IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OLINK PROTEOMICS AB and OLINK PROTEOMICS INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 23-1303-MN
ALAMAR BIOSCIENCES, INC.,	)	
Defendant.	)	

REPORT AND RECOMMENDATION

Presently pending before the Court in this patent infringement case is Defendant Alamar Biosciences, Inc.'s ("Alamar" or "Defendant") motion seeking dismissal of Plaintiffs Olink Proteomics AB and Olink Proteomics Inc.'s (collectively, "Olink" or "Plaintiffs") Complaint, which was filed pursuant to Federal Rule of Civil Procedure 12(b)(6) (the "Motion"). (D.I. 8) For the reasons that follow, the Court recommends that Alamar's Motion be GRANTED-IN-PART and DENIED-IN-PART.

I. BACKGROUND

A. Factual Background

Olink, a global leader in the proteomic analysis field, was founded in 2004 to develop and commercialize the Proximity Ligation Assay ("PLA"). (D.I. 1 at ¶ 14) Olink's founders invented PLA, a valuable tool for quantitative protein analysis. (*Id.*) PLA utilizes pairs of antibodies that are each linked to a DNA oligonucleotide. (*Id.*) When the antibodies find and bind to their respective target proteins, the DNA oligonucleotides become close to each other. (*Id.*) The proximity of the DNA oligonucleotides allows these DNA pieces to hybridize to a splint oligonucleotide, which creates a unique DNA sequence that may be detected and

quantified by various methods. (*Id.*) The signals that are generated by this process are proportional to the amount of the target proteins in the sample. (*Id.*) Olink has several patents relating to PLA technology; the Complaint alleges that United States Patent No. 7,883,848 (the "asserted patent" or the "'848 patent") is one such patent. (*Id.* at ¶ 15)

Olink asserts the '848 patent in this case. (*Id.* at ¶ 1) The '848 patent is entitled "Regulation Analysis by Cis Reactivity, RACR[,]" and it issued on February 8, 2011. ('848 patent, ex. A at 1)[1] The Complaint states that the '848 patent is related to methods of detecting functional interactions between at least two molecules of interest. (*Id.* at ¶ 11) Olink alleges that Alamar's Nucleic acid Linked Immuno-Sandwich Assay ("NULISA") platform, used with or without its ARGO system, infringes at least claim 1 of the '848 patent. (*Id.* at ¶¶ 1, 12, 20) The patent contains one independent claim and 19 dependent claims. Independent claim 1, which we will be dealing with here, recites:

> **1.** A method of detecting functional interactions between at least two molecules of interest, the method comprising:
>
> a. forming a plurality of interactors by coupling each molecule of interest with at least one nucleic acid moiety, the nucleic acid moiety comprising an identification sequence element and an association element;
>
> b. forming a plurality of cis-reactive cells wherein a cis-reactive cell comprises at least two interactors bound in proximity to one another by an associated oligonucleotide formed from the association between at least two nucleic acid moieties, wherein the associated oligonucleotide comprises at least two identification elements derived from the at least two nucleic acid moieties;
>
> c. subjecting the plurality of cis-reactive cells to conditions which stimulate a desired functional interaction having a detectable trace;
>
> d. selecting all cis-reactive cells exhibiting the detectable trace; and

[1] The asserted patent is attached as an exhibit to the Complaint. (D.I. 1, ex. A) Herein, the Court will cite to the patent by its patent number.

> e. subjecting the associated oligonucleotides from the cis-reactive cells selected in step (d) to an analysis that permits detection of the at least two identification sequence elements.

('848 patent, col. 41:37-58)

The accused product, NULISA, is a liquid biopsy platform that was developed to address the need for "ultra-high sensitivity to detect low-abundance proteins in the blood proteome[.]" (D.I. 1, ex. D at PageID 88; *see also id.* at PageID 75) NULISA achieves ultra-high sensitivity by "adopt[ing] the principle of PLA" while using additional methods to suppress various background sources. (*Id.* at PageID 79, 88) In doing so, NULISA "improves the sensitivity of the proximity ligation assay[.]" (*Id.* at PageID 75) NULISA may be run on Alamar's ARGO system, which is a "fully automated, high-throughput precision proteomics platform." (D.I. 1 at ¶ 18; *id.*, ex. C at 1)

B. Procedural Background

Olink filed its Complaint on November 15, 2023. (D.I. 1) In lieu of filing an Answer, Alamar filed the instant Motion on April 1, 2024. (D.I. 8) The Motion was fully briefed as of April 22, 2024. (D.I. 17) On September 5, 2024, United States District Judge Maryellen Noreika referred the Motion to the Court for resolution. (D.I. 19)

Further relevant facts related to resolution of the Motion will be discussed as needed in Section III.

II. STANDARD OF REVIEW

The sufficiency of pleadings for non-fraud claims is governed by Rule 8, which requires "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" Fed. R. Civ. P. 8(a)(2). When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual and legal elements of a claim, accepting "all of

the complaint's well-pleaded facts as true, but [disregarding] any legal conclusions." *Id.* at 210-11 (citation omitted). Second, the court determines "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)).[2] "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). In assessing the plausibility of a claim, the court must "'construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.'" *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).

