

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECKMAN COULTER, INC.,
Petitioner,

v.

SIRIGEN II LIMITED,
Patent Owner.

IPR2022-01207
Patent 10,288,620 B2

Before DONNA M. PRAISS, JON B. TORNQUIST, and
BRIAN D. RANGE, *Administrative Patent Judges*.

TORNQUIST, *Administrative Patent Judge*.

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

I. INTRODUCTION

Beckman Coulter, Inc. (“Petitioner”) filed a Petition requesting *inter partes* review of claims 1–14, 18, and 19 of U.S. Patent No. 10,288,620 B2 (Ex. 1005, “the ’620 patent”). Paper 1 (“Pet.”). Sirigen II Limited (“Patent Owner”) filed a Preliminary Response. Paper 8 (“Prelim. Resp.”). With permission, Petitioner filed a supporting Reply (Paper 10 (“Prelim. Reply”)) and Patent Owner filed a supporting 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.” For the reasons set forth below, we determine that Petitioner has established a reasonable likelihood that it would prevail with respect to at least one claim. Thus, we hereby institute an *inter partes* review as to claims 1–14, 18, and 19 of the ’620 patent based upon Petitioner’s asserted grounds of unpatentability.

II. BACKGROUND

A. Related Matters

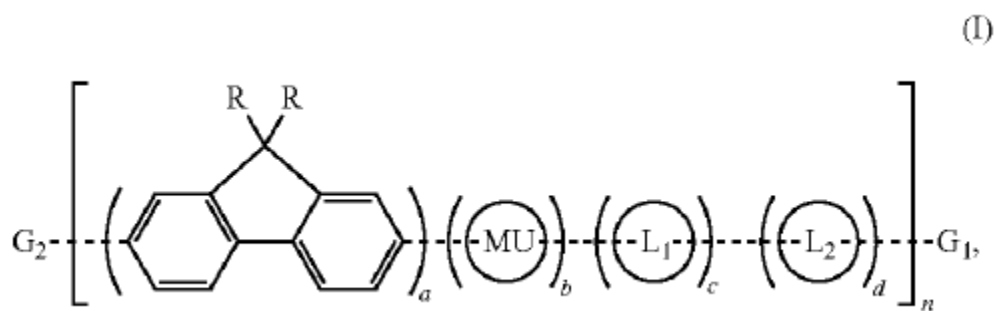
The parties indicate that the ’620 patent is the subject of *Becton, Dickinson & Co., Sirigen, Inc., and Sirigen II Limited v. Beckman Coulter, Inc.*, No. 3:21-cv-01173-CAB-NLS (S.D. Cal.) (“the parallel district court litigation”). Pet. 4; Paper 5, 2. The parties also identify the following proceedings as related matters: IPR2022-01203 (U.S. Patent No. 10,458,989), 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), and IPR2022-01208 (U.S. Patent No. 8,575,303). Pet. 3; Paper 5, 2.

B. The '620 patent

The '620 patent is titled “Reagents for Direct Biomarker Signal Amplification.” Ex. 1003, code (54). The '620 patent explains that fluorescent hybridization probes have become an important tool for the sequence-specific detection of DNA and RNA. *Id.* at 1:24–36. The '620 patent describes conjugated polymers as having potential for improving the detection sensitivity of these probes. *Id.* at 1:42–46. Specifically, the '620 patent states that conjugated polymers “can be made water soluble and adapted to amplify the fluorescent output of various probe labels.” *Id.* at 1:46–52.

The '620 patent describes conjugated polymers as highly promising for nucleic acid diagnostics, which benefit from methods to amplify or replicate nucleic acid targets. *Id.* at 1:53–57. The '620 patent states, however, that protein recognition lacks simple methods for amplifying targeted materials. *Id.* at 1:57–60. According to the '620 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 1:64–67. In addition, the '620 patent describes conjugated polymers as ideally suited for multiplexing, which provides the ability to detect multiple analytes in the same test. *Id.* at 2:1–17.

The '620 patent describes water soluble conjugated polymers having a structure of the following formula (Formula I):



In this formula, “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,” which can be selected from various substances; L₁ and L₂ are optional linkers that are aryl or heteroaryl groups; G₁ and G₂ are each independently selected from a number of elements and compounds, including “hydrogen, halogen, amine, carbamate, carboxylic acid, . . . boronic esters, boronic acids, optionally substituted fluorene and aryl or heteroaryl substituted with one or more pendant chains terminated with a functional group . . . , for conjugation to another substrate, molecule 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. *Id.* at 2:23–3:28.

C. Illustrative Claims

Claim 1 is the sole independent claim, with challenged claims 2–14, 18, and 19 depending directly or indirectly from claim 1. Ex. 1005, 213:9–

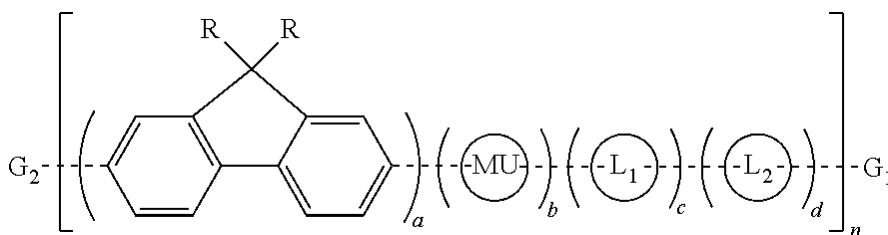
218:32, 220:5–11. Claim 1 is illustrative of the challenged claims and is reproduced below.

