

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AJINOMOTO CO., INC.,
Petitioner,

v.

ABTIS CO., LTD.,
Patent Owner.

IPR2025-00283
Patent 11,896,675 B2

Before JEFFREY N. FREDMAN, JO-ANNE M. KOKOSKI, and
LILAN REN, *Administrative Patent Judges*.

REN, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision

Disclaimer of All Challenged Claims

37 C.F.R. § 42.107(e)

Granting Patent Owner's Motion to Amend

35 U.S.C. § 318(a); 35 U.S.C. § 316(d); 37 C.F.R. § 42.121

Denying Petitioner's Motion to Exclude (Paper 34)

37 C.F.R. § 42.64(c)

Dismissing Patent Owner's Motion to Submit Evidence (Paper 37)

37 C.F.R. § 42.64(b)(2)

I. INTRODUCTION

Ajinomoto Co., Inc. (“Petitioner”) filed a Petition requesting *inter partes* review of claims 1–13 of U.S. Patent No. 11,896,675 B2 (Ex. 1001, “the ’675 patent”). Paper 2 (“Pet.”). AbTis Co., Ltd. (“Patent Owner”) filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). Patent Owner disclaimed claims 1–10, 12, and 13 of the ’675 patent, leaving only dependent claim 11 at issue in this proceeding. Ex. 2001 (disclaimer dated May 9, 2025). On July 2, 2025, the Acting Director referred the Petition to the Board to consider the merits and other non-discretionary considerations, as appropriate. Paper 13. On August 8, 2025, we instituted this *inter partes* review as to claim 11. Paper 16 (“Dec.”); 37 C.F.R. § 42.107(e) (“No *inter partes* review will be instituted based on disclaimed claims.”).

After we instituted this review, Patent Owner filed a Non-Contingent Motion to Amend (Paper 23, “Motion” or “Mot.”) requesting cancellation of claim 11 and proposing substitute claims 14–16, supported by a declaration of Dr. Zhaohui Sunny Zhou (Ex. 2004). Petitioner filed an Opposition to Patent Owner’s Motion (Paper 25, “Opposition” or “Opp.”) supported by a declaration of Dr. Lawrence Nathan Tumey (Ex. 1059). We issued Preliminary Guidance as to Patent Owner’s Non-Contingent Motion to Amend. Paper 27. Patent Owner filed a Reply to Petitioner’s Opposition (Paper 28, “Reply”) supported by a second declaration of Dr. Zhou (Ex. 2008), and Petitioner filed a Sur-Reply (Paper 33, “Sur-Reply”). Additionally, both parties filed a supplemental brief at the Board’s invitation on May 26, 2026. Paper 44, Paper 45.

Petitioner also filed a Motion to Exclude Exhibits 2008 and 2009. Paper 34. Patent Owner filed an Opposition (Paper 35), and Petitioner filed a Reply in support of its Motion to Exclude (Paper 39). Patent Owner filed a

Motion to Submit Supplemental Evidence (Paper 37) to which Petitioner filed Opposition (Paper 38).

We held an oral hearing at the request of both parties, the transcript of which has been entered into the record. Paper 43 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6. This is a Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons discussed below, Patent Owner’s Non-Contingent Motion to Amend (Paper 23) is granted as to the cancellation of claim 11 and granted as to adding substitute claims 14–16. Because the Motion is non-contingent, we provide a final decision on the patentability of substitute claims 14–16 instead of original claims 1–13. We determine Patent Owner has satisfied the statutory and regulatory requirements for a motion to amend, and Petitioner has not shown, by a preponderance of the evidence, that proposed substitute claims 14–16 are unpatentable. Petitioner’s Motion to Exclude is denied. Patent Owner’s Motion to Submit Supplemental Evidence is dismissed as moot.

II. BACKGROUND

A. Real Parties in Interest

Petitioner identifies itself as the real party in interest for Petitioner. Pet. 1. Patent Owner identifies itself as the real party in interest for Patent Owner. Paper 3, 2 (Patent Owner Mandatory Notices).

B. Related Matters

Petitioner states they are “not aware of any other current litigation or administrative proceedings involving the ’675 Patent that would affect, or be affected by, a decision in this proceeding.” Pet. 1. Patent Owner does not contest this statement by the Petitioner, but states that “[t]he ’675 Patent at issue in this IPR proceeding is a continuation of U.S. Patent Application

No. 16/980,503 which is a U.S. national phase application of PCT/KR2020/003282. The '675 Patent also claims priority to U.S. Provisional Patent Application No. 62/815,557.” Paper 22, 1.

C. The '675 Patent

The '675 patent, titled “Site-Specific Antibody Conjugation and Antibody-Drug Conjugate as Specific Embodiment Thereof,” “relates to technology capable of labeling a certain site of an antibody with a certain number of chemical functional groups or cargo moieties.” Ex. 1001, codes (54), (57). The '675 patent explains that “[a]ntibodies are biomolecules that have a function of recognizing certain molecules, and have been used for various industrial applications” and “for therapeutic purposes.” *Id.* at 1:35–41. “To expand the functions of such an antibody, there [have] been attempts to improve the antibody’s ability.” *Id.* at 1:43–44. For example, “when an antibody is labeled with an agent for treating a certain disease, the antibody may be used to maximize a therapeutic effect of the antibody. These attempts and technology are generally referred to as ‘antibody labeling.’” *Id.* at 1:48–53.

The '675 patent seeks to address antibody labeling issues associated with “randomly attaching a foreign substance to an antibody.” *Id.* at 1:55–56. According to the '675 patent, such random attachment “highly degraded [an] antibody’s ability to recognize by allowing a foreign substance to bind to an antigen-binding domain of an antibody or a site adjacent to the antigen-binding domain.” *Id.* at 2:4–7.

The '675 patent thus “provides technology for specifically transferring a chemical functional group to lysine 246 in the antibody” allowing “uniformly labeling an antibody in a site-specific manner.” *Id.* at 2:9, 2:26–28. More specifically, the '675 patent may provide technology both for

“specifically transferring a chemical functional group” and “specifically linking a cargo moiety to lysine 248 in the antibody.” *Id.* at 2:31–32, 2:51–52.

III. PATENT OWNER’S MOTION TO AMEND

In its non-contingent Motion to Amend, Patent Owner proposes substitute claims 14–16. *See generally* Mot. In support of its arguments, Patent Owner relies on declarations of Dr. Zhaohui Sunny Zhou (Exs. 2004, 2008). In support of its Opposition, Petitioner relies on a second declaration of Dr. Tumey (Ex. 1059).

Because Patent Owner’s Motion is non-contingent, we address only the patentability of substitute claims 14–16 in this Decision; we do not address the patentability of original claims 1–13, which have been cancelled.

A. *Proposed Substitute Claims*

Patent Owner’s proposed substitute claims 14–16 incorporate limitations from original claims 1 and 11. Original claim 11 depends directly from original claim 1 and is directed to a Markush group of three specific chemical moieties. According to Patent Owner, “[p]roposed substitute claims 14-16 are independent claims, each directed to one of the specific chemical moieties of canceled claim 11.” Mot. 2.

Proposed substitute claims 14–16 read as follows:¹

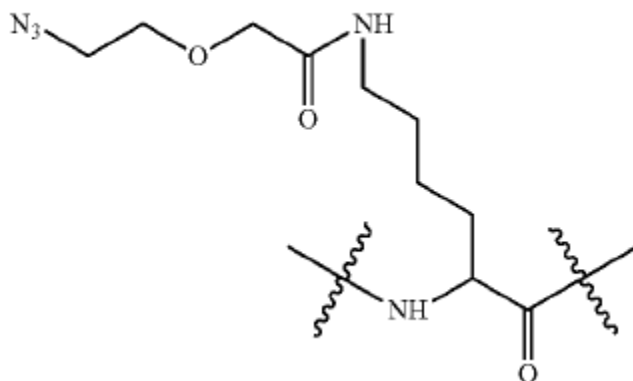
14. [14.pre] A modified antibody comprising a bio-orthogonal click chemistry functional group,
[14.a] wherein the modified antibody comprises one or more modified heavy chain,

¹ Bracketed numbers and letters added for reference purposes using the labels included in Patent Owner’s Motion. *See* Mot 27–30.

[14.b] wherein each of the modified heavy chain comprises a modified lysine residue at 248 position of heavy chain amino acid sequence,

[14.c] wherein the 248 position is determined by an EU numbering system, and

[14.d] wherein the modified lysine residue has following structure:



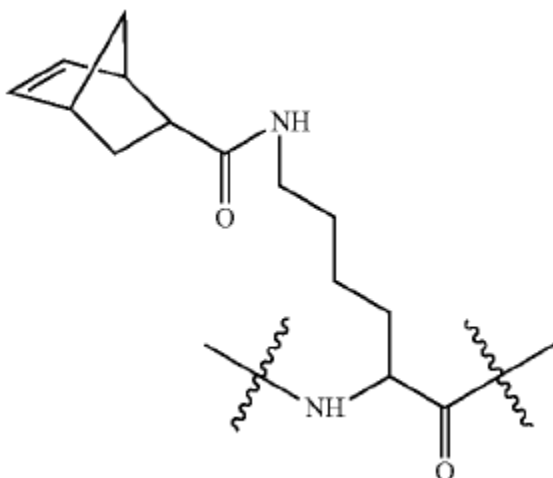
15. [15.pre] A modified antibody comprising a bio-orthogonal click chemistry functional group,

[15.a] wherein the modified antibody comprises one or more modified heavy chain,

[15.b] wherein each of the modified heavy chain comprises a modified lysine residue at 248 position of heavy chain amino acid sequence,

[15.c] wherein the 248 position is determined by an EU numbering system, and

[15.d] wherein the modified lysine residue has following structure:



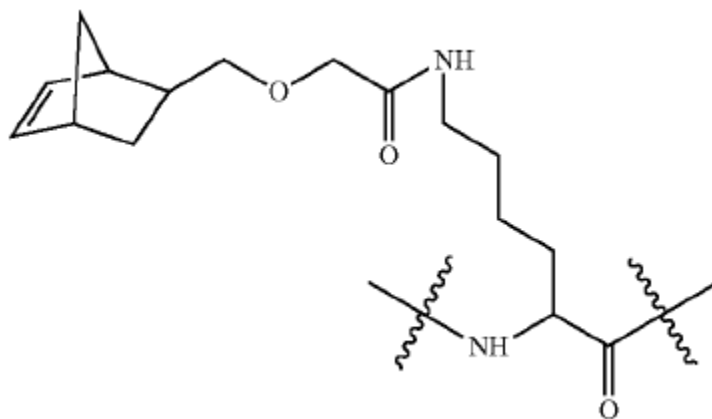
16. [16.pre] A modified antibody comprising a bio-orthogonal click chemistry functional group,

[16.a] wherein the modified antibody comprises one or more modified heavy chain,

[16.b] wherein each of the modified heavy chain comprises a modified lysine residue at 248 position of heavy chain amino acid sequence,

[16.c] wherein the 248 position is determined by an EU numbering system, and

[16.d] wherein the modified lysine residue has following structure:



Mot. 27–30.

