v.

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA; and BECTON, DICKINSON and COMPANY,

Plaintiffs,

AFFYMETRIX, INC.; and LIFE TECHNOLOGIES CORP.,

Defendants.

Case No.: 17-cv-01394-H-NLS

TENTATIVE CLAIM
CONSTRUCTION ORDER FOR
THE '613 PATENT, THE '303
PATENT, THE '869 PATENT, AND
THE '008 PATENT

In the present action, Plaintiffs the Regents of the University of California, Becton, Dickinson and Company, Sirigen, Inc., and Sirigen II Limited assert claims of patent infringement against Defendants Affymetrix, Inc. and Life Technologies Corp., alleging infringement of U.S. Patent No. 8,455,613, U.S. Patent No. 8,575,303, U.S. Patent No. 9,139,869, and U.S. Patent No. 9,547,008. (Doc. No. 101, FAC ¶¶ 82-115.) On June 15,

In this action, Plaintiffs also assert claims of patent infringement against Defendants for infringement of U.S. Patent No. 9,085,799, U.S. Patent No. 8,110,673, and U.S. Patent No. 8,835,113 (Doc. No. 101, FAC ¶¶ 52-81.) The Court issued a prior claim construction order for the '799 patent, the '673 patent, and the '113 patent on March 26, 2018. (Doc. No. 138.) In addition, on May 1, 2018, the Court granted Defendants' motion for summary judgment of non-infringement of the '799 patent. (Doc. No. 170.)

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2018, the parties filed their joint claim construction prehearing statement, chart, and worksheet, identifying the disputed claim terms from the '613 patent, the '303 patent, the '869 patent, and the '008 patent. (Doc. No. 195.) On July 20, 2018, the parties each filed an opening claim construction brief. (Doc. Nos. 219, 221.) On August 3, 2018, the parties each filed a responsive claim construction brief. (Doc. No. 252, 253.)

A claim construction hearing for the '613 patent, the '303 patent, the '869 patent, and the '008 patent is scheduled for Friday, August 31, 2018 at 10:00 a.m. (Doc. No. 105 at 14.) In anticipation of the hearing, the Court issues the following tentative claim construction order.

Background

On July 10, 2017, Plaintiffs Regents and Becton, Dickinson filed a complaint for patent infringement against Defendants Affymetrix and Life Technologies, alleging infringement of U.S. Patent No. 9,085,799, U.S. Patent No. 8,110,673, and U.S. Patent No. 8,835,113. (Doc. No. 1, Compl.) On September 8, 2017, Defendants filed an answer to Plaintiffs' complaint. (Doc. No. 37.)

On October 6, 2017, the Court issued a scheduling order. (Doc. No. 55.) On November 20, 2017, the Court denied Plaintiff Becton, Dickinson's motion for a preliminary injunction without prejudice. (Doc No. 69.) On November 30, 2017, the Court issued an amended scheduling order. (Doc. No. 76.)

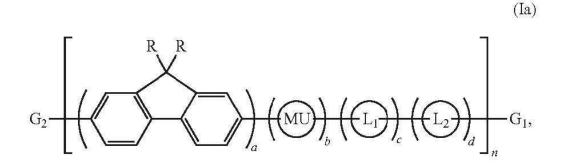
On February 7, 2018, the Court granted the parties' joint motion for leave for Plaintiffs to file a first amended complaint and to modify the scheduling order. (Doc. No. 100.) On February 9, 2018, Plaintiffs filed an amended complaint: (1) adding Sirigen and Sirigen II as additional Plaintiffs and adding claims that Defendants' products infringe four Sirigen patents: U.S. Patent No. 9,547,008, U.S. Patent No. 9,139,869, U.S. Patent No. 8,575,303, and U.S. Patent No. 8,455,613; (2) adding infringement allegations against additional accused products; and (3) adding allegations of induced infringement against Defendants. (Doc. No. 101, FAC.)

On February 23, 2018, the Court issued a second amended scheduling order. (Doc. No. 105.) On March 26, 2018, the Court issued a claim construction order, construing disputed claim terms from the '799 patent, the '673 patent, and the '113 patent. (Doc. No. 138.) On May 1, 2018, the Court granted Defendants' motion for summary judgment of non-infringement of the '799 patent. (Doc. No. 170.) On May 14, 2018, the Court denied Defendants' motion for summary judgment of non-infringement of the '673 patent and the '113 patent. (Doc. No. 183.)