1. A polymer-biomolecule conjugate comprising:

a water soluble conjugated polymer; and

a biomolecule covalently linked to the water soluble conjugated polymer;

wherein the water soluble conjugated polymer is of the formula:



wherein:

each R is independently 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, C₁-C₁₂ alkyl, C₂-C₁₂ alkene, C₂-C₁₂ alkyne, C₃-C₁₂ cycloalkyl, C₁-C₁₂ haloalkyl, C₁-C₁₂ alkoxy, C₂-C₁₈ (hetero)aryloxy, C₂-C₁₈ (hetero)arylamino, a C₂-C₁₈ (hetero)aryl group and (CH₂)_{x'}(OCH₂CH₂)_{y'}OCH₃ where x' is independently an integer from 0-20 and y' is independently an integer from 0 to 50;

L1 and L2 are linkers 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 the covalently linked 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 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 the covalently linked 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%.

Ex. 1005, 213:9–214:17 (spacing added to aid in readability).

D. Asserted Grounds of Unpatentability

Petitioner, supported by the declaration of Colin P. Nuckolls, Ph.D. (Ex. 1007), asserts the following six grounds of unpatentability (Pet. 15–16):¹

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–3, 8, 10, 11, 19	102	Xue ²
5–7, 9	103(a)	Xue, in view of Gaylord ³
1–14, 18	102	Gaylord
1–14, 18	103(a)	Gaylord, optionally in view of Bazan ⁴

¹ The relevant sections of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, took effect on March 16, 2013. The ’620 patent claims priority to continuation applications with filing dates before this date. *See* Ex. 1003, code (60), (63). Thus, for the purposes of this Decision, pre-AIA statutes apply.

² 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”).

³ US 2008/0293164 A1, published November 27, 2008, Ex. 1009 (“Gaylord”).

⁴ US 2006/0183140 A1, published August 17, 2006, Ex. 1011 (“Bazan”).

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
12	103(a)	Gaylord in view of Zalipsky ⁵ or Hermanson, ⁶ in further view of Xue or Sumranjit ⁷
19	103(a)	Gaylord in view of Gauthier, ⁸ Gordon, ⁹ or Lou, ¹⁰ in further view of Haugland ¹¹

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.

⁵ Samuel Zalipsky, *Functionalized Poly(ethylene glycol) for Preparation of Biologically Relevant Conjugates*, Bioconj. Chem., vol. 6, pp. 150–165 (1995), Ex. 1012 (“Zalipsky”).

⁶ Greg T. Hermanson, *Bioconjugate Techniques*, 2nd Edition (2008), Ex. 1013 (“Hermanson”).

⁷ Jitapa Sumranjit, *Conjugated Organic Molecules as Models for Potential Sensors*, Ph.D. Dissertation, University of Massachusetts Amherst (Feb. 2007), Ex. 1014 (“Sumranjit”).

⁸ Gauthier et al., *Peptide/protein-polymer conjugates: synthetic strategies and design concepts*, Chem. Comm., pp. 2591–2611 (2008), Ex. 1015 (“Gauthier”).

⁹ 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”).

¹⁰ Lou et al., *Polymer-Based Elemental Tags for Sensitive Bioassays*, Angew. Chem. Int’l Ed., vol. 46, pp. 6111–6114 (2007), Ex. 1017 (“Lou”).

¹¹ Rosaria P. Haugland, *Antibody Conjugates for Cell Biology*, Current Protocols in Cell Biology, 16.5.1–16.5.22 (2001), Ex. 1018 (“Haugland”).

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, 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 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 the 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).

Petitioner asserts that a person of ordinary skill in the art (POSITA) “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. 17 (citing Ex. 1007 ¶¶ 14–18). Patent Owner agrees that a POSITA may have a Ph.D. degree or master’s degree in chemistry, but asserts that a POSITA would also have “some experience with fluorescence” in addition to a degree in chemistry and that the experience of a POSITA with a master’s degree in chemistry is alternatively “industry experience in the field of biological detection systems.” Prelim. Resp. 10 (citing Ex. 2001 ¶ 7).

For purposes of this Decision, we need not choose between the parties’ proposed levels of one of ordinary skill in the art, which are quite similar, as neither party asserts that the anticipation or obviousness analyses in this case would turn on which definition is adopted. *See* Prelim. Resp. 10 (Patent Owner stating that its arguments and conclusions “would not change” if Petitioner’s definition were applied).

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 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.

Petitioner does not assert that any claim terms require express construction for purposes of this Decision.¹² Pet. 16–17.

Patent Owner contends the term “non-ionic side group capable of imparting solubility in water” requires construction. Prelim. Resp. 12–16.