B. Asserted Grounds of Unpatentability in the Opposition

Petitioner challenges the patentability of claims 14–16 on the following grounds (Opp. 2–25):

Claim(s) Challenged	35 U.S.C. §²	Reference(s)/Basis
14–16	112(a)	Written description
14–16	112(a)	Enablement
14–16	112(b)	Indefiniteness
14–16	102	CA959 ³
14–16	103	Yamada, ⁴ Matsuda ⁵

² The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. Because the filing date of the application for the ’675 patent was after that date, we refer to the post-AIA versions of §§ 102 and 103.

³ CA 3132959 A1 (“CA959”), published Sept. 17, 2020, filed Mar. 9, 2020 (Ex. 1005). CA959 claims priority to U.S. Provisional Application No. 62/815,557, filed on March 8, 2019. Petitioner contends that CA959 is prior art to the ’675 patent. Pet. 22. Patent Owner, on the other hand, disputes that this reference qualifies as prior art. Mot. 13; Reply 5. For the reasons discussed *infra*, we determine that CA959 does not qualify as prior art. For the remaining references, Patent Owner does not dispute the references are prior art to the ’675 patent.

⁴ Yamada, WO 2018/199337, published Nov. 1, 2018, , which claims priority to Japanese Patent Application No. 2017-090679, filed on April 28, 2017 (Exs. 1008, 1009 (US Application Pub. No. 2020/0190165)). Petitioner contends that Yamada is prior art to the ’675 patent under 35 U.S.C. § 102(a)(1). Pet. 28. Petitioner certifies that the U.S. national stage publication (Ex. 1009) “is a true, faithful, and accurate translation” of the Japanese publication, with a few identified, non-substantive exceptions. Ex. 1009, 1–2.

⁵ Matsuda, US 2021/0139541, published May 13, 2021, filed Dec. 11, 2020 which claims priority to Japanese Patent Application No. 2018-113962, filed June 14, 2018 (Exs. 1010, 1011 (English translation)). Petitioner contends that Matsuda is prior art to the ’675 patent under 35 U.S.C. § 102(a)(2). Pet. 28. Petitioner states that the English translation is certified. Ex. 1011.

Claim(s) Challenged	35 U.S.C. § ²	Reference(s)/Basis
14–16	103	PepTalk Poster, ⁶ Yamada, Matsuda
14–16	103	PepTalk Presentation ⁷ , Yamada, Matsuda

C. Legal Standards

In an *inter partes* review, amended claims are not added to a patent as of right, but rather must be proposed as a part of a motion to amend claims. 35 U.S.C. § 316(d). Ordinarily, the petitioner “bears the burden of persuasion to show, by a preponderance of the evidence, that any proposed substitute claims are unpatentable.” 37 C.F.R. § 42.121(d)(2); *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 3–4 (PTAB Feb. 25, 2019) (precedential).

Before considering the patentability of the substitute claims, we first must determine whether the motion to amend meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. *Lectrosonics*, Paper 15 at 4. In that regard, Patent Owner bears the burden of persuasion to show that: (1) the amendment proposes a reasonable number of substitute claims; (2) the amendment responds to a ground of unpatentability involved in the trial; (3) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter;

⁶ PepTalk Poster, “Development of a Novel Chemical Site-Specific Conjugation Platform for ADCs.” According to Petitioner, this poster was presented at an annual scientific conference called “PepTalk: The Protein Science Week” held from January 14–18, 2019 (Ex. 1006). Pet. 23.

Petitioner contends that PepTalk Poster is prior art to the ’675 patent. *Id.*

⁷ PepTalk Presentation. According to Petitioner, this presentation was presented at the same conference as PepTalk Poster (Ex. 1007). Pet. 26. Petitioner contends that PepTalk Presentation is prior art to the ’675 patent. *Id.*

and (4) the original disclosure sets forth written description support for each proposed substitute claim. *Id.*; 35 U.S.C. § 16(d); 37 C.F.R. § 42.121(d)(1).

D. Statutory and Regulatory Requirements

Patent Owner argues that the proposed substitute claims meet the statutory and regulatory requirements for a motion to amend. Mot. 2–13.

1. Reasonable number of substitute claims

A motion to amend must “propose a reasonable number of substitute claims.” 35 U.S.C. § 316(d)(1)(B); *see also* 37 C.F.R. § 42.121(a)(3) (“A motion to amend may cancel a challenged claim or propose a reasonable number of substitute claims.”). “There is a rebuttable presumption that a reasonable number of substitute claims per challenged claim is one (1) substitute claim.” *Lectrosonics*, Paper 15 at 4; *see also* 37 C.F.R. § 42.121(a)(3).

Patent Owner proposes to cancel original claim 11 and substitute proposed claims 14–16 for the cancelled claim. Mot. 2–3, 27–30 (App. A). Patent Owner contends the Motion proposes a reasonable number of substitute claims because: (1) proposed claims 14–16 are independent claims that are “each directed to one of the specific chemical moieties” of the Markush group of canceled claim 11; and (2) Patent Owner disclaimed twelve claims of the ’675 patent, “making the number of substitute claims less than one substitute per original claim.” *Id.* at 2–3.

Petitioner does not contend that Patent Owner proposes more than a reasonable number of substitute claims. *See generally* Opp.

We determine that Patent Owner proposes a reasonable number of substitute claims because Patent Owner proposes a less than one-to-one substitution for the original claims. Mot 2–3, 27–30; Ex. 2001; *see also* 37 C.F.R. § 42.121(a)(3).

2. Responsive to a ground of unpatentability

“A motion to amend may be denied where . . . [t]he amendment does not respond to a ground of unpatentability involved in the trial.” 37 C.F.R. § 42.121(a)(2)(i). The Petition asserts that original claims 1–13 are unpatentable over prior art. As discussed above, Patent Owner seeks to incorporate limitations from original claims 1 and 11 such that each of claims 14–16 is directed to one of the specific chemical moieties of canceled claim 11.

Patent Owner asserts that the newly added limitations in proposed substitute claims 14–16 distinguish these claims from the disclosures of one or more of the cited prior art references CA959, PepTalk Poster, PepTalk Presentation, Yamada, and Matsuda. *See* Mot. 12–25.

Petitioner does not contend that Patent Owner’s amendments are unresponsive to a ground of unpatentability involved in the trial. *See generally* Opp.

Because Patent Owner’s amendments attempt to distinguish over CA959, PepTalk Poster, PepTalk Presentation, Yamada, and Matsuda, we determine that the proposed amendments are responsive to a ground of unpatentability involved in this trial.

3. Do not enlarge the scope of the claims

An amendment may not enlarge the scope of the claims of the patent. 35 U.S.C. § 316(d)(3); 37 C.F.R. §§ 42.121(b)(1), 42.121(b)(2).

Patent Owner asserts that the Motion does not enlarge the scope of the claims of the patent because the Motion adds only narrowing limitations. *See* Mot. 3–8, 27–30.

Petitioner does not contend that the proposed substitute claims enlarge the scope of the original claims. *See generally* Opp.

We determine that proposed substitute claims 14–16 include narrowing limitations and do not violate the statutory and regulatory prohibition of enlarging the scope of patent claims.

4. *New matter*

An amendment may not introduce new matter. 35 U.S.C. § 316(d)(3); 37 C.F.R. §§ 42.121(b)(1), 42.121(b)(2). New subject matter is any addition to the claims that lacks sufficient support in the subject patent’s original disclosure. *See TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) (“When [an] applicant adds a claim . . . , the new claim[] must find support in the original specification.”). Patent Owner also is required to show written description support in “the original disclosure of the patent for each claim that is . . . amended,” and in “an earlier-filed disclosure for each claim for which benefit of the filing date of the earlier filed disclosure is sought.” 37 C.F.R. § 42.121(b).

“To satisfy the written description requirement the disclosure of the prior application must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession of the invention.” *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) (emphasis omitted; alteration in original; citations and quotations omitted). The sufficiency of written description support is based on “an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

Patent Owner contends proposed substitute claims 14–16 do not introduce new subject matter because each claim is supported by the specification for Application No. 18/154,998 (the “’998 application,”

Ex. 2002), which issued as the '675 patent, as well as Application No. 16/980,503 (the "'503 application," Ex. 2003) of which the '675 patent is a continuation. Mot. 8–11. For support, Patent Owner tabulates string citations to the '998 and '503 applications for each claim limitation. *Id.* at 10–11. We note that the specification of the '998 application is identical to the specification of the '503 application. Patent Owner argues that the '675 patent satisfies the written description requirement because "[t]he specification provides structural disclosure of the modified heavy-chain region, identifies the modification site at lysine 248, and describes the chemical moieties corresponding to the claimed modifications." Reply 4.

Based on our review and consideration of the full record, we find that there is sufficient written description support for claims 14–16, and claims 14–16 do not introduce new subject matter. Petitioner does not dispute the portions of the specification that Patent Owner cites in support of these claim elements. *Compare* Opp. 2–5, *with* Mot. 10–11. Petitioner instead argues that the proposed substitute claims lack written description support for claim elements 14[a], 15[a], and 16[a],⁸ which each recite "wherein the modified antibody comprises one or more modified heavy chain" (*see* Opp. 2–5; Mot. 27–30 (App. A)) because "[w]hile the specification describes 'an antibody or a fragment thereof comprising one or more amino acid sequences selected from formula 8-1, formula 8-2, and formula 8-3' . . . a 'modified antibody' that 'comprises one or more modified heavy chain[s]'" as recited in proposed substitute claims 14–16 "may encompass amino acids adjacent to the modified Lys 248 that are

⁸ For ease of reference, we refer to the claim limitations of the proposed substitute claims using the alphanumeric designations listed in Appendix A of Patent Owner's Motion and above. *See* Mot. 27–30.

different from those shown in each of formulas 8-1, 8-2, and 8-3.” Opp. 3 (citing Ex. 2003 ¶ 59).

Petitioner’s argument is unpersuasive. Paragraph 59 of the ’503 application describes formula 8-1 but does not support Petitioner’s argument that other unknown formulas may be included in the recited modified heavy chains. Ex. 2003 ¶ 59. Petitioner’s hypothesis that the recited heavy chains may (or may not) encompass unknown formulas is also inapposite to the written description inquiry before us — that is, whether the inventor was in possession of the subject matter recited in claims 14–16 based on the disclosure including formulas 8-1, 8-2, and 8-3. *See PowerOasis*, 522 F.3d at 1306.

