UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AJINOMOTO CO., INC.

Petitioner,

v.

ABTIS CO., LTD.

Patent Owner.

CASE: IPR2025-00283

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

PATENT OWNER'S ARGUMENT FOR DISCRETIONARY DENIAL

TABLE OF CONTENTS

TABLE OF PATENT OWNER EXHIBITS

Exhibit No.	Description
2001	Statutory Disclaimer of U.S. Patent No. 11,896,675

Patent Owner, AbTis Co., Ltd. ("AbTis" or "Patent Owner"), submits this paper regarding discretionary denial pursuant to the Board's recent guidance on "Interim Processes for PTAB Workload Management," dated March 26, 2025 ("Guidance").

I. INTRODUCTION

The Petition—strategically filed mere weeks after the deadline to file a PGR—challenges Claims 1-13 of U.S. Patent No. 11,896,675 ("the '675 Patent") across seven challenge grounds. Claim 11, however, is the only claim relevant to the Board's consideration of the Petition because Patent Owner statutorily disclaimed Claims 1-10 and 12-13, resulting in the mootness of Grounds 2, 4, and 6 of the Petition. Ex. 2001; *see infra* Section II. Under the prior discretionary denial standard (including that set forth in *Advanced Bionics, LLC v. Med-El Elektromedizinishe Geräte GMBH*, IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) (precedential)), and pursuant to the new factors set forth in the Guidance, the Petition is a prime candidate for exercising discretion with respect to the remaining Grounds (1, 3, 5, and 7) to better allocate the Board's resources elsewhere, especially given there is no underlying litigation.

Turning first to Grounds 3, 5, and 7, the Petition fails because Petitioner either intentionally or negligently misrepresents the '675 Patent's prosecution history.

Petition, 84-86. The Petition wrongly alleges that *Matsuda*—a reference relied on in Grounds 3, 5, and 7—was not of record or considered by the Patent Office during prosecution of the '675 Patent. *Id.* at 84. This is false. The U.S. National Stage application of *Matsuda*, U.S. Patent Publication No. 2021/0139541 ("*Matsuda* '541") (Ex. 1011), was of the record and considered by the examiner during prosecution of the '675 Patent. The '675 Patent cites *Matsuda* '541 on its face. Ex. 1001, at 1. The Petitioner here even uses *Matsuda* '541 (Ex. 1011) as the certified translation for *Matsuda*, yet somehow claims that this very reference was not of record during prosecution of the '675 Patent. Petitioner's egregiously negligent oversight, or potential intentional misrepresentation, plagues Grounds 3, 5, and 7 under § 325(d), as *Matsuda* is relied on extensively in those grounds.

Apart from *Matsuda*, the remaining art the Petition presents is the same or substantially the same art as previously submitted during prosecution of the '675 Patent warranting discretionary denial under the precedential decision of *Advanced Bionics, LLC v. Med-El Elektromedizinishe Geräte GMBH*, IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) (precedential). A strong presumption exists that the Patent Office considered and approved the Challenged Claim over the art and arguments raised in the Petition. As a result, denying this Petition will appropriately reallocate the Board's resources to matters needing the Board's intervention. The

Petition's obviousness combinations in Grounds 3, 5, and 7 are also ripe for discretionary denial because of the Petition's overreliance on expert testimony rather than disclosure from the references themselves. Petitioner's expert declaration is largely comprised of conclusory testimony unsupported by any evidence, which is entitled to little or no weight. Without that conclusory and overused testimony, Petitioner fails to establish that a POSA would have been motivated to combine the references sufficient to support Grounds 3, 5, and 7.

Turning to Ground 1, the Petition's anticipation theory relying on a priority application in the chain of the '675 Patent is legally insufficient because the "prior art" reference is not prior art at all. Indeed, the Petition fails to establish that the alleged anticipatory reference is entitled to a priority date earlier than the priority date of Claim 11. With the proper priority date in hand, Ground 1, like all the other grounds in the Petition, fails.

The Petition's deficiencies speak for themselves, and the Petition could be denied strictly based on its misrepresentations of the '675 Patent's prosecution history and based on the Petition's failure to establish proper combinations rendering Claim 11 obvious. The Petition's improper overreliance on expert testimony and non-prior art references further supports discretionary denial. Additional considerations also support denial of this Petition, including that there is no co-

pending litigation and that the Patent Owner disclaimed all claims except Claim 11 to narrow the dispute for the Board.

