

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

10X GENOMICS, INC. and PROGNOSYS
BIOSCIENCES, INC.,

Plaintiffs,

v.

NANOSTRING TECHNOLOGIES, INC.,

Defendant.



C.A. No. 21-cv-653-MFK

PUBLIC REDACTED VERSION

**PLAINTIFFS' CONSOLIDATED BRIEF (1) IN OPPOSITION TO NANOSTRING
TECHNOLOGIES, INC.'S SUMMARY JUDGMENT AND DAUBERT BRIEF AND (2)
REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT OF NO
INVALIDITY FOR NO INDEFINITENESS AND DAUBERT MOTION TO EXCLUDE
CERTAIN OPINIONS OF MICHAEL LASINSKI**

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CUMULATIVE TABLE OF PLAINTIFFS' EXHIBITS

Ex. No.	Description	Declaration to which the Exhibit is attached
1	U.S. Patent No. 11,293,917, bearing production numbers 10XN653-00171129-10XN653-00171163	D.I. 227 (Plaintiffs Decl.)
2	Excerpts of the Expert Report of Rahul Satija, D. Phil., dated April 24, 2023	D.I. 227 (Plaintiffs Decl.)
3	Excerpt of the prosecution history of U.S. Patent No. 11,293,917, dated January 19, 2021, bearing production numbers 10XN653-00170520-10XN653-00170537	D.I. 227 (Plaintiffs Decl.)
4	Excerpt of the prosecution history of U.S. Patent No. 11,293,917, dated March 3, 2021, bearing production numbers 10XN653-00170556-10XN653-00170588	D.I. 227 (Plaintiffs Decl.)
5	Excerpt of the prosecution history of U.S. Patent No. 11,293,917, dated May 3, 2021, bearing production numbers 10XN653-00170596-10XN653-00170613	D.I. 227 (Plaintiffs Decl.)
6	Excerpt of the prosecution history of U.S. Patent No. 11,293,917, dated October 14, 2021, bearing production numbers 10XN653-00170949-10XN653-00170958	D.I. 227 (Plaintiffs Decl.)
7	Excerpt of the prosecution history of U.S. Patent No. 11,293,917, dated January 14, 2022, bearing production numbers 10XN653-00171022 - 10XN653-00171032	D.I. 227 (Plaintiffs Decl.)
8	Excerpts of the Opening Expert Report of Jeremy Edwards Regarding Validity, dated March 24, 2023	D.I. 227 (Plaintiffs Decl.)
9	Highlighted excerpts of the transcript of the deposition of Jeremy Edwards, dated June 9, 2023	D.I. 227 (Plaintiffs Decl.)
10	U.S. Patent No. 11,008,607, bearing production numbers 10XN653-00019775-10XN653-00019806	D.I. 227 (Plaintiffs Decl.)
11	U.S. Patent No. 10,961,566, bearing production numbers 10XN653-00019649-10XN653-00019681	D.I. 227 (Plaintiffs Decl.)
12	U.S. Patent No. 10,662,467, bearing production numbers 10XN653-00019618-10XN653-00019648	D.I. 227 (Plaintiffs Decl.)
13	U.S. Patent No. 10,996,219, bearing production numbers 10XN653-00019713-10XN653-00019743	D.I. 227 (Plaintiffs Decl.)
14	U.S. Patent No. 10,472,669, bearing production numbers 10XN653-00019588-10XN653-00019617	D.I. 227 (Plaintiffs Decl.)
15	Exclusive License Agreement between REDACTED REDACTED	D.I. 227 (Plaintiffs Decl.)
	or	

Ex. No.	Description	Declaration to which the Exhibit is attached
	"NanoString License"), bearing production numbers NANO10x-00022551-NANO10x-00022577	
16	Expert Report of Michael Lasinski, dated April 24, 2023	D.I. 227 (Plaintiffs Decl.)
17	Highlighted excerpts of the transcript of the deposition of John Quackenbush, Ph.D., dated May 30, 2023	D.I. 227 (Plaintiffs Decl.)
18	Highlighted excerpts of the transcript of the deposition of Joseph Beechem, dated October 6, 2022	D.I. 227 (Plaintiffs Decl.)
19	Highlighted excerpt of the transcript of the deposition of Brad Gray, dated October 25, 2022	D.I. 227 (Plaintiffs Decl.)
20	Highlighted excerpts of the transcript of the deposition of Michael Lasinski, dated June 8, 2023	D.I. 227 (Plaintiffs Decl.)
21	License Agreement between 10x and Prognosys (the "Prognosys License), signed November 18, 2018, bearing production numbers PROG-00004841-PROG-00004867	D.I. 227 (Plaintiffs Decl.)
22	Excerpt of the Expert Report of Julie Davis, dated March 24, 2023	D.I. 227 (Plaintiffs Decl.)
23	Excerpt of Exhibit 3 to the June 8, 2023 deposition of Michael Lasinski REDACTED bearing production numbers 10XN653-00033317- 10XN653-00033335 and REDACTED	D.I. 227 (Plaintiffs Decl.)
24	Reply Expert Report of Julie Davis, dated May 24, 2023	D.I. 227 (Plaintiffs Decl.)
25	U.S. Patent No. 10,983,113, bearing production numbers 10XN653-00019682-10XN653-00019712	D.I. 227 (Plaintiffs Decl.)
26	U.S. Patent No. 11,001,878, bearing production numbers 10XN653-00019744-10XN653-00019774	D.I. 227 (Plaintiffs Decl.)
27	Exhibit 2 to the June 8, 2023 deposition of Michael Lasinski (excerpt of REDACTED bearing production number 10XN653-00184526)	D.I. 227 (Plaintiffs Decl.)
28	Excerpts of the Reply Expert Report of Dr. Jeremy S. Edwards to the Expert Report of Rahul Satija, dated May 24, 2023	Plaintiffs Suppl. Decl.
29	Supplemental excerpts of the Expert Report of Rahul Satija, D. Phil., dated April 24, 2023 (additional excerpts added to those from Exhibit 2)	Plaintiffs Suppl. Decl.
30	Excerpts of the Expert Report of Rahul Satija, dated	Plaintiffs Suppl. Decl.

Ex. No.	Description	Declaration to which the Exhibit is attached
	June 15, 2023	
31	Excerpts of Plaintiffs' Second Supplemental Objections and Responses to NanoString's First Set of Interrogatories (Nos. 3, 4, 5), dated May 31, 2022	Plaintiffs Suppl. Decl.
32	Excerpts of Plaintiffs 10x Genomics, Inc. and Prognosys Biosciences, Inc.'s Final Rebuttal Contentions Regarding Validity, dated August 26, 2022	Plaintiffs Suppl. Decl.
33	Excerpts of the Expert Report of Julie Davis, dated March 24, 2023(additional excerpts added to those from Exhibit 22)	Plaintiffs Suppl. Decl.
34	Excerpts of the transcript of the deposition of Julie Davis, dated June 7, 2023	Plaintiffs Suppl. Decl.
35	Excerpts of the transcript of the deposition of Dr. Stacey Gabriel, dated November 1, 2022	Plaintiffs Suppl. Decl.

**I. THE PROGNOSYS SPECIFICATION DESCRIBES THE CLAIMED INVENTIONS
IN ACCORDANCE WITH 35 U.S.C. § 112**

A. Introduction

There is no mismatch between the Asserted Claims, as recently construed by the Court, and the written description of the Prognosys Patents. NanoString's summary judgment argument turns on the same issue the parties briefed, and the Court decided at *Markman*, whether the disclosed technologies, options, and goals of the invention show that the patent was drafted to encompass encoding and patterning off the sample in addition to on the sample. The Court's order identifies multiple disclosures and examples from the written description that support the claims as construed, including techniques of sample segmentation, liquid-handling for targeted removal, and nucleic acid tagging for encoding sample locations after removal from the sample.

The most important change between NanoString's loss at claim construction and NanoString's attempt to renew these arguments at summary judgment is the procedural posture. Now, after full discovery, Prognosys and 10x's showing that the ordinary meaning of the claims is fully supported and was in the possession of Dr. Chee, the inventor, is fleshed out in thorough detail by an expert witness as an *issue of fact*. Dr. Satija addresses the dispositive technical issues concerning what was known in the art in 2011, how a POSA would understand the disclosures in that context, and why the examples and options in the patents evidence the inventor's possession of a broader and more flexible set of inventions than NanoString continues to allege. To the extent these issues remain in dispute, they are genuine disputes of fact for trial.

B. Legal Standard

A patent is presumed valid. 35 U.S.C. § 282. Movant bears the burden to prove invalidity by clear and convincing evidence. *Microsoft Corp. v. I4I Ltd. P'ship*, 564 U.S. 91, 97 (2011).