In a patent infringement case, the plausibility standard is met when the allegations provide the defendant with "fair notice of infringement of the asserted patents." *Disc Disease Sols. Inc. v. VGH Sols, Inc.*, 888 F.3d 1256, 1260 (Fed. Cir. 2018). At the pleading stage, a plaintiff is not required to prove its case, *Nalco Co. v. Chem-Mod, LLC,* 883 F.3d 1337, 1350 (Fed. Cir. 2018), and "[s]pecific facts are not necessary to support every allegation in the complaint[,]" *AlexSam, Inc. v. Aetna, Inc.*, 119 F.4th 27, 39 (Fed. Cir. 2024) (internal quotation marks and citation omitted). That said, the factual allegations of infringement must be of sufficient detail such that, when they are taken as true, a reviewing court can understand "why it is plausible that the accused product infringes the patent claim." *Bot M8 LLC v. Sony Corp. of*

[2] In resolving a motion to dismiss, a court typically considers the allegations in the complaint, the exhibits attached thereto, documents or facts that are incorporated by reference into the complaint or that are otherwise integral to the complaint's allegations, matters of public record and items for which the court can take judicial notice. *See Siwulec v. J.M. Adjustment Servs., LLC*, 465 F. App'x 200, 202 (3d Cir. 2012); *ING BANK, fsb v. PNC Fin. Servs. Grp., Inc*., 629 F. Supp. 2d 351, 354 (D. Del. 2009).

Am., 4 F.4th 1342, 1353 (Fed. Cir. 2021); *see also Kajeet, Inc. v. Gryphon Online Safety, Inc.*, C.A. No. 19-2370 (MN), C.A. No. 20-1339 (MN), 2021 WL 780737, at *3 (D. Del. Mar. 1, 2021) ("[T]o state a claim of direct infringement sufficient to withstand a motion to dismiss, a plaintiff must plead facts that plausibly suggest that the accused product meets each limitation of the asserted claim(s)."); *DIFF Scale Operation Rsch., LLC v. MaxLinear, Inc.*, Civil Action No. 19-2109-LPS-CJB, 2020 WL 2220031, at *1 & n.2 (D. Del. May 7, 2020).

A plaintiff therefore cannot assert a plausible claim for infringement by "reciting the claim elements and merely concluding that the accused product has those elements." *Bot M8 LLC*, 4 F.4th at 1353. But on the other hand, a plaintiff need not necessarily "plead infringement on an element-by-element basis." *Id.* at 1352. The United States Court of Appeals for the Federal Circuit has explained that "[t]he level of detail required in any given case will vary depending upon a number of factors, including the complexity of the technology, the materiality of any given element to practicing the asserted claim(s), and the nature of the allegedly infringing device." *Id.* at 1353; *see also AlexSam*, 119 F.4th at 39.[3]

III. DISCUSSION

Alamar asserts that it is entitled to dismissal of Olink's Complaint for failure to state a claim for two reasons. (D.I. 9 at 2-3) Alamar first argument goes as follows: (1) the '848 patent expressly disclaims proximity ligation from the scope of the invention; (2) but NULISA uses proximity ligation, and the Complaint specifically accuses NULISA of infringement based on its use of proximity ligation; and, therefore, (3) in light of the patent's express disavowal of proximity ligation, "NULISA's platform simply cannot infringe the '848 [p]atent as a matter of

[3] The law of the Federal Circuit applies to the question of whether a complaint states a plausible claim of patent infringement. *AlexSam*, 119 F.4th at 35.

law." (D.I. 9 at 9; *see also id.* at 2-3, 10-17; D.I. 17 at 10 ("The '848 patent disclaimed the steps of proximity ligation without reservation, and the Complaint alleges that NULSA infringes for practicing those same steps" which means that "the Complaint should be dismissed with prejudice")) Second, Alamar contends that the Complaint fails to plausibly plead that NULISA meets certain limitations of claim 1 of the '848 patent. (D.I. 9 at 3, 18-20; D.I. 17 at 2-4) The Court takes up these arguments in turn.

A. Whether express disclaimers in the '848 patent preclude coverage of NULISA

The Court first addresses Alamar's assertion that the '848 patent includes an express disclaimer of proximity ligation that, in turn, precludes the patent claims from covering NULISA (a product that in some way utilizes proximity ligation). In doing so, as an initial matter, the Court will set out the law regarding express disclaimer. Then it will evaluate the merits of Alamar's disclaimer argument.

