

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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AJINOMOTO CO., INC.

Petitioner,

v.

ABTIS CO., LTD.

Patent Owner.

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CASE: IPR2025-00283

U.S. PATENT NO. 11,896,675

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**PATENT OWNER PRELIMINARY RESPONSE**

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**TABLE OF PATENT OWNER EXHIBITS**

| <b>Exhibit No.</b> | <b>Description</b>                                 |
|--------------------|----------------------------------------------------|
| 2001               | Statutory Disclaimer of U.S. Patent No. 11,896,675 |

Patent Owner, AbTis Co., Ltd. (“AbTis” or “Patent Owner”), submits this Patent Owner Preliminary Response (“Response”) pursuant to 37 C.F.R. § 42.107(a) to the *Inter Partes* Review petition (“Petition”) filed by Ajinomoto Co., Inc. (“Petitioner”) for Claims 1-13 (the “Challenged Claims”) of U.S. Patent No. 11,896,675 (the “’675 Patent”) (Ex. 1001).

Although Petitioner challenges Claims 1-13 of the ’675 Patent, only Claim 11 is relevant to the Board’s consideration of the Petition because Patent Owner statutorily disclaimed Claims 1-10 and 12-13. Ex. 2001. “The patent owner may file a statutory disclaimer” and “[n]o inter partes review will be instituted based on disclaimed claims.” 37 CFR § 42.107.

## **I. INTRODUCTION**

The ’675 Patent describes and claims a modified antibody comprising a lysine residue at position 248 of the heavy chain, wherein the lysine is functionalized with a terminal bio-orthogonal click chemistry group. *E.g.*, Ex. 1001, cl. 11. The claimed invention encompasses modified lysine residues bearing functional groups including an azide or norbornene functional group. *Id.*

Notably, the Petition does not identify a single reference that includes the claimed composition. Instead, the Petition relies on hindsight bias to reconstruct the novel features of the ’675 Patent using the ’675 Patent’s compositions as a roadmap.

The Petition compounds this issue by forcing combinations of references without providing any analysis as to why a POSA would have combined the references, thereby improperly offloading its analysis to the Board. The Board should deny institution of the Petition.

## **II. BACKGROUND OF THE PROCEEDING**

All thirteen claims of the '675 Patent are challenged in the Petition; however, to streamline the Board's review of the Petition, Patent Owner filed a statutory disclaimer of Claims 1 to 10 and 12 to 13. *See* Ex. 2001. As a result, only dependent Claim 11 is subject to the Board's consideration. Patent Owner also concurrently submits its Argument for Discretionary Denial, detailing the discretionary reasons why the Board should deny this Petition and allocate its resources to petitions that better adhere to the framework set forth in the Board's recent guidance on "Interim Processes for PTAB Workload Management," dated March 26, 2025 ("Guidance"). Here, Patent Owner explains additional reasons why the Petition should be denied, including that each of the remaining grounds relevant to the Board's consideration (Grounds 1, 3, 5, and 7) fail to anticipate or render obvious the only remaining challenged claim, dependent Claim 11. *See* Section V, below.

### **A. Overview Of The Petition**

The Petition challenges the '675 Patent's claims under seven grounds:

- Ground 1 challenges Claims 1 to 13 as anticipated by CA 3132959 (Ex. 1005) (“the ’959 Publication”);
- Ground 2 challenges Claims 1, 4, and 8 to 10 as anticipated by PepTalk Poster (Ex. 1006);
- Ground 3 challenges Claims 1 to 13 as obvious over PepTalk Poster, WO 2018/199337 (Ex. 1008) (“*Yamada*”), and WO 2019/240288 (Ex. 1010) (“*Matsuda*”)<sup>1</sup>;
- Ground 4 challenges Claims 1, 4, and 8 to 10 as anticipated by PepTalk Presentation (Ex. 1007);
- Ground 5 challenges Claims 1 to 13 as obvious over PepTalk Presentation, *Yamada*, and *Matsuda*;
- Ground 6 challenges Claims 1, 4, and 8 to 10 as anticipated by *Yamada*; and

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<sup>1</sup> All citations to *Matsuda* in the Petition are to the U.S. National Stage application of *Matsuda*, U.S. Patent Publication No. 2021/0139541 (“*Matsuda* ’541”) (Ex. 1011), which Petitioner asserts is “certified as an accurate translation of the corresponding PCT.” Petition, 28-29.

