relieve the practitioner of the obligation to assess in detail all relevant market conditions and their effects when determining a dominant position in order to be able to make a sufficiently well-founded determination as to the IP right holder's ability to behave to a large extent independently of competitors and customers in the market concerned. In the field of patent-protected technology, a narrowing of the product market to the patent and thus the procurement of market dominance by the patent is conceivable if no other technology of the same market is available. Market dominance can also be conveyed by de facto standards, which - unlike in the case of standard essential patents - are not based on an agreed standard, but on an actual enforcement against other technical solutions. The lack of standard essentiality of a patent does not necessarily preclude the assumption of market dominance by the patent proprietor. Market dominance can also result solely from the superiority of the patent-protected technology.

The burden of proof for a dominant position of the applicants lies with the respondents, who invoke a licence claim under European antitrust law against the asserted application for a prohibition.

(a.) However, the respondents argue that the patent in suit is not valid and that the applicants are building up an illegal thicket of invalid patents with the patent in suit, among other things. Thus, there is already a lack of conclusive argumentation regarding a dominant position of the

Applicants, because invalid patents cannot, in principle, create a dominant position for their owner and, consequently, a licence claim against the patent owner, since they can be declared invalid at the request of a competitor.

(b.) However, if one assumes - as the local board did - that the patent in suit is valid (see IV. above) and also takes into account the applicants' submissions when assessing the situation under cartel law, the following results:

The applicants submitted that the patented invention allowed for the first time the detection of 1000 and more analytes in *a* sample in *situ,* whereas on the basis of the prior art it had at most been possible to detect a maximum of 6 to 10 analytes in *situ in* a sample. It was therefore a **technological leap forward,** which made previously unattainable quantitative and qualitative findings possible, especially for research institutions. The applicants' submission thus at least suggests the assumption of market dominance due to the superiority of the patent-protected technology.

However, the respondents have argued that the *challenged embodiment* is technologically unique; research institutions and pharmaceutical companies are **dependent on** the challenged embodiments for their work and **cannot replace them with an alternative analytical method available on the market** (opposition of 21 July 2023, point 933). Compared to all other in situ profiling instruments available on the market, the challenged embodiments could detect the largest number of RNA molecules in a sample. The methods used with the product were protected by patents from at least 9 patent families.

It thus follows from the parties' submissions that both sides refer to unique, non-substitutable and patent-protected technologies for the relevant product market, which potentially constitute a dominant position. Based on the respective alleged technological strength of the market participants, the submission thus provides indications for the existence of a dominant position.

interdependence. Accordingly, it cannot be assumed without further ado that the applicants have unilateral market power.

(c) However, a complete and conclusive assessment of the question of market control is not possible for the local chamber in summary proceedings due to the scarcity of the parties' submissions in this respect.

(2.) Even if one were to assume a dominant position of the applicants, there is no abuse of this position by the applicants.

The European Court of Justice has ruled in Case C-170/13 (Huawei./.ZTE) that Art. 102 TFEU must be interpreted as meaning that the *owner of a standard-essential patent* (SEP) who has irrevocably undertaken vis-à-vis the standardisation organisation to grant a licence to any third party on fair, reasonable and non-discriminatory terms (so-called FRAND terms) does not abuse his dominant position by bringing an action for an injunction, if he has informed the alleged infringer of the patent infringement before filing the action, the infringer has then expressed a corresponding willingness to grant a licence and the patent proprietor has then submitted a concrete written licence offer to the infringer on these terms, in particular indicating the licence fee. The owner of an SEP therefore acts abusively if he does not submit a concrete written licence offer to a licence seeker who is willing to take a licence.

However, this case law only relates to standard-essential patents. The European Court of Justice explicitly justifies the offer obligation imposed on the patent proprietor by stating that the patent proprietor has undertaken vis-à-vis the standardisation organisation to grant a licence for this patent to any third party on FRAND terms. This obligation is, in a sense, the consideration of the patent holder for the inclusion of his patent-protected invention in the standard.