Summary judgment is appropriate only when "the movant shows that there is no genuine

dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). The movant bears the burden of establishing there is no genuine issue of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The evidence of the non-moving party is to be believed, “and all justifiable inferences are to be drawn in his favor.” *Id.* at 255.

The test for sufficiency of a patent’s written description “is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *CenTrak, Inc. v. Sonitor Techs., Inc.*, 915 F.3d 1360, 1365 (Fed. Cir. 2019) (quoting *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010)). “[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.” *Ariad*, 598 F.3d at 1351. Whether a claimed invention satisfies the written description requirement is a question of fact. *Id.*

C. The Prognosys Specification Describes the Claims As Construed

1. This Court Found that the Disclosure Supports the Ordinary Meaning of the Claims and the Evidence Confirms the Scope of the Disclosure

The Prognosys patents recognized the need for “reproducible, high-resolution spatial maps of biological molecules in tissue,” (Ex. 1¹, (“917 Patent”), 2:9-10)², and that the goal of the invention was to “analyze at high resolution the spatial expression patterns of large numbers of genes, proteins, or other biologically active molecules simultaneously.” Ex. 28, (Edwards Reply Rpt.) ¶ 96. Dr. Chee’s solutions to the need in the art were methods and technologies for high

¹ “Ex. _” refers to exhibits submitted by Plaintiffs to the Declaration of Kiley White (D.I. 227) or the Supplemental Declaration of Kiley White submitted concurrently.

² All patent citations refer to U.S. Patent No. 11,293,917 (Ex. 1) unless noted.

plex spatial mapping through adapting methods from massively parallel digital sequencing technologies, including next-generation sequencing (NGS) and NGS-like data processing.

Dr. Chee's patents teach enabling spatial mapping with an encoding scheme that occurs either through targeted delivery (where different encoding agents are delivered in a targeted way to the tissue sample so that upon removal location is already embedded in the reagent) or targeted removal (where discrete sections are removed and transferred to another vessel in a way that preserves information about spatial position in the pattern of reagents used off sample to generate encoded nucleic acids for sequencing). The patent discloses liquid-handling technologies designed to implement both types of methods—capillary channels, pumps, and other components that add or remove liquid and reagents from whole samples or segmented areas for targeted removal. The patent also teaches encoding methods that work on or off of the sample, including tags and sequencing adapters used to generate new, encoded nucleic acids at different points in a workflow.

The Asserted Claims include claims that cover both on- and off-sample encoding.

Representative Claims 1-3 of the 607 Patent are shown below.

1. A method of detecting a target mRNA in a tissue sample, comprising:

contacting³ a tissue sample with a plurality of probes, wherein a probe of the plurality of probes comprises a capture agent that specifically binds a target mRNA of the tissue sample and is coupled to an oligonucleotide comprising a sequence;

generating a nucleic acid molecule comprising all or a portion of the sequence of the oligonucleotide or a complement thereof and one or more nucleic acid tags that can be used to determine a location of the target mRNA in the tissue sample; and

³ Claim 1 in each of the method patents at issue all contains a step of introducing probes to the sample, either by "contacting a tissue sample with a plurality of probes" or "delivering a plurality of probes to a tissue sample." This Court found the contacting and delivering steps should be construed "together and with the same result" of plain and ordinary meaning. D.I. 207 at 10-11.

determining all or a portion of a sequence of the nucleic acid molecule or a complement thereof to detect the target mRNA and determine its location in the tissue sample.

2. The method of claim 1, further comprising separating unbound probes of the plurality of probes that do not interact with the target mRNA from the tissue sample.

3. The method of claim 2, further comprising removing the oligonucleotide from a region of interest in the tissue sample prior to generating the nucleic acid molecule.

Ex. 10, 607 Patent, Claims 1-3. Because these claims do not specify a location for “generating a nucleic acid molecule comprising . . . tags that can be used to determine a location,” the claim is directed to both on-sample generation of encoded nucleic acids, and also off-sample coding of nucleic acids that have been removed from “region[s] of interest” in a targeted way, encoding the pattern of removal by using different encoding reagents off-sample for different segments.

During *Markman*, NanoString posited that the only way to achieve spatial mapping within the patents was “by preserving location information as probes are *introduced* to the tissue—not as they are *removed*.” D.I. 207 at 20. Rejecting that the patents were so limited, the Court found “maintaining the integrity of spatial patterns—through preserving location information in some form—can be accomplished in a number of ways,” and “[w]hat is central to the patented system is its ability to ensure discrete delivery or retrieval.” *Id.* at 14.

The Court based its finding that the claims were not limited to spatial patterning and encoding on the tissue sample on the express disclosures in the specification of methods, technologies, and techniques for spatial patterning through targeted removal and encoding off tissue. First, the Court noted that off-tissue encoding was in line with the intent of the invention and Dr. Chee never “disparage[d] the absence of spatial patterned reagent delivery.” *Id.* at 8. Further, each construction was based on disclosures to support claim breadth, which alone is sufficient to support finding adequate written description support. Additional evidence including

expert opinion testimony and extrinsic evidence further confirms this Court’s understanding of how one skilled in the art would understand the patented invention—that central to the patented invention is preserving the encoding scheme either through targeted delivery or targeted removal.

a. Segmenting and Reagent-Handling Technologies

In construing “delivering a plurality of probes to a tissue sample” to have its plain and ordinary meaning, the Court found that “the patents describe multiple ways for delivering reagents with and without a spatial pattern,” including targeted delivery of encoded probes (Fig. 1), indiscriminate delivery of probes followed by targeted delivery of encoding reagents (Fig. 2), and indiscriminate delivery followed by targeted removal because “the specification describes that the probes can be delivered to ‘segment[ed] or sequester[ed]’ regions for ‘biological target determination.’” D.I. 207 at 6-7 (quoting 16:41-45). The specification states at 16:41-45:

For several applications, it may be preferred to segment or sequester certain areas of the biological samples into one or more assay areas for different reagent distributions and/or biological target determination. The assay areas may be physically separated using barriers or channels.

This Court reasoned that “the use of specific areas and channels in the segmentation method allows reagents to be removed in a targeted fashion that preserves location information.” D.I. 207 at 7. Because targeted removal effects spatial mapping by encoding off tissue, “[t]he claims and the shared specification thus indicate that spatial patterning must occur somewhere in the process and with some form of reagent—but they do not disclaim all formulations other than ‘immobilizing a plurality of probes on the tissue sample in a spatial pattern.’” D.I. 207 at 8.

In construing “reagent delivery system” to have its ordinary meaning, the Court found that “the ‘917 patent describes a number of different methods and tools to deliver reagents to and collect them from discrete portions of a tissue sample in a way that preserves the integrity of the encoding scheme,” including “through a ‘flow-cell’ that can deliver reagents ‘across the

substrate’ or ‘only to certain portions of the array, restricting the amount and type of reagent delivered to any specific section of the array.’” D.I. 207 at 14 (quoting 27:29-36). The relied upon passage states:

In a more specific example, one or more flow-cells can be attached to the substrate from above. The flow-cell can include inlet and outlet tubes connected thereto and optionally an external pump can be used to deliver the sample or reagents to the flow-cell and across the substrate. The flow cell is configured to deliver reagents only to certain portions of the array, restricting the amount and type of reagent delivered to any specific section of the array.

The Court also cited portions of the specification (D.I. 207 at 15) that state:

The flow-based systems for reagent delivery in the present invention can include one or more pumps, valves, fluid reservoirs, channels, and/or reagent storage cells. 917 Patent, 27:12-15.

Pumps generally include any mechanism for moving fluid and/or reagents disposed in fluid. In some examples, the pump can be configured to move fluid and/or reagents through passages with small volumes (i.e., microfluidic structures). The pump can operate mechanically by exerting a positive or negative pressure on fluid and/or on a structure carrying fluid. 917 Patent, 27:44-50.

In construing “removing the oligonucleotide from the region of interest” (and rejecting NanoString’s argument that removal must occur *en masse* by elution) this Court explained how the patent disclosures of segmenting by physical barriers or channels along with liquid handling technologies for discrete fluid delivery and removal effected targeting removal. D.I. 207 at 21-22. The Court reasoned that the specification “does describe alternative techniques and technologies for separating oligonucleotides from probes beyond elution,” including that the “patent discloses [] moving fluid into segmented or sequestered channels. Another alternative is found in claim 5 of the ’917 patent, which recites that the ‘reagent delivery system [is] to deliver an elution composition sequentially to the first and second regions of interest to remove the first and second portions of the tissue sample.’” D.I. 207 at 21 (citing 34:14-17).