Patent Owner respectfully submits that the Petition is not a good use of the Board's time and resources. To maintain the other statutory deadlines in existing proceedings, and the workload needs of the PTAB, the Petition should be denied so resources can be properly allocated to Petitions that better adhere to the framework set forth in the Trial Practice Guide.

II. BACKGROUND OF THE PROCEEDING

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*");[1]

[1] 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.

- 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
- 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.

III. STATUTORY DISCLAIMER UNDER 37 C.F.R. § 1.321(a)

Patent Owner strongly disagrees with each of the grounds advanced against the Challenged Claims in the Petition. Nevertheless, on May 9, 2025, Patent Owner

1011), which Petitioner asserts is "certified as an accurate translation of the corresponding PCT." Petition, 28-29.

filed a statutory disclaimer, disclaiming all claims except Claim 11 of the '675 Patent under 35 U.S.C. § 253(a) and in compliance with 37 C.F.R. § 1.321(a), using the form approved for such submissions by the PTO and accompanied by the appropriate fee. Ex. 2001. Because "no *inter partes* review will be instituted based on disclaimed claims" (37 C.F.R. § 42.107(e)), Patent Owner respectfully submits that institution of a trial here would be improper with respect to disclaimed Claims 1-10 and 12-13, which resolves any issue with respect to Grounds 2, 4, and 6 in the Petition. *See Unified Pats. Inc. v. Sound View Innovations, LLC*, IPR2019-01113, Paper 8 at 7-8 (P.T.A.B. Nov. 22, 2019) (denying institution and holding "[b]ecause [some of the challenged] claims . . . have been disclaimed under 35 U.S.C. § 253(a) in compliance with 37 C.F.R. § 1.321(a), we cannot institute a trial on these claims"); *SFC Co., Ltd. v. LG Chem, Ltd.*, IPR2020-00178, Paper 16 at 7-8 (P.T.A.B. May 29, 2020); *Delta Elecs., Inc. v. Vicor Corp.*, IPR2024-00134, Paper 8 at 11-12 (P.T.A.B. May 17, 2024); *see also Tandus Flooring, Inc. v. Interface, Inc.*, IPR2013-00526, Paper 7 (P.T.A.B. Feb. 14, 2014) (denying institution when patent owner disclaimed all challenged claims); *Inguran, LLC d/b/a Sexing Techs. v. Premium Genetics (UK) Ltd.*, IPR2016- 00756, Paper 9 (P.T.A.B. Aug. 31, 2016).

IV. THE PETITION SHOULD BE DISCRETIONARILY DENIED UNDER § 325(d)

The Petition should be denied under § 325(d) because (1) *Matsuda* was of record and considered by the PTO during prosecution of the '675 Patent, and Petitioner's argument otherwise is an inexcusable misrepresentation; and (2) the Petition presents references that are cumulative of art that was already considered by the PTO.

A. Petitioner's Egregious Misrepresentations Of The '675 Patent's Prosecution History Should Not Be Given Any Weight

The Petition's § 325(d) arguments constitute either intentional or negligent misrepresentations of the '675 Patent's prosecution history. Petition, 84-86. The Petition asserts that "Matsuda w[as] not of record or considered by the Patent Office during prosecution of the '675 Patent." Petition, 84. However, the U.S. National Stage application of *Matsuda*, *Matsuda* '541 (Ex. 1011), was unequivocally part of the record and considered by the examiner during prosecution of the '675 Patent. Specifically, the '675 Patent cites *Matsuda* '541 on its face. Ex. 1001, 1. Moreover, *Matsuda* '541 was submitted in an IDS November 13, 2023, and subsequently considered by the examiner on November 20, 2023, as evidenced by the List of References Considered by Examiner dated December 7, 2023. Ex. 1035, 108 (signed "List of References Considered by Examiner" dated 12/7/2023). Petitioner's

negligent oversight, or potential intentional misrepresentation, plagues Grounds 3, 5, and 7, as *Matsuda* is relied on extensively in those grounds.