However, the European Court of Justice has not ruled on whether the obligation to make a licence offer applies equally in other cases -

for example in the case of a de facto standard. If one assumes, in accordance with the above, a possible dominant position of the applicants, the decisive difference to the SEP constellation decided by the European Court of Justice is, in particular, the **licensing promise** made by the patent proprietor in favour of third parties. Such a promise is lacking under US law applicable to the facts to be assessed here (see the decision of the *District Court of Delaware).*

In contrast to SEP constellations, in which the patent proprietor is obliged to make a third party favourable offer, the dominant patent proprietor is in principle not obliged to offer to allow the use of the invention. Therefore, a concrete licence offer by the licence seeker on non-obstructive or discriminatory terms is required. If the patent proprietor refuses this, he abuses his dominant position.

The applicants did not make a concrete licence offer before the oral proceedings, but merely requested - several times - that *the second applicant* make a *licence offer* (see duplicate, paragraph 321). However, the second applicant was not obliged to tolerate the use of the patent in suit by companies that were not prepared to offer to conclude a corresponding licence agreement themselves.

Insofar as the respondents made a licence offer to the second applicant during the oral proceedings with reference to Annex BP 1 (Exclusive Licence Agreement between the applicants), this offer was made too late with regard to the order to be made, as the second applicant was not able to respond to it during the oral proceedings. In addition, BP 1 only had a licence to the *German part of* the *parent patent* ("...licence under the German national part of EP 2 794 928...").

". . under the German national part of any divisional patent of EP'928. ."

and thus cannot constitute licensing of the patent in suit, which as a unitary patent has no national parts. In addition, there is the fact that

the offer made at the oral proceedings is also not an acceptable offer on reasonable terms because the offer is only directed to the future without also reflecting the use of the patent in suit already made in the past by corresponding billing and payment commitments.

VIII. Finally, the order sought is also justified in the light of the balancing of interests to be carried out (Article 62(2) EPCÜ, Rule 211(3) Verfo).

Pursuant to Art. 62(2) UPCA (Rule 211(3) IR), the court shall exercise its discretion to weigh the interests of the parties with a view to issuing the order or dismissing the application; in doing so, all relevant circumstances shall be taken into account, in particular the possible damage which the parties may suffer as a result of issuing the order or dismissing the application for an order. For the exercise of the discretion, the degree of probability to which the court is convinced of the existence of the individual circumstances to be included in the weighing is also decisive. The more certain the court is that the right holder is asserting the infringement of a valid patent, that it is necessary to issue an injunction due to factual and temporal circumstances and that possible damages of the opponent or other justified objections are not opposed, the more likely it is that the issuance of an injunction is justified. The sooner, on the other hand, there are relevant uncertainties with regard to individual circumstances relevant for the weighing of interests that are detrimental to the conviction of the court, the court will have to consider as a more lenient measure the admission of the continuation of the alleged infringement conditional on the provision of security or even the dismissal of the application.

On this basis, the local chamber comes to the following conclusion:

The applicants entitled to file an application are infringed by the acts of the respondents in dispute in their rights arising from the patent in suit; the local division assumes this with a very high degree of certainty.

likelihood. The local division is also convinced with a clear preponderance of probability that the patent in suit is valid; this conviction is not diminished by the auxiliary request filed by the applicants at the oral proceedings at the suggestion of the local division, which asserts the patent in suit in a limited version. The Local Board is also clearly convinced that provisional measures are necessary due to the infringement of a valid patent, both in terms of subject matter and time. In particular, the Local Board is convinced that the applicants cannot argue against the requested injunction that a licence claim exists against the second applicant.) The local chamber also does not consider the possibility of long-term damage caused by the order for interim measures or their rejection to be unilaterally detrimental to the respondents.

