

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*.

PRELIMINARY GUIDANCE
PATENT OWNER'S MOTION TO AMEND
37 C.F.R. § 42.121(e)

I. INTRODUCTION

On August 8, 2025, we instituted trial as to claim 11 of U.S. Patent No. 11,896,675 B2. Paper 16. After institution, Patent Owner filed a Non-Contingent Motion to Amend. Paper 23 (“Motion” or “Mot.”). Petitioner filed an opposition on January 23, 2026. Paper 25 (“Opposition” or “Opp.”).

In the Motion, Patent Owner requests that we provide preliminary guidance concerning the Motion in accordance with 37 C.F.R.

§ 42.121(a)(1)(ii). Mot. 2; *see* 37 C.F.R. § 42.121(e)(1); *see also Rules Governing Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board*, 89 Fed. Reg. 76,421 (Sept. 18, 2024) (“Final Rule”). We have considered Patent Owner’s Motion and Petitioner’s Opposition.

In this Preliminary Guidance, we provide information indicating our initial, preliminary, non-binding views on whether Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend in an *inter partes* review and whether Petitioner establishes a reasonable likelihood that the substitute claims are unpatentable. 37 C.F.R. §§ 42.121(e)(1), (2); *see also* 35 U.S.C. § 316(d) (statutory requirements for a motion to amend); 37 C.F.R. §§ 42.121(a)(2), (a)(3), (b) (regulatory requirements and burdens for a motion to amend); *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 (PTAB Feb. 25, 2019) (precedential) (providing information and guidance regarding motions to amend). The reasonable likelihood standard this Preliminary Guidance applies is different from the preponderance of the evidence standard applied when ultimately deciding the Motion. *Compare*

37 C.F.R. § 42.121(e)(1) *with* § 42.121(d). Finally, this preliminary guidance is not a “decision” for purposes of rehearing under 37 C.F.R. § 42.71(d). 37 C.F.R. § 42.121(e)(2).

For purposes of this Preliminary Guidance, we focus on the proposed substitute claims, and specifically on the amendments proposed in the Motion. *See* 37 C.F.R. § 42.121(e)(1); Final Rule, 89 Fed. Reg. at 76,425. We do not address the patentability of the originally challenged claim. *See id.* Moreover, in formulating our preliminary views on the Motion and Opposition, we have not considered the parties’ other substantive papers on the underlying merits of Petitioner’s challenges. We emphasize that the views expressed in this Preliminary Guidance are subject to change upon consideration of the complete record, including any revision to the Motion filed by Patent Owner. Thus, this Preliminary Guidance is not binding on the Board when rendering a final written decision or any other subsequent decision in this proceeding. 37 C.F.R. § 42.121(e)(2); *see Medytox, Inc. v. Galderma S.A.*, 71 F.4th 990, 1000 (Fed. Cir. 2023).

II. PRELIMINARY GUIDANCE

A. Statutory and Regulatory Requirements

Patent Owner bears the ultimate burden to show that its motion to amend complies with the requirements of 35 U.S.C. §§ 316(d)(1) and (3) and 37 C.F.R. §§ 42.121(a)(2), (a)(3), (b)(1), and (b)(2). 37 C.F.R. § 42.121(d)(1). For the reasons discussed below, at this stage of the proceeding, and based on the current record, it appears that Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend. *See* 37 C.F.R. § 42.121(e)(1).

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); 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. Patent Owner has shown it proposes a reasonable number of substitute claims because Patent Owner proposes a less than one-to-one substitution. *Id.*; Ex. 2001; *see also* 37 C.F.R. § 42.121(a)(3) (“The presumption is that only one substitute claim would be needed to replace each challenged claim, and it may be rebutted by a demonstration of need”). Petitioner does not argue otherwise. *See generally* Opp.