While "[t]he written description part of the specification itself does not delimit the right to exclude" (as that is the purpose of the claims), *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996), in some cases, "the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor"; in such instances, "the inventor's intention, as expressed in the specification, is regarded as dispositive[,]" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005). "Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) (internal quotation marks and citation omitted). "Mere criticism of a particular embodiment encompassed in the plain

meaning of a claim term" is not enough to constitute disavowal; instead, "[t]o constitute disclaimer, there must be a clear and unmistakable disclaimer." *Id.* at 1366-67; *see also Cont'l Cirs. LLC v. Intel Corp*., 915 F.3d 788, 797 (Fed. Cir. 2019) ("To disavow claim scope, the specification must contain 'expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.'") (citation omitted). A court must consider the "specification as a whole" in determining whether the patentee disclaimed criticized subject matter. *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1365-67 (Fed. Cir. 2004); *see also Cont'l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 798 (Fed. Cir. 2019); *Princeton Digit. Image Corp. v. Konami Digit. Ent. Inc*., Civil Action No. 12-1461-LPS-CJB, Civil Action No. 13-335-LPS-CJB, 2016 WL 7042066, at *8 (D. Del. Dec. 2, 2016), *report and recommendation adopted in relevant part*, 2017 WL 6375173 (D. Del. Dec. 13, 2017), *aff'd sub nom. Princeton Digit. Image Corp. v. Ubisoft Ent. SA*, 829 F. App'x 527 (Fed. Cir. 2020).

So what does Alamar point to in the '848 patent specification in support of its disclaimer argument? As noted above, the '848 patent relates to methods for detecting affinity interactions and functional interactions between molecules of interest. ('848 patent, cols. 1:11-14) The specification's "Background of the Invention" section acknowledges that several other approaches exist in the art to screen interactions between molecules of interest that "differ from the present inventive methods in significant ways." (*Id.*, col. 1:57-59)

One such approach that the specification discusses in columns 4 and 5 of the patent is "proximity ligation"; this discussion is the focus of Alamar's Motion. The patent specification first describes "proximity ligation" as follows:

> A method referred to as "proximity ligation" has been recently described [in "WO0161037" and "US2002051986"]. According to this method, targets are detected by utilizing two or more binders, e.g. antibodies, *with known affinity to the target*. The method is

> based upon the co-localization of the binder pair in the presence of a target. This target brings the binders into proximity, enabling ligation of nucleic acids located on the binder pair. . . .
>
> The primary embodiment of WO0161037 and US2002051986 aims at detection *of a defined target. Thus all the affinities in the system are known and there is always at least one molecule, the target, which does not have a nucleic acid attached to it*.

(*Id.*, col. 4:26-43 (emphasis added)) The specification then distinguishes the invention of the '848 patent from proximity ligation:

> The *current inventive method differs from proximity ligation in that it does not detect or quantify a predefined target in a sample*. *The present inventive methods do not utilize molecules with predefined affinities but rather the reverse; the inter-molecular affinities are retrieved as a result of the inventive method*.
>
> In the current invention the association of the nucleic acid is combinatorial and the novel nucleic acid produced by this association is then identified to yield information concerning the molecular interactions in the library. This enables interrogation of all intra-or inter-library member interactions. The proximity ligation methods always include at least one molecule which is not attached to a nucleic acid label and this "target" is the molecule which is detected. Thus the co-localization/proximity of the binders and thereby the nucleic acid in the assay *arises from the presence of a target molecule.*

(*Id.*, col. 4:48-63 (emphasis added)) The specification then distinguishes "the information gained" from the invention of the '848 patent and proximity ligation; while in the "present inventive methods[] combinations of interacting molecules may be detected and quantified[,]" proximity ligation art, "on the other hand, teaches high throughput screening of inhibitors for a defined binding event." (*Id.*, col. 4:64-5:2) The specification continues with respect to proximity ligation:

> For example, a protein affinity interaction is identified first by some other method and proximity ligation is employed to find an inhibitor *for the known affinity interaction*. The proximity ligation screening approach involves attaching nucleic acids to the two

> proteins which participate in the *predefined interaction.* Then different potential inhibitors are added to the reaction. These potential inhibitors are not labeled with nucleic acids and their action is monitored by observation of a reduced signal from the two labelled proteins. The *pre-defined affinity reagents* are labelled with nucleic acids and a pre-defined pair of nucleic acids is analyzed.

(*Id.*, col. 5:2-13 (emphasis added)) The "Background of the Invention" section then concludes by noting the "need" in the art "for methods capable of investigating affinity and/or functional interactions within libraries of molecules wherein such interactions *are not previously established to exist*" (and methods for quantification of any such detected interactions). (*Id.*, col. 5:14-18 (emphasis added))

Based on this discussion in the specification, Alamar argues that the '848 patent expressly disavowed at least certain specific elements of proximity ligation:

- Methods involving the "detection of a defined target" by "utilizing two or more binders, e.g. antibodies, with known affinity to the target[,]" (*id.*, col. 4:30-31, 40);
- Methods involving co-localization of the binder pair arising in the presence of a target which "brings the binders into proximity, enabling ligation of nucleic acids located on the binder pair[,]" (*id.*, col. 4:32-34); and
- Methods where this "target" is the "molecule which is detected" and in which "there is always at least one molecule, the target, which does not have a nucleic acid attached to it[.]" (*Id.*, col. 4:41-43, 60-61)