Petitioner next argues that “claims 14-16 necessarily encompass antibodies with exactly/only one modified heavy chain and antibodies with three or more modified heavy chains,” but “the specification only describes antibodies with two modified heavy chains” and “fails to provide any disclosure indicating position of an antibody having exactly/only one modified heavy chain or an antibody with three or more modified heavy chains, and it likewise fails to disclose a process for making or using either such antibody.” Opp. 3–4 (emphasis omitted) (citing Ex. 1059 ¶¶ 17–21). According to Petitioner, “the specification provides only a single example of each claimed modification, and in each instance the sole modified antibody (trastuzumab) has two modified heavy chains.” *Id.* at 4 (citing Ex. 1059 ¶¶ 18–19; Ex. 2003 ¶¶ 1272–329).

Petitioner’s arguments are unpersuasive. Dr. Tumey acknowledges that a skilled artisan “would understand that modification reactions such as those described in [the ’998 application] could produce a trastuzumab molecule with one modified heavy chain, two modified heavy chains, or

zero modified heavy chains.” Ex.1059 ¶ 19. Dr. Tumey’s testimony is consistent with Dr. Zhou’s testimony that “[w]ith regard to modifying the antibody at only one heavy chain, the claim reflects the practical reality of modifying antibodies” and more specifically, “a preparation that has an average DAR [drug-antibody ratio] of approximately 1.0 may reflect a mixture of antibody molecules containing one modified heavy chain while others contain no modified heavy chains” and the “preparations having an average DAR of approximately 1.8 may reflect typical reaction product distributions including modified antibodies that contain two modified heavy chains while others contain fewer than two modified heavy chains.” Ex. 2008 ¶ 47.

Petitioner’s argument (Opp. 4), citing Dr. Tumey’s testimony that “it would require a tremendous amount of work to develop a process that *always* resulted in exactly one modified heavy chain, if it were possible at all” (Ex. 1059 ¶ 20) is not commensurate in scope with the claim language at issue. The claim does not require such a process or an antibody that always has exactly one modified heavy chain and no other. Dr. Tumey’s testimony is unpersuasive as it does not specify what “a tremendous amount of work” entails and does not explain whether the purported amount of work is undue experimentation. In any event, Dr. Tumey’s testimony does not adequately explain why the purported work shows the inventor was not in possession of the antibodies that claims 14–16 recite given the level of ordinary skill in the art. *Ariad*, 598 F.3d at 1340 (“We now reaffirm that § 112, first paragraph, contains a written description requirement separate from enablement[.]”).

Dr. Tumey also testifies that “the phrase ‘one or more modified heavy chain’ logically extends to ‘antibodies’ such as IgM that have five heavy

chains, as well as other proteins that ‘have the same or similar structures’” but “the specification fails to provide any evidence that [Patent Owner] possessed a method to produce a modified form of any antibody that has three or more modified heavy chains[.]” Ex.1059 ¶ 21. Dr. Tumey’s testimony is unpersuasive because it is solely based on the claim term “antibody” without considering the remaining claim elements, such as the “lysine residue at 248 position . . . [as] determined by the EU numbering system,” which further limit the recited antibody. As Dr. Zhou testifies: “A POSA would understand the claim itself to limit the modified antibodies to those with lysine at position 248.” Ex. 2008 ¶ 46.

Petitioner also argues claims 14–16 lack written description support because they omit limitations requiring that the sequence of the Fc domain is SEQ ID NO: 1, which is an essential element of the invention and that a person of ordinary skill in the art would understand is “an essential element because the examples of the ’675 patent rely on sequence affinity to bind to that Fc domain sequence in order to affect the site-specific modification.” Sur-Reply 8–9.

Petitioner’s argument is unpersuasive because the argument is based on the false premise that the scope of claims 14–16 is as broad as the claim term “antibody” without being limited by all other claim elements. That is, Petitioner argues that “the expansive scope of the claims” should include all “naturally occurring immunoglobulins” such as “isotypes IgA, IgD, IgE, IgG, and IgM” as well as “all ‘recombinant proteins, fusion proteins, chimeric proteins, human immunoglobulins, non-human animal immunoglobulins . . . which have the same or similar structures.’” Sur-Reply 2, 3. Petitioner’s argument that claims 14–16 encompass proteins that lack a lysine residue at a 248 position improperly excludes all other claim

elements such as the “lysine residue at 248 position . . . [as] determined by the EU numbering system.” *See id.* at 4 (arguing that “the specification contains no guidance or teaching how to introduce a Lys at a 248 position in proteins that lack it”). Because Petitioner acknowledges that “[t]he disclosure of SSFI that only binds to IgG1 Fc domains (SEQ ID NO:1) is consistent with the limited scope of examples in the ’675 patent” (Sur-Reply 5) and because the scope of the antibody that claims 14–16 recite is limited by all claim elements beyond the recited “modified antibody” such as the lysine residue position 248, we are not persuaded by Petitioner’s argument that the full scope of claims 14–16 lacks written description support. *See Teva Pharms. Int’l GmbH v. Eli Lilly & Co.*, 172 F.4th 1367, 1380 (Fed. Cir. 2026) (holding that there is not “a bright-line, always-applicable rule” for a proper written description inquiry and that “the representativeness inquiry accounts for the specific circumstances of the invention”).

Petitioner also argues that claims 14–16 lack written description support because claim elements 14[a], 15[a], and 16[a] are open-ended, and “encompass modification of antibodies with, for example, four heavy chains (e.g., naturally occurring dimers of IgA; EX1034, Fig. 1) or even ten heavy chains (e.g., naturally occurring pentamers of IgM; EX1034, Fig. 1),” but “[t]he ’675 patent fails to exemplify these additional species that fall within the claimed genus and also insufficiently describes a structure-function relationship.” Sur-Reply 9. Petitioner argues further that claims 14–16 lack written description support because the ’675 patent does not show possession of modified forms of any isotype of immunoglobulin except human IgG1. *Id.*

Petitioner’s arguments that the genus recited in claims 14–16 lack written description support are unpersuasive first and foremost because the

arguments are based on reading all other claim elements out of claims 14–16 but the claim term “antibody.” Petitioner’s arguments also are unpersuasive because Petitioner acknowledges that the inventor was “in possession of the modified lysine structures recited in claims 14-16 in the context of human IgG1.” Sur-Reply 9. Petitioner does not adequately explain why a skilled artisan, based on “[t]he only examples in the ’675 patent [which] relate to modifying a specific human IgG1 (trastuzumab), and the ’675 patent only discloses SSAI/SSFI for modifying human IgG1” (*id.*) would not understand that the inventor was in possession of the invention claimed which encompasses antibodies to which the requirements of claims 14–16 such as the recited lysine position and the recited moieties are applicable. *See Teva*, 172 F.4th at 1374 (holding that “there are no ‘bright-line rules governing . . . the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention”) (quoting *Ariad*, 598 F.3d at 1350).

The ’998 and ’503 applications define “antibody” as “an immunoglobulin molecule or a fragment thereof,” including “naturally occurring immunoglobulins” and “all recombinant proteins, fusion proteins, chimeric proteins, human immunoglobulins, non-human animal immunoglobulins, and the like, which have the same or similar structures.” *See* Ex. 2002 ¶ 209; Ex. 2003 ¶ 208. Dr. Zhou testifies that “each proposed substitute claim describes a modified antibody in which the Fc heavy-chain lysine residue at position 248 (EU numbering) is covalently modified with a specific attachment with a terminal bio-orthogonal click-chemistry functional group. The specification describes targeted transfer of a chemical functional group to lysine 248” and that “[a] POSA would understand the

claim itself to limit the modified antibodies to those with lysine at position 248.” Ex. 2004 ¶ 48; Ex. 2008 ¶ 47.

“Petitioner does not contend that modification at lysine 248 cannot be routinely performed using the ’675 Patent’s method.” *Compare* Reply 2, with Sur-Reply 8–10. Dr. Tumey acknowledges that a skilled artisan “would understand that modification reactions such as those described in [the ’998 application] could produce a trastuzumab molecule with one modified heavy chain, two modified heavy chains, or zero modified heavy chains” (Ex. 1059 ¶ 19), whereas Dr. Zhou’s testimony explains that “[w]ith regard to modifying the antibody at only one heavy chain, the claim reflects the practical reality of modifying antibodies” that “a preparation that has an average DAR of approximately 1.0 may reflect a mixture of antibody molecules containing one modified heavy chain while others contain no modified heavy chains.” Ex. 2008 ¶ 47 (Dr. Zhou further explaining that the “preparations having an average DAR of approximately 1.8 may reflect typical reaction product distributions including modified antibodies that contain two modified heavy chains while others contain fewer than two modified heavy chains”).

Patent Owner also argues that “a POSA would understand that the phrase ‘one or more modified heavy chain’ encompasses antibodies within typical DAR [(‘drug-to-antibody ratios’)] distributions (i.e., fractional numbers) rather than requiring a distinct process for producing antibodies bearing modified heavy chains in exact integers.” Reply 2–3. Moreover, Patent Owner argues that PepTalk Presentation demonstrates that “a POSA would understand antibody conjugation products to exist as mixtures rather than discrete whole number species” because PepTalk Presentation “presents DAR values as non-integer measurements, i.e. DARs of 1.8 and 1.9

reflecting such distributions.” *Id.* at 3 (citing Ex. 1007, 28). According to Patent Owner, “preparations having an average DAR of approximately 1.8 (commonly referred to in practice as ‘DAR2’) may reflect typical reaction distributions in which some antibodies contain two modified heavy chains while others contain fewer.” *Id.* at 3 (citing Ex. 2008 ¶ 46). Petitioner does not rebut these statements. *See* Sur-Reply 2–8.

The record before us shows that, based on “an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art,” the inventor was in possession of the modified antibodies as defined by the claim elements of claims 14–16. *See Ariad*, 598 F.3d at 1351. We accordingly determine that Patent Owner has shown that proposed substitute claims 14–16 are supported by the ’675 patent and do not introduce new matter.

5. Conclusion Regarding Statutory and Regulatory Requirements

In view of the foregoing, we determine that Patent Owner has shown that proposed substitute claims 14–16 meet the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121.

E. Unpatentability

Having considered whether Patent Owner has shown that claims 14–16 meet the statutory and regulatory requirements for a motion to amend, we next consider whether Petitioner demonstrates that the claims are unpatentable. Petitioner contends claims 14–16 are unpatentable because they lack written description support, lack enablement, are indefinite, are anticipated, and would have been obvious. We discuss each of these grounds of unpatentability and related issues below.