The Court’s observations about how the specification supports an ordinary meaning of

the claims that encompasses encoding through either removal or delivery, and use of encoding reagents both on- and off-sample, is backed up by substantial expert testimony. Plaintiffs' expert Dr. Satija opines as to how one skilled in the art would understand the patents as of April 5, 2011 (the filing date of the full written description) including the disclosures relied upon by this Court. Dr. Satija opines at length how "[t]he patent teaches techniques, technologies, and methods to associate spatial identity with target molecules without performing targeted delivery in a spatial pattern of probes or oligonucleotides to the tissue sample" based on disclosures that a POSA would understand describe each of the following: delivering reagents indiscriminately to segmented areas (Ex. 29, (Satija Rep.) ¶¶ 63, 64, 82-86, 90, 100, 101, 104)), followed by targeted removal from each sub-sample (segment) by the described liquid handling technologies (Ex. 29, ¶¶ 62, 64, 87-90, 93, 104, 108-117, 128), adding encoding tags including during the standard NGS sample preparation workflow (Ex. 29, ¶¶ 61, 65, 86, 91, 92, 94-98, 100, 101, 104, 121-122, 132-134) by delivering each subsample to a standard reaction vessel such as a microwell plate where each well can correspond to a sub-sample so as to preserve spatial information (Ex. 29, ¶¶ 65, 85, 86, 88, 97, 100, 198, 174), followed by decoding through sequencing to associate targets with their spatial location (Ex. 29, ¶¶ 86, 98, 101, 122, 175). Dr. Satija explains how a POSA would understand the passages individually and how a POSA would understand them together to disclose methods for spatial mapping where encoding happens off-tissue.

In opining that the specification discloses encoding through targeted removal, Dr. Satija explains how a POSA would understand relevant disclosures (including segmenting and liquid-handling technologies disclosures) and how the liquid-handling instruments would be used to remove reagents from discrete segments to effect targeted removal. Dr. Satija explains that a

POSA reading the patent's description of "barriers or channels" to define regions for performing spatial assays (16:41-45, 24:38-44) would understand "the specification is describing an invention that enables the preservation of spatial (segment) information when probe reagents are delivered indiscriminately." **Ex. 29**, ¶ 84. Dr. Satija explains that a POSA would understand segmenting is described for two different purposes (either "different reagent distribution" or "biological target determination"), and that "segmenting or sequestering areas for 'biological target determination' without a 'different reagent distribution' represents a form of non-targeted delivery (i.e. delivering the same reagents to multiple segments)." **Ex. 29**, ¶ 85. The physical separation creates separate sub-samples that allows the reagents to be "subsequently removed in a targeted fashion (i.e. separately removing reagents from different segments)." **Ex. 29**, ¶ 85.

Dr. Satija also explains how a POSA would understand that this targeted removal from segments would preserve spatial information. By "removing reagents from different segments [it] can preserve the material in each segment as a separate sub-sample." **Ex. 29**, ¶ 85. For example, each regional sub-sample can be transferred to a typical well-plate used in NGS sample prep that "permit[s] 'biological target determination' on a segment-by-segment basis" (**Ex. 29**, ¶ 90) while "preserv[ing] location information without requiring that probes be delivered in a spatial pattern." **Ex. 29**, ¶ 85. As discussed below, Dr. Satija also explains that the patent discloses various technologies for moving fluid into and from each discrete segment for the purpose of maintaining the encoding scheme, and that upon targeted removal of reagents, the specification discloses tags that can be added to encode spatial location for further analysis. **Ex. 29**, ¶ 86.

Dr. Satija also explains that a POSA would understand that the patent's descriptions of fluid-handling technologies, including descriptions of flow-based technologies, bi-directional pumps, and valve systems, that these technologies can be used for removing reagents and not just

one-way delivery. **Ex. 29**, ¶¶ 62, 87-89. Dr. Satija explains that a POSA reading the patent's descriptions of "flow-based technologies that include channels, such as microfluidic devices, flow cells, and microcapillaries" would understand that they can "be used both for applying and removing reagents from precisely defined segments." **Ex. 29**, ¶¶ 64, 88, 90. Dr. Satija explains that a POSA reading the specification's description that "the pump can operate mechanically by exerting a positive or negative pressure on fluid and/or on a structure carrying fluid" would understand this to describe "how pumps can be configured to move fluid and/or reagents through passages in two different directions," with positive pressure used to "deposit[] reagents into a defined region" and negative pressure to "move fluid in the opposite direction (i.e. removing reagents out of a defined region)." **Ex. 29**, ¶ 88. Dr. Satija also explains that a POSA reading the descriptions of the valve systems would understand that they allow bi-directional movement of fluid through specific channels, enabling "both the introduction and removal of fluids from specific segments defined by channels." **Ex. 29**, ¶ 88.

Dr. Satija explains that, in addition to a POSA's understanding of how the reagent handling technologies operate (including for removing reagents), the patent links liquid-handling reagents and segments together. For example, the patent states:

The reagent delivery system of the invention can be any system that allows the *delivery of reagents to discrete portions* of the array in order *to keep the integrity of the defined spatial patterns of the encoding scheme*. Such discrete delivery can be achieved in a number of different ways. In one exemplary aspect, the reagent delivery system can be a flow-based system. The flow-based systems for reagent delivery in the present invention can include one or more pumps, valves, fluid reservoirs, channels, and/or reagent storage cells. Such a reagent delivery system is *configured to move fluid in contact with a discrete section* of the substrate surface. **Ex. 29**, ¶ 89 (quoting 917 Patent, 27:6-17).

Dr. Satija explains that a POSA reading this passage would further understand that the "discrete sections" reference in "reagent delivery system is configured to move fluid in contact with a discrete section" is referring to, for example, "a section where reagents are sequestered by

physical barriers or channels,” as described at 16:36-41, 24:28-37. **Ex. 29**, ¶¶ 89-90. Because a POSA would understand that the patent “describes different reagent handling technologies suitable for moving fluids to and from discrete sections [] permit ‘biological target determination’ on a segment-by-segment basis”, this “segmented identification of biological targets is compatible with indiscriminate delivery of probes and represents an alternative workflow to the delivering encoding agents to the tissue in a defined spatial pattern.” **Ex. 29**, ¶ 90.

Dr. Satija explains why a POSA reading the patent’s teaching of segmenting and sequestering in context would confirm that “mov[ing] fluid in contact with a discrete section” is one way to “keep the integrity of the defined spatial patterns of the encoding scheme” the patent is “presenting a system capable of associating biological molecules with specific spatial locations” even “in the absence of spatially patterned delivery.” **Ex. 29**, ¶¶ 89-90. Dr. Satija explains that a POSA would understand that when one uses reagent handling technologies to remove reagents from the segmented areas, each sub-sample would be transferred to a separate reaction vessel like a well one at a time to maintain the integrity of the encoding scheme and allow for subsequent encoding for further analysis. **Ex. 29**, ¶¶ 89, 90, 94, 97. Dr. Satija explains that a POSA would understand that because encoding can happen in a subsequent step off tissue after section-by-section removal of reagents. **Ex. 29**, ¶ 90. Consistent with this understanding, the specification discloses various tags that a POSA would understand to encode the spatial information off tissue after targeted removal, as discussed next.

b. Adding Encoding Tags Off-Tissue

In addition to enabling spatial patterning through targeted removal of reagents from segmented areas, the patents describe off-sample encoding and generation of tagged nucleic acids to preserve location information for segments within samples. The patent relies upon known NGS technologies (including sequencing adapters (7:1-33, 13:1-14, 14:61-15:3, 19:7-38,

25:52-26:11), PCR amplification (13:1-14, 14:6-14, 14:61-15:3, 23:53-63, 25:52-26:11), and commercial NGS platforms, patents, and publication (19:8-38) where tagging during the NGS workflow necessarily happens off-tissue. The patent also describes tagging after cleaving and collecting probes. 10:11-33. The Court at *Markman* found many of these disclosures supported finding the claim scope of “generating a nucleic acid molecule comprising . . . the sequence of the oligonucleotide . . . and one or more nucleic acid tags that can be used to determine a location of the target” to include tagging or encoding both on and off the tissue. D.I. 207 at 12-13. The opinion testimony of Dr. Satija as to how a POSA would understand the invention based on the specification including documentary evidence further confirms this Court’s findings and provides substantial evidence supporting the validity of these claims for trial.

In construing “generating” to have its plain and ordinary meaning (and rejecting that generating must occur on the tissue in a spatial pattern) the Court noted that while generating happens after contacting but before determining, generating is not described as constrained to the sample. D.I. 207 at 12-13. The Court provided multiple examples from the specification of generating being accomplished off-tissue, including “adding oligonucleotide ‘tags’ to probes that have been transformed by cleavage, by PCR amplification (which occurs off the tissue), or with sequencing adapters.” *Id.* at 13. Plaintiffs’ expert, Dr. Satija, details how and why these steps happen off tissue, and explains how one skilled in the art would understand the patent’s NGS and tagging references in the context of the background knowledge of those skilled in the art.