There are also no further circumstances to be considered in the context of the weighing of interests that speak against an injunction:

- To the extent that the respondents argue that an injunction would in any case be disproportionate because the challenged process is "a completely subordinate part of a larger, complex product", the Local Board is already unable to determine how the process executable with the challenged embodiments can be described as a "part" of a product or what proportion is to be attributed to it; in any case, it is obviously not one of the individual parts indicated by the respondents as 2394 pieces. Even in summary proceedings, the local division cannot reliably determine which other patents or systems - possibly developed at great expense - are used in the challenged embodiments, how valuable they are and how they compare to the patent in suit. Nor is there any legal principle within the scope of application of the UPCA to the effect that the rights of third parties can be infringed with a complex product without the consequence of an injunction if a high financial outlay was made for the development of the product concerned. It

There is also no specific submission as to why there is no (technical) possibility of offering the multi-functional embodiment 1 without its patent-infringing function according to the submission of the defendants. In addition, the defendants apparently did not see any reason to approach the second defendant with a licence offer in order to avert a possible injunction, even after the prohibition pronounced by the Munich Regional Court I with regard to the products at issue here.

- To the extent that the respondents further argue on the proportionality of an injunction that the second applicant, as a non-practicing entity ("NPE"), has no interest worthy of protection in the enforcement of an injunction, since it is only pursuing monetary interests as a licensor, the local division does not follow this argument either. Pursuant to Art. 62(2) EPC, possible financial damage in particular can justify an injunction; the local division assumes that the second applicant will suffer such damage as a patent proprietor and licensor with long-term consequences if further infringements by the respondents are not prevented. Art. 47 EPC also shows that the status as NPE in itself has no significance for the entitlement to file an application.

- To the extent that the respondents argue that the disproportionate nature of an injunction also results from the fact that the challenged embodiments are non-substitutable and thus of indispensable importance for research into a large number of serious, life-threatening diseases and the development of therapies against these in the EPC contracting states, this argument does not hold water either: the applicants have argued that they are *competing products* in relation to the first applicant's products. This is confirmed by the respondent in its reply of 24 August 2023 (para. 341), when it states that the products are

> ". .the contested embodiment 1, as well as the competing product of applicant 1. is an object with a very long life.

> product life ("...product that is purchased for use over many years or decades ...spanning"). This is precisely what leads to the fact that an interim injunction would permanently block the market for the defendants. "(Inj.
> by the local chamber)

However, if the products are competing products and the products of the first applicant substitute those of the defendants in such a way that the market for the defendants' products would be blocked even if an injunction were lifted, it cannot be assumed at the same time that the challenged embodiments are products that are not substitutable on the market.

The defendants' submission on the possible consequences of a cease-and-desist order for the research activities of third parties is a mere assertion on which no concrete, verifiable and admissible facts have been presented. In particular, it is unclear which concrete research projects and results would be put at risk. In this context, the submission does not make any reference to the existing exceptions under Art. 27 EPC.

Nor can the Local Board find within the scope of possibilities of summary proceedings that the applicants - as alleged by the respondents - are building up an **unlawful thicket of** patents that are not legally stable. In this respect, at least it cannot be established that all of the patents asserted by the applicants in connection with the challenged embodiments are invalid. At least for the patent in suit, the local chamber assumes validity; according to the preliminary view of the Federal Patent Court, the German part of the parent patent is also legally valid, at least in the auxiliary request. The local division is also precluded from assessing further patents in view of the at most general submission of the respondents in this respect. At least according to the current assessment of the local division, an "illegal patent thicket" cannot be assumed.

- The facts to be assessed here are also - contrary to the view expressed by the opposing party - not *unsuitable* for ordering interim measures. In view of the rules in the UPCA and the RP, the local chamber sees no evidence that the UPCA is not suitable in the case of highly complex technologies and because of the large number of issues to be dealt with (here: admissibility, jurisdiction, active participation): Admissibility, jurisdiction, capacity to act, existence of rights, US law, mapIIreGht, direct/indirect patent infringement) that the EPC should refrain from ordering provisional measures. In its recitals, the UPCA precisely states that the EPC should be able to ensure rapid and highly qualified decisions.

Taking into account and assessing all these circumstances, the local chamber concludes that the requested measures - essentially in line with the application - are to be ordered without the provision of security and that a continuation of the infringement against the provision of security would not be appropriate. The further arguments put forward by the respondents do not lead to a different result.

B.