1. Level of Ordinary Skill in the Art

Determining whether an invention would have been obvious under 35 U.S.C. § 103 requires resolving the level of ordinary skill in the pertinent art at the time the invention was made. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The person of ordinary skill in the art is a hypothetical person who knows the relevant art. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Factors in determining the level of ordinary skill in the art include the types of problems encountered in the art, the sophistication of the technology, and the educational level of active workers in the field. *Id.* One or more factors may predominate. *Id.*

Petitioner contends that a person of ordinary skill in the art (“POSA”) in the field of the ’675 patent

as of the earliest claimed priority date or the filing date of the ’675 Patent would have had specialized knowledge in the field of antibody-drug conjugates, which would entail (1) a Ph.D. degree in organic chemistry, biochemistry, medicinal chemistry, and/or pharmacology, along with at least 1-2 years of relevant applied research and/or industry experience in the field of antibodies or antibody-drug conjugates, or, alternatively, (2) a Master’s or Bachelor’s degree in one of the aforementioned fields with at least 3-5 years, or 5-7 years, respectively, of relevant applied research and/or industry experience in the field of antibodies or antibody-drug conjugates. That person would have familiarity, gained through study, training, and/or experience, with the design and development of antibody-drug conjugates and antibody modifications.

Pet. 3 (citing Ex. 1002 ¶ 36).

Patent Owner does not address the specific knowledge that Petitioner contends that ordinarily skilled artisan would possess. *See generally* Mot.

We adopt Petitioner’s unopposed definition of the level of ordinary skill in the art as it appears consistent with the disclosures of the ’675 patent

and the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

2. Claim Construction

In an *inter partes* review, we apply the same claim construction standard as would be used by a district court to construe a claim in a civil action involving the validity or infringement of a patent. 37 C.F.R. § 42.100(b). Under that standard, claim terms are given their ordinary and customary meaning, as would have been understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc); *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365–66 (Fed. Cir. 2012). “The Board is required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’” *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (quoting *Vivid Techs., Inc. v. Am. Sci. Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner proposes express constructions for multiple claim terms. Pet. 9–13. Patent Owner does not address Petitioner’s proposed claim constructions, nor does Patent Owner propose its own claim constructions. *See generally* Mot. After reviewing Petitioner’s arguments and the evidence before us, we determine that we do not need to expressly construe any claim term to resolve any controversy in the proceeding.

3. Written Description

Petitioner contends claims 14–16 lack written description support. Opp. 2–5; Sur-Reply 8–10. Patent Owner disagrees. Reply 3–4. For the reasons discussed above, we determine Petitioner has not demonstrated by a

preponderance of the evidence that claims 14–16 lack written description support. *See* § III.D.4, *supra*.

4. *Enablement*

Petitioner contends claims 14–16 are not enabled. Opp. 2–5; Sur-Reply 2–8. Patent Owner disagrees. Reply 1–3. We address the parties’ arguments below.

a. *Legal Standards*

The enablement requirement asks whether “the specification teach[es] those in the art to make and use the invention without undue experimentation.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). “[T]he specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable.” *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023). To satisfy this requirement, “[t]he specification must contain sufficient disclosure to enable an ordinarily skilled artisan to make and use the entire scope of the claimed invention at the time of filing.” *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012). “Enablement is a question of law based on underlying factual findings.” *Id.* at 1380.

In analyzing undue experimentation, we consider:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Wands, 858 F.2d at 737.

b. Analysis

In the Opposition, Petitioner argues that claims 14–16 are not enabled and lack written description under the same heading without separate analyses. Opp. 2–5. Our reviewing court has emphasized that “§ 112, first paragraph, contains a written description requirement separate from enablement,” *Ariad*, 598 F.3d at 1340, and Petitioner’s argument in the Opposition that the enablement requirement is not satisfied “given the scope of a ‘modified antibody’ that ‘comprises one or more modified heavy chain[s]’” (Opp. 5) does not sufficiently explain why any purported experimentation is “undue.” *Ariad*, 598 F.3d at 1352 (explaining that written description and enablement are separate requirements “although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described.”). Petitioner’s assertion that the scope of claims 14–16 is broad (Opp. 5) alone does not establish that these claims are not enabled because “[t]hat some experimentation is necessary does not constitute a lack of enablement.” *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212 (Fed. Cir. 1991) (“The essential question here is whether the scope of enablement of [the claim at issue] is as broad as the scope of the claim.”).

As we note *supra*, Petitioner’s argument (Opp. 4), citing Dr. Tumey’s testimony that “it would require a tremendous amount of work to develop a process that *always* resulted in exactly one modified heavy chain, if it were possible at all” (Ex. 1059 ¶ 20) is not commensurate in scope with the claim language at issue, which does not require such a process or an antibody that always has exactly one modified heavy chain and no other. *See also* Ex.

1059 ¶ 19; Ex. 2008 ¶ 47. Dr. Tumey’s testimony does not specify what “a tremendous amount of work” entails and does not explain whether the purported amount of work is undue based on the knowledge of the ordinary artisan. Although a proper enablement analysis does not always require an analysis of every *Wands* factor, the analysis must provide evidence establishing that “the requisite amount of experimentation is undue” to make and use the full scope of the invention. *Elan Pharms., Inc. v. May Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054–55 (Fed. Cir. 2003). Dr. Tumey’s testimony does not provide the requisite evidence.

Petitioner’s separate enablement arguments in the Sur-Reply fare no better. Petitioner argues that the ’675 patent does not enable claims 14–16 because the ’675 patent does not

teach a skilled person how to make a ‘modified antibody’ with sequences other than 8-1, 8-2, and 8-3 comprising “one or more modified heavy chain” across the full scope of all “naturally occurring immunoglobulins” and “all recombinant proteins, fusion proteins, chimeric proteins, human immunoglobulins, non-human animal immunoglobulins . . . which have the same or similar structures.”

Sur-Reply 2–3 (quoting Ex. 1001, 23:40–54). Petitioner argues that “[N]aturally occurring immunoglobulins’ include isotypes IgA, IgD, IgE, IgG, and IgM, and ‘IgG and IgA isotypes can be further divided into six subclasses . . . that also have unique structural differences, primarily in the hinge region’” such that a POSA “knew that Fc domains of these immunoglobulins each have ‘unique structural features that impact antibody function.’” *Id.* at 3 (modifications in original, citing Ex. 1002 ¶¶ 67, 80; Ex. 1034, 3). Given these differences, Petitioner argues “the specification contains no guidance or teaching how to introduce a Lys at a 248 position in proteins that lack it, nor would it be a simple matter of ‘recognizing’ which

Fc domain sequences beyond 8-1, 8-2, and 8-3 would work as asserted by Patent Owner.” *Id.* at 4.

Petitioner argues further that a POSA would not “simply ‘recognize which antibodies have a heavy chain Fc domain that can be substituted with the claimed moieties.’” Sur-Reply 5. More specifically, Petitioner argues that the ’675 patent describes a “site-specific antibody interactome” (“SSAI”) which is “a novel peptide for bringing a molecule to be labeled into close contact with a certain site of an antibody,” and a “site-specific Fc interactome” (“SSFI”) which “may have binding activity for the Fc domain of the antibody.” *Id.* at 4 (quoting Ex. 1001, 33:18–23, 33:39–40). However, according to Petitioner, the ’675 patent “only discloses SSAI that [] bind to an Fc domain (i.e., the ’675 patent only discloses SSFI), and to this end, it only discloses SSFI designed to bind to IgG1 SEQ ID NO: 1 and ‘acceptable’ variant sequences 8-1, 8-2 and 8-3.” *Id.* (citing Ex. 1001, 28:27–37). Petitioner argues that the ’675 patent discloses that “the precise sequence of the Fc domain (SEQ ID NO:1) impacts whether or not it is possible for the SSFI to succeed in modifying the Lys 248 residue.” *Id.* at 5.

Petitioner summarizes the argument as the following:

Because IgA, IgM, IgD, and IgE have altogether distinct Fc domains relative to IgG, modifying these immunoglobulins would require an entirely different, undisclosed and untested SSAI/SSFI in order to make a “modified antibody” with “one or more modified heavy chain” according to any one of claims 14-16. Moreover, in instances in which the “modified antibody” does not naturally have a lysine at position 248, incorporating “a modified lysine residue at 248 position of heavy chain amino acid sequence” into the “one or more modified heavy chain” would further require a substitution of the native amino acid at position 248 as well, which is nowhere taught, described, or exemplified in the ’675 patent.

Sur-Reply 6.

These arguments in the Sur-Reply are unpersuasive to show a lack of enablement first and foremost because the arguments do not specifically provide evidence showing that any purported experimentation is undue. *See* Sur-Reply 2–8 (asserting, but without providing evidence under any specific *Wands* factors, that the examples and guidance in the specification do not extend to the broad scope of all antibodies); *see Wands*, 858 F.2d at 737. We again emphasize that the analysis of undue experimentation does not necessarily require every *Wands* factor to be explicitly addressed but the analysis must be based on “weighing many factual considerations” depending on the nature of the invention and underlying art. *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013). The assertion that the claim scope is broad alone does not suffice to show a lack of enablement based on the record before us.

Moreover, as we note *supra*, Petitioner’s claim scope argument is based on the false premise that the scope of claims 14–16 is as broad as the claim term “antibody” without taking into account all other claim elements. For example, Petitioner does not disagree with Patent Owner’s statement that “[t]he ’675 Patent’s specification discloses the structural modification site, the chemistry used to modify that residue, and working examples demonstrating the modification” (Reply 2), but asserts only that “[t]he disclosure of SSFI that only binds to IgG1 Fc domains (SEQ ID NO:1) is inconsistent with the expansive scope of the claims.” Sur-Reply 5. Petitioner’s argument that the claims encompass proteins that lack a lysine residue at a 248 position improperly excludes from the claim language the “lysine residue at 248 position . . . [as] determined by the EU numbering system” that claims 14–16 require. As Dr. Zhou testifies, “each proposed

substitute claim describes a modified antibody in which the Fc heavy-chain lysine residue at position 248 (EU numbering) is covalently modified with a specific attachment with a terminal bio-orthogonal click-chemistry functional group. The specification describes targeted transfer of a chemical functional group to lysine 248” and when claims 14–16 are considered in their entirety, which includes all claim elements, “[a] POSA would understand the claim itself to limit the modified antibodies to those with lysine at position 248.” Ex. 2004 ¶ 48; Ex. 2008 ¶ 47.