(1) Sample Indexing

Dr. Satija opines that a POSA reading the patent’s disclosures relating to sample indexing, including sequencing adapters, PCR amplification, and commercial NGS platforms, related patent documents, and journal publications, would understand that the patent describes adding spatial coding tags off-tissue during the “next-generation sequencing library preparation to

distinguish one sample location from other sample locations.” **Ex. 29**, ¶¶ 94-100. Based on these NGS-related disclosures, along with the segmentation and reagent handling technologies, Dr. Satija opined “[a] POSA would understand that sample multiplexing, which is a common step in a NGS workflow, provides a way to add tags after collection from segmented areas to preserve and track location information.” **Ex. 29**, ¶ 94; *see* ¶¶ 94-100.

Dr. Satija explains that as of 2011, NGS was “common in the art, and was widely appreciated as a highly parallel method for DNA sequence analysis.” **Ex. 29**, ¶ 95. Dr. Satija notes that the patent itself “describes a variety of NGS methods that are commercially available or described in patent documents and journal articles.” **Ex. 29**, ¶ 94 (citing 19:8-38). To illustrate that NGS was common in the art, Dr. Satija cites to exemplary technological documents. *See* **Ex. 29**, ¶ 95 (citing Voelkerding, “Next-Generation Sequencing: From Basic Research to Diagnostics,” a 2009 review article discussing the numerous commercial NGS platforms (and a prior art reference NanoString relied upon to show how common NGS was at the time of the invention); a 2011 Illumina patent application (cited prior art for the patents in suit); and a 2010 user guide from the commercial Illumina NGS platform).

Dr. Satija explains that as of 2011, NGS was “widely appreciated as a highly parallel method for DNA sequence analysis.” **Ex. 29**, ¶ 95. One of the advances of NGS sequencing was that it “permit[ted] multiplexing, where molecules from multiple samples can be sequenced together as part of the same sequencing run.” **Ex. 29**, ¶ 98. NGS allowed for multiplexing because, during the sample preparation workflow to enable analysis on the sequencer, “unique index codes (‘sample barcodes’ or ‘tags’)” would be introduced “onto the sequencing library molecules from an individual sample.” **Ex. 29**, ¶ 98. These unique tags could “distinguish molecules originating from one sample from molecules originating from another.” **Ex. 29**, ¶ 98.

Dr. Satija explains that sample indices allow for multiplexing because “the index sequences retain the information for each molecule’s sample-of-origin.” **Ex. 29**, ¶ 98. Because the origination site was maintained, multiple samples could be pooled together. **Ex. 29**, ¶ 100. As articulated in the Prognosys patents a “POSA would understand that multiplexing through NGS addresses the insufficient plexy of in-situ hybridization.” **Ex. 29**, ¶ 101 (citing 1:60-63).

Dr. Satija opines that, by 2011, a POSA would be familiar with the basic NGS workflow steps, including that the “preparation process involves fragmenting the input DNA and adding specialized adapter sequences . . . [to] enable hybridization to the surface of the Illumina sequencing flow cell” (**Ex. 29**, ¶ 96), and preparation also included a “process to introduce unique index codes (‘sample barcodes’ or ‘tags’)” for multiplexing. **Ex. 29**, ¶ 98. Dr. Satija explains that ligation and PCR are common laboratory techniques that would be implemented to add the sequencing adapters to the fragment, and PCR steps could also be used to subsequently amplify the molecules, and that these same laboratory techniques would be used to add index tags next to the adapters. **Ex. 29**, ¶ 96. Dr. Satija explains that “[i]n keeping with standard practice in the art, the patent teaches adding sequencing adapters to probes via PCR, [a] POSA would know that this molecular reaction would occur away from the tissue, for example in a test tube, or in a well of a microwell plate.” **Ex. 29**, ¶ 97 (quoting 13:1-14, 25:52-55).

Dr. Satija explains that sample multiplexing is also a common step in an NGS workflow (**Ex. 29**, ¶ 94), that the index tags that are used for multiplexing would be added using the same standard laboratory techniques that are used to add the sequencing adapters, including ligation and PCR (**Ex. 29**, ¶ 98), and that index tags “can be placed adjacent to the sequencing adapters” (**Ex. 29**, ¶ 98). Dr. Satija opines that— “consistent with the teachings of the patent,” (19:8-38)— a “POSA would understand that performing tagging after removal from the tissue (i.e., ‘off-

sample') can be accomplished during next-generation sequencing library preparation to distinguish one sample location from other sample locations." **Ex. 29**, ¶ 94.

Dr. Satija explains how a POSA would understand that the patent is describing an alternative to spatial encoding on the tissue based on the NGS-related disclosures and segmentation for biological target determination. **Ex. 29**, ¶ 100. First, Dr. Satija explains that the sub-samples in each segment allow for independent analysis, and that a POSA would understand sample index tagging to be compatible with segmenting for biological target determination in that a POSA "would understand that when using the routine multiplexing techniques present in the described Illumina systems during biological target determination, the amplicons or 'tags' are added during library preparation away from the tissue sample to distinguish libraries of material to be sequenced from one another." *Id.* Dr. Satija explains how segmenting followed by NGS sample prep allows the tags "to be associated with the region or segment that it was collected from" and that "[s]equencing deconvolutes the tags for location association with the target." *Id.* Segmenting with sample indexing meets the invention's goal by "address[ing] the limited plexity of biological targets that can be measured via in-situ hybridization" and that "combining segmentation with next-generation sequencing provides the user 'the ability to look at many different biological targets in many locations, providing the resolution of in situ hybridization with the highly-parallel data analysis of sequencing.'" **Ex. 29**, ¶ 101 (quoting 2:34-36).

(2) Tagging Cleaved Probes

As discussed above, in furtherance of finding that nucleic acid molecule generation can happen on or off tissue, this Court relied upon the disclosure of adding oligonucleotide 'tags' to probes that have been transformed by cleavage. D.I. 207 at 13. The specification states:

In cases where probes have been transformed via cleavage, the transformed probes can be separated, e.g., by capturing the non-transformed probes via a tag that is removed from the transformed probes during the transformation (e.g., by

cleavage), or by adding a new tag at the site of cleavage. Once the reacted (transformed) or interacted encoded probes are separated from the unreacted or un-interacted encoded probes, the sequence of the reacted and/or interacted encoded probes is determined at step 150 by, preferably, sequencing. The sequence of the encoded probes allows the mapping of the assay results at step 160 back to locations in the biological sample. 917 Patent, 10:21-33.

Dr. Satija also relies upon the passage and explains that “a POSA would recognize that the addition of tags to probes after they have been cleaved (and collected) from the tissue sample represents a disclosure that allows for the preservation of spatial location information.” **Ex. 29**, ¶ 91. Dr. Satija notes that the tags “could serve various purposes within different assays, including encoding the location or source of a particular set of cleaved probes” because encoding location is consistent with “numerous disclosures throughout the patent that teach encoding spatial location via tags.” **Ex. 29**, ¶ 92. Dr. Satija opines that because the patent discloses sequencing as part of the spatial mapping process, a POSA reading the tagging passage in this context would understand that “tags added post-collection can indeed be employed to encode the collection location for a specific set of cleaved probes.” **Ex. 29**, ¶ 92; *see* ¶ 122. As these tags are added after cleavage and collection, a POSA would understand this encoding takes place away from the tissue sample, using tagging reagents to preserve the pattern of collection. Consequently, a “POSA would comprehend that the inventor possessed methods for implementing spatial assays without patterned delivery of probes or encoding agents,” including probes gathered from segmented areas for biological target determination. **Ex. 29**, ¶ 92.

The portions of the written description cited by the Court’s *Markman* Order, and explained in detail by Dr. Satija, confirm that the ordinary-meaning scope of the claims matches the patent’s teachings of encoding spatial patterns both on and off the sample.

2. The Prognosys Specification Meets the Written Description Requirement Under the Correct Legal Test

The patent specification—including the portions identified by Dr. Satija and this Court—

“reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *CenTrak*, 915 F.3d at 1365. By 2011, Dr. Chee was in possession of methods for spatial mapping using next-generation sequencing to increase plex of *in-situ* hybridization, and these methods include encoding spatial patterns both on and off of the tissue. The specification passages discussed above, in the context of the knowledge of a POSA, show that Dr. Chee was in possession of the full scope of the ordinary meaning of the claims.

Instead of attempting to carry its clear-and-convincing evidentiary burden by having a qualified expert analyze the totality of the patent disclosure and the portions of the specification relied upon by this Court and Dr. Satija, NanoString pushes a legally-erroneous narrative: that spatial patterning during delivery of encoded agents is “essential” to the invention and must limit all claims. D.I. 233 at 4. NanoString contends that one form of spatial patterning is referred to “[o]ver and over” (D.I. 233 at 2) while relying on attorney argument to minimize the “three concepts” related to spatial patterning off tissue (D.I. 233 at 6). These arguments are inconsistent with the controlling law.