Worse still, the Petition's Discretionary Denial argument relies on Petitioner's erroneous assertion that "Matsuda w[as] not of record or considered by the Office during prosecution of the '675 Patent." Petition, 84. This is particularly striking given that, rather than submitting a certified translation of *Matsuda*, Petitioner simply submits that *Matsuda* and *Matsuda* '541 are sufficiently identical such that *Matsuda* '541 functions as a certified English translation of *Matsuda*. Petition, 28-29. As a result, the Petition fails to address—at all—why the Examiner's consideration of *Matsuda* during prosecution was somehow insufficient or flawed.[2]

B. The Petition Presents The Same Or Substantially The Same Art As Previously Presented To The PTO

The Board should further exercise its discretion to deny institution of the *inter partes* review of the Challenged Claim of the '675 Patent under 35 U.S.C. § 325(d) because the other references in the Petition are cumulative, and the arguments presented by Petitioner add nothing new from what was already known and

[2] Because the Petition was filed before the Guidance, the Petition preemptively addresses arguments under § 325(d). The Petitioner should not get a second chance at addressing this requirement because it failed to do so in the first instance.

evaluated by the Examiner during prosecution. A strong presumption, therefore, exists that the PTO considered and approved the Challenged Claim over the art and arguments raised in the Petition, and in the absence of some showing of error in that process—which Petitioner has not shown—institution should be denied.

The Board applies a two-part framework for evaluating discretionary denials under § 325(d): (1) whether the same or substantially the same art or arguments were presented to the PTO during the original prosecution; and (2) whether the Petitioner has demonstrated that the PTO erred in a manner material to the patentability of Challenged Claims. *Adv. Bionics*, IPR2019-01469, Paper 6 at 8. Once the Board determines that part one of the framework is satisfied, it then considers whether Petitioner has shown "material" error. Because of the Board's "commitment to defer to previous Office evaluations[,]" an Examiner does not err in a manner material to patentability "[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments." *Adv. Bionics*, IPR2019-01469, Paper 6 at 9.

The Board considers several non-exclusive factors (the *Becton, Dickinson* factors) when assessing whether to exercise its discretion under Section 325(d), including: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the

asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art; (e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments. *See Adv. Bionics*, Paper 6 at 9 (citing *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (P.T.A.B. Dec. 15, 2017) (precedential as to § III.C.5, first paragraph)). Here, all of the *Becton, Dickinson* factors weigh in favor of denying institution.

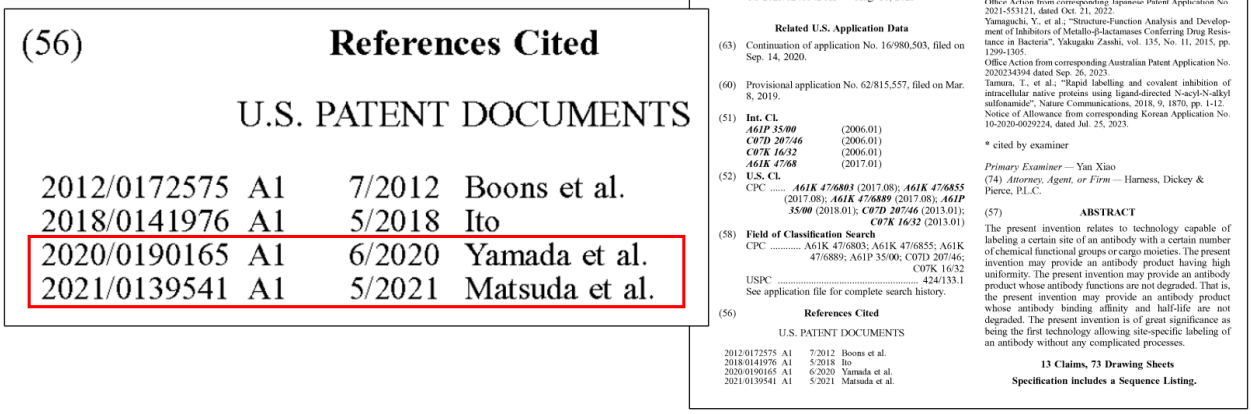
Matsuda and *Yamada* were unequivocally involved during the prosecution of the '675 Patent. *See* '675 Patent, Cover (listing *Yamada* on its face); *see also* Ex. 1035, 322-330 (Non-Final Office Action dated August 16, 2023) (rejecting claims as anticipated by *Yamada*).[3] *Matsuda* '541 (Ex. 1011), likewise, was listed in

[3] The Petition cites to the U.S. Patent Pub. No. 2020/0190165 (Ex. 1009) for *Yamada* because PCT/JP2018/017345 (*Yamada*, Ex. 1008) is in Japanese. Thus, Petitioner handles *Yamada* the same way as *Matsuda* and *Matsuda* '541, but somehow

an IDS signed by the Examiner and cited on the face of the '675 Patent. Ex. 1035, 108; Ex. 1001, Cover.