We also note that Patent Owner states “a POSA would understand that the phrase ‘one or more modified heavy chain’ encompasses antibodies within typical DAR distributions (i.e., fractional numbers) rather than requiring a distinct process for producing antibodies bearing modified heavy chains in exact integers.” Reply 2–3. Moreover, Patent Owner states that PepTalk Presentation demonstrates that “a POSA would understand antibody conjugation products to exist as mixtures rather than discrete whole number species” because PepTalk Presentation “presents DAR values as non-integer measurements, i.e. DARs of 1.8 and 1.9 reflecting such distributions.” *Id.* at 3 (citing Ex. 1007, 28). According to Patent Owner, “preparations having an average DAR of approximately 1.8 (commonly referred to in practice as ‘DAR2’) may reflect typical reaction distributions in which some antibodies contain two modified heavy chains while others contain fewer.” *Id.* at 3 (citing Ex. 2008 ¶ 46). Petitioner does not rebut these statements. *See* Sur-Reply 2–8.

Based on the foregoing, the evidence before us does not show any purported experimentation is undue. *See Wands*, 858 F.2d at 737. We accordingly determine that Patent Owner has shown that proposed substitute claims 14–16 are enabled by the specification of the ’675 patent.

c. Conclusion Regarding Enablement

Based on the foregoing, we determine that Petitioner has not shown by a preponderance of the evidence that limitations 14[a], 15[a], and 16[a] are not enabled.

5. Indefiniteness

Petitioner contends claims 14–16 are indefinite. Opp. 5–6. Patent Owner disagrees. Reply 4–5. We address the parties’ arguments below.

a. Legal Standards

“[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). “Where it would be apparent to one of skill in the art, based on the specification, that the invention set forth in a claim is not what the patentee regarded as his invention, we must hold that claim invalid under § 112, paragraph 2.” *Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1348–49 (Fed. Cir. 2002).

b. Analysis

Petitioner contends proposed substitute claims 14–16 are indefinite because they each recite “[a] modified antibody comprising a bio-orthogonal click chemistry functional group” in the preamble but do not reference a “bio-orthogonal click chemistry functional group” in any of the other claim limitations. Opp. 5–6 (emphasis omitted). As a result, Petitioner argues that a person of ordinary skill in the art could interpret the claims in at least two ways: wherein the modified lysine 1) “is the same as the earlier referenced ‘bio-orthogonal click chemistry group,’” or 2) “represents a separate structure containing a bio-orthogonal click chemistry group in addition to

the other ‘bio-orthogonal click chemistry functional group’ referenced earlier in the claim.” *Id.* at 6 (emphasis omitted).

Patent Owner responds that “Petitioner’s indefiniteness argument ignores the structure of the claim and improperly isolates individual phrases rather than reading the claim language as a whole as required under *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014).”

Reply 4. Patent Owner argues that “when read as a whole, each proposed substitute claim could not, as Petitioner contends, be understood as describing a modified lysine structure containing a bio-orthogonal click chemistry group and a separate bio-orthogonal click chemistry functional group elsewhere.” *Id.* at 5.

Petitioner does not respond to Patent Owner’s argument. *See generally* Sur-Reply.

We are not persuaded that proposed substitute claims 14–16 are indefinite. “[A] claim is not indefinite merely because its scope is not ascertainable from the face of the claims.” *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003). Rather, “[a] claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention.” *Id.*

Here, the specification of the ’675 patent describes various formulas of compounds and antibodies that include “first click chemistry functional group[s]” labeled as H₁. *See, e.g.*, Ex. 1001, 3:3–25, 8:1–42. The specification discloses that H₁ “is selected from norbornene, tetrazine, azide and dibenzocyclooctyne-amine.” *Id.* at 3:22–25. Given these disclosures, the record indicates that a person of ordinary skill in the art reading the claims in light of the specification would have understood that the modified lysine residues recited in proposed substitute claims 14–16 (azide and norbornene)

are the bio-orthogonal click chemistry functional groups recited in the preambles. More specifically, the preambles of proposed substitute claims 14–16 each recite “[a] modified antibody comprising a bio-orthogonal click chemistry functional group,” and the remaining limitations of the claims provide the location and structure of the claimed bio-orthogonal click chemistry functional groups by reciting modified heavy chains and modified lysine residues described in the specification. Mot. 27–30 (App. A); *see also* Ex. 1001, 3:3–25, 8:1–42.

c. Conclusion Regarding Indefiniteness

Based on the foregoing, we determine that Petitioner has not shown by a preponderance of the evidence that proposed substitute claims 14–16 are indefinite.

6. Anticipation by CA959

Petitioner alleges claims 14–16 are anticipated by CA959. Opp. 7–10; Sur-Reply 10. Patent Owner disagrees. Reply 5. We address the parties’ arguments below.

a. Legal Standards

A claim may be unpatentable as anticipated 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) (citation 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).

b. Summary of CA959

The parties agree that CA959 is entitled to the same priority date as the provisional application, filed on March 8, 2019. Pet. 22; Prelim. Resp. 5. The parties agree that CA959 and '675 patent contain essentially identical disclosures. Pet. 16; *see* Prelim. Resp. 9.

c. Analysis

Petitioner contends CA959 qualifies as prior art to the '675 patent because “the '675 Patent and the applications to which it claims priority (e.g., EX1004, 2002 & 2003) do not enable or provide sufficient written description for claims 14-16” for the reasons discussed above. Opp. 7; *see also* Sur-Reply 10. Petitioner contends the proposed substitute claims are anticipated by Example 3 of CA959. Opp. 7–10.

Patent Owner argues that CA959 is not prior art to the '675 patent or the proposed substitute claims under 35 U.S.C. § 102(a) because it was not published before the effective filing date, and the inventors are the same. Mot. 13. Patent Owner contends “the earlier-filed applications disclose every limitation of each of proposed substitute claims 14-16,” and claims 14–16 are entitled to their claimed priority dates because they are fully supported by the earlier-filed applications. Reply 5.

The record before us indicates that CA959 does not qualify as prior art against the '675 patent. Under 35 U.S.C. § 120, “in a chain of continuing applications, a claim in a later application receives the benefit of the filing date of an earlier application so long as the disclosure in the earlier application meets the requirements of 35 U.S.C. § 112, ¶ 1, including the written description requirement, with respect to that claim.” *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326 (Fed. Cir. 2008). As discussed above, Petitioner has not shown that claim elements 14[a], 15[a], and 16[a]

lack written description support and/or are not enabled. As a result, CA959 shares the priority chain of the '675 patent because it claims the benefit of the same provisional application as the '675 patent, U.S. Provisional Application No. 62/815,557, filed on March 8, 2019. *Compare* Ex. 1001, code (60) *with* Ex. 1005, code (30). Accordingly, CA959 has the same priority date as the '675 patent and is not prior art to the '675 patent under 35 U.S.C. § 102.

d. Conclusion Regarding Anticipation

Based on the foregoing, we determine that Petitioner has not shown by a preponderance of the evidence that proposed substitute claims 14–16 are anticipated by CA959.

7. Obviousness

Petitioner argues the proposed substitute claims would have been obvious over Yamada and Matsuda for the same reasons discussed in the Petition. Opp. 14–19 (citing Pet. 49–56); Sur-Reply 11–12. Petitioner also argues the proposed substitute claims would have been obvious over PepTalk Poster or PepTalk Presentation, combined with Yamada and Matsuda. Opp. 20–23; Sur-Reply 11–12. Patent Owner disagrees. Reply 6–11. We address the parties' arguments below.

a. Legal Standards

A patent claim is unpatentable under 35 U.S.C. § 103 if “the differences between the subject matter sought to be patented 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.” The question of obviousness is resolved based on 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 presented, objective evidence of obviousness or nonobviousness, i.e., secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

The obviousness inquiry typically requires an analysis of “whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”)). A patent claim “is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* In particular, “[a]lthough the *KSR* test is flexible, the Board ‘must still be careful not to allow hindsight reconstruction of references . . . without any explanation as to *how* or *why* the references would be combined to produce the claimed invention.’” *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1066 (Fed. Cir. 2016) (alteration in original) (quoting *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1368 (Fed. Cir. 2012) (emphases added)). An obviousness determination based on a combination of references requires finding “both ‘that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.’” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016) (quoting *Kinetic Concepts*, 688 F.3d at 1360); *see KSR*, 550 U.S. at 418. Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements,” but “must instead articulate specific reasoning, based on evidence of record, to support the legal

conclusion of obviousness.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016); *see also In re NuVasive, Inc.*, 842 F.3d 1376, 1383 (Fed. Cir. 2016) (a finding of a motivation to combine “must be supported by a ‘reasoned explanation’” (citation omitted)).

b. Obviousness over Yamada and Matsuda

i. Summary of Yamada

Yamada, titled “Compound Having Affinity Substance to Soluble Protein, Cleavable Portion and Reactive Group, or Salt Thereof” “provides a technique enabling modification of a soluble protein and in particular regioselective modification of a soluble protein.” Ex. 1009, codes (54), (57). The ’675 patent describes Yamada in multiple paragraphs. Pet. 7. For example, the ’675 patent notes that Yamada “is similar to the present invention in terms of the form of an agent for transferring a first chemical functional group to an antibody, but is different . . . in that the cross-linker includes two NHS esters.” Ex. 1001, 33:4–8. The ’675 patent notes that Yamada “aims to site-selectively modulate lysine 246 or 248 in an Fc domain using an analogue of Fc-III and use a biorthogonal functional group.” *Id.* at 69:48–51. The ’675 patent, however, also states that “any lysine residue is highly likely to be labeled” in Yamada because “the first carbonyl group has high reactivity and has no vicinity condition for reaction.” *Id.* at 69:54–56. According to the ’675 patent, this is because Yamada “uses a disuccinimidyl cross-linker” resulting in “the first carbonyl group and the second carbonyl group [being] equally highly reactive.” *Id.* at 69:51–53. The ’675 patent provides two reasons why “the uniformity and yield of the antibody may be inevitably low” when Yamada “site-selectively modulate[s] lysine 246 or 248 in an Fc domain using an analogue of Fc-III.” *Id.* at 70:13–18.

ii. Summary of Matsuda

Matsuda, titled “Compound Having Affinity Substance to Antibody and Biorthogonal Functional Group, or Salt Thereof,” provides “novel techniques enabling modification of an antibody, particularly regioselective modification of an antibody.” Ex. 1011, code (54), ¶ 8. Matsuda observes that “when the number of bonds and the bond positions of a drug of an ADC are changed, pharmacokinetics, and a releasing rate and effects of the drug change” and notes that “next-generation ADCs are required to control the number and positions of a drug to be conjugated.” *Id.* ¶ 4. Matsuda states that “when the number and positions are fixed, the problems of expected efficacy, variations in conjugation medicines, and lot difference, or what is called regulation, will be solved.” *Id.*

iii. Analysis

(1) Claims 14 and 16

Petitioner argues that Yamada’s Formula (IV), L1-B-R’-T, teaches the modified lysine structure recited in claims 14 and 16. Opp. 15. Citing Dr. Tumey’s declaration, Petitioner argues Yamada teaches the necessary components for Formula (IV) to arrive at the structures recited in claims 14 and 16, and a person of ordinary skill in the art would have been motivated to select the components of those structures. *Id.* at 17 (citing Ex. 1059 ¶¶ 29–36, 38–43). Petitioner also provides two flow charts, prepared by Dr. Tumey, illustrating how to assemble the modified lysine structures recited in claims 14 and 16 from Yamada’s Formula (IV). *Id.* at 15–17 (citing Ex. 1002 ¶ 276).

