

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

CORNELL UNIVERSITY, CORNELL
RESEARCH FOUNDATION, INC., LIFE
TECHNOLOGIES CORPORATION, and
APPLIED BIOSYSTEMS, LLC,

Plaintiffs,

v.

ILLUMINA, INC.,

Defendant.

C.A. No. 10-433-LPS-MPT

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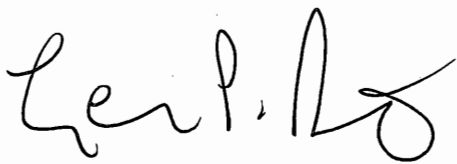
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MEMORANDUM OPINION

January 10, 2017
Wilmington, Delaware



STARK, U.S. District Judge:

Pending before the Court are issues of claim construction of a number of disputed claims terms in the asserted patents as well as Defendant's motion for leave to amend its answer and counterclaims.

I. BACKGROUND

Cornell University, Cornell Research Foundation, Inc., Life Technologies Corporation, and Applied Biosystems, LLC (collectively, "Cornell" or "Plaintiffs") filed a patent infringement suit against Illumina, Inc. ("Illumina" or "Defendant") on May 24, 2010, alleging infringement of two families of patents: the Array patents and the LDR-PCR patents. The Array patents (U.S. Patent Nos. 7,083,917; 7,892,746; 7,893,233; 8,288,521; 8,624,016; and 8,703,928) relate to tools that utilize oligonucleotides with particular sequence properties to detect target molecules in a sample.¹ The LDR-PCR patents (U.S. Patent Nos. 6,797,470; 7,166,434; 7,312,039; 7,332,285; and 7,429,453) describe the combination of a ligase detection reaction ("LDR") with polymerase chain reaction ("PCR") to test for genetic changes with high specificity and sensitivity.²

Chief Magistrate Judge Thyng issued a Report and Recommendation ("R&R") on May 6, 2016, recommending resolution of the claim construction disputes involving the Array patents and LDR-PCR patents. (D.I. 449) Judge Thyng also issued an R&R on May 27, 2016, recommending that the Court grant Illumina's motion for leave to amend its answer and

¹Because the specifications of the Array patents are identical in substance, the Court's citations are generally to the '917 patent.

²Because the specifications of the LDR-PCR patents are identical in substance, the Court's citations are generally to the '928 patent.

counterclaims to allege inequitable conduct before the Patent and Trademark Office (“PTO”) with respect to the prosecution of the LDR-PCR patents. (D.I. 451)

Cornell’s objections to the R&Rs on claim construction and on Illumina’s motion for leave to amend are pending before the Court. The parties completed briefing on July 21, 2016. (See D.I. 474) The Court held a hearing on November 29, 2016. (See D.I. 517 (“Tr.”))

II. LEGAL STANDARDS

A. Claim Construction

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). “It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). “[T]here is no magic formula or catechism for conducting claim construction.” *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

“[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312-13 (internal citations and quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). The patent specification “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of

a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered.

Phillips, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent” *Id.* (internal citation omitted).

It is likewise true that “[d]ifferences among claims can also be a useful guide For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court “should also consider the patent’s prosecution

history, if it is in evidence.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370 (1996). The prosecution history, which is “intrinsic evidence,” “consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

In some cases, “the district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva*, 135 S. Ct. at 841. Extrinsic evidence “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, while extrinsic evidence “may be useful” to the court, it is “less reliable” than intrinsic evidence, and its consideration “is unlikely

to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int’l Trade Comm’n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

B. Motion for Leave to Amend

At this stage of the proceedings, a party “may amend only with leave of the court or the written consent of the opposing party.” *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000) (citing Fed. R. Civ. P. 15(a)). The court exercises discretion in deciding whether to grant a motion to amend, *see Foman v. Davis*, 371 U.S. 178, 182 (1962), and “[t]he court should freely give leave when justice so requires,” Fed. R. Civ. P. 15(a)(2). Under the Third Circuit’s liberal policy favoring the amendment of pleadings, which aims to “ensure[] that a particular claim will be decided on the merits rather than on technicalities,” *Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990), an amendment ordinarily is permitted absent a showing of “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendment previously allowed, undue prejudice to the opposing party by virtue of the allowance

of the amendment, futility of the amendment, etc.,” *Foman*, 371 U.S. at 182.

