

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

OLINK PROTEOMICS AB AND OLINK)
PROTEOMICS INC.,)

Plaintiffs,)

v.)

ALAMAR BIOSCIENCES, INC.,)

Defendant.)

C.A. No. 23-1303-MN

**PLAINTIFFS OLINK PROTEOMICS AB AND OLINK PROTEOMICS INC.'S
ANSWERING BRIEF IN OPPOSITION TO DEFENDANT
ALAMAR BIOSCIENCES, INC.'S MOTION TO DISMISS OLINK'S COMPLAINT
FOR FAILURE TO STATE A CLAIM**

Of Counsel:

Huiya Wu
Tiffany Mahmood
GOODWIN PROCTER LLP
620 8th Avenue
New York, NY 10018
(212) 813-8800
HWu@goodwinlaw.com
TMahmood@goodwinlaw.com

Kelly E. Farnan (#4395)
Sara M. Metzler (#6509)
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com
Metzler@rlf.com

Attorneys for Plaintiffs

Tara R. Thigpen
Kristin M. Beale
Emma L. Murray
GOODWIN PROCTER LLP
100 Northern Ave
Boston, MA 02210
(617) 570-1000
TThigpen@goodwinlaw.com
KBeale@goodwinlaw.com
EMurray@goodwinlaw.com

Dated: April 15, 2024

TABLE OF CONTENTS

TABLE OF AUTHORITIES	i
I. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS.....	1
II. SUMMARY OF THE ARGUMENT	1
III. STATEMENT OF FACTS	3
A. Olink and Its Patented Technology.....	3
B. Alamar’s Infringing NULISA Product	3
C. Olink’s Allegations That Alamar’s NULISA Platform Infringes the Asserted Patent.....	4
IV. STATEMENT OF LAW.....	6
A. Pleading Standard	6
B. Claim Disavowal.....	7
V. ARGUMENT	8
A. Olink’s Complaint Asserts a Plausible Claim of Infringement Against Alamar.....	8
B. Alamar’s Disavowal Argument Is a Claim Construction Issue That Should Not Be Decided at the Motion To Dismiss Stage	12
C. Olink Did Not Disavow Proximity Ligation.....	15
D. Amendment of the Complaint Would Not Be Futile	18
VI. CONCLUSION.....	19

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Absolute Software, Inc. v. Stealth Signal, Inc.</i> , 659 F.3d 1121 (Fed. Cir. 2011).....	8
<i>Alpizar-Fallas v. Favero</i> , 908 F.3d 910 (3d Cir. 2018).....	6
<i>Alvin v. Suzuki</i> , 227 F.3d 107 (3d Cir. 2000).....	18
<i>Amgen Inc. v. Coherus Biosciences Inc.</i> , 931 F.3d 1154 (Fed. Cir. 2019).....	12, 13
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	6
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544, 570 (2007).....	6
<i>In re Bill of Lading Transmission & Processing Sys. Patent Litig.</i> , 681 F.3d 1323 (Fed. Cir. 2012).....	9, 14
<i>Bot M8 LLC v. Sony Corp. of Am.</i> , 4 F.4th 1342 (Fed. Cir. 2021)	11, 12
<i>In re Burlington Coat Factory sec. Litig.</i> , 114 F.3d 1410 (3d Cir. 1997).....	7
<i>Cisco Sys., Inc. v. Int'l Trade Comm'n</i> , 873 F.3d 1354 (Fed. Cir. 2017).....	7, 16
<i>Continental Circuits LLC v. Intel Corp.</i> , 915 F.3d 788 (Fed. Cir. 2019).....	7, 16
<i>Disc Disease Sols. Inc. v. VGH Sols., Inc.</i> , 888 F.3d 1256 (Fed. Cir. 2018).....	6, 7, 8
<i>Eagle Pharms., Inc. v. Slayback Pharma LLC</i> , 382 F. Supp. 3d 341 (D. Del. 2019).....	13
<i>Kaempe v. Myers</i> , 367 F.3d 958, 965 (D.C. Cir. 2004).....	10

<i>Lifetime Indus., Inc. v. Trim-Lok, Inc.</i> , 869 F.3d 1372 (Fed. Cir. 2017).....	7
<i>Mobility Workx, LLC v. Unified Patent, LLC</i> , 15 F.4th 1146 (Fed. Cir. 2021)	10
<i>Nalco Co. v. Chem-Mod, LLC</i> , 883 F.3d 1337 (Fed. Cir. 2018).....	7, 11, 14
<i>North Star Innovations, Inc. v. Micron Tech., Inc.</i> , No. 17-506-LPS-CJB, 2017 WL 5501489 (D. Del. Nov. 16, 2017)	18
<i>Ottah v. Fiat Chrysler</i> , 884 F.3d 1135 (Fed. Cir. 2018).....	12, 13
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005).....	12
<i>Pragmatus AV, LLC v. TangoMe, Inc.</i> , C.A. No. 11-1092-LPS-CJB, 2013 WL 571798 (D. Del. Feb. 13, 2013).....	14
<i>Promos Techs., Inc. v. Samsung Elec. Co. Ltd.</i> , No. 18-307-RGA, 2018 WL 5630585 (D. Del. Oct. 31, 2018)	7
<i>Rambus, Inc. v. Infineon Techs. AG</i> , 318 F.3d 1081 (Fed. Cir. 2003).....	8, 16
<i>Sanderling Mgmt. Ltd. v. Snap Inc.</i> , 65 F.4th 698 (Fed. Cir. 2023)	19
<i>Standard Oil Co. v. Am. Cyanamid Co.</i> , 774 F.2d 448, 452 (Fed. Cir. 1985).....	12
<i>Tenaha Licensing LLC v. Vocera Commc'ns, Inc.</i> , No. CV 19-208-LPS-SRF, 2020 WL 30489 (D. Del. Jan. 2, 2020)	19
<i>Thorner v. Sony Comput. Ent. Am. LLC</i> , 669 F.3d 1362 (Fed. Cir. 2012).....	8
<i>Voda v. Cordis Corp.</i> , 536 F.3d 1311 (Fed. Cir. 2008).....	8, 16
Other Authorities	
Fed. R. Civ. P. 12(b)(6).....	1, 6, 14
Fed. R. Evid. 201(b)(2)	10

I. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS

On November 15, 2023, Plaintiffs Olink Proteomics AB and Olink Proteomics Inc. (collectively, “Olink” or “Plaintiffs”) filed a complaint for patent infringement alleging that Defendant Alamar Biosciences, Inc.’s (“Alamar” or “Defendant”) Nucleic acid Linked Immuno-Sandwich Assay (“NULISA”) platform, used with or without its ARGO system, infringed at least one claim of U.S. Patent No. 7,883,848 (“the ’848 Patent”). D.I. 1, Ex. A. On April 1, 2024, Alamar filed a motion to dismiss under Fed. R. Civ. P. 12(b)(6) (“Alamar’s Motion”) contending that Olink has failed to adequately plead infringement because of alleged disclaimers in the ’848 Patent of a technique called proximity ligation assay (“PLA”).¹ D.I. 8, 9. Olink hereby opposes Alamar’s Motion because Olink’s Complaint articulates a plausible patent infringement claim against Alamar, and Alamar’s disavowal argument improperly asks this Court to determine the scope of the ’848 Patent claims without claim construction or any evidentiary or expert support.

II. SUMMARY OF THE ARGUMENT

Alamar’s arguments fail for several reasons, and Alamar’s Motion should be denied.

First, Olink’s Complaint meets the *Twombly/Iqbal* standard as applied by the Federal Circuit and this Court because Olink described the nature and operation of its patented technology, identified Alamar’s infringing product (its NULISA platform), and used publicly available information to show how Alamar infringes each element of at least one claim of the ’848 Patent, including infringing features of NULISA that are not “proximity ligation.” Olink did not accuse Alamar of infringement based on NULISA’s “use of proximity ligation,” as Alamar asserts, but because it infringes at least one claim of the ’848 Patent for the reasons outlined in the Complaint.

¹ Olink notes that Alamar appears to use the terms “PLA”, “proximity ligation assay” and “proximity ligation” interchangeably. The term “PLA” appears nowhere in the ’848 Patent, and these terms can refer to various technologies. What “PLA” or “proximity ligation” means or what each encompasses requires expert discovery and should not be decided at the pleading stage.

Although Alamar now asserts that its NULISA platform uses proximity ligation or PLA (*see, e.g.*, heading IV.B. of Alamar’s Motion) in an attempt to escape infringement, Alamar has repeatedly represented the opposite—that its NULISA platform is distinguishable from proximity ligation—including before the U.S. Patent and Trademark Office. Olink is not required to prove its case at this stage; there is no question that Olink has asserted a plausible infringement claim and that Alamar knows the exact nature of the claim against it.

Second, claim disavowal is ultimately a claim-scope-limiting doctrine requiring claim construction and analysis of the specification through the lens of a person of ordinary skill in the art (“POSA”)—an issue that should not be decided at the pleading stage.

Third, Alamar improperly states as fact, without evidentiary support, that the ’848 Patent disavowed all of “proximity ligation”—it did not.² The single cherry-picked section Alamar points to in the specification does not evidence “clear and unmistakable” disavowal as required by law. A POSA, reading the specification as a whole, would reasonably conclude that there is no disclaimer of “proximity ligation,” as there are several places throughout the specification that demonstrate the inventor relied on certain principles of proximity ligation in his invention and thus did *not* disavow “proximity ligation.”

Fourth, amendment to the Complaint would not be futile. While Olink believes no amendment is necessary because its Complaint asserts a plausible infringement claim against Alamar, if the Court disagrees, Olink should be allowed to amend its Complaint to assert additional facts to further clarify that Alamar’s NULISA platform infringes the ’848 Patent not because it

² As noted above, “proximity ligation” and “PLA” can refer to various technologies, including traditional PLA, circular PLA, and solid-phase PLA, which cuts against Alamar’s claim that the inventor of the ’848 Patent has disavowed all of “proximity ligation” or “PLA.”

“uses proximity ligation,” but because it meets each and every limitation of the claims—including those distinguishable from “PLA” and the prior art referenced in the ’848 Patent.