More specifically, Petitioner argues that a person of ordinary skill in the art would have been motivated to select the components in the structures recited in claims 14 and 16 because Yamada and Matsuda disclose azide and

norbornene as suitable functional groups, and azide and norbornene were “among the most well-established and commonly used click chemistry groups at the time.” Opp. 17 (citing Ex. 1050; Ex. 1053; Ex. 1054; Ex. 1055; Ex. 1059 ¶¶ 31–32, 39).

Petitioner argues that a person of ordinary skill in the art would have selected the linker connecting the click chemistry group to lysine in claims 14 and 16 because short linkers were preferred as “they provide flexibility, which can be helpful for subsequent reactions, and both Yamada and Matsuda (as well as the PepTalk References) disclose short alkyl linkers similar to those in the claims.” Opp. 17 (citing Ex. 1002 ¶¶ 256, 267, 351, 362; Ex. 1059 ¶¶ 33–36, 39–43). Moreover, Petitioner argues that a person of ordinary skill in the art would have used a linker with an oxygen ether heteroatom because “[b]oth Yamada and Matsuda provide multiple examples of linkers with a heteroatom,” and an oxygen heteroatom “would provide stability in a variety of reaction conditions and improve solubility in circulation.” *Id.* at 17–18 (citing Ex. 1009 ¶¶ 622, 633; Ex. 1011 ¶¶ 1154, 1161–68; Ex. 1059 ¶¶ 34–35, 50–52, 75).

Patent Owner, on the other hand, argues Petitioner has not shown that (1) a POSA would have selected the structures of the claimed moieties; and (2) a POSA would have had a reasonable expectation of success in making the claimed moieties. Reply 6–11. Patent Owner argues:

Petitioner does not identify a prior art disclosure of how to make the claimed moieties that does not teach away from them because *Yamada* does not disclose how to make them, *Matsuda* teaches away from the ether oxygen (β)-heteroatom spacer, and Petitioner’s new references are either not prior art or do not provide a scientifically feasible way to make the claimed moieties.

Reply 6 (citing Ex. 2008 ¶¶ 2–10). Patent Owner also argues that “Petitioner does not provide a single source for all of the limitations of the proposed substitute claims, and continues to use *Yamada* as a chemical encyclopedia without it giving any particular direction or preference for a substitution.”

Reply 6. According to Patent Owner, “*Yamada* discloses millions or billions of compounds in the variable structure of Formula (IV) L1-B-R’-T,” but “Formula (IV) is not a standalone class of compounds, but is the product of a specific reaction: the synthesis in Figure 2,” which the parties agree “cannot produce the claimed compounds.” *Id.* at 7 (citing Ex. 2008 ¶¶ 32–34).

Moreover, Patent Owner argues that *Yamada* and *Matsuda* do not disclose a modified antibody example with a norbornene group (claim 16) or a modified antibody with a (β) ether spacer (claims 14 and 16). Reply 7 (citing Ex. 2008 ¶¶ 26–34). More particularly, Patent Owner contends “*Yamada* does not disclose an ether spacer in any example, and the only ‘oxygen, specifically’ is a carbonyl oxygen, which is not the same.” *Id.* at 8 (citing Ex. 2008, ¶¶ 29, 35).

Regarding *Matsuda*, Patent Owner argues that the reference “provides no instance of a (β)-heteroatom that worked—each did not progress.” Reply 8 (citing Ex. 2008 ¶¶ 29, 35); *see also id.* at 10. Patent Owner asserts that “a POSA reading *Matsuda* would understand that the ether-containing spacer required by proposed substitute claims 14 and 16 was disfavored relative to other alternative spacer designs disclosed in *Matsuda*,” but “Petitioner relies on *Matsuda* to justify pursuing precisely that approach, without identifying any teaching or suggestion that a POSA would have selected the ether-containing spacer or expected it to succeed under the reaction conditions required to generate the claimed moieties.” *Id.* at 10 (citing Ex. 2008 ¶¶ 42–43).

Petitioner responds by arguing that Dr. Zhou's opinions are entitled to little or no weight because they are "devoid of any substantiating citation or reference to underlying facts." Sur-Reply 11. Petitioner argues further that "[t]he cited art teaches the necessary components of Yamada Formula (IV) to arrive at claims 14–16," and a POSA would have had a motivation to select those components. *Id.* at 12 (citing Ex. 1059 ¶¶ 29–36, 38–43).

Having considered all evidence and arguments before us, we are not persuaded that a preponderance of the evidence shows claims 14 and 16 would have been obvious over Yamada and Matsuda. As Patent Owner points out, Petitioner does not adequately explain why the combination of Yamada and Matsuda teaches or suggests an ether spacer as claims 14 and 16 both require. Reply 7–8. Petitioner acknowledges that neither Yamada nor Matsuda discloses the ether spacer but only that they "disclose short alkyl linkers similar to those in the claims." Opp. 17; *see also* Ex. 1059 ¶ 17 (Dr. Tumey testifying that "'when an azide group' is used, the linker/spacer 'would most likely be an alkyl or cycloalkyl'").⁹

Petitioner, citing Dr. Tumey's testimony (Opp. 17), does not adequately explain why a skilled artisan would have specially chosen azide

⁹ We note that Dr. Tumey and Petitioner do not clearly distinguish the terms "linker" and "spacer" and use them interchangeably. For example, Dr. Tumey provides his analysis regarding the "linker/spacer" issue and states that "Yamada specifically disclosed short alkyl linker/spacers that can optionally include a heteroatom, and link/spacer constructs like these were commonly used at the time." Ex. 1059 ¶ 36, ¶¶ 33–36; *see* Opp. 17 (citing Ex. 1059 ¶¶ 33–36 for the proposition that "[s]hort linkers—like those in claims 14 and 16—were preferred . . . and both Yamada and Matsuda (as well as the PepTalk Reference) disclose short alkyl linkers similar to those in the claims"). In this Decision, we use Patent Owner's term "spacer" unless we are quoting from Dr. Tumey or Petitioner.

and norbornene from the large list of possible functional groups in Yamada with regard to lysine residue 248 as the claims require. *See* Ex. 1009 ¶¶ 626–27 (Yamada listing various possible functional groups). More specifically, Dr. Tumey testifies that “[n]orbornene is repeatedly described in Yamada as a suitable biorthogonal click chemistry group for modifying the lysine at position 248” and that “norbornene-tetrazine click chemistry was also well-established and commonly used in bio-orthogonal click reactions at the time the ’675 Patent was filed.” Ex. 1059 ¶ 39. Dr. Tumey testifies that “Yamada itself presents an azide at the beginning of the list of suitable biorthogonal functional groups (it is the third group listed), and azide-cycloalkyne click chemistry was among the most well-established and commonly utilized bio-orthogonal click reactions at the time” of the ’675 patent. *Id.* ¶ 32.

Dr. Tumey testifies that both PepTalk Poster and PepTalk Presentation “teach using an azide as the biorthogonal function group,” but they do not explain why a skilled artisan would have chosen the azide as the functional group for lysine residue 248 as claim 14 requires. *Id.* ¶ 53 (Dr. Tumey testifying instead that “neither reference provides a person of ordinary skill any reason to avoid modifications at this site”). The mere assertion that azide and norbornene are well-known click chemistry groups does not, in and of itself, suffice as the requisite reason to be chosen by the skilled artisan with regard to lysine residue 248 as the claims require. *Ruschig* explained this standard by analogizing a genus and its constituent species to a forest and its trees, noting that:

It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail . . . to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

In re Ruschig, 379 F.2d 990, 994–95 (CCPA 1967). We find Petitioner has not identified any blaze marks directing the ordinary artisan to select species within the scope of the instant claims.

Based on the foregoing, we determine Petitioner has not shown by a preponderance of the evidence that proposed substitute claims 14 and 16 would have been obvious over Yamada and Matsuda.

(2) Claim 15

Petitioner contends a person of ordinary skill in the art would have been motivated to select the components in the structure recited in claim 15 because Yamada and Matsuda disclose norbornene as a suitable functional group, and norbornene was “among the most well-established and commonly used click chemistry groups at the time.” Opp. 17 (citing Ex. 1050; Ex. 1053; Ex. 1054; Ex. 1055; Ex. 1059 ¶¶ 31–32, 39).

Petitioner argues further that a person of ordinary skill in the art would have prepared a modified lysine with no linker as recited in claim 15 to keep the molecule simple. Opp. 18 (citing Ex. 1059 ¶ 41).¹⁰ Dr. Tumey opines that “a person of ordinary skill preparing a modified lysine with a norbornene as the terminal bio-orthogonal click chemistry group would logically start by preparing the simplest structure, which is the structure recited in proposed substitute claim 15.” Ex. 1059 ¶ 41. Dr. Tumey explains that the structure of claim 15 “would serve as the standard of comparison (i.e., control) to determine the functional impact of adding a spacer/linker” because “there is always a logical and implicit need to begin one’s

¹⁰ Petitioner states that, “[w]ith respect to claim 16, a POSA would have been motivated to keep molecules simple by preparing a modified lysine with no linker.” Opp. 18 (citing Ex. 1059 ¶ 41). We understand the sentence to refer to claim 15 instead of 16.

development with the simplest modification and then iterate and develop from there.” *Id.*

Patent Owner, on the other hand, argues that Yamada and Matsuda do not disclose a modified antibody example with a norbornene group or a modified antibody without a spacer. Reply 7 (citing Ex. 2008 ¶¶ 26–34).

We are not persuaded that a preponderance of the evidence shows claim 15 would have been obvious over Yamada and Matsuda. Petitioner, citing Dr. Tumey’s testimony, does not establish, by a preponderance of the evidence, why the combination of Yamada and Matsuda teaches or suggests the spacer-free structure as claim 15 requires. Dr. Tumey testifies that “there is an implicit motivation to keep molecules simple, a la Occam’s razor. . . . As a result, a person of ordinary skill preparing a modified lysine with a norbornene as the terminal biorthogonal click chemistry group would logically start by preparing the simplest structure, which is the structure recited in proposed substitute claim 15.” Ex. 1059 ¶ 41. Dr. Tumey testifies that “there was a motivation for a person of ordinary skill to prepare the modified lysine of proposed substitute claim 15.” *Id.* Dr. Tumey’s testimony does not cite to evidence in the record and is uncorroborated.