2. Respond to Ground of Unpatentability

A motion to amend must respond to a ground of unpatentability involved in the proceeding. 37 C.F.R. § 42.121(a)(2)(i). Patent Owner responds to a ground of unpatentability involved in this proceeding by asserting 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 CA 3132959A1 (“CA959,” Ex. 1005); PepTalk Poster (Ex. 1006); PepTalk Presentation (Ex. 1007); WO 2018/199337 (“Yamada,” Ex. 1009); and WO 2019/240288 (“Matsuda,” Ex. 1011). *See* Mot. 12–25. Petitioner does not argue otherwise. *See generally* Opp.

3. Scope of Amended Claims

A motion to amend may not enlarge the scope of the claims of the patent. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii). Patent Owner's Motion does not enlarge the scope of the claims of the patent because the Motion only adds narrowing limitations. *See* Mot. 3–8, 27–30 (App. A). Petitioner does not argue otherwise. *See generally* Opp.

4. New Matter

A motion to amend may not introduce new subject matter. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii). 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 provides a table containing 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.

Petitioner contends the proposed substitute claims lack written description support for claim limitations 14[a], 15[a], and 16[a],¹ which each recite “wherein the modified antibody comprises one or more modified heavy chain.” *See* Opp. 2–5; Mot. 27–30 (App. A). Petitioner contends the proposed substitute claims lack written description support because “claims 14-16 necessarily encompass antibodies with exactly/only one modified

¹ For ease of reference, we refer to the claim limitations of the proposed substitute claims using the alphanumerical designations listed in Appendix A of Patent Owner's Motion. *See* Mot. 27–30.

heavy chain and antibodies with three or more modified heavy chains,” but “the specification only describes antibodies with two modified heavy chains.” Opp. 3–4 (emphasis omitted). 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).

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

On this record, we disagree with Petitioner that claim limitations 14[a], 15[a], and 16[a] introduce new subject matter. “In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue;” however, the disclosure must convey with reasonable clarity to those skilled in the art that the inventors were in possession of the invention. *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). “Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims.” *Id.*

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. As Dr. Tumey opines, a person of ordinary skill in the art reading the definition of “antibody” in the specifications would have understood that it encompasses IgM, an antibody with five heavy chains. *See* Ex. 1002 ¶ 67; Ex. 1059 ¶ 11. Moreover, as Dr. Tumey opines, a person of ordinary skill in the art would have understood “that ‘antibody’ as used in the ’675 Patent claims is not limited to IgG, but rather includes additional isotypes (e.g., IgM, IgA, IgE, and IgD).” Ex. 1002 ¶ 67. The record before us shows that a person of ordinary skill in the art reading the specification could “immediately discern” (*Purdue Pharma L.P.*, 230 F.3d at 1323) that it described and contemplated “modified antibodies” comprising exactly one modified heavy chain or three or more modified heavy chains from the applications.

Based on the foregoing, the record before us indicates that Patent Owner’s proposed claims 14–16 do not introduce new matter at this stage of the proceeding.

B. Unpatentability Arguments by Petitioner

Petitioner bears the ultimate burden to show that any proposed substitute claims are unpatentable. 37 C.F.R. § 42.121(d)(2). For the reasons discussed below, at this stage of the proceeding, the current record²

² We express no view on the patentability of original claim 11 in this Preliminary Guidance. Instead, we focus on Patent Owner’s proposed substitute claims.

indicates that Petitioner has not shown a reasonable likelihood that proposed substitute claims 14–16 are unpatentable. *See* 37 C.F.R. § 42.121(e)(1).

1. Written Description

Petitioner contends the proposed substitute claims are unpatentable as lacking adequate written description support for claim limitations 14[a], 15[a], and 16[a]. Opp. 2–5. On this record, Petitioner has not shown a reasonable likelihood that limitations 14[a], 15[a], and 16[a] lack written description support at this stage of the proceeding for the reasons discussed above.

2. Enablement

Petitioner contends claim limitations 14[a], 15[a], and 16[a] are not enabled because “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” such that “[i]t 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.” Opp. 4 (citing Ex. 1059 ¶¶ 18–21; Ex. 2003 ¶¶ 1272–329) (emphasis omitted). Petitioner argues further that “the specification provides no examples, direction or guidance with respect to modifying antibodies and ‘similar structures’ that have more than two heavy chains.” Opp. 4.