By the present claim construction briefs, the parties request that the Court construe disputed claim terms from the '613 patent, the '303 patent, the '869 patent, and the '008 patent. (Doc. Nos. 219, 221.) The '613 patent, the '303 patent, the '869 patent, and the '008 patent are all entitled "Reagents for Directed Biomarker Signal Amplification," and these patents all share a common specification. U.S. Patent No. 8,455,613 (filed Jun. 4, 2013), at (54); U.S. Patent No. 8,575,303 (filed Nov. 5, 2013), at (54); U.S. Patent No. 9,139,869 (filed Sep. 22, 2015), at (54); U.S. Patent No. 9,547,008 (filed Jan. 17, 2017), at (54). The invention disclosed in the patents at issue relate to "neutral conjugated water-soluble polymers with linkers along the polymer main chain structure and terminal end capping units." '613 Patent at (57) (abstract).

As an exemplary claim, Claim 1 of the '303 Patent provides:

1. A water soluble conjugated polymer having the structure of Formula (Ia):



wherein:

each R is independently a non-ionic side group capable of imparting solubility in water in excess of 10 mg/mL;

MU is a polymer modifying unit or band gap modifying unit that is evenly or randomly distributed along the polymer main chain and is optionally substituted with one or more optionally substituted substituents selected from halogen, hydroxyl, C_1 - C_{12} alkyl, C_2 - C_{12} alkene, C_2 - C_{12} alkyne, C_3 - C_{12} cycloalkyl, C_1 - C_{12} haloalkyl, C_1 - C_{12} alkoxy, C_2 - C_{18} (hetero)arylamino, $(CH_2)_x$ (OCH_2CH_2) $_y$ OCH $_3$ where each x' is independently an integer from 0-20, y' is independently an integer from 0 to 50, or a C_2 - C_1 8 (hetero)aryl group;

each optional linker L_1 and L_2 are aryl or heteroaryl groups evenly or randomly distributed along the polymer main chain and are substituted with one or more pendant chains terminated with a functional group selected from amine, carbamate, carboxylic acid, carboxylate, maleimide, activated esters, N-hydroxysuccinimidyl, hydrazines, hydrazids, hydrazones, azide, alkyne, aldehydes, thiols, and protected groups thereof for conjugation to another substrate, molecule or biomolecule;

G₁ and G₂ are each independently selected from hydrogen, halogen, alkyne, optionally substituted aryl, optionally substituted heteroaryl, halogen substituted aryl, boronic acid substituted aryl, boronic ester substituted aryl, boronic esters, boronic acids, optionally substituted fluorine and aryl or heteroaryl substituted with one or more pendant chains terminated with a functional group, molecule or biomolecule selected from amine, carbamate, carboxylic acid, carboxylate, maleimide, activated esters, N-hydroxysuccinimidyl, hydrazines, hydrazids, hydrazones, azide, alkyne, aldehydes, thiols, and protected groups thereof for conjugation to another substrate, molecule or biomolecule;

wherein the polymer comprises at least 1 functional group selected from amine, carbamate, carboxylic acid, carboxylate, maleimide, activated esters, N-hydroxysuccinimidyl, hydrazines, hydrazids, hydrazones, azide, alkyne, aldehydes, and thiols within G_1 , G_2 , L_1 or L_2 that allows, for functional conjugation to another molecule, substrate or biomolecule;

n is an integer from 1 to about 10,000; and

a, b, c and d define the mol % of each unit within the structure which each can be evenly or randomly repeated and where a is a mol % from 10 to 100%, b is a mol % from 0 to 90%, and each c and d are mol % from 0 to 25%.

'303 Patent at 239:29-240:56.

Discussion

I. Legal Standards for Claim Construction

Claim construction is an issue of law for the court to decide. <u>Teva Pharm. USA, Inc. v. Sandoz, Inc.</u>, 135 S. Ct. 831, 838 (2015); <u>Markman v. Westview Instr., Inc.</u>, 517 U.S. 370, 372 (1996). Although claim construction is ultimately a question of law, "subsidiary factfinding is sometimes necessary." <u>Teva</u>, 135 S. Ct. at 838.

"The purpose of claim construction is to 'determin[e] the meaning and scope of the patent claims asserted to be infringed." O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1360 (Fed. Cir. 2008). "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) (en banc).

Claim terms "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." Id. at 1312–13. "In some cases, the ordinary meaning of claim language as understood by a [PHOSITA] may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." Id. at 1314. "However, in many cases, the meaning of a claim term as understood by persons of skill in the art is not readily apparent." O2 Micro, 521 F.3d at 1360. If the meaning of the term is not readily apparent, the court must look to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean," including intrinsic and extrinsic evidence. See Phillips, 415 F.3d at 1314. A court should begin with the intrinsic record, which consists of the language of the claims, the patent specification, and, if in evidence, the prosecution history of the asserted patent. Id.; see also Vederi, LLC v.

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<u>Google, Inc.</u>, 744 F.3d 1376, 1382 (Fed. Cir. 2014) ("In construing claims, this court relies primarily on the claim language, the specification, and the prosecution history.").

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language of the claims. See Vitronics, 90 F.3d at 1582; see also Comark Commc'ns v. Harris Corp., 156 F.3d 1182, 1186 (Fed. Cir. 1998) ("The appropriate starting point . . . is always with the language of the asserted claim itself."). The context in which a disputed term is used in the asserted claims may provide substantial guidance as to the meaning of the term. See Phillips, 415 F.3d at 1314. In addition, the context in which the disputed term is used in other claims, both asserted and unasserted, may provide guidance because "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." Id. Furthermore, a disputed term should be construed "consistently with its appearance in other places in the same claim or in other claims of the same patent." Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001); accord Microprocessor Enhancement Corp. v. Texas Instruments Inc., 520 F.3d 1367, 1375 (Fed. Cir. 2008); see also Paragon Sols., LLC v. Timex Corp., 566 F.3d 1075, 1087 (Fed. Cir. 2009) ("We apply a presumption that the same terms appearing in different portions of the claims should be given the same meaning." (internal quotation marks omitted)). Moreover, "[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." Vederi, 744 F.3d 1383.

In determining the proper construction of a claim, a court should first look to the

A court must also read claims "in view of the specification, of which they are a part." Markman, 52 F.3d at 979; see 35 U.S.C. § 112(b) ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."). "'Apart from the claim language itself, the specification is the single best guide to the meaning of a claim term." Vederi, 744 F.3d at 1382. For example, "a claim construction that excludes [a] preferred embodiment [described in the specification] 'is rarely, if ever, correct and would require highly persuasive evidentiary support." Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 616 F.3d 1283, 1290 (Fed. Cir. 2010).

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exclude. That is the function and purpose of claims." Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc). Therefore, "it is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." Dealertrack, Inc. v. Huber, 674 F.3d 1315, 1327 (Fed. Cir. 2012); see also Kara Tech. Inc. v. Stamps.com Inc., 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.").

But "[t]he written description part of the specification does not delimit the right to

In most situations, analysis of the intrinsic evidence will resolve claim construction disputes. See Vitronics, 90 F.3d at 1583; Teva, 135 S. Ct. at 841. However, "[w]here the intrinsic record is ambiguous, and when necessary," district courts may "rely on extrinsic evidence, which 'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 711 F.3d 1348, 1360 (Fed. Cir. 2013) (quoting Phillips, 415 F.3d at 1317). A court must evaluate all extrinsic evidence in light of the intrinsic evidence. Phillips, 415 F.3d at 1319. "Extrinsic evidence may not be used 'to contradict claim meaning that is unambiguous in light of the intrinsic evidence." Summit 6, LLC v. Samsung Elecs. Co., 802 F.3d 1283, 1290 (Fed. Cir. 2015); see also Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc., 262 F.3d 1258, 1269 (Fed. Cir. 2001) ("[E]xtrinsic evidence . . . may not be used to vary, contradict, expand, or limit the claim language from how it is defined, even by implication, in the specification or file history."); Vederi, 744 F.3d at 1382 ("[E]xtrinsic evidence may be less reliable than the intrinsic evidence."). In cases where subsidiary facts contained in the extrinsic evidence "are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence." Teva, 135 S. Ct. at 841.

"[D]istrict courts are not (and should not be) required to construe every limitation

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present in a patent's asserted claims." O2 Micro, 521 F.3d at 1362. In certain situations, it is appropriate for a court to determine that a claim term needs no construction and its plain and ordinary meaning applies. See id.; Phillips, 415 F.3d at 1314. But "[a] determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute." O2 Micro, 521 F.3d at 1361. If the parties dispute the scope of a certain claim term, it is the court's duty to resolve the dispute. Id. at 1362; accord Eon Corp. IP Holdings v. Silver Spring Networks, 815 F.3d 1314, 1318 (Fed. Cir. 2016).

II. Analysis of the Disputed Claim Terms

A. "NH₂"

Plaintiffs propose that the term "NH₂" be construed as "an -NH₂ group, or an -NH-group that is the product of conjugation of an -NH₂ group to another chemical group." (Doc. No. 221 at 6.) Defendants propose that the term "NH₂" be construed as "an -NH₂ group." (Doc. No. 219 at 7.) Here, the parties dispute whether "NH₂" can include a -NH-group that is the product of conjugation of an -NH₂ group to another chemical group. Because the parties dispute the scope of this claim term, the Court must resolve the parties' dispute. See O2 Micro, 521 F.3d at 1361; Eon, 815 F.3d at 1318.

The Court begins its analysis of the parties' dispute by examining the claim language. Claim 1 of the '303 Patent claims "[a] water soluble conjugated polymer" having a structure where "each optional linker L_1 and L_2 are . . . for conjugation to another substrate, molecule or biomolecule." '303 Patent at 239:58-67. Further, dependent claim 5 of the '303 patent expressly claims the polymer of claim 1 "wherein optional linker L_1 or L_2 are" a structure including "NH₂." <u>Id.</u> at 244:36-50; <u>see also</u> '613 Patent at 231:2, 232:20-38. Here, claim 5 of the '303 patent describes a polymer having a linker with a -NH₂ group that allows the polymer to be conjugated to another substrate, molecule, or biomolecule. This is notable because both parties' experts agree that after a -NH₂ group is conjugated to another group, the chemical structure is no longer -NH₂. (Doc. No. 195-3, Swager Decl.

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¶¶ 10, 13; Doc. No. 195-4, Burgess Decl. ¶ 33.) The end product is -NH-, not -NH₂. (<u>Id.</u>) As such, the claim language supports Plaintiffs' proposed construction. <u>See Phillips</u>, 415 F.3d at 1314 ("[T]he usage of a term in one claim can often illuminate the meaning of the same term in other claims.").

In addition, Plaintiffs' proposed construction is well supported by the patents' The specification provides: "In some instances, a signaling common specification. chromophore is attached to the polymer via the NH₂ group." '613 Patent at 21:1-2. Plaintiffs' proposed construction for the term "NH₂" would include this particular embodiment disclosed in the specification whereas Defendants' proposed construction would exclude it. "[A] claim construction that excludes [a] preferred embodiment [described in the specification] 'is rarely, if ever, correct and would require highly persuasive evidentiary support." Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 616 F.3d 1283, 1290 (Fed. Cir. 2010). Here, there is no such highly persuasive support in the record for excluding this preferred embodiment. To the contrary, dependent claim 4 of the '613 expressly claims this embodiment described in the specification. Dependent claim 4 claims a signaling chromophore that is attached to the claimed polymer via the linker, where the linker may include a -NH₂ group. See '613 Patent at 231:2, 232:20-38, 233:21-22. As such, the specification in addition to the claim language strongly supports Plaintiffs' proposed construction.

In sum, the Court adopts Plaintiffs' proposed construction for this claim term, and the Court rejects Defendants' proposed construction. The Court tentatively construes the term "NH₂" as "an -NH₂ group, or an -NH- group that is the product of conjugation of an -NH2 group to another chemical group."

B. "polymer modifying unit"

Plaintiffs propose that the term "polymer modifying unit" be construed as "a unit in the polymer different than the units wherein the ratios are denoted by the letters a, c, and d." (Doc. No. 221 at 12.) Defendants argue that the claim term "polymer modifying unit" is indefinite. (Doc. No. 219 at 11.)

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Section 112 of the Patent Act requires that a patent's specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention." 35 U.S.C. § 112, ¶ 2. In Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2124 (2014), the Supreme Court "h[e]Id that a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." See also id. at 2129 ("[W]e read § 112, ¶ 2 to require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty."). Definiteness is measured from the viewpoint of a PHOSITA at the time the patent was filed. Id. at 2128.

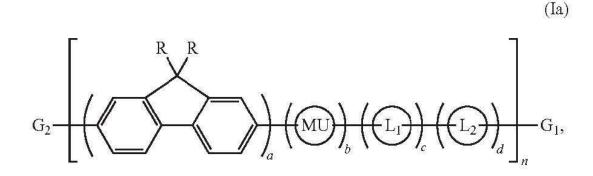
Indefiniteness is a question of law involving underlying factual determinations. Teva Pharm. USA, Inc. v. Sandoz, Inc., 789 F.3d 1335, 1341 (Fed. Cir. 2015); Green Edge Enters., LLC v. Rubber Mulch Etc., LLC, 620 F.3d 1287, 1299 (Fed. Cir. 2010). The party challenging the validity of the patents-in-suit bears the burden of proving indefiniteness by clear and convincing evidence. See Nautilus, 134 S. Ct. at 2130 n.10 (citing Microsoft Corp. v. i4i Ltd. Partnership, 131 S. Ct. 2238, 2242 (2011)); see, e.g., Teva, 789 F.3d at 1345.

Defendants argue that the term "polymer modifying unit" is indefinite because the term has no meaning to a person of ordinary skill in the art, and the common specification for the patent provides no guidance as to its meaning. (Doc. No. 219 at 11.) Defendants state that the term "polymer modifying unit" is not a term of art, and it has no commonly accepted definition. (Id. at 13.) But even assuming this is true, there is no requirement that a claim term must be a term of art or have a commonly accepted definition in order to be definite under section 112.

Defendants further argue that the common specification for the patents fails to provide sufficient guidance to a person of skill in the art as to the meaning of the term. (Doc. No. 219 at 13.) The Court disagrees. The term itself provides guidance as to its

meaning. The Court agrees with Plaintiffs that each of the words used in the phrase "polymer modifying unit" has a common meaning that is understandable to a person of ordinary skill in the art. (Doc. No. 221 at 12.) Under its plain language, the term means a unit in the claimed polymer that modifies the polymer. Further, the specification provides sufficient examples of how the "polymer modifying unit" modifies the claimed polymer to give one skilled in the art reasonable certainty regarding the scope of the claim term. See '613 Patent at 52:1-19. As a result, Defendants have failed to meet their burden of establishing that the claim term "polymer modifying unit" is indefinite.

Plaintiffs' proposed construction is supported by the claim language. For example, claim 1 of the '303 patent claims "[a] water soluble conjugated polymer having the structure of Formula (Ia):



wherein: . . . MU is a polymer modifying unit '303 Patent at 239:29-46. Here, the claim depicts the polymer modifying unit as being a unit that is different from the units that are denoted by the letter a, c, and d. Nevertheless, the Court slightly alters Plaintiffs' proposed construction to include the requirement that the unit modify the polymer.

In sum, the Court rejects Defendants' contention that the claim term "polymer modifying unit" is indefinite. The Court adopts Plaintiffs' proposed constructed as modified. The Court tentatively construes "polymer modifying unit" as "a unit in the polymer that modifies the polymer and is different than the units wherein the ratios are denoted by the letters a, c, and d."

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C. "band gap modifying unit"

Plaintiffs propose that the term "band gap modifying unit" be construed as "a unit in the polymer that modifies the wavelengths at which the polymer absorbs or emits light." (Doc. No. 221 at 14.) Defendants propose that the term be construed as "a unit in the polymer that either increases or decreases the band gap of the polymer." (Doc. No. 219 at 17.) Because the parties dispute the scope of this claim term, the Court must resolve the parties' dispute. See O2 Micro, 521 F.3d at 1361; Eon, 815 F.3d at 1318.

As an initial matter, the Court notes that the parties and their experts agree on the definition for the term "band gap." Plaintiffs' expert, Dr. Swager, explains that: "A 'band gap' is a particular property of a material that refers to the energy gap between the highest occupied molecular orbital and the lowest unoccupied molecular orbital." (Doc. No. 195-3, Swager Decl. ¶ 31.) Defendants' expert, Dr. Burgess, explains: "The term 'band gap' is conceptually used to describe the gap in energy between the highest occupied molecular orbital and the lowest unoccupied molecular orbital." (Doc. No. 195-4, Burgess Decl. ¶ 43.) In light of this agreement between the experts as to the term "band gap," the Court tentatively construes the term "band gap" as "the energy gap between the highest occupied molecular orbital and the lowest unoccupied molecular orbital."

Turning to the full phrase "band gap modifying unit," Defendants' proposed construction is supported by a review of the intrinsic record. The claim language provides an initial definition for this claim term. For example, claim 1 of the '303 patent claims: "A water soluble conjugated polymer having the structure of Formula (Ia) . . . wherein: . . . MU is a polymer modifying unit or band gap modifying unit that is evenly or randomly distributed along the polymer main chain." '303 Patent at 239:29-48. Here, the plain language of claim 1 of the '303 patent describes the "band gap modifying unit" as a unit in the polymer that modifies the band gap. Further, the specification explains the manner in which these units modify the bandgap. The common specification provides: "Incorporation of repeat units that decrease the band gap can produce conjugated polymers with such characteristics." '613 Patent at 52:41-42. Here, the specification explains that

the units at issue modify the band gap by decreasing it. As such, Defendants' proposed construction providing that a "band gap modifying unit" is a unit in the polymer that either increases or decreases the band gap is well supported by the intrinsic record.²

Plaintiffs argue that Defendants' proposed construction for the term "band gap modifying unit" would be unhelpful to the jury because it uses the technical term "band gap" within the proposed construction. (Doc. No. 221 at 15.) But any concerns regarding Defendants' use of the term "band gap" in their proposed construction are alleviated by the Court separately construing the term "band gap" based on the experts' agreed upon definition. As such, the Court rejects Plaintiffs' contention. In addition, the Court agrees with Defendants that Plaintiffs' proposed construction is flawed because it replaces the agreed meaning of the term "band gap" with its downstream effect. (See Doc. No. 219 at 18.)

In sum, the Court adopts Defendants' proposed construction for this claim term, and the Court rejects Plaintiffs' proposed construction. The Court tentatively construes the term "band gap modifying unit" as "a unit in the polymer that either increases or decreases the band gap of the polymer."

D. "solubility"

Plaintiffs propose that the term "solubility" be construed as "miscible in a solvent with no visible particulates." (Doc. No. 221 at 16.) Defendants propose that the term "solubility" be construed as "ability or tendency of a substance to dissolve a solvent." (Doc. No. 219 at 20.) Here, the parties dispute whether the term "solubility" requires that the polymer be capable of being mixed in water or an aqueous solution such that no visible particulates remain. Because the parties dispute the scope of this claim term, the Court must resolve the parties' dispute. See O2 Micro, 521 F.3d at 1361; Eon, 815 F.3d at 1318.

In their claim construction brief, Defendants argue that the Court's construction for the term "band gap modifying unit" should cover both increasing and decreasing the band gap. (Doc. No. 219 at 18-20.) In response, Plaintiffs explain that it is not their position that that the "band gap modifying unit" should be read narrowly to mean only decreasing the band gap. (Doc. No. 252 at 8.) As such, the Court's tentative construction for this claim term will cover both increasing and decreasing the band gap.

an explicit statement of redefinition." (citation omitted)); Phillips, 415 F.3d at 1321 ("[T]he specification 'acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.").

Defendants argue that the passage at issue fails to set forth a clear definition for the term "solubility" because the passage is merely describe one preferred embodiment of the claimed invention. (Doc. No. 219 at 21.) The Court disagrees. The Court recognizes that "it is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." Dealertrack, 674 F.3d at 1327. But in the passage at issue, the common specification does not appear to be describing a preferred embodiment. Rather, the common specification provides a clear explanation of what the term "solubility" refers to with respect to the claimed

In support of their proposed claim construction, Plaintiffs argue that the common

specification for the patents at issue provides an express definition for the term "solubility."

(Doc. No. 221 at 16.) The Court agrees. The common specification provides: "Non-ionic

side groups capable of imparting solubility in water as used herein refer to side groups

which are not charged and allow the resulting polymer to be soluble in water or aqueous

solutions with no visible particulates." '613 Patent at 548-11. Here, the common

specification explains that the term "imparting solubility" as used herein means to allow

"the resulting polymer to be soluble in water or aqueous solutions with no visible

particulates." Id. Plaintiffs' proposed construction properly incorporates this definition

from the common specification. See Honeywell Int'l, Inc. v. Universal Avionics Sys.

Corp., 493 F.3d 1358, 1361 (Fed. Cir. 2007) ("When a patentee defines a claim term, the

patentee's definition governs, even if it is contrary to the conventional meaning of the term.

A claim term may be defined in a particular manner for purposes of a patent even 'without

Defendants further argue that Plaintiffs' proposed construction is flawed because it uses the term "miscible," which refers to the ability of liquids and gasses to mix. (Doc.

invention. As such, the Court rejects Defendants' argument.

No. 219 at 21-22.) Defendants argue that conjugated polymers are neither liquid nor gas, and, thus, the word "miscible" makes no sense in this context. (<u>Id.</u> at 22.) In response, Plaintiff explain that the words "mixable" and "miscible" are synonyms. (Doc. No. 252 at 9 n.3.) As such, the Court slightly alters Plaintiffs' proposed construction for this term to use the word "mixable" instead of "miscible."

In support of their proposed construction, Defendants merely rely on extrinsic evidence, specifically expert testimony and dictionary definitions. (Doc. No. 219 at 20.) But "[e]xtrinsic evidence may not be used 'to contradict claim meaning that is unambiguous in light of the intrinsic evidence." Summit 6, 802 F.3d at 1290; see Bell Atl. Network, 262 F.3d at 1269. The common specification contains clear language explaining what is meant by the term "solubility." Accordingly, Defendants cannot use extrinsic evidence to contradict or vary this clear language contained in the specification.

In sum, the Court adopts Plaintiffs' proposed construction for this claim term, and the Court rejects Defendants' proposed construction. The Court tentatively construes the term "solubility" as "mixable in a solvent with no visible particulates."

E. "where the specific signal is at least 3 fold greater than the same antibody conjugated to Pacific Blue"

Plaintiffs argue that the claim term "where the specific signal is at least 3 fold greater than the same antibody conjugated to Pacific Blue" needs no construction. (Doc. No. 221 at 16.) Plaintiffs propose, in the alternative, that if this claim term must be construed, the Court construe the claim term as "a specific signal that is at least 3 fold greater than the signal of the same antibody conjugated to the fluorescent dye Pacific Blue, with an inherent upper limit in the range of about 20-25 fold." (Doc. No. at 17.) Defendants propose that this claim term be construed as "a specific signal that is 3 fold or more greater than the signal of the same antibody conjugated to Pacific Blue, with no upper limit." (Doc. No. 219 at 22.) Here, the parties dispute whether the phrase "at least three fold greater" contains an inherent upper limit of about 20-25 fold. Because the parties dispute the scope of this claim term, the Court must resolve the parties' dispute. See O2 Micro, 521 F.3d at 1361;

Eon, 815 F.3d at 1318.

The Court begins its analysis of the parties' dispute regarding the phrase "at least three fold greater" by examining the claim language. The claim language places no upper limit on the increase in signal. For example, claim 21 of the '303 patent provides: "The water soluble conjugated polymer of claim 20, wherein the polymer and antibody excited at about 405 nm in a flow cytometry assay where the specific signal is at least 3 fold greater than the same antibody conjugated to Pacific Blue." '303 Patent at 253:66-254:3. The claim language of claim 1 of the '799 patent requires that the signal generated by the polymer and the antibody be at least 3 fold greater than when the same antibody is conjugated to Pacific Blue. The claim language does not provide an upper range. The claim language merely requires that the increase be at least 3 fold greater. Further, the Court notes that the Federal Circuit has held that "[o]pen-ended claims are not inherently improper." Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1376 (Fed. Cir. 2007) (quoting Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1572 (Fed. Cir. 1991)). Accordingly, the claim language supports Defendants' proposed construction, not Plaintiffs' proposal.

In support of their assertion that the phrase "greater than 4 fold increase" has an inherent upper limit of about 20-25 fold, Plaintiffs rely on Federal Circuit case law holding that open-ended claims have inherent upper limits. (Doc. No. 221 at 17.) In <u>Andersen Corp. v. Fiber Composites, LLC</u>, the Federal Circuit explained that open-ended claims are permissible, and "they may be supported if there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit. <u>Andersen Corp. v. Fiber Composites, LLC</u>, 474 F.3d 1361, 1376–77 (Fed. Cir. 2007). Plaintiffs assert that the evidence in the record shows that at the time of the invention a person of ordinary skill in the art would understand that the phrase "greater than 4 fold increase" had an inherent upper limit of approximately 20-25 fold. (Doc. No. 221 at 18 (citing Doc. No. 195-3, Swager Decl. ¶ 42).) But the problem with Plaintiffs' argument is that Plaintiffs have failed to provide the Court with any authority holding that the inherent

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upper limit of an open-ended claim term must be limited to what was known in the art at the time of the invention and would not include changes to that upper limit in the future. In the absence of such authority, the Court declines to adopt Plaintiffs' proposed inherent upper limit of about 20-25. Further, the data relied on by Plaintiffs' expert, Dr. Swager, does not actually support the imposition of an inherent upper limit of about 20-25. In his calculations, Dr. Swager utilizes an extinction coefficient of exactly 2,500,000 for the polymer dye, (Doc. No. 195-3, Swager Decl. ¶ 42), but the portion of the specification where Dr. Swager obtained this number from actually states that the extinction coefficient is "greater than 2,500,000." (Id. ¶ 41 (citing '613 Patent at 161:23-162:4).)

In sum, the Court adopts Defendants' proposed construction for this claim term, and the Court rejects Plaintiffs' proposed construction for this claim term. The Court tentatively construes the term "where the specific signal is at least 3 fold greater than the same antibody conjugated to Pacific Blue" as "a specific signal that is 3 fold or more greater than the signal of the same antibody conjugated to Pacific Blue."

F. Certain Chemical Structures

The parties dispute the proper constructions for several chemical structures claimed in the patents at issue. Plaintiffs argue that no construction of these chemical structures is necessary. (Doc. No. 221 at 18.) Plaintiffs argue, in the alternative, that if the Court must add a construction to these chemical structures, the structure claims should be construed to mean that "the chemical groups referred to have the chemical structures shown and have substitutions at the positions indicated by, for example, R, R', or R_{25} ." (Id. at 20.) Defendants propose that these chemical structures be construed as "the chemical structure of this unit does not show hydrogen atoms, but the structure as shown is otherwise substituted only where indicated by R, R', or R_{25} . * = site for covalent attachments to

The Court slightly alters Defendants' proposed construction to delete the phrase "no upper limit." Further, the Court notes that at this time the Court is merely construing the disputed claim terms from the patents at issue as is proper at the <u>Markman</u> stage of an action for patent infringement. The Court's decision at claim construction should in no way be interpreted as resolving any potential disputes the parties may have regarding enablement or written description issues.

unsaturated backbone." (Doc. No. 219 at 4.)

Plaintiffs argue that the chemical structures at issue need no construction because line structures such as these are common in organic chemistry and fully convey to chemists the entire structure of the molecule in a simple and easy to understand manner. (Doc. No. 221 at 18 (citing Doc. No. 195-3, Swager Decl. ¶¶ 45-48).) But, here, the parties have a dispute regarding whether the claimed structures can include substitutions other than at R, R', or R_{25} . (Compare Doc. No. 219 at 5 with Doc. No. 221 at 19.) Because the parties dispute the scope of these claimed structures, the Court must resolve the parties' dispute. See O2 Micro, 521 F.3d at 1361; Eon, 815 F.3d at 1318.

The Court begin its analysis of the parties' dispute by reviewing the claim language. The claims at issue use chemical line structure drawings to define the scope of the claims. For example, claim 1 of the '613 patent claims the following chemical structure: "linker L_1 is"

'613 Patent at 232:20-30. In another example, claim 23 of the '869 patent claims the following chemical structure: "wherein the optional linkers L_1 or L_2 have the structure:"

'869 Patent at 249:12-22. The parties' experts agree that for the claim terms at issue, the terms "R," "R'," or " R_{25} " in the claims are substitutions on the chemical structures shown.

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(Doc. No. 195-3, Swager Decl. ¶ 45 ("the chemical groups . . . have substitutions at the positions indicated by R, R', or R_{25} "); Doc. No. 195-4, Burgess Decl. ¶¶ 17, 22-23.) Further, Plaintiffs' expert, Dr. Burgess, concedes that the claimed structures "do[] not literally show substituents at other positions." (Doc. No. 195-3, Swager Decl. ¶ 50.) Thus, the claim language supports Defendants' proposed construction.

Plaintiffs argue that an organist chemist would appreciate that other substitutions are possible. (Doc. No. 221 at 19.) But Plaintiffs fail to support this assertion with any citations to the intrinsic record. Plaintiffs fail to identify any language in the intrinsic record suggesting that other substitutions on the claimed structures at issue are possible. As such, the intrinsic record supports Defendants' proposed construction, not Plaintiffs' proposal.⁴

In addition, the latter portion of Defendants' proposed construction requiring that * = site for covalent attachments to unsaturated backbone is directly supported by both the claim language and the specification of the patents at issue. For example, claims 4, 7, 10 and 33 of '303 provide: "*=site for covalent attachment to [unsaturated] backbone." '303 Patent at 241:60, 244:35, 249:1, 252:50, 257:32; accord '869 Patent at 237:61, 240:8, 243:43, 248:45, 249:24. In addition, the common specification for the patents at issue provides: "*=site for covalent attachment to [unsaturated] backbone." '613 Patent at 3:59, 4:8, 4:54, 5:11, 8:13, 11:48, 16:15, 25:39, 27:15, 30:40. As such, the latter portion of Defendants' proposed construction is well supported by the intrinsic record.

In sum, the Court adopts Defendants' proposed construction for these chemical structures, and the Court rejects Plaintiffs' proposed construction. The Court tentatively

Because Defendants' proposed construction is supported by the intrinsic record, the Court rejects Plaintiffs' argument that the Court's construction should not include the negative limitation that the chemical structure "is otherwise not substituted." See, e.g., Eon, 815 F.3d at 1322-23 (construing the claims in the context of the specification to not cover "utility meters"); In re Gabapentin Patent Litig., 503 F.3d 1254, 1258, 1264-65 (Fed. Cir. 2007) (affirming district court's construction for the term "adjuvants" that contained a negative limitation explaining that the term "[does not] refer to the ingredients of capsule shells or tablet coatings.'").

construes the chemical structures at issue as "the chemical structure of this unit does not show hydrogen atoms, but the structure as shown is otherwise substituted only where indicated by R, R', or $R_{25.}$ * = site for covalent attachments to [unsaturated] backbone."

Conclusion

For the reasons above, the Court tentatively adopts the constructions set forth above.

IT IS SO ORDERED.

DATED: August 30, 2018

MARILYN L. HUFF, District Udge UNITED STATES DISTRICT COURT

The Court notes that its tentative construction for these chemical structures does not preclude Plaintiffs from arguing infringement under the doctrine of equivalents.