III. STATEMENT OF FACTS

A. Olink and Its Patented Technology

Olink is a global leader in the field of proteomic analysis and traces its origins to 2004 when Olink AB was founded to develop and commercialize the groundbreaking “Proximity Ligation Assay,” invented by its founders. D.I. 1, ¶ 14. This technique is useful for detecting the interaction between two molecules, which provides a more comprehensive understanding of cellular networks, biomarker and drug discovery, and disease mechanisms. In this technique, pairs of antibodies which can bind a target are each linked to a “DNA oligonucleotide,” which is essentially a small piece of DNA that scientists can engineer in various ways. *Id.* When the antibodies find and bind to their respective target, the DNA pieces get close to each other. *Id.* This proximity allows the DNA to join together, and the joining of these DNA pieces creates a unique DNA sequence that can be detected and quantified using various methods known in the field to provide information about the target. *Id.* Olink AB continued to develop technology **building on** principles of proximity ligation and obtained several patents on such developments, including the ’848 Patent. D.I. 1, ¶ 15.

B. Alamar’s Infringing NULISA Product

As described by Alamar, Alamar’s NULISA platform, whether used alone or with its ARGO system, aims to achieve “superior sensitivity for detecting low-abundance proteins,” with “ultra-high sensitivity [to] enable the detection of previously difficult-to-detect but biologically important, low-abundance biomarkers.” D.I. 1, ¶ 19. Alamar has publicly acknowledged several times that its NULISA technology is **based on** Olink’s PLA technology but is distinguishable. D.I. 1, Ex. D at 15 (“NULISA **reduces the assay background of traditional PLA** by more than 10,000-

fold by incorporating a unique molecular design of the DNA-antibody conjugate that enables sequential purification of the immunocomplexes on two solid surfaces prior to proximity ligation.”); Ex. E at 1 (“The NULISA system is ***based on the proximity [ligation] assay (PLA)*** originally commercialized by Olink Bioscience, the forerunner of Olink” and “According to Yuling Luo, Alamar’s founder, chairman, and CEO, the NULISA approach improves upon the standard PLA method by using a two-stage wash and capture workflow that reduces assay background, thereby improving its sensitivity.”) (emphasis added.) On or around April 13, 2023, Alamar announced the unveiling of its NULISA platform for “early-access release later this year and a broad commercial launch in 2024.” D.I. 1, ¶ 29, Ex. E.

C. Olink’s Allegations That Alamar’s NULISA Platform Infringes the Asserted Patent

Olink alleged in its Complaint that Alamar’s manufacture, use, offer for sale, sale, marketing and/or distribution of its NULISA platform, with or without its ARGO system, directly or indirectly infringes the ’848 Patent, ***not*** because NULISA “uses proximity ligation,” but because it infringes at least one claim of the patent. D.I. 1, ¶¶ 18–27, 34–40. These good-faith allegations are based on publicly available information, including statements from Alamar describing its technology. *Id.* at Ex. D, E. Olink further alleged how use of the NULISA platform would plausibly practice each limitation of at least one claim, including those features that distinguish NULISA from “PLA.” D.I. 1, ¶¶ 18–27, 34–40.

Specifically, Olink alleges that use of the NULISA platform practices each and every step of claim 1 of the ’848 Patent by using:

- (i) probes consisting of an antibody and small piece of DNA, that form “a plurality of interactors” (D.I. 1, ¶ 21);

- (ii) matched antibody pairs conjugated with DNA—one antibody conjugate containing a poly-A tail, which is a sequence of adenine (A) nucleotides added to the end of a DNA molecule (termed “capture antibody”) and the other containing a biotinylated oligo, which is a short DNA sequence that has been chemically modified to attach a biotin molecule that binds specifically to streptavidin (termed “detection antibody”) (*id.* ¶ 22); both the poly-A tail and the biotinylated DNA serve to facilitate the selection of the target complex for further quantification in the assay;
- (iii) DNA on each antibody that contains the claimed “identification sequence element” as the DNA on both the “capture antibody” and “detection antibody” consist of partially double stranded DNA and a target-specific barcode for detection of a DNA strand containing a further barcode, unique to a specific sample, ligated between the two pieces of DNA (*id.* ¶ 23);
- (iv) DNA that infringes the claimed “association element” that facilitates association between the DNA probe arms as “a ligation mix containing T4 DNA ligase and a specific DNA ligator sequence is added to the streptavidin beads, allowing the ligation of the proximal ends of DNA attached to the paired antibodies” (*id.* ¶ 24);
- (v) “both antibodies [which] are incubated with a sample containing the target molecule, [where] an immunocomplex is formed. The formed immunocomplexes are captured by added paramagnetic oligo-dT beads and subsequent dT-polyA hybridization” (*id.* ¶ 25);

- (vi) a “specific DNA ligator sequence” that binds to the single stranded nucleic acid moieties after the immunocomplex is formed, and this association forms a double-stranded DNA molecule connecting the interactors, *i.e.* an “associated oligonucleotide” (*id.* ¶ 26);
- (vii) “a ligation mix containing T4 DNA ligase and a specific DNA ligator sequence is added to the streptavidin beads, allowing the ligation of the proximal ends of DNA attached to the paired antibodies and thus generating a new DNA reporter molecule containing unique target-specific barcodes” (*id.*); and
- (viii) “select[ion] of all cis-reactive cells exhibiting a detectable trace” results from the so called “dual capture and release mechanism” (*id.* ¶ 27). This element is not present in traditional proximity ligation.