Moreover, *Yamada* was likewise of record and considered during prosecution of the '675 Patent. *See* '675 Patent, Cover (listing *Yamada* on its face); *see also* Ex. 1035, 322-30 (Non-Final Office Action dated August 16, 2023) (rejecting claims as anticipated by *Yamada*). *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 (*see* Ex. 1035, 108; Ex. 1001, Cover):

concludes that only *Yamada* and not *Matsuda* was of record during prosecution of the '675 Patent. *See* Petition, Section XI.



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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.

US011896675B2

(12) **United States Patent**
Chung et al.

(10) **Patent No.: US 11,896,675 B2**
(45) **Date of Patent: Feb. 13, 2024**

(54) **SITE-SPECIFIC ANTIBODY CONJUGATION AND ANTIBODY-DRUG CONJUGATE AS SPECIFIC EMBODIMENT THEREOF**

(71) Applicant: **AbTis Co., Ltd.**, Gyeonggi-do (KR)

(72) Inventors: **Sang Jeon Chung**, Gyeonggi-do (KR); **Ju Hwan Kim**, Gyeonggi-do (KR); **Young Geun Lee**, Gyeonggi-do (KR); **Tae Jin Lee**, Gyeonggi-do (KR); **Jin Woo Seo**, Gyeonggi-do (KR)

(73) Assignee: **AbTis Co., Ltd.**, Gyeonggi-do (KR)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **18/154,998**

(22) Filed: **Jan. 16, 2023**

(65) **Prior Publication Data**

US 2023/0248842 A1 Aug. 10, 2023

Related U.S. Application Data

(63) Continuation of application No. 16/980,503, filed on Sep. 14, 2020.

(60) Provisional application No. 62/815,557, filed on Mar. 8, 2019.

(51) **Int. Cl.**
A61P 35/00 (2006.01)
C07D 207/46 (2006.01)
C07K 16/32 (2006.01)
A61K 47/68 (2017.01)

(52) **U.S. Cl.**
CPC ***A61K 47/6803*** (2017.08); ***A61K 47/6855*** (2017.08); ***A61K 47/6889*** (2017.08); ***A61P 35/00*** (2018.01); ***C07D 207/46*** (2013.01); ***C07K 16/32*** (2013.01)

(58) **Field of Classification Search**
CPC A61K 47/6803; A61K 47/6855; A61K 47/6889; A61P 35/00; C07D 207/46; C07K 16/32
USPC 424/133.1
See application file for complete search history.

(56) **References Cited**

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2020/0190165 A1 6/2020 Yamada et al.
2021/0139541 A1 5/2021 Matsuda et al.

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KR 10-2020-0002858 A 1/2020
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WO WO-2020/184944 A1 9/2020

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Van Geel, R. et al.; Chemoenzymatic Conjugation of Toxic Payloads to the Globally Conserved N-Glycan of Native mAbs Provides Homogeneous and Highly Efficacious Antibody-Drug Conjugates, Bioconjugate Chemistry, 2015, 26, pp. 2233-2242.
International Search Report from corresponding PCT Application No. PCT/KR2020/003282, dated Jun. 16, 2020.
Written Opinion from corresponding PCT Application No. PCT/KR2020/003282, dated Jun. 16, 2020.
Extended European Search Report from corresponding European Patent Application No. 20770235.8, dated Oct. 10, 2022.
Kurosaki Hiromasa et al: "Irreversible Inhibition of Metallo-[beta]-lactamase (IMP-1) by 3-(30Mercaptopropionylsulfanyl)propionic Acid Pentafluorophenyl Ester", Angewandte Chemie International Edition, vol. 44, No. 25, Jun. 10, 2005, pp. 3861-3864.
Office Action from corresponding Japanese Patent Application No. 2021-553121, dated Oct. 21, 2022.
Yamaguchi, Y., et al.; "Structure-Function Analysis and Development of Inhibitors of Metallo-β-lactamases Conferring Drug Resistance in Bacteria", Yakugaku Zasshi, vol. 135, No. 11, 2015, pp. 1299-1305.
Office Action from corresponding Australian Patent Application No. 2020234394 dated Sep. 26, 2023.
Tamura, T., et al., "Rapid labelling and covalent inhibition of intracellular native proteins using ligand-directed N-acyl-N-alkyl sulfonamide", Nature Communications, 2018, 9, 1870, pp. 1-12.
Notice of Allowance from corresponding Korean Application No. 10-2020-0029224, dated Jul. 25, 2023.

