

Guiding principles:

1. In the event of violations of orders pursuant to Art. 62 UPCA, a penalty payment may be imposed without a further judicial enforcement order pursuant to Art. 82 para. 4 UPCA.
2. The conditions for the imposition of periodic penalty payments are regulated conclusively in Art. 82 para. 4 UPCA; in this respect, more extensive enforcement requirements under the law of the contracting member states are not to be taken into account.
3. Rule 118.8 of the CPR, according to its clear wording ("The orders referred to in paragraphs 1 and 2(a)..."; Art. 62 UPCA is not mentioned there) does not apply to orders under Art. 62 UPCA.

Arrangement
of the Court of First Instance of the Unified Patent Court in
proceedings for interim measures UPC_CFI_2/2023
ACT_459746/2023
App_577241/2023
issued on 05.12.2023

APPLICANT

- 1) **10x Genomics, Inc.** (Applicant) - Represented by:
6230 Stoneridge Mall Road - Tilman Müller-Stoy
94588-3260 - Pleasanton - US

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

APPLICANT

- 1) **NanoString Technologies Inc** Represented by:
(Respondent) - 530 Fairview Ave N - Oliver Jan Jüngst
98109 - Seattle (WA) - US

- 2) **NanoString Technologies Germany** Represented by:
GmbH (defendant) - Birketweg 31 - Oliver Jan Jüngst
80639 Munich - DE

- 3) **NanoString Technologies** Represented by:
Netherlands B.V. (Respondent) - Oliver Jan Jüngst
Paasheuvelweg 25 - 1105BP -
Amsterdam - NL

Facts of the case

On June 1, 2023, the applicants applied to the Unified Patent Court (Munich Local Division) for interim measures to be ordered due to the infringement of EP 4 108 782 (patent in suit) by the defendants.

The Local Division issued the following order on September 19, 2023:

- A. The defendants are ordered to refrain from the following 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
- I. a method for detecting a plurality of analytes in a cell or tissue sample, comprising
- (a) Mounting of 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 sufficient period 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, whereby
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 reagent and the plurality of predetermined subsequences are conjugated to each other;
 - (d) detecting the plurality of predetermined subsequences in a time sequential manner, wherein the detecting comprises:
 - (i) hybridizing a set of decoder probes with a partial sequence of the detection reagents, wherein the set of decoder probes has a

A plurality of subpopulations of decoder probes, and wherein each subpopulation of decoder probes comprises a detectable marker, wherein each detectable marker produces a signal signature;

- (ii) Detection of the signal signature produced by the hybridization of the set of decoders;
 - (iii) Removing the signal signature; and
 - (iv) repeating (i) and (iii) using a different set of decoder probes to detect different subsequences of the detection reagents, thereby producing a temporal order of the signal signatures that is unique for each subpopulation 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 it 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 carrying out a method for detecting a plurality of RNAs in a cell or tissue sample, comprising
- (a) Mounting of 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 sufficient period of time 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, where

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

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

- (d) detecting the plurality of predetermined subsequences in a time sequential manner, wherein the detecting comprises:
 - (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) Detection of the signal signature produced by the hybridization 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 other subsequences of the detection reagents, thereby producing a temporal sequence of signal signatures that is unique for each subpopulation 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 use of the procedure 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 expressly, conspicuously and prominently indicate 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 without the consent of applicant
- 2) as the owner of EP 4 108

782 may be used for the detection of RNA in a procedure according to section A.I. and must not be used for the detection of RNA without the consent of the applicant under 2),

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

(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 of 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 sufficient period 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, whereby 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 reagent and the plurality of predetermined subsequences are conjugated to each other;
 - (d) detecting the plurality of predetermined subsequences in a time sequential manner, wherein the detecting comprises:
 - (i) hybridizing a set of decoder probes with a partial sequence 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

- marker, with each detectable marker producing a signal signature;
- (ii) Detection of the signal signature produced by the hybridization of the set of decoders;
 - (iii) Removing the signal signature; and
 - (iv) repeating (i) and (iii) using a different set of decoder probes to detect different subsequences of the detection reagents, thereby producing a temporal order of the signal signatures that is unique for each subpopulation 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 use of the procedure 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;

(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 of 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 sufficient period of time 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, where
each of the plurality of detection reagents comprises: a probe reagent targeting one RNA of the plurality of RNAs, and

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

- (d) detecting the plurality of predetermined subsequences in a time sequential manner, wherein the detecting comprises:
 - (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) Detection of the signal signature produced by the hybridization 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 other subsequences of the detection reagents, thereby producing a temporal sequence of signal signatures that is unique for each subpopulation 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 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.