IV. STATEMENT OF LAW

A. Pleading Standard

In ruling on a motion to dismiss under Rule 12(b)(6), the Court must accept all well-pleaded factual allegations in the complaint as true and view them in the light most favorable to the plaintiff. *See Alpizar-Fallas v. Favero*, 908 F.3d 910, 914 (3d Cir. 2018). Dismissal under Rule 12(b)(6) is only appropriate if a complaint does not contain “sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “Specific facts are not necessary; the statement need only give the defendant fair notice of what the . . . claim is and the ground upon which it rests.” *Disc Disease Sols. Inc. v. VGH Sols., Inc.*, 888 F.3d 1256, 1260 (Fed. Cir. 2018) (internal quotations and citations omitted). Further, “[t]here is no requirement for [a plaintiff] to prove its case at the pleading stage . . . Our precedent requires that a complaint place the alleged infringer on notice of what activity . . . is being accused of infringement.” *Lifetime*

Indus., Inc. v. Trim-Lok, Inc., 869 F.3d 1372, 1379 (Fed. Cir. 2017) (internal citations and quotations omitted); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (“The issue is not whether a plaintiff will ultimately prevail but whether the complainant is entitled to offer evidence to support the claims.”).

The Federal Circuit affirmed the *Iqbal/Twombly* pleading standard as applied to patent infringement. For example, in *Disc Disease*, the Federal Circuit affirmed that the plaintiff’s infringement allegations were sufficient where the complaint attached the asserted patent, identified the accused products by name and attached photos of packaging, and alleged that the accused products met “each and every element of at least one claim” either literally or under the doctrine of equivalents (“DOE”). *Disc Disease*, 888 F.3d at 1259–60 n.3; *see also Promos Techs., Inc. v. Samsung Elec. Co. Ltd.*, No. 18-307-RGA, 2018 WL 5630585, at *4 (D. Del. Oct. 31, 2018) (plaintiff plausibly pled infringement where it specifically identified the accused product and alleged that “it practices each limitation of at least one claim.”). The Federal Circuit has also clarified that a plaintiff is not required to “plead facts *establishing* that *each element* of an asserted claim is met.” *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1350 (Fed. Cir. 2018) (emphasis added).

B. Claim Disavowal

“The standard for disavowal is exacting, requiring clear and unequivocal evidence the claimed invention includes or does not include a particular feature. Ambiguous language cannot support disavowal.” *Cisco Sys., Inc. v. Int’l Trade Comm’n*, 873 F.3d 1354, 1361 (Fed. Cir. 2017). The Federal Circuit has confirmed that disavowal of claim scope, whether in the patent’s specification or prosecution history, must be “clear and unmistakable” to one of ordinary skill in the art. *See Continental Circuits LLC v. Intel Corp.*, 915 F.3d 788, 798 (Fed. Cir. 2019) (internal

quotations omitted); *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1367–68 (Fed. Cir. 2012).

While in some circumstances, a patentee’s reference to a certain limitation or a preferred embodiment as “this invention” or the “present invention” can limit claim scope, such language is not so limiting; for example, “where the references to a certain limitation as being the ‘invention’ are not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent.” *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1136–37 (Fed. Cir. 2011) (citing *Voda v. Cordis Corp.*, 536 F.3d 1311, 1320–22 (Fed. Cir. 2008)) (although parts of the specification referred to a certain embodiment as the “present invention,” the specification did not uniformly refer to the invention as being so limited, and the prosecution history did not reveal such a limitation); *Rambus, Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1094–95 (Fed. Cir. 2003) (although portions of the written description referred to the term at issue as limiting the claimed invention to a preferred embodiment, “the remainder of the specification and the prosecution history shows that Rambus did not clearly disclaim or disavow such claim scope in this case”). Thus, allegedly disavowing language “must be read in context of the entire specification and the prosecution history.” *Rambus*, 318 F.3d at 1094.

V. ARGUMENT

A. Olink’s Complaint Asserts a Plausible Claim of Infringement Against Alamar

Olink’s Complaint meets the *Twombly/Iqbal* standard as applied by the Federal Circuit to patent infringement cases such as in *Disc Disease*. Olink’s Complaint attached the ’848 Patent and described in layman’s terms the nature and operation of its protected technology. D.I. 1, ¶¶ 10–17, Ex. A. Olink identified Alamar’s infringing product: Alamar’s NULISA platform which may be run on its ARGO System. D.I. 1, ¶ 18. Olink further attached publicly available materials

showing that Alamar’s NULISA platform works in the same way as claimed in the ’848 Patent. *Id.* at Ex. D, E. Using the information available to it at this early stage, Olink also alleged in detail that the NULISA platform met each and every element of at least one claim of the ’848 Patent. *Id.* ¶¶ 18–27; *see also supra* § III.C. Olink further provided evidence that Alamar has and continues to actively market, offer to sell, and/or sell its NULISA platform and ARGO system. D.I. 1, ¶¶ 28–33, Ex. C, E, G. Taking Olink’s allegations as true and viewing them in the light most favorable to Olink, Olink has plausibly pled that Alamar’s NULISA platform infringes the ’848 Patent. For this reason alone, Alamar’s Motion should be denied.