* cited by examiner

Primary Examiner — Yan Xiao
(74) *Attorney, Agent, or Firm* — Harness, Dickey & Pierce, P.L.C.

(57) **ABSTRACT**

The present invention relates to technology capable of labeling a certain site of an antibody with a certain number of chemical functional groups or cargo moieties. The present invention may provide an antibody product having high uniformity. The present invention may provide an antibody product whose antibody functions are not degraded. That is, the present invention may provide an antibody product whose antibody binding affinity and half-life are not degraded. The present invention is of great significance as being the first technology allowing site-specific labeling of an antibody without any complicated processes.

13 Claims, 73 Drawing Sheets
Specification includes a Sequence Listing.

Ex. 1001, Cover (annotated).

"The precedential decision in *Advanced Bionics* unambiguously instructs, however, 'Previously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent.'" *Nespresso USA, Inc. v. K-Fee Sys. GMBH*, IPR2021-01223, Paper 9 at 13 (P.T.A.B. Jan. 18, 2022) (denying institution under Section 325(d) (citing *Adv. Bionics*, Paper 6 at 7-8)). As detailed above, the Petition wrongly states *Matsuda* was not of record and

therefore the Petitioner failed to meet its burden to demonstrate any material error in the Examiner's consideration of *Matsuda*.

As for *Yamada*, that reference was fully evaluated and distinguished during the prosecution of the '675 Patent. In fact, the Examiner rejected 10 out of 13 claims as anticipated by *Yamada*, which the Petitioner admits. Petition, 84. Specifically, the Examiner relied on *Yamada* for disclosure of a compound containing an affinity agent for soluble protein (e.g., antibody) and a bioorthogonal functional group; modification of lysine residue (positions 248) of the antibody; THTCPPCPAPELLGGPSVFLFPPKPKDTLMISR (SEQ ID NO: 40) comprising Formula 8-2, modified trastuzumab (which comprises two heavy chains); and for the disclosure of the bioorthogonal functional group is an azide residue (which is a group capable of participating cycloaddition reaction). Ex. 1035, 326-27 (Non-Final Office Action dated August 16, 2023) (rejecting claims as anticipated by *Yamada*). After the claims were rejected, the applicant amended the claims and distinguished *Yamada*, leading to a notice of allowance. The Petition relies on *Yamada* to anticipate most of the claims and render obvious the remainder. As a result, the subject matter being relied upon for this Petition was fully disclosed in *Yamada* and evaluated during prosecution of the '675 Patent. That Petitioner disagrees with the Examiner's evaluation of prior art does not demonstrate a material error, but rather

falls under the guidance in *Advanced Bionics* that "reasonable minds can disagree regarding the purported treatment of [*Yamada*]," and therefore "it cannot be said that the Office erred in a manner material to patentability." *Adv. Bionics*, Paper 6 at 9.

While the PepTalk Poster and PepTalk Presentation (collectively, the "PepTalk References") were not formally of record during prosecution of the '675 Patent, the references are cumulative of *Yamada*. Specifically, *Yamada* fully discloses all of the purported differences in the prior art asserted in this Petition, and the PepTalk References add nothing new that *Yamada* did not already disclose. In fact, *Yamada*, the PepTalk Poster, and the PepTalk Presentation are all references created by Petitioner. *See* Ex. 1009, Cover; *see also* Ex. 1006, 1; Ex. 1007, 38. All of the named inventors of *Yamada* are authors of the PepTalk Presentation, and five out of six of the named inventors are authors of the PepTalk Poster:

***Yamada*:**

(72)	Inventors:	**Kei Yamada**, Kawasaki-shi (JP); **Yutaka Matsuda**, Kawasaki-shi (JP); **Tomohiro Fujii**, Kawasaki-shi (JP); **Natsuki Shikida**, Kawasaki-shi (JP); **Reiko Yuji**, Kawasaki-shi (JP); **Kazutaka Shimbo**, Kawasaki-shi (JP); **Yuji Ito**, Kagoshima-shi (JP)
(73)	Assignee:	**Ajinomoto Co., Inc.**, Tokyo (JP)