Upon review of the parties’ arguments and supporting evidence we determine that only the term “non-ionic side group capable of imparting solubility in water” requires construction. *See, e.g., Nidec Motor Corp. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e 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))).

non-ionic side group capable of imparting solubility in water

Claim 1 requires that “each R is independently a non-ionic side group capable of imparting solubility in water.” Ex. 1005, 213:27–28. Patent Owner contends that this claim phrase should be construed to mean “a side group that is not charged and allows for an excess of 10 mg/mL of the

¹² Both parties note that the meaning of certain claim terms of the ’620 patent were agreed to by the parties and adopted by the court in the parallel district court litigation. Pet. 16–17; Prelim. Resp. 10–12.

resulting polymer to be soluble in water or aqueous solutions with no visible particulates.” Prelim. Resp. 12.

Patent Owner contends this construction is supported by the written description of the ’620 patent, which defines “non-ionic side groups capable of imparting solubility in water” as “side groups which are not charged and allow the resulting polymer to be soluble in water or aqueous solution with no visible particulates.” *Id.* (quoting Ex. 1005, 53:66–54:2). Patent Owner further notes that the written description of the ’620 patent provides various solubility thresholds for the disclosed conjugated polymers, the lowest of which is consistently “in excess of 10 mg/mL.” *Id.* at 12–13 (quoting Ex. 1005, 2:38–39, 16:49–50, 22:35–36, 30:24–25, 52:59–60, 54:2–10, 70:21–22).

The express language of claim 1 requires no solubility threshold, and dependent claim 10 demonstrates that where a solubility threshold was intended by the inventors of the ’620 patent they knew how to expressly set forth that threshold in the claims. *Compare* Ex. 1005, 213:26–27 (“capable of imparting solubility in water”), *with id.* at 218:12–14 (“The method according to claim 1, wherein each R is a non-ionic side group capable of imparting solubility in water in excess of 10 mg/mL.”). Thus, the claim language does not support applying a particular solubility threshold in claim 1.

As noted by Patent Owner, the written description of the ’620 patent explains that “[i]n some embodiments, each R is independently a non-ionic side group capable of imparting solubility in water in excess of 10 mg/mL.” *Id.* at 54:2–10; Prelim. Resp. 12–13. This solubility threshold, however, is not in claim 1, and we decline to import such a limitation from the written

description into claim 1 absent compelling reasons for doing so. *See SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001) (explaining that “reading a limitation from the written description into the claims” is “one of the cardinal sins of patent law”); *see also Thorner v. Sony Comp. Entm’t Am., LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) (“It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation. We do not read limitations from the specification into claims; we do not redefine words.”).

In view of the foregoing, we construe the term “non-ionic side group capable of imparting solubility in water” to not include any particular numeric solubility threshold.¹³

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. 36–47. 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

¹³ Patent Owner contends that the solubility in question in claim 1 is with respect to the claimed conjugated polymer and not some different polymer. Prelim. Resp. 14. We need not decide this issue in this case as there is no dispute that the non-ionic side groups disclosed in the asserted prior art references impart solubility in water to the associated conjugated polymers.

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.*

We address the *Fintiv* factors below and explain our reasons for not 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 asserts this factor is neutral. Prelim. Resp. 38. According to Patent Owner, “[t]he district court in the Parallel Litigation denied [Petitioner]’s request to halt all activity in the Parallel Litigation pending the Board’s decision on institution.” *Id.* (citing Ex. 2007, 2). Patent Owner nevertheless acknowledges that the district court litigation is stayed, but asserts “the case will be stayed for just a few weeks in between the close of fact discovery and the decision on institution.” *Id.* at 39. Patent Owner “anticipates” that the district court’s stay “will be lifted at least as to each patent for which [the] petition is denied.” *Id.*

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 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.¹⁴ See Prelim. Reply. 4–5. 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.

2. *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. 40 (quoting Ex. 2006, 2). Patent Owner also argues that trial is expected to occur in October or November 2023 based on the Southern District of California’s median time-to-trial of around 29 months as well as Patent

¹⁴ 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 that the first five *Fintiv* factors weigh (often strongly) against discretionary denial.

Owner's expectation that the stay will be lifted if any one of Petitioner's six petitions is denied. *Id.* at 40–41, n.8.

Petitioner argues that there is no trial date set, and Patent Owner agrees. Prelim. Reply 6; Prelim. Sur-Reply 4.

The Director of the U.S. Patent and Trademark Office recently clarified the application of the second *Fintiv* factor in a Memorandum titled “Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings With Parallel District Court Litigation.”¹⁵ 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. Thus, although the median time-to-trial statistics submitted by the parties indicate a trial date before our statutory deadline if no stay had been granted, 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

¹⁵ Available at https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf.

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.

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 because 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. 43. 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 43–44.

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 for experts. *Id.* In other words, in making its stay ruling, the court found that the resources expended on the litigation to date did not outweigh the potential benefit from waiting for the

IPR to potentially streamline the issues. We agree, and find that this factor weighs against discretionary denial of institution.

4. *Overlap of issues*

Patent Owner asserts there is vast overlap between the arguments in the Petition and the parallel litigation, with every patent claim asserted in the litigation similarly challenged in the Petition over the same prior art references. Prelim. Resp. 44–45. Patent Owner also contends that denial of institution is supported by the fact that Petitioner has not provided a stipulation to not pursue the same grounds or any grounds that could have reasonably been raised before the PTAB in the parallel litigation. *Id.* at 45.