Olink is not required to prove its case at the pleading stage, to present detailed claim charts, or to disprove Alamar’s as-of-yet untested statements about Alamar’s product or the claim scope of the ’848 Patent. *See In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1342 (Fed. Cir. 2012) (warning against requiring a “level of factual specificity” in pleading patent infringement that “would be dangerously close to requiring a plaintiff to prove he is entitled to relief at the pleading stage.”). The facts presented by Olink in its Complaint state a plausible claim of infringement, under any application of *Twombly/Iqbal*, and Olink has more than met its burden. Further, there is no question that Alamar knows the exact nature of Olink’s claims against it: infringement of at least one claim of the ’848 Patent by Alamar’s manufacture, use, offer for sale, sale, marketing and/or distribution of its NULISA platform with or without its ARGO system. D.I. 1, Count I. In fact, Alamar’s Opening Brief in Support of its Motion makes clear Alamar understands the infringement allegations because its brief is dedicated to responding to these very allegations. *See* D.I. 9 at 1, 7–9.

Alamar’s argument that Olink’s Complaint pleads an “implausible” allegation of infringement fails for several reasons.

First, Alamar mischaracterizes Olink’s infringement allegations. Olink does not allege in its Complaint that NULISA infringes the ’848 Patent *because* it “uses proximity ligation” as Alamar claims (D.I. 9 at 2.); it alleges that NULISA infringes because it meets each and every element of at least one claim of the ’848 Patent. D.I. 1, ¶¶ 18–27. Olink stated in its Complaint, and Alamar has repeatedly confirmed publicly, that the NULISA platform is *based on* PLA but is ultimately distinguishable from PLA. D.I. 1, ¶ 19, Ex. D at 15 (“NULISA reduces the assay background of traditional PLA by more than 10,000-fold by incorporating *a unique molecular design* of the DNA-antibody conjugate that enables sequential purification of the immunocomplexes on two solid surfaces prior to proximity ligation); *see also* D.I. 1, Ex. E at 1 (“The NULISA system is *based on* the proximity ligation assay originally commercialized by Olink Bioscience, the forerunner of Olink.”); *see also id.* ¶ 19 (Alamar video describing NULISA as “very similar to PLA” and highlighting differences from PLA.).)

Despite now alleging its NULISA platform uses proximity ligation (*see* D.I. 9 at 6.), Alamar has previously argued that NULISA involves something different than “PLA,” convincing the U.S. Patent and Trademark Office (“USPTO”) that NULISA is distinguishable from several prior art references disclosing various types of proximity ligation (including traditional PLA, circular PLA, and solid-phase PLA) in order to secure a patent. *See, e.g.*, U.S. App. No. 17/330,331, Jan. 26, 2023 Amendment and Response to Non-Final Office Action at 10, 12, 19. (Exhibit A); Notice of Allowance (Exhibit B).³ Among other things, Alamar argued to the USPTO

³ Olink requests that the Court take judicial notice of Alamar’s U.S. Patent App. No. 17/330,331 and file history (including the Notice of Allowance issued Apr. 9, 2024). *See* Fed. R. Evid. 201(b)(2); *Mobility Workx, LLC v. Unified Patent, LLC*, 15 F.4th 1146, n.1 (Fed. Cir. 2021) (citing *Kaempe v. Myers*, 367 F.3d 958, 965 (D.C. Cir. 2004) (determining that USPTO documents were “public records subject to judicial notice.”)). The Amendment and Response to Non-Final Office Action and Notice of Allowance are attached as Exhibits A and B to the Declaration of Kelly E. Farnan in Support of Olink’s Answering Brief in Opposition to Alamar’s Motion to Dismiss.

that NULISA’s distinguishing features include those directed to the dual capture and release mechanism. To claim that NULISA is distinctive from “PLA” on the one hand, and then attempt to avoid infringement here by asserting that NULISA practices “PLA” ignores Olink’s well-pled allegations that NULISA infringes because it meets each and every element of at least one claim of the ’848 Patent.

Second, Alamar’s claim that Olink only alleged infringement against those portions of NULISA that practice “proximity ligation” is incorrect. *See* D.I. 9 at 11; *see also* § IV.C. Olink alleges in its Complaint, for example, that NULISA “practice[s] the claim limitation of ‘selecting all cis-reactive cells exhibiting detectable trace’ as a result of NULISA’s ‘dual capture and release mechanism.’” D.I. 1, ¶ 27, Ex. A, ’848 Patent at claim 1(d). As explained above, this is one of the features of NULISA that Alamar has stated distinguishes its product from traditional PLA. D.I. 1, Ex. D, E. Alamar conveniently excludes the fact that Olink alleged infringement of the dual capture and release features of NULISA in its argument that Olink has only alleged infringement against those features of NULISA “specific to proximity ligation.” *See, e.g.*, D.I. 9 at 14–15. Regardless, Olink is not required to plead facts establishing that each element of an asserted claim is met. *See Nalco*, 883 F.3d at 1350.