(D.I. 9 at 13, 17) Alamar asserts that the patent describes the invention claimed therein as "differ[ing]" from proximity ligation in *not* detecting a predefined target; the invention does not utilize molecules with *predefined* affinities but instead utilizes the "*reverse*"—i.e., the inventive method *figures out* previously unknown inter-molecular affinities. ('848 patent, col. 4:48-53 (emphasis added); *see also* D.I. 9 at 6, 13)

Alamar's argument that there is express disclaimer in the '848 patent of at least certain specific elements or steps of proximity ligation seems a strong one.[4] The specification clearly says, for example, that the method claimed in the '848 patent is different than at least certain aspects of "proximity ligation" (which is aimed at "detection of a defined target" and "teach[ing] high throughput screening of inhibitors for a defined binding event")—in that the claimed method "does not detect or quantify a predefined target in a sample" and thus "do[es] not utilize molecules with predefined affinities" but, instead, the "inter-molecular affinities are retrieved as a result of the inventive method." ('848 patent, cols. 4:39-40, 48-53, 4:67-5:2) Moreover, in making these distinguishing statements, the patentee used phrases such as "[t]he current inventive method" and "[t]he present inventive methods" and "[i]n the current invention"—phrases that are typically understood to be a way of "alert[ing] the reader that this description limits the scope of the invention." *Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1025 (Fed. Cir. 2015) (internal quotation marks and citation omitted); *see also SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343 (Fed. Cir. 2001) ("[T]he [repeated] characterization of the coaxial configuration as part of the 'present invention' is strong evidence that the claims should not be read to encompass the opposite structure."). Therefore, by pointedly distinguishing aspects of the prior art proximity ligation method as detecting a predefined target—and specifically noting that this is the "reverse" of what the "present inventive methods" do—the patentee seems to have signaled, at least in this respect, that the "claims should not be read so broadly as to encompass the distinguished prior art" method.

[4] However, while Alamar's disclaimer argument appears to be broadly directed to "proximity ligation assay[,]" (D.I. 9 at 1), it is not clear to the Court that the aspects of proximity ligation that are distinguished in the specification cover *all* aspects of "proximity ligation assay," full stop, as opposed to something less than that, (*see, e.g.*, D.I. 15 at 2 n.2).

SciMed Life Sys., 242 F.3d at 1341-43; *see also Indivior Inc. v. Dr. Reddy's Lab'ys, S.A.*, 930 F.3d 1325, 1337 (Fed. Cir. 2019) (concluding that the specification disclaims conventional top air drying where, *inter alia,* "the specification repeatedly disparages conventional top air drying because such drying does not produce uniform films, the central object of the claimed invention").[5]

However, even if Alamar is correct that the '848 patent specification disavows at least certain aspects of proximity ligation (e.g., detecting or quantifying a predefined target in a sample/utilizing molecules with predefined affinities/teaching high throughput screening of inhibitors for a defined binding event), that is not the end of the inquiry. Rather, dismissal at this early stage of the case would require the Court to: (1) understand how that disavowal impacts the claim scope of the limitations in claim 1 of the '848 patent; and (2) agree with Alamar that

[5] Olink's substantive response to Alamar's claim scope disavowal argument was not especially persuasive. Olink argues that two portions of the specification demonstrate that while the '848 patent *improves* upon proximity ligation, it does not *exclude* the use of molecules with predefined affinities. (D.I. 15 at 17) First, Olink points to a part of the specification noting that "[s]ignificantly, the invention allows investigation of all possible interactions within or between libraries of molecules[.]" ('848 patent, col. 5:25-27 (*quoted in* D.I. 15 at 17)) According to Olink, a person of ordinary skill in the art would understand this "all possible interactions" language as "not limited to only those affinities or targets that are undefined or unknown." (D.I. 15 at 17) Second, Olink cites a passage wherein the patentee explains that "it is contemplated that in some embodiments the [cis reactive cells] may be created by relying on intrinsic [molecule of interest] affinities" which, according to Olink, demonstrates that the claimed method may use "molecules with predefined affinities." ('848 patent, col. 16:3-5 (*quoted in* D.I. 15 at 17))

But these arguments do not seem strong. At a minimum, these two passages do not *clearly* convey that the claimed invention covers molecules with *predefined* affinities. And this is problematic for Olink, particularly when one takes into account the preceding (and *very clear*) statements distinguishing the claimed invention from at least that aspect of proximity ligation. Moreover, in arguing that there is no disavowal in light of these passages, Olink never really meaningfully grapples with the specific language in the portions of the specification (i.e., in columns 4 and 5) that Alamar highlights—those that discuss the "current inventive method" and contrast it with certain aspects of the proximity ligation method. (*See* D.I. 17 at 7, 9; *see also* D.I. 15 at 16)

the Complaint alleges that NULISA infringes certain '848 patent claim limitations because it practices those disclaimed aspects of proximity ligation. But the record on these issues is just not very clear.[6]