- Ground 7 challenges Claims 1 to 13 as obvious over *Yamada* and *Matsuda*.

Petition, 2-3.

Patent Owner statutorily disclaimed all challenged claims except dependent Claim 11. *See* Ex. 2001. Because Claim 11 is not challenged in Grounds 2, 4, or 6, those grounds are now moot as a result of Patent Owner's statutory disclaimer. Now, the only remaining challenge grounds are Grounds 1, 3, 5, and 7.

**B. Overview Of The Patent Owner's Arguments For Discretionary Denial<sup>2</sup>**

i. The Petition Improperly Relies On Non-Prior Art

The issues to be decided by the Board are even more narrow upon a cursory review of the challenge grounds. For example, and as explained in Patent Owner's

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<sup>2</sup> The Patent Owner's Argument for Discretionary Denial sets forth the detailed discussion of the Petition's significant issues with relying on non-prior art and prior art references that were already considered during prosecution, or that are cumulative of prior art that was considered. However, Patent Owner includes a brief overview with this Response to show how Petitioner's cited art and misrepresentations of the prosecution history, are fatal to the Petition's arguments.

Arguments for Discretionary Denial, Ground 1 challenges Claim 11 as anticipated by the '959 publication, which is in the same patent family as the '675 Patent, and claims priority to the same provisional application: U.S. Provisional Application No. 62/815,557, filed on March 8, 2019. Petitioner has failed to establish that Claim 11 is not entitled to its priority date of March 8, 2019. The '959 publication is not prior art to Claim 11 of the '675 Patent, and Ground 1 fails.

ii. The Petition Relies On Art That Was The Same, Or Substantially The Same As Art Considered By The Patent Office During Prosecution Of The '675 Patent

Each of the remaining grounds, Grounds 3, 5, and 7, rely on art that was directly considered by the Patent Office during prosecution of the '675 Patent or on art that is cumulative of the art considered during prosecution.

It should be noted at the outset that, while Petitioner claims that “Matsuda w[as] not of record or considered by the Office during prosecution of the '675 Patent,” *Matsuda* was of record during prosecution. *See* Ex. 1001, Cover (listing *Matsuda* '541 on its face). Moreover, *Yamada* was likewise of record and considered during prosecution of the '675 Patent. *See id.* (listing *Yamada* on its face); *see also* Ex. 1035, 322-330 (Non-Final Office Action dated August 16, 2023) (rejecting

claims as anticipated by *Yamada*).<sup>3</sup> *Matsuda* '541 (Ex. 1011), the publication relied upon in the Petition's citations, likewise, was listed in an IDS signed by the Examiner and cited on the face of the '675 Patent:

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                 |                |              |                 |        |     |                 |        |               |                 |        |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------------|--------------|-----------------|--------|-----|-----------------|--------|---------------|-----------------|--------|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p style="text-align: center;"><b>(56) References Cited</b></p> <p style="text-align: center;"><b>U.S. PATENT DOCUMENTS</b></p> <table style="width: 100%; border-collapse: collapse;"><tr><td style="width: 30%;">2012/0172575 A1</td><td style="width: 20%;">7/2012</td><td style="width: 50%;">Boons et al.</td></tr><tr><td>2018/0141976 A1</td><td>5/2018</td><td>Ito</td></tr><tr style="border: 2px solid red;"><td>2020/0190165 A1</td><td>6/2020</td><td>Yamada et al.</td></tr><tr style="border: 2px solid red;"><td>2021/0139541 A1</td><td>5/2021</td><td>Matsuda et al.</td></tr></table> | 2012/0172575 A1 | 7/2012         | Boons et al. | 2018/0141976 A1 | 5/2018 | Ito | 2020/0190165 A1 | 6/2020 | Yamada et al. | 2021/0139541 A1 | 5/2021 | Matsuda et al. | <div style="text-align: right; margin-bottom: 10px;"><br/>US011896675B2</div> <div style="text-align: center;"><b>United States Patent</b><br/><b>Chung et al.</b></div> <div style="text-align: right; margin-top: 10px;"><b>(10) Patent No.: US 11,896,675 B2</b><br/><b>(45) Date of Patent: Feb. 13, 2024</b></div> <div style="margin-top: 10px;"><p><b>(54) SITE-SPECIFIC ANTIBODY CONJUGATION AND ANTIBODY-DRUG CONJUGATE AS SPECIFIC EMBODIMENT THEREOF</b></p><p><b>(71) Applicant:</b> AbTis Co., Ltd., Gyeonggi-do (KR)</p><p><b>(72) Inventors:</b> Sang Jeon Chung, Gyeonggi-do (KR); Ju Hwan Kim, Gyeonggi-do (KR); Young Geun Lee, Gyeonggi-do (KR); Tae Ju Lee, Gyeonggi-do (KR); Jia Woo Seo, Gyeonggi-do (KR)</p><p><b>(73) Assignee:</b> AbTis Co., Ltd., Gyeonggi-do (KR)</p><p><b>(*) Notice:</b> Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.</p><p><b>(21) Appl. No.:</b> 18/154,998</p><p><b>(22) Filed:</b> Jan. 16, 2023</p><p><b>(65) Prior Publication Data</b><br/>US 2023/0248842 A1 Aug. 10, 2023</p><p><b>Related U.S. Application Data</b><br/>(63) Continuation of application No. 16/980,503, filed on Sep. 14, 2020.</p><p>(60) Provisional application No. 62/815,557, filed on Mar. 8, 2019.</p><p><b>(51) Int. Cl.</b><br/><i>A61P 35/00</i> (2006:01)<br/><i>C07D 207/46</i> (2006:01)<br/><i>C07K 16/32</i> (2006:01)<br/><i>A61K 47/68</i> (2017:01)</p><p><b>(52) U.S. Cl.</b><br/>CPC: <i>A61K 47/6803</i> (2017:08); <i>A61K 47/6855</i> (2017:08); <i>A61K 47/6889</i> (2017:08); <i>A61P 35/00</i> (2018:01); <i>C07D 207/46</i> (2013:01); <i>C07K 16/32</i> (2013:01)</p><p><b>(58) Field of Classification Search</b><br/>CPC: <i>A61K 47/6803</i>; <i>A61K 47/6855</i>; <i>A61K 47/6889</i>; <i>A61P 35/00</i>; <i>C07D 207/46</i>; <i>C07K 16/32</i><br/>USPC: <i>424/133.1</i><br/>See application file for complete search history.</p><p><b>(56) References Cited</b><br/>U.S. PATENT DOCUMENTS<br/>2012/0172575 A1 7/2012 Boons et al.<br/>2018/0141976 A1 5/2018 Ito<br/>2020/0190165 A1 6/2020 Yamada et al.<br/>2021/0139541 A1 5/2021 Matsuda et al.</p></div> |
| 2012/0172575 A1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 7/2012          | Boons et al.   |              |                 |        |     |                 |        |               |                 |        |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 2018/0141976 A1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 5/2018          | Ito            |              |                 |        |     |                 |        |               |                 |        |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 2020/0190165 A1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 6/2020          | Yamada et al.  |              |                 |        |     |                 |        |               |                 |        |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 2021/0139541 A1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 5/2021          | Matsuda et al. |              |                 |        |     |                 |        |               |                 |        |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

Ex. 1035, 108; Ex. 1001, Cover (annotated).

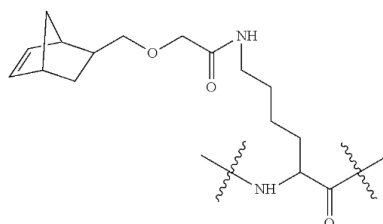
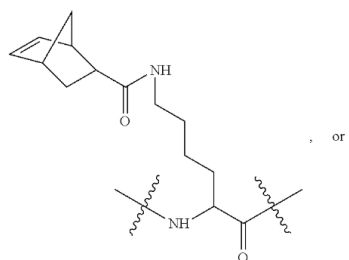
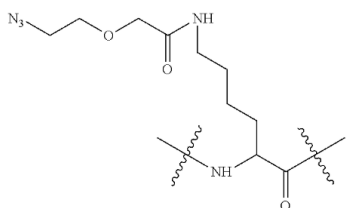
<sup>3</sup> The Petition cites to the U.S. Patent Pub. No. 2020/0190165 (Ex. 1009) because *Yamada* (Ex. 1008) is in Japanese. Thus, Petitioner handles *Yamada* the same way as *Matsuda* and *Matsuda* '541, but somehow concludes that only *Yamada* and not *Matsuda* was of record during prosecution of the '675 Patent. See Petition, XI.