On this record, we disagree with Petitioner that claim limitations 14[a], 15[a], and 16[a] that recite “wherein the modified antibody comprises one or more modified heavy chain” are unenabled. Proposed substitute claims 14–16 do not limit the type of antibody that is modified, or require a process that always results in exactly one modified heavy chain.

Furthermore, Petitioner has not persuasively explained why the disclosures in the specification describing modifying heavy chains are not enabling for modifying one heavy chain or more than two heavy chains. “The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without ‘undue experimentation.’” *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. 2003). As Dr. Tumey acknowledges, a person of ordinary skill in the art would have understood that “modification reactions such as those described in EX2002, paras. [1272]-[1329] could produce a trastuzumab molecule with one modified heavy chain, two modified heavy chains, or zero modified heavy chains.” Ex. 1059 ¶ 19.

Based on the foregoing, the record before us indicates that Petitioner has not shown a reasonable likelihood that limitations 14[a], 15[a], and 16[a] are not enabled at this stage of the proceeding.

3. Indefiniteness

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).

On this record, we disagree with Petitioner that proposed substitute claims 14–16 are indefinite. “The standard of indefiniteness is somewhat high; 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.

Based on the foregoing, the record before us indicates that Petitioner has not shown a reasonable likelihood that proposed substitute claims 14–16 are indefinite at this stage of the proceeding.

4. Anticipation by CA959³

Petitioner contends CA959 (Ex. 1005) 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. Petitioner contends the proposed substitute claims are anticipated by Example 3 of CA959. *Id.* at 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. Mot. 13. Patent Owner also argues that CA959 “is not prior art to the proposed substitute claims under 35 U.S.C. § 102(b) because the inventors are the same.” *Id.*

The record before us indicates that CA959 does not qualify as prior art against the '675 patent. As discussed above, Petitioner has not shown a reasonable likelihood that limitations 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 is not prior art under 35 U.S.C. § 102.

³ CA 3132959 A1 (“CA959”), published Sep. 17, 2020, filed Mar. 9, 2020 (Ex. 1005).

Based on the foregoing, the record before us indicates that Petitioner has not shown a reasonable likelihood that proposed substitute claims 14–16 are anticipated by CA959 at this stage of the proceeding.

5. Obviousness

Petitioner contends the proposed substitute claims would have been obvious because all of their claim limitations “are disclosed in PepTalk References (EX1006; EX1007), Yamada (EX1009), and Matsuda (EX1011).” Opp. 12–14. Petitioner’s obviousness grounds are discussed further below.

i. Obviousness over Yamada⁴ in View of Matsuda⁵

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). We address Petitioner’s arguments for each proposed substitute claim below.

a. Claims 14 and 16

Petitioner contends 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 in support of the Opposition, Petitioner argues Yamada

⁴ Yamada, WO 2020/199337, published June 18, 2020, filed Oct. 25, 2019, 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 states that the English translation is certified. Ex. 1009, 1–2.

⁵ Matsuda, US 2021/013954, published May 13, 2021, filed Dec. 11, 2020, which claims priority to Japanese Patent Application No. 2018-113962, filed Jun. 14, 2018 (Exs. 1010, 1011 (English translation)). Petitioner states that the English translation is certified. Ex. 1011.

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 contends 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 argues claims 14 and 16 are patentably distinguished over Yamada and Matsuda because Petitioner’s arguments are based on hindsight. Mot. 16–20. Patent Owner contends that Yamada does not disclose the claimed modified lysine residues, and “Petitioner provides no reason to choose any one of the functional groups in the claims from among the billions in Yamada, let alone all of them at once.” *Id.* at 16–17 (emphasis omitted). More specifically, Patent Owner argues Petitioner’s flow charts are the result of cherry-picking “individual substituent definitions and variables that were never presented together in Yamada.” *Id.* at 17–18 (emphasis omitted, citing Ex. 2004 ¶¶ 98–101). According to Patent Owner, “[e]ach of L₁, B, R’, for example, is independently variable, with Yamada listing dozens of potential atoms, groups, and chain lengths for all” such that “[t]he specific subset that would yield the claimed ether-linked D₁ spacer joined to a click-reactive group at lysine 248 represents one of many billions of theoretical combinations.” *Id.* at 21 (citing Ex. 2004 ¶¶ 85–93, 99) (emphasis omitted).