Third, Alamar relies on *Bot M8 LLC v. Sony Corp. of Am.* to advocate that courts have granted motions to dismiss where factual allegations are “inconsistent with the patent specification,” but *Bot M8* is distinguishable from the present case. 4 F.4th 1342 (Fed. Cir. 2021). In *Bot M8*, the Federal Circuit affirmed dismissal where the plaintiff explicitly alleged facts inconsistent with the asserted **claim language**. *Id.* at 1353–54. Alamar misrepresents the court’s holding in *Bot M8*, stating that the court affirmed dismissal of infringement claims “after comparing allegations to the patent specification and claims.” *See* D.I. 9 at 10. But the court never

considered the specification. It relied solely on the claim language, which contained an explicit limitation that two elements of the invention be stored separately. *Bot M8*, 4 F.4th at 1353–54. Inconsistent with the claim limitation, plaintiff alleged that defendant’s product stored the elements together. *Id.* Unlike the allegations in *Bot M8* demonstrating that the accused produce ***did not*** meet a claimed element, Olink has set out how Alamar meets each and every element of at least one claim of the ’848 Patent. *See* D.I. 1, ¶¶ 18–27. Further, while the claims in *Bot M8* could be interpreted without examination of the specification or extrinsic evidence, *i.e.*, no claim construction or expert opinion was necessary, that is not the case here. Alamar’s request that the Court determine claim scope based on one cherry-picked portion of the specification without first construing the claims is premature and improper.

For all the reasons stated above, Olink’s Complaint meets the *Twombly/Iqbal* standard by plausibly pleading infringement and Alamar’s Motion should be denied.

B. Alamar’s Disavowal Argument Is a Claim Construction Issue That Should Not Be Decided at the Motion To Dismiss Stage

Any analysis of disavowal would require claim construction because disavowal fundamentally is a claim construction issue, as it involves narrowing the scope of the claims in light of the specification. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (quoting *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985)) (“[t]he descriptive part of the specification aids in ascertaining the scope and meaning of the claims inasmuch as the words of the claims must be based on the description.”). Alamar cites to various cases in support of its argument that a finding of implausibility at the pleading stage can rest on doctrines that limit claim scope. *See* D.I. 9 at 11. However, these cases are inapposite.

In *Ottah* and *Amgen*, the court found that prosecution history estoppel applied where plaintiffs clearly surrendered the allegedly infringing embodiments during prosecution. *Ottah v.*

Fiat Chrysler, 884 F.3d 1135, 1141–42 (Fed. Cir. 2018); *Amgen Inc. v. Coherus Biosciences Inc.*, 931 F.3d 1154, 1160–62 (Fed. Cir. 2019). Similarly, the court in *Eagle* held that the disclosure dedication doctrine prevented plaintiff from asserting a DOE infringement theory where the written description explicitly identified an unclaimed alternative to a claim limitation. *Eagle Pharms., Inc. v. Slayback Pharma LLC*, 382 F. Supp. 3d 341, 345–46 (D. Del. 2019). These cases involved simpler technology and the surrender of claim scope was explicitly clear. For example, in *Ottah*, plaintiff tried to assert its book holder patent over defendants’ camera holder product, despite the claim language referring exclusively to “books” and the use of “books” in claim 1 having been used to limit the scope of examination to prior art book holders, as reflected in the prosecution history. *Ottah*, 884 F.3d at 1141.

Further, defendants in those cases pointed to specific terms in the claims that were impacted by the alleged disclaimer. In *Eagle*, the claim limitation at issue was the “solvent limitation” and whether claims directed to “polyethylene glycol” could cover, under DOE, defendants’ use of an alternative solvent described in the specification but not claimed. *Eagle*, 382 F. Supp. 3d at 343–45. In *Ottah*, claim 1 directly recited “a book holder” yet plaintiff alleged infringement against defendants’ camera holder product. *Ottah*, 884 F.3d at 1137–39. In *Amgen*, the claim language at issue was a “combination of a first and a second salt” wherein “the first and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate,” and patentee had argued during prosecution that the invention was novel due to the specifically claimed combination of salts; the infringement issue was whether defendants’ use of a different combination of salts could infringe the claimed salt limitation under DOE. *Amgen*, 931 F.3d at 1157–59. The case at hand is distinguishable at least because Alamar makes broad allegations that the ’848 Patent disavows all of “proximity ligation” but it is unclear what specific

claim language should be limited in scope to exclude “proximity ligation” due to such alleged disavowal.

To render a decision on Alamar’s Motion, Alamar asks this Court to determine what “proximity ligation” means and which claim terms were disavowed. Such a determination is a claim construction issue, which the Federal Circuit and this Court have repeatedly dismissed as inappropriate at the pleading stage. *See Nalco*, 883 F.3d at 1350 (“It is not appropriate to resolve [claim construction] disputes, or to determine whether the method claimed in the [] patent should be confined to the preferred embodiment, on a Rule 12(b)(6) motion, without the benefit of claim construction.”); *In re Bill of Lading*, 681 F.3d at 1343, n.13 (concluding that “claim construction at the pleading stage—with no claim construction process undertaken—was inappropriate.”); *Pragmatus AV, LLC v. TangoMe, Inc.*, C.A. No. 11-1092-LPS-CJB, 2013 WL 571798, at *7 (D. Del. Feb. 13, 2013) (“To engage in the claim construction process upon review of a motion to dismiss would be to go beyond the scope of a court’s traditional gatekeeping role in reviewing such a motion; it would instead amount to a more in-depth evaluation of the merits of a plaintiff’s case.”).