A big part of the problem here is that, as Olink notes, Alamar does not do a great job pointing out "specific terms in the claims that [are] impacted by the alleged disclaimer" and then plainly explaining exactly why that is so. (D.I. 15 at 13; *see also id.* at 13-14 ("[I]t is unclear what specific claim language should be limited in scope to exclude 'proximity ligation' due to such alleged disavowal.")) This failing is underscored by the various cases that Alamar relies on for support in its briefing. In each of those cases, it was not difficult for the reviewing court to understand, simply based on the record before it at the pleading stage: (1) what characteristic or element the patentee had disclaimed as not being a part of the invention (either in light of the patent's language, or in light of the patentee's comments made during prosecution); (2) what claim term in the patent(s)-in-suit bore a relationship to the characteristic or element that had been disclaimed; and (3) how the record demonstrated that it was implausible that the accused product satisfied that relevant claim limitation (in light of the disclaimer, and in light of the nature of that product).

For example, in *Eagle Pharms., Inc. v. Slayback Pharma LLC*, 382 F. Supp. 3d 341 (D. Del. 2019), *aff'd*, 958 F.3d 1171 (Fed. Cir. 2020), the defendant's motion was "focuse[d] on [a particular] claim limitation" (a limitation requiring some combination of propylene glycol

[6] In light of the Court's conclusion herein (i.e., that Alamar has not sufficiently demonstrated that it is implausible that it infringes claim 1 of the patent-in-suit in light of its disclaimer argument), the Court need not decide (and is not now deciding), as a matter of law, whether and to what extent the patentee's statements in the specification regarding proximity ligation actually limit the scope of the asserted claims. That said, Alamar is free to re-raise this disclaimer issue (for which, again, it seems to have a strong argument in at least certain respects) at an appropriate point in the future.

and polyethylene glycol, or the "solvent limitation") that the plaintiff alleged was infringed under the doctrine of equivalents ("DOE"). 382 F. Supp. 3d at 343 (*cited in* D.I. 9 at 11, 16). The defendant argued that the "disclosure-dedication doctrine bars [the plaintiff's] claims for infringement of the solvent limitation under the [DOE] because the common written description of the asserted patents discloses, but does not claim, [the defendant's] second solvent as a specific alternative to propylene glycol." *Id.* at 345. The Court agreed with the defendant, concluding that "it would be clear to a POSITA that the asserted patents disclose [the defendant's] second solvent as an alternative to propylene glycol, a claim limitation found in each of the independent claims"—and that the plaintiff was therefore barred by the disclosure-dedication doctrine from alleging that the defendant's product infringes the solvent claim limitation. *Id.* at 348.

Similarly, in *Amgen Inc. v. Coherus BioScis. Inc.*, 931 F.3d 1154 (Fed. Cir. 2019), the defendant's motion to dismiss focused on a specific claim limitation that required a salt combination chosen from one of three pairs: citrate and sulfate, citrate and acetate, or sulfate and acetate (the "salt combination limitation"). 931 F.3d at 1157 (*cited in* D.I. 9 at 11). The plaintiff there alleged that the defendant's manufacturing process infringed under the DOE; a DOE-type infringement allegation was the only option for the plaintiff to pursue, since the salt combination used in the accused process did not match any of the three expressly claimed salt combinations in salt combination limitation. *Id.* at 1158. The defendant moved to dismiss, arguing that during prosecution of the patent, the plaintiff had clearly and unmistakably (and repeatedly) surrendered combinations other than the particular salt combinations that were recited in the claims. *Id.* The Court and the District Judge agreed, concluding that the prosecution history demonstrated a clear

and unmistakable surrender of claim scope with respect to the salt combination limitation; the Federal Circuit later affirmed. *Id.* at 1158-59, 1161.

Likewise, in *Ottah v. Fiat Chrysler*, 884 F.3d 1135 (Fed. Cir. 2018), the only claim of the asserted patent claimed a "book holder." *Id.* at 1137-38 (*cited in* D.I. 9 at 11). The plaintiff alleged that the defendants' camera holders infringed this claim. *Id.* at 1138. The Federal Circuit affirmed the district court's conclusion that the claimed "'book holder' could not plausibly be construed to include or be the equivalent of a camera holder, in view of the specification and the prosecution history." *Id.* at 1141-42.[7]

Here, in contrast to all of these cases, in its briefing Alamar did not clearly: (1) identify a particular claim term that was affected by the disclaimer; and then (2) cogently and