First, NanoString’s reliance on *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998) is misplaced as the Courts have made clear that *Gentry Gallery* did not establish a “heart of the invention” or “essential element” test. *See Cooper Cameron Corp. v. Kvaerner Oilfield Prods.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002) (“[W]e did not announce a new ‘essential element’ test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements.”); *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1333 (Fed. Cir. 2003) (rejecting an essential element requirement, “one sees the holding in *Gentry* for what it really was: an application of the settled principle that a broadly drafted claim must be fully supported by the written description”).

Second, the apparent focus of a specification on one embodiment or the fact that an alternative embodiment receives a relatively short disclosure does not establish a failure to describe claims that cover both. *See CenTrak*, 915 F.3d at 1366 (“A specification’s focus on one particular embodiment or purpose cannot limit the described invention where that specification expressly contemplates other embodiments or purposes.”); *In re Hayes Microcomputer Prods. Patent Litig.*, 982 F.2d 1527, 1534 (Fed. Cir. 1992) (“Certainly no length requirement exists for a disclosure to adequately describe an invention.”). The test of disclosure is that articulated in *Ariad*, not a “heart of the invention” or “essential element” test.⁴

D. The Dispute Over How One of Skill in the Art Would View the Content of the Written Description in Context Is a Dispute of Fact for Trial

NanoString cannot meet its burden at summary judgment to show by clear and convincing evidence—and without a genuine dispute of fact—that the Prognosys patents are invalid for lack of written description. As shown above, whether the patents describe spatial patterning away from the sample is a highly technical issue and Plaintiffs have provided voluminous and persuasive expert opinion testimony of Dr. Satija as to how one skilled in the art would understand passages related to reagent delivery and removal, tagging and NGS, sample segmentation and indexing, and other techniques. Dr. Satija has also explained factually what the state-of-the-art context was for the patent’s description by reference to documents readily

⁴ None of the cases NanoString relies on impact the adequacy of written description in this case, as it was never even suggested the subject patents contained any express disclosures or embodiments to support the claims. *See Gentry Gallery* 134 F.3d at 1478-79 (arguing “an applicant need not describe more than one embodiment of a broad claim to adequately support that claim”); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998) and *Lipocine Inc. v. Clarus Therapeutics, Inc.*, 541 F. Supp. 3d 435 (D. Del. 2021) (arguing representative species were sufficient to meet the broad claim); *MHL Custom, Inc. v. Waydoo USA, Inc.*, No. 21-0091-RGA, 2023 U.S. Dist. LEXIS 19476, at *25-27 (D. Del. Feb. 2, 2023) (“[s]tatic stability distinguishes the invention from the prior art” and “[t]here is nothing in the specification that would signal to a POSA that the patentee invented a watercraft that is statically unstable”).

available to POSAs; to show that NGS and sample indexing were commonly known as of the 2011 filing date of the patent, Dr. Satija cited to an Illumina sequencing user guide, a patent application, and Voelkerding, a review article that NanoString has relied upon as prior art.

By contrast, NanoString's motion is notably devoid of evidence that could meet its burden, let alone overcome the testimony of Dr. Satija. NanoString had a technical expert (Dr. Edwards) provide opinion testimony as to validity, but NanoString fails to cite Dr. Edwards to back up the assertions of NanoString's brief. *See* D.I. 233 at 1-15 (one citation to Edwards). NanoString's contentions about these highly technical issues of fact rest on attorney argument, which is insufficient to meet its burden for summary judgment. *See Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1068 (Fed. Cir. 2005) ("Unsubstantiated attorney argument regarding the meaning of technical evidence is no substitute for competent, substantiated expert testimony. It does not, and cannot, support [] burden on summary judgment."); *Enzo Biochem v. Gen-Probe, Inc.*, 424 F.3d 1276, 1284 (Fed. Cir. 2005) ("Attorney argument is no substitute for evidence.").

Disputes as to what the disclosures would mean to a skilled artisan in the context of the patent and whether these disclosures are sufficient to show possession by the inventor are issues of material fact for which the courts routinely find summary judgment is inappropriate. *See, e.g., Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 683 (Fed. Cir. 2015) (reversing summary judgment because expert "point[ed] to specific portions of the '006 patent as showing how to access disparate databases" creating "genuine issue of material fact on whether the specification shows how to achieve the functionality of accessing disparate databases"); *Nexstep, Inc. v. Comcast Cable Commc'ns., LLC*, No. 19-1031-RGA-SRF, 2021 U.S. Dist. LEXIS 177819, at *57-58 (D. Del. Aug. 20, 2021) ("[E]xperts' factual disputes regarding how a person of ordinary skill in the art would understand the disclosure of the [] patent preclude an award of

summary judgment.”); *Bioverativ Inc. v. CSL Behring LLC*, No. 17-914-RGA, 2020 U.S. Dist. LEXIS 38211, at *8 (D. Del. Mar. 5, 2020); *Echologics, LLC v. Orbis Intelligent Sys., Inc.*, No. 21-cv-01147-H-AHG, 2023 U.S. Dist. LEXIS 60453, at *31-32 (S.D. Cal. Mar. 27, 2023).

Instead of providing evidence to meet its own burden, and in attempt to avoid any dispute of fact, NanoString asks the Court to disregard expert testimony altogether by characterizing Dr. Satija’s opinions as improper “gap filling.” D.I. 233 at 15⁵; *id.* at 9 (citing *Rivera v. ITC*, 857 F.3d 1315 (Fed. Cir. 2017) (“The knowledge of ordinary artisans may be used to inform what is actually in the specification, but not to teach limitations that are not in the specification, even if those limitations would be rendered obvious by the disclosure in the specification.”)). Dr. Satija’s opinions are in accord with the law. “In written description cases, the primary consideration is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure.” *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 996 (Fed. Cir. 2000). Having experts provide the context for understanding the patent is not at all improper: “a patentee may rely on information that is well-known in the art for purposes of meeting the written description requirement, because the specification is viewed from the perspective of one of skill in the relevant art.” *Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1359 (Fed. Cir. 2019); *Zoltek Corp. v. United States*, 815 F.3d 1302, 1308 (Fed. Cir. 2016) (“The written description need not include information that is already known and available to the experienced public.”). While a “‘mere wish or plan’ for obtaining the claimed invention does not satisfy the written description requirement,” *CenTrak*, 915 F.3d, at 1365, “[t]he background knowledge of those skilled in the art can supplement the teaching in the specification to provide

⁵ *Lipocine*, 541 F. Supp. 3d at 461 is also inapposite, involving a functional genus claim, where a POSA was to “use the prior art to ‘prioritize’ excipients” by “run[ning] ‘factorial design experiment[s]’ to ‘expose information about the most important features of the formulation.’”

written description support,” *Rivera*, 857 F.3d, at 1322.

NanoString’s reliance on *Rivera* to criticize Dr. Satija’s opinion is misplaced. D.I. 233 at 9. *Rivera* stands for the unremarkable proposition that where there is a complete absence of teaching in a patent supporting a broader claim, that vacuum cannot be wholly replaced with the knowledge of those skilled in the art. *See CenTrak*, 915 F.3d, at 1367 (The “patent’s disclosure of an ultrasonic embodiment, albeit brief, distinguishes the instant case from *Rivera v. International Trade Commission*, 857 F.3d 1315, 1322 (Fed. Cir. 2017), in which we affirmed an invalidity finding because the specification at issue did not make any mention of the later-claimed container with an integrated filter and thus did not provide written description.”); *Mondis Tech. Ltd. v. LG Elecs., Inc.*, No. 15-4431 (SRC), 2017 U.S. Dist. LEXIS 168767, at *5 (D.N.J. Oct. 12, 2017) (“*Rivera* thus establishes no bright line rule about how the knowledge of the skilled artisan may be used to help satisfy the written description requirement.”).

Dr. Satija performed the proper analysis using the “knowledge of ordinary artisans . . . to inform what is actually in the specification.” *Rivera*, 857 F.3d at 1322. Dr. Satija explained affirmative disclosures in the patents from the perspective of one skilled in the art. For example, Dr. Satija pointed out the use in the patent of Illumina sequencing and sequencing adapters, along with related patent applications and scientific publications (**Ex. 29**, ¶ 94 (citing 19:8-38)) and explained how a POSA would understand those disclosures as of 2011. **Ex. 29**, ¶¶ 94-98. He explained that a POSA would be familiar with the NGS workflow generating nucleic acid molecules through the addition of “sequencing adapters” as a precursor to the claimed next generation sequencing and PCR amplification. **Ex. 29**, ¶ 92 (citing 13:1-14, 25:52). He explained that the advance of NGS was multiplexing, which includes adding sample index tags while incorporating sequencing adapters to maintain sample origination information. **Ex. 29**, ¶ 98.