In its motion, Alamar cites to certain claim language and attempts to argue non-infringement without the benefit of claim construction. Namely, Alamar argues that Olink did not, and cannot, allege facts that NULISA is a “method of detecting functional interactions between at least two molecules or interest” or requires that the two interactors be “bound in proximity to one another by an associated oligonucleotide.” D.I. 9 at 18–20. Alamar argues that “[t]his failure is predictable, given that NULISA is about identifying *known* molecules using pre-defined interactions, not about detecting previously unknown functional interactions between molecules—the ’848 Patent’s “molecules of interest.” *Id.* at 18 (emphasis in original). Yet, the scope of

“molecule of interest” has not been determined, including whether the ’848 Patent requires such a narrow reading (it does not) as to be limited to “known molecules” or those with “predefined interactions” or affinities. Alamar further alleges that Olink “pleads itself out of Court” because it alleges that the two NULISA probes are *bound to an analyte* and not “bound by an associated oligonucleotide” as required by the claims. D.I. 9 at 19 (emphasis in original). Yet again, the scope of “bound in proximity to one another by an associated oligonucleotide” has not been determined.

Thus, Alamar asks the Court to step beyond its traditional gatekeeping role in reviewing Olink’s Complaint and conduct a more in-depth evaluation of the merits of Olink’s case, including the meaning and scope of the ’848 Patent’s claims. Whether the claims of the ’848 Patent cover “proximity ligation” and/or NULISA requires, at minimum, claim construction, and Alamar’s improper attempt to narrow the scope of the claims without claim construction should be rejected. Moreover, whether Olink disavowed all of “proximity ligation” should be viewed through the lens of a POSA. *See Continental Circuits*, 915 F.3d at 798 (disavowal of claim scope, whether in the patent’s specification or prosecution history, must be “clear and unmistakable” *to one of ordinary skill in the art.*) (emphasis added). Alamar’s Motion should therefore be denied because the issue of whether NULISA is distinguishable from “proximity ligation” or “PLA” or whether it is outside the scope of the claims of the ’848 Patent requires claim construction, fact discovery and expert opinion.

C. Olink Did Not Disavow Proximity Ligation⁴

Alamar improperly states as fact, without evidentiary support, that the ’848 Patent disavowed all of “proximity ligation”—it did not. Disavowal of claim scope must be “clear and

⁴ Given the nature and stage of the proceedings, Olink herein identifies certain examples of statements made by the inventor in the specification of the ’848 Patent that make clear he did not

unmistakable” to one of ordinary skill in the art. *See Continental Circuits*, 915 F.3d at 798; *Cisco Sys.*, 873 F.3d at 1361. The Federal Circuit has found that use of the phrase “present invention” or “this invention” is not always limiting, such as where other portions of the intrinsic evidence are not uniform or where other positions of the intrinsic evidence do not support applying the limitation to the entire patent. *See Voda*, 536 F.3d at 1320–22 (although parts of the specification referred to a certain embodiment as “this invention,” the specification did not uniformly refer to the invention as being so limited); *see also Rambus*, 318 F.3d at 1094–95. Here, Alamar has not shown disavowal through clear and unequivocal evidence, that the specification uniformly limits the invention to exclude “proximity ligation” as understood by a POSA, or that the prosecution history includes statements expressly disavowing “proximity ligation.”

In fact, despite Alamar’s use of several pages of its brief to allege that Olink “expressly” and “unequivocally” disavowed “proximity ligation,” it only identifies a single portion—column 4 line 26 to column 5 line 2—in the entirety of the 44-column patent where such alleged disavowal occurs. *See* D.I. 9 at 3–6, 11, 14–15 (Table), 16–18 (citing ’848 Patent at 4:26–5:2). However, a POSA would reasonably read the specification as a whole as not disavowing “proximity ligation,” as there are several places throughout the specification that indicate the inventor has *not* disavowed “proximity ligation.” For example, Alamar alleges that because the ’848 Patent disavowed “proximity ligation,” the invention cannot include the claim limitations such as “detection of a defined target,” “utilizing molecules with predefined affinities,” or allowing for “co-localization of the binder pair in the presence of a target” (among “other limitations”) because these steps involve principles associated with “proximity ligation,” (D.I. 9 at 17) but there are several places

disavow “proximity ligation.” These are non-limiting examples and Olink maintains that arguments concerning disavowal should be supported by the opinion of a POSA.

in the specification where the inventor explicitly relies on these principles of “proximity ligation” to practice the invention:

Significantly, the invention allows investigation of *all possible interactions* within or between libraries of molecules, such as proteins, and also permits relative quantification of the detected interactions.

’848 Patent at 5:25–28 (emphasis added). A POSA would understand “all possible interactions” as not limited to only those affinities or targets that are undefined or unknown. Elsewhere, the specification states:

The result of the forced NAM association is a secondary library of cis reactive cells (CRCs). A CRC is a co-localization of two or more interactors which are associated by their NAMs (associated oligonucleotide). Thus the MOI components of the same CRC are brought in proximity although the MOIs might not have any intrinsic affinity. However, it is contemplated that in some embodiments the CRCs may be created by relying on intrinsic MOI affinities or a combination of both MOI affinity and NAM affinity.