[7] The same is true of the other cases involving motions to dismiss that Alamar relies upon. In *Bot M8 LLC v. Sony Corp. of Am.*, 4 F.4th 1342 (Fed. Cir. 2021), the claim required that a game program and authentication program be stored together, separately from the motherboard—but the complaint alleged that the defendant's product's authentication program was located on the motherboard itself. 4 F.4th at 1354 (*cited in* D.I. 9 at 11). In *Grecia Est. Holdings LLC v. Meta Platforms, Inc.*, 605 F. Supp. 3d 905 (W.D. Tex. 2022), the defendant argued that the relevant claim's "correspond" limitation plainly required a particular relationship between the claimed "membership verification token" and the "encrypted digital media." 605 F. Supp. 3d at 914 (*cited in* D.I. 9 at 17). The plaintiff had alleged that the defendant's user's "PayPal account or Debit and Credit Card number" is the claimed "membership verification token[,]" but the court granted the defendant's motion to dismiss because the plaintiff had argued in an *inter partes review* proceeding that payment account numbers do not correspond to any particular digital media. *Id.* at 914-15 (internal quotation marks and citation omitted). In *Almirall, LLC v. Torrent Pharms., Ltd.*, 548 F. Supp. 3d 443 (D. Del. 2021), all of the claims of the asserted patent recited pharmaceutical compositions with "a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer" ("A/SA")—but the complaint alleged that the defendant's product contained Carbopol, which was something other than an A/SA. 548 F. Supp. 3d at 446 (*cited in* D.I. 9 at 17). The court granted the defendant's motion to dismiss, finding that the prosecution history clearly and unmistakably demonstrated that the patentee surrendered Carbopol as an equivalent for the claimed A/SA. *Id.* at 449. Finally, in *Cumberland Pharms. Inc. v. Sagent Agila LLC*, C.A. No. 12-825-LPS, 2013 WL 5913742 (D. Del. Nov. 1, 2013), all claims covered only a formulation "free from a chelating agent," but the complaint alleged that the defendant's product contained a chelating agent; on these facts, the Court agreed that the complaint failed to plausibly plead infringement. 2013 WL 5913742 at *1-3 (*cited in* D.I. 9 at 12).

understandably explain why any alleged disclaimer relates to that claim term and renders it impossible that NULISA infringes claim 1. The closest Alamar came to attempting this was by including a chart in its opening brief. In that chart, Alamar makes reference to six particular claim terms located in claim 1; below each listed term, Alamar cites to a portion of the Complaint ("Complaint Allegations") and a portion of the specification wherein the patentee purportedly disclaimed something having to do with proximity ligation ("Disclaimed Proximity Ligation"). (D.I. 9 at 14-15) And in the paragraph just before the chart, Alamar states: "As shown below, Olink accuses specific steps of NULISA, which are the same steps in proximity ligation disclaimed in the '848 [p]atent[.]" (*Id.* at 14; *see also id.* at 16 ("Olink pleads infringement based on NULISA practicing steps that precisely match the '848 [p]atent's description (and disavowal) [in the specification] of proximity ligation")) But this chart does not accomplish all that Alamar asks of it.

By way of example, the Court refers to the first of the six entries in the chart. There, Alamar highlights the "plurality of interactors" element of claim 1. (*Id*. at 14) As to this element, the chart then cites the following portion of column 4 of the specification regarding a purported "[d]isclaime[r]" (with the italics and bolded text provided by Alamar):

> According to this method, targets are detected by utilizing ***two or more binders***, e.g. ***antibodies***, with known affinity to the target. The method is based upon the co-localization of the binder pair in the presence of a target. This target brings the binders into proximity, enabling ligation of ***nucleic acids located on the binder pair.***

(*Id.* at 14 (quoting '848 patent, col. 4:29-31) (emphasis and bolded text in original, internal quotation marks omitted)) The Court assumes that these references to "antibodies" and "nucleic acids located on the binder pair" amount to the claimed "plurality of interactors[,]" as it seems that this is Olink's allegation in the Complaint. (D.I. 1 at ¶ 21; D.I. 9 at 8) But the chart also

seems to suggest that in making reference here in the specification to the use of "antibodies" and "nucleic acids located on the binder pair" that the patentee was *disclaiming something*. Yet is that so? As the Court noted above, Alamar has done a good job of explaining how *some* of the patentee's comments in column 4 and 5 of the specification might amount to disclaimer of at least *some aspects* of PLA. But is any use of "antibodies" and "nucleic acids located on the binder pair"—in and of itself—one of the things that was disclaimed? It is hard to say that it is, on this record.

Or look at the fifth entry in this chart—one where Alamar refers to the claim term "associated oglionucleotide." In the chart, when discussing this term, Alamar again cites to the same portion of the specification as in the entry listed above (again, with the italics and bolded text provided by Alamar):

> The [proximity ligation] method is based upon the ***co-localization of the binder pair in the presence of a target.*** This target ***brings the binders into proximity, enabling ligation of nucleic acids located on the binder pair.***

(D.I. 9 at 15 (quoting '848 patent, col. 4:31-34) (emphasis and bolded text in original, internal quotation marks omitted)) Here, the Court thinks it understands (for the reasons set out above) why Alamar is suggesting that something relating to the concept of "co-localization of the binder pair" is an aspect of PLA technology that the patentee disclaimed. But what Alamar does not explain very well is: (1) why the claim term "associated oglionucleotide" (or its use in claim 1) necessarily amounts to the same thing that the specification is discussing here; and (2) how Alamar's product is alleged to infringe by doing whatever was disclaimed.