The legal basis for the order requiring the respective defendant to pay the court a penalty payment of up to EUR 250,000.00 per infringement in the event of each infringement of the orders under A.I. to A.IV. is Rule 354 No. 3 of the Rules of Procedure. The indication of a maximum amount is appropriate with regard to the sales value of the challenged embodiments under 1 and, in the case of other embodiments, leaves the court the necessary leeway to set an appropriate penalty payment under Rule 354 No. 4 IR.

C.

The application had to be dismissed insofar as the applicants requested not only an injunction but also the cessation of the infringing acts.

D.

The respondents, who have been largely unsuccessful, are to be ordered to pay the costs under Article 69(1) and (2) UPCA. The minor dismissal of the application for an order does not result in any costs.

E.

The immediate enforceability of the orders results from Rules 350 No. 2, 354 No. 1 of the Rules of Procedure; according to these rules, the orders made here are directly enforceable in each Contracting Member State from the day of their service.

F.

The application of the respondents to make the granting of interim measures dependent on the provision of a security by the applicants for the enforcement was to be dismissed.

Pursuant to Rule 211(5) of the Rules of Procedure, the court may order the applicant to provide adequate security for any reasonable compensation to be paid by him to the defendant for the damage likely to be suffered by the defendant in the event that the court revokes the order for interim measures.

According to the submissions of the parties, there are no indications for the local division that, in the event of a possibly necessary enforcement of a claim for compensation of the respondents pursuant to Rule 211 No. 5 of the Rules of Procedure against the applicants in the USA, difficulties are to be expected in connection with the enforcement which require the provision of security; this applies both in view of the economic condition of the applicants and in view of US enforcement law.

For these reasons, the Munich Local Chamber of the EPG, composed of the presiding judge Dr. Zigann, the legally qualified judges Kupecz and Pichlmaier, and the technically qualified judge Enderlin, hereby rules as follows

Decision and orders

A. Orders the defendants, in the territories of the Republic of Austria, the Kingdom of Belgium, the Republic of Bulgaria, the Kingdom of Denmark, the Republic of Estonia, the Republic of Finland, the French Republic, the Federal Republic of Germany, the Italian Republic, the Republic of Latvia, the Republic of Lithuania, the Grand Duchy of Luxembourg, the Republic of Malta, the Kingdom of the Netherlands, the Portuguese Republic, the Republic of Slovenia and/or the Kingdom of Sweden, to cease and desist from

I. A method for detecting a plurality of analytes in a cell or tissue sample comprising

(a) Mounting the cell or tissue sample on a solid support;

(b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, wherein the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents;

(c) incubating the cell or tissue sample together with the plurality of detection reagents for a time sufficient to allow binding of the plurality of detection reagents to the analytes; wherein

each subpopulation of the plurality of detection reagents targets a different analyte, wherein

each of the plurality of detection reagents comprises: a probe reagent targeting an analyte of the plurality of analytes; and

a plurality of predetermined subsequences, wherein the probe reagence and the plurality of predetermined subsequences are conjugated to each other;

(d) detecting said plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

(i) Hybridizing a set of decoder probes with a subset of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes, and wherein each subpopulation of the decoder probes comprises a detectable label, wherein each detectable label produces a signal signature;

(i@ Detecting the signal signature produced by hybridising the set of deco- der probes;

(iii) Removing the signal signature; and

(iv) repeating (i) and (iii) using a different set of decoder probes to detect different sub-sequences of the detection reagents, thereby producing a temporal sequence of signal signatures unique to each sub-population of the plurality of detection reagents; and

(e) using the temporal order of the signal signatures corresponding to the plurality of predetermined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of analytes in the cell or tissue sample,

in the territory of one or more of the states mentioned under A. or to offer them for use in the territory of one or more of the states mentioned under A.;

(direct infringement of claim 1 of EP 4 108 782)

II. Devices suitable for performing a method for detecting a plurality of RNAs in a cell or tissue sample, comprising

(a) Mounting the cell or tissue sample on a solid support;

(b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, wherein the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents;