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 discretionary denial of institution.

5. *Identity of parties*

Patent Owner asserts that denying institution is supported by the fact that the same parties are involved in both the Petition and the parallel litigation. Prelim. Resp. 45.

Petitioner 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). Here, because the final written decision in this case is more likely to precede the trial in the parallel district court litigation in view of the order staying the parallel litigation, this factor weighs against discretionary denial of institution.

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. 46. 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. 46. Moreover, the record does not support Patent Owner’s assertion that the

Petition evidences “gamesmanship.” *Compare* Prelim. Resp. 46 n.10, with Ex. 2006, 2 (district court order answering Patent Owner’s assertion that Petitioner initiated this proceeding at “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 does not support discretionary denial and is therefore neutral.

7. *Balancing the Fintiv Factors*

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. We have considered the circumstances and facts before us in view of the *Fintiv* factors, none of which favor discretionary denial, and determine that the circumstances presented do not support exercising our discretion to deny institution under § 314(a).

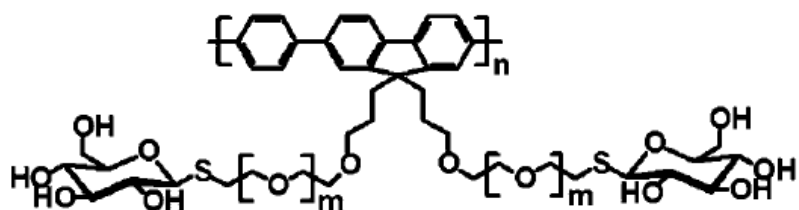
E. *Overview of the Asserted Art*

1. *Xue*

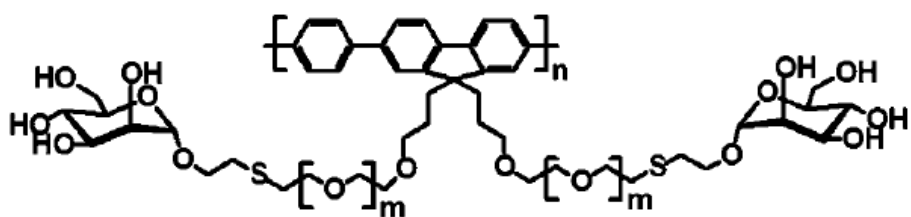
Xue is a paper titled “Highly Water-Soluble, Fluorescent, Conjugated Fluorene-Based Glycopolymers with Poly(ethylene glycol)-Tethered Spacers for Sensitive Detection of *Escherichia coli*.” Ex. 1010, 1. Xue explains that a few fluorescent conjugated glycopolymers have been prepared for biosensing applications 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.* The chemical structure of Xue’s polymers B and C are reproduced below.



Polymer B



Polymer C

Id. at 2290. The figures above depict the chemical structure of Polymers B and C of Xue.

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 the bacterial clusters could be visualized under a fluorescent microscope. *Id.*

2. *Gaylord*

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.

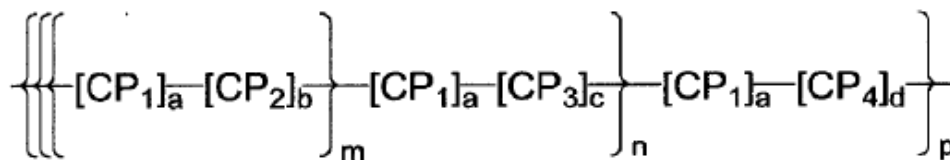
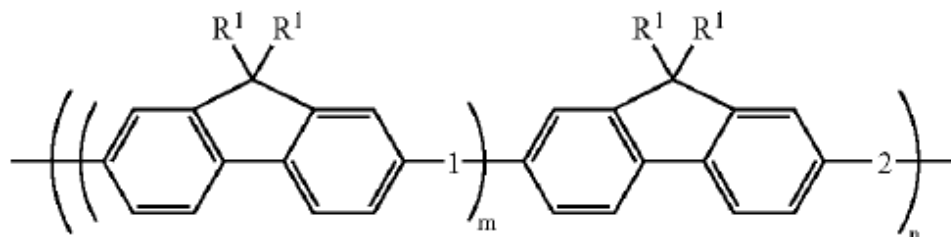


FIG. 18

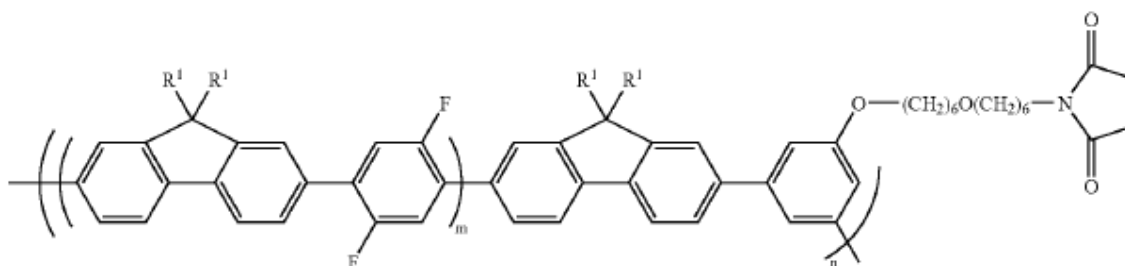
Figure 18 depicts the general structure for a conjugated polymer as a linear multichromophore. *Id.* ¶¶ 69, 184. Gaylord explains that the conjugated polymers include “low bandgap repeat units.” *Id.* ¶ 181. Gaylord describes CP1, CP2, CP3, and CP4 as “optionally substituted conjugated polymer segments 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 R¹ 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 R¹ can be “a solubilizing group” that can be an ethylene glycol oligomer, ethylene glycol polymer, or other substances. *Id.* ¶ 19.