Dr. Satija explained how a POSA would understand each of these highly technical disclosures including what steps are present in NGS sample preparation workflow. Ex. 29, ¶¶ 94-100. Dr. Satija did not simply posit that a POSA would take a known technology wholly outside the patent and use that to change the nature of the disclosure.

Using a POSA's knowledge to understand the full scope of the specification is not improper—it is the standard inquiry factfinders perform in evaluating the written description. See *Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d 1357, 1362 (Fed. Cir. 2018) (considering the knowledge of a POSA in whether disclosure of “fibre optic bundle” is sufficient for “light guide” when specification never expressly stated “light guide”); *Mondis*, 2017 U.S. Dist. LEXIS 168767, at *3 (expert opined that to a POSA “a display ‘type’ referred to the technology type of the display such as whether it was based on cathode ray tube (CRT) technology” for determining whether disclosure of a cathode-ray tube showed the inventor had possession of a claim to “a type of display unit” when a type of display unit was absent from the disclosure).

NanoString also erroneously objects to the use of contemporaneous extrinsic evidence to help show how the written description would be understood through the eyes of POSA. D.I. 233 at 8. Because written description turns on how a POSA would understand patent disclosures in the context of a POSA's background knowledge, it is entirely appropriate and routine to consider extrinsic evidence to build out that context, even where the background material is not incorporated by reference in the patent. See *Falkner v. Inglis*, 448 F.3d 1357, 1368 (Fed. Cir. 2006) (“written description requirement does not require either the recitation or incorporation by reference” of “accessible literature sources”); *Streck, Inc. v. Research & Diagnostic Sys.*, 665 F.3d 1269, 1287 (Fed. Cir. 2012) (relying on “well-known use of true reticulocytes in the prior art”); *Bioverativ*, 2020 U.S. Dist. LEXIS 38211, at *8-9 (relying on scientific publications).

Dr. Satija relied upon several documents directly implicated by the Prognosys patents' use of Illumina NGS workflows. For example, Dr. Satija relied on an Illumina patent application, US2012/0202704A1 (which is in fact cited prior art included in the patents in suit), an Illumina user guide associated with the commercial Illumina NGS platform expressly referenced in the patent, and Voelkerding (2009), a review article summarizing commercial NGS platforms that NanoString has asserted as prior art within the knowledge of a POSA. Dr. Satija appropriately used these documents to explain why a POSA would have understood the references' use of Illumina methods in practicing the Prognosys patent inventions would involve generating nucleic acids and indexing sub-samples, thus describing and enabling off-tissue encoding.

Summary judgment is often denied because extrinsic evidence creates a factual dispute as to whether a technological feature was well known in the art. *See Butamax(TM) Advanced Biofuels LLC v. Gevo, Inc.*, 746 F.3d 1302, 1315-16 (Fed. Cir. 2014) ("Butamax also relies on extrinsic evidence purportedly teaching how to deactivate the pathway. . . . Gevo's experts disagree with Mr. Klibanov and his interpretation of these references, but this merely indicates the existence of a genuine dispute of material fact. There is a genuine dispute with respect to whether in 2005 it was generally well-known in the art."); *Mondis*, 2017 U.S. Dist. LEXIS 168767, at *3-6 (summary judgment denied because expert cited "several prior art patents" to show "it was well-known in the art at the time of invention what 'type of display unit' means").

NanoString's challenge to not only Dr. Satija's opinion as to how common in the art sample indexing was as of 2011, but as to how a POSA would understand the passages describing segmentation, liquid-handling technologies, and tagging in the context of the patent highlights how many additional disputes of fact there are to be resolved at trial rather than the summary judgment stage. *See, e.g., Echologics*, 2023 U.S. Dist. LEXIS 60453, at *31-32 ("At

summary judgment, the evidence of the non-movant [], ‘is to be believed, and all justifiable inferences are to be drawn in [its] favor.’ . . . At best, the cited evidence demonstrates that there is a genuine dispute of material fact as to this issue and provides material for cross-examination of Dr. Young at trial. It does not provide a basis for summary judgment.”).

NanoString’s citation to other witness testimony to support its position further confirms the presence of genuine factual disputes. NanoString asserts in a footnote that Dr. Chee testified

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D.I. 233 at 14, n.4. NanoString mischaracterizes Dr. Chee’s testimony. The cited testimony was not in reference to the disclosures of the patents-in-suit but as to one of the multiple invention disclosures and, as Dr. Satija explained, “Dr. Chee testified that the segmentation paragraphs in the Prognosys patents were not limited to REDACTED

REDACTED Ex. 29, ¶ 141 (citing Chee Depo., 223:4-224:2). Dr. Satija explained that a POSA would understand REDACTED

Ex. 29, ¶ 142.

NanoString also discusses testimony of a third expert, Plaintiffs’ claim construction expert, Dr. Stacey Gabriel, apparently in an effort to find expert testimony that conflicts with Dr. Satija’s opinions. D.I. 233 at 14-15. On the merits there is no conflict—Dr. Gabriel testified in agreement with Dr. Satija as to how a POSA would understand the disclosures. *See, e.g.*, Ex. 29, ¶ 138 (citing Gabriel Depo. at 153:8-17, 155:12-24 (targeted removal)); Ex. 29, ¶ 139 (citing Gabriel Depo. at 124:21-125:16 (liquid-handling reagents)); Ex. 29, ¶ 144 (citing Gabriel Depo. at 143:7-21 (tagging)). However, if the two experts did not agree, that fact would again illustrate the existence of genuine disputes of how a POSA would view disclosures in light of the knowledge of a skilled artisan in 2011—an issue not appropriate for summary judgment.

II. DR. SATIJA'S OPINIONS ARE BASED ON SOUND METHODOLOGY

Instead of grappling with the core factual, technological questions at issue—how the options and examples in the patent would be understood by a POSA in context—NanoString asks the Court to exclude all of the expert testimony it disagrees with. Legally, there is no basis for a *Daubert* challenge to Dr. Satija. As explained above, Dr. Satija's analysis tracks the methodology called for by the Federal Circuit, answering the question of whether the patent disclosures read by a POSA with the POSA's perspective and knowledge describe the full scope of the claims. Dr. Satija does not opine on written description independent of the patent's disclosure. Indeed Dr. Satija testified that his "understanding is that mere knowledge of a person of ordinary skill in the art independent of the specification is not sufficient to satisfy the written description requirement." **Ex. 30** (Satija Dep.) at 149:7-150:4. Dr. Satija did not "gap-fill" but properly explained how a POSA would understand what the specification already disclosed.

NanoString's new contention, that certain of Dr. Satija's opinions are in question because the patents may be entitled to a pre-2011 priority date, is a red herring. The priority date has never been disputed. **Ex. 29**, ¶ 77, n.4. The filing date of the complete specification for the patents in suit is April 5, 2011 (the filing date of the 598 Patent Application). Dr. Satija relies upon that 2011 date for his opinions on written description, which address the complete specification. That complete specification incorporated a *provisional* application that was filed one year earlier (April 5, 2010) that makes up portions of the complete written description.

While NanoString contends that "Plaintiffs just changed their priority date from 2010 to 2011" (D.I. 233 at 17), Plaintiffs did no such thing. In response to Interrogatory No. 3 seeking a priority date, Plaintiffs responded, "[the claims] are entitled to a priority date of no later than April 5, 2011, based on U.S. Patent Application No. 13/080,616, filed on April 5, 2011, and based on Provisional Application No. 61/321,124, filed on April 5, 2010." **Ex. 31** at 17. In

response to Interrogatory No. 4 (seeking written description support in priority disclosures), Plaintiffs stated the claims “are entitled to a priority date of April 5, 2011” and cited disclosures from both priority documents. **Ex. 31**, at 17-23. In Plaintiffs’ validity contentions, in each written description response, Plaintiffs provided April 5, 2011 as the invention date. *See, e.g., Ex. 32* at 7 (“One skilled in the art would recognize from reading the specification, including all disclosures, that Dr. Chee possessed the full scope of the claimed inventions as of April 5, 2011.”).

NanoString bears the burden of proof on invalidity, and its expert, Dr. Edwards, did not provide any opinion on the correct priority date. Nor did Dr. Edwards opine that a priority date of 2010 has any impact on the knowledge of a POSA or how a POSA would understand the written description. NanoString highlights that certain cited references would post-date NanoString’s new 2010 priority date, but NanoString cannot contend that Dr. Satija included evidence that post-dates the 2011 date. D.I. 233 at 16. Dr. Satija’s methodology in applying the 2011 priority date for the complete written description is not in dispute. If NanoString now plans to assert that the patents are entitled to an earlier priority date (to the extent it is not waived), it would be a factual dispute for cross examination, not a ground for *Daubert* exclusion.