Indeed, after providing this chart in its opening brief, Alamar concludes by stating that "*[w]hatever method* the '848 [p]atent claims, it cannot be proximity ligation[.]" (*Id.* at 17 (emphasis added)) But that is the issue. Alamar must provide argument that clearly

demonstrates what is the *particular method* that the '848 patent claims—and how that method is impacted by what was purportedly disclaimed—in order for the Court to ably conclude that NULISA cannot plausibly infringe such a method claim. After all, the accused product is not compared to the *patent specification* to determine infringement. It is compared to the patent's *claims*. *See, e.g.*, *Markman*, 52 F.3d at 976 (explaining that an infringement analysis entails two steps: (1) determining the meaning and scope of the patent claims asserted to be infringed; and (2) comparing the properly construed claims to the product accused of infringing).

It is also important to note that the claimed invention involves complex technology. In light of that complexity—and the lack of good, clear guidance from Alamar in its briefing here—the Court cannot be expected to go line-by-line through the claim, hoping to discern on its own how and whether disclaimer might apply to the various infringement allegations. Among other things, doing so would wrongfully require the Court to perform claim construction—and to do it in the dark. *See, e.g.*, *Bausch & Lomb Inc. v. SBH Holdings LLC*, C.A. No. 20-1463-LPS, 2022 WL 856750, at *4 (D. Del. Mar. 23, 2022) ("Defendant's theory of no literal infringement . . . requires the Court to . . . perform an early claim construction, [a] practice[that is] either unpermitted or unwarranted at the motion to dismiss stage."); *Pragmatus AV, LLC v. TangoMe, Inc.*, Civil Action No. 11-1092-LPS, 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.").[8]

[8] The Complaint does allege that the '848 patent relates to proximity ligation technology and that such technology is the "basis of NULISA[.]" (D.I. 1 at ¶¶ 15, 19) Indeed, Olink seems to acknowledge that when one uses NULISA one must be practicing at least certain elements present in traditional proximity ligation. (*See* D.I. 15 at 4-6 (Olink summarizing its infringement allegations and noting that *one* of the aspects of NULISA that it accuses "is not

In the end, it is just not crystal clear to the Court that Olink's allegations of infringement are implausible due to disavowal. Alamar might ultimately prevail in this case on such a rationale. But the Court cannot recommend granting it this victory at the pleading stage, based on the current record. For this reason, the Court recommends that Alamar's motion be denied with respect to its disavowal argument.

B. Whether the Complaint fails to plausibly plead that NULISA meets certain limitations of claim 1 of the '848 patent

Alamar's second argument for dismissal is more straightforward: i.e., that "Olink fails to plausibly plead that [] NULISA[] practices crucial limitations for nearly every step" of claim 1; this is so, Alamar asserts, "because those steps are not practiced by proximity ligation or NULISA." (D.I. 9 at 3) With this argument, Alamar focuses on two particular claim limitations.

First, Alamar contends that the Complaint fails to plead that NULISA is a "method of detecting functional interactions between at least two molecules of interest" (a term found in claim 1's preamble). (*Id.* at 18; D.I. 17 at 2) Alamar's argument seems to be that Olink cannot plead this limitation since NULISA is a method used to identify known molecules using pre-defined interactions, but the specification has disclaimed the use of such a method. (D.I. 9 at 18-19) In response, Olink does not argue that the preamble is not limiting. And although Olink generally avers that it has alleged that use of NULISA practices "each and every step of claim 1[,]" (D.I. 15 at 4-6), it never specifically identifies where the Complaint gave any indication of how NULISA is a "method of detecting functional interactions between at least two molecules of interest[,]" (*id.*; *see also* D.I. 17 at 1, 2 (Alamar pointing this out)). Nor is this clear to the Court.

present in traditional proximity ligation"); *see also id.* at 11, 18) Yet it also seems clear that Olink is alleging that the method practiced by NULISA is not the *exact same method* as that employed by the "standard PLA method[.]" (D.I. 1, ex. E at 1; *see also id.*, ex. D at PageID 88)

At most, Olink seems to argue that this is a claim construction and infringement issue, (D.I. 15 at 14-15), without saying much of anything about why that is so.

The Court agrees that the Complaint fails to plead that NULISA practices this limitation. Perhaps if Olink's Complaint had clearly asserted infringement as to all of the *remaining limitations* in claim 1, then drawing all reasonable inferences in Olink's favor, it would be plausible to come to a different conclusion. But as Alamar points out, the Complaint also does not do this. That is because the pleading does not assert (at least not in an understandable way) that NULISA practices steps (c) and (e) of claim 1—steps that seem key to the claimed process of detecting functional interactions between the molecules of interest. (D.I. 9 at 20 n.5; D.I. 17 at 2-3 & n.2)[9]

While it is true that a plaintiff need not "plead infringement on an element-by-element basis[,]" it is also true that the level of detail required in a case depends upon, *inter alia*, the complexity of the technology and the materiality of an element to practicing the asserted claim. *Bot M8 LLC*, 4 F.4th at 1352-53; *see also Vytacera Bio, LLC v. CytomX Therapeutics, Inc*., Civil Action No. 20-333-GBW-CJB, 2023 WL 7125196, at *5 (D. Del. Oct. 30, 2023) ("After all, a claim of patent infringement is subject to the *Twombly/Iqbal* pleading standard. And if a Court cannot understand why it is plausible that a defendant infringes a patent, then it cannot articulate how or why a challenged claim of patent infringement has withstood a Rule 12 challenge.")