Patent Owner contends further that “Yamada does not identify any preference, advantage, or motivation to choose the claimed options from among the many disclosed, let alone a reasonable expectation of success in doing so.” Mot. 18 (citing Ex. 2004 ¶ 94) (emphasis omitted). “For example, there is no teaching in Yamada or another reference that an ether-containing spacer group of substitute claims 14 and 16 should be used, or that the chosen arrangement would confer any benefit over other spacer

variants.” *Id.* (citing Ex. 2004 ¶¶ 94–97; Ex. 2006, 174:16–175:3) (emphasis omitted).

Patent Owner contends Matsuda teaches away from using the β -heteroatom (ether oxygen) chain substituents of proposed substitute claims 14 and 16 because Matsuda discloses that antibody modification reactions do not progress with beta-heteroatom compounds 26 or 60. Mot. 21–23 (citing Ex. 1011 ¶¶ 1150–52; Ex. 2004 ¶ 107). According to Patent Owner, “[i]n both cases, Matsuda discloses that the antibody modification reaction ‘had not progressed,’ even after extended incubation at physiological temperature,” and Matsuda “teaches that conjugation successfully proceeded when using analogs lacking the β -heteroatom (compounds 27–29).” *Id.* at 22 (citing Ex. 1011 ¶¶ 1150–52; Ex. 2004 ¶ 107) (emphasis omitted).

Petitioner, on the other hand, argues that Matsuda does not teach away from using a β -heteroatom linker because “Matsuda’s suggestion that a single reaction with compounds 26 or 60 ‘had not progressed’ does not mean that the reaction did not work at all or would not work under other conditions.” Opp. 24 (citing Ex. 1059 ¶¶ 64–67; Ex. 1060, 160:5–22, 163:3–19).

The record before us indicates that Patent Owner has the better position. Petitioner does not adequately explain why a person of ordinary skill in the art would have specially chosen azide and norbornene from the large list of functional groups in Yamada. *See* Ex. 1009 ¶¶ 626–27. Moreover, Yamada itself does not provide a particular reason to select azide and norbornene because the reference merely lists many functional groups without indicating that any of them are preferred. *Id.*

Based on the foregoing, the record before us indicates that Petitioner has not shown a reasonable likelihood that proposed substitute claims 14 and 16 would have been obvious over Yamada and Matsuda at this stage of the proceeding.

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

Patent Owner argues that claim 15 is patentably distinguished over Yamada and Matsuda because Petitioner’s arguments are based on hindsight. Mot. 16–20. Patent Owner contends Yamada does not disclose

the claimed modified lysine residues, and “Petitioner provides no reason to choose any one of the functional groups in the claims from among the billions in Yamada, let alone all of them at once.” *Id.* at 16–17 (emphasis omitted). More specifically, Patent Owner argues “Yamada does not identify any preference, advantage, or motivation to choose the claimed options from among the many disclosed, let alone a reasonable expectation of success in doing so.” *Id.* at 18 (emphasis omitted, citing Ex. 2004 ¶ 94). For example, “there is no teaching that the very short spacer group of claim 15 would confer any benefit over other spacer variants.” *Id.* at 19 (citing Ex. 2006, 175:5–13).

The record before us indicates that Patent Owner has the better position. Petitioner does not adequately explain why a person of ordinary skill in the art would have specifically chosen norbornene from the large list of functional groups in Yamada. *See* Ex. 1009 ¶¶ 626–27. Moreover, Yamada itself does not provide a particular reason to select norbornene because the reference merely lists many functional groups without indicating that any of them are preferred. *Id.*

Based on the foregoing, the record before us indicates that Petitioner has not shown a reasonable likelihood that proposed substitute claim 15 would have been obvious over Yamada and Matsuda at this stage of the proceeding.