While NanoString seems to fault Dr. Satija for not simply relying on the priority date put forward by a different expert, Dr. Stacey Gabriel, during claim construction, to do so would have been contrary to law. *See In re Fluidmaster, Inc., Water Connector Components Prods. Liab. Litig.*, No. 14-cv-5696, 2017 U.S. Dist. LEXIS 48792, *75-76 (N.D. Ill. Mar. 31, 2017) (“[An] expert must make some findings and not merely regurgitate another expert’s opinion. This kind of impermissible bolstering is neither helpful to the trier of fact nor is it based on sufficient facts.”); *Quiles v. Bradford-White Corp.*, No. 10-CV-747, 2012 U.S. Dist. LEXIS 54662, *25 (N.D.N.Y. Apr. 18, 2012) (“[A]n expert’s opinion must be based upon his own application of

principles within his expertise to the facts of the case. An expert cannot simply parrot the findings of another.”). Nor is there a requirement to assert only one priority date. *See Ajinomoto Co. v. ITC*, 597 F.3d 1267, 1277 (Fed. Cir. 2010) (“A patentee may also argue in the alternative for different priority dates at trial.”); *Eagle View Techs., Inc. v. Xactware Sols., Inc.*, No. 15-7025, 2017 U.S. Dist. LEXIS 195828, at *25 (D.N.J. Nov. 29, 2017) (“To the extent defendants argue plaintiffs are barred from asserting alternative priority dates the Court disagrees.”).

NanoString also faults Dr. Satija for “his reliance on confidential invention disclosure forms.” D.I. 233 at 17. This is not an appropriate challenge to Dr. Satija’s methodology. Dr. Satija relied on the specification (*see, e.g.*, **Ex. 29**, ¶¶ 94-98) and then stated that the patent disclosures were

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Ex. 29, ¶ 99.

It was Dr. Edwards who relied first on Invention Disclosures in offering opinions on written description, and the opinions NanoString now challenges directly rebut the type of evidence NanoString itself hopes to offer at trial. **Ex. 29**, ¶ 136. Highlighting NanoString’s inconsistency, NanoString next attempts to fault Dr. Satija for *not* relying on additional extrinsic evidence in the form of a different

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These arguments demonstrate

why these issues are appropriate for cross examination rather than *Daubert*.

III. SUMMARY JUDGMENT FOR NO INDEFINITENESS (ALL PATENTS) AND OPPOSITION TO SUMMARY JUDGMENT FOR INDEFINITENESS (917 PATENT)

NanoString does not come close to meeting its burden to show indefiniteness by clear and convincing evidence. NanoString relies on attorney argument and a portion of one office action. That is plainly insufficient to meet its burden. Claim language alone resolves this issue. There is no genuine dispute that a POSA would understand with reasonable certainty that claim 1 is drafted entirely as a “system” with software components with built-in functionality (“configured to”). NanoString appears not to dispute: claim 1 is a system claim; “configured to” is structural

(not a method); and “wherein the software comprises instructions configured to cause the processing circuit arrangement to display an image...and control the reagent delivery system to remove a portion of the tissue” recites structural capability. D.I. 233 at 34.

NanoString argues that the first “wherein” clause is a new and separate step. It is not. The “wherein” clause describes a feature within the “configured to” structural limitation by giving an example of a material the system is configured to remove. Ascertaining infringement does not require the performance of a method by a person in a lab. Infringement occurs upon the making of the system, requiring only the structural features that are *configured to* remove portions of samples (probe oligonucleotides) if at a future point the system is used on a sample.⁶

NanoString’s prosecution-history argument rests on one sentence of an Office Action where the Applicant distinguishes a prior art reference (Wheeler). D.I. 233 at 28 The entire discussion is in the context of how Wheeler lacks “*software instructions configured to cause . . .* the reagent delivery system to remove a portion of the tissue sample.” The Applicant pointed out Wheeler is working in a different context—a system for cell *dispensing* rather than *removing*—thereby implying that Wheeler’s software would not be understood as configured to remove. **Ex. 7** at 8, 10. The Applicant never states that the claim requires a person to use the machine and actually perform a method. Nor does the Wheeler discussion involve the “wherein” clause at all,

⁶ NanoString argues that Plaintiffs’ expert Dr. Quackenbush relied on evidence of NanoString’s performance of the method claims to show infringement of the system claims and did not review NanoString source code. D.I. 233 at 28 n.9. First, infringement of a system claim occurs not only at the time of making or selling the system (when NanoString manufactures a GeoMx system), but also when it is used—these are separate acts of infringement. Second, Dr. Quackenbush relied on voluminous evidence from NanoString documentation on the purpose and capabilities of the system, about how the system software is put into practice. The configuration of the software is evidenced by how it is actually used. Third, NanoString has not moved for summary judgment of non-infringement of the system claims, and the sufficiency of proof on infringement is an issue for trial to the extent NanoString has preserved such non-infringement arguments.

and it is the “wherein” clause that NanoString claims causes indefiniteness.

Plaintiffs’ motion for summary judgment of no indefiniteness should be granted, and NanoString’s cross-motion for summary judgment should be denied, because the intrinsic evidence and Plaintiffs’ unopposed expert opinion show that a POSA would understand with reasonable certainty the processing circuit limitation.⁷

IV. MS. DAVIS’S REASONABLE ROYALTY OPINION IS PROPER

Ms. Julie Davis has opined that 10x should recover both lost profits and reasonable royalty damages to adequately compensate 10x for NanoString’s infringement of the patents-in-suit. NanoString has not sought to strike any portion of Ms. Davis’s lost profits analysis, does not challenge her credentials, and does not dispute that her proposed testimony would help the jury understand the evidence. Rather, NanoString attacks her reasonable royalty analysis on two grounds that, as described below, relate to the application of facts to her methodology, rather than to the methodology itself, and should be addressed, if at all, in cross-examination.

A. Ms. Davis’s Reliance on the 10x-ReadCoor Agreement is Proper.

NanoString criticizes Ms. Davis’s reliance on the 10x-ReadCoor agreement. Like the hypothetical license in this case,

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In 2020, through the 10x-ReadCoor agreement, 10x (the licensee) acquired rights to foundational *in situ* patents that were already exclusively licensed from Harvard to ReadCoor. Dr. Quackenbush and Ms. Davis

⁷ Plaintiffs identified in their opening brief additional terms NanoString seems to assert are indefinite based on a brief statement in the opening report of Dr. Edwards, although NanoString has not moved for summary judgment of indefiniteness on these terms. Nor has NanoString provided any response, D.I. 233, and summary judgment of no invalidity should be granted because a POSA would understand each term with reasonable certainty.

provided thorough analyses as to the technological and economic comparability of the licensed patents.

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Citing no authority on point, NanoString argues that “[a]s a matter of commonsense” the ReadCoor agreement is an unreliable starting point because it was a “complex corporate acquisition that involved far more than a patent license.” D.I. 233 at 21. That conclusion is an oversimplification that ignores

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NanoString simply states that the agreement is an improper benchmark because it involved other assets. NanoString cites no support for the exclusion of an agreement simply because it includes assets in addition to the comparable patent rights. To the contrary, the law supports a finding that use of such agreements is appropriate and that any criticisms go to weight. *See Fresenius Med. Care Holding, Inc. v. Baxter Int’l, Inc.*, 224 F.R.D. 644, 653 (N.D. Cal. 2004) (“The amount paid to acquire a company with desired patents, and the amount allotted to a particular patent is relevant to the establishment of a reasonable royalty.”). *See also ActiveVideo Networks v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1333 (Fed. Cir. 2012) (district court properly allowed expert to opine on agreement that covered patents and software services; “The degree of comparability of the []

license agreements as well as any failure . . . to control for certain variables are factual issues best addressed by cross examination and not by exclusion.”). Here, Ms. Davis analyzed the other assets and adequately explained why she allocated certain values to the technologically comparable patents, which she (and documents at the time of the agreement) explained served as a primary rationale for the agreement. **Ex. 33**, at 54-56; **Ex. 34**, (Davis Dep.) at 81:16-83:8. NanoString merely disagrees with Ms. Davis’s factual analysis and her allocation of value to certain assets and not others. Any such attack is not on the methodology but on the facts applied to the methodology and should, therefore, go to the weight of her testimony, not admissibility.⁸

NanoString also erroneously argues that Ms. Davis ignored the Harvard-ReadCoor and the 10x-Prognosys licenses. D.I. 233 at 20. She did not. Ms. Davis has an extensive analysis of the Harvard-ReadCoor license (**Ex. 33** at 57-61) and **REDACTED**

Ex. 33 at 51, 61. Ms. Davis also performed a detailed analysis of the 10x/Prognosys agreement but, again, concluded that **REDACTED**

Ex. 33 at 51; **Ex. 24** (Davis Reply Rpt.) at 7-8. *See, e.g., Edgewell Pers. Care Brands, LLC v. Munchkin, Inc.*, No. LACV 18-3005 PSG (JPRx), 2022 U.S. Dist. LEXIS 208857, at *24-26 (C.D. Cal. Oct. 12,

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Ex. 33 at 54-56; **Ex. 34** at 73:15-76:18.