Petitioner’s arguments with regard to norbornene are addressed *supra* in the analysis of claim 16. As we note with regard to claim 16, the mere assertion that norbornene is a well-known click chemistry group does not, in and of itself, suffice as the requisite reason to be chosen by the skilled artisan with regard to lysine residue 248 as claim 15 require.

Based on the foregoing, we determine Petitioner has not shown by a preponderance of the evidence that proposed substitute claim 15 would have been obvious over Yamada and Matsuda.

*c. Obviousness over PepTalk Poster or PepTalk
Presentation, Combined with Yamada and Matsuda*

i. Summary of PepTalk Poster¹¹

Petitioner states that PepTalk Poster “was presented at an annual scientific conference called ‘PepTalk: The Protein Science Week’ held from January 14-18, 2019, in San Diego, California.” Pet. 23. PepTalk Poster relates to “antibody-drug conjugates (ADCs)” which “can be expected to provide treatment breakthroughs by offering increased efficacy and decreased toxicity compared to traditional chemotherapeutic cancer treatments.” Ex. 1006. PepTalk Poster describes a “site-specific conjugation technique[]” known as AJICAP¹² which may “conjugate payloads with a native mAbs [monoclonal antibody] chemically in a site-specific manner.” *Id.* Figure 1 below reproduces an illustration from PepTalk Poster showing the capability of the AJICAP technique. *Id.*

¹¹ Based on our review of the record before us, PepTalk Poster qualifies as prior art. *See* Pet. 23–26. Patent Owner does not contest the prior art status of this reference. *See generally* Mot.; Reply.

¹² The term “AJICAP” usually appears in the record with a trademark or “TM” designation. *See, e.g.*, Ex. 1006. In this proceeding, we do not express any view on whether the term “AJICAP” is properly designated as a trademark.

1. Capability of **AJICAP™**

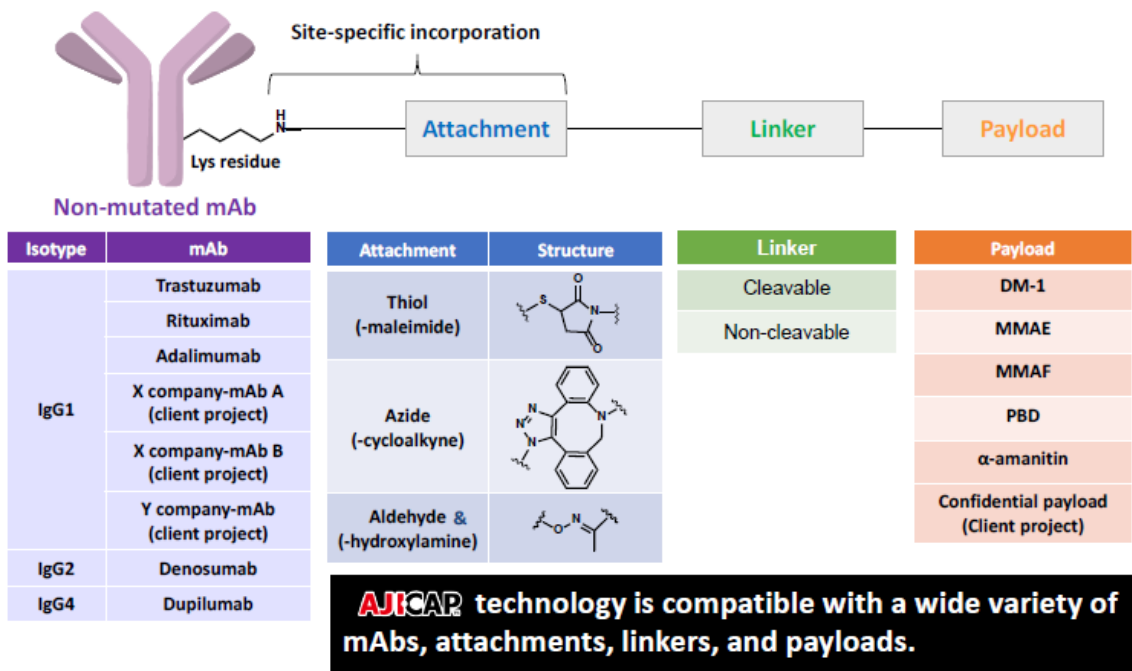


Fig. 1 — A reproduction of an illustration of PepTalk Poster.

Figure 2 below reproduces an illustration from PepTalk Poster showing a target lysine residue as 248. *Id.*

2. Determine Target Lysine Residue

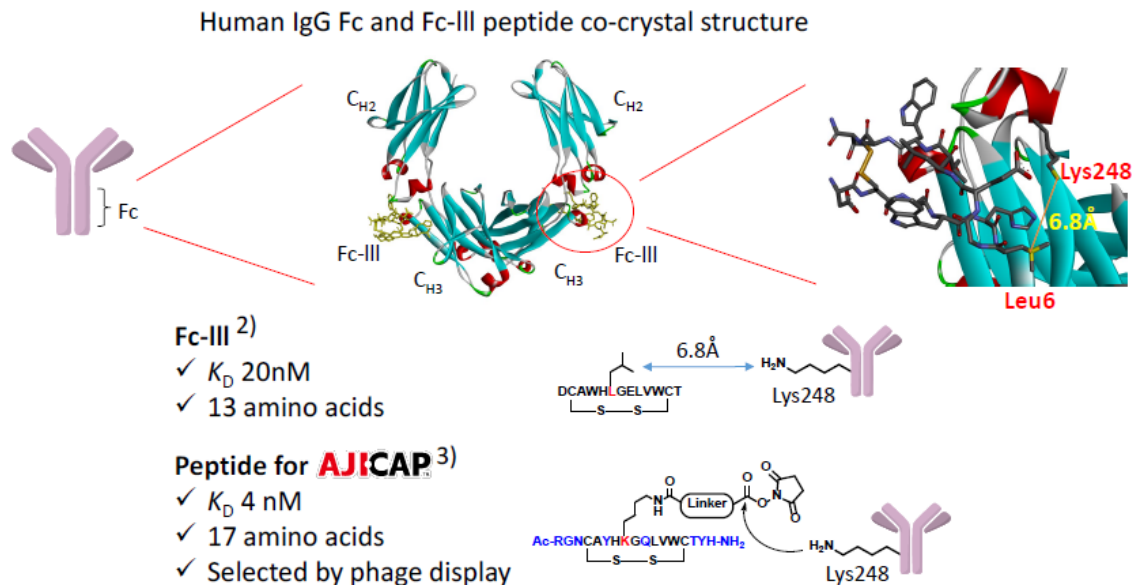


Fig. 2 — A reproduction of an illustration of PepTalk Poster.

ii. Summary of PepTalk Presentation¹³

Petitioner states that PepTalk Presentation “was presented on January 16, 2019, at the same 2019 PepTalk conference” as PepTalk Poster. Pet. 26. According to Petitioner, the “PepTalk Presentation contains much of the same information as PepTalk Poster” with additional technical details. *Id.* at 57 (citing various portions of Ex. 1007).

iii. Analysis

Petitioner argues the proposed substitute claims would have been obvious over PepTalk Poster or PepTalk Presentation, combined with Yamada and Matsuda. Opp. 20–23. In addition to the teachings discussed above for the proposed combination of Yamada and Matsuda, Petitioner contends “the PepTalk References teach an azide as a suitable bio-

¹³ Based on our review of the record before us, PepTalk Presentation qualifies as prior art. See Pet. 26–28. Patent Owner does not contest the prior art status of PepTalk Presentation. See generally Mot.; Reply.

orthogonal click chemistry group to modify the lysine at position 248, and they disclose a linker that differs from the linker of claim 14 only with respect to the oxygen ether.” Opp. 20 (citing Ex. 1006; Ex. 1007, 16, 20; Ex. 1059 ¶¶ 47, 49); *see also id.* at 22. Petitioner also argues “Yamada and Matsuda likewise disclose the use of an azide, and Matsuda discloses an azide structure that only differs from claim 14 by having a carbon in the beta position instead of an oxygen.” *Id.* at 21 (citing Ex. 1009, Figs. 1–2, ¶¶ 151–53, 581–98, 607, 1019, 1108–09, 1944–71; Ex. 1011 ¶¶ 92, 593, 739; Ex. 1059 ¶¶ 44, 46).

Regarding the linker used to attach the functional group to the lysine, Petitioner argues that a person of ordinary skill in the art would have been motivated to incorporate an oxygen heteroatom because “both Yamada and Matsuda provide examples of incorporating a heteroatom into the linker, including examples of incorporating oxygen.” Opp. 21 (citing Ex. 1002 ¶ 453; Ex. 1009 ¶¶ 622, 633; Ex. 1011 ¶¶ 1154, 1161–68; Ex. 1059 ¶¶ 44, 67).

Petitioner asserts that although PepTalk Poster and PepTalk Presentation “do not explicitly disclose norbornene, the utility of norbornene was well-established, and Yamada and Matsuda both explicitly suggest it.” Opp. 22 (citing Ex. 1059 ¶¶ 39–42, 48–49). Petitioner argues that the structure of the norbornene functional group recited in claims 15 and 16 would have been obvious for the same reasons discussed above for the proposed combination of Yamada and Matsuda. *Id.* at 23.

Petitioner argues that the linker exemplified in PepTalk Poster and PepTalk Presentation “is highly similar to the linkers in claims 15 and 16.” Opp. 22–23 (citing Ex. 1006; Ex. 1007, 16; Ex. 1059 ¶ 56). Regarding claim 15, Petitioner argues that a person of ordinary skill in the art would have

removed the linker because it would have been “one of the only ways the structure in the PepTalk References could be simplified.” *Id.* at 23 (citing Ex. 1059 ¶¶ 41, 48–49). Regarding the linker used to attach the functional group to the lysine in claim 16, Petitioner argues that a person of ordinary skill in the art would have altered the linker to include an oxygen heteroatom because both Yamada and Matsuda include examples of heteroatoms in the linker. *Id.* (citing Ex. 1009 ¶¶ 622, 633; Ex. 1011 ¶¶ 1154, 1161–68; Ex. 1048; Ex. 1052; Ex. 1059 ¶¶ 48, 67).