(c) incubating the cell or tissue sample together with the plurality of detection reagents for a time sufficient to allow binding of the plurality of detection reagents to the RNAs; wherein

each subpopulation of the plurality of detection reagents targets a different RNA, whereby

each of the plurality of detection reagents comprises: a probe reagent targeting an RNA of the plurality of RNAs, and

a plurality of predetermined subsequences, wherein the probe reagence and the plurality of predetermined subsequences are conjugated to each other;

(d) detecting said plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

(i) Hybridising a set of decoder probes with a subsequence of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes, and wherein each subpopulation of decoder probes comprises a detectable label, wherein each detectable label produces a signal signature;

(ii) Detection of the signal signature produced by hybridisation of the set of decoder probes;

(iii) Removing the signal signature; and

(iv) repeating (i) and (iii) using a different set of decoder probes to detect different sub-sequences of the detection reagents, thereby producing a temporal sequence of signal signatures unique to each sub-population of the plurality of detection reagents; and

(e) using the temporal order of the signal signatures corresponding to the plurality of predetermined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of RNAs in the cell or tissue sample,

to offer and/or supply in the territory of one of the States mentioned under A. for use in the territory of one of the States mentioned under A. or in the territories of several of these States for use in the territory of one or more of the States mentioned under A.

without

(1) to state explicitly, conspicuously and prominently on each offer, on the first page of the operating instructions, in the delivery documents and on the packaging that the devices may not be used for the detection of RNA in a procedure pursuant to section A.I. without the consent of the second applicant) as owner of EP 4 108 782 and that they may not be used for the detection of RNA without the consent of the second applicant),

(2) impose on the purchasers a written obligation not to use the devices for the detection of RNA without the prior consent of the second applicant, subject to the imposition of a reasonable contractual penalty to be paid to the second applicant, to be determined by the second applicant and, if necessary, to be reviewed by the competent court, for each case of infringement;

(indirect infringement of claim 1 of EP 4 108 782)

III. Detection reagents suitable for carrying out a method for detecting a plurality of analytes in a cell or tissue sample, comprising

(a) Mounting the cell or tissue sample on a solid support;

(b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, wherein the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents;

(c) incubating the cell or tissue sample together with the plurality of detection reagents for a time sufficient to allow binding of the plurality of detection reagents to the analytes; wherein

each subpopulation of the plurality of detection reagents targets a different analyte, wherein

each of the plurality of detection reagents comprises: a probe reagent targeting an analyte of the plurality of analytes; and

a plurality of predetermined subsequences, wherein the probe reagence and the plurality of predetermined subsequences are conjugated to each other;

(d) detecting said plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

(i) Hybridizing a set of decoder probes with a subset of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes, and wherein each subpopulation of the decoder probes comprises a detectable label, wherein each detectable label produces a signal signature;

(ii) Detect the signal signature produced by hybridising the set of deco- der probes;

(iii) Removing the signal signature; and

(iv) repeating (i) and (iii) using a different set of decoder probes to detect different sub-sequences of the detection reagents, thereby producing a temporal sequence of signal signatures unique to each sub-population of the plurality of detection reagents; and

(e) using the temporal order of the signal signatures corresponding to the plurality of predetermined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of analytes in the cell or tissue sample,

in the territory of one of the States mentioned under A. for the use of the process in the territory of one of the States mentioned under A. or in the territories of several of these States for use in the territory of one or more of the States mentioned under A. to offer and/or supply;

(indirect infringement of claim 1 of EP 4 108 782)

IV. Decoder probes suitable for performing a method for detecting a plurality of RNAs in a cell or tissue sample, comprising

(a) Mounting the cell or tissue sample on a solid support;

(b) contacting the cell or tissue sample with a composition comprising a plurality of detection reagents, wherein the plurality of detection reagents comprises a plurality of subpopulations of the detection reagents;

(c) incubating the cell or tissue sample together with the plurality of detection reagents for a time sufficient to allow binding of the plurality of detection reagents to the RNAs; wherein

each subpopulation of the plurality of detection reagents targets a different RNA, whereby

each of the plurality of detection reagents comprises: a probe reagent targeting an RNA of the plurality of RNAs, and

a plurality of predetermined subsequences, wherein the probe reagence and the plurality of predetermined subsequences are conjugated to each other;