3. Gauthier

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*

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

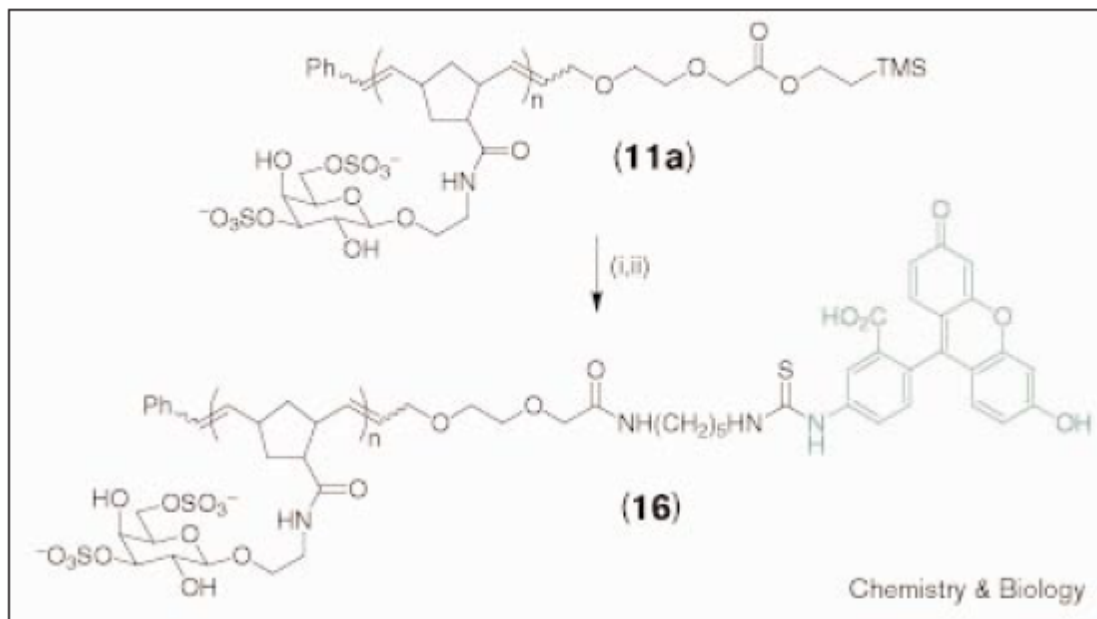


Figure 5 depicts the “[s]ynthesis of fluorescent neoglycopolymer 16.” *Id.* at 12.

5. Lou

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 water-soluble 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*

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*

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*

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*

Sumranjit is a doctoral dissertation titled “Conjugated Organic Molecules as Models for Potential Sensors.” Ex. 1014, 3¹⁶. 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 asserts that claims 1–3, 8, 10, 11, and 19 are anticipated by Xue under 35 U.S.C. § 102, citing the Declaration of Dr. Nuckolls for support. Pet. 28–35 (citing Ex. 1007).

a. *Claim 1*

Petitioner identifies where it contends that Polymers B and C of Xue expressly disclose the limitations of independent claim 1. Pet. 28–35. In particular, Petitioner contends that: (1) Polymers B and C disclose a water-soluble conjugated polymer, the structure of which falls within Formula Ia of the ’620 patent, that is covalently linked to a biomolecule in the form of a sugar group (*id.* at 28–29 (citing Ex. 1010, 2289; Ex. 1007 ¶¶ 116–121, 372–379)); (2) Polymers B and C utilize band gap modifying

¹⁶ For clarity, we refer to the Exhibit 1014’s page number rather than the document’s original page number.

units (phenyl repeats) that satisfy the MU limitation of claim 1 (*id.* at 30 (citing Ex. 1010, 2290; Ex. 1007 ¶ 374)); (3) L₁ and L₂ are not required for anticipation (*id.* at 30–31 (citing Ex. 1053, 1–2 (noting that b and c of formula Ia, which modify the L₁ and L₂ groups, may be 0%))); (4) the end units G₁ and G₂ of Polymers B and C may be, among other things, hydrogen, boronic ester, or boronic acid (*id.* at 32 (citing Ex. 1007 ¶ 377)); (5) Polymers B and C include a polymer with approximately 36 repeat units, i.e., n=36 (*id.* at 33 (citing Ex. 1007 ¶ 378; Ex. 1010, 2294)); and (6) the mol% of a and b in Polymers B and C are approximately 50% and the mol % of c and d are 0% (*id.* at 33 (citing Ex. 1007 ¶ 379)).