A. mentioned countries without

- (1) to expressly, conspicuously and prominently point out 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 method according to section A.I. without the consent of the applicant under 2) as the owner of EP 4 108 782 and that use for the detection of RNA without the consent of the applicant under 2) is prohibited,

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

2) for the detection of RNA;

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

- B. **For each individual infringement of the orders under A.I. to A.IV., the respective defendant must pay a (possibly repeated) penalty payment of up to EUR 250,000 to the court.**
- C. In all other respects, the application for interim measures is dismissed.
- D. The applications made by the defendants are dismissed.
- E. The defendants are ordered to pay the costs of the proceedings.
- F. **The above orders are effective and enforceable immediately.**

The order was served on the parties via CMS on September 20, 2023.

With their application for the imposition of a penalty payment dated September 28, 2023, the applicants claim that the defendants violated the order of September 19, 2023, by

- contrary to point A.I. of the orders of September 19, 2023, advertised the performance of the patent-infringing process in the CX-Lab in Amsterdam;
- still offered the contested embodiment 1 (CosMx) on the internet for the UPC member states on September 26, 2023 without the notice required by the arrangement under point A.II;
- also offered CosMx at events in the UPC member states, including Germany and France, on September 26, 2023 ("Spatial Multiomics Summits");
- still offered the challenged embodiments 1 (CosMx) and 3 (decoder probes) in the "Instrument User Manual" and "Manual Slide Preparation" available on the Internet on September 27, 2023 without the information required by the orders in sections A.II. and IV;
- also offered a product presentation tour on its website <https://nano-string.com/about-us/cx-labs/cxlab-amsterdam/> on September 26, 2023, which affected all challenged embodiments in violation of the orders in paragraphs A.II, III and IV;

The applicants have therefore **applied**,

- I. order the defendants to comply with the order in point A.I. in the decision of the Court of First Instance of the Unified Patent Court in the proceedings for interim measures concerning EP 4 108 782, case number UPC CFI 2/2023, issued on September 19, 2023, by imposing a penalty payment of EUR 50,000 each.

II. the defendants

- by a penalty payment of EUR 250,000 in each case to comply with the order in section A.II., and
- by a penalty payment of EUR 100,000 in each case to comply with the order in sections A.III. and IV.

in the decision of the Court of First Instance of the Unified Patent Court in the proceedings for interim measures relating to EP 4 108 782, case number UPC CFI 2/2023, issued on September 19, 2023.

The defendants have **applied**,

to reject the application for the imposition of a penalty payment dated 28.09.2023 in its entirety and with costs;

in the alternative:

not to decide on the application for the imposition of a periodic penalty payment of 28.09.2023 without an oral hearing - possible as a video hearing pursuant to Rule 354.4 in conjunction with Rule 264 of the Rules of Procedure.

With reference to Article 82(3) UPCA*, the defendants are of the opinion that the conditions for enforcement are not met. Enforcement would be subject to the enforcement procedures and conditions applicable in the respective Contracting Member State in which enforcement takes place. In Germany, the enforcement of an interim injunction requires that a party has been served. In France, service of the decision by a bailiff is required. These requirements were not met.

Even if one were to assume that national enforcement conditions do not apply to interim measures under the UPC, it follows from general considerations of the protection of legitimate expectations that the enforcement creditor informs the enforcement debtor - if necessary also informally - that and to what extent the enforcement debtor is entitled to enforcement.

The extent to which he intends to enforce an order. This had also not happened before the application was filed.