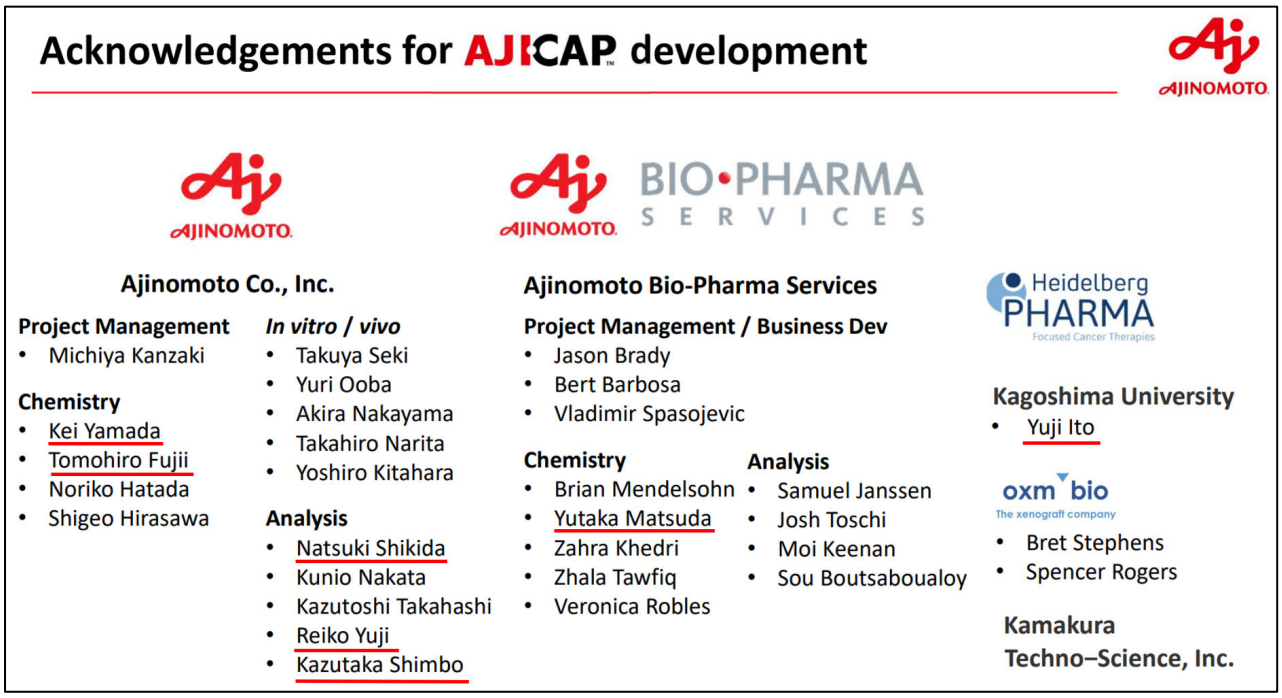
Ex. 1009, Cover (English translation of *Yamada* (Ex. 1008)).

PepTalk Poster:

Kei Yamada[1,2], Tomohiro Fujii[1], Takuya Seki[1], Yuri Ooba[1], Takahiro Narita[1], Akira Nakayama[1], Yoshiro Kitahara[1], Natsuki Shikida[1], Kazutaka Shimbo[1], Kunio Nakata[1]
Tatsuya Okuzumi[1*], Yuji Ito[2], Yutaka Matsuda[3], Zahra Khedri[3] and Brian A. Mendelsohn[3*]
[1]Ajinomoto Co., Inc., [2]Kagoshima University, [3]Ajinomoto Bio-Pharma Services

Ex. 1006, 1 (annotated).

PepTalk Presentation:



Ex. 1007, 38 (annotated).

Yamada, the PepTalk Poster, and the PepTalk Presentation each include disclosure relating to Petitioner's AJICAP™ technology. *See, e.g.*, Ex. 1006, Methods, ¶ 3 ("Synthesis of Site-Specific ADC by AJICAP™" resulting in "trastuzumab-DMI"); Ex. 1007, 13, 32 ("AJICAP™-trastuzumab-DM1 has an

expanded Therapeutic Window"); Ex. 1006, ¶ [1971] ("Synthesis of Regioselective Trastuzumab-DM1 Conjugate and Analysis of Average DAR.").