### III. THE '675 PATENT

The '675 Patent provides a modified antibody for the site-specific functionalization of antibodies by selectively labeling amino acid residues or linking cargo molecules, such as drugs or diagnostic agents, to the antibody. '675 Patent, Abstract. The composition allows for precise modification of antibodies at specific sites, such as lysine 248 on the heavy chain, using bio-orthogonal click chemistry. Ex. 1001, cl. 11. This targeted modification ensures uniformity in labeling. *Id.* at 14:20-24. The ability to attach a defined number of functional groups to an antibody enhances the control over therapeutic dosing and efficacy, which, in ADC applications, controlled payload delivery is crucial. *Id.*, 2:37-39.

The sole claim currently at issue in this proceeding, Claim 11, recites:

**11.** The modified antibody of claim 1, wherein the modified lysine residue has following structure:



*Id.*, cl. 11.

#### IV. THE PETITION FAILS TO SHOW THAT THERE IS A REASONABLE LIKELIHOOD THAT THE PETITIONER WILL PREVAIL ON CLAIM 11

##### A. Ground 1 Fails To Anticipate The Challenged Claim

Ground 1 relies on Petitioner's erroneous characterization of the priority date of Claim 11. With the proper priority date in hand, Ground 1 fails. The '975 publication is a non-prior art reference that cannot anticipate Claim 11 of the '675 Patent. Specifically, Ground 1 of the Petition relies on CA 3132959A1 (Ex. 1005) ("the '959 publication"), which is not prior art, but is in fact in the priority chain for

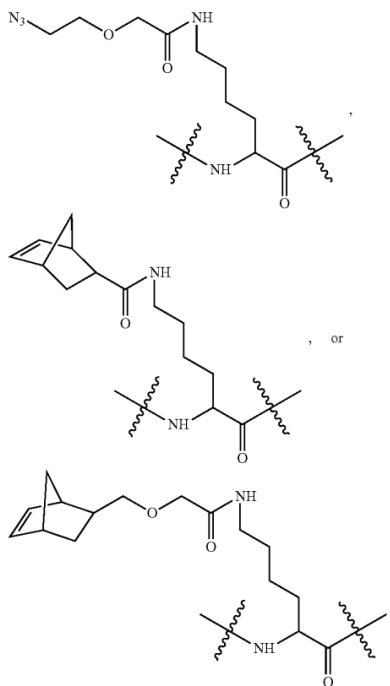
the '675 Patent. While Petitioner claims that the '959 publication does not adequately support the claims of the '675 Patent, there can be no dispute Claim 11 properly claims priority to the '959 publication. Indeed, the Petitioner concedes that the '959 publication and the '675 Patent contain “essentially identical disclosure” as they are in the same patent family, and further argues that the '959 publication anticipates Claim 11—i.e., that it discloses each and every element of Claim 11. Petition, 30.

The Petition’s focus on the negative limitation of disclaimed Claim 1 is no longer applicable because Claim 11 includes specific lysine residues that comprise a bio-reactive terminal group disclosed in the '675 Patent’s specification. Thus, the negative limitation is effectively negated by the addition of the specific structure in Claim 11. Pursuant to 35 U.S.C. § 282,

Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of the other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim.

35 U.S.C. § 282. Moreover, even if dependent Claim 11 is still interpreted to contain the negative limitation based on its dependency from independent Claim 1, the specification still “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1020 (Fed. Cir. 2022) (quoting

*Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010)). This is because Claim 11 specifies that the modified lysine residue has one of the following structures:



Ex. 1001, cl. 11. None of the three structures recited in Claim 11 comprise a “terminal bio-reactive functional group selected from terminal hydroxy group, terminal carboxyl group, terminal thiol group, terminal amino group, and terminal aldehyde group” as recited by disclaimed Claim 1. Thus, the inclusion of the three specific modified lysine terminal groups necessarily excludes the terminal groups

contained in the negative limitation,<sup>4</sup> and is sufficiently supported in the specification of the '675 Patent. Accordingly, the '675 Patent properly claims priority to March 14, 2018, and the '959 publication is not prior art. As a result, Ground 1 fails.

**B. Grounds 3, 5, And 7 Fail To Render Obvious Claim 11**

The remaining grounds that challenge Claim 11—Grounds 3, 5, and 7—rely on a combination of references to support Petitioner's arguments. *See* Petition, 2-3. However, the Petition does not establish that a POSA 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.” *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012).