With respect to the limitation requiring that “each R is independently a non-ionic side group capable of imparting solubility in water,” Petitioner contends that the PEG groups of Xue used in Polymers B and C are non-ionic side groups capable of imparting solubility in water. *Id.* at 29 (citing Ex. 1007 ¶¶ 37–41, 116–21, 373; Ex. 1010, 2289).

Patent Owner contends Petitioner’s arguments with respect to anticipation by Xue fail because the solubility of the disclosed polymers was no more than 0.075 mg/mL, which is many-fold less than the “in excess of 10 mg/mL” threshold of claim 1. Prelim. Resp. 17–18.

Patent Owner’s argument is unavailing. Xue expressly discloses that its glycopolymers utilizing poly(ethylene glycol)-tethered spacers (Polymers B and C) “are highly water-soluble due to their long, flexible, hydrophilic spacers.” Ex. 1010, Abstract, 2289–90. As claim 1 does not require any particular solubility threshold, on this record Petitioner sufficiently demonstrates that Xue expressly discloses the “R” limitation of independent claim 1.

Upon review of the parties' arguments and supporting evidence, we determine that Petitioner sufficiently identifies where Xue expressly discloses every limitation of claim 1. As such, Petitioner demonstrates a reasonable likelihood that claim 1 is anticipated by Xue.

b. Claims 2, 3, 8, 11, and 19

Petitioner identifies where it contends that Xue expressly discloses the limitations of dependent claims 2, 3, 8, 11, and 19. Pet. 34–35. In particular, Petitioner contends that: (1) Polymers B and C of Xue contain sugars that act as a sensor biomolecule (claims 2 and 3) (*Id.* at 34 (citing Ex. 1010, 2292; Ex. 1007 ¶¶ 380–381)); (2) MU in Polymers B and C is a phenyl (claim 8) (*id.* (citing Ex. 2290; Ex. 1007 ¶ 374)); (3) Polymers B and C comprise an “ethylene glycol oligomer, i.e., PEG” (claim 11) (*id.* at 35 (citing Ex. 1007 ¶ 384)); and (4) Polymers B and C are covalently linked at one or both ends to a biomolecule in the form of “sugar groups” (claim 19) (*id.* at 35 (citing Ex. 1007 ¶¶ 384–385; Ex. 1054)).

Patent Owner does not directly address Petitioner's arguments with respect to these dependent claims, apart from its arguments with respect to independent claim 1.

Upon review of Petitioner's arguments and supporting evidence, we determine that Petitioner demonstrates a reasonable likelihood that claims 2, 3, 8, 11, and 19 are anticipated by Xue.

c. Dependent Claim 10

Claim 10 depends directly from claim 1 and further requires “wherein each R is a non-ionic side group capable of imparting solubility in water in excess of 10 mg/mL.” Ex. 1005, 218:12–14. Petitioner contends that because the PEG groups recited in Xue are the same structures “taught in the

'620 patent corresponding to this limitation,” they therefore read on it.

Pet. 34. Patent Owner, however, raises reasonable questions with respect to this logic. For example, the '620 patent does not indicate that in all of its disclosed embodiments any disclosed PEG polymer will necessarily impart a solubility to the conjugated polymer “in excess of 10 mg/mL.” Prelim.

Resp. 17. Rather, the '620 patent discloses that these polymers will do so “[i]n some embodiments.” Ex. 1005, 54:2–5, 54:20–26. The parties are encouraged to further address this issue during trial.

2. *Obviousness of Claims 5–7 and 9 over Xue and Gaylord*

Claims 5–7 and 9 require selection of specific constituents for MU. Ex. 1005, 214:31–217:62, 217:66–67. Petitioner contends the MUs recited in these claims are expressly disclosed in Gaylord and that one of ordinary skill in the art would have sought to use these structures in Polymers B and C of Xue in order to modify the band gap of the polymer. Pet. 35–36. According to Petitioner, “[t]he use of MUs disclosed in Gaylord in the polymers of Xue is nothing ‘more than the predictable use of prior art elements according to their established functions.’” *Id.* at 37 (quoting *KSR*, 550 U.S. at 417).

Patent Owner does not address Petitioner’s arguments with respect to claims 5–7 and 9, apart from its arguments discussed above for independent claim 1, from which each of these claims depends. Prelim. Resp. 21–22 (asserting that Gaylord does not address the 10 mg/mL solubility limitation of claim 1).

Patent Owner does argue, however, that objective indicia of non-obviousness support the non-obviousness of the challenged claims. Prelim. Resp. 32–36. In particular, Patent Owner contends that “[i]t was

entirely unexpected that conjugated polymers with neutral solubilizing side groups would have water solubilities greater than 10 mg/mL” and that the conjugated polymers of the challenged claims “displayed significantly enhanced solubility compared to polymers with ionic sidechains, minimized the issue of non-specific binding, and showed remarkable brightness.” *Id.* at 33–34 (citing Ex. 2001 ¶¶ 89–91).