If a party moves for leave to amend the pleadings after a deadline imposed by a scheduling order, Rule 16 must also be satisfied. *See E. Minerals & Chems. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000). Under Rule 16(b), “a schedule may be modified only for good cause and with the judge’s consent.” “Good cause” exists when the schedule “cannot reasonably be met despite the diligence of the party seeking the extension.” Fed. R. Civ. P. 16(b)(4) Advisory Committee’s Notes (1983 amendments). “In contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party.” *Roquette Freres v. SPI Pharma, Inc.*, 2009 WL 1444835, at *4 (D. Del. May 21, 2009).

The Court may deny leave to amend on the basis that an amendment would be futile. “An amendment is deemed futile if it could not withstand a motion to dismiss.” *Enzo Life Scis., Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 489 (D. Del. 2003). “[I]n assessing futility of a proposed amendment, the same standard of legal sufficiency as under Rule 12(b)(6) is applied.” *Roquette Freres*, 2009 WL 1444835, at *3. The Court may grant a motion to dismiss only if, after “accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief.” *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted). “To survive a motion to dismiss, a civil plaintiff must allege facts that ‘raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).’” *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The complaint must allege “enough facts to state a claim to relief that is

plausible on its face.” *Twombly*, 550 U.S. at 570. A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Inequitable conduct before the PTO must be pleaded with particularity in accordance with Rule 9(b). See *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003). In relevant part, Rule 9(b) provides that “[i]n alleging fraud . . . a party must state with particularity the circumstances constituting fraud Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” “[T]o plead the ‘circumstances’ of inequitable conduct with the requisite ‘particularity’ under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). Although a party may plead facts upon “information and belief,” it must also set forth the “specific facts upon which the belief is reasonably based.” *Id.* at 1330. “Moreover, although ‘knowledge’ and ‘intent’ may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” *Id.* at 1328-29.

III. DISCUSSION

I. Claim Construction³

A. “solid support”

The Claim Construction R&R recommends adoption of Illumina’s proposed construction, that “solid support” means “a single unitary substrate,” which is partly based on prosecution history estoppel. (D.I. 449 at 4-7) Having reviewed the objections de novo, the Court SUSTAINS Cornell’s objections, REJECTS the R&R with respect to this claim term, and adopts Cornell’s proposed construction of “solid support.”

The Court agrees with Cornell that the term “solid support” should not be limited to “a single unitary substrate.” The specification suggests that the support “can be made from a wide variety of materials” and take any number of forms. ’917 patent col. 22 ll. 1-6; col. 43 ll. 49-55. There is nothing in the specification that supports Illumina’s argument that the support *must* be a single unitary substrate. *See Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (“There are no words of manifest exclusion or restriction.”). Illumina contends that in every embodiment disclosed in the specification, the solid support is a unitary substrate, but that is not a sufficient basis here to limit the scope of the claims. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1346-47 (Fed. Cir. 2015) (holding that claims are not generally not limited to disclosed embodiments even when specification discloses only single embodiment); *Teleflex*,

³Pursuant to 28 U.S.C. § 636(b)(1)(B) and Fed. R. Civ. P. 72(b)(3), the Court may accept, reject, or modify the recommendations of the Magistrate Judge. The Court may also receive further evidence or return the matter to the Magistrate Judge with instructions for further proceedings. Objections to the Magistrate Judge’s conclusions with regard to the legal issue of claim construction are reviewed *de novo*. 28 U.S.C. § 636(b)(1)(C); *see also Hand Held Prods., Inc. v. Amazon.com, Inc.*, 2016 WL 1275589, at *1 (D. Del. Mar. 31, 2016).

Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1328 (Fed. Cir. 2002).