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<sup>4</sup> To the extent the Board is inclined to hold that current dependent Claim 11 is not adequately supported by the specification due to the negative limitation recited in disclaimed Claim 1, Patent Owner intends to amend Claim 11 into independent form and remove the reference to the negative limitation.

i. The Failure To Establish A Motivation To Combine Any Of The Proposed Combinations Precludes Institution

“[I]n determining obviousness, the challenger bears the burden of establishing that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention....” *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1366 (Fed. Cir. 2017) (emphasis added) (internal citation and quotations omitted). The Petition appears to improperly rely on *KSR* for the proposition that obviousness may be established “when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *See* Petition, 45-46 (quoting *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416-17 (2007)). However, “*KSR* did not do away with the requirement that there must exist a motivation to combine various prior art references in order for a skilled artisan to make the claimed invention.” *Virtek Vision Int’l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 887 (Fed. Cir. 2024).

Throughout the 13,868-word Petition, Petitioner mentions some iteration of “motivation” only five times. *See* Petition, 4, 77, 78, 79. The 230-page expert declaration, only eight times. *See* Ex. 1002, ¶¶ 60, 61, 62, 403, 421, 422. And not once does the Petition or declaration “articulate any reason *why* a skilled artisan

would combine the[] references.” *Virtek Vision*, 97 F.4th at 882 (emphasis added). Each of the Petition’s deficient motivations are addressed in turn.

**First**, in the Petition’s “Technical Summary and Background” (Section IV), Petitioner sets forth a purported “motivation in the art.” Petition, 4. Specifically, that “[a]s of 2019, ... [t]here was an expectation that site-specific conjugation would decrease off-target toxicity and improve the pharmacokinetic properties of the ADC, and thus, there was a motivation in the art to pursue technologies for site-specific conjugation.” Petition, 4 (citing Ex. 1002, ¶¶ 60-61 (parroting Petition: “At the time, there was an expectation that site-specific conjugation would decrease off-target toxicity and improve the pharmacokinetic properties of the ADC, and thus there was a clear motivation in the art to pursue technologies that allowed site-specific conjugation”). The expert’s near-verbatim recitation of the Petition is not “persuasive or helpful as it repeats the Petitioner’s arguments and offers little or no elaboration as to how one of ordinary skill in the art would understand the term.” *See InfoBionic, Inc. v. Braemer Manuf., LLC*, IPR2015-01704, Paper 11 at 6 (P.T.A.B. Feb. 16, 2016) (denying institution). Further, this supposed “motivation in the art” as of 2019 does not satisfy Petitioner’s burden of establishing that a POSA would have combined the specific references relied upon in Grounds 3, 5, and 7 to achieve Claim 11.

**Second**, in Grounds 3 and 5, the Petition does not even attempt to set forth a motivation to combine analysis for its proposed combinations. Rather, the Petition simply alleges that “these claims are nothing more than ‘the mere substitution of one element for another known in the field’ and the substitutions ‘yield a predictable result.’” Petition, 46-47 (quoting *KSR*, 550 U.S. at 416-17). This, however, is not the appropriate analysis for establishing obviousness. The Petition provides no discussion of *why* a POSA would have combined PepTalk Poster, *Yamada*, and *Matsuda*, nor does the Petition elaborate on its conclusory statement that “a POSA could predictably combine these elements to arrive at the claims.” Petition, 49. Indeed, Petitioner’s conclusory statement demonstrates the proposed combinations are nothing more than hindsight driven efforts to arrive at the claim. *See TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1361 (Fed. Cir. 2019) (explaining petitioner cannot “use the challenged patent as a roadmap to reconstruct the claimed invention using disparate elements from the prior art—i.e., the impermissible *ex post* reasoning and hindsight bias that *KSR* warned against”).