- ii. Obviousness over PepTalk Poster⁶ or PepTalk Presentation⁷ in View of Yamada and Matsuda

⁶ PepTalk Poster, “Development of a Novel Chemical Site-Specific Conjugation Platform for ADCs” (Ex. 1006).

⁷ PepTalk Presentation (Ex. 1007).

Petitioner argues the proposed substitute claims would have been obvious over the PepTalk Poster or the PepTalk Presentation, combined with Yamada and Matsuda. Opp. 20–23. We address Petitioner’s arguments for each proposed substitute claim below.

In addition to the teachings discussed above for the obviousness combination over Yamada and Matsuda, Petitioner contends “the PepTalk References teach an azide as a suitable bio-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, Fig. 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 contends further that although the 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 obviousness combination over Yamada and Matsuda. *Id.* at 23.

Petitioner argues that the linker exemplified in the 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 the linker in 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 argues that claims 14–16 are patentably distinguished because the PepTalk Poster and the PepTalk Presentation “do not disclose compounds with an ether spacer as required by substitute claims 14 and 16, or compounds with no spacer as in substitute claim 15.” Mot. 24 (citing Ex. 2004 ¶¶ 59–62, 66, 73–76). Moreover, Patent Owner argues that the PepTalk Poster and the PepTalk Presentation “do not disclose compounds substituted with norbornene, as required in substitute claims 15 and 16.” *Id.* (citing Ex. 2004 ¶¶ 64–68, 78–82). Patent Owner contends that “[t]he only way Petitioner argues these are obvious is by using Yamada and hindsight to arrive at the claimed chemical moieties,” and “Petitioner has identified nothing that discloses the compounds of the substitute claims, let alone

teaches how or why a [person of ordinary skill in the art] would obtain them among the millions of structural options in Yamada.” *Id.* (emphasis omitted).

For the same reasons discussed above, the record before us indicates that Patent Owner has the better position. Petitioner does not adequately explain why a person of ordinary skill in the art would have specifically chosen azide and norbornene from the large list of functional groups in Yamada. *See* Ex. 1009

¶¶ 626–27. Moreover, Yamada itself does not provide a particular reason to select azide and norbornene because the reference merely lists many functional groups without indicating that any of them are preferred. *Id.*

Based on the foregoing, the record before us indicates that Petitioner has not shown a reasonable likelihood that proposed substitute claims 14–16 would have been obvious over the PepTalk Poster or the PepTalk Presentation, combined with Yamada and Matsuda, at this stage of the proceeding.

III. CONCLUSION

This concludes our Preliminary Guidance. Patent Owner has the option to reply to this Preliminary Guidance *or* to file a revised motion to amend (“MTA”) by DUE DATE 3. 37 C.F.R. §§ 42.121(e)(3), (f); Paper 17. Patent Owner’s reply or revised MTA may only respond to this Preliminary Guidance or Petitioner’s Opposition and may be accompanied by new evidence (including declarations). 37 C.F.R. § 42.121(e)(3). Petitioner has the option to file a sur-reply responsive to this Preliminary Guidance, Patent Owner’s reply, or Patent Owner’s revised MTA but may not present new evidence in the sur-reply. 37 C.F.R. § 42.121(e)(3).

Petitioner may also file a reply responding to the preliminary guidance if Patent Owner does not file a reply or revised MTA, but may not present new evidence in the reply. 37 C.F.R. § 42.121(e)(4).

In addition, Patent Owner is reminded that amendments of the challenged claims may also be pursued in a separate reissue or reexamination proceeding before, during, or after an AIA trial proceeding, including subsequent to the issuance of the Final Written Decision. We draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. §§ 42.8(a)(3), (b)(2).

IPR2025-00283
Patent 11,896,675 B2

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