On this preliminary record, Patent Owner’s arguments are unavailing for at least two reasons. First, Patent Owner’s arguments are directed to a solubility threshold of “greater than 10 mg/mL” that is not recited in the independent claims of the ’620 patent. Second, it is not evident that it was unexpected that non-ionic side chains could be used to impart solubility to a conjugated polymer, or that these side chains would provide enhanced solubility, minimize non-specific binding, or show remarkable brightness, as asserted by Patent Owner. For example, Sumranjit notes that non-ionic PEG polymers have been used “as water-solubilizing units in much research from the literature,” and Sumranjit expressly discloses using non-ionic PEG side chains to provide a PEGylated polymer that “was readily soluble in water, and exhibited strong blue fluorescence.” Ex. 1014, Abstract, 67; *see 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”). Accordingly, at best, Patent Owner raises a factual issue for trial with respect to objective indicia of non-obviousness.¹⁷

¹⁷ Patent Owner’s arguments for objective indicia of non-obviousness are

Upon review of the parties' arguments and supporting evidence, we determine that Petitioner demonstrates a reasonable likelihood that claims 5–7 and 9 would have been obvious over the combined disclosures of Xue and Gaylord.

3. *Anticipation by Gaylord*

Petitioner contends claims 1–14 and 18 are anticipated by Gaylord, citing the Declaration of Dr. Nuckolls for support. Pet. 37–49 (citing Ex. 1007).

a. *Claim 1*

Petitioner contends Gaylord discloses every limitation of independent claim 1, including: (1) a biomolecule covalently linked to a water soluble conjugated polymer having the structure set forth in Formula IA of the '620 patent (Pet. 37–38 (citing Ex. 1009, Fig. 18; Ex. 1007 ¶¶ 102–115, 185, 391–407)); (2) Polymers 1 and 2 that contain polymer modifying units or band gap modifying units (MU) that are evenly or randomly distributed (*id.* at 39–40 (citing Ex. 1009 ¶¶ 13–15, 18–19; Ex. 1007 ¶¶ 398–399)); (3) L₁ and L₂ in the form of conjugation cites for a molecule or biomolecule (*id.* at 41–42 (citing Ex. 1009 ¶¶ 11, 15, 26, 33, 147–149, 156, 185, Fig. 20; Ex. 1007 ¶¶ 102–115, 400)); (4) G₁ and G₂ that are one of hydrogen, a halogen, a boronic ester, or a boronic acid (*id.* at 42–43 (citing Ex. 1009 ¶¶ 57, 277–283, 324–326, 327–362, 484–486; Ex. 1007 ¶¶ 102–115, 402)); (5) n that can be 3, 4, 5, or more (*id.* at 43 (citing Ex. 1007 ¶ 403; Ex. 1011

made generally, without any specific application to a particular obviousness ground. Prelim. Resp. 33–35. Although we have discussed these arguments in connection with Xue and Gaylord, our analysis should be understood to apply to all obviousness grounds asserted by Petitioner.

¶ 85)); and (5) values for a, b, c, and d that are 50%, 50%, 0%, and 0%, respectively (*id.* at 43–44 (citing Ex. 1007 ¶¶ 404, 407)). With respect to the requirement that each R is “capable of imparting solubility in water,” Petitioner contends Gaylord expressly discloses the use of “ethylene glycol oligomers” and “ethylene glycol polymers,” and Dr. Nuckolls testifies that these polymers are water-soluble or solubilizing groups. *Id.* at 38–39; Ex. 1007 ¶¶ 393–394; Ex. 1009 ¶¶ 188–193.

Patent Owner contends Petitioner’s arguments with respect to anticipation of claim 1 by Gaylord are unpersuasive because Petitioner has not demonstrated that the solubilizing groups of Gaylord would necessarily impart a solubility in water in excess of 10 mg/mL. Prelim. Resp. 22.

On this record, Petitioner sufficiently explains where Gaylord expressly discloses every limitation of claim 1. Patent Owner’s counter-arguments are unavailing because we do not construe claim 1 to require a specific level of solubility, and it is not contested that Polymers 1 and 2 of Gaylord are soluble in water.

b. *Claims 2–9, 11–14, 18*

Petitioner contends that Gaylord discloses every limitation of claims 2–9, 11–14, and 18, including (1) a sensor biomolecule in the form of an antibody (claims 2–4) (Pet. 45 (citing Ex. 1009 ¶¶ 42–43, Abstract)); (2) low bandgap repeat units in the form of a phenyl group (claims 8 and 9) and a “benzothiadiazole” group (claims 5–7) (*id.* at 45–46 (citing Ex. 1009 ¶¶ 32, 182, 194; Ex. 1007 ¶ 412)); (3) R in the form of an ethylene glycol oligomer (claim 11) (*id.* at 47 (citing Ex. 1007 ¶ 415; Ex. 1012, 150; Ex. 1013, 937)); (4) mPEGs with a range of repeat units that encompass 11 repeat units (claim 12) (*id.* at 47–48 (citing Ex. 1007 ¶¶ 416–417;

Ex. 1009 ¶ 188; *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381–83 (Fed. Cir. 2015)); (5) a PEG side group that is $(\text{CH}_2)_2(\text{OCH}_2\text{CH}_2)_3\text{OCH}_3$ (claims 13 and 14) (*id.* at 48 (citing Ex. 1007 ¶ 418)); and (6) using signaling chromophores, such as fluorescent dyes (claim 18) (*id.* at 49 (citing Ex. 1007 ¶ 420; Ex. 1009 ¶¶ 147–149, Figs. 5, 14)).