The prosecution history does not persuade the Court otherwise. Illumina argues that the patentee disclaimed during prosecution any use of intermediate supports that may have been contemplated by the specification. (D.I. 449 at 6) During prosecution of the '917 patent, pending claim 120 recited “a linker or support suitable for coupling an oligonucleotide to the solid support.” (D.I. 421 at A1548) The examiner rejected the claim for indefiniteness, stating “it is not clear what does applicants mean by support suitable for coupling to the solid support. Does applicants mean the oligonucleotide is coupled to the solid support by using a different support.” (*Id.* at A1399-1400) In response, the patentees deleted “or support” from the claim and traversed the indefiniteness rejection in view of the amendment. (*Id.* at A1416, A1424)

“When the prosecution history is used solely to support a conclusion of patentee disclaimer, the standard for justifying the conclusion is a high one. For prosecution disclaimer to attach, [Federal Circuit] precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable.” *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016) (internal quotation marks and alterations omitted). The claim amendment here is not sufficiently clear to allow the Court to conclude that the patentees disclaimed non-unitary solid supports. While one reading of the prosecution history is consistent with Illumina’s view, another plausible reading is that the patentees merely simplified the language without changing claim scope. (*See* D.I. 454 at 6-7) There is no argument or discussion accompanying the amendment that provides additional insight. In sum, where, as here, “the alleged disavowal is ambiguous, or even ‘amenable to multiple reasonable interpretations,’ [courts] have declined to find prosecution disclaimer.” *Avid Tech*, 812 F.3d at

1045 (internal citation omitted).

Accordingly, the Court will adopt Cornell's proposal and construe "solid support" as "solid-phase substrate."

B. Claim Terms Related to the Connection of Oligonucleotides to the Solid Support

The Claim Construction R&R recommends adopting Illumina's proposals, with some modifications, for the claim terms "linker," "immobilized," "attached," "suitable for attachment," and "coupled to." (D.I. 449 at 9-13) This recommendation is based on the R&R's agreement with Illumina that "solid support" means "a single unitary substrate." Having rejected that construction and having reviewed Cornell's objections to the construction of these related terms de novo, the Court SUSTAINS Cornell's objections, REJECTS the R&R with respect to these claim terms, and adopts Cornell's proposed constructions of them.

The parties agree that the proper constructions of the "solid support" and "linker" terms turn on the same issue, which is the claim amendment made during prosecution of the '917 patent. (Tr. at 4, 13-14) As discussed above, the Court finds that this prosecution history is not clear and unmistakable. Therefore, the Court disagrees with the R&R's conclusion that "the claims do not cover intervening structures, like an additional support, for connecting oligonucleotides to solid supports." (D.I. 449 at 11)

Accordingly, the Court will adopt Cornell's proposed constructions of the terms "linker," "immobilized," "attached," "suitable for attachment," and "coupled to."⁴

⁴The adopted constructions are as follows:

- "linker" means "feature that connects an oligonucleotide to a solid support"

C. Claim Terms Related to Capture Oligonucleotides

The Claim Construction R&R recommends adoption of Illumina’s proposals for the claim terms “capture oligonucleotide probes,” “capture oligonucleotide(s),” and “capturing said one or more amplification products to a solid support.” (D.I. 449 at 13-26) Having reviewed the objections de novo, the Court OVERRULES Cornell’s objections and ADOPTS the R&R with respect to these claim terms.

The R&R recommends construing “capture oligonucleotide probes” and “capture oligonucleotide(s)” to mean “oligonucleotide [probe] which has no homology to a target sequence and is complementary to the addressable array specific portion of an oligonucleotide containing an addressable array specific portion and a target specific portion.” (*Id.* at 23) Cornell argues that homology and complementarity are not required for every capture oligonucleotide, pointing to certain claims that explicitly recite those features. (D.I. 454 at 12-13) These claim differentiation arguments are not compelling here. *See Atlas IP, LLC v. Medtronic, Inc.*, 809 F.3d 599, 607 (Fed. Cir. 2015). Cornell’s claim differentiation arguments relate to independent claims of different patents, and Cornell does not argue that its construction is “needed to maintain different claim scope.” *World Class Tech. Corp. v. Ormco Corp.*, 769 F.3d 1120, 1126 (Fed. Cir. 2014).

Cornell also asserts that the capture oligonucleotide need only be capable of hybridizing to a complementary nucleic acid. But Cornell’s proposed construction fails to give any meaning

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- “immobilized” means “restricted in mobility”
 - “attached” means “connected”
 - “suitable for attachment” means “capable of being connected”
 - “coupled to” means “connected to”

to the word “capture,” as every oligonucleotide is capable of hybridizing to a complementary nucleic acid. (D.I. 469 at 12 n.2) The specification makes clear that a “capture” oligonucleotide is a type of oligonucleotide that has specific properties. First, “[a] capture oligonucleotide probe sequence does not have any homology to either the target sequence or to other sequences on genomes which may be present in the sample.” ’917 patent col. 20 l. 65 - col. 21 l. 1. Second, “[t]he capture oligonucleotides are complementary to the addressable array-specific portions.” Col. 6 ll. 5-7; col. 9 ll. 44-46. Further, in describing the array invention, the specification states that “the present invention allows for the design of arrays of capture oligonucleotides with sequences which are very different from each other. Each LDR product will have a unique addressable array-specific portion, which is captured selectively by a capture oligonucleotide at a specific address on the solid support.” Col. 42 ll. 31-37. The specification makes clear that it is these features that make the claimed arrays universal and addressable. (D.I. 449 at 17-19)

Cornell also argues that the “capturing said one or more amplification products to a solid support” step of claim 10 of the ’453 patent does not require the amplification products to hybridize to “capture oligonucleotides.” This argument is unavailing. Each amplification product of claim 10 includes an addressable array-specific portion. *See* ’453 patent col. 83 ll. 52-56. As the specification of the ’453 patent describes, “the addressable array-specific portions . . . hybridize to the capture oligonucleotides during a capture phase.” Col. 35 ll. 60-63. Therefore, “capturing said one or more amplification products to a solid support” necessarily involves hybridization of the addressable array-specific portions of amplification products to capture oligonucleotides. Thus, Illumina’s proposed construction – which is “hybridizing the amplification products to capture oligonucleotides attached on the solid support” – is supported

by the specification.

Accordingly, the Court will adopt the R&R's constructions of "capture oligonucleotide probes," "capture oligonucleotide(s)," and "capturing said one or more amplification products to a solid support."

**D. Claim Terms Related to Differences
between Oligonucleotide Sequences**

The Claim Construction R&R recommends adopting Illumina's proposals for these claim terms. (D.I. 449 at 31-36) Having reviewed the objections de novo, the Court OVERRULES Cornell's objections and ADOPTS the R&R with respect to these claim terms.

The parties dispute whether these claim terms require each capture oligonucleotide to differ by 25% from every other capture oligonucleotide. The R&R construed the terms to include such a requirement.

The claim language does not provide a clear answer. For example, claim 1 of the '928 patent recites "a solid support comprising at least 25 types of capture oligonucleotides immobilized on the solid support at an array of positions, wherein each type of capture oligonucleotide . . . differs in nucleotide sequence, when aligned to another type of capture oligonucleotide that is located on an adjacent position of said solid support, by at least 25%." '928 patent col. 61 ll. 61-67. This language could mean, as Cornell suggests, that each type of capture oligonucleotide need only be compared one other type located on an adjacent position. Alternatively, this language could instead mean that any time one type of capture oligonucleotide is compared to another type of capture oligonucleotide adjacently located, they must differ by at

least 25%.⁵

Because the claim language leaves ambiguity, the Court turns to the specification. The specification is clear that capture oligonucleotides must be sufficiently different from one another to reduce cross-hybridization and allow for “high specificity detection of correct signal.” ’917 patent col. 42 l. 66 - col. 43 l. 1. For example, the specification states that “the present invention allows for the design of arrays of capture oligonucleotides with *sequences which are very different from each other*. Each LDR product will have a *unique* addressable array-specific portion, which is captured selectively by a capture oligonucleotide at a specific address on the solid support.” Col. 42 ll. 31-37 (emphasis added); *see also* col. 36 l. 55 - col. 37 l. 3. The patent repeatedly stresses the importance of designing capture oligonucleotides to have substantial sequence differences from all other capture oligonucleotides, in order to reduce cross-reactivity. (See D.I. 449 at 33) Cornell’s proposed constructions are inconsistent with these teachings, as they would not require capture oligonucleotides to be sufficiently different from one another. Accordingly, the Court will adopt the R&R’s recommended construction of these terms.⁶

⁵Illumina argues that “an” in “another type” or “its” in “its adjacent” is conclusive. But here the general rule that “the words ‘a’ or ‘an’ in a patent claim carry the meaning of ‘one or more,’” *TiVo, Inc. v. EchoStar Commc’ns Corp.*, 516 F.3d 1290, 1303 (Fed. Cir. 2008), does not compel Illumina’s proposed constructions. Illumina’s proposed construction is not stated in terms of “one or more than” but, rather, in terms of “all.”

⁶For example, the term “each capture oligonucleotide probe of the array differs in sequence from its adjacent capture oligonucleotide probe, when aligned to each other by at least 25%” is construed to mean “each capture oligonucleotide probe [of the array] differs in sequence from every adjacent capture oligonucleotide probe, when aligned, by at least 25% in nucleotide sequence.”

E. Claim Terms Related to Addressable Array-Specific Portions

The Claim Construction R&R recommends adopting Illumina's proposals for the claim terms "addressable array-specific portion," "address specific portion," and "zip code portion." (D.I. 449 at 40-44) Having reviewed the objections de novo, the Court OVERRULES Cornell's objections and ADOPTS the R&R with respect to these claim terms.

The R&R construed these terms to mean "portion of an oligonucleotide that selectively hybridizes to a complementary oligonucleotide located on an array, and does not hybridize to naturally occurring nucleic acids or to other oligonucleotides located on an array." (D.I. 449 at 43-44) Cornell objects to the requirement that the address array-specific portion binds to its complementary oligonucleotide on the array and to nothing else. But the claims themselves make clear that the addressable portion of a target oligonucleotide hybridizes to its complementary capture oligonucleotide. *See, e.g.*, '746 patent col. 61 ll. 62-67 (claim 1 reciting "contacting the sample . . . with the array . . . to hybridize the addressable array-specific portion of each target oligonucleotide to its complementary capture oligonucleotide."). The specification reinforces that the addressable portion is complementary to its capture oligonucleotide in order to enable hybridization. *See, e.g.*, '917 patent col. 42 ll. 34-37.

Because the addressable array-specific portion must hybridize to its complementary capture oligonucleotide and, as discussed above, the capture oligonucleotides must differ from each other by 25%, the addressable array-specific portion will not hybridize to other oligonucleotides located on an array. (*See* D.I. 469 at 21) It is this selective hybridization that allows "addressable array-specific portions [to] guide each LDR product to a designated address on the solid support." Col. 42 ll. 25-26.

Accordingly, the Court will adopt the R&R's construction of the terms "addressable array-specific portion," "address specific portion," and "zip code portion."

F. Claim Terms Related to Ligase Detection Reaction

The R&R recommends adoption of Illumina's proposals for the claim terms "ligase detection reaction," "ligase detection reaction cycles," and "suitable for ligation together." (D.I. 449 at 46-56) Having reviewed the objections de novo, the Court OVERRULES Cornell's objections and ADOPTS the R&R with respect to these claim terms.

The R&R construed "ligase detection reaction" to mean "reaction which detects the presence of target nucleotide sequences in a sample by using a ligase and one or more sets of two oligonucleotide probes in which the ligase joins the two oligonucleotide probes only if they are hybridized at adjacent positions on a target nucleotide sequence." (*Id.* at 54) Cornell objects to the requirement of adjacently hybridizing probes, arguing that claim differentiation compels the conclusion that adjacently hybridizing probes are not mandatory in a ligase detection reaction. "[T]he doctrine of claim differentiation is not a hard and fast rule" *Comark Commc 'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998). For example, "any presumption created by the doctrine of claim differentiation 'will be overcome by a contrary construction dictated by the written description or prosecution history.'" *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011) (quoting *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005)).

Here, the claim-differentiation presumption is overcome by the patent's definition of "ligase detection reaction." The '470 patent explicitly incorporates by reference patent application WO 91/17239 to Barany, which in turn provides express definitions for a number of

terms, including ligase detection reaction. (D.I. 422 at A2191 ll. 7-11) In defining ligase detection reaction, the Barany application states: “Ligase detection reaction (LDR)’ refers to the use of *two adjacent oligonucleotides* for the detection of specific sequences with the aid of a thermophilic ligase with linear product amplification.” (*Id.* at A2196 ll. 1-4 (emphasis added)) “When a document is ‘incorporated by reference’ into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein.” *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001). When a patent’s specification demonstrates that the patentee gave a “special definition [] to a claim term . . . that differs from the meaning it would otherwise possess . . . the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. Therefore, the definition of ligase detection reaction supplied by the Barany application, subsequently incorporated by reference into the ’470 patent, controls.

Accordingly, the Court will adopt the R&R’s constructions of “ligase detection reaction,” “ligase detection reaction cycles,” and “suitable for ligation together.”⁷

II. Illumina’s Motion for Leave to Amend

The R&R recommends that the Court grant Illumina’s motion for leave to amend its answer and counterclaims to allege inequitable conduct before the Patent and Trademark Office with respect to the prosecution of the LDR-PCR patents. (D.I. 451)

The parties disagree on the standard of review to be applied. The Court reviews

⁷The latter two terms, “ligase detection reaction cycles” and “suitable for ligation together” will be construed as: “cycles comprising at least the following steps: denaturation, hybridization, and ligation, with the denaturation step occurring at the beginning or the end” and “able to be ligated together only when hybridized adjacent to one another on the target nucleotide sequence,” respectively.

dispositive motions de novo, *see* 28 U.S.C. § 636(b)(1)(C); Fed. R. Civ. P. 72(b)(3), while non-dispositive motions are modified or set aside only when clearly erroneous or contrary to law, *see* 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a). “Under ordinary circumstances a motion to amend a complaint is ‘a pretrial matter not dispositive of a claim or defense of a party’ within the purview of Fed. R. Civ. P. 72(a).” *Pagano v. Frank*, 983 F.2d 343, 346 (1st Cir. 1993); *see also Cont’l Cas. Co. v. Dominick D’Andrea, Inc.*, 150 F.3d 245, 251 (3d Cir. 1998) (citing *Pagano* approvingly); *Smith v. State of Delaware*, 2009 WL 2175635, at *1 n.1 (D. Del. July 21, 2009) (“Motions for leave to amend pleadings are typically treated as ‘non-dispositive’ applications within the pretrial powers of a magistrate judge on referral.”). Therefore, the Court will review any factual findings for clear error. *See* 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a). Legal conclusions, however, will be reviewed de novo. *See Haines v. Liggett Grp., Inc.*, 975 F.2d 81, 91 (3d Cir. 1992) (“[T]he phrase ‘contrary to law’ indicates plenary review as to matters of law.”); *Eisai Co. v. Teva Pharm. USA, Inc.*, 629 F. Supp. 2d 416, 424 (D.N.J. 2009) (“[A] magistrate judge’s legal conclusions on a non-dispositive motion will be reviewed de novo.”); *Doe v. Hartford Life & Accident Ins. Co.*, 237 F.R.D. 545, 548 (D.N.J. 2006); *Lo Bosco v. Kure Eng’g Ltd.*, 891 F. Supp. 1035, 1037 (D.N.J. 1995).

Cornell does not challenge any of the factual findings made by Judge Thyng in recommending that Illumina’s motion to amend be granted. (*See* D.I. 462) For example, Cornell does not dispute any of the timing facts on which Judge Thyng relied in finding that Illumina acted diligently and therefore satisfied Rule 16(b). (*See* D.I. 451 at 9-12) Nor does Cornell challenge the findings that support the conclusion that Rule 15(a) is met, such as that Illumina did not unduly delay and that Cornell will not face undue prejudice. (*See id.* at 12-13)

Cornell objects solely to Judge Thyng's futility analysis. (See D.I. 462) Determining whether a motion to amend would be futile requires the Court to apply "the same standard of legal sufficiency as under Rule 12(b)(6)." *Roquette Freres*, 2009 WL 1444835, at *3. That determination, whether a claim survives a 12(b)(6) motion, is a "purely legal question." *Barefoot Architect, Inc. v. Bunge*, 632 F.3d 822, 835 (3d Cir. 2011); see also 5B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1357 (3d ed. 2004 & Supp. 2016) ("[T]he motion to dismiss under [Rule 12(b)] subdivision (6) raises only an issue of law"). Therefore, the Court will review de novo the determination that Illumina's motion would withstand a motion to dismiss and, therefore, is not futile. See *Maiden Creek Assocs. v. U.S. Dep't of Transp.*, 823 F.3d 184, 189 (3d Cir. 2016) ("[A]lthough we review a denial of leave to amend for abuse of discretion, we review the District Court's determination that the amendment would be futile de novo.").

Having reviewed Cornell's objections de novo, the Court SUSTAINS Cornell's objections and REJECTS the R&R. Illumina's motion for leave to amend (D.I. 405) is DENIED.

"[A] pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Exergen*, 575 F.3d at 1328-29. "A reasonable inference is one that is plausible and that flows logically from the facts alleged, including any objective indications of candor and good faith." *Id.* at 1329 n.5. Cornell argues that, considering the objective indications of candor and good faith in this case, it is not reasonable to infer that the applicants and their counsel intended to

deceive the PTO. Cornell also argues that the statement on which Illumina's claim relies could not be found to have been material to the PTO's issuance of the patent.

Illumina's inequitable conduct claim is based on a single inartful sentence in the prosecution history of the '470 patent. (Tr. at 74, 85) The PTO initially rejected claims in the '156 application – which later became the '470 patent – in light of three references. (D.I. 406 Ex. A at ¶ 19) The applicants submitted a declaration to swear behind those references, stating: “**Prior to June 22, 1994, we conceived and diligently reduced to practice, in the United States, the invention claimed in the above-identified patent application.**” (*Id.* at ¶ 21(e) (emphasis added))

Cornell concedes that reduction to practice did **not** take place before June 22, 1994; only conception did. (Tr. at 72-73) Consequently, in Illumina's view, because “the applicants were aware that reduction to practice did not take place prior to June 22, 1994 and that the applicants' declaration did not include actual dates of acts of diligence, . . . the applicants affirmatively misrepresented the inventors' reduction to practice and diligence with a false or misleading declaration.” (D.I. 406 Ex. A at ¶ 21(I)) Cornell counters that what the sentence in the declaration was intended to convey was that the applicants conceived before June 22, 1994, and **thereafter** subsequently diligently reduced to practice. Thus, any misrepresentation was, at worst, an inadvertent result of an inartfully-drafted sentence, not the result of intentional deception.

The Court concludes that it is not reasonable to infer from the applicants' statement that the applicants intended to mislead or deceive the PTO into believing that the applicants had **both conceived and reduced to practice** before the critical date. Instead, the more plausible reading is

that the applicants intended to convey to the PTO that they had *conceived* the invention prior to June 22, 1994, and had *thereafter* diligently reduced it to practice. This latter representation (if true) would be sufficient to enable applicants to swear behind the prior art references the Examiner had cited in rejecting the claims. See *Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1007 (Fed. Cir. 2016). In the Court’s view, at worst what occurred is that the drafter of the declaration inadvertently omitted a word such as “thereafter” or “subsequently” or “later” before the phrase “reduced to practice.”

Objective indications support Cornell’s reading of the declaration statement. Had the applicants been intentionally trying to deceive the PTO into believing that reduction to practice had taken place before the critical date, the applicants could have said simply that, without making any reference to conception or diligence. Reduction to practice before the critical date, alone, is sufficient to antedate references. See *Loral Fairchild Corp. v. Matsushita Elec.*, 266 F.3d 1358, 1361 (Fed. Cir. 2001); see also D.I. 406 Ex. A at ¶¶ 21(b), (c)) The concepts of conception and diligence are relevant only when reduction to practice takes place *after* the critical date. (D.I. 406 Ex. A at ¶ 21(b)) Hence, the declaration’s use of the terms conception and diligence, in addition to reduction to practice, strongly suggests that the applicants were not attempting to antedate references on the basis of reduction to practice before the critical date but, instead, were stating that they had conceived before the critical date and subsequently diligently reduced to practice.

This reading of the declaration is further supported by the amendment which was accompanied by the declaration. The amendment states: “In particular, prior to June 22, 1994, applicants conceived, in the United States, the invention claimed in the above-identified patent

application, and diligently reduced it to practice (Barany et al. Declaration ¶ 2).” (D.I. 429 Ex. C at 1258) Stated this way, applicants made even clearer that they were asserting that they had conceived before June 22, 1994, and then diligently reduced to practice. The amendment goes on to state that “[e]vidence of this conception prior to June 22, 1994, is provided,” again reinforcing that applicants’ intent was to state that they conceived before the critical date and thereafter diligently reduced to practice. (*Id.*; Ex. D at 1261)

Illumina notes that the declaration supplies no dates to prove diligence (D.I. 406 Ex. A at ¶ 21(f)), arguing that the lack of dates supports inferring deceptive intent.⁸ The lack of dates, however, does not detract from the fact that the declaration and accompanying amendment are replete with references to conception and diligence – references that would have been wholly unnecessary were applicants relying on reduction to practice. Moreover, the lack of an express showing of diligence only reaffirms that the declaration is not drafted in an ideal manner; applicants would need to provide additional information to prove their assertion of diligence. Still, however, the declaration does not provide a sufficient factual basis to support an inference of intent to deceive.

Illumina points to the depositions of inventors Francis Barany and Matthew Lubin and of attorney Michael Goldman as further support for an inference of deceptive intent. Illumina claims, based on these depositions, that “Applicants Francis Barany and Matthew Lubin now admit that they knew, at the time that the applicants signed the § 1.131 declaration that was subsequently filed, that the claimed LDR/PCR methods had not been reduced to practice ‘[p]rior

⁸As noted in the R&R, the Manual of Patent Examining Procedure requires that when relying on conception and diligent reduction to practice “the actual dates of acts relied on to establish diligence must be provided.” (D.I. 451 at 18)

to June 22, 1994,’ and that the laboratory work relating to the claimed LDR/PCR methods did not begin until July 11, 1994,” and further that “Michael Goldman now admits that he knew, at the time of filing the Amendment and the accompanying § 1.131 declaration, that the claimed LDR/PCR methods had not been reduced to practice ‘[p]rior to June 22, 1994.’” (*Id.* at ¶¶ 20(e), (f)) These statements, taken as true, do not strengthen Illumina’s position. The most reasonable inference to be drawn from the inventors’ and prosecuting attorney’s statements that there was no reduction to practice before June 22, 1994 is that the declaration sentence was inartfully drafted, in that it could be misunderstood to contradict the fact that reduction to practice took place after a (legally sufficient) pre-critical date conception.

Further, in other portions of the depositions, Drs. Barany and Lubin testified that they believed the declaration was true at the time they filed it (*see* D.I. 429 Ex. H at 27-28, 58; Ex. F at 412), and Mr. Goldman testified that he took steps to ensure that the inventors understood the declaration before they signed it (*see id.* Ex. E at 103-104). As Illumina relies on the depositions in the proposed amended counterclaim asserting inequitable conduct, the Court may consider these statements. *See Brody v. Hankin*, 145 F. App’x 768, 772 (3d Cir. 2005) (stating that when plaintiff mentions information from document in complaint, district court may consider that document, including deposition transcript, in evaluating Rule 12(b)(6) motion) (citing *Pension Benefit Guar. Corp. v. White*, 998 F.2d 1192, 1196 (3d Cir. 1993)). The inventors’ belief that the declaration was true when submitted to the PTO further negates any inference of an intent to deceive the PTO. *See Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1332 (Fed. Cir. 2009) (affirming finding of no deceptive intent where inventor “believed the statement to be true at the time that he made it”); *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 745 (Fed. Cir.

2002).

The Court also agrees with Cornell that Illumina's contentions regarding materiality are futile. Illumina insists that "a false . . . declaration is per se material." (D.I. 474 at 6 n.2 (quoting *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1294 (Fed. Cir. 2012)) But here Illumina's allegation that the declaration was false is not based on a reasonable inference. Additionally, Illumina does not suggest that the applicants were not diligent or that they "could not have provided the dates of their diligent reduction to practice if the examiner had asked for them" (D.I. 462 at 10 n.5), detracting from any inference that the applicant's declaration was but-for material. *See generally Network Signatures, Inc. v. State Farm Mut. Auto. Ins. Co.*, 731 F.3d 1239, 1242 (Fed. Cir. 2013).

Accordingly, Illumina's inequitable conduct claims would not survive a motion to dismiss and are, therefore, futile. Therefore, the Court will deny Illumina's motion to amend.

IV. CONCLUSION

The Court construes the disputed terms as explained above and will deny Illumina's motion to amend its answer and counterclaims. An Order consistent with this Memorandum Opinion follows.