The defendants are of the opinion that they have not violated the orders of September 19, 2023. They have made submissions in this regard,

- both the image of the CosMx on the homepage of the domain <https://nanosttring.com/> and the link to the product page of the CosMx (<https://nanosttring.com/products/cosmx-spatial-molecular-imager/cosmx-smi-single-cell-imaging-en/>) did not constitute an offer within the meaning of patent law; moreover, according to a screenshot taken on October 6, 2023, a disclaimer corresponding to the order was present on the product page. In addition, a screenshot taken on October 6, 2023, showed that a disclaimer corresponding to the order was present on the product page (Annex B- ZG ¹ⁱ), which - as a mandatory requirement - had already been attached on September 19, 2023;
- with a view to the manuals according to Annex BP ZV 9 and 10, the disclaimer ordered by the court is prominently positioned on the cover sheet and clearly highlighted there with a colored box; Annex BP-ZV 10a is an "old version", but the operative part of the orders only refers to the current operating instructions;
- in the CX-Lab in Amsterdam, there is no offer and no other relevant action relating to the challenged embodiments 1 to 3; the mere showing/display of the CosMx in the laboratory is not prohibited because there is no prohibition of bad taste;
- the laboratory activity with regard to the patent procedure had already ceased before the orders were served; the form headed "Request a Tour or Test Drive" on the subpage for the laboratory in Amsterdam (<https://nanosttring.com/about-us/cx-labs/cxlab-amsterdam/>) does not constitute an offer for the procedure at issue;
- with regard to the "Spatial Multiomics Summits" and "Experience the Power of Spatial Biology", there was no infringement, since the disclaimer ordered could be taken directly from Annex BP-ZV 7; the wording "measuring and

visualizing the full RNA reactome in situ" does not refer to the CosMx, but to the GeoMx Digital Spatial Profiler.

Reference is also made to the written submissions of the parties together with the annexes.

machine
translation

Reason

The application for a penalty payment, which is admissible pursuant to Art. 82 (4) UPCA, Rule 354.4 VerfO, is largely successful. The defendants have violated the orders of the Enforcement Division of September 19, 2023. Therefore, penalty payments are to be imposed on them pursuant to Art. 82 para. 4 UPCA. The Regional Court did not consider an oral hearing to be necessary.

- I. Contrary to the view of the defendants, the orders of September 19, 2023 were already directly enforceable pursuant to Rule 354.1 VerfO without any further court enforcement order or threat of enforcement as a result of service via the CMS on September 20, 2023 (for enforcement, see also Local Division Düsseldorf, UPC_CFI_177/2023, APP_552740/2023). Reference is made in this respect to point F. of the orders of September 19, 2023 ("Orders are immediately effective and enforceable").

In view of this, there was no need for prior notification by the applicants of their "actual intention to enforce". In view of the clear provision in Article 82(4) UPCA^x on the imposition of periodic penalty payments in the event of non-compliance with court orders, there was also no need for the parties to serve the orders of September 19, 2023 prior to the imposition of periodic penalty payments. The conditions for the imposition of periodic penalty payments are conclusively regulated in Art. 82 para. 4 UPCA^x; enforcement law requirements under the law of the contracting member states are not relevant in this respect (see also Local Division Düsseldorf, UPC_CFI_177/2023, APP_552740/2023); national enforcement law only becomes relevant in such a case if a debtor does not pay the penalty payment already imposed on him (see also in this respect Local Division Düsseldorf, UPC_CFI_177/2023, APP_552740/2023).

Rule 118.8 of the RP, according to its clear wording ("The orders referred to in paragraphs 1 and 2(a)...") does not apply to orders under Art. 62 UPCA.

- II. The defendants violated these orders several times after the orders were served on September 20, 2023.

- 1. Violation of point A.I. of the orders of September 19, 2023**

By continuing to offer to carry out patent-infringing processes at the CX-Lab in Amsterdam on September 26, 2023 via the website <https://nanosting.com>, the defendants violated point A.I. of the order of September 19 ("...to use or offer to use ... a process").

On the website <https://nanosting.com/about-us/cx-labs/cxlab-amsterdam/>, the defendants still offered to carry out the infringing process in their CX-Lab in Amsterdam on September 26, 2023. This is shown by the screenshot of the website from September 26, 2023 (Annex BP ZV 2).

There, in the context of the current presentation of the CX-Lab in the section "Platforms Designed to Accelerate Sample to Discovery", the CosMx is named as one of the defendants' products available in the laboratory. In addition, the CosMx is highlighted as laboratory equipment in a presentation video available on the aforementioned website (screenshot of September 26, 2023 as Annex BP ZV 3).