(d) detecting said plurality of predetermined subsequences in a time sequential manner, said detecting comprising:

(i) Hybridising a set of decoder probes with a subsequence of the detection reagents, wherein the set of decoder probes comprises a plurality of subpopulations of decoder probes, and wherein each subpopulation of decoder probes comprises a detectable label, wherein each detectable label produces a signal signature;

(ii) Detection of the signal signature produced by hybridisation of the set of decoder probes;

(iii) Removing the signal signature; and

(iv) repeating (i) and (iii) using a different set of decoder probes to detect different sub-sequences of the detection reagents, thereby producing a temporal sequence of signal signatures unique to each sub-population of the plurality of detection reagents; and

(e) using the temporal order of the signal signatures corresponding to the plurality of predetermined subsequences of the detection reagent to identify a subpopulation of the detection reagents, thereby detecting the plurality of RNAs in the cell or tissue sample,

in the territory of one of the States mentioned under A. to use the procedure in the territory of one of the States mentioned under A. or in

the territories of several of these states in the territory of one or more of the states mentioned under A. to offer and/or supply,

without

(1) to point out explicitly, conspicuously and prominently on each offer, on the first page of the operating instructions, in the delivery documents and on the packaging that the decoder probes may not be used for the detection of RNA in a procedure pursuant to section A.I. without the consent of the second applicant) as owner of EP 4 108 782 and that they may not be used for the detection of RNA without the consent of the second applicant),

(2) impose on the purchasers a written obligation not to use the decoder probes for the detection of RNA without the prior consent of the second applicant, subject to the imposition of a reasonable contractual penalty to be paid to the second applicant, to be determined by the second applicant and, if necessary, to be reviewed by the competent court, for each case of infringement;

(indirect infringement of claim 1 of EP 4 108 782)

B. For each individual infringement of the orders according to section A.I. to A.IV., the respective defendant shall pay to the court a penalty payment (repeated, if applicable) in the amount of up to EUR 250,000.

C. In all other respects, the application for interim measures is dismissed.

D. The applications made by the respondents are dismissed.

E. Order the respondents to pay the costs of the proceedings.

F. The above orders are effective and enforceable immediately.

G. The amount in dispute is set at EUR 7 million.

INFORMATION ON THE VOCATION

The present decision may be appealed by any party contesting in whole or in part its

If the application was unsuccessful, an appeal may be lodged with the Court of Appeal within two months from the date of notification of the decision (Art. 73 (1) EPCÜ, R. 220.1 (a), 224.1
(a) Verfo).

INFORMATION ON COMPLETION (ART. 82 EPC. ART. 37f2) EPGS, R. 118.8.

158.2, 354. 355.4 VERFO\:

A certified copy of the enforceable decision shall be issued by the Deputy Registrar at the request of the enforcing party, Rule 69 RegR.

INFORMATION ON THE DECISION AND THE O R D E R S

Procedure number: UPC_CFI_2/2023
Number of the related application: ACT 459746/2023
Type of application: Application for interim measures Further

procedural workflow number: App 528389/2023 Type of

procedural workflow: Summons to oral proceedings

Dr Zigann Presiding Judge	Matthias ZIGANN Digitally signed by Matthias ZIGANN Date: 2023.09.19 14:46:47 +02'00'
Pichlmaier Rapporteur	Tobias Günther Pichlmaier Digitally signed by Tobias Günther Pichlmaier Date: 2023.09.19 1450:00 +02'00'
Kupecz legally qualified judge	András Ferenc Kupecz Digitally signed by András Ferenc Kupecz Date: 2023.09.19 14:47:42 +02'00'
Enderlin technically qualified judge	Eric, André Enderlin Digitally signed by Eric, André Enderlin Date: 2023.09.19 14:48:28 +02'00'
Schmidt Clerk	Silke Anette Schmidt Digitally signed by Silke Anette Schmidt Date: 2023.09.19 14:SO:32 +02'00'