Patent Owner does not address Petitioner’s arguments with respect to claims 2–9, 11–14, and 18, beyond its arguments discussed above with respect to independent claim 1.

Upon review of the parties’ arguments and supporting evidence, we determine that Petitioner demonstrates a reasonable likelihood that claims 2–9, 11–14, and 18 are anticipated by Gaylord.

c. Claim 10

As discussed above, claim 10 depends directly from claim 1 and further requires “wherein each R is a non-ionic side group capable of imparting solubility in water in excess of 10 mg/mL.” Ex. 1005, 218:12–14. Petitioner contends that the ’620 patent “provides that PEG groups like the ones taught in Gaylord are structures that are ‘capable of imparting solubility in water in excess of 10 mg/mL’ as recited in [claim 10].” Pet. 46–47 (citing Ex. 1007 ¶ 413; Ex. 1005, 54:20–22, 70:21–25).

Patent Owner contends that Petitioner has not established that any conjugated polymer disclosed in Gaylord necessarily possesses a solubility in water in excess of 10 mg/mL, and that the ’620 patent’s disclosures only suggest that PEG polymers of the type disclosed in Gaylord may, “in some embodiments,” impart a solubility in water in excess of 10 mg/mL. Prelim. Resp. 24.

On this record, we agree with Patent Owner that a significant question exists as to whether Gaylord's PEG polymers impart a solubility in water in excess of 10 mg/mL, regardless of which constituents are chosen for MU, L₁ and L₂, G₁ and G₂, n, and a, b, c, and d. The parties are encouraged to further address this issue during trial.

4. *Obviousness over Gaylord and Bazan*

Petitioner contends that the subject matter of claims 1–14 and 18 would have been obvious over the combined disclosures of Gaylord and Bazan. Pet. 49–53. In particular, Petitioner contends that to the extent any of claims 1–14 and 18 are not anticipated by Gaylord, the subject matter of these claims would have been obvious in view of the teachings and guidance in both Gaylord and Bazan. *Id.* at 49–50.

Patent Owner's arguments with respect to this ground are based on the alleged requirement that the conjugated polymer have a water solubility in excess of 10 mg/mL. Prelim. Resp. 27–28.

Having determined that Petitioner demonstrates a reasonable likelihood that claims 1–9, 11–14, and 18 are anticipated by Gaylord, including the solubility limitation of claim 1, we do not address Petitioner's additional obviousness arguments with respect to Gaylord and Bazan.¹⁸

5. *Obviousness of Claim 12 over Gaylord and Zalipsky or Hermanson, in further view of Xue or Sumranjit*

Claim 12 depends indirectly from claim 1 and further requires that “each R is a non-ionic side group comprising mPEG5, mPEG8, mPEG11, or

¹⁸ Petitioner's obviousness arguments with respect to Gaylord and Bazan do not address the specific solubility threshold of claim 10. Pet. 51–52. As such, in this ground we have the same questions regarding claim 10 that are discussed above with respect to anticipation by Gaylord.

mPEG24.” Ex. 1005, 218:18–20. Petitioner contends the subject matter of claim 12 would have been obvious over the combined disclosures of Gaylord and Zalipsky or Hermanson, in further view of Xue or Sumranjt. Pet. 53–54.

Patent Owner contends that the additional references relied upon by Petitioner in this ground do not render obvious a conjugated polymer that has a solubility in water in excess of 10 mg/mL. Prelim. Resp. 31–32.

As we have found a reasonable likelihood that claim 12 is anticipated by Gaylord, including the solubility limitations of claim 1, we do not address Petitioner’s additional obviousness ground with respect to this claim.¹⁹

6. *Obviousness of Claim 19 over Gaylord, Gauthier, Gordon or Lou, and Haugland*

Claim 19 depends from claim 1 and further requires “wherein G₁ or G₂ comprise the covalently linked biomolecule.” Ex. 1005, 220:8–10. Petitioner contends that simply following Gaylord’s teachings “will yield polymers meeting this limitation.” Pet. 54–55. Moreover, Petitioner contends one of ordinary skill in the art would have understood from the prior art, such as Gauthier, that end-group functionalization is one of just “two strategies” for covalently attaching biomolecules to polymers, and Petitioner asserts that selecting either of these options would have been obvious. *Id.* at 55.

Patent Owner contends that none of the additional references cited by Petitioner would render obvious the solubility limitation of claim 1. Prelim. Resp. 31. As such, Patent Owner contends claim 19 would not have been

¹⁹ We will address this issue at trial, however, should it become necessary.

obvious for the same reasons discussed above with respect to independent claim 1. *Id.*

Upon review of Petitioner's arguments and supporting evidence, we determine that Petitioner demonstrates a reasonable likelihood that the subject matter of claim 19 would have been obvious over Gaylord, Gauthier, Gordon or Lou, and Haugland. Patent Owner's counter-argument is unavailing because it has not demonstrated that claim 1 requires a specific solubility threshold.

IV. CONCLUSION

For the reasons set forth above, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner will prevail with respect to at least one challenged claim of the '620 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 1–14, 18, and 19 of the '620 patent is hereby instituted with respect to the ground 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.

IPR2022-01207
Patent 10,288,620 B2

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