The defendants offer that guests of the laboratory can carry out the procedure with the assistance of employees of the defendants. For this purpose, a request form can be found on the aforementioned website, in which, among other things, a "test drive" using "CosMx" technology can be selected. The form also shows that the device is used in the laboratory of the opponents primarily for the detection of RNA (and not only for protein analysis), in which the infringing objects 2 (detection reagent) and 3 (decoder probe) are used. On the website <https://nano-string.com/about-us/legal/terms-of-sale/> (Annex BP ZV 4) under the title

"CosMx™ Spatial Molecular Imager Technology Access Program Services" the conditions under which the defendants use the CosMx with samples from customers. This shows that the defendants use the challenged embodiments 2 and 3 for RNA detection.

The EPG member states, such as Germany, can be selected in the country selection of this form.

Thus, contrary to point A.I. of the order, the application of the patent procedure is offered in the territory of the UPC. The screenshot of October 6, 2023, submitted by the applicants, which shows a disclaimer, is irrelevant with regard to an offer made without a disclaimer on September 26, 2023, as shown in Annex BP ZV 2. It is also irrelevant that the laboratory activity with regard to the patent-compliant process was allegedly already discontinued before the orders were served, because the implementation of the patent-infringing process was still advertised on September 26, 2023. The limitation to the protein application obviously does not date from September 26, 2023 either.

2. Violations of sections A.II, III and IV of the orders of September 19, 2023

The defendants also violated sections A.II., III. and IV. of the orders of September 19, 2023 by the actions described in the application for a penalty payment.

According to Art. 25 (a) UPCA, the term "offering" includes any act committed within the scope of the patent in question which, according to its objective explanatory value, makes the subject matter of the demand available in an externally perceptible manner for the acquisition of the power of disposal.

a. Internet presence (<https://nanosting.com>)

On the homepage of the website at the URL <https://nanosting.com>, the CosMx (challenged execution form 1) was still offered on September 26, 2023 (Annex BP ZV 5).

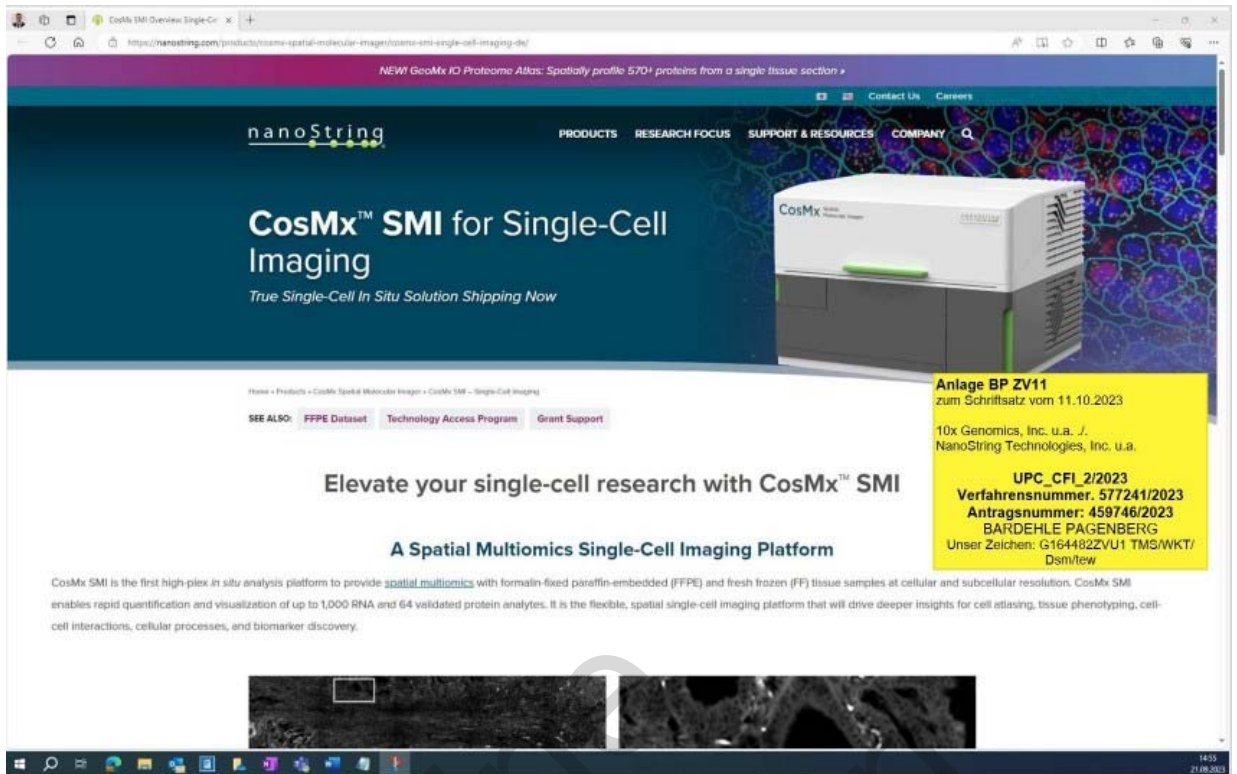


Whether this product presentation on the homepage, which apparently remained unchanged after the decision of September 19, 2023, already constitutes a violation of the orders of September 19, 2023, can be left open; if you follow the "Learn more" button, you can still access the product page with the following image on September 21, 2023, according to Annex BP ZV 11:

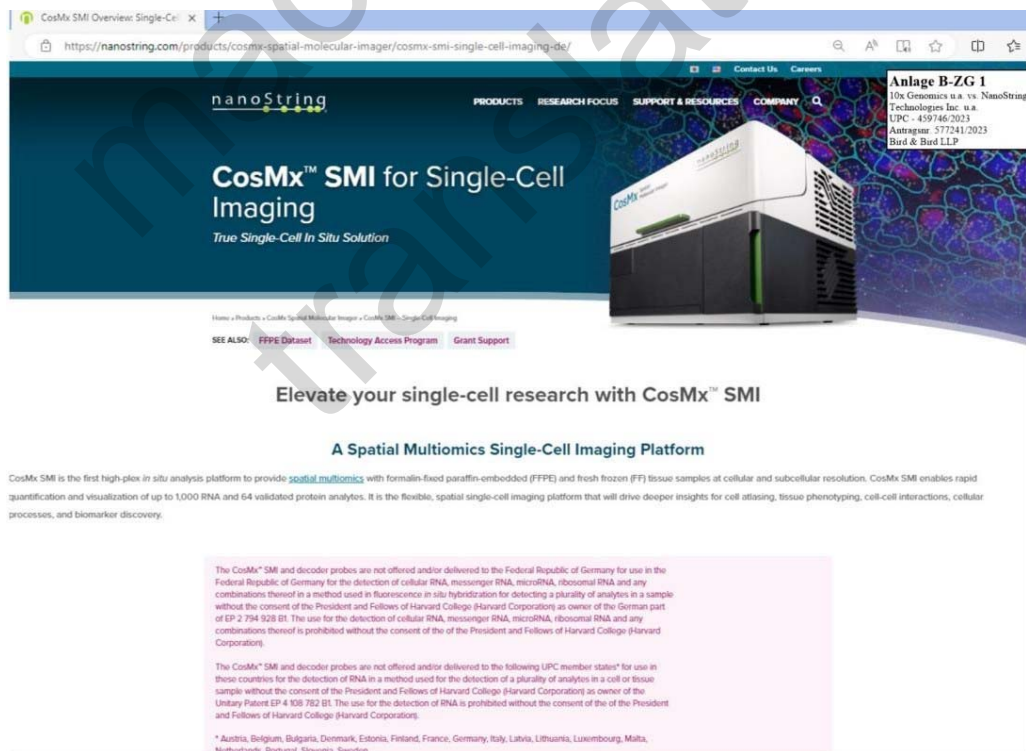


At least the display shown after clicking on the "Learn more" button clearly represents an offer to deliver the CosMx ("Shipping now") from the point of view of the local Division.

Insofar as the defendants submitted Annex B-ZG ¹ⁱ, stating that *on October 6, 2023*, i.e. the day of the response to the application for a periodic penalty payment, a disclaimer corresponding to the order was located below the above image, this does not change the fact that at least on September 21, 2023 (Annex BP ZV 11) such a disclaimer was not yet located there, as the following image excerpt from this annex shows:



Insofar as the defendants claim, by submitting Annex B-ZG ¹¹ (insertion below), that such a disclaimer was already there on September 19, 2023,



After comparing the annexes BP ZV 11 and B-ZG 1, the Local Board must assume that the respondents are making false statements in this respect. It is inexplicable to the Local Board how this disclaimer is supposed to have been inserted on September 19, 2023, but is missing from the screenshot of September 21, 2023, submitted by the applicant. The defendants have also not offered any evidence for their claim that the disclaimer was already inserted on September 19, 2023.

Consequently, by offering CosMx on the product page, the defendants violated Section A.II. of the orders of September 19, 2023. A disclaimer that was only added on October 6, 2023 is irrelevant in view of an infringement that already occurred in September 2023. The applicants did not withhold this information from the local Division, as the disclaimer was obviously only affixed after September 21, 2023.

b. "Spatial Multiomics Summits" from October 10 to 13, 2023 in Paris and Frankfurt

The presentation of CosMx at events in UPC member states ("Spatial Multiomics Summits" from October 10 to 13, 2023 in Paris and Frankfurt; Annex BP ZV 7) was announced on September 26, 2023 without restriction, i.e. also for the purpose of RNA detection, on the website <https://nanosting.com>.

Insofar as the defendants argue that the term "measuring and visualizing the full RNA reactome in situ" used in this context refers specifically to the GeoMx system (i.e. not to the CosMx in dispute), this restriction cannot be inferred from the explanation concerning all devices listed below and preceding their enumeration; the restriction concerning the CosMx ("CosMx ... for protein analysis") on the website in question as of 6 October 2023 speaks for itself in this respect.

Insofar as the defendants point out that, with regard to the presentation of the device in Paris and Frankfurt, Annex BP ZV 7 contains an appropriate notice, this notice was confusing for the target public in that, according to the event announcement of

26 September 2023 in Paris and Frankfurt for unrestricted use ("... measuring and visualizing the full RNA reactome..."). From the perspective of a potential customer, an announcement that a device will also be presented for a purpose that may not be included in the scope of the offer due to a court order is confusing.

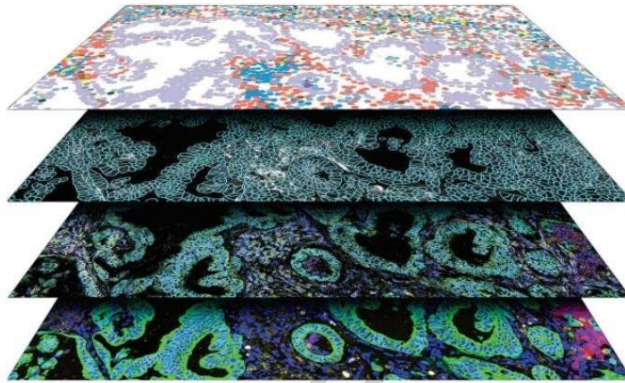
c. "Instrument User Manual" and "Manual Slide Preparation"

The defendants have filed an appeal against paragraphs A.II. and IV. of the order of 19 September by still offering the challenged embodiments 1 (CosMx) and 3 (decoder probes) on 27 September 2023 without providing them with the information prescribed in points A.II. and A.IV. of the orders.

On the version of the operating instructions "Manual Slide Preparation" (Annex BP ZV 10a) downloaded on September 27, 2023 from the page <https://university.nano-string.com/page/document-library>, which concerns the attacked embodiments 1 and 3, there is no reference at all in accordance with the orders of September 19, 2023. Insofar as the defendants argue that Annex BP ZV 10a is an "old version", this is irrelevant; the only decisive factor for determining a violation of the orders of September 19, 2023 is whether such a version was available on the Internet after September 19, 2023. There is also no restriction in the orders to the effect that they only refer to current operating instructions.

The operating instructions for the CosMx™ SMI "Instrument User Manual" and "Manual Slide Preparation" (Appendices BP ZV 9 and 10) downloaded on September 27, 2023 from <https://university.nano-string.com/page/document-library> contain the following note at the bottom of the first page.

Instrument User Manual



MAN-10161-02-1 | Software Version L1 | January 2023

FOR RESEARCH USE ONLY. Not for use in diagnostic procedures.
©2022-2023 NanoString Technologies, Inc. All Rights Reserved.

nanoString

The CosMx™ SMI and decoder probes are not offered and/or delivered to the following UPC member states* for use in these countries for the detection of RNA in a method used for the detection of a plurality of analytes in a cell or tissue sample without the consent of the President and Fellows of Harvard College (Harvard Corporation) as owner of the Unitary Patent EP 4 108 782 B1. The use for the detection of RNA is prohibited without the consent of the President and Fellows of Harvard College (Harvard Corporation). *Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Slovenia, Sweden. The CosMx SMI is not offered and/or delivered to the Federal Republic of Germany for use in the Federal Republic of Germany for the detection of cellular RNA, messenger RNA, microRNA, ribosomal RNA and any combinations thereof in a method used in fluorescence in situ hybridization for detecting a plurality of analytes in a sample without the consent of the President and Fellows of Harvard College (Harvard Corporation) as owner of the German part of EP 2 794 928 B1. The use for the detection of cellular RNA, messenger RNA, microRNA, ribosomal RNA and any combinations thereof in the Federal Republic of Germany is prohibited without the consent of the President and Fellows of Harvard College (Harvard Corporation).

However, due to the font size and in relation to the overall illustration, this does not comply with the requirement of visual prominence laid down in the decision. The notice is clearly printed in small print and has only minimal line spacing. This design of the notice cannot be assessed as "expressly and eye-catchingly emphasized"; rather, its design gives the impression that it is unimportant and can remain unread. It is not a disclaimer that is "prominently positioned on the cover page and clearly highlighted there with a colored box". Contrary to the clear intention of the orders of September 19, 2023, the design does not make it clear to the reader that this is an important notice that should definitely be read. Insofar as the notice was colored red in a later version, this does not change the existing and retrievable design on September 27, 2023.

d. Offer of the contested embodiments with the promotion of the product presentation tour

The offer of a product presentation tour on the website <https://nanosttring.com> (Annex BP ZV 2 dated September 26, 2023) also constitutes a violation of the orders of September 19, 2023.

This is not merely a matter of issuing the CosMx in the laboratory; according to Annex BP ZV 2, the CosMx is offered for test use in the CX-Lab without the instructions required under point A.II. of the instructions, expressly also with regard to RNA analysis. It is undisputed that the contested embodiments 2 and 3 are also used. This constitutes a violation of section A.III. ("... offering detection reagents ... for use with the method ...") and section A.IV. ("... offering decoder probes ... for use with the method ... without ..."); in the case of the use of the decoder probes, the obligation to provide information is not met.

- III. Insofar as the defendants 2) and 3) argue that they are not responsible for the website (www.nanosttring.com), reference should be made to the statements in the decision of September 19, 2023 (section A.I.) regarding the attribution of the offer actions.
- IV. Since the defendants have violated the cease and desist order of the local Division by designing their website in the period until October 6, 2023, the imposition of a penalty payment of € 100,000.00 is necessary but also appropriate to effectively enforce the cease and desist order and to enforce future compliance by the defendants.

Pursuant to Art. 82 para. 4 sentence 2 UPCA, the penalty payment must be proportionate to the importance of the order to be enforced. Correspondingly, the amount of the penalty payment to be paid to the court in the event of a breach must be determined in accordance with R. 354.4 VerfO with regard to the significance of the order in question. The decisive criterion for determining the amount of the penalty payment is therefore the significance of the order and thus ultimately the creditor's interest in its enforcement.

Enforcement. The penalty payment is intended to reliably deter the debtor from future infringements and violations and therefore primarily has a deterrent function. However, as both the English ("penalty payment"; "be sanctioned") and French ("sanctionnée") versions of Art. 82 para. 4 UPG^x make clear, the penalty payment is also a penalty-like sanction for the violation of the court prohibition, which is why the imposition of penalty payments also requires fault on the part of the debtor as an unwritten element of the offense.

This dual purpose of the penalty payment requires the penalty payment to be calculated primarily with regard to the debtor and their conduct. In particular, the type, scope and duration of the infringement, the degree of culpability, the benefit to the infringer from the infringing act and the dangerousness of the committed and possible future infringing acts for the infringed party must be taken into account. The more frequently and intensively the debtor has violated the cease and desist order imposed on him, the more clearly he has expressed his unwillingness to comply with the cease and desist order. This must be taken into account when calculating the penalty payment: If the debtor has already violated the cease and desist order several times in the past, the pressure required to force him to comply with the order in the future is increased. If, on the other hand, the debtor has already shown his willingness to comply with the cease and desist order in the past, this can reduce the necessary pressure and thus the penalty payment to force the debtor to comply with the order in the future. When assessing the intensity of the infringement, the debtor's entire conduct must therefore be taken into account. In particular, the type, scope and duration of the infringement, the degree of culpability and the dangerousness of the committed and possible future infringements for the creditor must be taken into account

(see already LK Düsseldorf
UPC_CFI_177/2023/ACT_525740/2023/App_552740/2023).