[9] Step c requires "subjecting the plurality of cis-reactive cells to conditions which stimulate a desired functional interaction having a detectable trace" and step e requires "subjecting the associated oligonucleotides from the cis-reactive cells selected in step (d) to an analysis that permits detection of the at least two identification sequence elements[.]" ('848 patent, col. 41:50-52, 55-58) Paragraph 27 of the Complaint does allege generally that the NULISA platform practices claim limitations relating to the "detectable trace[,]" but then it only goes on to identify how that is so with respect to step (d) ("selecting all cis-reactive cells exhibiting the detectable trace"). (D.I. 1 at ¶ 27)

(citing cases), *report and recommendation adopted*, 2024 WL 4512400, at *1 (D. Del. Oct. 17, 2024). Olink acknowledges that the technology at issue here is not "simple[.]" (D.I. 15 at 13) And the detection of functional interactions between molecules of interest is obviously material to the claim. (D.I. 1 at ¶ 11 (stating that the '848 patent is generally directed to "methods of detecting functional interactions between at least two molecules of interest"))

Thus, absent factual allegations addressing this limitation, the Complaint does not assert a plausible claim for patent infringement. The Court therefore recommends that the Motion be granted on this ground.[10] That said, it seems possible that Plaintiff might be able to plead the missing allegations in a further amended complaint. In light of this, and in light of Federal Rule of Civil Procedure 15's admonition that leave to amend should be freely permitted "when justice so requires[,]" Fed. R. Civ. P. 15(a)(2), the Court will recommend that such dismissal be without prejudice.[11]

Second, Alamar asserts that the Complaint does not plausibly allege that NULISA satisfies the "forming a plurality of cis-reactive cells wherein a cis-reactive cell comprises at least two interactors bound in proximity to one another by an associated oligonucleotide"

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[10] *See, e.g.*, *LS Cloud Storage Techs., LLC v. Amazon.com, Inc.*, 1:22-CV-1167-RP, 2023 WL 2290291, at *4 (W.D. Tex. Feb. 27, 2023) (granting a motion to dismiss, where the complaint failed to identify what aspect of the accused product performed the corresponding step, and noting that "[g]iven the complexity of the technology involved, [p]laintiff's level of specificity falls short of the Federal Circuit's *Bot M8* pleading standard"); *Lexington Luminance LLC v. Bulbrite Indus., Inc.*, Civil Action No. 22-3787, 2023 WL 143911, at *3-6 (D.N.J. Jan. 10, 2023) (granting motion to dismiss where the technology was complex and the complaint failed to adequately plead the presence of two key claim elements).

[11] Alamar suggests that Olink cannot plead that NULISA is a "method of detecting functional interactions between at least two molecules of interest" because this limitation is about detecting *previously unknown* functional interactions—in light of the statements distinguishing the invention from proximity ligation—and that NULISA does not do this. (D.I. 9 at 18-19) But this argument is premature.

limitation. (D.I. 9 at 19; D.I. 17 at 3) The Complaint alleges that "the two NULISA probes are bound to an analyte" to form "a plurality of cis-reactive cells" comprising "at least two interactors." (D.I. 1 at ¶ 25 (internal quotation marks omitted)) Alamar says that this allegation renders infringement implausible, since the claim requires that the two interactors be bound by an "*associated oligonucleotide*" but the probes in NULISA are "bound to an *analyte*[.]" (D.I. 9 at 19 (emphasis in original) (internal quotation marks omitted); *see also* D.I. 17 at 4 ("Olink identifies no claim construction issue that could transform "bound . . . by an associated oligonucleotide" to mean "bound to an analyte.")))

Alamar seems to be suggesting that if the two "interactors" at issue are "bound to an analyte" that means that it is impossible that they are bound "by an associated oligonucleotide[.]" But Alamar never really explains *why* that is so or (relatedly) *how* the record conclusively demonstrates that is so. The Court surely does not know the answer on its own. And Olink pleaded (in a way that seems plausible) that this "associated oligonucleotide" limitation is satisfied by the accused product. (D.I. 1 at ¶ 26) And at the pleading stage, the Court cannot conclude otherwise simply based on Alamar's say-so. Therefore, the Court recommends that the Motion be denied with respect to this particular argument.

IV. CONCLUSION

For the foregoing reasons, the Court recommends that the Motion be GRANTED-IN-PART without prejudice and DENIED-IN-PART, in the manner set out above.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the

loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: January 23, 2025

Christopher J. Burke
Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE