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# UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECKMAN COULTER, INC., Petitioner,

v.

SIRIGEN II LIMITED, Patent Owner.

IPR2022-01203 Patent 10,458,989 B2

Before CHRISTOPHER L. CRUMBLEY, JON B. TORNQUIST, and BRIAN D. RANGE, *Administrative Patent Judges*.

CRUMBLEY, Administrative Patent Judge.

DECISION Granting Institution of *Inter Partes* Review 35 U.S.C. § 314

#### I. INTRODUCTION

Beckman Coulter, Inc. filed a Petition requesting *inter partes* review of claims 1–10, 12–14, and 17–19 of U.S. Patent No. 10,458,989 B2 (Ex. 1001, "the '989 patent"). Paper 1 ("Pet."). Sirigen II Limited identified itself as the assignee of the '989 patent (Paper 4) and filed a Preliminary Response. Paper 8 ("Prelim. Resp."). With permission, Petitioner filed a preinstitution Reply (Paper 10 ("Prelim. Reply")) and Patent Owner filed a preinstitution Sur-Reply (Paper 11 ("Prelim. Sur-Reply").

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." The following findings of fact and conclusions of law are not final, but are made for the sole purpose of determining whether Petitioner meets the threshold for initiating review. Any final decision shall be based on the full trial record, including any response timely filed by Patent Owner. Any arguments not raised by Patent Owner in a timely-filed response may be deemed waived.

For the reasons stated below, we determine that Petitioner has established a reasonable likelihood that it would prevail with respect to at least one claim. Patent Owner has not persuaded us that we should exercise our discretion to deny institution. We hereby institute an *inter partes* review as to claims 1–10, 12–14, and 17–19 of the '989 patent based upon Petitioner's asserted grounds of unpatentability.

#### II. BACKGROUND

#### A. Related Matters

The parties indicate that the '989 patent is the subject of *Becton*, *Dickinson & Co., Sirigen, Inc., and Sirigen II Limited v. Beckman Coulter, Inc.*, No. 3:21-cv-01173-CAB-NLS (S.D. Cal.) ("the parallel district court litigation"). Pet. 3; Paper 4, 2. The parties also identify the following Board proceedings as related matters: IPR2022-01204 (U.S. Patent No. 10,365,285), IPR2022-01205 (U.S. Patent No. 10,955,417), IPR2022-01206 (U.S. Patent No. 10,302,648), IPR2022-01207 (U.S. Patent No. 10,288,620), and IPR2022-01208 (U.S. Patent No. 8,575,303). Pet. 3; Paper 4, 2.

#### B. The '989 patent

The '989 patent, entitled "Reagents for Directed Biomarker Signal Amplification," issued October 29, 2019. Ex. 1001, codes (45), (54). The '989 patent explains that fluorescent hybridization probes have become an important tool for the sequence-specific detection of DNA and RNA. *Id.* at 1:21–23. Conjugated polymers are described as having potential for improving the detection sensitivity of these probes, due to the fact that conjugated polymers "can be made water soluble and adapted to amplify the fluorescent output of various probe labels." *Id.* at 1:29–35.

The '989 patent describes conjugated polymers as highly promising for nucleic acid diagnostics, which benefit from methods to amplify or replicate nucleic acid targets. *Id.* at 1:40–44. Protein recognition, however, is said to lack simple methods for amplifying targeted materials. *Id.* at 1:44– 46. According to the '989 patent, integrating conjugated polymers into methods for detecting protein targets promises "to provide a dramatic boost in the performance of such assays, enabling detection levels previously

unattainable with conventional fluorescent reporters (e.g., dyes)." *Id.* at 1:46–54. In addition, the '989 patent describes conjugated polymers as ideally suited for multiplexing, which provides the ability to detect multiple analytes in the same test. *Id.* at 1:55–57, 1:59–60.

The '989 patent describes a number of water-soluble conjugated polymers, including those having a structure of the following formula:

$$G_{2} \cdots \left[ \left( \cdots \left( Ar \right)^{-} \right)_{a} \cdots \left( \cdots \left( MU \right)^{-} \right)_{b} \cdots \left( \cdots \left( L_{1} \cdots \right)^{-} \right)_{c} \left( \cdots \left( L_{2} \cdots \right)^{-} \right)_{d} \right]_{n} G_{1}$$

*Id.* at 33:23–30. The formula graphically depicts a chemical structure with the letters Ar, Mu, L<sub>1</sub>, and L<sub>2</sub> encircled and put within a bracket with subscript n.  $G_2$  is on the left side of the bracket, and  $G_1$  is on the right side. In this formula, "Ar is an aryl or heteroaryl and is optionally substituted with one or more optionally substituted substituents," which can be selected from various substances. Id. at 33:32–39. The '989 patent describes MU as "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 various groups. *Id.* at 2:20–29. "[E]ach 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 for conjugation to another substrate, molecule or biomolecule" that are selected from various substances. Id. at 2:30–38. The '989 patent also states that G<sub>1</sub> and G<sub>2</sub> are each independently selected from a list of possibilities that includes, for example, hydrogen, halogen, optionally

substituted aryl, and "optionally substituted fluorene and aryl or heteroaryl substituted with one or more pendant chains terminated with a functional group." *Id.* at 2:39–48.

C. Illustrative Claim

Claim 1 is sole independent claim challenged in the Petition. Ex. 1001, 221:2–59. Claims 2–10, 12–14, and 17–19 depend from claim 1. *Id.* at 221:60–225:30, 225:44–50, 226:31–231:10. Claim 1 is reproduced below.

1. A water-soluble conjugated polymer having the structure of the formula:

$$G_{2} \cdots \left[ \left( \cdots \left( Ar \right)^{-} \right)_{a} \cdots \left( \cdots \left( MU \right)^{-} \right)_{b} \cdots \left( \cdots \left( L_{1} \cdots \right)^{-} \right)_{c} \left( \cdots \left( L_{2} \cdots \right)^{-} \right)_{d} \right]_{n} G_{1}$$

wherein:

- Ar is an aryl or heteroaryl unit substituted with a non-ionic side group capable of imparting solubility in water;
- 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<sub>1</sub>-C<sub>12</sub> alkyl, C<sub>2</sub>-C<sub>12</sub> alkene, C<sub>2</sub>-C<sub>12</sub> alkyne, C<sub>3</sub>-C<sub>12</sub> cycloalkyl, C<sub>1</sub>-C<sub>12</sub> haloalkyl, C<sub>1</sub>-C<sub>12</sub> alkoxy, C<sub>2</sub>-C<sub>18</sub> (hetero)aryloxy, C<sub>2</sub>-C<sub>18</sub> (hetero)arylamino, a C<sub>2</sub>-C<sub>18</sub> (hetero)aryl group and (CH<sub>2</sub>)<sub>x'</sub>(OCH<sub>2</sub>CH<sub>2</sub>)<sub>y'</sub>OCH<sub>3</sub> where x' is independently an integer from 0-20 and y' is independently an integer from 0 to 50;
- optional linkers L<sub>1</sub> and L<sub>2</sub> are each independently an aryl or a heteroaryl group evenly or randomly distributed along the polymer main chain and are substituted with one or more pendant chains terminated with: i) a functional group selected from amine, carbamate, carboxylic acid, carboxylate, maleimide, activated ester, N-

hydroxysuccinimidyl, hydrazine, hydrazide, hydrazone, azide, alkyne, aldehyde, thiol, and protected groups thereof for conjugation to a molecule or biomolecule; or ii) a conjugated organic dye or biomolecule;

G<sub>1</sub> and G<sub>2</sub> 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 ester, boronic acid, optionally substituted fluorene and aryl or heteroaryl substituted with one or more pendant chains terminated with: i) a functional group selected from amine, carbamate, carboxylic acid, carboxylate, maleimide, activated esters, N-hydroxysuccinimidyl, hydrazine, hydrazide, hydrazone, azide, alkyne, aldehyde, thiol, and protected groups thereof for conjugation to a molecule or biomolecule; or ii) a conjugated organic dye or biomolecule;

wherein:

n is the number of repeat units;

- the polymer comprises at least 1 functional group selected from amine, carbamate, carboxylic acid, carboxylate, maleimide, activated ester, N-hydroxysuccinimidyl, hydrazines, hydrazide, hydrazone, azide, alkyne, aldehyde, and thiol within G<sub>1</sub>, G<sub>2</sub>, L<sub>1</sub> or L<sub>2</sub>, or a conjugated organic dye or biomolecule; 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%.

*Id.* at 221:2–59.

# D. Asserted Grounds of Unpatentability

Petitioner, supported by the declaration of Colin P. Nuckolls, Ph.D.

(Ex. 1007), asserts the following grounds of unpatentability (Pet. 16):

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| Claim(s) Challenged | 35 U.S.C. § <sup>1</sup> | Reference(s)   |
|---------------------|--------------------------|--|
| 1, 5, 7, 12, 17, 19 | 102(b)                   | Xue <sup>2</sup>   |
| 2-4,6               | 103(a)                   | Xue, Gaylord <sup>3</sup>  |
| 1–10, 12–14, 19     | 102(b)                   | Gaylord  |
| 1–10, 12–14, 19     | 103(a)                   | Gaylord, Bazan <sup>4</sup>  |
| 8                   | 103(a)                   | Gaylord, Zalipsky, <sup>5</sup><br>Hermanson, <sup>6</sup> Xue, Sumranjit <sup>7</sup> |

<sup>4</sup> US 2006/0183140 A1, published August 17, 2006, Ex. 1011 ("Bazan").

<sup>&</sup>lt;sup>1</sup> The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, took effect on March 16, 2013. The '989 patent claims priority to applications with filing dates before this date. *See* Ex. 1001, code (60), (63). Although Petitioner argues that the '989 patent is not entitled to claim priority to any provisional application, it does not dispute that priority can be claimed to the first nonprovisional application in the priority chain, filed January 19, 2011. Pet. 18–20. For the purposes of this Decision, we apply pre-AIA statutes.

<sup>&</sup>lt;sup>2</sup> Xue et al., *Highly Water-Soluble, Fluorescent, Conjugated Fluorene-Based Glycopolymers with Poly(ethylene glycol)-Tethered Spacers for Sensitive Detection of* Escherichia coli, Chem. Eur. J., vol. 15, 2289–2295 (2009), Ex. 1010 ("Xue").

<sup>&</sup>lt;sup>3</sup> US 2008/0293164 A1, published November 27, 2008, Ex. 1009 ("Gaylord").

<sup>&</sup>lt;sup>5</sup> Samuel Zalipsky, *Functionalized Poly(ethylene glycol) for Preparation of Biologically Relevant Conjugates*, Bioconj. Chem., vol. 6, pp. 150–165 (1995), Ex. 1012 ("Zalipsky").

<sup>&</sup>lt;sup>6</sup> Greg T. Hermanson, Bioconjugate Techniques, 2nd Edition (2008), Ex. 1013 ("Hermanson").

<sup>&</sup>lt;sup>7</sup> Jitapa Sumranjit, *Conjugated Organic Molecules as Models for Potential Sensors*, Ph.D. Dissertation, University of Massachusetts Amherst (Feb. 2007), Ex. 1014 ("Sumranjit").

| Claim(s) Challenged | 35 U.S.C. § <sup>1</sup> | Reference(s)  |
|---------------------|--------------------------|---|
| 17–18               | 103(a)                   | Gaylord, Gauthier, <sup>8</sup> Gordon, <sup>9</sup><br>Lou, <sup>10</sup> Haugland <sup>11</sup> |

Petitioner contends that all references cited in the grounds of unpatentability qualify as prior art under pre-AIA 35 U.S.C. § 102(b). Pet. 14–15. Patent Owner does not, at this stage of the proceeding, challenge the availability of any of the references as prior art. We presume, for purposes of this decision, that all references relied on by Petitioner are prior art to the '989 patent.

# III. ANALYSIS

# A. Legal Standard

A claim may be invalid as anticipated by a prior art reference if "each and every limitation is found either expressly or inherently in a single prior art reference." *Sanofi–Synthelabo v. Apotex, Inc.,* 470 F.3d 1368, 1375 (Fed. Cir. 2006) (internal quotation marks omitted). Anticipation under § 102 may be established by showing, as a matter of fact, that all elements arranged as specified in a claim are disclosed within the four corners of a reference,

<sup>&</sup>lt;sup>8</sup> Gauthier et al., *Peptide/protein-polymer conjugates: synthetic strategies and design concepts*, Chem. Comm., pp. 2591–2611 (2008), Ex. 1015 ("Gauthier").

<sup>&</sup>lt;sup>9</sup> Gordon, et al., *Synthesis of end-labeled multivalent ligands for exploring cell-surface-receptor-ligand interactions*, Chem. & Biol., vol. 7, pp. 9–16 (1999), Ex. 1016 ("Gordon").

<sup>&</sup>lt;sup>10</sup> Lou et al., *Polymer-Based Elemental Tags for Sensitive Bioassays*, Angew. Chem. Int'l Ed., vol. 46, pp. 6111–6114 (2007), Ex. 1017 ("Lou").

<sup>&</sup>lt;sup>11</sup> Rosaria P. Haugland, *Antibody Conjugates for Cell Biology*, Current Protocols in Cell Biology, 16.5.1–16.5.22 (2001), Ex. 1018 ("Haugland").

either expressly or inherently, in a manner enabling one skilled in the art to practice an embodiment of the claimed invention without undue experimentation. *See ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1344 (Fed. Cir. 2012).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and "the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of obviousness or nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

#### B. Level of Ordinary Skill in the Art

In order to determine whether an invention would have been obvious at the time the application was filed, we consider the level of ordinary skill in the pertinent art at critical time. *Graham*, 383 U.S. at 17. The resolution of this question is important because it allows us to "maintain[] objectivity in the obviousness inquiry." *Ryko Mfg. Co. v. Nu–Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991). In assessing the level of ordinary skill in the art, various factors may be considered, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995)

(quotation omitted). Generally, it is easier to establish obviousness under a higher level of ordinary skill in the art. *Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011) ("A less sophisticated level of skill generally favors a determination of nonobviousness... while a higher level of skill favors the reverse.").

Petitioner asserts that a person of ordinary skill in the art "would have at least a Ph.D. degree in chemistry, or a bachelor's or master's degree plus experience involving the use and design of fluorescent probes or dyes." Pet. 18 (citing Ex. 1007 ¶¶ 14–18). Patent Owner agrees that a person of ordinary skill may have a Ph.D. degree or master's degree in chemistry, but asserts that a they would also have "some experience with fluorescence" in addition to a Ph.D. degree in chemistry, and that someone with a master's degree in chemistry would alternatively have "industry experience in the field of biological detection systems." Prelim. Resp. 5–6 (citing Ex. 2001 ¶ 7).

For purposes of this Decision, we need not resolve these differences between the parties' definitions, because any differences do not affect our analysis.<sup>12</sup> If either party believes that adopting its preferred definition of the level of ordinary skill would have a material effect on the outcome of this proceeding, the party should address this issue during the instituted trial.

#### C. Claim Construction

In an *inter partes* review proceeding based on a petition filed on or after November 13, 2018, a patent claim shall be construed using the same

<sup>&</sup>lt;sup>12</sup> Patent Owner likewise agrees that the difference in definitions would not affect its arguments. Prelim. Resp. 6 (Patent Owner stating that its arguments and conclusions "would not change if Petitioner's definition were applied").

claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. §282(b). 37 C.F.R. §42.100(b) (as amended Oct. 11, 2018). This rule adopts the same claim construction standard used by Article III federal courts, which follow *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), and its progeny. Under this standard, the words of a claim are generally given their "ordinary and customary meaning," which is the meaning the term would have to a person of ordinary skill at the time of the invention, in the context of the entire patent including the specification. *See Phillips*, 415 F.3d at 1312–13.

# 1. Undisputed Constructions

The parties state that they agreed to the following construction in the parallel district court litigation:

| Claim Term  | Agreed Construction   |
|---|---|
| A water-soluble conjugated<br>polymer / A conjugated<br>polymer / A conjugated<br>polymer complex | A polymer containing an extended series of<br>unsaturated bonds with at least one<br>conjugated pi electron system that extends<br>across two or more repeat units. |
| polymer modifying unit  | A unit in the polymer that modifies the polymer and is different from the units denoted by the letters $a, c$ , and $d$ .   |
| band modifying unit   | A unit in the polymer that either increases<br>or decreases the band gap of the polymer.  |

Pet. 16; Prelim. Resp. 10–11.

Petitioner also asserts that "[t]he Court further held that 'MU is not required to be present in the structure of the water-soluble conjugated polymer' in independent claim 1 in the '989 patent, meaning that *b* can be zero mol %." Pet. 16–17 (citing Ex. 1053, 1–2). Petitioner states that it does

not dispute this construction. *Id.* Patent Owner contends that the Board should adopt this construction. Prelim. Resp. 11.

Patent Owner also asserts that Petitioner does not dispute the District Court's construction of "b is a mol% from 0 to 90%" as "0' is zero, meaning the limitation is not present in the structure" and construction of "substituted with one or more pendant chains terminated with [identified group]" as:

If a linker is present in the structure, it must have at least one pendant chain that terminates with a functional group that meets the remaining claim limitation. The plain language of the claim does not require that all chains pendant from a linker terminate with a functional group, or with the same functional group.

*Id.* at 11–12. Patent Owner argues that we should also adopt these constructions. *Id.* We have reviewed these constructions, but do not find it necessary to adopt any express constructions of these terms in order to resolve the dispute between the parties for purposes of institution. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("we need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng 'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

# 2. the polymer comprises at least 1 functional group . . . within $G_1$ , $G_2$ , $L_1$ or $L_2$ , or a conjugated organic dye or biomolecule

Petitioner asserts that the limitation "the polymer comprises at least 1 functional group selected from [identified functional groups] within G<sub>1</sub>, G<sub>2</sub>, L<sub>1</sub> or L<sub>2</sub>, or a conjugated organic dye or biomolecule" should be construed as "either '[1] the polymer comprises at least 1 functional group selected from

[the recited list] within  $G_1$ ,  $G_2$ ,  $L_1$  or  $L_2$ , 'or '[2] the polymer comprises . . . a conjugated organic dye or biomolecule.'" Pet. 17 (citing Ex. 1007 ¶¶ 96–100). According to Petitioner, "Patent Owner has contended that the preferred embodiments incorporate a conjugated organic dye or biomolecule within  $G_1$ ,  $G_2$ ,  $L_1$  or  $L_2$ " but "the claims should not be so limited where their plain language is broader." *Id.* Petitioner acknowledges that "[n]evertheless, the district court agreed with Patent Owner and construed the term as 'the polymer must include within  $G_1$ ,  $G_2$ ,  $L_1$  or  $L_2$  at least one of the identified functional groups, a conjugated organic dye, or a biomolecule."" *Id.* at 18 (citing Ex. 1053, 2).

Patent Owner disputes Petitioner's construction of this limitation, and asks that we instead adopt the District Court's construction. Prelim. Resp. 12-16. According to Patent Owner, Petitioner's proposed construction interprets the limitation in a vacuum, based only on a grammatical argument that the claim locates the "at least 1 functional group" within G<sub>1</sub>, G<sub>2</sub>, L<sub>1</sub>, or L<sub>2</sub> before reciting the words "dye" or "biomolecule." *Id.* at 15. Patent Owner argues that the claim itself contradicts this argument, because the preceding G<sub>1</sub>/G<sub>2</sub> and L<sub>1</sub>/L<sub>2</sub> limitations "each expressly contemplate that the units may have one of the recited functional groups, an organic dye or a biomolecule." *Id.* at 13. Patent Owner also argues that its interpretation is supported by the written description of the '989 patent, which states that the purpose of the claimed functional groups is to provide conjugation sites, and repeatedly describes the conjugation as occurring at the G<sub>1</sub> or G<sub>2</sub> end caps or the L<sub>1</sub> or L<sub>2</sub> units. *Id.* at 14–15.

While we recognize that the plain language and grammar of the claims supports Petitioner's proposed construction, we have also considered

the District Court's adopted construction and Patent Owner's arguments which find support in the written description of the '989 patent. In the end, however, we need not resolve this dispute at this time. Because the Petition provides sufficient evidence that the prior art references disclose the claimed functional groups, biomolecules, or organic dyes under either construction, it is not necessary for us to construe this claim term at this stage of the proceeding.

#### 3. capable of imparting solubility

Patent Owner asks us to construe "a non-ionic side group capable of imparting solubility in water" as "a side group that is not charged and allows for an excess of 10 mg/mL of the resulting polymer to be soluble in water or aqueous solutions with no visible particulates." Prelim. Resp. 16. Patent Owner acknowledges that this term was not construed by the District Court nor addressed in the Petition, and argues that the Petition is fatally flawed on this basis. Prelim. Resp. 3, 18–19. Patent Owner contends that Petitioner implicitly applies a construction that "as long as a side group is capable of making some polymer water soluble, the side group meets the limitation." *Id.* at 18.

In support of its construction, Patent Owner argues that its construction of "an excess of 10 mg/mL" is "reinforced throughout the specification," because the '989 patent repeatedly specifies that for various polymers certain R groups are selected in order to impart solubility in water in excess of 10 mg/mL. *Id.* at 17 (citing Ex. 1001, 2:18–19, 15:64–65, 21:64–65, 30:12–13, 53:2–3, 70:21–22). According to Patent Owner, "nowhere does the '989 Patent refer[] to a polymer solubility threshold of less than 10mg/ml." *Id.* Because the patent "indicates the importance" of the

solubility, Patent Owner argues that it is appropriate for us to read the solubility limit into the claims. *Id.* (citing *Techtronic Indus. Co. Ltd. v. ITC*, 944 F.3d 901, 907 (Fed. Cir. 2019)).

In response, Petitioner contends that we should not read any numerical solubility limit into the claims, noting that the '989 patent expressly defines "non-ionic side groups capable of imparting solubility in water" as simply "side groups which are not charged and allow the resulting polymer to be soluble in water or aqueous solution with no visible particulates." Prelim. Reply 1 (citing Ex. 1001, 54:9–13). Petitioner notes that this definition contains no numerical limit, and that it is followed by a statement that *in some embodiments*, the R group is capable of imparting solubility in excess of 10 mg/mL. Id. at 2 (citing Ex. 1001, 54:13–16). Petitioner contends that reading a limitation from "some embodiments" into the claims would be "one of the cardinal sins of patent law." Id. (citing Phillips, 415 F.3d at 1320; Polaris Innovations Ltd. v. Brent, 48 F.4th 1365, 1375–76 (Fed. Cir. 2022)). Petitioner also directs our attention to related patents that expressly claim a solubility in excess of 10 mg/mL, arguing that when Patent Owner sought to claim such polymers, it knew how to do so. Id. (citing Ex. 1005, 218:11–12; Ex. 1006, 239:43–45, 252:51–52, 254:39–40, 262:56-57, 269:31-35).

After considering the parties' arguments and evidence presented, we agree with Petitioner that Patent Owner's proposed definition reads into the claim a numeric threshold for solubility from an embodiment that is nowhere apparent from the claim itself. "[I]nterpreting what is *meant* by a word *in* a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper." *In re Cruciferous Sprout Litigation,* 

301 F.3d 1343, 1348 (Fed. Cir. 2002) (internal quotation marks and citations omitted; emphasis in original). Although we must read a patent's claims in light of the specification, see, e.g., Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed. Cir. 1998), that obligation does not authorize "reading a limitation from the written description into the claims." SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337, 1340 (Fed. Cir. 2001). Confining the scope of "capable of imparting solubility" to an unexpressed minimum solubility taken from only "some" embodiments encompassed by the '989 patent crosses that line. See, e.g., E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1432–34 (Fed. Cir. 1988) (Claims to a co-polymer improperly interpreted to include two properties). In view of the foregoing, we construe the phrase "a non-ionic side group capable of imparting solubility in water" to not require any particular numeric threshold of solubility. No further construction of the claim is necessary to resolve the dispute between the parties with respect to institution of trial.

#### D. Discretionary Denial under 35 U.S.C. § 314(a)

Patent Owner argues that we should exercise our discretion under 35 U.S.C. § 314(a) and not institute trial, given the state of the parallel district court litigation. Prelim. Resp. 40–50. For the reasons stated below, we do not exercise our discretion to deny institution in view of the parallel proceeding.

Institution of an *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a) (authorizing institution of an *inter partes* review under particular circumstances, but not requiring institution under any circumstances); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) ("[T]he

agency's decision to deny a petition is a matter committed to the Patent Office's discretion."); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) ("[Section] 314(a) invests the Director with discretion on the question whether to institute review . . . ." (emphasis omitted)); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d at 1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.").

When determining whether to exercise discretion to deny institution in view of a parallel proceeding with an earlier trial date, the following factors may be relevant:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;

2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;

3. investment in the parallel proceeding by the court and the parties;

4. overlap between issues raised in the petition and in the parallel proceeding;

5. whether the petitioner and the defendant in the parallel proceeding are the same party; and

6. other circumstances that impact the Board's exercise of discretion, including the merits.

*Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 6 (PTAB Mar. 20, 2020) (precedential) ("*Fintiv*"). "These factors relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding." *Id.* 

At the outset, we have doubts that analysis of the so-called *Fintiv* factors is necessary in this case at all. The analysis set forth in *Fintiv* applies to situations when "the patent owner raises an argument for discretionary

denial under *NHK* due to an earlier *trial date.*" *Id.* at 5 (emphasis added) (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential)); *see also id.* at 3 ("*NHK* applies to the situation *where the district court has set a trial date* to occur earlier than the Board's deadline to issue a final written decision") (emphasis added). And the Director of the U.S. Patent and Trademark Office has recently provided guidance that "the precedential import of *Fintiv* is limited to facts of that case." *See* Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings With Parallel District Court Litigation ("Interim Procedure Memorandum"), 2.<sup>13</sup>

We need not address whether, under this guidance, *Fintiv* applies only in situations where a district court trial date is set to occur before the issuance of the Board's final written decision. The facts and reasoning of *Fintiv* are, at a minimum, only applicable to cases in which the district court has *actually set* a trial date in a copending litigation. But here, as will be discussed below, the parties agree that no trial date has been set, and the District Court has stayed the litigation. Prelim. Reply 8; Prelim. Sur-Reply 6 ("There has never been a trial date."). Furthermore, that stay will continue until our final determination should we decide to institute trial. Without a trial date, we see no need to engage in a full analysis of the *Fintiv* factors,<sup>14</sup> as there is no basis for Patent Owner's argument for discretionary denial.

<sup>&</sup>lt;sup>13</sup> Available at https://www.uspto.gov/sites/default/files/documents/ interim\_proc\_discretionary\_denials\_aia\_parallel\_district\_court\_litigation\_ memo\_20220621\_.pdf.

<sup>&</sup>lt;sup>14</sup> We recognize that other panels of the Board have engaged in a *Fintiv* analysis even where the district court proceeding has been stayed. *See, e.g.*,

Nevertheless, below we address the *Fintiv* factors, in order to explain why, even if analyzed, they do not support exercising discretion to deny institution based on § 314(a).

# 1. Likelihood of a stay

A district court stay of parallel litigation pending resolution of an *inter partes* review allays concerns about inefficiency and duplication of efforts, which strongly weighs against exercising the authority to deny institution. *Fintiv* at 6.

Patent Owner nevertheless asserts this factor is neutral. Prelim. Resp. 42–43. According to Patent Owner, "[t]he district court in the Parallel Litigation granted a brief stay pending resolution of the IPR petitions." *Id.* at 42 (citing Ex. 2006, 2). Patent Owner "anticipates" that the District Court's stay "will be lifted at least as to each patent for which petition is denied," and that as a result, "[t]he practical effect is that the delay to the case schedule 'will be short." *Id.* at 42 (citing Ex. 2007, 2).

The record paints a different picture: it is far from certain the stay will be lifted for each patent for which the petition is denied. As noted above, there are six related petitions at the Board involving the patents before the court. The District Court stayed the litigation "pending resolution of the IPR proceedings that have been instituted on the patents at issue in

Snap, Inc. v. SRK Tech., LLC, IPR2020-00820, Paper 15 at 7–19 (PTAB Oct. 21, 2020) (precedential as to § II.A). In Snap, however, prior to the stay a trial date earlier than the Board's statutory date had been set, in contrast to the present case where there is no trial date. See *id.* at 8. In any event, as shown in our discussion below, where a parallel district court action is stayed and the court has indicated that the stay will remain in place if *inter partes* review is granted, we determine the first five *Fintiv* factors weigh (often strongly) against discretionary denial.

this case." Ex. 2006, 2. Regarding the length of the stay, the District Court explicitly ordered the parties not to use continuance of the fact discovery to October 28, 2022 "as grounds for . . . opposing institution of any post-grant proceeding." Ex. 2007, 2. Regarding when the stay will be lifted, the order merely gives Patent Owner the opportunity to "seek to lift the stay as to any patents that are *not instituted for review*." Ex. 2006, 2 (emphasis added). But we decline to speculate whether the District Court would grant such a motion directed only to one of the six patents. Among the reasons warranting a stay of the litigation, the District Court found "IPR has the potential to streamline issues for trial" and "the resources the parties will need to expend for experts could be significantly impacted by the outcome of any instituted IPR proceedings." *Id*.

Thus, the litigation is stayed pending the outcome of the six related proceedings, not merely the outcome of this institution decision, and the District Court stayed the litigation for the explicit purpose of gaining efficiency and avoiding duplication of efforts by letting this *inter partes* review proceed to its conclusion first. *See* Prelim. Reply. 3–4. While Patent Owner may seek to lift the stay as to any patent for which institution is denied, the grant of any such request is uncertain. Accordingly, this factor strongly weighs against discretionary denial of institution.

 Proximity of trial date to projected statutory deadline The projected statutory deadline for issuance of a final written decision in this proceeding is in January 2024. According to Patent Owner, the original scheduling order in the parallel district court litigation set May 2023 for a pre-trial hearing and the District Court indicated any delay to the timetable due to the ordered stay "will be short." Prelim. Resp. 44 (quoting

Ex. 2006, 2). Patent Owner also argues that trial is expected to occur in October or November 2023 "[u]sing the same time frames for expert discovery and summary judgment as per the Court's original schedule," as well as Patent Owner's expectation that the stay will be lifted if any one of Petitioner's six petitions is denied. *Id.* at 44. Petitioner argues that there is no trial date set, and Patent Owner agrees. Prelim. Reply 4–5; Prelim. Sur-Reply 3–4.

The Director recently clarified the application of the second *Fintiv* factor in the Interim Procedure Memorandum. Specifically, the Interim Procedure Memorandum states that when applying the second factor, the Board "will consider the speed with which the district court case may come to trial and be resolved," but that "the proximity to trial should not alone outweigh all . . . other factors." *Id.* at 8. While parties may submit median time-to-trial statistics for the district court for the Board's consideration, we will "also consider additional supporting factors such as the number of cases before the judge in the parallel litigation and the speed and availability of other case dispositions." *Id.* at 8–9.

Here, the District Court ordered a stay "pending resolution of the IPR proceedings that have been instituted on the patents at issue in this case." Ex. 2006, 2. The parties have not submitted any median time-to-trial statistics in this proceeding; even if they had, according to the Interim Procedure Memorandum we must also take into account the District Court's stay, and the lack of any set trial date, as "additional supporting factors." In light of the stay, any trial date would be after the issuance of a final written decision if this IPR is instituted, as the Court's order explicitly states. And as noted above, at present no trial date is set. Patent Owner's expectation that trial

would occur in October or November 2023 if any one of multiple petitions were denied is purely speculative; the District Court's order merely provides Patent Owner the opportunity to make such a request "as to any patents that are not instituted for review." Ex. 2006, 2. Accordingly, this factor weighs strongly against discretionary denial of institution.

# 3. Investment in the parallel proceeding

Patent Owner asserts the parties have "expended very significant resources in the Parallel Litigation and will continue to do so in the time leading up to the Board's decision on whether to institute." Prelim. Resp. 46. Patent Owner points to the time and resources spent adjudicating Patent Owner's preliminary injunction motion and "Petitioner's deliberate decision not to file [the Petition] expeditiously" as support for this factor favoring denial of institution. *Id.* at 45–47.

The record does not support Patent Owner's arguments. The District Court's order staying the litigation points out that any delay in filing the Petition "is due in no small part to [Patent Owner's] refusal to narrow the case at the beginning . . . to focus the issues for IPR." Ex. 2006, 2. In calculating whether a stay was appropriate, the District Court already determined that at the end of fact discovery and before expert discovery, the IPR proceeding could potentially streamline issues for trial and significantly impact the parties' need to expend resources for experts. *Id*. <sup>15</sup> In other words, in making its stay ruling, the Court found that the resources expended

<sup>&</sup>lt;sup>15</sup> We also note that the District Court ordered that "[n]o party shall use a party's agreement to this fact discovery continuance for ... seeking or opposing institution of any post grant proceeding." Ex. 2007, 2. Patent Owner's arguments concerning ongoing fact discovery (Prelim. Resp. 46) appear inconsistent with this Order.

on the litigation to date did not outweigh the potential benefit from waiting for this proceeding to potentially streamline the issues. We agree, and find that this factor weighs against denial of institution.

# 4. Overlap of issues

Patent Owner asserts there is a "vast overlap" between the Petition and the parallel litigation, with every patent claim asserted in the litigation challenged in the Petition over the same prior art references, which supports denying institution. Prelim. Resp. 47–48. Patent Owner also contends that denial of institution is also supported by the fact that Petitioner has not provided a stipulation to not pursue in parallel litigation the same grounds or any grounds that could have reasonably been raised before the Board. *Id.* at 48.

Concerns about the degree of overlap may be mitigated where a petitioner agrees not to pursue in the parallel proceeding the grounds advanced in the petition. *Sand Revolution II, LLC, v. Continental Intermodal Group-Trucking LLC*, IPR2019-01393, Paper 24 at 11–12, n.5 (PTAB June 16, 2020) (informative). A petitioner stipulating not to pursue "any ground raised or that could have been reasonably raised" weighs strongly in favor of not exercising discretionary denial. *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18–19 (PTAB Dec. 1, 2020) (precedential as to § II.A).

Here, Petitioner has not provided a stipulation. Nevertheless, because the district court litigation is stayed "pending resolution of the IPR proceedings that have been instituted on the patents at issue in this case," the projected statutory deadline for a final written decision will predate any trial date in the parallel district court litigation. As such, any overlap in issues

will serve to streamline the issues in the litigation, as opposed to creating duplication or redundancy. Accordingly, we determine that the fourth *Fintiv* factor weighs against denial of institution.

# 5. *Identity of parties*

Patent Owner asserts that denying institution is supported by the same parties being involved in both the Petition and the parallel litigation. Prelim. Resp. 49.

The Petitioner here is a defendant in the parallel district court litigation. The Board has found that "this factor favors denial if trial precedes the Board's Final Written Decision and favors institution if the opposite is true." *See, e.g., Huawei Tech. Co. v. WSOU Inv., LLC*, IPR2021-00225, Paper 11 at 14 (PTAB June 14, 2021) (internal quotation marks omitted). Thus, because the final written decision in this case is likely to precede trial in the parallel district court litigation in view of the District Court's order staying the parallel litigation, this factor weighs against exercising our discretion to deny institution under § 314(a).

#### 6. Other circumstances, including the merits

Patent Owner contends that "[o]nly compelling, meritorious challenges may be allowed to proceed at the PTAB where district court litigation is proceeding in parallel." Prelim. Resp. 49. This is an inaccurate statement of USPTO policy, as set forth in the Director's Interim Procedure Memorandum. The Memorandum states that "where the PTAB determines that the information presented at the institution stage presents a compelling unpatentability challenge, that determination *alone* demonstrates that the PTAB should not discretionarily deny institution under *Fintiv*." Interim Procedure at 4–5 (emphasis added). Thus, the Interim Procedure does not

change the statutory standard for institution under 35 U.S.C. § 314(a), but, rather, negates the need to consider any of the other *Fintiv* factors in the face of a compelling challenge.

We discuss the merits of this case below and determine that Petitioner's evidence and arguments are sufficient to meet our standard for instituting *inter partes* review. Thus, we do not agree with Patent Owner's assertion that Petitioner's challenges lack merit. Prelim. Resp. 49–50. Moreover, the record does not support Patent Owner's assertion that the Petition evidences "gamesmanship." *Compare id.* at 49 n.6, *with* Ex. 2006, 2 (District Court order answering Patent Owner's assertion that Petitioner initiated this proceeding "the last possible moment" by finding that "[a]ny delay in . . . filing for IPR is due in no small part to [Patent Owner's] refusal to narrow the case at the beginning."). Accordingly, we determine that *Fintiv* factor six is neutral.

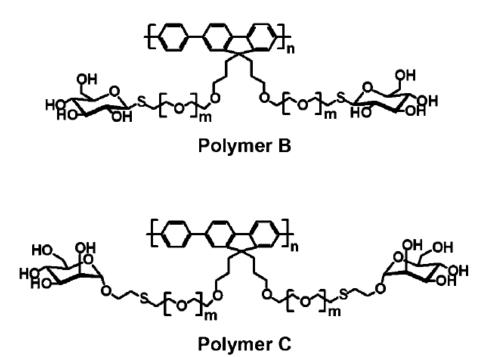
#### 7. Balancing the Fintiv Factors

We have considered the circumstances and facts before us in view of the *Fintiv* factors, none of which favor discretionary denial. Absent a compelling reason to the contrary, we take "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review" when evaluating these factors. *Fintiv*, Paper 11 at 6; Interim Procedure. Having evaluated all of the factors on this record, we determine that the circumstances presented here do not support exercising our discretion under § 314(a) to deny institution of this *inter partes* review.

# E. Overview of the Asserted Art1. Xue (Exhibit 1010)

Xue is a paper titled "Highly Water-Soluble, Fluorescent, Conjugated Fluorene-Based Glycopolymers with Poly(ethylene glycol)-Tethered Spacers for Sensitive Detection of *Escherichia coli*." Ex. 1010, 1. Xue explains that a few fluorescent conjugated glycopolymers have been prepared for biosensing applications for lectins and bacteria but some neutral conjugated glycopolymers display low water solubility. *Id.* Xue describes the introduction of anionic groups, such as carboxylic acid, to conjugated polymers to enhance water solubility but also explains that this could cause potential interfering responses of the conjugated polymers. *Id.* In view of this, Xue states that "it is important to explore new approaches to prepare a variety of highly water-soluble, neutral, fluorescent, conjugated glycopolymers for bacterial and viral biosensing applications." *Id.* 

Xue describes the synthesis of "bromide-bearing, fluorene-based, conjugated polymers with oligo(ethylene glycol)- and poly(ethylene glycol)tethered spacers." *Id.* Xue states that two of the glycopolymers, polymers B and C, "are highly water-soluble due to their long, flexible, hydrophilic spacers." *Id.* Xue's polymers B and C are reproduced below.



*Id.* at 2290. Xue describes incubating polymer C with strains of *E. coli* to investigate binding to polymer C. *Id.* at 2292. According to Xue, this resulted "in the formation of fluorescently stained bacterial clusters from which the polymer was not removed by rinsing and centrifugation" and that the bacterial clusters could be visualized under a fluorescent microscope. *Id.* 

#### 2. Gaylord (Exhibit 1009)

Gaylord describes "a multichromophore and/or multichromophore complex for identifying a target biomolecule." Ex. 1009, code (57). Gaylord states that "[a] sensor biomolecule, for example, an antibody can be covalently linked to the multichromophore" and that "[a]dditionally, a signaling chromophore can be covalently linked to the multichromophore." *Id.* Gaylord explains that "the signaling chromophore is capable of receiving energy from the multichromophore upon excitation of the multichromophore." *Id.* 

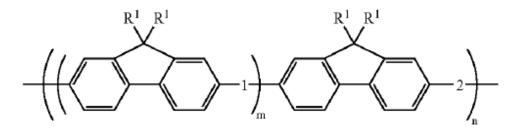
Gaylord's Figure 18 is reproduced below.

$$\left\{\left[(CP_{1}]_{a} [CP_{2}]_{b}\right]_{m} [CP_{1}]_{a} [CP_{3}]_{c}\right]_{n} [CP_{1}]_{a} [CP_{4}]_{d}\right]_{p}$$

# **FIG. 18**

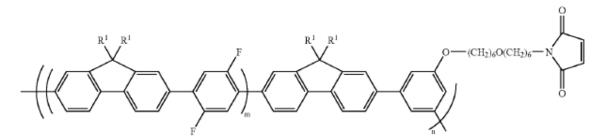
Figure 18 depicts the general structure for a conjugated polymer as a linear multichromophore. *Id.* ¶¶ 69, 184. Gaylord explains that the conjugated polymers include "low bandgap repeat units." *Id.* ¶ 181. Gaylord describes CP1, CP2, CP3, and CP4 as "optionally substituted conjugated polymer segments or oligomeric structures, and may be the same or different from one another." *Id.* ¶ 185. Gaylord states that "CP1, CP2, CP3, and CP4 may be aromatic repeat units" and may be fluorene. *Id.* Gaylord further describes CP1, CP2, CP3, and CP4 as being optionally substituted at one or more positions with certain groups "with the proviso that the polymer as a whole must be substituted with a plurality of cationic, anionic, or charge neutral water-soluble groups." *Id.* ¶ 188.

Gaylord describes an embodiment of a multichromophore having the following structure:



*Id.* ¶ 13. Gaylord states that  $R^1$  can be "a solubilizing group" that can be an ethylene glycol oligomer, ethylene glycol polymer, or other substances. *Id.* 

Gaylord describes another multichromophore embodiment that has the following structure:



*Id.* ¶ 18. As with the previous embodiment, Gaylord states that  $R^1$  can be "a solubilizing group" that can be an ethylene glycol oligomer, ethylene glycol polymer, or other substances. *Id.* ¶ 19.

# *3. Gauthier (Ex. 1015)*

Gauthier is a paper titled "Peptide/protein–polymer conjugates: synthetic strategies and design concepts." Ex. 1015, 2591. Gauthier describes peptide/protein-polymer conjugates "as hybrid constructs combining (i) a defined number of peptide/protein segments with uniform chain lengths and defined monomer sequences (primary structure) with (ii) a defined number of synthetic polymer chains." *Id*.

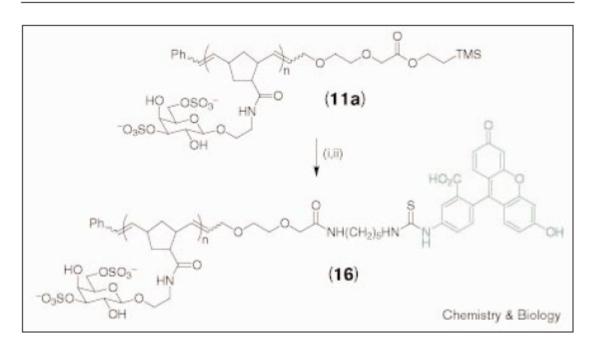
Gauthier explains that "[p]eptide/protein conjugation can be accomplished using either side-chain or end-group reactive polymers." *Id.* at 2600–2601. Gauthier states that "[p]olymers with side-chain functional groups are of interest for introducing many copies of pendant peptides," for introducing peptides bearing functional groups incompatible with polymerization conditions, and for preparing polymers with high molecular weight. *Id.* at 2601.

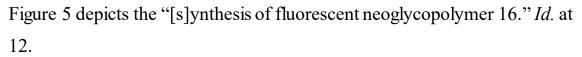
# 4. Gordon (Ex. 1016)

Gordon is a paper titled "Synthesis of end-labeled multivalent ligands for exploring cell-surface-receptor-ligand interactions." Ex. 1016, 9. Gordon relates to "[r]ing-opening metathesis polymerization (ROMP)," which Gordon describes as "a powerful synthetic method for generating unique materials. *Id.* Gordon states that "[t]he functional group tolerance of ruthenium ROMP initiators allows the synthesis of a wide range of biologically active polymers." *Id.* 

Gordon's Figure 5 is reproduced below.

# Figure 5





# 5. Lou (Ex. 1017)

Lou is a paper titled "Polymer-Based Elemental Tags for Sensitive Bioassays." Ex. 1017, 6111. According to Lou, "[t]o identify a rare (e.g.,

diseased or foreign) cell in a complex mixture, or to understand the proteomic complexity of cells, one needs to be able to measure simultaneously and quantitatively a large number of proteins or other biomarkers that may be present in a complex sample." *Id.* To accomplish this task, Lou states that they have developed "a high-sensitivity assay based upon elemental tags that will enable the simultaneous measurement of many proteins in a single sample." *Id.* 

Lou describes an assay that "is based upon the concept of a watersoluble polymer bearing multiple metal-chelating ligands." *Id.* Lou states that "[t]he chelating ligand is chosen to form high-affinity complexes with lanthanide ( $Ln^{3+}$ ) ions." *Id.* Lou further states that "[t]he polymer contains a terminal maleimide group for coupling to cysteine -SH groups on the Fc portion of an antibody." *Id.* 

#### 6. Haugland (Ex. 1018)

Haugland is a chapter titled "Antibody Conjugates for Cell Biology" from the book *Current Protocols for Cell Biology*. Ex. 1018, 16.5.1. Haugland states that "[a]ntibody conjugates are extremely useful reagents for probing many biologically and chemically important molecules in vitro or in vivo." *Id*. Haugland describes "some basic protocols" for conjugating antibodies with fluorescent dyes, with biotin, and with enzymes. *Id*.

Haugland states that "[t]he appropriate number of labels per antibody molecule depends on the probe" and that "4 to 8 moles of probe per mole of an IgG antibody are possible in the case of relatively small or hydrophilic molecules (such as fluorescein, biotin, or sulfonated dyes) or 2 to 4 moles, in the case of hydrophobic probes, such as rhodamines." *Id.* at 16.5.19.

# 7. Zalipsky (Ex. 1012)

Zalipsky is a paper titled "Functionalized Poly(ethylene glycol) for Preparation of Biologically Relevant Conjugates." Ex. 1012, 150. Zalipsky states that poly(ethylene glycol) "possesses an array of useful properties," such as "a wide range of solubilities in both organic and aqueous media." *Id.* According to Zalipsky, poly(ethylene glycol) has been "used extensively as a covalent modifier of a variety of substrates." *Id.* Zalipsky states that "[s]ubstrates modified with PEG include low molecular weight compounds, almost every class of biological macromolecules as well as particulates, and surfaces of artificial materials." *Id.* Zalipsky describes the object of this work as by being prompted "by a desire to alter one or more properties of a substrate of interest to make it suitable (or more suitable) for a particular biological application," such as improving solubility properties. *Id.* 

Zalipsky describes monomethyl ether of PEG (mPEG) as being "often used for preparation of various conjugates, particularly when it is desirable to link multiple chains of the polymer to the intended substrate. *Id.* Zalipsky explains that "[t]he presence of only one derivatizable end group on mPEG minimizes the possibilities for crosslinking and improves homogeneity of such preparations." *Id.* 

# 8. Hermanson (Ex. 1013)

Hermanson is an excerpt from the book *Bioconjugate Techniques*. Ex. 1013. Hermanson states that interest in the "polymer modification of biological molecules has grown incessantly" and "PEG coupled to other molecules can be used for altering solubility characteristics in aqueous or organic solvents." *Id.* at 937. Hermanson explains that "PEG can be conjugated to other molecules through its two hydroxyl groups at the ends of

each linear chain" and that "[m]onomethoxypolyethylene glycol (mPEG) contains only one hydroxyl group per linear chain, thus limiting activation and coupling to one site and preventing the crosslinking and polymerization of modified molecules." *Id.* at 938.

# 9. Sumranjit (Ex. 1014)

Sumranjit is a doctoral dissertation titled "Conjugated Organic Molecules as Models for Potential Sensors." Ex. 1014, 3<sup>16</sup>. Sumranjit describes "water-soluble phenylenevinylene (PV) and sensor-capable PV systems," including "oligo PVs and poly(phenylenevinylenes) (PPVs)." *Id.* at 10. Sumranjit further describes that a "type of water-soluble, segmented copolymer based on PPV was made that incorporated a nonionic but hydrophilic poly(ethylene glycol) (PEG)," which "was readily soluble in water, and exhibited strong blue fluorescence." *Id.* Sumranjit explains that PEG's "degree of water solubility can be adjusted by its degree of polymerization" and that PEG is biocompatible. *Id.* at 84.

- *F.* Unpatentability Grounds
  - *1. Anticipation by Xue*

Petitioner, citing the Declaration of Dr. Nuckolls for support, asserts that claims 1, 5, 7, 12, 17, and 19 are anticipated by Xue and therefore unpatentable under 35 U.S.C. § 102(b). Pet. 30–37 (citing Ex. 1007). Patent Owner disputes that Xue teaches all limitations of these claims, focusing specifically on the solubility and functional group limitations. Prelim. Resp. 19–27. We have reviewed the parties' arguments and have found Petitioner's

<sup>&</sup>lt;sup>16</sup> For clarity, we refer to the Exhibit 1014's page number rather than the document's original page number.

evidence to be sufficient to meet the threshold of § 314(a). Below, we address independent claim 1 and address the dependent claims collectively.

#### a. *Claim 1*

Petitioner addresses each limitation of claim 1, setting forth how Xue allegedly teaches the limitations. Pet. 30–36. For example, Petitioner notes that the preamble of claim 1 recites "[a] water-soluble conjugated polymer having the structure . . . ," and contends that Xue discloses such a conjugated polymer because it describes water-soluble conjugated Polymers B and C comprising fluorene repeat units substituted with PEG chains. Pet. 30 (citing Ex. 1010, 2289–90; Ex. 1007 ¶¶124–32). Similarly, with respect to claim 1's recitation that "MU is a polymer modifying unit or band gap modifying unit that is evenly or randomly distributed along the polymer main chain," Petitioner argues that Xue discloses phenyl repeat units, labeled in orange, that satisfy this recitation. Pet. 31–32 (citing Ex. 1007 ¶126; Ex. 1010, 2290). Except for the two limitations discussed below, Patent Owner does not dispute these assertions. Prelim. Resp. 19. We have reviewed Petitioner's evidence as to these undisputed limitations and find it sufficient to support institution of trial.

Claim 1 also requires that the Ar group is "an aryl or heteroaryl unit substituted with a non-ionic side group capable of imparting solubility in water." Petitioner directs our attention to Xue's disclosure of Polymers B and C, each of which contain a fluorene repeat unit substituted with polyethylene glycol (PEG). Pet. 31 (citing Ex. 1010, 2289–90). Dr. Nuckolls testifies that a person of ordinary skill in the art would have understood that inclusion of side chains based on PEG was a known technique for imparting solubility in water. Ex. 1007 ¶¶ 37–41, 118, 125.

Patent Owner and its declarant, Timothy M. Swager, Ph.D., do not directly counter Petitioner's analysis or the assertion that a person of ordinary skill in the art would have known that adding PEG side chains would have increased solubility. Prelim. Resp. 20–22; Ex. 2001 ¶¶ 100–107. Rather, their argument is grounded in the assertion that claim 1 should be construed to require a solubility in excess of 10mg/mL, which we discussed above. *Id.* According to Patent Owner, because Petitioner did not show that Xue's polymers have a solubility above this threshold—and because Xue indicates its polymers' solubility is below 0.075mg/mL—the Petition does not provide evidence of anticipation. Prelim. Resp. 21.

Patent Owner's arguments are predicated on the Board adopting its proposed claim construction on solubility above, which we declined to do on the present record. For this reason, we find them unpersuasive. In addition, we note that Xue expressly discloses that its glycopolymers utilizing PEGtethered spacers (Polymers B and C) "are highly water-soluble due to their long, flexible, hydrophilic spacers." Ex. 1010, Abstract, 2289–90. Petitioner sufficiently sets forth why a person of ordinary skill in the art would have considered the PEG side chains of Xue to impart solubility in water, which is all we have construed the claims to require.

Claim 1 also recites that:

the polymer comprises at least 1 functional group selected from amine, carbamate, carboxylic acid, carboxylate, maleimide, activated ester, N-hydroxysuccinimidyl, hydrazines, hydrazide, hydrazone, azide, alkyne, aldehyde, and thiol within  $G_1$ ,  $G_2$ ,  $L_1$ or  $L_2$ , or a conjugated organic dye or biomolecule.

Petitioner sets forth two alternative arguments based on differing claim constructions. Under its proposed claim construction, where the polymer simply has to comprise a conjugated organic dye or molecule somewhere in the structure, Petitioner notes that each of Polymers B and C comprises a sugar, which is a conjugated biomolecule, in the polymer. Pet. 35 (citing Ex.  $1007 \P$  131).

Petitioner's analysis under Patent Owner's construction—which requires the conjugated biomolecule to be located within one of the  $G_1, G_2$ , L<sub>1</sub> or L<sub>2</sub> groups—is more complex. Petitioner argues that Xue discloses Polymers B and C which are "alternating copolymers where fluorene and phenyl alternate." Pet. 33 (citing Ex. 1007 ¶¶ 116–21, 128). Petitioner reasons that, because of this alternating configuration, "each end of any given molecule of Polymers B or C is either a fluorene unit or phenyl unit." *Id.* Dr. Nuckolls illustrates, as an example, a molecule having fluorene at one end and phenyl at the other. Id. at 33–35 (citing Ex. 1007 ¶¶ 120, 128– 129; Ex. 1054<sup>17</sup>). Petitioner further argues that a person having ordinary skill in the art would have understood from Xue that its polymer would either have fluorene units at both ends, phenyl at both ends, or have fluorene at one end and phenyl at the other. Id. at 33 (citing Ex. 1007 ¶ 120). According to Petitioner, the polymer ends with fluorene "comprise an 'aryl' (fluorene) 'substituted with one or more pendant chains' (the PEG side chains) 'terminated with a conjugated biomolecule" (a  $\beta$ -glucose or  $\alpha$ -mannose sugar), and the polymer ends with phenyl also qualify as a substituted aryl, because phenyl is itself an aryl. Id. at 34 (citing Ex. 1007 ¶¶ 128–129). These fluorene or phenyl end groups are identified by Petitioner and Dr. Nuckolls as the  $G_1$  or  $G_2$  end groups of claim 1. *Id.*; Ex. 1007 ¶ 129.

According to Petitioner, these end groups, because they contain

 $<sup>^{17}</sup>$  Exhibit 1054 is a representation of Xue's Polymers B and C generated by Dr. Nuckolls. Ex. 1007  $\P$  118.

sugars, also satisfy the "polymer comprises at least 1 functional group . . . within  $G_1, G_2, L_1$  or  $L_2$ , or a conjugated organic dye or biomolecule," under Patent Owner's construction of that term as requiring the conjugated biomolecule to be located within  $G_1, G_2, L_1$  or  $L_2$ . Pet. 35–36. Based on the current record, we find Petitioner's assertion to be persuasive. The position is supported, for example, by the Xue reference and the testimony of Dr. Nuckolls. Ex. 1010, 2290; Ex. 1007 ¶¶ 116–121, 252–254; Ex. 1054. Patent Owner's arguments do not convince us otherwise, for the reasons discussed below.

Patent Owner argues that Petitioner has not shown Xue to disclose polymers having a functional group, conjugated organic dye, or conjugated biomolecule within  $G_1$ ,  $G_2$ ,  $L_1$  or  $L_2$ , because none of the groups of Xue qualify as  $G_1$  or  $G_2$ . Prelim. Resp. 22–27. In particular, Patent Owner argues that Petitioner cannot rely on Xue's Polymers B and C as end groups because these are repeat units rather than end groups. *Id.* at 24–25. Claim 1, however, does not require that  $G_1$  or  $G_2$  be structurally distinct from Ar, Mu,  $L_1$ , or  $L_2$ . Just to the contrary, Ar "is a polycyclic repeat unit substituted with an ethylene glycol oligomer side group" and  $G_1$  and  $G_2$  can likewise be "optionally substituted fluorene and aryl or heteroaryl substituted with one or more pendant chains terminated with a conjugated biomolecule." Thus, on this record, there does not appear to be anything in the '989 patent that prevents Petitioner from relying on Xue's repeat units as satisfying  $G_1$  or  $G_2$ when the repeat unit is at the end of Xue's polymer chain.

Patent Owner further argues that a person having ordinary skill in the art would understand that Xue's end group would be "residual iodides, boronic acids, or their degradation products (including hydrogen)" and that

none of these end groups include the functional groups, conjugated organic dyes, or conjugated biomolecules that claim 1 requires. Prelim. Resp. 24; Prelim. Sur-Reply 4. Patent Owner emphasizes that Petitioner's witness, Dr. Nuckolls, testified in litigation as follows:

The discussion of how the polymers in Xue are synthesized makes it clear that each end of Polymers B and C can consist of only three possible groups: a boronic acid, an iodine, or possibly hydrogen. . . . That is, G1 is one of hydrogen, halogen, or boronic acid, and G2 also is one of hydrogen, halogen, or boronic acid.

Prelim. Resp. 26 (quoting Ex. 2009 ¶ 82) (emphasis removed). Patent Owner alleges that this prior testimony contradicts the current position of Dr. Nuckolls where, in a "disingenuous new argument," Dr. Nuckolls maps Xue's Polymer B and C (in other words, Xue's fluorene or phenyl unit) to  $G_1$  and  $G_2$ . *Id.* at 26–27.

The record does not suggest that Petitioner's present position is "disingenuous," as Patent Owner argues. Patent Owner cites Dr. Nuckolls' litigation quote from a declaration opposing a motion for preliminary injunction. Ex. 2009, 1. In that declaration, Dr. Nuckolls was applying the first claim construction discussed above, wherein a conjugated biomolecule anywhere in the polymer would satisfy claim 1. *Id.* ¶ 89. Because, under this construction,  $G_1$  or  $G_2$  need not contain the conjugated biomolecule, Dr. Nuckolls explained that Xue teaches repeating Polymer B and Polymer C blocks where the final block eventually terminates with hydrogen, an iodine, or boronic acid (rather than being connected to yet another Polymer B and Polymer C). *Id.* ¶¶ 82–87. Thus, Dr. Nuckolls testified that  $G_1$  and  $G_2$  were

met by taking a "zoomed in view" of the Xue polymer that maps merely the final termination of Polymer B or Polymer C to  $G_1$  and  $G_2$ . *Id*.

In this proceeding, Petitioner has again asserted this construction of claim 1, but also applied the construction asserted by Patent Owner and adopted by the District Court, wherein either L<sub>1</sub>, L<sub>2</sub>, G<sub>1</sub>, or G<sub>2</sub> must comprise a functional group, conjugated organic dye, or conjugated biomolecule. In our view, Dr. Nuckolls does not change his position regarding the physical makeup of Xue's polymer to reach this alternative construction. Rather, it appears his testimony in this proceeding looks at the same Xue polymer from a different perspective. Instead of zooming in on only what caps off the final Polymer B and C and mapping this final portion of Polymer B and C to G<sub>1</sub> and G<sub>2</sub>, Dr. Nuckolls zooms out to consider entire substituted fluorene units that will necessarily be at the end of Xue's polymer chain. Ex. 1007 ¶¶ 116–121, 252–253; Ex. 1054. This is consistent with Dr. Nuckolls' preliminary injunction declaration, where he described Xue's polymers as "hav[ing] a phenyl at one end and a fluorene at the other, or a phenyl at both ends or a fluorene at both ends." Ex. 2009, ¶ 94. As discussed above, these substituted fluorene units meet the requirement for G<sub>1</sub> and G<sub>2</sub>. In other words, on the present record Dr. Nuckolls provides testimony that appears consistent regarding the physical makeup of Xue's polymer chain and how the chain ends; the testimony merely differs in what part of the chain is considered to map to different recitations of different patent claims, which seems appropriate given the alternative possible claim constructions. Under either claim construction, we find that Petitioner has set forth sufficient evidence that the polymers of Xue would meet the claim limitation.

Based on the evidence in the present record, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that Xue discloses all elements of claim 1. Thus, we are persuaded that Petitioner has sufficiently established a reasonable likelihood of establishing Xue anticipates claim 1.

### b. Dependent Claims 5, 7, 12, 17, and 19

Petitioner accounts for the limitations recited in claims 5, 7, 12, 17, and 19. Pet. 36–37. Petitioner explains how Xue discloses the recitations of these claims. *Id*. Patent Owner does not, at this stage of the proceeding, address the application of Xue's disclosure to the dependent claims, other than the limitations of claim 1 addressed above. Prelim. Resp. 27.

Based on evidence in the present record, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that Xue discloses all limitations recited in claims 5, 7, 12, 17, and 19. Having reviewed Petitioner's arguments and supporting evidence in the present record, we are persuaded that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 5, 7, 12, 17, and 19 are unpatentable as anticipated by Xue.

# 2. Obviousness over Xue and Gaylord

Petitioner asserts that claims 2–4 and 6 are unpatentable, as their subject matter would have been obvious over the combined disclosures of Xue and Gaylord. Pet. 38–40, Specifically, Petitioner contends that a person of ordinary skill in the art would have modified polymers B and C of Xue to incorporate one of the MUs recited in Gaylord, specifically Gaylord's "low bandgap repeat units" used to modify the band game of a polymer. Pet. 38 (citing Ex. 1007 ¶¶ 138–140; Ex. 1009 ¶¶ 22, 182, 194). Gaylord's low

bandgap repeat units include benzothiadiazole, recited in claims 2–4, and a difluorophenyl structure recited in claim 6. *Id.* at 39 (citing Ex. 1007 ¶ 139). Petitioner contends that a person of ordinary skill in the art would have had reason to make this modification because using the specified low bandgap repeat units enables dyes that use a single excitation wavelength and allow the selection of a desired absorption and emission spectrum of the polymer. *Id.* Dr. Nuckolls testifies that a person of ordinary skill in the art would have had a reasonable expectation of success in making this modification, because it used known techniques. Ex. 1007 ¶ 140 (citing Ex. 1019, 1743; Ex. 1009 ¶¶ 32, 182, 194).

Patent Owner does not contest Petitioner's proposed combination of Xue with Gaylord, or contend that a person of ordinary skill in the art would not have had a reasonable expectation of success in modifying Xue's polymers to include Gaylord's bandgap repeat units to arrive at the subject matter of the challenged claims. Prelim. Resp. 27–28. Patent Owner focuses on its arguments regarding anticipation by Xue, and its contention that Xue does not disclose all elements of claim 1, and then argues that the combination with Gaylord does not remedy this deficiency. *Id.* We have found Patent Owner's arguments regarding Xue unpersuasive on this record; thus, they do not convince us here that the combination of Xue with Gaylord would not have rendered claims 2–4 and 6 obvious.

Patent Owner also asserts that evidence of objective indicia supports the nonobviousness of the claims. Prelim. Resp. 35–39. Specifically, Patent Owner states that while there is "extensive evidence" of objective indicia, it is limiting its discussion at this stage of the proceeding to a showing of unexpected beneficial results, namely that it was "entirely unexpected that

conjugated polymers with neutral solubilizing side groups would have water solubilities greater than 10 mg/mL." *Id.* at 35–37. Dr. Swager testifies that, as of the priority date of the '989 patent, "it would have been unexpected that neutral side chains would provide greater solubility than ionic side chains," and identifies Polymer P20 of the '989 patent as an embodiment commensurate with the scope of the claims that showed unexpectedly good solubility. Ex. 2001 ¶ 91. Dr. Swager goes on to concede, however, that "P20 does not contain a functional group, dye or biomolecule as recited in the challenged claims." *Id.* 

We are not convinced on this record that Patent Owner's evidence of objective indicia of nonobviousness is sufficiently strong to overcome Petitioner's evidence of obviousness. While the '989 patent does appear to show that some polymers with nonionic side chains showed increased solubility, it is unclear why this would have been unexpected given Petitioner's evidence that side chains such as PEG were known to increase solubility. *See, e.g.*, Ex. 1012 (Zalipsky), 150 ("During the last two decades [PEG] was used extensively as a covalent modifier . . . [t]his often included improvement of solubility properties."); Ex. 1014 (Sumranjit), Abstract ("PEGylated PPV was readily soluble in water, and exhibited strong blue fluorescence."); *see also Bristol-Myers Squibb Co. v. Teva Pharma. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014) (noting that, "[w]hile a 'marked superiority' in an expected property may be enough in some circumstances to render a compound patentable, a 'mere difference in degree' is insufficient").

We note that Patent Owner's arguments seem to presume that the claims require solubility in excess of 10 mg/mL, which allegedly would

have been unexpected. Prelim. Resp. 38. But as discussed above, at this stage of the proceeding we do not construe the solubility limitation of claim 1 to require this numerical limit, nor to require any degree of increased solubility. We also note Dr. Swager's testimony that P20, which he cites in reaching his conclusion of unexpected results, does not contain certain groups required by claim 1, not to mention the additional limitations of claims 2–4 and 6. For these reasons, Patent Owner's evidence does not persuade us that Petitioner does not have a reasonable likelihood of success in showing the obviousness of claims 2–4 and 6.<sup>18</sup>

Based on evidence in the present record, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that the combination of Xue and Gaylord teaches or suggests all limitations recited in claims 2–4 and 6. Having reviewed Petitioner's arguments and supporting evidence in the present record, we are persuaded that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 2–4 and 6 are unpatentable as having been obvious over Xue and Gaylord.

## 3. Anticipation by Gaylord

Petitioner asserts that claims 1–10, 12–14, and 19 are unpatentable as anticipated by Gaylord. Pet. 40–52. Patent Owner disputes that Gaylord teaches all limitations of these claims, focusing specifically on the solubility limitation. Prelim. Resp. 27–28. We have reviewed Petitioner's arguments

<sup>&</sup>lt;sup>18</sup> Patent Owner's arguments for objective indicia of nonobviousness are made generally, without any specific application to a particular obviousness ground. Prelim. Resp. 35–39. Although we have discussed these arguments here in connection with the Xue and Gaylord obviousness ground, our analysis of the objective indicia should be understood to apply to all obviousness grounds asserted by Petitioner.

and evidence and have found them to be sufficient to meet the threshold of § 314(a). Below, we address independent claim 1 and address the dependent claims collectively.

#### a. *Claim 1*

Petitioner addresses each limitation of claim 1, setting forth how Gaylord allegedly teaches the limitations. Pet. 40–48. For example, Petitioner notes that the preamble of claim 1 recites "[a] water-soluble conjugated polymer having the structure . . . " and contends that Gaylord discloses such a conjugated polymer because it describes water-soluble conjugated Polymers 1 and 2 comprising fluorene-based polymers with substituent groups that may include PEG. Pet. 40–41 (citing Ex. 1009 ¶¶ 13– 15, 18–19; Ex. 1007 ¶¶ 102–115, 142–158). Similarly, with respect to claim 1's recitation that "MU is a polymer modifying unit or band gap modifying unit that is evenly or randomly distributed along the polymer main chain," Petitioner argues that Gaylord discloses that CP<sub>1</sub>, CP<sub>2</sub>, CP<sub>3</sub>, and CP<sub>4</sub> may be selected from "bandgap-lowering  $[\pi]$ -conjugated repeat units" that contribute to absorption in a particular wavelength range. Id. at 42–43 (citing Ex. 1009 ¶¶181–82; Ex. 1007 ¶147). Except for the solubility limitation discussed below, Patent Owner does not dispute these assertions. Prelim. Resp. 28–29. We have reviewed Petitioner's evidence as to these undisputed limitations and find it sufficient to support institution of trial.

With respect to claim 1's requirement that the Ar group is "an aryl or heteroaryl unit substituted with a non-ionic side group capable of imparting solubility in water," Petitioner observes that Gaylord's Polymers 1 and 2 include fluorene repeat units, substituted with solubilizing groups R<sup>1</sup> that may be ethylene glycol oligomers or ethylene glycol polymers. Pet. 41–42.

Dr. Nuckolls testifies that a person of ordinary skill in the art would have understood that these substituent groups were capable of imparting solubility in water. Ex. 1007 ¶¶ 144–146. As with the Xue ground above, Patent Owner and Dr. Swager do not directly contradict these assertions. Prelim Resp. 28–29; Ex. 2001 ¶¶ 83–84, 163–167. Instead, Patent Owner argues that under its proffered construction requiring solubility in excess of 10 mg/mL, Petitioner has failed to show that Gaylord teaches that its polymers were sufficiently soluble to meet claim 1. *Id*.

As with the Xue anticipation ground above, Patent Owner's arguments do not convince us that Petitioner has not established a reasonable likelihood of success on this ground, because we have not adopted a construction of claim 1 that requires a numerical threshold for solubility. Petitioner sufficiently sets forth why a person of ordinary skill in the art would have considered the substituent groups of Gaylord to impart solubility in water, which is all we have construed the claims to require. For this reason, based on the evidence in the present record, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that Gaylord discloses all elements of claim 1. Thus, we are persuaded that Petitioner has sufficiently established a reasonable likelihood of establishing Gaylord anticipates claim 1.

## b. Dependent Claims 2–10, 12–14, and 19

Petitioner accounts for the limitations recited in claims 2–10, 12–14, and 19. Pet. 48–52. Petitioner explains how Gaylord discloses the recitations of these claims. *Id.* Patent Owner does not, at this stage of the proceeding, address the application of Gaylord's disclosure to the dependent claims,

other than the solubility limitation of claim 1 addressed above. Prelim. Resp. 28–29.

Based on evidence in the present record, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that Gaylord discloses all limitations recited in claims 2–10, 12–14, and 19. Having reviewed Petitioner's arguments and supporting evidence in the present record, we are persuaded that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 2–10, 12–14, and 19 are unpatentable as anticipated by Gaylord.

#### 4. Obviousness Over Gaylord and Bazan

As an alternative to the preceding anticipation ground, Petitioner also contends that claims 1-10, 12-14, and 19 would have been unpatentable as having been obvious over the combined disclosures of Gaylord and Bazan. Pet. 52–56. Petitioner argues that a person of ordinary skill "could have arrived at the claimed invention merely by following the teachings and guidance of Gaylord (in conjunction with Bazan, as Gaylord directs) and arrive at the claimed combination of Ar, MU, L<sub>1</sub>, L<sub>2</sub>, G<sub>1</sub>, and G<sub>2</sub>, as well as the use of non-ionic side groups such as PEG." *Id.* at 52. Patent Owner opposes this ground of unpatentability based on the same argument addressed above, that the references do not disclose solubility in excess of 10 mg/mL. Prelim. Resp. 29–31.

Because we determined above that Petitioner has established a reasonable likelihood of proving that Gaylord anticipates claims 1–10, 12– 14, and 19, we need not separately address whether the combination of Gaylord and Bazan teaches or suggests all limitations of the same claims. On this record, Petitioner has shown sufficiently for purposes of institution that

claims 1–10, 12–14, and 19 would have been obvious over the combined disclosures of Gaylord and Bazan.

# 5. Obviousness over Gaylord, Zalipsky, Hermanson, Xue, and Sumranjit

Claim 8 depends from claim 7 and further requires that the non-ionic side group substituent on the Ar group of claim 1 comprises mPEG5, mPEG8, mPEG11, or mPEG24. Ex. 1001, 225:15–17. Petitioner asserts that the subject matter of claim 8 would have been obvious over the combination of Gaylord, Zalipsky, Hermanson, Xue, and Sumranjit. Pet. 56–57. Specifically, Petitioner contends that "Zalipsky and Hermanson independently teach the advantages of using monomethoxy PEGs," while "Xue and Sumranjit independently teach that the water-solubility of conjugated polymers can be tuned by varying the number of PEG repeats." *Id.* Petitioner contends that a person of ordinary skill in the art would have modified the polymers of Gaylord in light of these teachings, and would have arrived at the water-soluble conjugated polymer of claim 8. *Id.* 

Patent Owner does not, at this stage of the proceeding, contest Petitioner's description of the teachings of the prior art references or dispute that a person of ordinary skill in the art would have modified Gaylord's polymers in the manner proposed. Prelim. Resp. 32–34. Instead, Patent Owner relies on its arguments, addressed above, that Gaylord does not disclose a polymer having solubility in excess of 10 mg/mL, and argues that the secondary references do not remedy this deficiency. *Id.* Because this argument relies on a claim construction we have not adopted, we do not find it persuasive on this record.

Based on evidence in the present record, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that the combination of Gaylord with Zalipsky, Hermanson, Xue, and Sumranjit teaches or suggests all limitations recited in claim 8, and has set forth a reasoned explanation why a person of ordinary skill would have made the combination. Having reviewed Petitioner's arguments and supporting evidence in the present record, we are persuaded that Petitioner has established a reasonable likelihood of prevailing on its assertion that claim 8 is unpatentable as having been obvious over Gaylord, Zalipsky, Hermanson, Xue, and Sumranjit.

# 6. *Obviousness over Gaylord, Gauthier, Gordon, Lou, and Haugland*

Claim 17 depends from claim 1 and requires that at least one of  $G_1$  or  $G_2$  comprise a functional conjugation site, whereas claim 18 depends from claim 17 and specifies that at least one of  $G_1$  or  $G_2$  has a particular structure having an  $R^{11}$  substituent selected from a listed genus. Ex. 1001, 226:31–64. Petitioner asserts that claims 17 and 18 are unpatentable under 35 U.S.C. § 103(a) as having been obvious over the combined disclosures of Gaylord, Gauthier, Gordon, Lou, and Haugland. Pet. 57–61. According to Petitioner, a person of ordinary skill in the art would have known from Gauthier that end-group functionalization is one strategy for covalently attaching molecules to polymers, while Gordon and Lou teach that adding functional groups at polymer termini permits attachment of detection elements. *Id.* (citing Ex. 1015, 2600–01; Ex. 1016, 9; Ex. 1017, 6111; EX1007 ¶181). Petitioner contends that a person of ordinary skill would have had reason to modify Gaylord's polymers according to these teachings (Pet. 59), and Dr. Nuckolls

testifies that the artisan would have placed the attachment points at the end of the polymers to achieve a ratio of at least one fluorophore to each conjugated antibody, as taught by Haugland. Ex.  $1007 \, \P \, 182$  (citing Ex. 1018, 16.5.19).

Patent Owner does not contest Petitioner's proposed combination of these references, or contend that a person of ordinary skill in the art would not have had a reasonable expectation of success. Prelim. Resp. 34–35. Patent Owner again limits its arguments to those based on the claims requiring a solubility in excess of 10mg/mL, which we have found unpersuasive for the reasons described above.

Based on the evidence in the present record, we are persuaded that Petitioner has shown sufficiently for purposes of this Decision that each element of claims 17 and 18 is taught or suggested by the combined teachings of the cited references and that Petitioner sufficiently shows reason to combine the references' teachings with rational underpinning and reasonable expectation of success. Thus, we are persuaded that Petitioner has sufficiently established a reasonable likelihood of establishing claims 17 and 18 would have been obvious in view of Gaylord, Gauthier, Gordon, Lou, and Haugland.

#### IV. CONCLUSION

For the reasons above, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail with respect to at least 1 of its challenges to the patentability of claims 1–10, 12–14, and 17–19 of the '989 patent. At this juncture in the proceeding, we have not made a final determination with respect to the patentability of the challenged claims, or with respect to claim construction.

# V. ORDER

For the foregoing reasons, it is

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–10, 12–14, and 17–19 of the '989 patent is hereby instituted with respect to all grounds of unpatentability set forth in the Petition; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; the trial will commence on the entry date of this Decision.

#### **PETITIONER:**

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