The Petition admits that "PepTalk Presentation contains much of the same information as PepTalk Poster." Petition, 57. And, given the identity of subject matter and authors across these three references, there is little doubt they are cumulative. Accordingly, the Petition is presenting precisely the same arguments that were previously presented by the PTO when the PTO rejected multiple claims as anticipated by *Yamada*. Petition, 84. Because the PepTalk References merely restate what was already disclosed in *Yamada*, and Petitioner submits substantially the same arguments here as were presented during prosecution, there is no material difference between the prior art or arguments asserted in this Petition and those previously considered by the PTO.

V. GROUND 1 OF THE PETITION PRESENTS A LEGALLY ERRONEOUS "ANTICIPATION" THEORY

The only remaining ground in the Petition, Ground 1, relies on Petitioner's erroneous characterization of the priority date of Claim 11. With the proper priority date in hand, Ground 1, like all the other grounds in the Petition, fails.

Specifically, Ground 1 of the Petition relies on CA 3132959A1 ("the '959 publication" (Ex. 1005)), 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

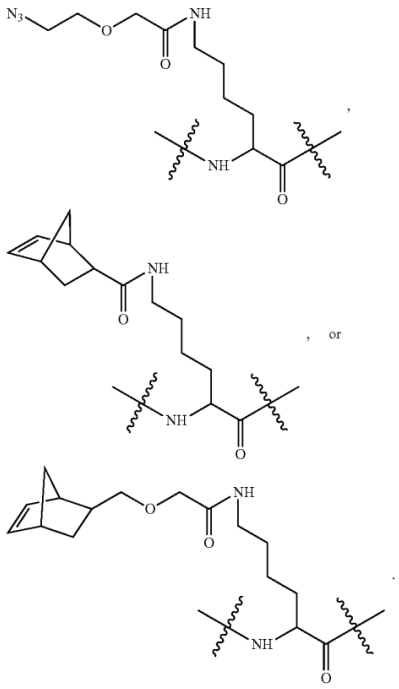
adequately support the claims of the '675 Patent, there can be no dispute Claim 11 properly claims priority to the '959 publication. Indeed, the Petitioner concedes that the '959 publication and the '675 Patent contain "essentially identical disclosure" as they are in the same patent family, and further argues 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 a specific modified lysine residue that comprises 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 functional groups 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 "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.[4] Accordingly, the '675 Patent properly claims priority to March 14, 2018, and the '959 publication is not prior art. As a result, Ground 1 of the Petition has zero merit, which further supports discretionary denial.

VI. OTHER DISCRETIONARY ISSUES CONFIRM THAT DENIAL OF INSTITUTION IS APPROPRIATE

A. The Petition Is Over-Reliant On Expert Testimony Favoring Discretionary Denial

Discretionary denial is also warranted based on the Petition's overreliance on expert testimony and non-prior art references. The Guidance states that one relevant factor within the Board's "discretionary considerations" is "[t]he extent of the petition's reliance on expert testimony." Guidance, 2. The Petition in this proceeding far surpasses reasonable reliance on expert testimony because: (1) the Petition expressly bases all remaining alleged Grounds of unpatentability on expert testimony (i.e., based on what "would be obvious to a POSA"); and (2) the Petition's reliance on a POSA's purported knowledge is typically presented as a conclusory

[4] 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.

statement that, in its analysis of Claim 11, consistently and repeatedly fails to cite to any evidence, and is therefore entitled to little weight. *In re Ethicon, Inc.*, 844 F.3d 1344, 1348, 1352 (Fed. Cir. 2017) (concluding that the Board properly gave "little weight" to conclusory expert testimony).

Absent this reliance on conclusory expert testimony and what "would be obvious to a POSA,"—i.e., removing this improper expert testimony—each remaining Ground fails to render Claim 11 obvious. This improper expert testimony is not relied on for only a minor portion of the Petition. Rather, throughout the Petition, Petitioner does not cite any evidence that corroborates what was purportedly well-known to a POSA at the time of the invention. Neither the Petition, nor the supporting expert declaration cites to a single reference or article besides the primary and secondary references relied upon for the obviousness combination, again references already considered by the Examiner or cumulative to art of record. The expert's conclusory characterizations of the combination references and of what a POSA purportedly would have recognized are inadequate to support Petitioner's obviousness theories.