2022) (allowing expert's testimony distinguishing a license to the patents-in-suit from the hypothetical negotiation because of economic differences and the relationship of the parties).⁹

B. Ms. Davis's ^{REDA}_{CTED} Implied Royalty Rate Is Based on Proper Methodology.

Ms. Davis's allocation

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Ex. 33, at 60. Using Dr. Quackenbush's analysis,

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This opinion is thorough and careful, and any criticism NanoString has of it can and should be addressed, if at all, on cross examination. *Zak v. Facebook, Inc.*, No. 4:15-CV-13437-TGB-MJH, 2021 U.S. Dist. LEXIS 189166, at *8 (E.D. Mich. Sept. 30, 2021) ("disputes with an expert's conclusion apportioning

⁹ NanoString's cases are distinguishable. See *ePlus, Inc. v. Lawson Software, Inc.*, 764 F. Supp. 2d 807, 814 (E.D. Va. Jan. 26, 2011) (excluding testimony when expert ignored three litigation settlements based "on avoidance of litigation" but relied on two other settlements); *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 79 (Fed. Cir. 2012) (not economically sound when expert reasoned the patent licenses were entered into when the market was less established, but the record showed the market was already saturated); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 870 (Fed. Cir. 2010) (criticizing reliance on "re-bundling licenses," which "furnished finished software products and source code...to other software companies in exchange for ongoing revenue-based royalties" and did not involve any patents).

relative value among patents in a transaction go to the weight that should be afforded an expert's opinion, not its admissibility”) *Immersion Corp. v. HTC Corp.*, No. 12-259-RGA, 2015 U.S. Dist. LEXIS 21555, at *5-6 (D. Del. Feb. 24, 2015) (expert’s opinion “ that the patents-in-suit are the most valuable in the portfolio” went to weight, not admissibility).¹⁰

Ms. Davis’s analysis is readily distinguishable from the excluded testimony in *Guardant* where the court’s holding was based on the finding that the expert did not “tie the relative value of the patented features to [] accused products, which is meant to be the focus of the apportionment analysis” and instead discussed the asserted patents in the general technical field. *Guardant Health Inc. v. Foundational Med. Inc.*, No. 17-1616-LPS-CJB, 2020 U.S. Dist. LEXIS 86387, at *42-43 (D. Del. April 22, 2020). Ms. Davis properly REDACTED

Ex. 33, at 60. Ms. Davis’s opinions on the ReadCoor agreement and Harvard/ReadCoor license are not the unsupported speculation that Rule 702 is intended to guard against; any issue can be addressed on cross-examination.

C. Ms. Davis Properly Applied the Analytical Approach.

NanoString criticizes Ms. Davis’s application of the analytical approach but does not

¹⁰ Ms. Davis did not engage in “raw patent counting” as NanoString asserts. D.I. 233 at 24. As a general matter, “a patent counting approach is not *by itself* grounds for exclusion.” *GPNE Corp. v. Apple, Inc.*, No. 12-CV-02885-LHK, 2014 U.S. Dist. LEXIS 53234, at *30 (N.D. Cal. 2014). Further, NanoString’s REDACTED

Ex. 24 (Davis Reply Report at 10); Ex. 34 at 114:16-116:9.

dispute that is it a well-established methodology.¹¹ The analytical approach “compare[s] the expected profit margin of the infringing product to the typical profit margin for the relevant business.” *Novozymes A/S v. Genecor Int’l, Inc.* 474 F. Supp. 2d 592, 606 (D. Del. 2007). NanoString had, at the time of the hypothetical negotiation, two-products: nCounter and GeoMx. The analytic approach looks to whether NanoString, as the accused infringer, would choose to sell its existing product only (nCounter) at its profit of ^{REDACTED}_{TED} or pay for a license in order to sell the accused GeoMx product at a ^{REDACTED}_{TED} margin. Ms. Davis concluded that the total ^{REDACTED}_{TED} difference supports her ^{REDACTED}_{CTED} royalty conclusion.

NanoString incorrectly asserts that the *TWM* “requires” the use of net profits as opposed to gross profits. D.I. 233 at 25-26; *TWM Mfg. Co. v. Dura Corp.*, 789 F.2d 895 (Fed. Cir. 1986). The *TWM* court held that a court has discretion to use the analytical approach and recognized that the analysis in that case used a comparison of net profits. It did not hold that comparison of “net profits” is required, and courts have allowed other comparisons under the analytic approach, including comparing gross profit margins or simply sales prices.¹² See *Eko Brands, LLC v. Adrian Rivera Maynez Enters.*, No. C15-522-JPD, 2018 U.S. Dist. LEXIS 52657, at *8 (W.D. Wash. Mar. 28, 2018) (allowing analytical approach comparing gross profits); *Bd. of Regents*, 2022 U.S. Dist. LEXIS 223143, at *11-12 (allowing analytical approach comparing sales prices to get the accused products’ profit premium). Ms. Davis explained that the margins she used were proper because

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¹¹ The methodology has been used by Mr. Lasinski in other cases. See *Numatics, Inc. v. Balluff, Inc.*, 66 F. Supp. 3d 934 (E.D. Mich. 2014).

¹² *Wonderland Switz. AG v. Evenflo Co.*, 564 F. Supp. 3d 320 (D. Del. 2021) does not support NanoString’s position. The court accepted the analytic approach but altered the profit attributable to the patented technology to account for patented features verses non-patented features.

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Ex. 24 at 12; Ex. 34 at 37:23-38:5.

NanoString also claims, without authority, that the analytical approach is “logically flawed” because Ms. Davis fails to account for the “substantial differences” between the nCounter and GeoMx and “differences in their lifecycles.” D.I. 233 at 26. These are not valid attacks on an analytic approach. Ms. Davis’s opinion explains that the differences between two platforms are not relevant to the analytical approach analysis because the hypothetical negotiators would consider that the REDACTED was made possible by the fact that it was in a newer technology space enabled by the asserted patents. That newer patented technology is precisely what would allow NanoString to sell the GeoMx products at higher margins as compared to the lower margin nCounter products.”

V. MOTION TO EXCLUDE CERTAIN OPINIONS OF MR. MICHAEL LASINSKI

The REDACTED License is neither technologically comparable to the patents-in-suit nor economically comparable to the hypothetical negotiation. REDACTED

To establish technological comparability, a party must show that the licensed technology is ‘substantially similar’ to the technology claimed by the asserted patents.” *Skyhook Wireless, Inc. v. Google, Inc.*, No. 10-11571-RWZ, 2015 U.S. Dist. LEXIS 194007, at *7 (D. Mass. Feb. 18, 2015). Dr. Edwards, on whose opinion Mr. Lasinski relied, admitted that he did not evaluate how the GeoMx workflow “matches with the claims^{RE} REDACTED invention.” Ex. 9, 124:10-125:20. No substantial similarity analysis was performed.

Mr. Lasinski's reliance on Dr. Edwards's comparability opinion is based on double hearsay. Dr. Edwards admitted that his opinion that REDACTED

Ex. 9, 123:16-124:8, 124:10-25. This is not a reliable independent opinion. Dr. Edwards admitted he did not draft and merely read the REDACTED comparability section of his report. Ex. 9, 122:22-123:1. NanoString also says nothing about the lack of economic comparability of REDACTED REDACTED between competitors like 10x and NanoString.

Mr. Lasinski's methodology for valuing the Prognosys license should also be excluded. The issue is not whether he could rely on the one projection that he chose, but that he cannot cherry-pick a single projection and ignore (without explanation) other, more accurate projections. As NanoString concedes, "selective use of evidence is the hallmark of unreliable methodology worthy of exclusion." D.I. 233 at 22. *See Lust v. Merrell Dow Pharms.*, 89 F.3d 594, 596 (9th Cir. 1996) (affirming exclusion when the expert "'pick[ed] and chose' ... from the scientific landscape and present[ed] the Court with what he believes the final picture looks like").¹³

¹³ NanoString's one cited case on this point, *Rossano v. Maxon*, No. 5:21-cv-01352-JMG, 2023 U.S. Dist. LEXIS 35545, at *24 (E.D. Pa. Mar. 3, 2023) merely states that an expert does not need to rely on inadmissible evidence and does not involve a situation that an expert picks and chooses among similar types of evidence without sound reasoning.

Respectfully Submitted,

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