Patent Owner, on the other hand, argues that PepTalk Poster and PepTalk Presentation do not disclose a modified antibody example with a norbornene group (claims 15 and 16), a modified antibody with a (β) ether spacer (claims 14 and 16), or a modified antibody with no spacer (claim 15). Reply 8 (citing Ex. 2008 ¶ 35). Patent Owner argues there is no support in any reference for the modifications Petitioner applies, including Petitioner’s position that “a POSA would be motivated to incorporate oxygen into the linker,” and “that removing both carbons from the shortest linker is ‘one of the only ways’ to ‘simplify’ the spacer.” *Id.*

Moreover, Patent Owner argues “there are numerous amino acid sites for substitution on the Fc domain disclosed in the prior art, and Petitioner provides no reason to select lysine 248 from among them.” Reply 9 (citing Ex. 2008 ¶¶ 7, 28). For example, Patent Owner contends PepTalk Poster and PepTalk Presentation do not clearly teach modifying lysine 248 because “both mention lysine 248 as a previous technology, but then go on to suggest that other lysine sites are the target of Ajinomoto’s next generation technology.” *Id.* (citing Ex. 2008 ¶¶ 7, 28).

We are not persuaded that claims 14–16 would have been obvious over PepTalk Poster or PepTalk Presentation combined with Yamada and

Matsuda. For example, neither PepTalk Poster nor PepTalk Presentation provides any teaching or suggestion to arrive at the spacer-free structure of claim 15. Opp. 23 (citing Ex. 1059 ¶¶ 41, 48, 49); Ex. 1059 ¶ 41 (Dr. Tumey testifying, without corroboration, that “a la Occam’s razor” theory supports simplifying the structure in claim 15, “which lacks a spacer/linker” and “would serve as the standard of comparison (i.e., control) to determine the functional impact of adding a spacer/linker”). These references “do not explicitly disclose norbornene” as Petitioner acknowledges (Opp. 22), and the mere assertion that norbornene is a well-known click chemistry group does not, in and of itself, suffice as the requisite reason to be chosen by the skilled artisan with regard to lysine residue 248 as claims 15 and 16 require. Petitioner also acknowledges that neither PepTalk Poster nor PepTalk Presentation teaches or suggests the ether spacer that claims 14 and 16 require. Opp. 20. Dr. Tumey’s testimony that “neither [PepTalk] reference provides a person of ordinary skill any reason to avoid modifications at this site” (Ex. 1059 ¶ 53) does not adequately explain why a skilled artisan would have chosen azide from the lists in Yamada to modify lysine residue 248 as claim 14 requires.

Based on the foregoing, we determine Petitioner has not shown by a preponderance of the evidence that proposed substitute claims 14–16 would have been obvious over PepTalk Poster or PepTalk Presentation, combined with Yamada and Matsuda.

IV. MOTION TO EXCLUDE

Petitioner filed a Motion to Exclude seeking to exclude Exhibit 2008 as lacking authentication and for hearsay, and seeking to exclude Exhibit 2009 as an unverified translation that lacks authentication. MTE 4. We consider the parties’ arguments regarding each exhibit below.

A. Exhibit 2008

Exhibit 2008 is Patent Owner’s second declaration of Dr. Zhaohui Sunny Zhou filed in response to Petitioner’s Opposition to Patent Owner’s Motion to Amend (Paper 29). Petitioner objects to Exhibit 2008 “under FRE 802 as hearsay without exception” and also “under FRE 901- 902 as lacking authentication and not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.” Paper 29, 1–2.

With regard to the lack of authentication issue, Petitioner argues that the Board should exclude Exhibit 2008 and the statements relying on the exhibit in Patent Owner’s Reply because the declaration is not properly executed under 35 U.S.C. § 25 and 37 C.F.R. § 1.68. MTE 5–6. Petitioner argues that Exhibit 2008 “lacks the statutorily-required oath or caveat for a declaration” and therefore is “without authentication” and “constitutes hearsay without exception because it represents an out-of-Board statement not ‘made under oath or other circumstances that impress the speaker with the solemnity of his statements.’” *Id.* at 5–6 (citing *Chambers v. Mississippi*, 410 U.S. 284, 298 (1973)). Petitioner argues that “AbTis does not dispute that EX2008 contained no warning about willful false statements and was not given under penalty of perjury” and should therefore be excluded. Petitioner’s Reply to Opposition to Motion to Exclude (Paper 39), 1.

Petitioner and Patent Owner dispute whether Petitioner properly preserved the objection under 37 U.S.C. § 42.64(c) and whether the undisputed deficiency is curable under the relevant rules. *See, e.g.*, Patent Owner’s Opposition to Petitioner’s Motion to Exclude (Paper 35), Paper 39. Both parties argue that *Liquidia Techs., Inc. v. United Therapeutics Corp.*, IPR2020-00770, 2021 WL 4860773 (PTAB Oct. 8, 2021) favors their respective position. Paper 35, 4–6; Paper 39, 2. Petitioner argues that Patent

Owner's argument against the Motion to Exclude "is contradicted by the *Liquidia* decision it cites" and therefore the Board should rule in Petitioner's favor. Paper 39, 2 (citing *Liquidia Techs., Inc. v. United Therapeutics Corp.*, IPR2020-00770, Paper 45 at 55 (PTAB Oct. 8, 2021)). The Board in *Liquidia*, however, decided to deny the motion to exclude notwithstanding certain "concerns" over evidence in dispute in that case. 2021 WL 4860773 at *25.

In this case, Patent Owner's expert "Dr. Zhou signed the second declaration, stood behind its contents, and was available for cross-examination." Paper 35, 4. Petitioner does not dispute this statement. Paper 39, 1. Petitioner does not identify any specific undue prejudice caused by Exhibit 2008. For example, Petitioner argues that "the failure to impress upon a witness that a statement is under oath goes to the heart of its reliability as evidence" and that "as the Board has recognized, hearsay is inherently unreliable" without specifying what statement in Exhibit 2008 lacks reliability. Paper 39, 4. Because Petitioner does not provide specific evidence of undue prejudice, we find Petitioner has suffered no such undue prejudice in this case. *See Liquidia*, 2021 WL 4860773 at *25. We therefore deny Petitioner's Motion to Exclude on the basis of lack of authenticity.

With regard to the assertion that Exhibit 2008 is hearsay, Petitioner objects to the exhibit because the testimony is based "on other informal and unpublished documents that are hearsay under FRE 802." Paper 29, 1. Petitioner does not specify what such "informal and unpublished documents" are. *See id.* Federal Rule of Evidence 703 expressly states, "[a]n expert may base an opinion on fact or data in the case that the expert has been made aware of or personally observed." The facts or data "need not be

admissible for the opinion to be admitted.” Fed. R. Evid. 703. We therefore deny Petitioner’s Motion to Exclude on the basis of hearsay.

B. Exhibit 2009

Exhibit 2009 is an English translation of Kirmse et al., Destabilisierte 2-Norbornyl-Kationen, 97(1) ANGEW. CHEM. 51–52 (1985). Petitioner filed the original document in German as Exhibit 1057. Petitioner objects to Exhibit 2009 under 37 C.F.R. § 42.63(b). Paper 29, 2.

Petitioner contends the Board should exclude Exhibit 2009 and the portions of Exhibit 2008 and Patent Owner’s Reply citing to the exhibit because “Patent Owner did not establish that EX2009 is a true and accurate representation of the original Kirmse article” under 37 C.F.R. § 42.63(b) by filing the purported German document being translated and a verified translator’s declaration. MTE 6–7. Petitioner argues that “[b]y omitting the filing of the purported German document, Patent Owner necessarily also omitted the required certification of the purported foreign document” because “a foreign public document must be certified by the appropriate foreign certifying authority.” *Id.* at 7 (citing FRE 902(3)).

Patent Owner, on the other hand, argues that “Exhibit 2009 is not a party-created translation of a foreign-language document” but “[r]ather . . . an officially published English-language edition of a peer-reviewed scientific journal article.” Paper 35, 6. Patent Owner argues that “[n]othing in the PTAB’s rules requires a party to object to a foreign-language reference when the same publication is available in an official English edition.” *Id.* at 9. Patent Owner also argues that “Petitioner does not allege any inaccuracy, mistranslation, or discrepancy between the English and German editions. Nor does Petitioner contend that Exhibit 2009

misrepresents or distorts the disclosed science.” *Id.* Petitioner does not dispute these statements.

We deny Petitioner’s motion to exclude Exhibit 2009.

V. MOTION TO SUBMIT SUPPLEMENTAL EVIDENCE

Patent Owner filed a Motion to Submit Supplemental Evidence. Paper 37. More specifically, Patent Owner moves to enter into the record Exhibit 2012, which is a corrected declaration by Dr. Zhou that, according to Patent Owner, “is substantively identical to his original second declaration (Ex. 2008) and addresses only a procedural, non-substantive deficiency: the absence of explicit perjury oath language.” Paper 37, 1. Petitioner does not dispute that the only difference between Exhibit 2008 and Exhibit 2012 is the addition of the requisite perjury or oath statement by Dr. Zhou in compliance with 37 C.F.R. § 42.63.

Because we deny Petitioner’s Motion to Exclude Exhibit 2008, Patent Owner’s Motion to Submit Supplemental Evidence is dismissed as moot. The supplemental evidence at issue, namely Exhibit 2012, is not part of the record for this proceeding and we did not consider it in the rendering of this Decision.

VI. CONCLUSION

For the foregoing reasons, we cancel claim 11 of the ’675 patent, grant Patent Owner’s motion to amend the ’675 patent to add proposed substitute claims 14–16, deny Petitioner’s Motion to Exclude Exhibits 2008 and 2009, and dismiss Patent Owner’s Motion to Submit Supplemental Evidence.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
14–16	112(a)	Written description		14–16
14–16	112(a)	Enablement		14–16
14–16	112(b)	Indefiniteness		14–16
14–16	102	CA959		14–16
14–16	103	Yamada, Matsuda		14–16
14–16	103	PepTalk Poster, Yamada, Matsuda		14–16
14–16	103	PepTalk Presentation, Yamada, Matsuda		14–16
Overall Outcome				14–16

Motion to Amend Outcome	Claim
Original Claims Disclaimed	1–10, 12, 13
Original Claims Cancelled by Amendment	11
Substitute Claims Proposed in the Amendment	14–16
Substitute Claim: Motion to Amend Granted	14–16
Substitute Claim: Motion to Amend Denied	
Substitute Claims: Not Reached	

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner’s Non-Contingent Motion to Amend (Paper 23) is *granted* as to its non-contingent request to cancel claim 11;

FURTHER ORDERED that claim 11 of the ’675 patent is cancelled;

FURTHER ORDERED that Patent Owner’s Non-Contingent Motion to Amend (Paper 23) is *granted* as to adding substitute claims 14–16;

FURTHER ORDERED that Petitioner’s Motion to Exclude is *denied*;

FURTHER ORDERED that Patent Owner’s Motion to Submit Supplemental Evidence is *dismissed* as moot; and

IPR2025-00283

Patent 11,896,675 B2

FURTHER ORDERED that any party seeking judicial review must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2025-00283
Patent 11,896,675 B2

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