This is important because for Grounds 3 and 5, the Petition admits that the primary reference, the PepTalk Presentation[5] "does not explicitly teach the specific D_1 structures recited in claims 5-7 or the structures recited in claim 11." Petition, 50, 65. Then, the Petition alleges that "short alkyl or cycloalkyl linkers would be obvious to a POSA." Petition, 50. For "support," the Petition cites to two paragraphs of the expert declaration, one of which states "the D1 component would ***most likely*** be an alkyl or cycloalkyl when using an azide as the bio-orthogonal click chemistry group." Ex.1002, ¶ 267 (emphasis added). The expert cites no other evidence—not even the references relied upon for the combination—to support this conclusory, ambiguous opinion. *Id.* Because the expert failed to set forth the underlying facts and data that supported his conclusions as required under FRE 702, this factor favors exercising discretion and denying this Petition.

[5] In Ground 3, Petitioner states that the "PepTalk ***Presentation*** does not explicitly teach the specific D1 structures recited in claims 5-7 or the structures recited in claim 11." While factually true, the Petition's statement appears to be an error because Ground 3 proposes a combination of the PepTalk ***Poster***, *Yamada*, and *Matsuda*. The PepTalk Poster, like the PepTalk Presentation, does not explicitly disclose the structures recited in Claim 11.

The Petition concludes its analysis of Claim 11 for Grounds 3, 5, and 7 by alleging that "[b]ecause the structures in claim 11 fall within the scope of the respective definitions of D1 in claims 5-7, all of the elements of claims 5-7 were taught by Yamada, and combining these with the [primary reference][6] would be nothing more than 'the mere substitution of one element for another' to yield a predictable result." Petition, 55 (Ground 3), 67-68 (Ground 5), 82-83 (Ground 7). Not so.

It is fatal that neither the Petition, nor the expert declaration provides any explanation as to why a POSA would have combined the references as proposed by Petitioner. Further, the Petition fails to even explain why, much less establish that these combinations would have achieved the invention claimed in Claim 11 with a

[6] Again, for both Grounds 3 and 5, the Petition alleges that "all of the elements of claims 5-7 were taught by Yamada, and combining these with ***PepTalk Poster*** would be nothing more than" a mere substitution. Petition, 55, 67-68. However, Ground 5 relies on a combination of "the ***PepTalk Presentation*** Yamada." Petition, 67-78. While the PepTalk Poster and PepTalk Presentation disclose substantially the same subject matter, this is yet another error in the Petition that shifts the burden to the Board and Patent Owner to excavate the actual grounds of the challenge.

reasonable expectation of success. The traditional, and governing, rule is to reject testimony such as Dr. Tumey's because it is nothing more than "conclusory statements and unspecific expert testimony." *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1338 (Fed. Cir. 2020) (quoting *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1366 (Fed. Cir. 2016)); *In re Ethicon*, 844 F.3d at 1348, 1352.

These deficiencies favor exercising discretion and denying this Petition.

B. There Is No Co-Pending Litigation

The absence of a parallel district court proceeding strongly favors a discretionary denial. There is no active dispute that may warrant further examination of the '675 Patent's validity, and the Board's intervention becomes much less necessary and compelling.

C. Patent Owner's Disclaimer Narrows The Dispute, Further Supporting Denial

Patent Owner has narrowed the scope of the dispute by disclaiming all but Claim 11, reducing the issues in contention and simplifying the proceeding. *See supra* Section II. This narrowing reflects a deliberate decision to focus the proceeding on a single, dispositive claim that Patent Owner believes is valid and fully distinguishable over the asserted prior art. The disclaimed claims are no longer at issue, significantly reducing the scope of the proceeding and eliminating the need for the Board to address arguments that are now moot.

This procedural posture underscores Patent Owner's commitment to resolving the central dispute efficiently. In light of this significant narrowing—and for the reasons discussed throughout this Paper—Patent Owner respectfully submits that instituting a full trial on dependent Claim 11 of the '675 Patent is unnecessary and would not serve the interests of "improv[ing] PTAB efficiency, maintain[ing] PTAB capacity to conduct AIA proceedings, reduc[ing] pendency in *ex parte* appeals, and promot[ing] consistent application of discretionary considerations in the institution of AIA proceedings." Guidance, 1, 3.

VII. CONCLUSION

Under the factors set forth in the Guidance, and the factors set forth in *Advanced Bionics*, Patent Owner respectfully requests that the Petition be denied as an inefficient use of the Board's time and resources.

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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 4,460 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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CERTIFICATE OF SERVICE

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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