Based on these principles, the local division considers the imposition of a penalty payment of EUR 100,000.00 to be justified, but also appropriate in order to force the defendants to comply with the injunction imposed on them in the future. Each of the defendants is individually obliged to pay the penalty payment imposed; the payment is deemed to have been settled for all defendants as soon as the total amount has been received by the Unified Patent Court.

All of the infringements that are the subject of the application for a periodic penalty payment dated September 28, 2023 are based on the design of the website of the defendants' group of companies. It appears that the defendants did not fully adapt this in a timely manner after service of the orders. Since the asserted individual infringements are all due to the fact that the website was not adapted in a timely manner, this is a uniform cause, so that a uniform penalty payment was to be imposed. When determining the amount of the penalty payment, it had to be taken into account that the period between the service of the orders of September 19, 2023 and the application for the penalty payment is short. It also had to be taken into account that the defendants had used the application for a penalty payment as an opportunity to make further adjustments to the website. On the other hand, the large number of infringements found, which were at least grossly negligent, were to be assessed against the defendants. It also had to be taken into account that each of the devices offered by the applicants (CosMx) is associated with considerable sales, whereby this also affects the downstream market for reagents and decoder probes; this results in a high risk of the committed and possible future infringements for the applicants.

- V. The decision on costs is based on a corresponding application of rule 118.5 sentence 1 VerfO. When allocating the costs, the local division took into account that all of the violations asserted by the applicants were also to be considered violations, meaning that the applicants were completely successful with their application in this respect.

However, the fact that the applicants have formally applied for the imposition of significantly higher periodic penalty payments does not, in the view of the Division, lead to the applicants having to bear part of the costs of the periodic penalty payment proceedings, taking into account the fundamental considerations on the allocation of costs in Art. 69 (1) and (2) UPCA, since the determination of the amount is at the discretion of the court (Rule 354.4 RP) and the amount stated by the applicant can at most have the character of a proposal in this respect.

- VI. Since the present order is one of the first to impose periodic penalty payments for breach of an order of the court, the Local Division considers it appropriate to allow the appeal for both parties and thus give them the opportunity to have the order reviewed by the Court of Appeal (Art. 73 (2) (b) (ii) UPCA, Rule 220.2, 354.4 VerfO).
- VII. There was no reason to make the order dependent on the provision of a security within the meaning of Rule 352.1 VerfO.

Arrangement

- I. A penalty payment to be paid to the Unified Patent Court in the total amount of € 100,000.00 is imposed on the defendants for violation of the orders issued in proceedings UPC_CFI_2/2023 on September 19, 2023.
- II. In all other respects, the application for a penalty payment is dismissed.
- III. The costs of the penalty payment proceedings are imposed on the defendants.
- IV. This order is immediately enforceable.
- V. The appeal is allowed.

VI. The amount in dispute for the penalty payment proceedings is set at € 250,000.00.

Dr. Zigann Presiding Judge	Matthias ZIGANN Digitally signed by Matthias ZIGANN Date: 2023.12.05 15:09:12 +01'00'
Pichlmaier Rapporteur	Tobias Günther Pichlmaier Digitally signed by Tobias Günther Pichlmaier Date: 2023.12.05 15:06:24 +01'00'
Kupecz Legally qualified judge	András Ferenc Kupecz Digitally signed by András Ferenc Kupecz Date: 2023.12.05 15:11:35 +01'00'
Enderlin Technically qualified judge	Eric, André Enderlin Signature numérique de Eric, André Enderlin Date: 2023.12.05 15:40:43 +01'00'

INFORMATION ABOUT THE APPOINTMENT

Both parties may appeal against this order within 15 days of its notification (Art. 73 (2) (b) (ii) UPCA, Rules 220.2, 354.4 RP).

PAYMENT INFORMATION:

The penalty payment is to be paid to the court to the following account:

LU55 0019 7355 1895 9000.