Id. at 15:64–16:6. Thus, the inventor specifically contemplated that his method may use “intrinsic MOI affinities” or molecules with predefined affinities. In the context of the ’848 Patent, a POSA would understand the passage cited by Alamar in column 4 to convey that the inventor has improved upon known methods described in Landegren and Baez, *i.e.*, the claimed methods are not limited to using molecules with predefined affinities.

The specification does not define the molecule of interest in a manner that limits it to an “unknown target” or having unknown affinity for another molecule. In other words, Alamar is trying to construe the claims of the ’848 Patent too narrowly because the practicing of the claimed methods may include the use of molecules with predefined affinities, as contemplated by the inventor. Olink therefore did not disavow “proximity ligation” and as such, Alamar’s Motion should be denied.

D. Amendment of the Complaint Would Not Be Futile

To the extent that this Court finds that Olink's Complaint does not meet the *Twombly/Iqbal* standard, Olink should be permitted to amend its Complaint. Dismissal with prejudice is not a proper remedy even if the Court determines that Olink's Complaint does not currently state plausible infringement claims. Instead, amendment should be granted freely; in *North Star Innovations, Inc. v. Micron Tech., Inc.*, this Court granted the plaintiff leave to amend its infringement claims for a third time because "dismissal with prejudice is 'rarely' a proper sanction." No. 17-506-LPS-CJB, 2017 WL 5501489, at *3 (D. Del. Nov. 16, 2017). Amendment of a complaint will only be denied if it is deemed futile, that is, if the Court determines that no amendment will be able to remedy a complaint's ability to meet the pleading standard. *Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000).

While Olink does not believe any amendment is necessary here, as discussed above, to the extent that the Court disagrees, Olink should be allowed to amend its Complaint to assert additional facts to further clarify that Alamar's NULISA platform infringes the '848 Patent not because it "uses proximity ligation," but because it meets each and every limitation of one or more claims—including those limitations distinguishable from "proximity ligation." Such amendments would include the addition of further facts that, for example, the NULISA platform performs the "selecting" step of claim 1(d) of the '848 Patent, a step that Alamar claimed distinguishes the NULISA platform from PLA during prosecution of its own patent applications directed to its NULISA platform. Specifically, that NULISA uses the steps of "capturing the immunocomplex on the first pragmatic beads," "washing the immunocomplex," "releasing the immunocomplex," "recapturing the immunocomplex on the second pragmatic beads," and "washing to remove unbound molecules." Ex. A at 3. Such amendments would not be futile as they would further

elaborate on why Alamar infringes the '848 Patent, and if assumed to be true under the *Twombly/Iqbal* standard would further support a claim for patent infringement against Alamar.

The cases cited by Alamar to support its arguments that amendment of the Complaint would be futile where “the specification affirmatively contradicts Plaintiff’s arguments” or where new allegations would be “contrary [to] teachings of the specification” are again, inapposite. *Tenaha Licensing* was a 35 U.S.C. § 101 patent ineligible subject matter case where plaintiff “made no attempt to rebut [Defendant’s] assertion of futility, did not request leave to amend, and failed to propose[] any additions to the Complaint that could plausibly overcome Defendant’s Motion.” *Tenaha Licensing LLC v. Vocera Commc’ns, Inc.*, No. CV 19-208-LPS-SRF, 2020 WL 30489, at *9 (D. Del. Jan. 2, 2020). *Sanderling*, like *Tenaha*, was a 35 U.S.C. § 101 ineligibility case where plaintiff’s “proposed amendment merely sought to add conclusory statements that the claimed steps were not well-known, routine, and conventional.” *Sanderling Mgmt. Ltd. v. Snap Inc.*, 65 F.4th 698, 706 (Fed. Cir. 2023). Here, Olink asserts a plausible infringement claim and has proposed amendments that makes its infringement claims even more plausible by providing additional detail and explanation for its basis for believing that Alamar infringes at least one claim of the '848 Patent. Therefore, an amendment of Olink’s Complaint, to the extent necessary, would not be futile and should be permitted.

VI. CONCLUSION

For each of the above reasons, Olink respectfully requests that the Court deny Alamar’s Motion to Dismiss without prejudice, or in the alternative, grant Olink leave to amend its Complaint.

Of Counsel:

Huiya Wu
Tiffany Mahmood
GOODWIN PROCTER LLP
620 8th Avenue
New York, NY 10018
(212) 813-8800
HWu@goodwinlaw.com
TMahmood@goodwinlaw.com

Tara R. Thigpen
Kristin M. Beale
Emma L. Murray
GOODWIN PROCTER LLP
100 Northern Ave
Boston, MA 02210
(617) 570-1000
TThigpen@goodwinlaw.com
KBeale@goodwinlaw.com
EMurray@goodwinlaw.com

Dated: April 15, 2024

/s/ Kelly E. Farnan

Kelly E. Farnan (#4395)
Sara M. Metzler (#6509)
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com
Metzler@rlf.com

Attorneys for Plaintiffs