**Third**, in Ground 7, the Petition alleges that “Yamada provides motivation for a POSA to prepare an antibody regioselectively modified with a bio-orthogonal functional group at the lysine residue at position 248.” Petition, 77. Then, the Petition alleges that “Matsuda provides further motivation for a POSA to

regioselectively modify an antibody at lysine 248 according to claim 1.” Petition, 78. According to Petitioner, because “Yamada and Matsuda both suggest regioselectively modifying Lys248 with a terminal bio-orthogonal functional group,” the references “taken together[,]” a POSA would be motivated and able to prepare a modified antibody according to claim 1 with a reasonable expectation of success.” Petition, 78-79. Petitioner’s conclusory argument fails, which makes sense given that Claim 11 was allowed over these very references. *See* Patent Owner’s Argument or Discretionary Denial Paper, 7-13. “It does not suffice to meet the motivation to combine requirement to recognize that two alternative arrangements ... were both known in the art.” *See Virtek Vision*, 97 F.4th at 888 (explaining arguments “grounded in the fact that the claim elements are known in the prior art” without more “does not show a motivation to combine” (citing *KSR*, 550 U.S. 398, 418 (2007) (“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.”))); *see also Dome Patent L.P. v. Lee*, 799 F.3d 1372, 1380 (Fed. Cir. 2015) (“If all elements of a claim are found in the prior art, as is the case here, the factfinder must further consider the factual questions of whether a person of ordinary skill in the art would be motivated to combine those references, and whether in making that

combination, a person of ordinary skill would have had a reasonable expectation of success.”).

Petitioner’s assertion that “Yamada explains prior ADC production methods result in nonuniformity and varying DARs. ... The DAR can impact a variety of pharmacokinetic parameters (*id.*; Ex. 1027, 541), and therefore a POSA would be motivated to regioselectively modify an antibody to prepare consistent DARs” fares no better. Petition, 77. The Petition is impermissibly “defining the problem” *Yamada* addresses “in terms of [the] solution” *Yamada* discloses, which constitutes improper hindsight reasoning. *See Shenzhen Buxiang Network Tech. Co., Ltd. v. Sun Pleasure Co. Ltd.*, No. 2022-1912, 2024 WL 3451830, at \*6 (Fed. Cir. July 18, 2024) (affirming PTAB’s decision that claims were not unpatentable) (citing *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 859 (Fed. Cir. 2015))).

Moreover, like the petitioner in *Virtek Vision*, Petitioner here provides “no argument about common sense in the [P]etition or in Dr. [Tumey’s] declaration. There [i]s no evidence that there are a finite number of identified, predictable solutions. There is no evidence of a design need or market pressure.” *Virtek Vision*, 97 F.4th at 887-88. Thus, like *Virtek Vision*, “this case involves nothing other than an assertion that because [regioselectivity modifications at lysine 248] were disclosed in a prior art reference and were therefore ‘known,’ that satisfies the

motivation to combine analysis.” *Id.* at 888. The Federal Circuit has made clear that such an analysis “is an error as a matter of law. It does not suffice to simply be known. *A reason for combining must exist.*” *Id.* (emphasis added).

The Petition fails to establish why a POSA would have combined any of the references relied upon in Grounds 3, 5, and 7 to achieve the claimed invention, and institution should be denied.

ii. The Lack Of Factual Support For A Reasonable Expectation Of Success Precludes Institution

Similar to the Petition’s lacking motivation to combine analysis, the Petition fails to establish any factual support that a POSA would have a reasonable expectation of success of combining the references. The following statement is representative of the handful of other instances the Petition mentions a reasonable expectation of success: “Thus, all of the elements of claim 2 are disclosed in PepTalk Poster and Matsuda, and a POSA could readily combine these disclosures to predictably arrive at claim 2 with a reasonable expectation of success.” Petition, 101. This conclusory assertion does not explain why a POSA would have had a reasonable expectation of success, nor does it address any technical challenges or compatibility concerns associated with the proposed combination. As such, it fails to meet Petitioner’s burden of providing a reasoned analysis supported by evidence,

rather than mere attorney argument. *See KSR*, 550 U.S. at 418; *see also Dome Patent L.P.*, 799 F.3d at 1380.

## V. CONCLUSION

As each of the Grounds fail on the merits (as well as for the discretionary reasons detailed in Patent Owner's concurrently filed Argument for Discretionary Denial), institution of the Petition should be denied.

Dated: May 12, 2025

Respectfully submitted,

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**Certification of Word Count Under 37 C.F.R. § 42.24(d)**

The undersigned hereby certifies that the foregoing contains 3,244 words according to the word count of the word-processing software used to prepare the foregoing and accounting for the words in the figures as required by the Trial Practice Guide.

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I hereby certify that on May 12, 2025, a true and correct copy of the foregoing was caused to be served on the following counsel of record for Petitioner by electronic mail at the following address:

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